Presidential Advisory Committee

Department of Health and Human Services

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)

Advisory Board on Radiation and Worker Health

VOLUME I

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TRANSCRIPT LEGEND

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In the following transcript a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

In the following transcript (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

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In the following transcript "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

(8:15 a.m.)

DR. ZIEMER: Good morning, everyone. I'd like to call to order the third or fourth, depending whether you count the teleconference. I guess it's the fourth official meeting of the Advisory Board on Radiation and Worker Health.

We're pleased at this meeting to welcome one new member to the Advisory Board. That new member is Mark Griffon. Mark, you can raise your hand over here. I'm sure most or all of the Board members have met Mark, but just let me take a moment and indicate a little bit about Mark's background.

Mark has served as president of Creative Pollution Solutions in New Hampshire since 1992 and in that capacity he performs consulting services in the radiation and hazardous waste field. He also presently serves as program director for the Department of Energy's medical surveillance research program for the gaseous diffusion plant exposure assessment, and he also is a member of the advisory board of the U.S. Transuranium and Uranium Registries. Mark did his undergraduate work at Rensselaer Poly Tech and his graduate work, including an M.S. and Ph.D. from the University at Massachusetts at Lowell. And Mark, we welcome you to the committee, look forward to your

participation.

MR. GRIFFON: Just one correction there -- I don't have the Ph.D. yet.

DR. ZIEMER: Well, that's interesting, because President Bush thinks you do.

(LAUGHTER)

DR. ZIEMER: We'd better keep that secret. No, actually what I just read is from the White House news page, so -- well, even worse than that, they had my name spelled wrong, so...

Okay, in any event, we still welcome you, Mark, in spite of your lack of that degree.

I'd like to remind everyone here, including the Board members and all visitors, to please register your attendance with us today. There's a registration or sign-in book on the table, so please take care of that if you have not already.

Those of the general public who wish to make comments during the public comment period, there is a sign-up page in one of the other books there at the table and we ask you to sign up, simply so we can assess how many will be wanting to speak and the allotment of times.

We're pleased to have with us this morning Dr. Kathleen Rest, who is the acting director of NIOSH -- Rust, I said Rest -- it is Rest; I get a little rust on my eyes here. Dr. Rest is acting

director of NIOSH. We're pleased to have her with us this morning again. And Dr. Rest, if you would, please come and address the group and we'll give you the podium here for that purpose. Thank you.

DR. REST: Thank you and good morning, everyone. I guess we have to speak up over the rain. Larry Elliott just looked up and said I hope this doesn't leak.

I'm happy to be here this morning and to welcome all of you again on behalf of NIOSH, the National Institute for Occupational Safety and Health, to this the fourth meeting of this Advisory Board on Radiation and Worker Health. And I'd like to start off first of all by thanking you for all of the efforts that you've made on behalf of NIOSH, HHS and this program. Really and truly, you've worked very hard over the past number of months to help us meet some of the new responsibilities and accomplishments that we had to achieve, and I truly appreciate the energy and the dedication that you brought to the task, so thank you very much for that.

Now I think that you all know that this program is really a very high-priority program both for NIOSH and for the Department of Health and Human Services. And we at NIOSH have been working really hard to be able to deliver on the many new

responsibilities that we've been given under this program.

Larry Elliott later on this morning is going to give you more of an up-date and status report and some of the details on our activities to date, but I just wanted to highlight a couple of significant milestones for you and we can turn it over and get on with the grist of the meeting.

I think that you all know that as of today the final rules on dose reconstruction and probability of causation have been published in the *Federal Register*, thanks in part to your own intense efforts to help us make this happen. A little history here is that we began drafting these rules last April, published both of them as -- well, one as a proposed rule and one as an interim final rule last October, and then obtained public comment, public input and Board input through February. And all of your efforts, as well as the efforts of the public and the public comments that we got, really helped us improve those rules and paved the way for their publication today. This publication now really makes it possible for claimants to have their cancer claims adjudicated by the Department of Labor, so beginning today, all cancer claims that are related to the non-Special Exposure Cohort claims will be able to be adjudicated by the

Department of Labor using the new probability of causation rules with completed dose reconstructions under the dose reconstruction rule that has been finalized and put out there today.

So we're very pleased that this is now behind us and that this helps move the whole program forward. And I think that finalizing -- developing and then finalizing these rules in the months that it took us to do it really I think is evidence of our strong commitment to the program. It seems like a very long time I guess for a rule to take a year from start to finish. But in truth, sometimes it's rather remarkable to have something published in that amount of time. So we did work as quickly and as hard as we could to get them out there. We thank you and we thank all of the members of the public that were able to provide the comments on this, and I'm pleased that they're there and that the program is now really able to be up and running in terms of the individual claims that will be submitted to the Department of Labor.

Now another important milestone that we really had hoped to be able to meet in time for your meeting here today relate to the procedures that the Department of Health and Human Services will use to consider petitions for additions to the Special Exposure Cohort, the SEC procedures. Unfortunately,

you don't have them in front of you here today and we are also disappointed that they're not in front of you here today, and I want to make it I guess clear that we have worked as hard as we could to try to get them in front of you and they are now, I'm happy to say, in the final process of review. So I really expect that they will be published very soon for public comment and for Board review.

We understand that these procedures are important. We understand their relationship to the overall program and we are as eager as all of you to get them out there, so I want you to know that we're fully committed to do our very best to turn them around now that we've gotten all of the comments -- the internal review comments back. We're ready to move as quickly as we can on that.

So in addition to the recommendations and the review that you will give those procedures when you see them, we also look forward to receiving your input and your advice on the NIOSH-IREP program that you're going to hear a little more about today. And of course on the implementation of the dose reconstructions that we do, I know you'll be actively involved in doing some quality control and reviewing how we're doing, once we've gotten quite a number of dose reconstructions under our belts.

So with that and in conclusion, I'd just

like to thank you for all that you've done and assure the Board and assure all of our constituents about this -- our constituents in this program that NIOSH and the Department are really fully committed to see the implementation of this program proceed as quickly as possible, and to give you our very best efforts to make it run as smoothly and efficiently as possible.

So with that, I'm happy to answer any questions or I will turn it over to Dr. Ziemer to continue with your agenda.

DR. ZIEMER: Thank you, Dr. Rest. I think it would be appropriate to allow a moment for questions. We obviously don't want to delve into the details of the final rule. I think we'll have an opportunity to do that later in the meeting. But are there some general questions that anyone has? Jim.

DR. MELIUS: Yeah, Kathy. You and I have talked about this before the meeting, but I am disturbed that the Special Exposure Cohort guidelines are taking so long to get out, and I understand it is a lot of work and there are just practical issues that way. But I think they are key to what -- for our committee to function; more importantly, for the recipients of the compensation under this program to have as one avenue for

receiving compensation. And it makes it very difficult to put a whole -- understand the whole program and even to review parts of it without knowing how the whole program's going to put together.

And I guess one other thing I'm sort of concerned about and I -- this is a question for you, is why -- since these are guidelines, these are not regulations, as I understand it, why the committee cannot be involved in reviewing those -- you know, why do we have to wait for all these other reviews to take place and then get presented -- those presented to the committee as something that's maybe not finalized, but certainly has gone through a lot of work and has gotten comments from other agencies internally, and then we're presented them after -- sort of after the fact, same time as the public, and then that it sort of seems to me delays the process even further.

And I think a better process would be to involve the committee in reviewing the concepts and reviewing the document ahead of time, since they are guidelines, not rules.

Regulations, we don't have the same restrictions on public, you know, input and access to those. So is there a reason for that?

DR. REST: I think that -- I mean you hit on

it, in that they are procedures, and I think the issue is is that the Department that will be implementing the procedures wanted to make sure that they fully understand -- fully understood our thinking behind the proposed and draft procedures before putting them out for public comment and giving people an -- within, giving people an opportunity to take a look at them. I can tell you that -- you know, I fully agree with you. I couldn't agree more with the importance of getting these procedures out for public comment as quickly as possible, and I assure you that we will -- we are nearly there. We hope to have the public comment period quite long enough so that people will have an opportunity to really understand them. We're happy to do some briefings on them as soon as they get out there, and I think that where we are at the moment is weeks away from getting them in front of you and getting them in front of the public. So I do want to let you know that I fully appreciate what you're saying and I do understand the importance of it. I think we all do. And we will do our very best to get them to you as quickly as possible.

DR. ZIEMER: Are there further questions or comments? Thank you very much. I guess this constitutes our "Rest" break and we'll continue with the meeting.

DR. REST: Okay.

DR. ZIEMER: We have as an item of business the review and approval of draft minutes. There are three such sets of draft minutes from the two meetings that were held here, plus the teleconference meeting. And before we actually take action on those, I'd like to make a few remarks about what it is we're going to do in approving the minutes. And I do this recognizing that perhaps some of you did not see the minutes till you arrived here last evening and got your big books, although -- and the minutes I think are also on the web site, are they not? Right.

In any event, you have -- you have before you this morning -- we're all a little curious as to why we all got copies of *Roberts' Rules*, wondering if now that Mr. Griffon's on the committee we have to rein things in or whether we were so wild before that somebody's hinting something. But I don't think that's the case. I think there was a closeout sale from -- NIOSH, I guess we thank you for this. Yes, thank you -- always nice to have another book. But anyway, if you were to read in *Roberts' Rules* -- and it's around 150-something -- about minutes, what you learn is that minutes, under *Roberts' Rules*, basically consist of an enumeration of the formal actions taken; that is, the motions, any

amendments thereto, who made the motions and the voting; summary or listing of reports given, that sort of thing.

On the other hand, what we have and what's required under the rules of advisory boards of our type, under the FACA rules, is more than just what *Roberts' Rules* call for. It calls for additional information about the discussions and that sort of thing.

Now we could spend literally hours, because some of these minutes are pretty extensive. We could spend hours going through these line by line or paragraph by paragraph, and it would take very long. But in order to efficiently handle the approval of the minutes, and these three sets of minutes, what I'm asking that you do is consider the following. You can ask yourself two questions. Number one, are the motions and the votes correctly accounted for and correctly stated and recorded? And secondly, are there any significant omissions or errors of fact or -- in places where your view was stated -- any significant distortions or incorrect statements of things you might have said?

If there are other kinds of corrections, such as wordsmithing, spelling, grammatical things, we simply ask that you enumerate those on your own and pass those on to Cori. We're not going to

wordsmith the minutes here this morning. We're looking for substantive changes, additions or corrections in the actual actions of this Board, as well as substantive changes in items that were discussed.

Now let me ask the Board -- this is what I'm suggesting. Let me ask if you believe that that's an appropriate way to proceed on the actions on the minutes. Are there any objections to proceeding in that manner? I see no objections so I'll take it that that's fully agreeable.

And incidentally, minutes can always be corrected later. If there's something you find later that shows up and you say, you know, we didn't correct that, we can always do that again later.

Well, with that in mind, let us turn to the first set of minutes. And for the members of the public who are here, I believe there are sets of those minutes on the table in the rear corner, so if you want copies of those, they are available. I should tell you that in addition to the individual who originally prepared these minutes, the staff has reviewed them extensively. Your Chairman has spent a number of hours reviewing these, both for grammatical as well as technical content, and we have had a lot of changes already made.

The first set of minutes, which includes

both an executive summary and full description of our deliberations at our first meeting -- and there's some 36 pages in the body of those minutes, plus the pages of the executive summary -- I'd like to ask if there are any corrections or additions to those minutes, keeping within the guidelines that we just discussed.

Yes, Dr. Anderson?

DR. ANDERSON: I don't have any additions. I just wanted to get a clarification. Is there a transcript --

DR. ZIEMER: Yes --

DR. ANDERSON: -- a written -- is there a written transcript or is it just a recorded transcript?

DR. ZIEMER: No, there is also a transcript, which is pretty much verbatim of everything -- or most everything that was said. And let me ask, is that transcript also on the web site or -- it is on the web site, so a lot of pages there.

DR. ANDERSON: Yeah, because that pretty much captures -- so between the minutes and that, I think we're -- we're well-covered.

DR. ZIEMER: Thank you.

DR. ANDERSON: So I'd move we accept.

DR. ZIEMER: Okay, there's a motion to accept those minutes. Let me ask for a second, then

we'll --

DR. ANDRADE: Before you go forward, I would just like to note that I think this rises to the level above grammatical error, but on the first set of minutes -- not the executive summary -- in the list of attendants, yours truly was left off, and I know that I was here at least in body.

DR. ZIEMER: I think that rises above the grammatical error. Thank you for that. Please check your attendance list, make sure you're included.

With that understanding, a motion to approve, with the addition of -- was there a second to that?

DR. DEHART: I'll second.

DR. ZIEMER: Well, let me ask now for corrections or additions or -- Wanda?

MS. MUNN: I know it's better for me not to have a microphone sometimes, but... On page five of the February 5th minutes --

DR. ZIEMER: We're only doing the first set of minutes. Is that February 5th?

MS. MUNN: Oh, we're only doing the first --

DR. ZIEMER: We're on the January minutes right now.

MS. MUNN: We're on the January minutes.

DR. ZIEMER: Yes, so hold that thought.

MS. MUNN: All right, fine.

DR. ZIEMER: Any other items on the January minutes? Okay, I'll just call for a formal vote on approving. All in favor of approving the minutes with the addition of Tony Andrade's name, say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed, then say no.

(No negative responses)

DR. ZIEMER: The minutes are approved. Now we'll look at the February 5th minutes and that's the conference call meeting. Are there -- I'll simply call for corrections or additions to the minutes at this point. Now, Wanda, page five you say?

MS. MUNN: Yes. No, that's fine, go ahead.

DR. ZIEMER: You're okay, did you say?

MS. MUNN: Yeah, I'm okay. I was confusing one meeting with another.

DR. ZIEMER: Okay. We're on the February 5th minutes. Any additions or corrections? Hearing none, I'm simply going to call for an action. All in favor of approval of the minutes, say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed, say no.

(No negative responses)

DR. ZIEMER: Those minutes are approved. Let's now go to the minutes of the third meeting

held February 13th and 14th. Are there corrections or additions to the minutes?

(No response)

DR. ZIEMER: Any of the Board members wish to have a little more time? I'll just pause, I see you leafing through looking for markup.

MS. MUNN: Yes, I would really appreciate having an opportunity to actually go through these. I did not get them until last night and, mea culpa, I did not -- I was not aware that they were on the web site. I would have looked at them earlier.

DR. ZIEMER: I think we have time. Let me just -- I won't declare a recess, but let's take -- allow about ten minutes or so. Is that --

MS. MUNN: I'd very much appreciate that.

DR. ZIEMER: We'll just pause and allow about that much time, and others who -- in the general public who may have just gotten an opportunity to look at those may wish to have a chance to peruse them in any event, so we'll just pause in our proceedings here for the time being. You can take a break if you wish, but if you haven't had a chance to go through these, just take the opportunity and -- including the ones you just approved. If you need to back up, that's fine, we'll do that.

(Whereupon, the meeting was suspended

briefly to review the minutes.)

DR. ZIEMER: It appears that folks are done with reviewing the minutes since there are a number of sidebar conversations, so let's go back. Dr. Anderson? Thank you.

DR. ANDERSON: As one who typically just reads the minutes from a lot of meetings, I would like to see on all of the minutes, right up at the first statement there where it talks about convene the meeting, February 13 and 14, Washington Court Hotel -- I'd like somewhere in the minutes, and probably that's a good place, to say something like a court reporter transcribed the deliberations of the Board and the complete transcription is available for public review and on the web page or something like that, just so that, in a concise place like this, it is somewhat unusual to have a court reporting of -- verbatim of the whole meeting for a FACA committee. I think it's important for people to know that if you read the minutes and you say gee, I wonder what they were talking about, here it says where you can find it as well.

DR. ZIEMER: Your comments pertain to changing these minutes as well, or just the future minutes?

DR. ANDERSON: Yes, I would -- it could either be in the future, but I would think all of

the minutes, just to make a statement that it was reported. That way -- you know, it's part of the minutes that it was done.

DR. ZIEMER: That's a reasonable --

DR. ANDERSON: Yeah.

DR. ZIEMER: -- suggestion. Any objections to that?

(No response)

DR. ZIEMER: We'll take it by consent that future minutes should contain that. We can certainly add it -- there may be some other things on these that need some additional changes.

Okay, let me -- although we've officially approved the first and second meetings, let me ask, are there any other items on the first meeting? I have one. This does not include some additional dangling participles which I have now identified and I will pass along on the side, but one which is a technical matter occurs on page 24 -- I just double-checked this with Jim Neton -- and it talks about ICRP-60 rating factors, when in fact it should be talking about ICRP-60 weighting factors, so the word -- the last paragraph on page 24 should refer to the ICRP-60 weighting factors. We had in fact caught that earlier, but it somehow didn't get changed in the final version. It should be weighting factors.

Gen Roessler?

DR. ROESSLER: In the minutes of the first meeting on January 22nd -- I think I have the day right -- on page 14 is a comment I brought up and I just want to clarify a word there. Maybe if I went on the web site and found out my exact wording it would be clarified, but -- are you on page 14? -- it says discussion included, the third item is (Reading) Congress picked the 99 percent confidence level, but the claims of individuals with a cancer with little literature on it will be jeopardized --

And so on and so forth. I remember all the rest of that, but I don't think the word jeopardized is right. I think it's just the opposite. I think in the case where there's a large range of uncertainty, certainly jeopardized is the opposite of what -- am I right on that, Jim?

UNIDENTIFIED: That's correct.

DR. ROESSLER: So maybe a word -- we need to look at that word jeopardized. This goes down in the record. It is one of the main comments I had at that meeting and I'd like to make sure that that's corrected.

MS. MURRAY: Could you suggest a substitute, Dr. Roessler? Supported or aided?

DR. ROESSLER: Well -- what was the next one?

MS. MURRAY: Aided?

DR. ROESSLER: That would be putting it mildly, but it would be better than jeopardized.

DR. ANDRADE: Gen, can I suggest the word enhanced?

DR. ROESSLER: I like that, Tony, yes.

DR. ZIEMER: Any objection to changing the minutes then to read enhanced, which is technically what the concept is, just the opposite of what's here? So thank you.

Are there any others? We're still on the first meeting minutes.

MS. MUNN: I have a question.

DR. ZIEMER: You have a question? Thank you.

MS. MUNN: On page 3/5 up front, third paragraph, (Reading) Acute exposure was defined by the National Academy of Sciences as of hours of exposure.

I looked at that and thought we have a missing word somewhere.

DR. ZIEMER: It's the word of, there's an extra of, I think, it's -- As I recall, they were defining it as acute if it occurred over a period of hours, so it would be as --

MS. MUNN: I thought perhaps the number of hours.

DR. ZIEMER: -- as hours -- not necessarily

number.

MS. MUNN: No.

DR. ZIEMER: I think --

UNIDENTIFIED: Duration.

DR. ZIEMER: -- duration.

MS. MURRAY: A few -- a few -- chronic dose thereafter is defined as more than a few hours, so acute would be a few hours?

MS. MUNN: Acute hours (sic) is defined as two or more? What?

MS. MURRAY: I don't know.

DR. ZIEMER: I believe it was a little fuzzier than a number like two -- a few might -- would a few be agreeable? It's -- here again, it's the concept. A few hours of exposure is what it would read now. Is that okay?

UNIDENTIFIED: (Inaudible) less than a few hours?

DR. ZIEMER: A few hours of exposure or less? A few hours or less of exposure.

UNIDENTIFIED: Okay.

DR. ZIEMER: Now again, we're not trying to refine this to get at exact definitions, but we are trying to clarify what the concept was there, technically speaking. Thank you for that.

Now, any other significant changes to those minutes?

(No response)

DR. ZIEMER: Now although we approved them, we had pointed out that under *Roberts' Rules* certainly you can always go back. I'm not going to go through the formal process of asking that there be a motion to recall and all that. Let me simply ask now that we reaffirm our approval with these additional changes.

Are there any objections to approving with these additional changes?

(No response)

DR. ZIEMER: If not, I'll then call for simply a vote. All who favor approval of these minutes with these additional changes, say aye.

(Affirmative responses)

DR. ZIEMER: Are there any opposed? Say no.

(No negative responses)

DR. ZIEMER: Now they are reapproved. The new, improved version of the minutes.

Now, on the second set of minutes are there any additional things that got overlooked in our previous action? That's the teleconference minutes.

(No response)

DR. ZIEMER: No? We'll move on to the third set of minutes, which we haven't acted on at all yet. Are there corrections, additions or other changes for the third set of minutes? February --

what is it -- 13 and 14.

DR. MELIUS: I'm not sure --

DR. ZIEMER: Jim.

DR. MELIUS: -- we want to make this change, but it's a -- you go to page 18, beginning of -- February 14th where there's a discussion of topics suggested for the next meeting. I believe the discussion was obviously more extensive than is captured in these minutes. I think that's appropriate. I don't think the minutes should be detailed. But I do think that it would be helpful if there was a way of making sure that Larry or his staff captured these suggestions and they had come up -- the first meeting also at points we had talked about what topics should we discuss at future meetings. And I know when we then went to set up this meeting, and particularly when the special exposure guidelines got knocked off the agenda, then there was sort of a scramble, what should we do with this meeting, and I think it would be helpful if there was a -- someone kept a sort of a to-do list, you know, future meeting topics, information that needs to get to the committee and so forth, and that we have some way that we make sure we capture that. Not necessarily in the minutes, though. If the only way to do it is going to be in the minutes, then I suggest that we make sure that the minutes do

include that information, but I don't think that level of detail is necessary. You know, such as suggested speaker names and things like that.

DR. ZIEMER: We'll take this simply as a comment to staff. You're not suggesting a change on these minutes at this point.

DR. MELIUS: No --

DR. ZIEMER: Thank you.

DR. MELIUS: -- as long as Larry would think that we don't need to do it in the minutes to do that. I don't think we --

DR. ZIEMER: Track those suggestions, right. And Mark, did you have a comment? No. Other comments? Are you ready to take action on the third set of minutes then?

Okay, all who favor approval of the minutes of the February 13/14 minutes, please say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed, say no.

(No negative responses)

DR. ZIEMER: That motion carries. Thank you. Roy?

DR. DEHART: I would simply like to compliment the staff on the quality of the documents that we've just discussed. In reviewing them, as I had the opportunity to do last week, I found it not only brought the recall of what we were doing, it

refreshed my memory on the science and it far exceeded my own notes, and I very much appreciate the opportunity to have these documents before me.

DR. ZIEMER: So noted. Jim?

DR. MELIUS: One other procedural suggestion is I think it would be helpful if the staff could e-mail us when things are posted on the web site. I thought we had talked about this before, but not all of us check it every day and some of us get caught up in the basketball scores and other things and never quite get around to looking at your web site daily, and it would be helpful if someone could -- whenever a new document goes up -- just send an e-mail to the committee.

DR. ZIEMER: Duly noted. Comment from Larry?

MR. ELLIOTT: I do appreciate those suggestions and we will follow through with that. Our plan and intention has been to use e-mail to contact you as much and as frequently as possible. We did send the minutes out by e-mail. I regret that some of you evidently did not get the e-mail with the minutes. We need to check and make sure that we have your correct e-mail addresses and we will do so. But we did send out the minutes. All three sets of minutes went out by e-mail, and then they were also -- that e-mail also noted that they

were posted on the web site, so I'm sorry that they didn't get to all of you.

DR. ZIEMER: Thank you. Let's move on on our agenda. Next topic is program status report and Larry Elliott will present that. And there is a section in your Board booklet which is a copy of the power point materials.

MR. ELLIOTT: Well, good morning. I am pleased to be here with you at your fourth meeting. And at your last meeting I introduced this presentation to you as a program status report and described the process steps in handling claims at NIOSH. Today I will provide you with an up-date of claims status at the Office of Compensation Analysis and Support in NIOSH and I'll give you some statistics on several of the more pertinent steps in the process. And during that I will also touch upon some of the things I think you're very concerned and interested in.

Again, the intent of this program report presentation is to provide you with a broader context of claims status at NIOSH so that you may determine when and how best to proceed with your responsibility to review completed dose reconstructions for scientific validity and quality.

As of last Friday, April 26th, it is our understanding that the Department of Labor has more

than 15,000 non-Special Exposure Cohort cancer-related claims for which they are verifying employment and medical diagnosis. In addition to that number, the Department of Labor has forwarded 3,634 claims to NIOSH for dose reconstruction. While it's too early in the program to detect any trends in these numbers, as you can see, the receipt of claims at NIOSH has increased substantially each quarter. Keep in mind that we did not start receiving claims at NIOSH until October 11th, 2001.

Claims are received in batches each week from the four district offices of the Department of Labor. And on Tuesday of each week we send out acknowledgement letters to each claimant to let them know that we have received their claim from the Department of Labor and we also tell them in that letter what the next steps will be for their claim, what steps their claim will go through, and how they may contact us to monitor progress.

You may note at this step that we lag behind the total number of claims we have in hand. We've sent out acknowledgement letters for 3,391. This lag represents a single week of claims receipt, and it's also the last step in the process where claims are handled as a batch. Now in your Board booklets we've provided you example copies of the acknowledgement letter and of the other letters that

we use to communicate with claimants at various steps in the process.

As we approach the Department of Energy with requests for information to support dose reconstruction -- I'm sorry, I hit the -- and I can't back up.

(Pause)

As we approach the Department of Energy with requests for information to support dose reconstruction, each claim is handled individually. At this point the dose reconstruction portion of the case file is being developed for each individual claim. We evaluate the case file information for the cancer type, length of employment, the number of covered sites where the Energy employee worked and the number of different jobs that the Energy employee held. And if appropriate, we evaluate the NIOSH-held information for data pertinent to the claim. These evaluation steps enable us to focus our information needs based upon specific time periods and on location, where the employee might have worked, and to direct our requests to the Department of Energy -- the relevant sites for the Department of Energy.

You may note here that the number of claims achieving each succeeding step diminish as we proceed in the process. This is due to the time

that's required to assemble, evaluate and review the information that's needed for dose reconstruction on an individual claim basis. Thus we have requested information from the Department of Energy sites for 2,966 claims at this point. We anticipate when our dose reconstruction technical support contract is awarded next month that we will see more claims moving through the process at a much faster pace.

We're working very closely with the Department of Energy and the designated points of contacts at the DOE sites for the information that we need to conduct these dose reconstructions, and we're exploring ways to expedite the fulfillment of our information requests. We're exploring how to build site-specific profiles with the Department of Energy. We're also examining ways to validate the information that's been provided, and to establish access to confidential information or National Security-held information. And we're also evaluating how we can best verify that no further information exists.

We're currently negotiating all of these points with the Department of Energy in the language for the memorandum of understanding between HHS and the Department of Energy. Within the last month, as you see, we've seen an improved response to our requests for information from most of the DOE sites,

and I anticipate that we'll see improvement only get better as we proceed with a signed memorandum of understanding.

Relative to a given claim, we evaluate the information provided by the Department of Energy for adequacy and completeness with regard to our specified information request. And we're evaluating here that not only the quantity but also the quality of information provided in the light of what we need to conduct the dose reconstruction for an individual claim. Where we feel that the information is incomplete or inadequate, we have approached DOE again for the necessary information, and thus to date we have reapproached DOE for additional information to support dose reconstructions on 51 claims.

In some cases we have asked the Department of Energy to continue searching for information where none was provided in the initial request. And primarily this has been for the atomic weapons employer facilities, and the 21 requests that you see listed in the first quarter depict this type of secondary request. And since that time we've worked with DOE to establish what information they have and we captured the bulk of the information on the AWE's. We're continuing the process of gathering information on the AWE's as best we can.

In other cases we're seeking general information such as the limit of detection for a historical dosimetry practice, and this general information will assist the specific claim in question, as well as fulfill the site profile information for the benefit of all claims relevant to that site and that time period. And another example of secondary information that might be requested would be coworkers dosimetry data.

Once we have assembled and reviewed all relevant information from NIOSH records and received and examined the information from the Department of Energy, we schedule the interview with the claimant. As of today we've conducted 55 interviews. We have scheduled another 51 interviews to be conducted during the next four weeks. We currently count 75 dose reconstructions underway. And what we mean by this is we have received, we have assembled, evaluated and reviewed the readily-available information pertinent to a given claim. We have scheduled, and for 55 claims have conducted, the claimant interview.

For six claims we have completed the draft dose reconstruction report as specified in our rule 42 CFR Part 82. The six draft reconstruction reports will be provided to the respective claimants next week, and that will be followed up by a phone

call from the dose reconstructionist to explain the report, the process and the findings of the dose reconstruction. At that time we'll also seek the claimant's approval on the OCAS-1 form to close the dose reconstruction process and move the claim on to the Department of Labor for determination of probability of causation.

The number of phone calls that we've received in the Office of Compensation Analysis and Support have increased substantially each quarter as we handle more and more claims. Of these 1,454 calls received, 140 calls have been for general information on the program. They were not related to any specific claim. The remaining 1,324 calls that we have received were regarding a specific claim and these calls were actually only relevant to 679 claims, or approximately one-fifth of the 3,634 claims we have in hand. For these 679 claims, the number of calls range from one to 20.

The inquiries that we received during the phone calls seemed to center on essentially three questions: What's the status of my claim? Do you have my dose from DOE yet? And when will you schedule my interview? With regard to visitors at OCAS, we've only had one.

And I thank you for your attention. I'll answer any questions that you may have at this

point.

MR. GRIFFON: Larry, I'm just curious. You said -- mentioned several times that you're working with DOE to obtain more information, and in previous meetings you mentioned the memorandum of understanding, and I wonder if there's been any formalized MOU put out between the agencies regarding access to data for this.

MR. ELLIOTT: No. As I mentioned just a moment ago, we're working on the language. We're negotiating the various points I identified, so that's not available at this time.

MR. GRIFFON: Okay. Just the only concern I would have is that some of the things that you mentioned as -- you mentioned that you reviewed and evaluated based on readily-available information, and in another part you mentioned that some of the secondary information requests such as general bioassay program information -- I might view some of that as almost as important as the personal dosimetry records in piecing this all together. And the site profiles that you're doing I think are as important to get started early as getting the individual's personal information. Otherwise, you may be in a position where you're going back and revisiting claims after you've rejected them possibly or that sort of scenario may arise, so I

would just point that out, that I think some of the other information may give you a different perspective on the personal data files.

MR. ELLIOTT: I appreciate your comment, but I would ask you to keep in mind that we're not finalizing a dose reconstruction on the claim until we're satisfied we understand all of the information that we need and we have all that information, whether it's the individual's dose or it's the secondary level of information to better understand how we reconstruct that dose. And so the claim doesn't move forward until we have that. And we are building both site-based profiles and individual dose files as we proceed. They go on concurrently.

DR. ZIEMER: Larry, under the legislation itself, it's true is it not that DOE in fact is obligated to provide such information to NIOSH so that the function of the memorandum of understanding is mainly to make that a more smooth and well-understood process? I mean --

MR. ELLIOTT: Yes.

DR. ZIEMER: -- it doesn't prevent the information from coming, but what will we gain from the MOU that isn't already in the legislation?

MR. ELLIOTT: Well, the MOU language will address access to the information, the fact that we can go in and look at National Security-based

information and seek declassification or redaction of information pertinent to a given claim, that we can get DOE's certification or verification that there is -- they've searched all available information and there is no more to give. These are the collaborative relationships that will be established in the MOU.

DR. ANDRADE: A comment and then a quick question for clarification. Being from a DOE site I know that we've been sending information for months, so it's not that information is not flowing. That's my comment.

Number two is a quick question for clarification. On the sheet before you examples of communications to claimants there is an acronym. On number four it says summary of CATI report to claimant letter. Can you explain what that is?

MR. ELLIOTT: Computer-assisted telephone interview.

DR. ANDRADE: Okay.

MR. ELLIOTT: That's a CATI.

DR. ANDRADE: Thank you.

MR. ELLIOTT: I apologize for -- we run in a sea of acronyms. We don't always realize that everybody else doesn't have the same definitions we do.

DR. MELIUS: I don't know if you're going to

talk specifically about these letters and these communications here, but I really think someone should take another look at them or provide some supplemental information 'cause some of these are pretty technical. I don't know if most claimants are going to understand what a dose reconstruction is and terms like that. It seems that it's awfully -- a little bit too technical and doesn't really explain -- it's going to confuse people, and particularly the -- you didn't include the sign-off they do at the end to say they accept your dose reconstruction, but that letter I think really needs to be very clearly worded and communicated to people 'cause that's --

MR. ELLIOTT: We agree.

DR. MELIUS: -- got important implications, but --

MR. ELLIOTT: We agree.

DR. MELIUS: -- someone needs to go back through these letters I think and really look at them, you know, in terms of reading levels and things like that.

MR. ELLIOTT: I appreciate the comment and we do agree. And I would say this, that -- keep in mind, throughout this process we're having multiple contacts with the claimant, and each contact we're providing explanation. We're trying to educate them

along the way. The first letter that goes out has our brochure with it that talks about the program, but we also provide a fact sheet that talks about dose reconstruction in lay terms and tries to give them an insight in that. And no, you don't have a copy of the letter that sends the dose -- draft dose reconstruction report and the OCAS-1 form in your packet. We're working on those now as I speak. I have a health communication specialist who's working up the language in those and we're reviewing dose reconstructions --

DR. MELIUS: Yeah, just one comment. I think we always tend to sort of over-estimate our ability to communicate and expect that people will have read everything that we sent them before and that they'll understand it, and so the next letter is going to be readily understandable and that's not how --

MR. ELLIOTT: No, it's not how it works.

DR. MELIUS: -- they're very nervous, anxious about this. Many of them -- limited education and difficulty understanding. And I think having the ability to call you and so forth is important, but I also think it's as important that they have something clear in writing that they can share with someone to help them understand it --

MR. ELLIOTT: Sure.

DR. MELIUS: -- and so forth.

MR. ELLIOTT: Sure.

DR. ZIEMER: Might I ask, the brochure that you're talking about is sort of a layman's type brochure --

MR. ELLIOTT: Yes.

DR. ZIEMER: -- is it not, and did the Board get copies of that?

MR. ELLIOTT: We don't have that to you yet. We're --

DR. ZIEMER: I think it might be important to see that, simply -- that might alleviate some of the concerns in terms of knowing how well that does the job of laying out in lay terms what a dose reconstruction is about, and then the letter simply is a more --

MR. ELLIOTT: Sure.

DR. ZIEMER: -- formal document. But the comments certainly are well-taken. We had one over here -- Roy?

DR. DEHART: When you were discussing the memorandum of understanding with DOL -- Department of Energy -- is there not a requirement in there to deliver information within a certain number of days, which becomes a performance criteria?

MR. ELLIOTT: Well, we're working with the Department of Energy to have that language placed in

the MOU, yes. There is -- there is an intent from our perspective to have suspense dates. Currently our letters that go to the Department of Energy sites specify a response back to us within 60 days, and that means -- the way that request is phrased, if you don't find the information, we still want to hear back from you in 60 days on the status of your progress. If you do have the information, we would like to have it within 60 days.

DR. DEHART: The reason I asked the question, that would appear to be a metric that we might want to look at as we move forward with this.

MR. ELLIOTT: Thank you.

DR. ZIEMER: No other comments or questions? Okay, thank you.

Next -- oh, we do have a comment. Jim?

DR. MELIUS: Yeah, the dose reconstruction contract, I think you just said it was going to be awarded in June now?

MR. ELLIOTT: June, we hope.

DR. MELIUS: Huh?

MR. ELLIOTT: June, we hope.

DR. MELIUS: Okay.

MR. ELLIOTT: Next month.

DR. MELIUS: So where would that leave you in terms of between now and then being able to process claims?

MR. ELLIOTT: Well, we have 51 interviews scheduled. I can't predict how many dose -- draft dose reconstructions we're going to finish and get in the hands of the claimants in the next four weeks, but we have 75 underway, so each week -- each week I'm sure we're going to complete dose reconstructions. We'll send the draft reports out. But I am not in a position to predict at this time how many we're going to complete before the award.

DR. MELIUS: What is the delay in awarding that contract?

MR. ELLIOTT: Well, there's -- it's a competitive process and there are audits that are being performed on the proposed proposers to the award. That takes time. We've had an unfortunate death in our procurement office which I'm not sure has delayed us too much, but it certainly has slowed things down for that one week where we all reacted to that. And we have a series of questions that we're posing back to the individual proposers on certain issues, and so -- we're moving as fast as we possibly can trying to put this in place.

DR. MELIUS: One question, as long as -- I believe at the last meeting you mentioned that the proposers were supposed to prepare a conflict of interest --

MR. ELLIOTT: Plan.

DR. MELIUS: -- plan.

MR. ELLIOTT: Yes, sir.

DR. MELIUS: Is that part of what's -- the going back and forth now or is that -- have they done that satisfactorily?

MR. ELLIOTT: I can't comment on that.

DR. MELIUS: Okay.

DR. ZIEMER: Thank you. Then we'll move ahead to the next item on the agenda, which is the summary of the changes in the probability of causation rule. This basically is a report on the final rule, which incidentally hits the street today, I believe, in the *Federal Register*, and the final rule would include the -- dealing with not only this Board's comments but other input that the staff have received, so Ted Katz is going to take us through that. Ted?

MR. KATZ: Hi, thank you. One second while we get on board here.

So this is going to be a very brief summary of changes and how we got there. I understand you can actually buy the *Federal Register* at the news stand in Washington, so I don't know if any of you ran out and purchased your own copy, but let me just talk a little bit about public comments first.

We had 12 organizations and 24 individuals comment. The organizations included labor

organizations, community organizations, one big university system and then, again, 24 individuals. The comments were diverse, very diverse. There's really no massing of public opinion in any one area and pertaining to any particular provisions of these rules. In most cases we say -- you'll see through out the rule we say several commenters, and that really -- everything was several commenters, and really we're talking about, in most cases, two commenters said this, two commenters said that.

I'm going to just run through -- give you a sort of flavor for the comments we received. There were a lot of comments. I mean not many commenters, but lots of comments. I can't really capture them in any perfect way, but we had a number of comments, and this is probably one of the comments areas that was most numerous about peer review. There was much interest, questions about how IREP would be peer-reviewed, has been peer-reviewed. And likewise in the updating of NIOSH-IREP what sort of peer review would occur.

We also had a number of comments -- this is probably the most prevalent area -- relating to chemical cancer risks and how those would be attended. Really sort of three different ideas out there. One idea is how are we going to address occupational chemical carcinogens, are we going to

account for their risk as well. And then a second sort of comment relating to chemical risks is how are we going to address -- are we going to address the risk interaction between occupational chemical carcinogens and radiation. And then a third asking about how are we going to address, if we're going to address community non-occupational chemical carcinogen exposures and how that might affect, you know, the background risk for an individual for cancer.

Had a number of comments about the application of -- or really one I think actually here, the application of NIOSH-IREP updates. As you know, with progress in science, we intend to improve NIOSH-IREP down the road and we've laid out in the rule a number of areas in which we would do that. The comment here pertains to what would we do about claims that have already been adjudicated based on what would in effect then be the old NIOSH-IREP.

Documentation of NIOSH-IREP. There was some interest in how much documentation would there be of NIOSH-IREP. Is this going to be a black box or do people get to see what the assumptions and formula are that produce the results that come out of NIOSH-IREP.

And similarly the interest in the probability of causation calculations themselves,

what sort of documentation would be going to the claimant explaining, again, these assumptions and formula underlying the results that they receive.

Then we also had a large number of comments about really the specifics of NIOSH-IREP, the formula in there, the risk models, comments such as -- or questions as to whether it's appropriate to use the data from studies of the Japanese population, comments on both sides of the fence as to whether our plans for adjusting for smoking in risk calculations is appropriate -- either too high or too low. And a variety of comments that actually were presented to you in previous Board meetings, too, about the content of NIOSH-IREP.

And then we had a number of sort of theoretical and statutory-related comments, as well. For example, here one commenter is interested in -- in the literature out there there's proposals that compensation should be done rather than in an all or none sense where if you pass a certain threshold of probability of causation, you're compensated; if you don't, you're not -- that compensation should be done proportionally, proportionate to the probability of causation. This was a comment.

Another comment or a question about whether we should be establishing a radiation dose threshold for doing probability of causation calculations, and

the concern here was a concern that you've all addressed and discussed to some extent, rare cancers and whether uncertainty is a problem for rare cancers and hence might be addressed by using a radiation dose threshold. And on the other side of that same issue, we also received a comment suggesting that rare cancers should be presumed to be radiation-related.

And then comments as well about the relationship between the Regulatory Radiation Protection Standards, ICRP standards used for radiation protection and their use of those models for calculating probability of causation, whether those should be in sync or not.

Now this is just to be complete. I know you know what you did and I don't need to tell you what you did, but the Board made a recommendation as well, which was to formalize or incorporate what was previously in the preamble and has always been our intent, the role of the Board in reviewing NIOSH updates of the NIOSH-IREP program as we incorporate new models and so on. And the Board also asked that the public have opportunity for review and comment in those instances.

How did we actually change the final rule. We spent a lot of time, and these are reflected in the preamble of the rule addressing the public

comments. The actual change is really two substantial areas of change in the rule. One we added provisions as the Board recommended, bring from the preamble into the rule itself provisions for updating NIOSH-IREP, and we also added a provision to allow NIOSH to update NIOSH-IREP to address chemical-radiation risk interactions.

Let me tell you a little bit more about these. For updating NIOSH-IREP, the Board and the public have the opportunity for input on the front end, to make recommendations as to changes that ought to be done to NIOSH-IREP, as well as there are really extensive provisions for notice, opportunity for review and comment before any changes would be made, both by the public and by the Board. And then of course full notice of when changes are actually made.

And with chemical-radiation risk interaction, this is -- here we're talking about of course -- I've told you sort of three areas of comment, but this relates to occupational exposures to chemicals. And this was an issue that was discussed when we were drafting the rule and we concluded -- it was raised again in public comments, which is why we ended up addressing it here. At the time we were drafting the rule, we fairly firmly concluded that the science wouldn't support doing

this at this point. And as well, and perhaps practically more important, that it's practically an enormous problem to address chemicals in probability of causation calculations and that's because the Department of Labor already has really an enormous burden of data collection to be able to make this adjudication process work, and this would be throwing into it a very sizeable new burden on top of what they're already trying to achieve. And for producing timely decisions, this would be very difficult. But we've included it anyway. We've included -- with the understanding that the world can change and at some point in the future we may be able to both scientifically and practically address chemical-radiation risk interaction.

Let me just conclude then. The bulk of the comments we received regarded really implementation issues on the one hand, and those are going to be extremely useful to us in thinking about updating NIOSH-IREP and so on since we got a lot of comments on the details of NIOSH-IREP, and also have helped us in thinking about how we work with the claimant, where we got a lot of comments.

And then there were a lot of comments that really relate to statutory requirements, and those -- those issues are really issues for Congress, as we explained in the preamble and addressed in these

comments.

There was substantially silence on a lot of substantive policy issues or policy decisions included in these -- how we use IREP in this program, how we address multiple cancers, how we address secondary cancers -- a lot of substantive issues, commenters were silent. And that is encouraging for us. We think that we may have gotten it right if there wasn't a lot of consternation about these approaches.

And then finally I'd just like to say we're now faced with the very big job ahead of helping DOL to implement these. We've recently -- Russ Henshaw, who you'll hear from later, has been traveling around the country working with DOL to get them prepared to apply these guidelines, but we realize there's going to be a lot of work to do to make this program work smoothly in the future.

And that concludes my presentation. I'll be happy to take questions.

DR. ZIEMER: Thank you, Ted, and just for the Board, let me mention that in the draft -- well, it's the final version, but our copy of the final version which begins right after Ted's overheads in your packet, the section on the public comments begins on page 22. It summarizes what Ted has given us in the slide version here and goes through the

various categories of comments and how they were handled. And then beginning on page 56 of that draft it has a section on the recommendations of this Board and the response of staff to those recommendations. Basically it's only the third recommendation that required a particular response, and that was the one dealing with moving into the body of the rule the issue of how the rule or how the models are amended and the issue of the public input on that and that sort of --

MR. KATZ: That's correct.

DR. ZIEMER: Now let me see if there are questions or additional comments. Yes, Mark?

MR. GRIFFON: Just a quick question, Ted, and this might be more appropriate later, so if they're going to cover it later -- Mary and Russ -- you can tell me. But the DDREF value, if I'm reading this right, NIOSH has made a decision to slightly modify that to lower it to --

MR. KATZ: Mary let --

MR. GRIFFON: -- more toward unity?

MR. KATZ: That is actually a good issue to let Mary address.

DR. ZIEMER: Okay, so we'll come back to that. Is that agreeable, Mark? Okay. Roy?

DR. DEHART: Realizing that this is not a regulation but a rule, is it subject to Federal

litigation? And if so, is there any suggestion that someone may take this to court?

MR. KATZ: Is there any suggestion? I mean this is a rule -- this is a regulation and it is subject to litigation, and I think most regulations with real substance to them end up being litigated at some point on some basis. I mean it's hard to know. I think we expect there may be some litigation here as -- we don't know, you know, from what quarter it's going to come on what basis, but these rules mean a lot for a lot of people, so --

DR. DEHART: That could indicate there would be delay then, if it went to the court.

MR. KATZ: Well, I mean they're -- you mean a stay of the rules?

DR. DEHART: Yes, that or other --

MR. KATZ: This is really sort of out of my terrain, but we don't have any indication that anyone is planning to stop the rules now from going into effect. I think people are anxious to actually see us implementing these rules.

DR. ZIEMER: Are there other comments or questions for Ted?

MS. GADOLA: I have a comment, and it's also a question. You mentioned about the possibility of more scientific information being available about the synergistic effects of chemical carcinogens and

ionizing radiation, and reading this you said that you did not have the scientific evidence to support a change in IREP at this time. How would that affect future cases?

MR. KATZ: So if down the road we were to be able to address chemical-radiation risk interactions for future cases, we would do that. Is that what you're asking or are you asking --

MS. GADOLA: Well, you said that in the future, and the way the rule is written now, how would that allow future information to be introduced?

MR. KATZ: The rule allows us to update NIOSH-IREP to take into account improvements that we can make, and we had previously, in the proposed rule, iterated a number of areas in which NIOSH-IREP -- we may be working on NIOSH-IREP in the future. And what we did in this case was add another area in which we may be able to improve NIOSH-IREP in the future. And if at such time as we can do that, we do that, then claims following that would be adjudicated with a NIOSH-IREP that takes into account those interactions. Is that getting to your --

MS. GADOLA: That helps.

MR. KATZ: -- or am I missing --

MS. GADOLA: I think my concern, along with

a lot of others that probably made comments about this, is that the history shows that a lot of the people that develop certain types of cancers also worked with chemicals that have been suspected or labeled as carcinogens, and there's a possibility that the radiation dose may not substantiate that their cancer was caused by radiation. But because there is a high number of those cases and because they worked with chemicals, a lot of scientists suspect that it was a synergistic effect of both the chemicals and the ionized radiation. And I was just wondering how much of that will be dealt with in the future as more science is available.

MR. KATZ: That really -- it relies on two things, both science progressing far enough that you could address those issues, and second, as I noted, there's a practical concern, completely aside from the science, which is how would DOL be able to obtain sufficient information for all these claims to be able to make use of such information, even if the science told us how to. So there are really two issues in the way of actually implementing changes to NIOSH-IREP related to chemical-radiation risk interaction.

MS. GADOLA: I know that also some of these claims then also go to the states' workers comp programs, but in the past, anytime claimants have

tried to do this it's been very, very rare that they were awarded anything. So I know this is not particularly what this deals with, but I think it is something that's important when we look at the whole picture.

MR. KATZ: And there is -- just to note, there is another provision of EEOICPA, of this law, that addresses assisting claimants with state workers comp claims, and that's certainly an issue that they're going to face with those claims as people were exposed both to chemical carcinogens and radiation.

MS. GADOLA: Thank you.

MR. KATZ: You're welcome.

DR. ZIEMER: Ted, is there anything in the law that would prevent a worker from going back, once there is new scientific information -- someone whose claim had been turned down on the basis of radiation exposure alone could go back later, could they not, if there was --

MR. KATZ: Let me --

DR. ZIEMER: -- some additional scientific information on the chemical aspect?

MR. KATZ: Right, there's -- there are two provisions that are relevant here. The science that probably doesn't move fast enough for claimants, so claimants have a year to go back to DOL on a denied

claim, but DOL, foreseeing issues like this, new information, has a provision in their rule that also allows them to reopen a claim at any time -- for example, on the basis of new information, progress in science -- and so this is something DOL has foreseen as an issue and addressed in their rule.

DR. MELIUS: Yeah, seems to me that in doing this rule you've done two things. You've finalized the regulation and made some procedural changes. At the same time you're also making changes in the NIOSH-IREP, or making some adjustments in that, and those are really covered in the preamble more than they're covered in the rule. And my question is, how -- what are going to be the criteria for what are major changes in the NIOSH-IREP and how are you going to -- what's the procedure going to be for -- or the threshold for alerting the committee to that --

MR. KATZ: Right.

DR. MELIUS: -- and the public and sort of the procedure for that 'cause it seems to me that when I'm reading over this regu-- I'm paying -- focusing on one thing, the IREP, when you're -- in their preamble, and then procedural issues in your regulation, and we've had this going on in sort of a parallel track.

MR. KATZ: Yeah, this is actually -- I think

this is addressed, and in effect you will see any change to NIOSH-IREP that has a substantive effect on people's -- on calculations of probability of causation. Now there may be changes that we make to NIOSH-IREP that don't have a bearing on that but that make it more user-friendly for Department of Labor and so on, all sorts of things. We're going to be improving the documentation that's available through NIOSH-IREP, so there'll be a number of changes to NIOSH-IREP that don't need, I think, to be vetted. But wherever they have a bearing on probability of causation findings, you will see those changes as proposed changes first, and have an opportunity for review.

DR. ZIEMER: Okay. Are there further comments or questions? There appear to be none, so we will take a break at this time and reconvene at whenever it says on the agenda, which is what -- 10:15. Thank you.

MR. KATZ: Thanks.

(Whereupon, a recess was taken.)

DR. ZIEMER: Before we call on Ted to give us the presentation on part 82 rule, I'd like to call attention to the fact that we did receive a response from Secretary Thompson on our comments that had been sent to him earlier. In case you hadn't noticed, his response is in the insert --

what do you call it, the inner cover, I guess, of your Board book this time. And for the general public, there's a copy of Tommy Thompson's letter to the Board on the rear table back there.

The other thing, again before Ted begins, we delayed introducing others who are with us today. I'd like to take a moment -- Larry, if we could introduce any of the other NIOSH staff that are here besides Ted, and of course we've already heard from Dr. Rest earlier today, but are there some other NIOSH staff we might just identify for members of the public, as well as for the Board?

MR. ELLIOTT: Certainly. We have Tracy Gilbertson, who's a technical information specialist on staff, back in the corner there. Russ Henshaw I think you met at a meeting before. I don't see him in the room right now. Then we have office of the general counsel who's assigned to NIOSH over on this side of the room with Mary Armstrong, Alice Kelley and Liz Homoki-Titus. I think that's all the NIOSH -- oh, Jim Neton is here, and you all know Jim. And I think that's all of us.

DR. ZIEMER: Thank you. We also like to both welcome and have introduced to us our visitors from either other agencies or representing other groups or private individuals, members of the public. And I'd like to ask those who are here as

members of the public, observers and representatives of other agencies if you would please introduce yourself to us. Just give us your name and who you are representing. There's a mike here and you can use that. Please, we'd like to welcome all of you.

MR. BLANKENSHIP: Jim Blankenship for the Department of Labor.

MR. EAGAN: Jeff Eagan, Department of Management.

MR. SLOCOMB: Jeff Slocomb, Department of (inaudible).

DR. ZIEMER: We have (inaudible) signing in from EPA. Consider yourselves all introduced.

Let's proceed with the next item on the agenda, the dose reconstruction final rule, Ted Katz.

MR. KATZ: Hi again. Bad penny here. So I'm going to run through this rule as I did the other, quickly. This time we had 13 organizations and 23 individuals, so one organization added and one individual dropped out. And the comments in this case really covered all aspects of the rule -- all aspects of the rule, really. And in many cases, all sides of an issue, so it was sort of very thorough vetting, I think, in this case of this rule. Maybe the dose reconstruction rule is just friendlier material for the public, or I don't know,

but -- and give you a flavor for these comments, if I can make this move.

We had comments about feasibility, precision and reliability -- you know, whether we can do dose reconstructions, how precise is precise enough and how good is the information that we're basing the dose reconstructions on.

Comments on both sides of the issue with respect to efficiency measures. Some commenters thought this was absolutely the way to go, the only way to go. And others raised concerns about what implications that might have using the efficiency measures in terms of litigation that might occur down the road and so on, since the government's producing these estimates.

We had comments -- numerous comments about the role of claimants, again on both sides of the issue. Some were concerned that claimants were being overly burdened or might be overly burdened. And on the other side, suggesting that claimants should be as fully involved as possible -- something I hope we've achieved.

Comments about the scope of covered exposures, comments in really three areas -- X-rays, the use of X-rays as part of the dose, and there I'm talking about medical screening X-rays that are required for employment -- as a condition of

employment. Also whether chemicals should be covered, chemical exposures to occupational carcinogens should be covered, and whether we should be accounting for non-occupational exposures to radiation as well.

Then we had, similar to the probability of causation model issues, concerns about using ICRP models other than those that are used for radiation protection programs in the United States.

Also had a comment -- or several comments about use of the dose of record. That's the dose of record produced by DOE, how those would be used in this program.

Comments about updating the scientific elements. Here in particular there's a concern -- and this again sort of parallels the probability of causation guidelines. As we update scientific elements, what about claims that were already adjudicated. Well, we've already completed the dose reconstruction. What would we do about those.

Comments about the involvement of DOE, in particular whether DOE should be a reviewer at different stages of a dose reconstruction.

And comments about oversight and peer review, similar to the probability of causation rule comments, and specifically about the roles of the Board in providing such oversight, whether that role

of the Board should be prescribed in the regulation and comments as to what the extent of technical capacity of the Board is to serve as providing oversight and as peer-review source for NIOSH.

The Board -- you -- provided a number of comments on this rule. A parallel comment to the probability of causation rule to incorporate the Board as a peer reviewer of scientific updates and to involve the public in that process as well. And you also identified a number of provisions that needed to be clarified. I've listed them here -- application of the Privacy Act -- we've simplified that so that's clear -- to dose reconstruction records. The procedure for NIOSH to conclude a dose reconstruction; here you were concerned about ensuring that the claimant would have sufficient time -- always be afforded sufficient time to provide additional information that the OCAS-I form that we ask them to sign at the conclusion of dose reconstruction, that they have -- there's a time limit on that, but that that time limit not be applied while they're still in the process of obtaining additional information they believe is relevant to their dose reconstruction. And you wanted us to clarify that we would be using current ICRP models.

How did we change the rule? We added a

process for updating methods, along the lines we did for the probability of causation rule, providing full opportunity for public input, as well as Board input in what ought to be changed, as well as review and comment as we propose changes and pursue them, as well as notification when changes are implemented.

We added a provision allowing NIOSH to review completed dose reconstructions on its own initiative. This relates directly to the comment we'd received, so what will we do in cases where we've updated our methods for dose reconstructions that were completed and used by DOL in adjudication and the claim was denied. So we wanted to have the ability to revisit those dose reconstructions using the new methods.

We clarified the process involving the claimant in a number of ways, clarified that the interviews we would conduct with them could be iterative and involve a number of sessions. This wasn't a one-opportunity, one day to speak to NIOSH and then we close the door. And clarified the process of concluding the dose reconstruction, as I mentioned earlier, so that the claimant is assured the time they need to provide information they're seeking related to their dose reconstruction.

And we clarified our potential use of all

relevant types of information. We had, in the section specifying what sorts of information we would apply to dose reconstructions before, written the list as if they were conclusive lists, so we have added basically provisos to each of those that we would use other information that was relevant, that we may not -- may not have occurred to us in preparing that list, nor did we try really to be comprehensive in those lists, but to make it clear that we would be making use of all information that is relevant in producing these dose reconstructions.

We also -- we clarified, as the Board recommended, that we would be using current ICRP models.

We removed Table 1. Table 1 included -- specified the ICRP radiation weighting factors, current -- those current weighting factors. A commenter rightly indicated that if we had that table in there, then we would have to change the regulation to make use of any update that ICRP did, and we didn't want to be in that position so we removed the table and made it clear that we would be using the current factors, whatever they might be.

We clarified, as you recommended, the Privacy Act application to availability of dose reconstruction records to the public.

And we clarified a variety of other

procedures as well -- how we would worst-case assumptions, how and when, information to interpret bio-monitoring data, particularly old bio-monitoring data that may have substantial limitations and so on.

And in conclusion, the comments were really remarkably balanced on various sides of every issue. Many issues, many comments, really, related to -- again to implementation issues and will be useful to us as we go forward in building a better program continually. And very clear from the comments from claimants and others that we have a very large educational task at hand, both to educate the claimants about our dose reconstruction process and also a lot of learning to do ourselves in how to do this well.

And that concludes my prepared remarks. I'm happy to --

DR. ZIEMER: Thank you very much, Ted. Before we have comments, I'd like to call attention to the fact that you have HHS news bulletin that's hot off the press that indicates the publication today of the two -- is this for -- both rules covered here? Yes, part 81 and part 82. You have the text of part 82 that was submitted and which apparently now is available in its Code of Federal Regulations form, but you have the text as it was

submitted as almost an insert in your booklet. I don't believe that this one is even punched, it's so fresh off the press, as it were.

And the discussion on the dealing with the public comments that Ted has just summarized begins on page 13 of the text that the Board has, and the issues that were raised -- that is the recommendations of this Board and their resolution -- begins on page 63 of that text, in case you wish to look at that directly. In this case the Board had a number of comments. Ted has summarized them well and they indicate in detail here how each of the comments of this Board -- how each was handled.

Now let's ask if there are questions or comments that you have for Ted. Who's first, who's second? Mark looks like he's raring to say something, but he's hesitating.

MR. GRIFFON: I just have a similar request as was made earlier on the minutes, that we just -- you know, we just came in and saw these and I'm thumbing through it as fast as I can, and I'm not sure -- probably my questions will be held off for Jim Neton anyway, but can we have a few minutes just to thumb through --

DR. ZIEMER: Right, but you recognize that the rule now has been published. We're not in a position to recommend any changes in the rule. We

went through the rule -- that is the draft rule -- in great detail at our previous meetings, so what Ted has summarized really is what the final rule looks like compared to the earlier versions, where they have added detail, where they have changed things and so on. But we certainly -- if you -- let me do this. Let's wait and try to stay on schedule. These are pretty lengthy and I think it would not be appropriate right now to sit and take time to read these, but there will be an opportunity later in the meeting if we need to spend a little time just looking at the changes and making sure the comfort zone is pretty good. But recognize that in this process, as they go through the rule-making, there's really not a practical way to come back to the Board every time they respond to a comment. They've tried to, on balance, deal with all comments, from us and from others. But the Board does not have the final say on this. We are -- we recommend things, just as others do.

DR. MELIUS: Yeah, but --

DR. ZIEMER: And they are responsive, right.

DR. MELIUS: Just to follow up on that, I think that it is appropriate for the Board to ask for clarification on these issues to try to understand it better.

DR. ZIEMER: Right.

DR. MELIUS: I guess my question -- is Ted going to be here tomorrow, so --

MR. KATZ: Yes.

DR. MELIUS: Okay. So there is an opportunity --

MR. KATZ: Yes, I was going to suggest that, actually. I'll be here tomorrow and I'll be happy to --

DR. ZIEMER: Yeah, and perhaps an opportunity after you look it over to raise issues about how things are going to work and how they're going to be dealt with. This is basically sort of an overview of the changes as they appear in the final rule.

Okay. Henry's next.

MR. KATZ: Yes.

DR. ANDERSON: Yeah, my comments more are your implementation issues and to kind of put on the list for subsequent meetings. I think it'd be very helpful to maybe have a discussion of the specifics on what the recommendations or concerns people had about implementation as we move forward. As you say, the rules are fixed and now we're into how are they going to be applied and what are the potential problems, so I would think if we have an implementation discussion of -- I don't know if they're specifically listed here or not, but what

the public comments were that you found would be helpful to you, it'd be helpful I think to us to also know what those comments were and have a discussion on so how are we going to address those issues in the future. So just put it on the parking list.

DR. ZIEMER: And you may want to take the time later to go through those sections that I identified where each of the categories of comments were raised and the discussion on how they addressed those.

The other thing is to keep in mind on implementation that under the rule-making, there are guidelines which will deal with the sort of more detailed implementation issues, and we looked at some of those before I think.

MR. KATZ: Right.

DR. ZIEMER: Yeah. Okay, other comments or questions? Thank you, Ted.

MR. KATZ: Thank you.

DR. ZIEMER: The committee is going to be -- or the Board will be addressed in a few moments, we hope, by Dr. Land. We're a little bit -- a few minutes ahead of schedule, so...

(Pause)

DR. ZIEMER: Just a comment here. Larry, yes?

MR. ELLIOTT: Well, we're trying to track down Dr. Land and make sure he's on his way here. We also have a little bit of a predicament with Mary Schubauer-Berigan being locked down in the airport in Cincinnati, not being able to get out due to weather. And so we're trying to figure out where these folks are at and what we can do about your agenda at this point, so if you'd bear with us.

DR. ZIEMER: I'll just exercise the Chair's prerogative here. We'll take a break for about five minutes. That is a time break in terms of the action here, give Dr. Land an opportunity to arrive, and this would be a good time for you to do some reading on the final rules if you wish, or if you need to take a break already, you can do that. We'll just come to a brief standstill here for a few moments. Okay? Just give him a chance to get settled here a minute.

(Whereupon, a recess was taken.)

DR. ZIEMER: We're pleased to have Dr. Charles Land with us. Dr. Land is a statistician from the National Cancer Institutes, an individual whose expertise is very critical to the sorts of things that are being done here, and he will talk to us about the IREP program at NCI. Now there's -- well, I don't want to spend too much time myself, but there's IREP and then there's sort of IREP, Jr.

or something, there's a NIOSH application of IREP. But we start out with the program as it was developed at NCI. So Dr. Land, we're pleased to have you with us today and welcome you to the Advisory Board activities here.

DR. LAND: Thank you. Let's see, do I ask --

DR. ZIEMER: Yeah, you have --

DR. LAND: You haven't found it yet. Okay.

DR. ZIEMER: You have a --

DR. LAND: It's also my talking notes, so if I don't look at you when I talk to you, you'll know why.

DR. ZIEMER: You will be able to advance them with the switch there.

DR. LAND: Okay, that's great -- good.

(Pause)

DR. LAND: Well, you can see that we have kind of a small group working on this, and maybe it wasn't a good idea actually to do it at all, but I decided that I really wanted to do it, so that's how we got to where we are. There's Ethel Gilbert and myself from NCI; Jim Smith from CDC, he has been more of an administrative advisor; and then Owen Hoffman, Iulian Apostoeai and Brian Thomas from our contractor, SENES Oak Ridge, which is your contractor, as well.

Well, the 1985 report was a response to a Congressional mandate, which was the Orphan Drug Act of something like 1983 or something like that. And the idea was that maybe the whole idea of making -- of claim adjustments, and maybe even legal stuff, could be based on the idea of probability of causation, which is just the excess risk divided by the baseline plus the excess, which is -- in epidemiological terms, it's the excess relative risk divided by one plus the excess relative risk as estimated from epidemiological data.

And the 1985 report provided tables and algorithms for 13 cancers, and there were uncertainty analyses, but they were in a separate chapter. They were sort of -- I mean it was a serious attempt, but it should probably have been integrated.

The interesting thing is that the committee recognized that for X-rays really the relative biological effect of this was greater than one, but didn't have the data to do anything with it, so we just followed current practice and treated all low LET radiation as the same. And part of the mandate was periodic revisions.

Well, the Department of Veterans Affairs used it, has used it. They use it to adjudicate compensation claims for radiation-induced cancer.

But they found the tables kind of hard to work with and they commissioned CIRRPC to devise a screening approach based on the 1985 tables. And in effect, that -- the CIRRPC screening approach -- screened -- used the probability -- the uncertainty distributions. It screened out claims for which the upper 99 percent credibility limit or upper probability limit for the PC's was much less than 50 percent.

I don't think CIRRPC intended that that would be the rule, but that's actually the way it's turned out to be because after you've done that, well, then what else do you do? And it turns out there isn't that much information.

The Department of Defense has used it, the Navy has, and then of course now there is this Energy Employees Occupational Illness Compensation Act of 2000.

And the reasons for the update. Well, the -- mainly because the VA wanted us to do it. And the 1985 tables report was outmoded. It was based largely on 1980 BEIR's III report. Of course since there there've been new data, longer follow-up, and especially new A-bomb survivor dosimetry, which have changed the estimates somewhat; and also the development of the RERF -- the Radiation Effects Research Foundation -- Tumor Registry into something

that you can really use, comprehensive incidence data. And if you're going to estimate risk, incidents are -- incidence data are better because the data are more accurate and they're more timely, also.

New inferences have been made. Of course there's -- a great one is the methodological advances which take advantage of the greater computing power of that laptop, for example, compared to anything we had at the time. They do more flexible modeling and use a more sophisticated treatment of uncertainty.

Now we took this job on with the understanding that it was an interim update, it would bridge the gap between BEIR III and BEIR VII -- which hasn't happened yet, they haven't had their report -- carried out by a small working group, based mainly on A-bomb survivor data which we could get easily, and especially original incidence data from the RERF Tumor Registry.

And emphasis was placed on uncertainty because it seemed that uncertainty -- the upper limits was in fact the way things were going to be done. And so we fitted statistical uncertainty based on likelihood contours of fitted risk estimates. That's a statistician sort of thing. And our treatment of other sources of uncertainty

follows the two NCRP reports, the Commentary 14, which was written by Owen Hoffman, and Report 126, which was led by Orin Sinclair.

We had -- the 1985 group had an NAS oversight committee, and a rather high-powered one, and they emphasized a number of points, one of which was that PC values pertain to populations, not individuals. They're not probabilities in the usual sense. They're really properties of the group to which a person belongs, but they are -- it's a societal convention. We agree to do this. We assign to the person, for purposes of compensation, the probability of causation or the assigned share or the attributable risk that belongs to a group in which this person belongs. We have no idea what an individual's probability of getting cancer is. Really, it's -- we just have this thing on groups. And insurance companies work the same way.

The oversight committee recommended replacing probability of causation by assigned share and -- to emphasize the difference, and we've done that, and I don't suppose it's going to stick.

The 1985 committee thought about it and decided not to do it because everybody was using PC, but we decided to do it, but it probably won't make any difference, either.

The neat thing about this is that the

assigned share value and its uncertainty -- and its uncertainty, and I emphasize uncertainty -- summarize what we know and what we think we know about excess risk or especially excess relative risk of cancer following radiation exposure. It's our best estimate and it's also our estimates that we think are allowable or reasonable. And these scientific findings also may be relevant to the adjudication of an individual claim. And we don't make any claims regarding the influence of factors that we haven't studied.

There are a lot -- obviously there are a lot of things to determine whether a person gets cancer, and there are probably a lot of things that we don't know about that determine why a person gets cancer after radiation exposure. If we don't know about it, well, we can't do anything about it.

I mention that there is a critical view especially enunciated by Sandra Greenland that it's a logically flawed concept. It's subject to bias and it's unsuitable as a guide to adjudication of compensation claims in cases of possibly radiation-induced cancer.

And I -- my answer to this is that, you know, he's probably right, if he's thinking about an individual's probability. But we don't know -- we know that we can't do that. And his particular

example, argument by counter-example, doesn't seem very persuasive, but things may change. And just generally, population characteristics are often used as a guide in individual decisions, so this isn't anything new. We're just doing what we always do.

Some differences with the 1985 report. Well, I've mentioned that we're using incidence rather than mortality. We have more sites because we have more data and can do more things with it. It includes -- the previous report mostly was based on sites for which there was a proven association of cancer risk with radiation dose. And what that means is that the lower uncertainty limit, the statistical uncertainty limit, was greater than zero. Okay? That's -- if you're -- if you are interested in proving that a particular cancer or in -- generally a cancer is related to radiation, that's a good criterion to follow. But if you're adjudicating a claim, I think it's different because it seems that -- I think that if you followed that rule you probably wouldn't ever compensate anybody at all because you'd be dealing with absolute, ironclad proof. We know that this is related to radiation. The question is, is the possibility enough to be worth -- so that it's reasonable to award a claim.

We based our treatment -- this is of radon-

associated lung cancer was based on the 1995 RECA report for the Department of Justice. We used a computer program instead of tables. I think that's a big advance. And more -- again, more emphasis on uncertainty; little on point estimates. It relies on Monte Carlo simulation for calculation of most of the uncertainty distributions. That's not necessarily a better thing to do, but it's certainly a lot easier and that's why we did it; we can do it.

I'm going to give you a graphical synopsis of our approach, stating with the statistical uncertainty distribution, which is for the A-bomb survivors and it's in fact what we would use as the basis of the assigned share calculation for members of that population, if A-bomb survivors were making claims. That's what we would use because it's based them. So this example is a sex-averaged excess relative risk per Sievert for all solid cancers, and it looks sort of like that. That's the probability density of the uncertainty distribution and things that are in the middle are pretty likely and -- or we think are pretty likely, and the ones off on the tails we think are very unlikely.

And that's the cumulative form of the same distribution and I'm just -- I have this here just to demonstrate that if you want to get an upper confidence limit, what you do is go up here to where

the 90 percent or 95 percent, you go over to the curve, then you drop down and that's your limit. I'm going to show you a lot of these things.

These are statistical uncertainty curves for leukemia, excluding chronic lymphocytic, by age at exposure and time after exposure. The green lines correspond to exposure age 20, for different times after exposure, and the purple lines correspond to exposure age 30, again by time after exposure. And you see that as the age at exposure gets older, the risk -- the distribution moves to the left, there's less risk, and also as the time after exposure, it lengthens, the curves move to the left.

Here again -- this is a different scale. You see that it's just the same thing carried on at larger numbers of years after exposure.

This is thyroid cancer by age at exposure. It doesn't really depend on -- as far as we can tell, depend on time after exposure. And thyroid cancer is the one cancer that has really the greatest dependency of excess risk on age at exposure. Thyroid cancer is much more likely to be caused by or to occur after a radiation exposure at a young age than it is at older ages. And in fact, there's some doubt whether among adults there's really any risk at all.

Now the next thing. That was the

statistical uncertainty. Now transferring to the U.S. population, we have several problems. One is the dosimetry. For the A-bomb survivors, has errors and biases and -- but it works just fine when we're doing things for the A-bomb survivors. But when -- but that doesn't pertain to the U.S. population, which has different dosimetry, so we are assuming that the U.S. population has an exact distribution -- and exact dosimetry, or one at least that is known in terms of uncertainty. And there is some adjustment that has to be done.

There's also the fact that baseline cancer rates, particularly site-specific baselines, differ between Japan and the U.S., and we don't know what effect that has on radiation-related risk. The differences are only a few percent for all solid cancers combined, but for stomach, liver, prostate gland -- and actually breast is close -- it's an order of magnitude, and it really makes a difference.

So first -- this is sort of out of line, but anyway, let me just say it. Okay, we don't know exactly how to adjust for either of these two factors, but they can't be ignored. There's information. It's not as well quantified as the statistical uncertainty shown in figure 1, and so we use expert judgment. So this is -- what you are

seeing is not what we get from the data, but also what we think we know after we thought about it a while. And the important thing is that we say how we got there. And if you want to do it differently, you can, you just have to specify how you got it. It's more or less the rules.

Okay. So again here's the statistical uncertainty distribution -- oh, sorry, that wasn't right. That was the statistical uncertainty distribution for dosimetry. It's just -- okay, that's sort of a throw-away.

This is the comparison of U.S. and Japanese breast cancer rates, and the thing here is they're very different. And let's say here's baseline based on A-bomb survivor data. And let's say this is the risk for some people who have -- estimated risk for people who have had a certain dose. And then we can take the difference and we can transfer it, or we can take the ratio and we can transfer that. And it really makes a lot of difference, so we have to handle that somehow, and the way we do it is by fuzzing, putting an uncertainty -- actually, the additive transfer is better because we do have information on breast cancer. But if we're just ignorant about it and we -- and on this graph, zero represents multiplicative and one represents additive, that's an ignorant uncertainty

distribution. Well, it's somewhere in there; we don't know. And maybe it might be in fact maybe sub-multiplicative or super-multiplicative at/or super-additive, and so we have a little bit of probability out just beyond these things, but one represents additive, zero represents multiplicative and things in the middle represent linear combinations of the two.

This is what we did for breast cancer. We had quite a bit of evidence that the breast cancer situation -- it corresponds more to an additive transfer, so we put -- I think that what we really put it is we put half of the probability on one and we have put half the probability on the ignorant distribution. So this is a subjective uncertainty distribution for the combined dosimetry and population factors. So there's -- it sort of leans a bit to the left, but there's this tail that goes out here that allows for risk to be considerably greater.

And what have we got? I hate this when this happens. Okay.

(Pause)

So we, in a sense -- in essence, this is the distribution of a factor that we use to multiply our uncertain risk estimate by, so -- there we are. And the red dash thing -- I'm really surprised at that

-- is the original one, and -- oh, this is wrong. It's wrong. I corrected it on another one, but it's wrong. This distribution -- really the distribution should look more like this.

UNIDENTIFIED: Speak up, please.

DR. LAND: Pardon? The redistribution should look more like this. That's an error, and I'll show a graph later that you'll see it corrected.

Okay. The most -- this is a statistical and epidemiological fact. The most informative epidemiological data on radiation risk -- related risk pertained to acute, high-dose exposures. And it's a signal to the problem. You have -- when the dose is high, you have a nice high excess, you don't have to worry so much about the variation in the baseline. If you have a very low dose, you do have to worry about that and it's the information -- it's -- you don't really get very informative data. So you have to extrapolate estimates from high doses to low doses.

And a lot of work has been done on this using -- which suggests that the risk per Sievert is less at low doses and low dose rates than for acute high-dose exposures, and so there is a dose-and-dose-rate-effectiveness factor which is sometimes applied. The ICRP recommends using a DDREF of two

for doses less than two and for chronic -- sorry, doses less than .2 Sieverts and for chronic doses. We didn't -- we thought that was kind of abrupt.

This is the -- what the NCRP Report 126 used, a subjective uncertainty DDRF factor for low-dose extrapolation of risk, and this is what we used. It's discreet. Doesn't make much difference, really, and it has more weight on one and it has a little weight on the possibility that actually the risk might even be a little greater at low doses. Not much, but some. Actually it's -- it probably is pretty influential.

This actually is more in keeping with the mainstream thought now, I think. At least that's what I get from the ICRP.

You know, I think I'll just forget -- this is the DDREF we -- which is -- what it means to have a DDREF of one, what it means to have a DDREF of one and a half, that's in red; what it means to have a DDREF of two, that's in green, and so forth. And this is the distribution of the threshold of the way the DDREF is assumed to come in. Remember, you're dividing by this value. And for a threshold dose, and the previous graph showed -- or assumed a distribution for the threshold dose, dose which is log-uniform. Again, it's something that is open to discussion. People can change it, but that's what

we used.

Now here the red is -- again, is our original statistical uncertainty distribution. The green is what we get when we apply the transfer between populations, the error in the dosimetry and the DDREF. The DDREF is an extremely powerful thing. It really changes -- it really changes things.

And this is in terms of the upper confidence limits. You see the -- you probably can't see the number in green, but anyway, it changes the 95 percent upper confidence limit from .76 to .56 for the excess relative risk per Sievert.

And this is just a -- the figure on -- up in the upper corner is the original statistical uncertainty. The figure in the right -- upper right is the one that was messed up before and it's -- you see it moves a little bit over to the left and it spreads out more. And then the one here in the lower left is the one I just showed you, after you've applied the DDREF, and then the cumulative form. That's essentially it. That's how we do it.

And this is taking the same thing and shifting from the excess relative risk, which can go up to anything, I guess, to an assigned share, which is constrained to be between zero and one. And so in this case, the assigned share for a low-dose

exposure, .1 for all solid cancers combined, is about -- is a little over five percent. The upper limit, 95 percent.

I'm almost done, actually, and this is a -- just a list of our -- a group of advisors who met with us from the very beginning -- Pat Buffler; Lars-Erik Holm, Swedish Radiation Protection Institute; Jerry Puskin, EPA; Dan Schafer, Department of Statistics, Oregon State; Lincoln Grahlfs, Atomic Veterans Association; Seth Tuler, Social and Environmental Research Institute.

We also had -- were reviewed in -- in 2000 we actually went to the review on -- presented in May and then we got their report at the end of November in year 2000, and they -- a very thoughtful review. They suggested a lot of things that we might think they could do and things they really wanted us to do, and one of the things they really wanted us to do was to -- not to have sites that have -- that are based on very few cases. They said they recommended grouping -- grouping the sites where you have fewer than 50 -- actually I don't think they said 50, but that's what we did -- exposed cases. That is, cases among those who had -- were radiated.

And a shared-site modeling for estimation of modifying influences of age at exposure and at

diagnosis. That's easy to say, but it's kind of involved and it took us a while to do it.

And finally, inclusion of estimates for radon-related lung cancer and non-melanoma skin cancer, neither of which we wanted to do. The lung cancer because the BEIR VII -- I'm sorry, the BEIR VI and BEIR IV models for radon-related lung cancer are really kind of hard to translate into probability of causation or assigned share because the risk curves go like this (indicating). And you can imagine somebody saying who is here instead of here. You know, it wouldn't be a happy thing. But we found that there was a dataset and a report, this RECA report, and we based our -- we actually did an analysis of the original data for the RECA report. And they also recommended -- well, non-melanoma skin cancer, we didn't want to do that because the non-melanoma skin cancer rates in the United States -- it's not a reportable cancer and it's kind of hard to get -- to get rates, but we -- finally we talked ourselves into it and there is this -- there was this study of the A-bomb survivors which we could use in calculating because in Japan non-melanoma skin cancer is reportable because they don't have very much of it.

And finally NIOSH -- NIOSH was concerned about the motivation for our NCI changes in default

modification -- default -- what am I -- what is that they say? Oh, our treatment of exposure age and attained age, and it's -- this model is -- this is the standard model.

That is the standard that's been used in most recent analyses of A-bomb survivors, particularly the Tumor Registry, and it means that there's -- the modification of excess relative risk is a smooth function of age at exposure and a smooth function of attained age. But you get right down to it, it's really driven by things in the middle. And you really don't know, particularly for very older ages, there isn't really a whole lot of information that suggests that the excess relative risk keeps going on, going down, and so we used a modified one which said we were -- instead of having this kind of a function, something that goes like that, we picked one that went like that. So that at the extreme ages we had something that was more like the rest. And it turns out that in fact the -- that function fits the data every bit as well as the other one. And since it's friendlier to the claimant, we decided to use it.

This is a completely NIOSH initiative. We were -- had planned just to use the ICRP RBE's, but they commissioned with SENES for a comprehensive report -- treatment on uncertain RBE's for photons

with different energies, electrons, neutrons and alpha particle radiation other than radon. And it's -- I understand it's still under peer review, but it -- I've talked to people that know a lot about this, in particular, Keith Eckerman, and he thinks it's all right, and that's good enough for me.

And then this creation of a separate NIOSH version of IREP which incorporates NIOSH's administrative rules for application of our report to claim adjudication. It's sort of like -- it's sort of like a combination, I understand, of CIRRPC and the original one, and I think that's -- I think that's just fine.

I always say we have this kind of light that we really care about the scientific questions of getting the best scientific information that we can, given our poor abilities and so forth, but we really do want to stay away from the administrative decisions about how you actually award things. So we think that what we give you, this uncertainty distribution, is the best we can do as far as a summation of the scientific evidence relating to a particular claim. And then what you do about it is really up to you. It's about to the administrating agencies, it's up to NIOSH, it's up to the Department of Labor, it's up to the VA. And it seems that's it.

DR. ZIEMER: Thank you, Dr. Land. We probably have a number of questions, so let's open the floor for questions at this time. Perhaps I'll start the questions. You raised an issue concerning radon and the use of radon in this model. In general, radon is part of everyone's background exposure of course, but in some facilities radon is part of the occupational exposure. It wasn't clear to me how radon is handled in your models here.

DR. LAND: We use --

DR. ZIEMER: Of course they're not using dose data, to start with. They're using --

DR. LAND: No, it's exposure data and working level months, and we -- we really tried very hard -- the dataset we had was slightly different from the one used at RECA. It didn't have some of the really high doses in it, but we -- first thing, we tried to duplicate certain tables in the RECA report, and we managed to do that. And then we then went to the logical way of modeling the excess relative risk as a function of age at last exposure and time since last exposure. And it's a -- I can't exactly remember the model, but it's -- actually it's working level months -- it's something like the .83 power, so it's kind of -- it has the sort of downward curvature. And the dependence on age at last exposure and time since last exposure is

similar to what we did with age at exposure and age at diagnosis for the other cancers. That is flat -- down flat.

DR. ZIEMER: But you still used the exposure information -- you don't convert it to dose in any way --

DR. LAND: No.

DR. ZIEMER: -- first. Yeah.

DR. LAND: No, it's -- the whole thing is -- the whole thing was -- the data are in terms of working level months.

DR. ZIEMER: Right.

DR. LAND: Yeah. So -- yeah. I don't want to get into that.

DR. ZIEMER: No.

DR. LAND: That would be really difficult.

DR. ZIEMER: Okay. Gen Roessler?

DR. ROESSLER: With regard to your grouping of sites with less than 50 exposed cases, I kind of have this picture of a lot of people sitting in a room and a lot of cases on the table and you're trying to think how to put them together. What is your rationale for grouping? Is it biological or physiological or anatomical or -- I mean I can't quite envision that.

DR. LAND: For example -- an example would be -- let's see, this is cancer -- no, not cancer of

the pharynx. Okay, well, just say -- take an example, miscellaneous digestive cancers. There I think what else can you -- are you going to use? Because we can't really do an estimate -- a separate estimate for miscellaneous digestive cancers. The data wouldn't support much. So we just say well, it's -- let's -- this is a suggestion, by the way. I would not be so bold as to say well, you should use this. It's suggested you use it. It suggests that it's a reasonable thing to do. But if you want to do something else, that's your decision. But we're trying to -- we're doing the sort of the groupings that we thought were most logical, as a convenience, really. Let me think of a -- oh, we did bladder and -- let's see. I'm sorry, I'm trying to think of examples, and I'm sort of blanking. I know we treated urinary, bladder and kidney and other urinary disease -- we thought that for bladder cancer you could justify a site-specific estimate. But for kidney and other cancers of the urinary system, we'd use the grouped, because you couldn't get over 50 cases. I don't feel that I'm really answering your question really well, but can you sort of see the drift of it?

DR. ROESSLER: I can kind of see the drift, and I think overwhelmingly I support the idea. I think to come up with a rationale for grouping makes

really a lot of sense.

DR. LAND: Yeah.

DR. ROESSLER: But I just wanted -- and I think you've kind of explained how you looked at it.

DR. LAND: We sort of did the best we could, I guess is what you'd have to say. We didn't try to take things that are way far afield, except there is a general residual category.

MR. GRIFFON: Just a question on the DDREF value. We heard from some other people who might have either -- either in written testimony or spoke before the Board that the recent RERF lifespan study group recommended actually a value of unity on DDREF. I'm not sure if I'm getting this right, so I just wondered if you considered their input into your analysis for distribution or...

DR. LAND: I'm sorry, I didn't understand the bit about RERF.

MR. GRIFFON: The lifespan study group.

DR. LAND: Yes, right.

MR. GRIFFON: Apparently they recommended a DDREF value of unity rather than previously-reported value of two, and I wondered if --

DR. LAND: RERF wouldn't do that.

MR. GRIFFON: Huh?

DR. LAND: I can't -- lifespan study? They don't work with X-rays and things -- or sorry, a

DDREF of -- oh, excuse me, I'm sorry. I get RBE's and DDREF's mixed up in my head sometimes. Yes, they do. That's because -- okay, that -- you actually touched on something that's really kind of hot.

Epidemiological data look linear. You would use a DDREF of one, yeah. The epidemiologists all say use a DDREF of one because -- and -- but it's based on linearity of the dose response. Okay? You have -- you're fitting -- you have all these doses and you're fitting -- and it's mostly depending on the high-dose stuff, and you get a line that just goes down and then hits some value at zero dose. And there's very little evidence to suggest not using a line. All right? If you take that as your default. But there's all this experimental evidence which -- and some of it is kind of strong, but it's not based on -- it's not really mostly cancer, it's analogous systems. It's chromosome elaborations and mutations and tridyscantia and that kind of thing, and you get this very clear curvilinear form -- function. And -- well, the ICRP says use two. The NCRP says use something like that, so how far do you go against the official consensus, you might say. Well, what we did is we fuzzed it and we have -- actually we have quite a lot of probability on one. We have some probability on less than one. And

actually as it comes -- moving a little probability on one makes a big difference in the upper 99th percentile of your uncertainty distribution. So you know, it's -- but we're not supposed to be sitting there with your thumb on the scale. But this -- it seemed reasonable.

DR. ZIEMER: Mark, does that answer the question? Yeah.

MR. GRIFFON: I had other questions, but I'll (inaudible).

DR. ZIEMER: Roy?

DR. DEHART: Physicians are not supposed to be very good on statistics, and I certainly fit that model, but I do know a little statistics. But would you mind going through figure seven and walking us through that specifically, that figure -- if they could bring it back up for you?

Particularly I'm interested in the ERR per Sievert that we're -- you're dealing with here and trying to understand what would happen if you had more than one dose exposure. Number seven -- it's this one.

DR. ZIEMER: There's some other figures --

DR. LAND: That's it. Okay. First place, it's the cumulative form of the probably more familiar density distribution that just preceded it.

DR. DEHART: Yes.

DR. LAND: And now the question again?

DR. DEHART: Would you just simply walk us through this -- this presentation, this graph.

DR. LAND: This particular graph --

DR. DEHART: Yes.

DR. LAND: -- well, it's how you get an upper confidence limit. It's just you take the uncertainty distribution, you use -- you put it in its cumulative form and then you want a -- if you want a 99 percent confidence limit, you move your figure -- oh, sorry. This is the uncertainty distribution for assigned share. And -- no, excuse me, I'm wrong. I'm confused again. This is for the low-dose excess relative risk, yes.

If I'm going to go very deep into it, I have to go back and use -- look at other graphs, but just given the uncertainty distribution, that density distribution, take the cumulative form of that density distribution, however you got it, and to get an upper confidence limit -- what's graphed here is the 95 percent upper confidence limit.

MR. GRIFFON: Actually, if I can offer -- your next slide I think on four steps that you went through to get to this one.

DR. LAND: Oh, yeah, that's true. Yeah, that's actually -- right. This is how we get there. Is that what you want?

DR. DEHART: I was just trying to -- how to get there and looking at figure seven. I'll do some studying and meet with some other people and try to understand it --

DR. LAND: Well, how you use it -- you go over to wherever you want it to go over here, you go down and that's your limit. But basically that's the statistical uncertainty distribution, and to its right is the statistical uncertainty distribution after you have multiplied the excess relative risk by an uncertain factor that adjusts for error in -- error bias in the A-bomb survivor dosimetry and for the problem of moving from one population to another. Okay? You multiply those two factors together and their distributions, they're the convolution of those two distributions, is the thing in green. Okay? And then we do the same thing again and we applied the DDREF. We apply -- the DDREF has this other distribution and so we multiply -- I'm sorry, we divide by the DDREF and the convolution of the distributions there, the uncertainty distributions is this and the cumulative part of this is that.

DR. ZIEMER: Okay. Mark, you have an additional question, apparently.

MR. GRIFFON: Going back to the Monte Carlo, and this is a -- since I'm a novice in Monte Carlo

calculations, one of your overheads said that Monte Carlo simulation for calculation of most uncertainty distributions, not necessarily better, but certainly easier.

DR. LAND: Yeah.

MR. GRIFFON: And I just wondered if you could expand upon that for those of us who don't understand Monte Carlo that well.

DR. LAND: Okay. Let me just say what analytically this would involve. If you had these various uncertainty distributions, you would have -- you'd have to -- if you -- if they were all lognormal distribution and you were multiplying and dividing them, it'd be real easy. If you have -- the kind of distributions we have, it would be really, really difficult to do.

But the Monte Carlo procedure just says well, all right, we have this factor and it has a certain distribution, and this factor and it has a certain distribution, and actually you do something like 1,000 replications of multiplying one factor and another, sampling from the -- where one distribution for the first factor and from the other distribution for the second factor, multiplying them -- those two together and you get a point. And you do that 1,000 times and you get a distribution, and that's what we use. That's the way it's done.

It's -- back in the days when we were doing the 1985 report, we wouldn't have done that because it would have taken a very long time. But now -- in fact, everything in the 1985 report was based on lognormal probabilities. But with -- now with computers so fast, it's really easier to do it this way.

If I could just take this and use it as a little bit of a soapbox, the problem is using the upper 99th percentile because it is -- unless you have a really large sample size, the 99th percentile is -- estimate is unstable. But if you have a really large sample size, it takes a long time to do the simulation and that's a real problem, a real, real problem. And I don't know how you're going to solve that. Maybe a super-computer or -- actually maybe not have it over the web -- not have people doing things over the web 'cause they'll sit there for ten minutes and they'll get very upset.

DR. ZIEMER: Tony?

DR. ANDRADE: By the same token, if you sample many, many times rather than just 1,000 -- say you go to 10,000 --

DR. LAND: Yeah.

DR. ANDRADE: -- doesn't the confidence --

DR. LAND: The estimate is much better for 10,000 than it is for 1,000.

DR. ANDRADE: Exactly. Doesn't it stabilize?

DR. LAND: It -- yeah, it's probably acceptably stable. But it's going to take you ten minutes.

DR. ANDRADE: Yeah, but today, using the computers that we have, that's nothing. And so --

DR. LAND: Oh, if you have a better computer, yeah. But real money rides on this. Right?

DR. ZIEMER: That's why they call it Monte Carlo.

Further questions? Okay, thank you very much, Dr. Land. We appreciate your being with us today here.

We're going to break for lunch in just a moment. I want to ask if there are any housekeeping announcements before lunch that we need to make. Staff people?

I will make one now, but will remind you of it later, and that is that at the end of the day today we need to clear everything out of the room because there will be a reception of some sort here -- not for our group, but a wedding reception or something later this evening, so you cannot leave things overnight expecting them to be here in the morning. So I tell you that, both Board members and

visitors, we do have to clear the room at the end of today's session.

UNIDENTIFIED: Can we get an invite?

DR. ZIEMER: Yeah, if you do a good job of cleaning up, why we'll give you a reward.

Now this afternoon we will have the presentation on NIOSH-IREP, and I think if Mary Schubauer-Berigan does not arrive, I think -- oh, she has arrived? Okay, great. I was going to say, Russ may have to give that, but we're glad that she now has arrived.

UNIDENTIFIED: I wanted Ted to give that.

DR. ZIEMER: We also have some other changes in the afternoon agenda that are different from -- or we have some changes from what you have in your booklet, and we'll tell you what those are when you return from lunch.

Our experience has been that it does generally take a good hour and a quarter to make sure everyone gets their lunch and can get back, so it's not quite quarter of, but we're going to recess at this point and we'll reconvene at 1:00 o'clock. Thank you very much.

(Whereupon, a luncheon recess was taken from 11:35 a.m. to 1:00 p.m.)

DR. ZIEMER: We're going to now reconvene and proceed with the next item on the agenda, which

is the presentation by Dr. Schubauer-Berigan, finalized NIOSH-IREP. So we'll proceed with that presentation, then have a chance for questions and discussion following.

DR. SCHUBAUER-BERIGAN: Good afternoon. I'm very glad to be here with you. It seemed that the weather was conspiring against my arrival in Washington this morning, but I'm glad to finally be with you and speak to you today about the software program, NIOSH-IREP, in its final form.

Today I will be discussing rather briefly the modifications that were made to NIOSH-IREP based both on the public comment and on scientific expert review.

I unfortunately missed most of Dr. Land's presentation this morning, but I did want to recapitulate some of the most important concepts in the probability of causation rule for you, just to make sure that we're all starting from the same page.

First is that EEOICPA requires the calculation and use of the probability of causation, which we abbreviate as PC. EEOICPA also mandates the use of the standard that the cancer was at least as likely as not to have been caused by the claimant's radiation exposure at the upper 99th percentile of its uncertainty distribution. This

requirement reduces the chances that a claim which meets this standard of being as likely as not caused by radiation would be denied, given the substantial uncertainties in the scientific information that's used to derive the probability of causation. Probability of causation is approximated by the calculation of assigned share. This is also known in epidemiology as the attributable fraction. It's important to note this because the NCI-IREP program is defined in terms of the term assigned share.

Some of the other important points about NIOSH-IREP include the fact that it allows for the incorporation of uncertainty in several factors -- dose, the dose-response relationship, as well as other factors that I'll discuss.

The upper 99th percentile PC will be calculated by the Department of Labor, using NIOSH-IREP software.

As you heard this morning, the basis of NIOSH-IREP is the NCI-IREP, which we have specifically adapted for use in EEOICPA.

NIOSH was required to develop methodology for all cancers that are deemed radiogenic. Therefore we have developed a program that allows DOL to do this.

And you -- again, this is probably a repeat for those of you who were here this morning, but

probability of causation is calculated as the relative risk minus one divided by the relative risk, or an equivalent expression is the excess relative risk divided by one plus the excess relative risk. Relative risk is estimated from epidemiologic models of dose and cancer risk. And separate models were produced for each cancer or group of similar cancers.

How is the probability of causation estimated? The models that are used incorporate uncertainty. This is a central tenet of the development and use of these models. They incorporate uncertainty from five major sources. First is the statistical uncertainty that exists about the relative risk estimates. Second is uncertainty associated with the exposure of the study population from the epidemiologic analysis. Third is uncertainty about the effects of confounding variables. Fourth is uncertainty in the method by which the risk should be transferred from the epidemiologic study to the population of interest. Lastly, there is uncertainty that is associated with the exposure of the claimant to radiation.

Now I'd like to talk about modifications that were made based on the comment period. First is that some of the risk coefficients were revised

for certain cancer models in NIOSH-IREP. Based on the comments of several of the reviewers; to wit, that squamous cell carcinoma does not tend to exhibit as strong a dose-response relationship as basal cell carcinoma, we have reverted to new models that were developed by NCI-IREP only very recently. These are separated into a model for basal cell carcinoma and one for squamous cell carcinoma, and upon review of the NCI's models and with the recommendations of our scientific experts, it seemed justified to develop -- to use two different models for these two cancer types. However, if the claimant's skin cancer -- non-melanoma skin cancer cell type cannot be determined by Department of Labor, they must use the basal cell carcinoma risk estimates, which are generally -- are always higher than the squamous cell.

A second alteration is for bone cancer. The original NIOSH-IREP used a set of risk coefficients that were published in an appendix of a study of the Japanese atomic bomb survivors, and on discussion with our scientific experts and with NCI, we determined that those models were really -- didn't lend themselves well to risk analysis because they were based on such small amounts of data. Instead we used the residual cancer risk coefficients that were developed by NCI, and those do include risks

from bone cancer cases, as well as other cancer sites.

Secondly we made modifications of the risk transfer functions for some cancers. For skin cancer we use a general uncertainty distribution which equally weights the multiplicative and additive interaction model. The previous version of NIOSH-IREP favored an additive model. However, on review -- further review of the literature and with recommendation of several subject matter experts, we determined that the general uncertainty distribution was more appropriate in this case.

Similarly, for male breast cancer we used the general uncertainty distribution rather than the distribution that favors an additive interaction.

We incorporated an inverse dose-rate uncertainty distribution for alpha radiation exposures. This brings the treatment of alpha exposures in line with other high LET radiation, mainly neutron exposure. There was initially the incorporation of an inverse dose-rate effect for neutrons, and we've simply added that distribution for alphas on the recommendation of subject matter experts and our own opinion.

I'll be talking about some of these modifications in the next couple of slides, but I wanted to show -- mention that we did modify the

dose and dose-rate effectiveness factor or DDREF to more heavily weight a value of one, on the basis of expert opinion.

We also modified some of the uncertainty distributions for the RBE factors, for low-energy photons and X-rays, for neutrons and for alpha particles, and I will discuss these in a minute or two.

To show you how we changed the DDREF, I made up this slide and I think this repeats some of what Charles Land told you this morning, but I wanted to illustrate the version that we used in the draft NIOSH-IREP with the final version.

The arrow here points to a sort of continuous-looking distribution, which was the draft distribution used, and that had a mode or a high value at two, a DDREF of two. We shifted the distribution, and this follows NCI's recommendation as well, to more heavily weight a value of one, and so you can see that it's no longer a continuous distribution. It's actually discreet and it is slightly shifted towards one. This is the distribution used for all solid cancers except breast and thyroid, which are showed here.

And this is a slightly different presentation. In both cases the distribution was discreet, and the final version is shown in the

back, just simply because it displayed better that way. What happened here is that the draft distribution had no values in the uncertainty distribution below one, and we felt that it was more consistent with the approach used for other solid cancers to include a probability -- a small probability that the DDREF is actually less than one, and so we've shifted some of the weight to that direction.

Those really are the changes that we've -- well, here let me talk about the RBE distributions. These are now given a different term. This was actually the subject of a lot of discussion between the subject matter experts, what should these things be called, and the decision was to revert to the use of the term radiation weighting factors. However, these will be defined differently than they're typically understood by the health physics community.

For photons there was a slight redefinition of the class that's considered high energy photons. That was changed from a lower bound of 200 keV and it was raised to 250 keV.

MR. ELLIOTT: Mary, could I interrupt you a moment?

DR. SCHUBAUER-BERIGAN: Yes.

MR. ELLIOTT: I'm sorry, but I know folks

are looking for this slide and I don't think it's included in the booklets that we gave you. It's a last-minute --

DR. SCHUBAUER-BERIGAN: That's right.

MR. ELLIOTT: -- introduction of that information.

DR. SCHUBAUER-BERIGAN: This will be alluded to towards the end, but I may as well mention it now. We had extensive review of the documentation of the RBE distributions, and we've only received some of the final subject matter expert comments within the last week, and so these revisions are literally hot off the press. Within the past several days these have become final and have delayed the production of the final NIOSH-IREP by about a week. So this is -- we were unable to produce this slide in time for you to have it in your packet, but it will be made available to you as soon as possible.

So for photons, there was also a small increase in the uncertainty distribution which raises the upper tail, making the distribution spread out in the upper regions more. This was on the basis of new data that was included in the analysis for the purposes of developing these RBE's.

For neutrons, the same change was made. There is a slight increase in both the central

tendency and in the uncertainty distribution for neutrons. And for alpha particles there was also a slight increase in that RBE uncertainty distribution.

DR. ZIEMER: Can I interrupt, just a quick question?

DR. SCHUBAUER-BERIGAN: Sure.

DR. ZIEMER: Are all of these distributions now discreet points rather than continuous, or just the one?

DR. SCHUBAUER-BERIGAN: No, they're -- the DDREF is -- there's -- that's been completely discreetized --

DR. ZIEMER: Right.

DR. SCHUBAUER-BERIGAN: -- so both of the final ones are. In the case of the RBE distributions there's a mixture of continuous and discreet distributions, and there's a table that will be produced with the final documentation that will clearly show what those distributions look like. I don't have it with me at the moment.

DR. ZIEMER: Has someone shown then that if you do a Monte Carlo with a discreet versus a continuous -- if you do enough samples you get about the same result?

DR. SCHUBAUER-BERIGAN: I don't know that that testing has been done. I wouldn't think it

would make a large difference.

DR. ZIEMER: Intuitively I wouldn't think so, either. I just wondered if anyone had actually tested it.

DR. SCHUBAUER-BERIGAN: It might be that it's been tested as part of the NCI's development, but we didn't do that for NIOSH-IREP.

DR. ZIEMER: Thank you.

DR. SCHUBAUER-BERIGAN: Lastly, there was some criticism of the use of the same RBE distribution for leukemia as for all solid tumors, and this led to the use of a hybrid distribution that actually adds weight to lower RBE's based on human evidence primarily that the leukemia RBE's might be lower. The compromise here is that since there is substantial uncertainty, this distribution is linked with the general solid tumor distribution so that those are combined to produce a separate distribution.

Since you've heard about the NCI's program, I wanted to talk a little bit about how NIOSH-IREP differs from NCI-IREP, and you'll see that most of the differences stem from the mandate that we were given under EEOICPA. We're back on the slides now that you have.

Well, first, the most important point is that the two versions of IREP agree very

substantially. There's very little difference between them. There are, however, differences in risk coefficients that are used for certain cancer models, namely malignant melanoma of skin and male breast cancer. I'd like to show you these differences and what led us to use these unique sets of coefficients.

In our subject matter expert review there was some criticism of our decision to use basal cell carcinoma risk coefficients for malignant melanoma cancer. We turned to the recommendation of NCI-IREP to help us decide what to do here. They don't, however, recommend any particular model at all for malignant melanoma. There is no model in NCI-IREP.

We decided to stay with the use of the basal cell carcinoma model for several reasons. First, from the A-bomb survivor studies conducted by Elaine Rahn and others, the point estimates for malignant melanomas are very similar to those for basal cell carcinoma. And there was also evidence from nuclear worker studies of an association between radiation exposure and malignant melanoma. Therefore we determined that it was appropriate to use a model, to have a model to estimate probability of causation for malignant melanoma, and we needed to decide which was the most appropriate model to use.

The two models we believed to be relevant

here were the basal cell carcinoma model and the residual cancer model. This graph is quite complex. I'll orient you to it. It shows the upper tail of the distribution of the ERR per Sievert for two different models at various ages of exposure and diagnosis. Age at diagnosis is along the X axis. The triangles show the results for the basal cell carcinoma model, and colors that are the same indicate, for the two models, the same ages at exposure. So initially what you see is that both of them show higher risk coefficients for younger ages at exposure. This first blue line is age 15 -- or I'm sorry, age 20, age at exposure. The sort of purplish line is the result for ages at exposure of 30, and then this line at the bottom is ages greater than or equal to 30. There's no change after age 30, age at exposure.

As you'd be able to tell if you had time to look at this, in every case the basal cell carcinoma risk coefficients are higher than those for squamous cell carcinoma, and we felt it was consistent with the policy we had applied elsewhere to, when there was doubt about the appropriate -- two scientifically-appropriate approaches, we would use the one most favorable to the claimant, and in this case that is the use of the basal cell carcinoma risk coefficients.

We applied the same reasoning to male breast cancer. Our approach in the initial NIOSH-IREP was to use female breast cancer risk coefficients applied to the background incidence rates for male breast cancer. This was questioned by one scientific reviewer, who suggested that we use the miscellaneous category. This indeed is what NCI-IREP has done. They have male breast cancer included in the residual cancer model.

However, our final version of NIOSH-IREP retains the use of the female breast cancer coefficients for virtually the same reasons as I alluded to earlier. Male breast cancer, we feel, is hormonally related and in that sense it's an appropriate approach to consider using female breast cancer coefficients. The residual cancer model produces generally lower risks per unit dose at the upper tail of the distribution than does the female breast cancer. And here it's much more difficult to see because at young ages of exposure the two models produce very similar risk coefficients, seen here in the red lines, the blue lines and the green lines for comparable ages at exposure.

So given our policy intent to give the benefit of doubt to the claimant, we decided to use female breast cancer risk coefficients for male breast cancer.

Continuing on the list of ways in which NIOSH-IREP differs from NCI-IREP, we use individual models for the miscellaneous categories. We split them into their individual cancer types, which are connective tissue, eye, non-thyroid endocrine gland and ill-defined cancers. These use a common estimate of the excess relative risk per Sievert, but the risk transfer function uses the background incidence rates for the specific cancer site.

There are also some differences in application, primarily designed to make the determinations as objective as possible, providing again the benefit of doubt to the claimant when necessary. First is the use of objective lists of cancer models for claims in which the primary cancer site is unknown. NCI-IREP doesn't speak to that issue.

Again, we have the required use of two leukemia models for certain leukemias, and this is generally done in the case where we're uncertain whether the subtype of leukemia is more important than age at exposure in being an influential risk modifier.

We also developed a set of operational definitions of smoking history for the lung cancer models.

I'd like to touch on some of the potential

future modifications that we can envision at this point resulting from new scientific information. First, it's always possible and highly probable that there will be improvements in the risk models, or adjustments of the uncertainty distributions. Some examples that have been mentioned by NCI include the update of risk coefficients from the Japanese atomic bomb survivor incidence cohort, which is expected around the same time as BEIR VII. Also we do anticipate that input from epidemiologic studies of nuclear workers, which played a very small role, if any, in the NCI-IREP program, will become a more important part of NIOSH-IREP in the future.

It's always possible that changes in dosimetry practices could lead to changes in NIOSH-IREP. The adjustment for temporal changes in U.S. cancer rates is a feature that we would really like to see added to NIOSH-IREP.

And several individuals and the NAS panel that reviewed the NCI-IREP recommended some consideration of adjustments for radiosensitive sub-populations. We were not able to do that at this time because of the state of scientific evidence, and the practical limitations in actually determining who is radiosensitive precluded our ability to do that.

Adjustments for other -- for interactions

with other work place exposures is an avenue we believe requires further investigation. The assumption in NIOSH-IREP is that these interactions are multiplicative. That is, your excess relative risk doesn't depend on what your -- for example, your chemical exposure history is.

In summary, we made several modifications to NIOSH-IREP in response to both public and subject matter expert comments. These include the modification of risk coefficients for bone and skin cancers, the use of certain risk transfer functions for skin cancer and for male breast cancer, the adjustment of DDREF and RBE distributions. We justified our modifications in the final PC rule and also in the final technical documentation of NIOSH-IREP, which will be available very soon, along with NIOSH-IREP itself. It will also be available -- this documentation will also be available on-line. That's a charge that we take very seriously because we believe that that will lead to increased understanding of how the probability of causation is actually calculated.

As you're aware, future modifications will be formalized and are subject to review and comment by you, the Advisory Board on Radiation and Worker Health. And with that I will finish and take questions.

DR. ZIEMER: Thank you very much. Who wishes to raise a question first?

DR. MELIUS: First a procedural question. I believe that -- I remember back to the first few meetings -- the committee agreed that we would review the current IREP in more detail, and that we were giving approval to the general concept and many of the principles involved. And I guess I'm trying to get a handle on procedurally how we would go from here. There are these scientific expert reviews that have been done that we've not been given access to yet. I presume we will at some point soon. Some of them clearly aren't finalized yet. And how do we bring this together procedurally into a -- into the function of the committee? And I don't know, Larry, if you've given thought to that or -- all or -- how we're going to proceed. I guess my point here is do -- we can ask a bunch of questions, but we've not been given full access to all the information yet and I don't want to sort of have Mary have to relay this expert said this and this and that. I think she's done a very good job of summarizing the information and fairly, but I think at the same time as a committee we have a responsibility to go into more detail at some point if we're going to be dealing with future modifications as well as some of the issues that may arise from the application of

this final model.

MR. ELLIOTT: Certainly your points are well-taken and we have thought about this. Given the push to put this in place so that claims can be adjudicated in the Department of Labor, we need to set the milestone -- the starting point or the -- put this in concrete, if you will, as to what will be used by Labor to calculate probability of causation on completed dose reconstructions we send to them. You certainly have not seen all of the subject matter expert comments and that's part of the documentation for the IREP that Mary's referred to. It is being finalized. The IREP itself, with these minor changes and modifications that she's iterated for you, are being completed this week. We hope that it'll be in place next week, and then by the following week or so, after we've got clearance from claimants on OCAS-I forms, to be able to transmit that information on dose reconstruction to the Department of Labor and they will use this IREP to adjudicate those claims.

So I guess this is your starting point. Any additional details and information that you want to see and you need to see, we're certainly ready and willing to provide that to you, and we want your thoughts and your input as to what you would recommend changes should be from that point on. But

this will be the starting point for claims to be adjudicated from.

I don't know that I answered your question, but...

DR. MELIUS: I still have a procedural question and would just point out that while we understand the need to get this in place to do, it is subject to our review and recommendation for modification, and that modification may be -- come sooner rather than later. We're assuming it'll come later and some of that will deal with further scientific study. But I think we need to -- as a committee to come to grips with some way of reviewing this information and coming to grips with it and not -- not in this -- you know, we've got this repeated pattern of sort of last-minute -- you know, here it is; approve it. And I think we need to get out of that at that mode and I guess that's what I'm --

MR. ELLIOTT: Well, you are out of that mode. You are out of that mode. When this is set next week, this will be the NIOSH-IREP. And from that point on, whatever recommended changes you have, we'll take under consideration. Whatever information needs you have to determine what recommendations you would like to provide, we will assist you in getting that information.

DR. MELIUS: Just that I'm personally uncomfortable with much of this information not being shared with us at -- ahead of a meeting so we can have a very reasonable discussion without again wasting a lot of time and effort and not without putting all the pressure on Mary to relay to us all this separate information. And I think we need to be provided with this information sooner rather than later.

MR. ELLIOTT: Well, we're providing you the information almost as it is made available to us. We're making policy decisions, as Mary's indicated today, and it's certainly your option and the Board has the responsibility to react to what we've done to date and to seek additional information for your better edification of the details behind this, and we'll provide that to you. So I hear you loud and clear. Believe me, I have a lot of empathy because we are living with this on a day-to-day basis ourselves.

DR. MELIUS: Then I'd like to open up for Board discussion, before we ask Mary questions, about what will be our process and procedures for doing this.

DR. ZIEMER: We're sort of asking ourselves that question --

DR. MELIUS: Well, again, no, I'm not --

DR. ZIEMER: -- in the sense of what we're doing, but --

DR. MELIUS: I'm not saying I have the answers or --

DR. ZIEMER: -- let me throw in some comments here, because it seems to me we have to distinguish between the sort of -- I will describe it as the program that grinds out the calculation and the underlying assumptions. I don't think any of us want to get into how they're doing the program. We're more interested in those underlying assumptions which involve, number one, the dose reconstruction and the distribution of uncertainties, and those -- because there's a number of models here. We have said that we will accept the ICRP-60 models, for example, and so that's kind of a universal thing for a certain piece of this calculation.

There are some assumptions about uncertainty distributions and dose distributions which are default assumptions, in the absence of real information about what the true distribution is. So it's those kinds of things I think we almost have to categorize them and say okay, are there some things in terms of risk coefficients that we're uncomfortable with; are there things about the dose rate factors; are there issues with assumptions on

the form of the distributions and that kind of thing.

Now over the past couple of meetings, the two previous meetings here, we've certainly received that information, at least in general terms, and in fact have had a chance to try out the IREP as it has been developed and sort of get a feel for the effect of changing parameters and so on. It's not clear to me that this committee is in a position to sort of fully bless the IREP. The IREP's simply a tool for them to carry out the calculational part of all of the other stuff. So it's not clear to me if you're concerned about IREP as a methodology or some of the underlying assumptions as I described them -- or both or neither.

DR. MELIUS: Well, it's probably both. But my concern is that we keep hearing today -- and I don't think it's inappropriate, but it is disturbing as an advisory committee. We keep hearing today that well, we got expert review and based on that and based on consensus, discussion, whatever, we made these changes. Well, we haven't gotten that -- seen that scientific review, and I do think, while we may not have the depth of expertise in a particular area that some of these outside experts have, I do think we -- I think to some extent have a responsibility for reviewing was that incorporation

appropriate or not. And I can't do that in the abstract. I can't -- again, not that we distrust the NIOSH staff or doubt their ability, but I think we do have some responsibility to look at those reviews, were those appropriately weighed and ask some questions. And it's very hard to do that in this context when they have all the information and we have none.

DR. SCHUBAUER-BERIGAN: Can I just make one --

DR. ZIEMER: Please.

DR. SCHUBAUER-BERIGAN: -- statement? It's not correct to say that you have none. You probably have about 75 percent of the subject matter expert reviews. At least they were made available on the NIOSH-OCAS web site. The exception is the RBE and DDREF distribution. And if that's what you're referring to, then yes, there is a set of subject matter expert comments that have only become available -- Monday, as of Monday. I mean it's been an extremely tight turnaround on those. So you do have many of them. And if you'd like to cover issues that don't pertain to either DDREF or the RBE distributions, you've got that information presumably and that -- those have been made available since about January, I believe.

DR. ZIEMER: Let me ask if there are

additional questions or maybe any reactions to what Jim had to say? Tony? Oh, I'm sorry, Henry, you go ahead.

DR. ANDERSON: Yeah, I just -- you know, it's one thing to have the reviews and not -- that's very helpful once we get those and have it on-line, but I think what also would help me is -- and just not to pick on it, but you've made some changes to the DDREF and you're saying that's based on reviewer comments. I guess what would be valuable to me, as well, would be well, how did you distill those comments? Was it unanimous that they felt you ought to just slightly modify this or how did you arrive at what now is a slight difference from the NCI DDREF and then why was this particular one chosen? Is there a science basis for this? Is it a policy decision? We heard this morning Dr. Land saying if you -- at least I took it as maybe a poor man's sensitivity analysis, but the major impact in this whole process is the choice of the DDRF and if you use the human epi data and you use one versus you use two, and now they went somewhere in between and you're also going somewhere in between, and the question is well, is that -- is your choice, which is different than either of the others, is that a policy decision? Is it a -- is the science -- what studies clearly indicate that this -- I mean that's

the kind of -- what are -- we've seen what your decision is and we've heard -- we can read what some of the comments are, but we haven't really heard particularly what the rationalization is other than well, we weighted it a little bit more towards one. How much of a difference did that make? And if you looked at what the possible doses you'd fit into this, does that now on your expectations increase the number of people that might meet the 50 percent criteria or doesn't it have really any impact at all? I think that ultimately -- this committee I think down the line we're going to want to say well, had you used a different factor, have we now, up front, eliminated a whole bunch of people from compensation by adjusting it just at the margins because we don't have what some of those distributions might be. I don't know if anybody's looking at that or if it's just a priori decision. I guess that was -- I'd like to know was it uniform by your experts to say that instead of this figure it ought to be 1.8765 versus two versus one, and on some of the others -- those kind of issues as to what was your thinking. Not that you made the wrong decision. The decision had to be made; you're moving forward. But it's hard for us to understand was there unanimity in your experts, just as we heard the public comments were all over the map,

this way, that way, and you then decided to go this way, but we haven't really heard the rationale for it, at least I don't understand it.

DR. SCHUBAUER-BERIGAN: Okay, I'll answer at least one aspect of your complex question, and that is that at this point our DDREF distribution is the same as the one that NCI is using. We haven't changed theirs. It's different from the one that we had in the program as the initial NIOSH-IREP, the draft NIOSH-IREP. But it was made on the basis of -- it wasn't made on the basis of consensus with our subject matter experts.

We didn't have any kind of group meeting of these people. In fact, I don't think we are permitted to do that for this process. We did get expert opinions. And those of you who work in the field of science know that it's very rare to have two people agree on anything, especially if they're coming at an approach without discussing it among themselves. So I wouldn't say that there was unanimous agreement among our subject matter experts about any particular change that needed to be made.

In this particular instance, we concurred with NCI -- which is important for distributions that are common to both the program they're developing and the program that we're developing -- that it was more appropriate to more heavily weight

a DDREF of one. Now this has the effect of generally increasing a claimant's chances of receiving compensation.

But there were instances where changes were made that went in the other direction. And the process of distilling those subject matter expert reviews is a completely separate question and I don't know that there is a document that's produced that addresses all of the subject matter expert comments that's in development, which will hopefully address many of the questions that you raise.

And Larry, I don't know if you had anything to add to that.

MR. ELLIOTT: Well, what I would add is that where we use science to the fullest advantage and we still have a decision to make, the policy decision comes to play and that, each and every time, has been to examine what's the more claimant-friendly approach, and that's the one we then decide to use. And in the documentation we will speak to that point, when and where we make those decisions. And again, we don't have that available for you today.

As Mary said earlier, we have shared those subject matter expert comments on the different risk models that we were employing, different coefficients -- yeah?

DR. SCHUBAUER-BERIGAN: And the initial RBE

distributions. Those have gone through two separate subject matter expert reviews and you've received the first set of reviews.

MR. ELLIOTT: I would also add, and I think this is accurate and fair to say -- correct me if I'm wrong, Mary -- but the subject matter expert comments that we received in not all cases were on the similar issues -- similar items, similar concerns. You know, they were cross-cutting. So in that regard, too, without having enjoined everybody who was a subject matter expert to discuss this, you know, it would have been very difficult to reach consensus even on those ones that they individual identified.

DR. ANDERSON: Yeah, I -- I guess it's more of a process issue is you're living with this day-in and day-out. And you know, when you say it's been made available, it's kind of like saying well, it's in the library. You know, all literature's in the library. You can find it if you want to take exception. As opposed to having you help us distill from the reviewers' comments what were the critical issues as opposed to reading them and seeing they're all over -- you know, if we're going to provide advice, you need to think about what is the information that we need in order to give you valuable advice from a broad set of backgrounds that

we have here, and that's partly what I'm just saying is it's -- maybe it's coming, but then our advice is at a different point than we haven't really been -- maybe it's just that it's evolving. We haven't been involved in those discussions -- decisions of getting up to speed. It all kind of comes -- decision -- here's what we've done, and what you explain has been done is rationally put together, sounds very reasonable. But we really don't know what were the various options and decisions as you went through it and then if you'd come to us and said well, here's a couple of -- here's a fork in the road, here's a couple of things, what do you guys think about this or that, you may have gotten -- just like you did from your experts -- this and that. Then you say well, you know, that's marginally helpful and you move on. So it's more as we move forward how is -- how are we going to feed into -- or get the information to be able to provide you with that kind of advice.

DR. ZIEMER: We've got -- I think Tony's next and then Wanda.

DR. ANDRADE: I'd like to offer a partial solution to this dilemma. I, too, feel like Dr. Melius that changes are being made without a full vetting. Now this is not to say that we need to second-guess the subject matter experts. As a

matter of fact, I doubt that this body would even like to. We're not an expert body. We're an Advisory Board.

However, there are changes, such as to DDREF and RBE's, that are important to me. And there are perhaps other factors that are important to members of this Board. Perhaps we could express our concern regarding certain of these distributions or some of these factors, and that we could at least take time in near future meetings to at least discuss the context within which changes were made and why a certain way was chosen rather than another.

I mean for example, you offered up today that it's important to be consistent with NCI. Well, that's -- that's okay, to a certain extent. But let's say in other cases -- in DDREF's, for example -- were changes made because of the latest paper that's out from some epi study? Was it the result of a compilation of many studies over many years that indicate that things should be tending toward -- down towards one? Or are we just being conservative? I'd like to know the context within which these decisions are being made.

So perhaps members of the Board can write down and provide directly to OCAS those areas in which they would like to at least hear, again, the context in which changes were made so that we can

either accept them comfortably or question them, rightfully so, and I think that is within our charter.

DR. ZIEMER: Wanda?

MS. MUNN: If I understood correctly, the original question was a procedural one. I don't personally believe that it's appropriate for this Board to insert itself or our activities in the ongoing process that other agencies are involved in right now. I personally very much appreciate having what I consider advance information provided for us at this meeting. I know most of this is hot off the press, as you said, and I'm very pleased to know that this is what's transpiring.

In earlier discussions about process we pointed out that it's possible to get some of this information to us electronically, sometimes perhaps only hours before we're meeting. But if that's possible to incorporate in the process whenever it's available, then that's to the benefit of all concerned as long as it does not interrupt the ongoing process of the agency in attempting to bring these things to an operable point.

I would suggest that it might be appropriate for us to ask that we be allowed to have at least the rudiments of any changes that are being made early on. Other than that, until the agency has

made its decision with respect to how they're going to deal with it, I don't believe we have anything to advise about, personally. So I would -- I guess my bottom line is I would suggest if information about relative changes are going to be available, even a few days beforehand, if this Board could be advised electronically of it so that we would know that the presentation is coming and know what to expect, and I think that would be helpful.

DR. ZIEMER: Thank you. Any other comments or suggestions? Or questions?

MR. ELLIOTT: If I may, let me just sum up. I think what I heard -- and I want to make sure this is duly recognized -- that we need to get to you not only the final information, but information that's being developed as we feel that it's appropriate to deliver to you. We should get that to you not only electronically, but we should send it to you by hard copy so that you have it as soon as it's possibly available. I hear that we need to identify for you -- and I hope that we could work together in this identification process -- what things you need to know about or hear about, what issues you want to examine in more detail, and you want to advise on and recommend upon those levels of detail and those different issues. I think -- and I hope we can agree on this -- that this is a starting

point, and what we need to do from this point with this final NIOSH-IREP is determine where you want to examine it in more detail, provide more information to you about that. We need to get you the RBE radiation weighting factors documentation document now that is being developed. We need to get you the subject matter expert comments on the DDREF and the weighting factors that we have that you've not seen, and then perhaps we need to include that as an agenda item in the next meeting or however you wish to take it up.

I think those are the things I heard and I just want to make sure that we agree that that's what was said and we can move forward.

DR. ZIEMER: I think I'll pursue that in just a moment. Let me insert here -- and then Henry, you can have some additional comments -- we certainly want to find a good balance between micromanaging the staff and doing our job, which is advisory, granted, but looking out after the broader interests almost nationally of how this law is administered. In that context, since the IREP becomes a key part of how the thing is conducted, I think the Board -- at least it's clear from the comments -- needs to at least reach a comfort level as to how the staff is going about developing the final product that will be used. Whether or not we

officially bless that, piece by piece or as a whole or whatever we wish to do, there's clearly some level of discomfort with the process in reaching the final thing here. It might be helpful in fact, and we will have time to do this since the next item on the agenda is one we announced at the front end isn't going to happen today, that we take some time to identify specifically the issues on the IREP that are of concern. I think we have a partial list now and there may be some other items.

With that comment, Henry, you had an additional one?

DR. ANDERSON: Yeah, I guess my -- and if we're moving forward, it's then where is advice helpful? My feeling has been advice on a fait accompli, you know, is not very helpful. And to this point are we been -- we've been asked to comment and provide advice after you've already formed your official position. So once NIOSH has decided here's our document, then advice is more difficult to have it fit into there because it then almost gets into well, it's a defensive sort of thing -- well, we did it because of this -- and then we're attacking what we think is different rather than being part of the team and saying here's the various options we're considering.

I mean you've already considered the

options. You've made your decision, and then you come to us and now -- I mean with this, again, it's -- we went through the two rules and I read here we're prominently quoted as signing on to say this is a great thing and our Board has got this, you know, high position of comment, but we're really not advising on here's the decisions that you're making as you go through this process. Here's the options and then here's our rationale for it. Now as we move forward again, once you have this in place, then my sense would be, and my experience with rules and everything else, once you've established the first one, making the changes, the bar that you have to get over, that hurdle to make those changes unless they're minor, becomes more difficult because you now have all of the past experience and the past thing to build on so that the time to be sure that everybody's up to speed is early on while we have to live with the circumstances, but we now have other things coming up. And I just want to be sure that if we're going to be in this for the long term that we learn up front so what are you thinking about, what are your thoughts on new literature coming up and that, before you come to us and say well, we've decided to make a change; what do you think about it. Once you've made your decision, it becomes -- at least I've found when I make a decision it's much

more difficult for me to change that once I have vetted it through internally to hit all the hurdles to get everybody to sign off on it, and now you come along and say I want to change this a little bit. It's much more difficult.

MR. ELLIOTT: I think what I hear you saying, though, Dr. Anderson, is an artifact of the process. We're so rushed to get this put in place so that claims can be adjudicated. And what we're saying to you is that -- and we've said it I think all along, IREP has been held apart from the rule, and we accept comments on IREP from now on. We're asking for you to -- we're not asking for you to bless IREP today. We're presenting IREP today with our decisions, policy and scientific-based decisions, and saying here's the starting point. And I'm asking you to help me and help my staff understand what additional issues you want to explore for any modifications from this point or how to handle comments that we might receive from technical commentors or the public on IREP.

Unfortunately, we've had a rough time of trying to balance the need to put this in place and bring the Board along in their understanding of these very technical and complex dynamics of probability of causation and dose reconstruction. Again, the rule is the rule now. IREP can be

changed, and we look forward to working with you all on that.

DR. MELIUS: I just want to clarify -- really it's not an artifact of the process but an artifact of how NIOSH chose to manage the process, and I think we understand the need to be able to handle claims and so forth, but frankly I don't think the committee's -- at least personally, I would not endorse what these changes that you've made because I don't think we've been given a fair opportunity to review them. You've decided to manage our review in a way that we haven't been given that opportunity.

I think what we should say if we're going forward is that we ought to, as Tony suggested, identify certain issues that we want to spend more time reviewing, that we should review the comments that have come in, see if other experts maybe outside our field would have raised some issues that we really think need further discussion and maybe we need to bring those experts in to hear from them and better understand certain issues that maybe we don't think are a problem but -- or don't need to be dealt with, but they do, in order to make this work properly. And I think that should be the process for going forward.

I think what does disturb me even more is

the change you're just making in the agenda now. We've gone from a day on Special Exposure Cohorts guidelines -- at least from what I read, the modified agenda was an hour and a half discussion of them, to now -- if I understand what Paul just said -- to no discussion. And we're going to be, I presume, presented with some set of guidelines some months from now to review, having missed the opportunity for this meeting and earlier meetings for any sort of discussion or input into that process. And I don't think that's a fair use of this committee's time or talents. And that pattern does bother me. These are not -- Special Exposure Cohorts are not regulations. There should be no prohibition against discussion of a number of the issues related to those, and now we're being told presumably that there will be no presentation or discussion of those. And I think there has to be some recognition of how NIOSH wants to work with this committee and to not have us become a rubber stamp or have to rush through a process of reviewing something. Because if those Special Exposure Cohort guidelines get presented to us in two months, I can assure you that you'll be telling us that you really need to rush and get them out and get them in place 'cause claimants are awaiting. Well -- and we'll be given, you know, two days or a day and a half or

whatever the meeting is to review them and I don't think that's fair to us or it's fair to the process, nor is it fair to the claimants and what was envisioned by Congress in setting up this Advisory Board. And I think we need to come to grips with that larger issue, also, in addition to what we just talked about in terms of the IREP.

DR. ZIEMER: Tony, did you have another comment or --

DR. ANDRADE: No.

DR. ZIEMER: Okay.

MR. ELLIOTT: If I could react to Dr. Melius. I'm not precluding you, as the Executive Secretary, from discussing Special Exposure Cohort procedures. But we made it clear in the e-mail that I sent around, I thought Dr. Rest made it clear this morning, we don't have anything to present to you on what those procedures look like today. So you're certainly welcome if you want to use your time this afternoon as a Board to discuss what you think are the critical, salient issues surrounding the Special Exposure Cohort petitioning process, but we are not in a position to share today with you what those draft procedures look like.

DR. MELIUS: Then can you explain to me why Ted Katz is listed at 2:15 to present on Special Exposure Cohort guidelines in this modified agenda?

MR. ELLIOTT: Well, that unfortunately was a mistake that got sent out as a modified agenda. It's a mistake that it was in the book. We didn't catch that early enough to take it out and replace it. We were scurrying around this morning trying to find the modified agenda that had been approved and we don't have it for you today. All we can say is we do not -- as Dr. Rest indicated this morning, we do not have the draft procedures available for your review today. If you wish to discuss SEC petitioning process and what your thoughts are about how that should be conducted and performed, that's certainly your option.

DR. ZIEMER: Let me also insert -- in fact, about -- I guess it was about a week ago that Larry indeed indicated to me that they would not be able to present on this and that item was to have been taken off the agenda. And when the final copy came to me at least, I myself didn't notice that it was still on the agenda, but I know it was the intent of the staff to have removed that from the agenda. In any event, it's as just described.

Now let me ask the Board at this point, would it be of value for us to go ahead and clarify and identify issues on IREP that individuals would like to see information on, specifically such as the things you mentioned, Tony. Can we do that now?

Would you find that useful to do right now?

DR. ANDRADE: Paul, at this particular point in time I'd rather us agree on a process and perhaps for the next meeting be able to discuss some of our individual concerns or have reps from NIOSH be able to discuss how some of these decisions were made on some of the important factors.

However, I wanted to pursue the issue that Dr. Melius brought up again on -- or regarding the draft procedures. I would find it perfectly acceptable to have an impromptu, informal, not even finally-prepared discussion on just what sorts of questions are being thought about, what issues are being contemplated with respect to these procedures before even -- before they're even put down in draft form. So I'd say that scheduling informal discussions for the future should not be out of the realm of this Board's deliberations.

DR. ZIEMER: Mark?

MR. GRIFFON: And I really just wanted to pick up on that point that Tony just made. I would reiterate that and I would even say that the statute mandates that this Advisory Board be involved and give input into the development of policies, rather than simply their review after policies are a final product. So I would reiterate that and would also ask for -- I think that'd be a valuable discussion

to have on Special Exposure Cohorts.

The other thing in terms of the process for the other stuff, for the IREP model, I think that it would be valuable to come up with topics -- I'm not sure I'm ready today. I have some ideas, but it would be valuable to have some topics and have some maybe experts come in to present. I like the ideas that both Jim and Tony presented.

Further than that, I think in the preamble of the regulation it says -- it has a phrase in there that basically says that the Advisory Board will review the current NIOSH-IREP, so I think we also have a responsibility to, in some way as a Board, put out a final review of the model, too, so that should be maybe the end product of this process.

DR. ZIEMER: Any other comments? I think we can let our speaker sit down, at least, since we apparently have no more questions for you.

Mark, did you have another question?

MR. GRIFFON: No.

DR. ZIEMER: No, oh, okay. Jim, you have another comment?

DR. MELIUS: Next time maybe it'll stay raining in Cincinnati.

Yeah, I agree we ought to -- I think it would be fair to discuss Special Exposure Cohort

guideline. I'd just point out that we'll be going -- be doing this while at the same time there's a document being circulated with what NIOSH's proposal is and that other people are commenting on that -- we're going to have sort of a parallel process, and I'm not clear that we're really being provided any input, but I think it would be worthwhile discussing that.

I think there's another issue that we have talked about briefly at the last meeting that I think was worth spending some time on and that is how is the Board going to review the dose reconstructions that are done? And I think we sort of have to make a decision towards the managing our time for the rest of the day and a half in terms of how to divide up some of this and my understanding's -- I don't believe David Michaels is in town today, but will be in tomorrow, so we're sort of caught with that time for his presentation. But I think if we could sort of regroup and decide how to spend our time for the next few days to make it -- or next two days to make it a useful use of that time I think would be helpful.

DR. ZIEMER: Thank you. Let me ask -- I guess I'll ask Tony. The question when you raised the issue of process, were you talking specifically about dealing with the IREP at this point or more

generally or generically?

DR. ANDRADE: Paul, I think I was talking -- well, I was talking about the way this Advisory Board functions and -- more generically, right.

DR. ZIEMER: Well, let me again, though, raise the question then, because we can finish up on this IREP topic and go ahead and identify issues or -- and then move on to the more generic question, if you wish. I mean -- leave it up to the Board because it's -- it's not something the Chair does unilaterally. I don't dictate our direction here. Sometimes I figure out where the Board's going and I try to get in front of them so I look like I'm leading it.

DR. ANDRADE: Paul, I understand the -- well, the reality of the situation. And again, I already mentioned the topics that are of most interest to me with respect to IREP. But I understand also that the representatives here from NIOSH are perhaps not ready to present to us, even in a five-minute informal manner, a discussion on the context in which some decisions were made with respect to dose and dose-rate effectiveness factors, and that's all we want to do. That's all I want to do and that's all I'd like to see the Advisory Board do is not micromanage the scientific process, but understand the decision-making that went on behind

it.

DR. ZIEMER: Yes. I think that's understood, and some of that might be able -- they might be able to address yet today. Or if there is -- if the answers are not complete, to come back to us. But as a starting point, can we identify the specific items? Let's start out with what, dose-rate effectiveness factor?

DR. ANDRADE: Absolutely.

DR. ZIEMER: What else? Did you have -- is that the issue for you, Tony?

DR. ANDRADE: And RBE's.

DR. ZIEMER: And RBE's. Any others? Mark, Jim, Richard, Robert, Roy, Sally, Henry?

DR. ANDERSON: Just the DDRF's.

MR. GRIFFON: I think there's others that I also understand are more long-range issues, but there are other issues such as age at exposure that I understand probably the current thinking leads them to decisions made in this model, but -- I don't know if we're making a full laundry list of issues within the realm of this program or --

DR. ZIEMER: Well, I don't think at this point we're at a point where we want to speculate where the IREP may be two years from now and anticipate. But I think it has to do with decisions that are being made almost in real time on some of

these particular factors, such as identifying -- apparently the staff is preparing to discuss some of those even today in more detail. Is that correct?

DR. NETON: Yeah, I'd just like to interject something here. I've been listening to this conversation with some interest, and I'd just like to point out that the Act requires us to use the Interactive RadioEpidemiological Program or its predecessor -- you know, its subsequent versions, which is the NCI-IREP. We are allowed to make modifications that are specific for our cohort, which we've done.

As far as DDREF and RBE, it is a virtual -- it's almost certain that we will have the same DDREF and RBE distributions as the NCI-IREP. There will be no difference. So to that extent, we are really adopting the NCI-IREP program.

I think the key things to focus on are the differences between us then and the NCI, which are the several areas that Mary pointed out, the risk coefficients for bone and skin, some of the different transfer coefficients that we've used. Those are the key differences in the programs.

That being said, you certainly have a right to review all of IREP, including NCI-IREP, but I'd just like to point out that if we adopt the NCI-IREP as part of NIOSH-IREP, then really we are in

fulfillment of what's contained in the Act. Does that make sense? I mean it's not something where we're diverging, you know. I think it's part of an artifact in the sense that these programs are both being developed in parallel and to the extent we interacted heavily with NCI. But where we either make suggestions or modifications and they agree that it made sense, it became the NCI-IREP program. So I'm not sure if that helps or hurts or --

DR. ZIEMER: I think the concern is that that's -- that appears to be sort of a closed loop now where it's not clear who's making the decision. Is NCI accepting it 'cause you guys have proposed it or vice versa, and I -- it's sort of -- the unease is in that loop there. It's sort of saying well, there are some changes being made. At least let's learn why they're being made, do they make sense to the -- do they pass any kind of a ho-ho test or whatever. I don't think we're saying that we're necessarily second-guessing the experts, but I think we want to know why certain decisions are made and the basis for whatever changes are coming about almost in real time.

Is that a fair reflection of -- yeah. Go ahead, Tony.

DR. ANDRADE: Absolutely, if I might, Paul. Jim -- right? Well, it's really nice that we're

being consistent, but again, I am uncomfortable as to why. We're striving to be consistent and is that the reason that we're adopting these -- these factors, in and of itself, or is it -- or is there some deeper scientific basis? I'm just simply curious.

DR. NETON: That's fine. I just wanted to point out that -- I think I heard that there was a belief that there were differences between our DDREF and the RBE distributions used in the NCI program. And the DDREF's are going to be the same. The RBE's have not been finalized, but it's my belief that the NCI -- and you heard Dr. Land this morning endorse the current RBE's as they are drafted -- so I believe that they will ultimately end up in there, although I can't speak for NCI. So I just want to point out that there are -- there's no difference between us and NCI in that area. So we're not going out there on our own modifying it for this cohort. I guess that's what I was trying to point out.

DR. ANDRADE: Okay. Yes, indeed, he had a wonderful talk this morning, and we all understood his endorsement. But I guess I'd like to know a little bit more about the basis for that endorsement. I mean he indicated but only indicated at a very high level that this is where scientific studies have -- are tending to shift the DDREF.

Well, is that, again, the result of a paper, two papers, a collection of work that has been done over the last decade? I'd just like to know the context.

DR. NETON: I completely understand. I do agree with what Wanda Munn mentioned, though, that there are several agencies involved here and we of course do not control the National Cancer Institute and these things happen to be going along in parallel. So I think some of the frustrations being sensed here is somewhat out of our control in that respect. But with that, I'll sit down.

MR. ELLIOTT: If -- Jim, I don't know if you could speak to this or not right now, but if the Board is interested, can you talk about the subject matter experts comments on the radiation weighting factors and DDREF? Is there a way you can briefly summarize what they will see once we are able to pass that information along in hard copy and by e-mail?

DR. NETON: I don't have the comments with me. I'd be reluctant to do them from memory, as old as I am nowadays. I can't remember as well as I used to, so I could give a hint as to what they are. They were not extremely substantive. I mean there were some changes being made, but I -- I'd be reluctant to do them from memory, I guess.

DR. ZIEMER: Well, several items have been

at least identified and perhaps could be followed up on. And are there other -- Jim, yeah.

DR. MELIUS: I just procedurally -- it's a little frustrating for everybody here and I think what we need to do is to talk about what we did before is let's identify a clear list. Let's go back and look at the comments the committee needs to and see if there are other issues, and then let's get information to NIOSH before the next meeting to prepare presentations on these and that's fair to your staff and I think will be fair to everybody involved.

DR. ZIEMER: I have identified, from what was said, DDREF, RBE, age at -- well, age at exposure's not in transition right now, is it? That's not -- oh, maybe --

MR. GRIFFON: Because there were some comments, public comments and expert comments on that issue I'd like to see.

DR. ZIEMER: Oh, okay.

MR. GRIFFON: Hear how it was resolved.

DR. ZIEMER: Were there some other items? Mark?

MR. GRIFFON: Yeah. Having heard what Jim said, and I agree, I would like to reflect on this more, but I at least think that I want some discussion about the transparency of the IREP model

in terms of the public. It's on the internet and in my view, that's about the only thing that's more transparent than the epi tables. The problem with this whole Monte Carlo approach is that, from the public and actually many health physicists, quite frankly, you plop a few numbers in and you get a result out, and what happens in the middle is a mystery. And I think that -- I think we need to address that because I think, from the claimant's standpoint, it is going to be like Monte Carlo. If they put that number in, roll the dice and then come out with a winning score, they're going to be happy. On the other hand, when they come out with a rejection letter, they're going to want to know -- oh, sure -- you know, how exactly was this calculated. And I think we -- so that's one topic is transparency of that model.

And the second thing is just the whole uncertainty analysis, how the Monte Carlo uncertainty analysis works. I think there's some assumptions that I want to understand better of if variables are not independent and you start combining variables, you get a whole -- to get your uncertainty in your entire final results, you know, that has to be assessed certainly, and I'm -- it's probably been considered, but I would like to have some sort of discussion or presentation from the

experts on how that was done.

DR. MELIUS: One additional exhibit actually Dr. Land brought up this morning was this -- the rarer cancers and this grouping issue and how one does calculations based on those, how one does the grouping and -- he got a little -- confused us, at least me, a little bit more in terms of trying to understand that issue, so I think it would be helpful to have -- that was, yeah, Genevieve's question.

DR. ZIEMER: Okay. Any others? And you've gotten the list there, I think. Okay.

Now my understanding that the request is also for copies of the comments from the technical reviewers for our information, and that will be forthcoming.

DR. MELIUS: I don't know, just -- I mean someone just could notify us when things go up. I think -- maybe not every item, but access to it. I think I could download it, just -- you know, I fail to check every day --

DR. ZIEMER: Just a note, the following are now on the web site? Yeah. Yeah, I think -- they're going to try to do that.

DR. MELIUS: Just say that you've added six comments, or not even -- also these other comments, we don't know when you sent them out so I don't know

when the set is complete up there. You may have the set up there, the comments. I don't know if you're still waiting for some or where they stand, so it's a little hard to understand when is the most efficient time to go in and take a look.

DR. ZIEMER: Okay. Mark, you have another comment?

MR. GRIFFON: Just one last question or request. I think I've asked this before, but the on-line version of IREP, I wondered if, as you release this in its final form here for use, whether this can be provided to the committee in disk form -- okay, that's one no.

The second question I have is can a model detail be added to the on-line version as they are not as complete as version 2.1 was. There's certain model details that are not -- you've added some stuff, but there's some critical stuff that has been deleted from -- I have a disk version of an earlier version, 2.1, where there's a lot more model details in there to look at, including the raw data, the ERR per Sievert data, by cancer type. And I think --

DR. ZIEMER: Do we know today whether that's --

DR. SCHUBAUER-BERIGAN: I'll just comment on that briefly. This is Mary Schubauer-Berigan again. The version that's currently on the web does have

some of the model details, but it stops at the point where you're trying to look at the ERR per Sievert coefficients. We're working with NCI -- since they derived the vast majority of those, we're working with NCI to get their permission to put them up on the web site, and until their version is actually finalized, which -- did Dr. Land mention when that was occurring this morning? If he did not, then we have no idea when that will be, but our intention is to make that documentation at least as transparent as the version that you refer to as 2.1. They put that version together because that was the version that was reviewed by the National Research Council, so that was the sort of final draft, and they're not at the point where they have the final final.

DR. ZIEMER: Okay. Any other comments on this issue? Okay, Sally?

MS. GADOLA: I have the feeling from a couple of the presentations that there were questions that the experts themselves had that were working on the IREP and that the National Cancer Institute had some questions, and I was hoping sometime in the future that we could have a discussion of that and what they would like to see change, what they would like better understood, because they seem like they were on the brink of saying something and all the evidence wasn't there

so it was like we will go with this. But I would like --

DR. ZIEMER: Let me --

MS. GADOLA: -- to pick their brain a little bit.

DR. ZIEMER: I'm going to partially answer, unless Dr. Land is still here, but I don't think we're ever going to be at an end point where we say we know the answers. These things are always what's the best information you have right now, and it's going to change and it's going to change -- we'll keep getting more and better information, but I don't think any of the folks at NCI or NIOSH or any of the other agencies or even the scientists are going to say we now know everything we need to know on any of these things.

MS. GADOLA: Well, I don't -- no, I don't expect an end point. My question is more like what else do they think we should be looking at, that you don't have all the details but because they are the experts, so often you will hear them say well, I wish I had a little bit more here or I wish I could say this a lot more clearly, but it isn't quite all together. But then they can give you a hint, and because we also come from a variety of backgrounds, we also often can identify people that have special interests. And even though things are supposed to

be scientifically accurate, they're not always there. There's a little bit of prejudice. Not people wanting to be prejudiced, but just from their particular viewpoint. And it's also so important to share what all the other people have, so as we do our job, I think it's our responsibility to learn as much as we can, too. And when you're making a list, my question would be what else do we need to be looking at? I would like to get the input from -- since we have this opportunity from experts, what else do you think we should be looking at? What can we help you do? What can our backgrounds bring to you or what questions can we ask?

DR. ZIEMER: Okay. Any others? Now we'll expect to have this item on our agenda for next time, at least, and see if questions have indeed been answered or if they remain, so we'll certainly come back to this as a follow-up next time.

Okay, we still have some additional things on this topic, so Russ Henshaw is on the agenda next. Russ, please.

MR. HENSHAW: I have the infinitely easier task of showing the Board and those here the improvements that have been made thus far to the user interface for the software, and there shouldn't be anything controversial about that part of it, so...

By the way, if I might just digress for a moment, I was the most delighted person in the room to discover that Mary could make it here today. About a year ago at this time, before I joined NIOSH -- several months before I had joined NIOSH, for example, I might have defined dose reconstruction as trying to figure out whether my grandfather took all of his medication last week. So I'm kind of a newbie here, so...

Also I might add, we have a less-than-perfect equipment setup. I'm going to be kind of walking back and forth between the microphone and manipulating the access to the software over the internet, but that's not a bad thing. It'll be a welcome relief from my monotonal voice.

I have no power point presentation, but if you could turn to your briefing book for the Board or the handouts if you are here as a member of the public, my -- I have a draft user's guide which follows Mary's power point presentation and the tab -- the NIOSH-IREP tab. I'd ask you to turn to page five of the draft user's guide.

The guide was developed by our contractor, SENES Oak Ridge, Incorporated. And again, this is a draft version. I just got back from a couple of weeks on the road demonstrating this to Department of Labor staff around the country, along with Brian

Thomas from SENES Oak Ridge and also Jeff Coach from the Department of Labor, who I believe is here today.

So to access the software, just a brief refresher, we go to the NIOSH/OCAS web page. We click on probability of causation. One difference already from the last Board meeting is you can see that we've added a direct link to the software right at the probability of causation page, so I'll click on that. It takes us right into the software program. You simply click on the begin button to start the software. That takes us to page six of the draft user's guide.

This is -- let me just scroll down here and show the -- try to show more of the screen. I think you'll see one difference already, this Use Data Input File, the Go To Upload Page button, which I've just clicked on. Prior to this improvement, the Department of Labor staff would have needed to enter data in every field of the software. With the creation of the input file, the -- we now have an Excel spreadsheet that will be sent to DOL with every claim, which includes all the information for the claim. When DOL uploads the file, it will automatically populate every field in the software.

Now there are three buttons here. One is Return to Inputs on the bottom that just takes us

back to the last page. There's also a Download Template button. If this is clicked on it brings up the Excel spreadsheet, which can be saved and changed as needed, although, again, the claims examiners at the Department of Labor will really not need to make any changes to the input file. So we'll click on the Upload File button.

Brings us to the Upload Saved File screen. We click on Browse. Now in this case I have a couple of example or sample claims, so for our purposes I'll click on Presentations and navigate to the Input Files folder. We'll just bring in what we're calling here example 1-A. Now when DOL -- when a claims examiner at the Department of Labor actually operates the software, he'll bring in the file from whatever format we're sending it to them. It could be a floppy disk or a CD-ROM or by e-mail encrypted. I don't think that decision has been made yet. Is that correct, Jim? It's possible that the first few claims may come with input files. That could change later to maybe an encrypted electronic format.

So we've brought in the file we need. I might also mention that the files will probably be named by the claimant's Social Security number. In this case it's just example 1-A. So I click on Upload File. It's kind of a reassurance message

there SENES worked into the software for DOL purposes. We click on Continue. And now we have populated every field in the software with the claimant information from this specific input file.

And we've made another change in the software. This button is now called Generate Results, just trying to keep it simple. So we click on the Generate Results button and this is what produces the probability of causation.

I might add for our sample file we're only using 500 iterations. The Department of Labor is required to use 2,000 iterations. However, for the training purposes, with ten or more computers practicing simultaneously, we cut the number down to 500 to speed up the process.

This is the Results Output file. It contains an abstract of all the information on the original Excel spreadsheet input file. We scroll down and here is the result. This claim would be compensable, 55 percent.

Now this is example 1-A. We have an example 2-B -- excuse me, example 1-B. The only difference, the input data is age at exposure. Example 1-A exposure age was 20, example 1-B is 40. I can put that one in and run it just to do another example, if you'd like.

This is really all that needs to be done to

run a claim when the claim arrives at the Department of Labor.

Now let me go back for a minute. You might recall that there's a special case involving multiple primary cancers which requires plugging in the results of separate software runs, one for each multiple cancer, into a mathematical equation. SENES Oak Ridge is currently at work on developing a button that will probably move this stuff over, maybe move the -- a button here that'll just say something like Calculation for Multiple Primary Cancers or something like that. That will -- once that's accomplished that will allow the Department of Labor claims examiner to punch in each probability of causation percentage into a table and the software will then run that equation automatically.

There's another example that -- another situation that could require multiple software runs, and I'll show you that by clicking on the Advanced Features button. This is a case where the probability of causation result is at least 45 percent but less than 50 percent. As you probably recall, the Department of Labor claims examiner in that scenario would be required to up the number of iterations and run the claim again.

Now initially we pondered whether to

distribute random number tables or how to get them accomplished that easily, but we finally decided it would be best to automate that function. Just actually within the last week SENES has added this Generate New Random Seed button, so all they'll need to do is click on that. It generates a random number between one and one million. Excuse me, I said earlier that the sample files used 500 iterations. It was 200. As you might recall, that scenario of probability of causation between 45 and 50, DOL is required to up the number of iterations from 2,000 to 10,000, so all they need to do in that event is click on that button, generate the new random seed and change their random sample size, and then submit the data and run it again.

I won't do that now because it does take quite a while. I'm sure the Board has better things to do than sit here and watch that time clock on the screen -- but that's essentially it. We think we've made it as user-friendly as possible, and the Department of Labor staff seemed to be very pleased with the improvements to the user interface that have been made. Really this has all been done in the last month.

So I can take questions or run another example or whatever you'd like.

DR. ZIEMER: In this newest version you

don't have to put in information about the distributions? It's just carrying the defaults unless you specify otherwise or...

MR. HENSHAW: That's correct, sir. The input file will contain all the information needed to run the claim.

DR. NETON: Russ, maybe it would help if you could show that --

DR. ZIEMER: Oh, so that's dumping it in automatically from the spreadsheet then.

MR. HENSHAW: Yes, sir.

DR. ZIEMER: Ah, gotcha.

MR. HENSHAW: Show the input file, Jim?

DR. NETON: Yeah, show that spreadsheet that you actually downloaded.

DR. ZIEMER: Before we did the enter doses business, as an example, manually. But here you would have the sheet downloaded that has all the doses and the distributions?

MR. HENSHAW: Yes, sir. Everything, including all the claimant personal information from gender to age at diagnosis, age at exposure. Really every single piece of information needed to run the claim.

This is again the Download Template button. We'll just open the file. Now the file can be saved and manipulated if needed, but again, the

claims examiners will not need to do that.

DR. DEHART: Is this in beta test now?

MR. HENSHAW: Claims have not yet been submitted to the Department of Labor. The intention -- we believe that this is working correctly, so this -- unless something comes to the surface, some problem with it, this will be what will be sent.

Just to show you a couple of things here, for example, let's just look at the top row. If we go to NIOSH district office, the field has a pull-down menu. We'd type in one of the four district offices, and that's a similar -- similarly for each of the fields, and I think that one you type in, but for exposure rate, again, the two choices, acute or chronic. Similarly for radiation type and the distributions.

Now most cases the distributions are going to be normal or lognormal or perhaps constant, so they have -- the other ones, as I understand it, will not come into play that often, but of course they're there as options in the pull-down menu.

MR. GRIFFON: An explanation -- number of exposures up there, is that one?

MR. HENSHAW: Uh-huh.

MR. GRIFFON: And you have a series of exposures here? Am I misinterpreting that?

MR. HENSHAW: That's a mistake.

MR. GRIFFON: 'Cause you're only looking at the first one that way. Right?

MR. HENSHAW: Right. Yes, that's correct. I think in this -- I think if one is in there -- let me just check something. I think for this example I think the function of one in that field means that we're only pulling one into the example scenario for ease of training purposes. But if we change that -- I forget how many we're on here. I think it was over 100, but if we change that to the correct number, it would take that much longer to run in the training, so... But for -- let me just get out of this, unless there are any more questions about the input file?

MR. PRESLEY: What do you do about chronic?

MR. HENSHAW: I'm sorry?

MR. PRESLEY: Chronic exposure? Just mark it?

MR. HENSHAW: Right.

MR. PRESLEY: Okay.

MR. HENSHAW: As I understand it -- Jim can correct me -- but most likely that will more often be acute because we default to acute if the exposure rate is unknown. Just minimize that for the time being.

DR. ANDERSON: This will also be on the web page then for the --

MR. HENSHAW: That's what I'm running off of now.

DR. ANDERSON: -- claimant?

MR. HENSHAW: Right. Sure.

DR. ANDERSON: Will they get any Excel -- going to be concern that the claimant's going to try to potentially run this thing and get a different -- a different result.

MR. HENSHAW: Right, we've --

DR. ANDERSON: You could give them the data file. They can run it to believe it and they'll get the same result.

MR. HENSHAW: I'm going to defer that question to Jim. I'm not sure what the intention is. Are we sending the input file directly -- the input file itself directly to the claimant, Jim?

DR. NETON: No, we didn't intend -- we're not intending to do that. We are sending them an exact copy of that spreadsheet, though, as part of their dose reconstruction report, so they could, if they wished to, enter the data themselves to determine if the Department of Labor's ultimate calculation was correct.

MR. HENSHAW: One other thing I just might show you. Again, all these -- all the changes were made with the Department of Labor claims examiners' staff in mind. Just generate results again.

Once the claim examiner has reached this stage, which is really it -- basically it's pushing a button, they then can save the file, and we're advising them to -- there are three choices. We can't control this; this is a Windows function. But I don't think Bill Gates would like us to get in there and change the Windows programming, but we're advising them to save it as a HTML-only file. Once they do that, if there was ever a need to open up the claim file again, it will appear exactly as it did in the first claim run, preserving the formatting and so forth.

MR. GRIFFON: I was just wondering, and I think -- I don't think you guys have gotten to this yet, but have you put together any sets of examples? I'm looking at something from Charles Land where he, in their publication, compared the IREP model to the old NIH 1985 epi tables and the outcomes at various ages for various types of cancer, he systematically did a table on this and I wondered if -- I know you've done different examples and scenarios. Have you put together any sort of systematic comparison of this IREP versus the previous -- and part of the reason I'm asking this is because I think we -- I've heard several times on this committee that when in doubt, we're trying to use the claimant-friendly -- or erring toward the

side of being friendly to the claimant. But without some knowledge of these numbers and comparing past numbers, I don't think we can really evaluate that as a committee, so I'd be interested in whether you've done that.

DR. ZIEMER: One thing we heard this morning was that, for example, if ICRP-60 model gives a lower probability of causation than the old model, they're not going to go back to the old model just for that purpose. In other words, they will consistently use the same models. So I don't think it's always making an assumption in favor of -- just for the claimant's sake by saying well, in this case we'll use a different model 'cause it helps the claimant. That was my understanding. So in this case, what is it that you default to in the absence of other information? I mean you're going to -- you're only going to default to those values and distributions where you don't have information to the contrary. Right? If you have information that says that the dose distribution was not lognormal --

MR. HENSHAW: Right, yes, the --

DR. ZIEMER: -- if there's actual data to support that --

MR. HENSHAW: Yes.

DR. ZIEMER: -- then you would go with the real data. Right?

MR. HENSHAW: Exactly. The health physicist will use a fitness of fit test and they'll pick the distribution that is the best fit to the data. Just that practically speaking it's most often going to be normal, lognormal or otherwise constant.

DR. NETON: One of the important differences between the IREP program and the interactive radioepi tables, as I understand it, is this program allows for the input of uncertainty distributions about the dose and as a function of various different energy radiation types. I think the way the tables do it, I believe that they select the 95th percentile and use that in the table to determine what the probability of causation, so I think it would be somewhat difficult -- you have to look at the whole picture and it would be difficult to compare based on a number of differences. Also in addition to what Dr. Ziemer pointed out, the differences in the dosimetry models themselves. So I guess it would be hard to make a direct comparison and the answer is we have not done that.

MR. GRIFFON: I know it's difficult. I might refer you to table E-4, though, in Charles Land -- I mean he did make an attempt. I mean he did make a distinction that there are some -- it has a lot of footnotes in it on why -- why it's hard to compare, but yeah.

DR. SCHUBAUER-BERIGAN: Yes, the recommendation of the NAS review panel, they did expand that comparison in their draft final report, so you should be seeing more of that. Given that presentation, we didn't feel the need to do the same since our -- the basis of our program is NCI-IREP. But I want to be clear that if the science provides information that is defensible and differs from the 1985 tables, the approach was to incorporate it. So you can't say that in every case distributions were shifted to favor the claimant. That certainly is not -- I would never say that that occurred in the development of NCI-IREP.

DR. ZIEMER: Okay. Further questions or comments?

We're due for our break here and let's take the break for 15 minutes, reconvene at 3:25.

(Whereupon, a recess was taken from 3:10 to 3:25 p.m.)

DR. ZIEMER: Russ Henshaw has a few additional comments he wants to share with us, so let me give Russ the floor again, please. Where'd he go? There he is.

MR. HENSHAW: Thank you. Actually I have four, based on some questions and comments I got during the break. I want to point out that there is a typo in one of the examples, and that's on page 17

of the user's guide. It's example number 2-A. If you'll look to the line that says dose, it says ten centisieverts. That should be 50 centisieverts.

It's particularly important -- it's an unfortunate typo but it's particularly important because in our training the whole purpose of examples 2-A and 2-B were to show the difference between a non-smoker -- the effect of non-smoking or a smoker in the probability of causation results, so everything in those two examples, all the input should be identical except for the never smoked versus smoker. So you can make that 50 centisieverts instead of ten.

Also just to clarify, if anyone wants to do that, you can still go into the software and enter data by hand. You need not use the template. You can also download the template, if it's simpler to do it that way, and change information on the template, save the file, and then upload the modified file.

And let's see, what else was there? Yeah, one final -- oh, two final things. I just want to direct your attention to a glossary on pages 11 through 15, which is in draft form. We're still adding terms to that and we have a number of terms to add just based on the feedback from our training sessions.

And finally, just a further clarification, the scenarios that require more than one software run -- that would be, for example, unknown primary cancer where the claim examiner has a secondary cancer, then you go to a table and it leads you to a number of plausible primary sites -- the Department of Labor will receive a separate input file for each run and they'll be marked something like file name with a small a, you know, and then a small b and a small c and so forth. Thanks.

DR. ZIEMER: I'm going to suggest, too, on your user's guide that you make sure as you go through that to use the SI system of units correctly, which -- and Gen Roessler will correct me if I'm wrong here, but if you have a unit named after a person, such as a Sievert, believe it or not, it is not capitalized when used in a sentence, but it is capitalized when abbreviated. So a volt is a little v-o-l-t, but an meV is a m-e capital V. So in here where you have -- well, for example, on the definition of a rad where it says one Gray, technically the Gray would be lower case, not upper case and so on. I assume the agency follows the SI system and ICRU system for those. I get a little picky on that 'cause I'm always picking on my students.

MR. HENSHAW: I'll make sure that those

changes are made.

DR. ZIEMER: Just go through the thing and make sure it's consistent with --

MR. HENSHAW: Right.

DR. ZIEMER: Thank you.

MR. HENSHAW: Thank you.

DR. ZIEMER: Now I want us to look at a couple of possible things here before us, realizing that there is the change in the agenda that we've already described. One thing I think would be useful if we did first and that is to go back and revisit very briefly the idea of future topics and items. This came up when we looked at the minutes and we talked about tracking those items, and if we can use that as a starting point -- which minutes -- those were the February 14th minutes, I believe. Could we use that as a starting point, see where we are on the items that were on that list and maybe you can just -- page 18 and tell us where we are. And then it would be helpful I think even right now if we could identify additional items and ask that for future meetings, future agenda items that people specifically want to make sure do not fall through the cracks. So could we then -- yeah.

MR. ELLIOTT: Okay. On the February 14th minutes, on page 18 you'll find a bulleted -- bulletized list of suggestions for future meetings.

And just so you have an understanding here of what we're going to attempt to do, we -- I've asked Marie Murray, our writer/editor, to capture for us, as you speak about things you'd like to see addressed, issues you'd like to see presented on, and I'm sure she's got many of those that we just talked about about the IREP, about the RBE's and DDREF. We're going to have that on a separate table where we can show you what's -- what action has been completed on them, what's pending, what things have been conducted fully.

In that regard, this first bullet, information that could be addressed by experts other than NIOSH staff, such as topics mentioned the previous day in connection with DOE records found to be deficient, I don't believe we have done anything in that regard for you, and I would appreciate any suggestions you might have about who those experts might be or what specific topics you would like for us to have covered for you.

The second bullet, a legislative background history, particularly as it relates to the SEC. And tomorrow I think you'll have that addressed for you by Dr. David Michaels, who'll talk more than just about the SEC, but the whole history of this legislation as it was passed.

So the third bullet there, background on

IREP model, issues discussed at the first meeting, I would like to think that we addressed some of that today with Dr. Land coming in to share with you where NCI's at on their revision to the IREP, and we certainly have I think heard you loud and clear and have a list that has been created this afternoon with regard to IREP, and we'll share that list with you in the table, as I mentioned.

The fourth bullet, comment on the statute's language describing the Advisory Board's review procedure, which is felt to be -- by some to be misleading, if not inaccurate, and require Board comments. I guess I -- I've looked in the statute and I've looked in the Executive Order and I would appreciate your help on identifying what your particular concern in this regard is. I don't know who offered this. I could go back to the transcript and find that, but I would ask you to assist us on that comment to narrow it down or determine exactly what it is you'd like to explore there.

I think that covers it.

DR. ZIEMER: Thank you. If someone can help clarify that fourth bullet, that would be helpful, and then are there other items that -- in addition to those we have already discussed today that you'd like to put on this sort of master list now that will be generated as the staff looks forward? And

if you don't think of them today, we can have input later.

Jim?

DR. MELIUS: Yeah, I think one other issue and it's this -- I think deferred partly because of these Special Exposure Cohort guidelines, but there's the issue of when NIOSH returns a claim -- what are the criteria for NIOSH making a determination that there's not sufficient exposure information in order to make a determination and how will that be -- you know, what will those criteria be? And I think they feed off Special Exposure Cohort guidelines, but I think they -- also independent of those, to some extent and I think they should be -- I would like a presentation discussion on those.

DR. ZIEMER: Do you see that as sort of being part of the dose reconstruction process where the data appear to be inadequate and what do they do then? Is that...

DR. MELIUS: Yeah, how do they make that determination? There's some procedural --

DR. ZIEMER: That there is an inadequate --

DR. MELIUS: Yeah, inadequate thing. As I say, it's one of the criteria for the Special Exposure Cohort, so -- but they're going to be making it on an individual basis also and those

might not necessarily have the same criteria. And it's also I think a question of what records are missing or unavailable or can't be found and then how far do you go to try to get those records and --

DR. ZIEMER: So it's part of the bigger dose reconstruction picture then, yes. Okay. I'm trying to sort of categorize these in my mind, so that's a piece of dose reconstruction, and others.

DR. MELIUS: Another piece of that which I mentioned earlier is the -- how is this committee going to review the dose reconstructions and what procedures will we have for that.

DR. ZIEMER: And that's a whole topic that we're going to have on the agenda, in fact -- well, that's a whole topic, yes. Right, thank you.

DR. MELIUS: And then I think an -- well, related to dose reconstruction is that if there's a contract let for that, what is going to be the -- how is conflict of interest issues going to be addressed. I think -- I think we had talked about it both in terms of the Board but also in terms of outside groups doing the -- under contract doing the review. There's issues that it's a relatively small professional community and that there have to be some guidelines, both for us, but I think also for the -- especially for this outside contractor and how that would be doing. I think we would -- I

think that's very critical to the credibility of the process and how people -- claimants will view it and so I think that's something that's worthy of a full discussion by the Board.

MR. ELLIOTT: Could I focus in on what you're asking for? Would it be something of the order of what is the quality -- the conflict of interest plan that is in place with regard to the contractor? Or what is it you really want to hear that --

DR. MELIUS: Yeah, I may not be being clear. One -- number one is the conflict of interest plan for the contractor and what that would be -- what that should be. It never fails that a cell phone goes off when you're talking. And secondly would be the -- so what will you have in place for the contractor? I think we really need to -- I guess we -- I'm sure we can say we can review that, but we need to -- I think we should be commenting on that and have that presented to us when you presumably reach some agreement with the contractor.

MR. ELLIOTT: At the risk of sounding like I'm managing the Board again, this is a procurement issue and the contract that is awarded will have in it a conflict of interest plan that has been negotiated and agreed upon between the Agency, the procurement office of that -- of our Agency and the

proposer. And I want to be very clear. I'm going to be honest with you and straightforward when and where I can be, you're not going to have an opportunity to provide advice on the content of that. You'll have opportunity to evaluate it, examine it and make, you know, whatever thoughts you have about it known and any recommendations, but that's going to be in place upon the award of that contract. And I have no -- we have no ability to bring you into play into that process.

DR. MELIUS: I think --

DR. ZIEMER: Let me interject here, Jim. I think what -- if I understand it correctly, though, you're saying it would be helpful for the Board to know what that conflict of interest plan is for the group that gets the award. They have to submit a conflict of interest plan as part of their proposal, as I understand it, and although it's a procurement issue, I think the Board is asking to be made aware of the details of that.

DR. MELIUS: Yeah, I just would -- I under -- you -- NIOSH has made a decision not to discuss that with us prior to awarding the contract, and there were -- you could have done it at an early meeting prior to the RFA going out and could have asked for input but you decided not to do that. So we realize we're reviewing after the fact, but I

think it's -- at least personally I think it's a very critical issue and it's going to be key to the credibility of this overall process. And if you put in place a deficient plan, I think it's our job to tell you that. Now you can then have to work within procurement guidelines, et cetera, to figure out what to do or whether or not to take our advice, but that's understood.

I think separate from that there's an issue how does this Board review that dose reconstructions? I think we have to be cognizant of potential conflicts of the Board, and I think that's a simpler process in terms of that review and in terms of how we do it, but it ought to be something we discuss there, also.

MR. ELLIOTT: I don't want to be misunderstood. I'm not saying you cannot see that. I'm just saying you're going to see it and you're going to have the opportunity to evaluate it, examine it, but it's going to be put in place. And then whatever comments you have about it, whatever recommendations you wish to make about it, if we can make change and we think it's appropriate to make change, we will. But I can't bring you into the -- to the process in advance of that.

DR. ZIEMER: Okay. Additional items for this master list? Okay, Robert and then Henry.

MR. PRESLEY: Would it be possible to have one of the legal -- the lawyers give us a overview of what we can say and what we can't say to claimants? I don't know how many people are getting calls, but I am, and if I'm the only one, then I'll be more than happy to talk to them one on one, but it might be a thing to have somebody come and talk to us about what can and cannot be discussed.

DR. ZIEMER: We're all thinking of just telling them to call Robert Presley.

MR. PRESLEY: Somebody's already done that.

DR. ZIEMER: Okay, so noted. Henry?

DR. ANDERSON: (Inaudible)

DR. ZIEMER: Okay, Roy?

DR. DEHART: It's perhaps a bit early, but I would like to get on the list the concept of -- at some point in time there is going to be publication of the process, as well as the results in terms of the numbers of cancers identified and so forth. And I think it would be helpful to see or begin to discuss what the plans are to assist that publication process.

MR. ELLIOTT: Let me make sure I understand. I'm trying to make sure I capture exactly what you want. Would you be talking about the statistics that we put forward about how many claims come through, how many lung cancer cases were examined,

how many awards were made, those kind of things?

MR. PRESLEY: Let me ask a quick question on that while we're on that --

DR. ZIEMER: Use your --

UNIDENTIFIED: Would you turn your microphone on? Thank you.

MR. PRESLEY: Could we do that also by site? Would that be -- or geo-- by area?

DR. ANDERSON: Actually my first issue was somewhere along that line. I think I would like to hear what NIOSH's kind of tracking plan is going to be. We've seen the slides of total numbers received by DOL and that, I think that's useful. But I think we may also want to look at some of the -- if there's additional plans which would be the type of cancers and kind of come up with what should be your kind of template for a updating report, how often are you going to generate your statistics, how often will that be then put up on the web if it's going to be on the web.

And then the other would be to look at are there some kind of quality control issues that you'd thought about that you're going to implement. One of those would be the -- do we want to track the number of days between when something is received, a letter goes out, how long it takes for final adjudication. I mean we're early on now so there's

plenty of time, but I think before you get into everybody asking you about what about that number, you're going to be chasing some statistic and it would be better to have a plan in place and why we're doing that. And then what would be the goal -- you know, like one project we've been on with the hospital, tracking how long does it take for a physician to get their report in and things like that. You can -- if there seems to be a number that's out of line, you can then work either with the contractor to improve that.

The other one later on -- I think we've got more than enough on our plate, but I would really like to hear, based upon your -- the dose reconstruction and the other IREP types of processes, where do you see the most significant gaps, kind of what's on the horizon for research. Is there anything we could help you with to support --

DR. ZIEMER: Problem issues, huh?

DR. ANDERSON: Yeah, on our behalf here are the critical issues that we need more data on. Are there studies underway that will come out in two years, those kind of issues.

DR. ZIEMER: That relates a little bit to what Sally was talking about, too, some of the critical issues that need to be addressed.

MR. ELLIOTT: So I have performance and quality control measures and I have what research questions or information gaps need to be addressed.

DR. ANDERSON: Yeah.

MR. ELLIOTT: Okay?

DR. ANDERSON: Yeah.

DR. ZIEMER: Jim?

DR. MELIUS: Yeah. This may be a related issue, but it goes to access to information from the Department of Energy facilities. You have a -- the MOU I guess is taking a while to finalize and either I guess I'd like to hear sort of a presentation when it's finalized -- what assurances are we providing to the applicants that a complete search has been done for information relevant to their particular case. I think that's, again, a real important credibility issue for the program. And absent an MOU, I think at our next meeting I'd like at least an update on what the -- where are you getting information and are there problems that you're perceiving with types of information that's more difficult. And I think there is going to be at some point sort of a balancing. How far do you go to try to get information that someone thinks is available or may be available and versus what's practical. I know you're wrestling with that on a day-to-day basis, but I think it would be helpful to have some

discussion of that, also.

DR. ZIEMER: Thank you. These are a good list of things to address. Got another one? Okay.

MR. GRIFFON: Just to follow up on that point, I think it would be useful to understand the records request process. In an earlier meeting I was sort of under the impression that the subcontractor doing the dose reconstruction would have direct access to records on the sites, and recently I've been convinced that that may not be the case, so just a description of how the records requests -- what kinds of records can be -- are being request -- are relevant, and then how the process works, DOE to NIOSH to subcontractor or how that works.

DR. ZIEMER: I'm going to interrupt this discussion. We can come back to it, but I have become aware that as the storm has gathered, we're losing some of our folks in the general public. And although no one had signed up for public comment, I do want to give one more opportunity. If there are members of the public who have comments, I don't want to preclude that, and let's do that now before everybody takes off and tries to beat the storm home or whatever. Are there -- is there anyone left that has public comment?

Okay, we have at least one, even though not

signed up, but you have no competition.

MR. MILLER: I assure you I'll limit my comments to less than five minutes so that others will have an opportunity as well. I'm --

DR. ZIEMER: You need to --

MR. MILLER: -- Richard Miller --

DR. ZIEMER: -- identify yourself, Richard, for the --

MR. MILLER: -- thank you, Mr. Elliott. I don't know if this is the right time to ask for this since the rule has now been published, and maybe I can stand being corrected as well. But at least in reviewing the web site up to this point for OCAS, I wasn't aware of the inter-- what's called the HHS family, interagency communications that dealt with comments on this rule. It's pretty plain from reading the -- it would seem -- it seemed to me at least plain from reading the preamble to the rule on the probability of causation that NCI played a disproportionate role in answering and addressing questions that either the public or your invited experts had raised. One particular example comes to mind from the preamble, which I don't have in front of me, but spoke to the question of what do you do about the age at exposure debate. And in there it said well, if this is going to be changed, we really would have to change it through NCI and this would

also involve how the program affecting -- I think it was the atomic veterans program, I think it was, would also have to be modified because the -- NCI's model would be applying to both that program as well as to this program, the energy employees compensation program. And so that would require an interagency and other committees deliberating. And so it was clear that what was happening was this was not a NIOSH rule and that any changes to it are going to have to involve interconnections with other programs and other agencies, or other arms of CDC, let's put it that way, or other arms of HHS. So I guess I would find it helpful, if it exists and if it's disclosable, to see the intra-agency communications between NCI and other agencies -- and I don't know who the others are that are involved. I heard Mr. Neton mention that there were other agencies and I don't know who they all are, but it would be very helpful to see that communications laid out, maybe posted on the web page may be the fastest way for us to get it, but it would help to have a little bit more transparency to understand what NCI communicated to NIOSH and vice versa, what NIOSH communicated to NCI, so we can see how we got this result in front of us today. That's sort of my comment and request.

MR. KATZ: Hi, Ted Katz. Richard, I'm not

entirely sure what the right response is to that in terms of what we can share in interagency communications, but certainly we'll share whatever we can share.

But let me just be clear. I think I'm able to say this, that the agencies we receive comments from and responded to comments from were not NCI, actually. They were HHS -- I mean our mother Department -- and the Department of Labor and the Department of Energy and the Department of Justice and the Office of Management and Budget. So in fact, NCI wasn't in the loop as a reviewer. Oh, and the Defense Threat Reduction Agency. Well, that -- right, they had public -- I mean they were part of public comments. I mean you can see all the public comments -- and a lot of these -- you know, we had public comments from the Department of Energy, for example, from their field offices and so on. Those are all a matter of public record and they're in our docket, so you can see those.

But in terms of interdepartmental review, those are the organizations that were part of the interdepartmental review. Those are the folks we responded to in making changes to the rule.

MR. MILLER: Thank you, Ted. I guess the thing that was startling perhaps to me in reading the preamble -- I mean I didn't -- maybe it was just

because I wasn't ready and wasn't prepared and didn't expect it -- was to look at specific comments that were raised, particularly with respect to the probability of causation rule. And rather than what it's saying NIOSH's position is -- there's insufficient evidence or that there's not a sufficient weight of evidence or that there are differing studies and we don't have this question resolved -- we hear NCI's views are there is insufficient evidence, there is insufficient weight. And so there was a confusion on my part -- maybe it was a typo, maybe it was my misreading -- but I was unprepared for that and I wasn't clear where NCI's role begins and ends and where NIOSH's role begins and ends and particularly in all of the policy decisions about applying this model.

MR. KATZ: I'm sorry, let me hop back up here again -- Ted Katz again. There really -- there are very few instances in these rules where we discuss NCI. And I think what you're thinking of is circumstances where, for example, you have an element of IREP that applies equally to the DOE/EEOICPA population and to the VA -- the VA's DOD population, where there's really no scientific reason to discriminate between them. Then you do what we have said, and I really think -- I believe there's just one instance of this, but there we're

saying if there's no scientific reason to distinguish between these populations and how you treat them scientifically, because this is one department, we do indeed want consensus in how to deal with that scientific issue. And so you're absolutely correct and there is an instance of this -- and I believe it's just one, but I could be wrong. But in that case, it's an issue that has no distinctions for the DOE population in effect.

MR. MILLER: Well, thank you, Ted. I'm not going to debate the distinctions between those that were at a single atomic bomb blast at the Nevada Test Site and the distinctions between those who had long-term exposures working in the weapons production program, but I think there are significant distinctions in the epidemiology that studies them because the nature of the exposures were different. You had a single blast at a single occasion in many of those that are covered under that particular program, and I think there's a fairly significant -- there are at least a number of, and you did reference them in the *Federal Register* notice, published studies which specifically speak on point to this question about, for example, age at exposure, the degree and extent to which one can adequately explain how it's possible that at age 40 somebody is one-third as

radiosensitive as somebody at age 20 to the identical exposure. And that will have a significant outcome upon the compensability of individuals who are in fact in very different work environments with different types of exposures and in different environments. And I would just say there are different studies that will apply to those who were let's say at ground zero as atomic vets in the Nevada Test Site at a blast and those who were working in an oxide facility handling alpha particles and ingesting them with inadequate protection.

And leaving that aside, the character of the exposures, it seemed to me we ought to deal with the population that's in front of us, for what it's worth. And if, to the extent and degree that NCI's going to play a role in determining what's appropriate for this population, then that ought to become a good deal more transparent. And I don't see that transparency and I guess I would like to -- that's why I'm asking for, if there are communications, whether they're e-mails, whether they're memorandum, recommendations, documents, briefing points, whatever it happens to be, it would be very helpful to have some transparency and some openness so this is out on the record so for those of us outside government we can have some window --

just some kind of insight -- to figure out how we got from point A to point B.

I'm not saying anything's wrong here. I'm saying we need more transparency because it's very confusing from the outside to read the preamble and to kind of guess what might have happened. So I'm just asking, if you've got those communications, if they're available, we'd sure like to know about them and we'd like to get them on the record.

DR. ZIEMER: Thank you very much. Are there any further public comments? There appear to be none.

Now I have two possible items -- let me see how we're doing on time. It's 4:00 o'clock so we have some time. Two possible items. One is to ask whether anyone wishes to discuss at this time, in general terms or just in terms of general views, the issue of Special Exposure Cohorts, realizing we do not have before us the document that's being developed on that issue by NIOSH. But the possibility of any particular issues that you want to raise now, to ask that they be addressed in connection with the presentation next time or anything related to Special Exposure Cohort at this point. Roy?

DR. DEHART: It may be covered tomorrow, and if so, certainly we can wait till then. But can

someone provide us a history of how this came about? It'll be tomorrow? Fine.

DR. ZIEMER: We will have the presentation by David Michaels tomorrow. David at the time was with the Department of Energy and has first-hand knowledge of the development of the legislation and related issue, and I think we can certainly discuss with David the issue of Special Exposure Cohort, at least in a general way, not with specific focus on the documents being prepared, but -- Jim?

DR. MELIUS: I was actually going to suggest that we do that as part of David's presentation, and if he could start a little earlier or something, if he's available, that might make it -- give us time to talk about that 'cause I think it will actually come out of that legislative history, be a lot easier to talk about and I think he can provide some background on that. And then I think we can more easier --

DR. ZIEMER: We can jump off from there, and I agree with that, but I didn't want to preclude, since it came up earlier, if people had particular items they wanted to put on the table now. But it certainly will be more natural tomorrow to do that and we'll proceed on that basis. Is that agreeable with everyone?

Then the final thing that I had jotted down

was to ask whether or not anyone wished to focus on any of the specific changes in the rule. We talked this morning when we had the general sort of discussion on the final versions of the rule and I don't know if you've had a chance to look at any of those or -- but are there any specific issues that people want to -- or do you want to take time now and say let's look at those rules and sort of step-by-step and look at the real changes and discuss any of them? I'm basically asking how you wish to proceed at this point. That was kind of a left-over item. I think there was some sense in which folks felt that, although we had a general description of those changes, it wasn't completely clear what the real final version looked like compared to the earlier versions. Henry?

DR. ANDERSON: Yeah, I just found it difficult to see where the wording was actually changed, and what would have helped is a red-line strikeout kind of a thing so you could hone in on where the -- I mean we could see where the changes that we recommended, the one, got put into some of them. But for some of the other discussion, it's harder to tell whether -- you know, how or how it might have been changed or how many words were actually changed. I don't have the earlier version here with me so I can't try to read the two at a

time.

DR. ZIEMER: Well, it certainly is clear to me that the changes that we recommended are there and I have --

DR. ANDERSON: Oh, yeah.

DR. ZIEMER: -- identified them, and --

DR. ANDERSON: That was new. I can see that.

DR. ZIEMER: -- I think perhaps rather than go through each change, no matter how great or small, the question would be are there particular issues that any of you were concerned about that we -- that might have been identified as changes and want to know exactly what is the change. Are there any of those? Or what was it before and after or --

DR. MELIUS: I just think we need time to look at it and -- I mean it's very hard to do it in abstract and I don't want to preclude a chance to discuss it, and I don't -- is there any way we could get a red-lined strikeout copy between now and tomorrow morning? Is there one sitting in a computer someplace?

DR. ZIEMER: I'm going to guess that's not going to be very easy since there's formatting things, but perhaps in the interest of efficiency we can -- we could declare just a working session and allow you to just spend some time looking at that

now and we can discuss it tomorrow. But you know, I leave it up to each of you if you wanted to do that here or in your rooms or whatever, but otherwise, as far as the agenda is concerned, we would have no additional agenda items today beyond that issue.

MR. KATZ: Let me just -- this might help, Jim, is as you go through the preamble, in the summary of the sections -- I mean at least for anything -- I think for all the substantial changes that are made, in the summary of the sections in the preamble, it will indicate that changes were made to that subsection so you don't really -- you don't have to -- it shouldn't be that hard for you to identify where the changes have been made.

DR. MELIUS: You know this in more detail, but my -- my recollection is that some of those say they're -- that the regulation's been changed but doesn't say what the change is, so you have to go and look at it and then try to remember what it was then before.

MR. KATZ: But it actually -- in the summary it'll describe what that change is doing. I think it should be readily identifiable.

DR. ZIEMER: Can you give us an example, Ted? Maybe just before we leave here today?

MR. KATZ: For example, if you look under -- in the probability of causation rule, if you look

for your change in terms of incorporating the Board's role in reviewing updates, then look at the summary section of the preamble for section -- seems like it would be 81.12, I think, and there should be indication there that that's added.

(Pause)

DR. ZIEMER: Okay, look on page 60, Ted, this is what -- (Reading) In the summary below, HHS indicates all the changes in the provisions made since the notice of proposed rule-making.

Then it goes through it section by section. Is that what you're saying?

MR. KATZ: Yes.

DR. ZIEMER: That begins on -- for part 81, begins on page 60, I believe.

MR. KATZ: So for example, look on page 63, the full paragraph.

DR. ZIEMER: Page 63, the first full paragraph where it says (Reading) Section 81.12 was added in response to comments -- da, da, da.

You see what Ted is saying? So beginning on page 60, it goes through it section by section and tells what the changes were.

So again let me suggest that with that in mind that you can individually digest that, either during the next hour or throughout the evening ahead. And then if there are questions, then we can

raise them tomorrow morning. Henry?

DR. ANDERSON: This is more just curiosity. Frequently in the *Federal Register* responses it indicates not just an anonymous set of comments received or several people or two people, it usually says so-and-so or an organization. I'm just curious why in this instance they're not identified. I mean you can go to the web site and get the actual comments, but it doesn't say -- and often that is helpful to understand, was it a public individual or was it an organization and were many of the things you responded to all coming out of one individual or one comment or -- just curious as to --

MR. KATZ: Yeah, and there's no beautiful answer for that. It just -- it just wasn't the approach we took.

DR. ANDERSON: It was just quicker to do it this way?

MR. KATZ: We just left it -- no, I mean not even quicker. It would have been just as quick, but it just would have -- out of a lot of verbiage that wouldn't have been enlightening, I think, so we left it anonymous like that.

DR. ZIEMER: Well, of course in some cases if you identify who the commenter is, people give more or less weight to that comment --

DR. ANDERSON: Right.

DR. ZIEMER: -- in terms of how it's handled.

DR. ANDERSON: Or if you were a commenter and you looked -- gee, I wonder if they're responding to my comments. It's difficult.

MR. KATZ: Right, but we had -- you know, two-thirds of the commenters were individuals who for most readers wouldn't be known.

DR. ANDERSON: Yeah.

MR. KATZ: And I think there's no tradition of using individuals' names in anyway, so those would have been left out.

DR. ANDERSON: That's okay, I -- you know. That's fine.

DR. MELIUS: I think what we're telling you is it would be enlightening and I think my -- to have individual names, and I believe that's what often is done with OSHA regs, which I've read. Preambles will include who provided the comments and names and so forth, and I think it is useful.

MR. KATZ: So the next time -- the next time we promulgate these rules we'll perhaps take a different course.

DR. ZIEMER: I want to ask again the Board's wishes. Do you wish to adjourn or recess at this point for the day, or are you so energetic -- okay. Henry does not wish to recess.

DR. MELIUS: I have one other important point. I think the committee should all recognize that it was Larry Elliott's birthday yesterday and wish him happy birthday. And probably should wish him happy birthday today because he probably aged another year putting up with us all day, so happy birthday again.

DR. ZIEMER: I thought that aged look was from the work and now it's just natural aging. Right?

MR. ELLIOTT: Thank you.

DR. ZIEMER: Happy birthday, Larry. Well, we're getting sufficiently jovial that I'm sure the day is over for serious work, so we'll declare a recess till tomorrow morning and -- what's our time in the morning? -- 8:30. Okay, 8:30 in the morning. Thank you.

Remember to take all your stuff.

(Whereupon, a recess was taken to Friday, May 3, 2002 at 8:30 a.m.)

Presidential Advisory Committee

Department of Health and Human Services

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)

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, 525 New Jersey Avenue, N.W., Washington, D.C., on May 2 and 3, 2002.

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TRANSCRIPT LEGEND

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In the following transcript "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

(8:40 a.m.)

DR. ZIEMER: Well, good morning. I'll officially declare us back in assembly and ready to go to work. We have several housekeeping things to take care of. I guess the first one is the issue of pictures for the web site. There's been a request that our pictures -- pictures of the Board be put on the web site. It's not mandatory that you do this, but if you're willing to, you do need to sign a release and then Ted Katz is going to be the photographer, have a beautiful portrait of each of you on the web site, action shot -- candid action shot, so who knows what it'll look like. No one will ever recognize you anyway.

Let's see, let me ask Cori for housekeeping -- is Cori still here? Yeah, do we have some housekeeping things pertaining to either travel forms or other things that the Board needs to address?

MS. HOMER: Just that everything's been paid -- or should have been. If you haven't been reimbursed for either travel voucher or salary, please let me know. I also have amounts, if you're curious about what should have gone into your direct deposit account, please ask me. I might can give you a general date when that should have gone into

your account.

DR. ZIEMER: Are we at a position to look at the schedule for next meeting yet? I know that you passed out calendar --

MS. HOMER: I gave those to you --

DR. ZIEMER: Oh --

MS. HOMER: -- and Larry.

DR. ZIEMER: Oh, we're the only ones that have these?

MS. HOMER: Yes.

DR. ZIEMER: Is everyone's -- Are everyone's bad dates on here? Well, we'll come back to that in just a moment then.

Let me also remind folks that if you have additional time in preparation for this meeting, you need to let Larry or Cori know what that is as well.

MS. HOMER: I'd also like to remind everybody that when you're calling the hotel to make your reservations, please remember that the rooms are on a block. Just in case you call and they say oh, gee, we don't have your name, the room is either blocked under NIOSH or CDC, and if you have any problems making your reservations or reservation, please let me know and I will contact the hotel and find out what the problem is. I think that's about all I have.

DR. ZIEMER: Before we talk about setting a

date, let's talk a bit about our work schedule and upcoming things. We have talked about some topical issues that may be somewhat dependent on availability of experts to address the group. We've talked -- very preliminary way -- about issues of how we assess, monitor, evaluate dose reconstruction activities, and that may be on down the road a bit, but we need to begin to formulate some strategies and plans as to how we will go about that.

We also need to have some idea of when the Special Exposure Cohort materials will be ready. I think there's a -- and I'm not asking you to commit to a certain date, but I think -- I get the feel that they might be ready within a couple of weeks. Is that unrealistic or -- I'm thinking in terms of the possibility of getting those out to the Board, maybe at least a couple of weeks in advance of a meeting, and then we can go from there and say okay, what's the time frame for setting our next meeting. It seems to me that may be a critical point.

MR. KATZ: Yeah, thanks, Ted Katz. Dr. Ziemer, I think it's probably -- I mean we would hope they'd be out in two weeks or so.

DR. ZIEMER: And I don't -- I'm not asking for a promise --

MR. KATZ: No, no, no --

DR. ZIEMER: -- but I want us to be

realistic. If it's going to be --

MR. KATZ: The other I just wanted to --

DR. ZIEMER: -- three weeks or four, just say that.

MR. KATZ: Right. I mean it's only a question of -- I think a lot of people are in the review chain in other departments or have a very busy week next week, so I don't know how things are going to go that respect, but I think that's reasonable.

The other thing I just wanted to mention for you to consider is that right now we're planning on a 60-day public comment period, but we would -- we need to adjust that -- we'll need to adjust that, depending on what sort of date you decide on because we want to, as has been made clear in comments that the Board and so on -- we want to be certain that you have plenty of time to review these procedures. So once we settle that, we'll adjust the procedures accordingly.

DR. ZIEMER: Well, it would appear that perhaps the earliest we might be talking about would be a month from now, but that may be a little bit optimistic if we want to allow some advance time for the Board to review the materials before the meeting. I just happened to notice on my calendar that from June 10th until June 24th I'm out of the

loop and you are, too. We're probably at the same meetings. American Nuclear Society is in that period, and I have some other ones going on -- they all pack together. And going earlier, that is the first week of June is just a month from now and I think that may be pushing a little bit. So then we're into, at the earliest, the last week of June or into early July. So I think realistically that's where we need to start looking at calendars.

Let's see, on this summary that I got from Cori, I don't -- no, actually I guess we need to ask you to look at your calendars because not everybody's name is on here. The ones who are named are all available the last week of June. And let's see, Sally's availability for July, unknown.

In June.

MS. GADOLA: July.

DR. ZIEMER: In July, okay. Well, let's find out how the last week of June is first. Anyone for whom the last week of June is bad?

DR. MELIUS: Thursday of that week is (inaudible).

UNIDENTIFIED: Yes.

DR. MELIUS: I don't know if that's going to --

DR. ZIEMER: That would be June 27th?

DR. MELIUS: 27th, yeah.

DR. ZIEMER: So that's out.

DR. MELIUS: That's just a one-day meeting.

MS. HOMER: That's just one day, but I'm not -- you're there. And we could actually possibly (inaudible).

DR. MELIUS: Yeah, it's not (inaudible).

DR. ZIEMER: It's a bad week for Larry, so let's just rule that week out.

Let's look at the first week of July. Of course there's the July 4th holiday in there which would be probably not a good time for most folks. Some folks are out barbecuing and things like that.

MS. MUNN: Well, if we did it Monday and Tuesday, we'd all be home.

DR. ZIEMER: 1st and 2nd? Let me ask -- those for whom the 1st and/or 2nd would be bad? So the 1st -- oh, it would be bad.

MR. PRESLEY: I could change my schedule if it's good for everybody else but me.

DR. ZIEMER: So possible 1st or 2nd -- 3rd is not good? Getting too close to the holiday?

UNIDENTIFIED: Travel would be bad.

DR. ZIEMER: Be bad? Okay. And of course the 5th would be out because it'd be just a single day. How about the week of the 8th?

DR. DEHART: I'm not available.

DR. ZIEMER: All week? It's out, that week.

Week of the 14th -- 15th? Week of the 21st? Well, let's see, I'm out the 23rd and 4th, 5th and 6th. Well, that's -- yeah, that is pretty much it. Okay.

And then finally, the last week of July, which carries over into the first of August.

DR. MELIUS: That's bad for me.

DR. ZIEMER: Bad for you. Whole week?

DR. MELIUS: Whole week.

DR. ZIEMER: Okay, bad for you. Now we actually have two days where we could even possibly meet, that's July 1st and 2nd, and my -- Robert, you said you could possibly rearrange?

MR. PRESLEY: If everybody else can meet, I could rearrange.

DR. ZIEMER: Why don't we pencil that in on people's calendars and, depending somewhat on how things develop there, if we can shoot for that and that's basically two months from now. Or actually -- yeah. Let's see, no, that's -- yeah, that gives you most of May and all of June.

MS. HOMER: I'll check the availability dates on the hotel. Or if you'd care to, we could have it someplace else.

DR. MELIUS: I really think we ought to start meeting outside of Washington in order to get just a little bit more public -- at least the possibility or -- of public participation.

DR. ZIEMER: Suggested locations?

MR. PRESLEY: I don't mind you all coming to Oak Ridge, but I'd need more than two months to try to get things organized.

MS. MUNN: As I've said before, you're certainly all welcome to come out to the west coast. **MS. MURRAY:** Put your microphone on.

MS. MUNN: Although I understand the plea for more public availability, from my point of view, coming into Washington, D.C. is much simpler than trying to get to another smaller, less easily available from Seattle location.

DR. ZIEMER: Other suggestions?

UNIDENTIFIED: We can do it in Cincinnati.

DR. MELIUS: Denver, relatively accessible from everywhere (inaudible).

DR. ZIEMER: Denver also is close to a DOE site, namely Rocky Flats.

DR. MELIUS: And there've been a number of public meetings out there so (inaudible) we've had active participation in the past.

UNIDENTIFIED: It's also going to be hot in (inaudible).

DR. DEHART: Yeah, Denver sounds a little cool.

DR. ZIEMER: Okay, I don't know if that's a

groundswell for Denver, but could we at least investigate Denver as a possibility? You might want to have a default. I mean some of the -- well, this isn't that big a meeting, so it may not be so hard to --

MS. HOMER: No, it all depends on the season and depends on availability, but I'll check.

DR. ZIEMER: Right, we'll look at Denver as a possibility. Other locations that are easy to get to and that are relatively near DOE sites include Chicago, which is near -- which is basically where Argonne is, although that's not quite as critical a site for these kinds of activities, but nonetheless, there are folks there.

MS. HOMER: Cincinnati --

DR. ZIEMER: And Cincinnati. Right.

Okay, we'll ask the staff to look into those possibilities. Any other housekeeping issues? I want to also indicate that if David Michaels does arrive before his appointed time, if it's agreeable I'd like to start him virtually right away if he gets here early. The reason being that some of the members -- some, I know that Tony's plane leaves at noon, which means nowadays you can't do what we used to and that's to leave from downtown about 30 minutes before flight time and expect to catch a flight, so Tony would probably have to leave about

10:30. And so if Dr. Michaels does arrive early, we'll try to put him on.

Then in the meantime we'll proceed. There's at least one item that we want to spend some time on, and possibly a second. The first item would be now to go back and see what additional questions folks have on the final rules as far as the clarification issues that were raised yesterday.

And then also if we have time, I think it would be useful for us to do a little brainstorming about how we might approach in the future the issue of our role in the dose reconstruction activities, monitoring, assessing, evaluating, whatever it is we wish to do.

So let's proceed -- shall we proceed first with Part 81? And Ted, you need to also be on deck to help answer questions, I suppose. And what I myself had been looking at was, beginning on page 22 and going through the public comments and kind of looking at what the comments were and how the staff handled those, I'm right now -- I'm sorry, I'm on PC -- POC, probability of causation. That's Part 81. Maybe there aren't any questions on that, but if there are, we need to take this opportunity and then we'll go on to Part 82.

But I assume that in general the kinds of questions that were raised about how the staff

addressed and resolved public comment issues maybe applies to both, so let's at least -- if there are concerns or areas where the Board wishes to raise questions or ask questions or make comments, let's -- if this is agreeable, we'll just systematically go through these areas, and if there's no questions or comments, we just move on. Is that agreeable?

So I'm looking, beginning on page 22 of the draft that we have, and I don't know if members of the public have any of this, but -- or where it would be if -- are the actual real versions now back on the table? 'Cause I can give I think maybe the section number. No, they're not available yet? Okay.

Well, let's proceed, in any event. The first topic was the appropriateness of adopting compensation policy used for atomic veterans, begins on page 23. And what I'll do is just pause and see if folks have concerns. I assume as you reviewed this if you had issues, you probably made marks and -- or highlighted or whatever.

How about item (b), compensability?

(Pause)

DR. ZIEMER: Okay. Item (c) on page 26, need for peer review? This included some public concerns about this Board's expertise in reviewing. Yes?

DR. ANDERSON: I guess I would go back to a question I had on (a) as far as the response. It's more of an administrative response as to why was -- why the tables and things were used. I think it would have been helpful and at some point to -- and that may be when we get into the compensation side, the doses are really quite different, the types of exposures are different between the atomic veterans and this particular group. And at least as I took the commenters' question was more to the issue is the compensation program for atomic veteran-type exposures appropriate for individuals who would have far lower and often more chronic exposures.

DR. ZIEMER: Okay, and perhaps Ted can answer that.

DR. ANDERSON: I mean I don't know what the -- I haven't looked at the commenter. I'm just saying that's one issue, and as we move forward it'll be important to explain to the public why systems set up --

DR. ZIEMER: We do understand and I believe this is correct that the law itself requires the use of the probability of causation and the NIH tables as updated.

UNIDENTIFIED: Yes, yes, yes, right.

DR. ANDERSON: I know it requires it, but --

DR. ZIEMER: But you're just --

DR. ANDERSON: -- but I'm just saying the

DR. ZIEMER: -- saying it's not clear to the --

DR. ANDERSON: -- I mean what Congress does is hopefully consistent with the science and I'm just saying that at some point I would expect -- at least the questions that I've gotten from a few people has been what's the underlying science, is that science appropriate, and I think at some point -- and I haven't looked at all the things on the web site, maybe there is an explanation of why exposure is exposure --

DR. ZIEMER: Yes, and actually you're in a sense raising a deeper question that's come up in this Board in somewhat different ways at different times, and that is the issue of the narrative that describes the intent of Congress and how much that intent of Congress reflects scientific reality --

DR. ANDERSON: I didn't want to put it --

DR. ZIEMER: -- with all due respect --

DR. ANDERSON: -- quite that way, but that was the gist of what I was saying.

DR. ZIEMER: With all due respect to the intent of Congress. And in fact, perhaps Dr. Michaels will help us understand that, as well. And I shouldn't say that in a derogatory fashion. Actually it's a view of reality that differs from

some other folks's view on a number of issues, including dose-effect relationships, including how one uses probability of causation and a number of other issues. And on none of these are there really clear right or wrong answers. There are scientific disagreements clearly on a number of these issues, and some of the underlying assumptions to those issues, as well.

DR. ANDERSON: I'm just trying to anticipate that if we start to have meetings out where we'll have more public participation, I would expect those may be the kind of questions. And to say well, that's what the law says --

DR. ZIEMER: That may not be satisfying.

DR. ANDERSON: That's not very satisfying, so I think to have an explanation as to why this is -- that having consistency also fits with some of the others that would I think be necessary to --

DR. ZIEMER: So you're not real happy with the idea of saying yeah, it doesn't make sense but Congress wanted it that way.

DR. ANDERSON: Right. Right.

DR. ZIEMER: Thank you. I've got to be careful how I state these things. I mean that in a friendly fashion.

Okay. Other comments? Yes.

MR. GRIFFON: Just to follow on to that

point, I mean I think you're right that it did require the NIH -- the adoption of the NIH tables, but as updated, as you said, so NIOSH did have an opportunity to update those and they did consider the DOE epidemiological studies, made a -- you know, I think again we want to see the basis, and I'm not saying right or wrong. I think timing and a wide variety of study results was one of the reasons they didn't use many of the DOE epi studies to be incorporated in the IREP model, and probably rightly so. But I think we need to see more of that basis again so that we have an understanding of that process.

DR. ZIEMER: Okay. We'll jump back to -- I think the point where we were back in (c), need for peer review. Any comments on that?

DR. ROESSLER: Under (c), peer review on page 27, I'm pleased to see the line in there, in that first paragraph (Reading) Moreover, the Board maintains the option to commission additional independent scientists to participate in the Board's review.

I think when we're questioned by our colleagues about the expertise on the Board, that always is a drop-back or a way to get more review.

DR. ZIEMER: Thank you.

MR. ELLIOTT: Let me comment on that, just

in the way we would handle that so that everybody at this point understands how we would proceed. If the Board's pleasure is to seek some expert consultation to support your review, we can make that happen through what we call a fee for service, and that's a pretty expedited process. We just need to know who it would be that you would like to seek out for consultation and we can put that in place.

DR. ZIEMER: Okay. Item (d), updating NIOSH-IREP to remain current with science.

(Pause)

DR. ZIEMER: No comments? Item (e), chemical or non-occupational radiation exposures as risk factors.

(Pause)

DR. ZIEMER: Item (f), covered exposures. I might insert here a comment. Henry, this is similar -- the same sort of thing. It simply invokes the requirement of the law -- although it does explain why. I mean the law limits it to the radiation exposures or perhaps radiation plus something, but not other things. But there is at least now a reason for that in terms of available science, but it -- another one of those where we need to be sure as we go forward in interacting with the public that there's a reason that the law is the way it is.

DR. ANDERSON: Back to the interactive

effects, at some point I think it would be helpful as just kind of an informational piece for us to have somebody from NIOSH or elsewhere come in and kind of give us the state of the art on interactive effects, and that could then lead us to a recommendation or support of a research activity or something like that. I think it'd be -- this is certainly one that was raised by the public and be a good idea to get a sense of where it's at, what's the --

DR. ZIEMER: That's a very good point, and in fact it would be nice to have kind of a summary of what research is underway, if that can be determined. I'm aware of the fact, for example, that even as we speak NIOSH itself -- another part of NIOSH -- has on the street a request for proposals for studies relating to, among other things, mixed exposures. By mixed in this case I mean radiation plus other agents.

Item (g), covered illnesses?

(Pause)

DR. ZIEMER: No comments? Okay. Item (h), radiation dose threshold for calculating probability of causation. Yes, Gen?

DR. ROESSLER: Again, I'm pleased to see several paragraphs in here addressing this. It's very controversial and I think it's explained or

it's stated very well here, so I think that's a good part of this section, both with regard to threshold and the uncertainty. They're both addressed here and those are questions that come up frequently.

DR. ZIEMER: Thank you. And also, Gen, the grouping of the rare cancers, and you raised the question yesterday on those and that's discussed here, too.

DR. ROESSLER: That's what I meant by the uncertainty, that part, yes.

DR. ZIEMER: Okay. Item (j), documentation of IREP.

(Pause)

DR. ZIEMER: I'm sorry, what's that? Oh, I missed, okay, bottom of the page there. Yes, sorry. Were there comments on that one? I knew there were none and I just skipped it. Okay, none on item (i) -- (j), documentation for IREP? Okay on that one?

(Pause)

DR. ZIEMER: I want to ask Mark Griffon -- 'cause you raised issues yesterday I think about the sort of transparency of documentation, so are you comfortable at this point as to where it's going on --

MR. GRIFFON: I think they've addressed that in the final version, the model details that I'm requesting will be in the final version. I'm

confused why they aren't right now, but that's a separate issue, so I think they've addressed that, yes.

DR. ZIEMER: Item (k), technical elements of IREP?

(Pause)

DR. ZIEMER: Jim?

DR. MELIUS: Just a comment. I would note that almost all these subjects are things that we've asked for further updates and further discussions of, so not to fault what's here, but I think they're all worthy of more attention.

(Pause)

DR. ZIEMER: Item (l) begins on page 50 of your document. It's discussion at this point on Part 82. Right? Within the context of this rule. But it's the section under dose reconstruction program as set forth in 82. I'm trying to understand why it's here. Oh, it's because the comments came in under 81 but they actually related to -- I'm sorry.

It's the fact that the comments were submitted as Part 81 comments, but they actually pertained to Part 82, so they are dealt with here.

DR. DEHART: Paul, could I come back just a minute to the rather lengthy section we just left --

DR. ZIEMER: Too late, you missed it. No,

please, go ahead.

DR. DEHART: The issue of age, was that on our list of items to --

DR. ZIEMER: Age at exposure?

DR. DEHART: Yes.

DR. ZIEMER: I think that was on the list.

MR. GRIFFON: I was just going to say part of that is also part of the healthy survivor effect; it's sort of tied together, so I think we've...

DR. ZIEMER: Item (m) is Special Exposure Cohort, a very brief discussion there. It simply refers to the fact that a separate document's being developed.

Item (n), Department of Labor responsibilities.

(Pause)

DR. ZIEMER: Now I think that's the last section dealing with comments other than the comments that this Board submitted, and those are dealt with and I think we're all aware of both our comments and their -- and the outcomes.

Now let me simply pose the question. Is there anything in the body of the rule, after having gone through the comments, in terms of how the actual rule finally ended up being worded. Any questions on that? I mean the rule is now the rule, but if -- well, I think if there are things that

really stick out that we're uncomfortable with, it doesn't hurt to point those out. I mean I think in terms of -- because we reviewed the draft rule in a fair amount of detail before and reached a certain comfort level, and now the level of discomfort revolves more around both the process and the policy issues surrounding how the decisions are made concerning changes and going forward.

Now let's -- are we okay to move ahead to Part 82?

(Pause)

DR. ZIEMER: Henry?

DR. ANDERSON: Just on page 82 I notice it lists cancer diagnosis by ICD-9 code --

DR. ZIEMER: Which one are you in?

DR. ANDERSON: I'm in the actual rule.

DR. ZIEMER: 82?

DR. ANDERSON: 81, but page 82.

DR. ZIEMER: Okay. The question on -- is this on the use of radiation dose information?

DR. ANDERSON: Under the -- yeah -- no, it's at -- no, up above that, it just lists (b) as cancer diagnosis by ICD-9 and of course now ICD-10 is out so I assume there's no -- there will be a conversion table or whatever or -- I mean that's a technicality, but --

DR. ZIEMER: How is that handled? Is it

automatic that you use the latest version or is this codified in a way that it's not readily changed? Ted, can you answer that?

DR. ANDERSON: It's more in the program issue.

MR. KATZ: Yeah, I think it's just an implementation issue, so DOL will have a correspondence table or whatever, but it's not a problem in terms of the --

DR. ANDERSON: You'll take the literal string and this is -- it would seem to me this is only going to apply -- you're going to put the code in so that it calls up the right things --

MR. KATZ: Right.

DR. ANDERSON: -- when you do the causation program and people just have to remember --

MR. KATZ: Right, and this is how we get the right risk model.

DR. ANDERSON: Yeah, and you'll just need to have a failsafe in so that if somebody puts in the wrong --

MR. KATZ: Yes, they'll be fired.

DR. ANDERSON: It won't get attributed to the liver when it's something else.

DR. ZIEMER: Malpractice on the code itself, okay. Thank you. Now I'm looking for my start page here on Part 82. Oh, here we are, it's page 13,

summary of public comments. The first group of comments had to do with the purpose of the rule, so let me ask if you have any questions or comments on that. That begins on page 14.

(Pause)

DR. ZIEMER: Claimant involvement, beginning on the bottom of 17.

(Pause)

DR. ZIEMER: Basics of dose reconstruction, page 22.

(Pause)

DR. ZIEMER: Who receives dose reconstructions, page 25 and following. Yes?

DR. ANDERSON: Just one thought that -- and we don't know the -- how quickly things will move, but for many of these individuals who have cancers, their life span may be relatively short and therefore the need to do an interview early on -- you know, somewhere in here you may need to get a sense of at what stage are they in their malignancy and their life expectancy so that the process of going back to reconstruct and whatever might take longer than the person's expected life expectancy, and then when it comes time to get interview, your first line person who has personal knowledge is gone. So NIOSH may need to take into account -- I don't know if it was written in here or -- it

wouldn't make sense to have it in the rule, but there needs to be --

DR. ZIEMER: I think as a practical matter --

DR. ANDERSON: -- that would be one thing -- we may want to track how many people file, and then you may want to go -- leapfrog into an interview, even though you're -- subsequently it may take months to get the records.

DR. ZIEMER: I think that's already happening, but Larry, would you fill us in?

MR. ELLIOTT: Sure. Surely. Of course we're not going to be able to know each and every situation's -- case's situation, but where we are made aware of an individual who is in dire straits, approaching their end, we have made a special category which we call compassionate, and we have instigated and initiated the interview as quickly as possible. We have several of those in that 75 that I talked about earlier.

DR. ZIEMER: That wouldn't necessarily be covered in the rule-making, but as a practical matter, they're doing that. Or trying to do that.

Okay, we were on item (d), who receives dose reconstruction. Anything else there?

Item (e), establish a time limit for dose reconstruction.

(Pause)

DR. ZIEMER: Okay, (f), use of records and information.

(Pause)

DR. ZIEMER: Okay. Item (g), this is specifically on the claimant and co-worker interviews.

(Pause)

MR. GRIFFON: I'm sorry, just back to (f) for one second. I mean I just wanted -- and we brought this up yesterday, too, but the -- this just brings up the whole bit about access to records, and I think the faster that NIOSH clarifies that process for the public, I think that'd be beneficial. There's one phrase in here that says -- on page 31 at the top -- the question that one commenter had on putting the burden of proof on the claimant, potential claimant, and it says that NIOSH -- (Reading) And most of the parameters relate to information held by NIOSH.

And I wonder if that's -- is that -- maybe I'm misreading this, but it seems to me that's suggesting that NIOSH is going to have a lot of this data, and I get the -- I'm of the opinion that some of those work histories that I've done at some of the sites, they throw a curve ball at me that I never expected, but when you go and start to

investigate, they're -- sometimes there's a lot of credibility to that, maybe sometimes not, but I think it's something that may have to be investigated at the individual sites, and you may need more data than what you might have initially requested, so I think NIOSH is intending on doing that, but I think that -- I just wanted to get that out there and I think the sooner we know more about that process of who is going to have access directly to records and how that whole thing is going to be handled, I think the public wants to know that and I think that's going to lend to the credibility of this whole process, too, that people are going to feel more comfortable to know that NIOSH had access to everything they needed to do the most accurate estimate they could.

DR. ZIEMER: I don't know if any of the staff have any specific response to that. It seems clear to me that NIOSH is very interested in getting very complete records, and one of the difficulties will be what NIOSH thinks is complete and perhaps what the DOE thinks is complete, and therein lies part of the issue, I suppose, but I'm speculating here.

MR. ELLIOTT: The active phrase that you left out there, Mark, is that "has the burden of conducting this evaluation." It's not DOE, it's

NIOSH. It's not the claimant, it's NIOSH. Whatever the claimant can give us only aids us in accomplishing a dose reconstruction and so we're placing the burden of assembling and reviewing and collecting all of the necessary information on ourselves and that's what'll go forward

If you recall yesterday I talked about developing the case file and developing the dose reconstruction portion of that case file. That's our burden, and your comment is well-taken and absolutely correct. We need to make sure that as we work with claimants they understand this whole process, and we need to educate the public in general about what this process is all about.

DR. ZIEMER: It also becomes very important for the Department of Energy to cooperate fully in making the records available to NIOSH, and this may be more than simply personnel dosimetry records because there's -- to do -- in some cases the dose reconstructions will require survey monitoring records and other records, 'cause we know that from other kinds of dose reconstructions done for epidemiological studies and for other purposes.

MR. GRIFFON: That's part of my point and I think I'm trying -- maybe I'm reading into this commenter or this comment, but I think when they see that DOE certification, there might have been some

uneasiness there about who's controlling this process to actually getting the records they need. Is NIOSH being handed from DOE or do they have actually direct access to get what they need. Maybe I'm reading into that, but that's the way -- I just think we need to be sensitive to that and make sure -- and I think NIOSH has the right intent on that, but I just wanted to state that.

DR. ZIEMER: It seems clear to me that NIOSH has the lead, as Larry has described. But it's also clear to me that there's a dependence upon full cooperation by the Department of Energy, and it would be -- I think this Board and certainly the public has every right to expect the Department of Energy to fully cooperate in this effort. Sally?

MS. GADOLA: I have a question along those lines, and maybe Larry could answer this best. What could we do, as a Board, to expedite this process and do you have -- and do you have enough funding allocated to this process, as you're learning more about what all this entails in getting the records from the various sites?

MR. ELLIOTT: Well, I hear two questions there. What can the Board do, and do we have enough resources available, and let me answer the second one first, 'cause it's easier. Our resources are guaranteed in this program to administer the program

and those funds are in the Department of Labor's appropriations, and then they're apportioned to us based upon a work plan and budget that we put forward to DOL. We think we have attended to that sufficiently.

It is the Department of Energy's responsibility to provide the records, provide us access to the records, and so they have to have whatever necessary resources they need to do that, and they have to attend to that through their funding mechanisms.

Now the first question, what can the Board do? Is there anything the Board can do to expedite the process? I assume you're talking about the establishment of this memorandum of understanding or establishment of our access, the provision of information and records to us that we need. I think your vigilance and your expressed concern and your continued observation of the process is the way you can help. At this point in time I don't see any way you can intervene as a Board to speed up the negotiation of the language of the MOU and seek the signatures that are necessary between the two Departments. That's within the Administration right now. But your continued vigilance, your continued expressed concerns and observations I think is what this Board can contribute.

DR. ZIEMER: Thank you. Further comments? Yes, Henry.

DR. ANDERSON: I guess following up on Mark's issue here, it seems like on page 31 at the top again it says (Reading) And most of the parameters relate to information held by NIOSH.

Is the "held by NIOSH" as opposed to held by DOE, is this -- is held by NIOSH the same as saying information that's held by DOE? Here it says NIOSH, but --

MR. ELLIOTT: Read the whole sentence. It says "rather than supplied by the claimant" so --

DR. ANDERSON: Right. Yeah, but --

MR. ELLIOTT: -- what we're saying is NIOSH has the authority -- the statutory authority here to determine what records and what information are necessary and pertinent to complete a dose reconstruction. And in this -- in the context of this passage, we're responding to one commenter who said don't put the burden on the claimant. Okay? So please don't -- this is the problem with taking phrases out of context. This whole sentence refers back to that one commenter, and we want the burden on us, we don't want it on the claimant. We're certainly interested in whatever records and information the claimant can provide. We need and are interested and will pursue at great lengths what

information and records the DOE has. And once we have all of that, it's the information in our hands that is the most critical information for us to decide upon when a dose reconstruction is complete.

DR. ZIEMER: Okay, thank you. Other comments?

(Pause)

DR. ZIEMER: Section (g), claimant and co-worker interviews?

(Pause)

DR. ZIEMER: Section (h), page 35, evaluating exposure characteristics.

(Pause)

DR. ZIEMER: Section (i), use of ICRP models. Gen Roessler.

DR. ROESSLER: This is a section that I think is particularly well done. It makes it possible for us to defend our evaluation that the very best science is being used in this whole process. It's not only -- well, it's well done. It brings up the important points. It's written concisely so you can understand the whole situation.

The one thing I'd like to point out, though, is that as I read through this, I think that there may be cases where, on an individual basis, there'll have to be decisions made by the dose reconstruction team. And this emphasizes the need for us to

establish how an independent review on some sort of a -- however it's done, certainly not on every case, but there has to be some method to show that we are doing or have done an independent review.

DR. ZIEMER: Thank you. Other comments?

(Pause)

DR. ZIEMER: Section (j), use of efficiency measures.

(Pause)

DR. ZIEMER: (k), types of information to be used.

(Pause)

DR. ZIEMER: Section (l), evaluating the completeness and adequacy of records.

(Pause)

DR. ZIEMER: Section (m) begins the bottom of 49, remedying limitations of monitoring and missed dose.

(Pause)

DR. ZIEMER: Section (n), accounting for uncertainty.

(Pause)

DR. ZIEMER: Section (o), completing and reporting dose reconstructions.

(Pause)

DR. ZIEMER: (p), reviews of dose reconstructions or dose reconstruction methods.

(Pause)

DR. ZIEMER: I'd just call attention to the comment on the bottom of 59. It's pertinent, Dr. Roessler, to the comment you just made, which is --

DR. ROESSLER: I have it marked and underlined.

DR. ZIEMER: Okay. I call attention to that to this Board. This is the last paragraph on page 59, the commenter indicating that the rule should require the Board to conduct an independent review of a sample of NIOSH dose reconstructions, and the response is (Reading) Since the review is specified to be independent, the Board, rather than HHS, must determine the procedures for the Board's review of the dose reconstruction.

And that has to do with the independence of the Board and I think it's a good comment. NIOSH has recognized that responsibility that we have and that's certainly looming big on our horizon.

Okay, item (o) (sic), when information is inadequate to complete a dose reconstruction.

(Pause)

DR. ZIEMER: Section (r), definitions of terms.

(Pause)

DR. ZIEMER: And then the last section there is (s) on Special Exposure Cohort, and it indicates

here that those comments are outside the scope of this rule and will be addressed separately.

And then there are the sections on the recommendations of this Board and how they were handled, and we're all aware of those.

That completes the discussion of the response to the public and public comments. Then there is the wording of the rule itself, as changed to its final form. Any questions on that, or comments?

(Pause)

DR. ZIEMER: Thank you. I think we have had opportunity then to look more closely at how the various comments were handled. This does not preclude pursuit in some depth of those items that we identified yesterday as being important as we move forward.

I want to pause here a minute and see if Dr. Michael has arrived yet. Has not arrived; okay, that's fine.

Let's go ahead and take a brief break here -- okay, I'm sorry, a question, Mark, first.

MR. GRIFFON: I was just going to ask, is there any listing of substantial changes to the regulation itself for this for the dose reconstruction rule. I've found a few in the summary that Ted pointed us to yesterday, but I feel

like I might be missing some. I saw that a table for the weighting factors was dropped --

DR. ZIEMER: And there was a reason --

MR. GRIFFON: Yeah, and I understand why, that's fine --

DR. ZIEMER: -- for dropping that so --

MR. GRIFFON: -- but I'm just wondering if there's -- that's what I would call a substantial change, not just editing.

DR. ZIEMER: That's only substantial in the sense that they're still using the table, but it's used by reference so that if ICRP changes the table, you don't have to change the rule.

MR. GRIFFON: I'm just -- yeah, but I'm just --

DR. ZIEMER: So that's only -- yeah, it's substantial in a certain sense, but --

MR. GRIFFON: But are there --

DR. ZIEMER: -- it's not changing how things are done.

MR. GRIFFON: I'm just looking at section 82.18, for example. It says there's new language in 82.18 to specify how NIOSH will select from exiting ICRP models, and I was trying to -- I don't have the old one to compare, so I'm just wondering --

DR. ZIEMER: Maybe Ted can address that, but apart -- we had that concern as to how they would

update without having to change the rule every time.

MR. GRIFFON: Yeah, I think it's a similar question --

DR. ZIEMER: I think that's --

MR. GRIFFON: -- but I was just trying to see how it was changed.

DR. ZIEMER: Ted --

MR. GRIFFON: Reading through it without the other one, I couldn't tell.

DR. ZIEMER: Is Ted still here, or Larry, can you --

MR. ELLIOTT: He's outside right now, sorry. On our web site there's still the prior version that was part of the docket. I don't have -- unfortunately, we don't have all of these copies here for you today. Ted went through yesterday what we consider to be substantial changes. He identified those for you.

You know, one of the biggest changes is -- Ted's here, he can perhaps respond to this, as well. Mark's question, Ted, is what other substantial changes besides those you perhaps presented yesterday, and I don't know how to --

DR. ZIEMER: Or did you identify all the substantial ones.

MR. ELLIOTT: Did you identify all the substantial changes, like dropping the ICRP

weighting factors table.

MR. KATZ: Yes, I think I -- I think I identified all the substantial changes.

MR. GRIFFON: The specific one that I was just citing was 82.18. It says you added new language on which ICRP models would be used, and I was just -- because I don't have the old version I just wondered --

MR. KATZ: Oh, and that's simply -- I think --

MR. GRIFFON: -- how that was changed. I was just looking for that.

MR. KATZ: -- just clarifying that current models, that's all, so that's a word or two, but it didn't involve substantial drafting.

MR. GRIFFON: So it just doesn't reference specific models, it just says --

MR. KATZ: Yes.

MR. GRIFFON: -- most current models or something --

DR. ZIEMER: And in fact I think this Board asked that it not simply say that they use ICRP models, because that could be model two or something -- or ICRP Report two, but that current models be used, so I think it was responsive to this Board's request, in fact.

MR. ELLIOTT: I think as you -- well, as we

perform rule-making, you should be aware that the rules that are put out for public comment, in the preambles of each of those rules we have to cover a lot of background information that is not here. So when you try to cross-walk these documents, the final rule with the one that was put forward for public comment, you're going to see substantial differences in content. Okay? So don't get -- I guess my note would be don't get confused by that. The preamble of the final rule doesn't cover as much background, perhaps.

DR. ZIEMER: I want to give us time for a brief break before Dr. Michaels' discussion. Let me also remind both the Board -- well, the Board has already done this, but any of you public visitors who haven't registered, there's a book in the back on the table to register your attendance with us. Also members of the public who wish to make public comment, there's a sign-up sheet there so please avail yourself of that, as well.

We'll take a break, about ten minutes or so, and then reconvene. Thank you.

(Whereupon, a recess was taken from 9:45 to 10:00 a.m.)

DR. ZIEMER: We do want to call the meeting back to order. I'm hesitating a little bit to give all the Board members a chance to reassemble. I

think a couple of them are actually in the process of checking out of the hotel, so they may be delayed briefly. But in the interest of time, particularly since some folks have to catch planes at a relatively early hour, we need to proceed.

We're pleased to have today Dr. David Michaels with us. As you see on the slide, Dr. Michaels is currently associated with George Washington University, but an important aspect of his background is the fact that during the period when this legislation was under development, the legislation for the public Act, Dr. Michaels served as Assistant Secretary for Environment Safety and Health in the U.S. Department of Energy. So in terms of his former role and his continuing activities in this area, it's very appropriate that we gain some insight from Dr. Michaels on how this program developed and, as you see, his presentation is entitled "Energy Employees Occupational Illness Compensation Program"; in our agenda it's referred to as "Legislative History" and we're really -- the Board, Dr. Michaels, is very interested in the development of this legislation and how it developed and perhaps some of the underlying -- both scientific and political issues that brought it about. So Dr. Michaels, we're pleased to have you with us this morning.

DR. MICHAELS: Can you hear me?

(Negative responses)

DR. MICHAELS: Can you hear me now? How's that?

DR. ZIEMER: Move over a few steps.

DR. MICHAELS: Do I need the microphone? Okay, I'm on there now. Thank you.

DR. ZIEMER: Just a little witticism -- very little, very little actually.

DR. MICHAELS: I'm sorry.

DR. ZIEMER: Go ahead, you're on.

DR. MICHAELS: One of the great advantages and pleasures in being the Assistant Secretary of Energy is essentially to be able to really stand on the shoulders of giants. And I was very fortunate when I arrived, I had two very illustrious predecessors, one of whom was Dr. Paul Ziemer, who many times when I was in the midst of difficult problems I'd find memos that really covered a lot of these same issues and could go back -- and didn't have to rethink all these issues and I'm very grateful for all the work that he did to make much of my work much more easy.

Let me also begin by thanking all of you. I know that serving on a government advisory panel is not particularly well-remunerated and is often not recognized at your own institutions as being of any

importance at all. But I know that NIOSH and my understanding of the various agencies of the government that are working on this all are very grateful for your help and your input, which has been very real and useful. And as someone who obviously has some personal involvement in this, I'm gratified that you were willing to take this on.

So this is really -- I put this together and I'm grateful to Larry for asking me to do this because it really was a nice opportunity to sort of try to compile all these things in one place and remember what was done when. As you know, legislations often has a tortured history that's easy to forget various points, and various people at DOE helped me put this together in the last few days. So let me move through this and let's talk a little bit about this legislation.

(Pause)

I thought I'd begin with when I was confirmed and sworn in late 1998. I was a few months behind Secretary Richardson. I was actually chosen by Secretary Peña, but Richard -- I was slow in getting to work and this actually has some significance here. I was finishing teaching a semester at City College in New York and Secretary Richardson went to Oak Ridge where he was accosted by a group of sick workers who said what are you

going to do about this? And he said if my new Assistant Secretary ever shows up for work, I'll send him down here and tell him to figure out what to do.

I got the message that I needed show up soon, so I did, even before finals week, and I immediately went to Oak Ridge. And what I learned from going to Oak Ridge and from visiting immediately sites around the country and talking to -- I never got to Anchorage, but immediately hearing from Senator Markowski's staff that everywhere in the complex we faced this same problem. Essentially, first there were sick workers at many DOE sites -- not surprising, there were older workers who were sick -- but there was a widespread perception that toxic exposures were the cause of these conditions. And that was true from Alaska to Savannah River, and Oak Ridge was obviously an important center. But everywhere you went, people believed that their exposures were caused by the manufacture, testing, cleaning up of nuclear weapons, and that was not beyond reasonable belief for several reasons.

One is they were working with among the most dangerous materials that we deal with in industrial situations. We were dealing with plutonium, beryllium, as well as the normal range of industrial

hazards -- asbestos, silica, et cetera. But the other thing we -- and there was a great deal of secrecy. People were told we can't tell you what you work with, or we'll tell you what you work with but you can't tell your doctor. So that sort of compounded the problem.

But in addition -- and this really was the key thing I saw, that no one believed DOE had any credibility around this issue. And that was unfortunate, but the long history of DOE on this issue really put DOE in a very difficult place. The history of fighting claims when people had made claims and lawsuits, DOE fought them. There were conditions in Colorado of conditions which DOE clearly said were work-related. There were a number of CBD claims around the Rocky Flats site -- not surprisingly; people were working with beryllium -- DOE actually had a screening program. More than half the people with chronic beryllium disease in Rocky Flats could not get Worker Compensation in Colorado, primarily because we had a number of different contractors -- we being DOE -- and when someone filed a claim, various -- the claim went into the system and the various contractors started pointing fingers at each other and saying it shouldn't be on our bill, even though they weren't going to pay the bill; it should be on the other

person -- the other contractor's bill because people were exposed over the course of working for at least three different employers -- you know, legally they were different employers, Rockwell, Dow, et cetera -- and DOE was paying the legal bills for each of these different contractors to fight each other in court over who should pay the bill. Of course the people who got nowhere were of course the people with CBD who had come to meetings with -- essentially attached to oxygen tanks saying how come we can't get compensation.

And I hesitated to use this word, but I finally decided I couldn't figure out a better one. I know it's a little bit of hyperbole, but anti-worker worker's compensation policies. And I don't mean to say that there are individuals who say we're going to go out and make life difficult for workers, but let me give you an example -- a real time example. This was when I was Assistant Secretary, after we had already announced many of these changes that had occurred, we started a beryllium disease screening program at Pantex. It was one of the later sites because beryllium, while it's -- there's a lot of beryllium there, it wasn't machined as much at Pantex as at some of the other sites, so anyway, we started the first screening program --

DR. ZIEMER: David, I'm going to interrupt

you a minute. We're getting a lot of noise on -- I don't know if it's your mike or -- we may have to switch back to the podium mike, I don't know.

(Pause)

DR. MICHAELS: How's that?

UNIDENTIFIED: Okay.

DR. MICHAELS: Okay. Now at Pantex, DOE told its contractor to start a beryllium disease screening program, start -- we started doing LPT tests down there. The first beryllium sensitivity cases were found even before some of the cases were referred for bronchial lavage to work them up, but the first sensitivity cases were found. DOE's contractor physician, with the full knowledge of DOE, said these workers better file worker's comp claims just to get your cases going, and we'll help you do that. And they filed the first claims and those claims came back rejected by DOE's third-party administrator, saying beryllium disease is a disease of everyday life, you didn't get it in your workplace, et cetera, the standard response that virtually every insurance carrier sends when they get an occupational disease claim.

Now several of you look shocked, but this is the reality of workers in the -- not just the DOE system, but most industrial plants when they file a claim for occupational illness. And this was -- we

were trying to turn DOE around and we said we acknowledge that we caused this beryllium disease, we want to take care of people, and that was still what was happening. So that's why the credibility issues were very important and so -- and finally there was a proliferation of expensive, no-win lawsuits, no-win meaning the government actually would win those cases eventually, they would be dismissed. But there were suits all around the country, not just around beryllium, but around radiation. We would generally prevail, at a tremendous cost to the government and the tremendous frustration of individuals who were suing and the very bad press in the communities.

There had to be a way out of this. And what Richardson -- he gave me a month. He said figure this out; you have till -- it was the end of December. He said you have till January 30th; give me a proposal. So I took a little bit longer, but...

So what we proposed originally and took this to the White House was essentially FECA, for contractor employees -- how many people here are Feds? And how many people have been Feds at one time? Well, so you know FECA. FECA is the Federal Employee Compensation Act. It covers Federal employees, all of us who were Feds or are Feds when

we're injured on the job. It's a worker's compensation system. The basic idea was we'd say these are contractor employees who are covered by state law and we go through all the problems of dealing with different contractors and state laws, let's eliminate that problem. Let's make it a Federal program and have equity with Federal workers.

There were some great advantages to that. Benefits under FECA -- wage-loss benefits are much better under FECA than in any state worker's compensation system, and particularly better than some of the states where we had big cohorts of workers. Tennessee, South Carolina, New Mexico have just very low benefit levels. And just as an aside, most worker's compensation programs cap wage replacement at two-thirds of the state median. And of course no one in the DOE complex makes less than the state median. In fact, most of them make quite a bit more. If you're in South Carolina or New Mexico, you make twice the state median wage or more. So if you get into state worker's comp in a place like New Mexico, even if you get into it successfully, your wage replacement is going to be pretty bad.

FECA, on the other hand, is two-thirds of your wage, except if you have dependents, in which

case it's three-quarters of your wage replacement, up to the -- essentially the GS-15 or SES levels, so there's no cap. It's a much better system. It's a more equitable system.

So we recommended that program and said cover all toxic-related illnesses and we'll figure out a system that either the Labor Department or HHS or perhaps the National Academy of Sciences would determine what conditions are work-related, but we'd get DOE out of the picture. DOE wouldn't adjudicate anymore whether a case was work-related 'cause they didn't have the credibility -- or frankly the staffing -- to do it.

It would be an exclusive remedy, which means we'd get out of the lawsuit business. People would go into the system. They couldn't sue otherwise, but they would get a reasonable settlement in this program, and it would be administered -- in our initial proposal -- by the Department of Labor since they administered the largest worker's compensation program in the country, FECA.

And from the very beginning -- you know, I called up Tom Markey, who at that time was the head of the FECA program and sort of dragged him into this, and they were very willing to help us from the get-go and I'm grateful for that. We also wanted to include beryllium vendor employees, and this was

really sort of -- the government's sort of stretching its arms out benevolently.

There were a number of sites around the country which did work for the nuclear weapons complex under contract with the AEC. The contracts were so specific they even include clauses which said this is what the -- this is the -- essentially it wasn't the PEL at the time, but the threshold -- the TLV or -- it was the time-weight average is what I'm saying. This is the sort of protection you should be providing people from beryllium. DOE sent or AEC sent in industrial hygienists to look at these places. These were really sort of extensions of the DOE complex.

They were private contractors, many of them were in eastern Pennsylvania, and what was particularly notable about these places is they had all closed down, and they had been closed for, at that time, probably more than ten years. There were dozens of workers with chronic beryllium disease. Not only were their employers bankrupt and gone, but their -- the law in Pennsylvania is that you have to apply for worker's compensation within 300 weeks of last exposure. It's the time of injury, but it's interpreted as last exposure in terms of illness.

Well, these plants had been closed for a lot longer, so all these people were out of luck, and

they were dying. And Congressman Kanjorski had introduced a bill saying we should take care of these people just as we take care of other people who are exposed to hazards involving nuclear weapons. And we thought that was right, because they were doing work for the nuclear weapons complex. They were getting nothing, and they were dying from beryllium disease.

So that was our initial proposal. The White House responded, and it was an interesting experience for me to learn about -- of course, as many of you know, an agency can't have a policy. An Administration has a policy. So we took it to the White House and we had OMB, the National Economic Council and all the other agencies.

We immediately were approved for beryllium. I mean it was -- that was such a clear egregious problem that we got a response said go ahead, propose legislation on beryllium. And the National Economic Council, which is the domestic equivalent of the National Security Council, was essentially tasked to examine the other issues -- should there be a larger program, other conditions, is it warranted. And that was an interagency process involving Energy, but also Labor, HHS, Defense Department.

And other agencies could all weigh in and

they all had a stake in it. EPA's obviously very interested 'cause they have clean-up sites. And the Nuclear Regulatory Commission is concerned greatly about radiation. NASA has big contractors so they were interested, and everybody came to very regular meetings to discuss this and we reviewed all the extant literature on exposures in the DOE complex. We did surveys of worker's compensation issues. We did a tremendous amount of work looking at this issue.

While this was going on, the Paducah Gaseous Diffusion Plant became sort of a front line issue to the Energy Department, and there's a Qui Tam suit -- that alleged multiple environment safety and health allegations around environmental exposures primarily -- was filed. It's still under discussion. My understanding is that the way Qui Tam suits work is the government has a certain time -- these are suits alleging that someone has defrauded the government. The government has a certain amount of time to decide whether to join in that suit. The government originally -- I guess they have six months; they've asked for numerous extensions and still, even though this occurred I think in 1999, the government -- the Justice Department still has not decided whether or not to join that suit and they keep asking for extensions and spending a lot of money investigating

the situation at Paducah.

The basic piece of it, though, was that recycled uranium was brought in from Hanford and that was contaminated with transuranics and some fission products, that there was off-site exposure as well as inadequate radiation protection for the workers. It was revealed in the *Washington Post* and therefore it got a lot of play.

We sent a team down there -- really the next -- two days later I sent a team of investigators -- and we found essentially poor radiological control before 1992. And a lot of problems, a lot of management-related problems. And a number of very -- memos really citing what we thought of as sort of egregious behavior. It raised all sorts of issues with us and obviously with Congress and with the press. One memo, for example -- I quote it from here because I thought it would be hard to read up here -- (Reading) Neptunium seems to be found in reclaimed feed.

That was pretty obvious.

(Reading) Workers are supposed to wear special face masks but they're not controlled -- actually too closely, I left the o out there.

And then it went on to talk about bioassays and there are some new bioassays; they're not great but they recommend using them. And (Reading) There

are possibly 300 people at Paducah who should be checked out but they hesitate to proceed to intensive study -- this is the contractor in this case -- because the union's use of this as an excuse for hazard pay.

And it was memos like that that said well, we have a real problem here. We had people exposed. Many people weren't told of the exposures. We didn't have adequate protection. How do we respond? And this raised essentially two different concerns or two different models. One was the Radiation Exposure Compensation Act program, which as many of you know is an older program that responded to a number of different problems of government exposure of people to radiation in this case, included programs on uranium miners, primarily in the southwest, who were exposed to radon in the course of work and there were really pretty -- some horrendous stories of that history; down-winders, primarily in southern Utah, who weren't told when radiation clouds were being -- were blown over their town after detonations at the Nevada test site. That was one set of examples.

The other came from the recently-completed Human Radiation Experiment panel that was really put together by President Clinton, but run out of my office before I got there. It was all done by the

time I was there. Which raised ethical issues, saying people who've been exposed without their knowledge deserve compensation whether or not they get sick, and that was signed by President Clinton. That was the other sort of big example we had to look at.

So we put together a proposal -- the initial Administration proposal which went through the National Economic Council and the OMB essentially was -- had two important components. There was a third component which I've been told is so minor I shouldn't bother talking about, but there's a chronic beryllium disease component and the Paducah cancer payment. The beryllium disease component -- essentially it looked like FECA. It had lost wages. First dollar prospective medical coverage, which is essentially from the time someone applies, we would cover their medical costs for claims that are found to be work-related. The Labor Department felt it would be too complicated to reimburse people for past medical costs, and the wage replacement also would be quite difficult to figure out because many of these people -- their plants closed years ago so what's the wage replacement if you're unemployed. So the idea here came from this idea of liquidated damages of $100,000 lump sum rather than wages or medical payments, was the initial proposal. And

that $100,000 actually came from Paul Kanjorski's bill.

So it was a choice. You would either get wages and medical or $100,000. The vendor employees were included. It was coverage for beryllium-sensitization -- not cash payment but medical coverage and surveillance -- and it was an exclusive remedy because there were suits around the country. And for the first time it extended the exclusive remedy to the beryllium vendor in some cases were being sued and the government was -- and this is controversial, but many cases DOE was reimbursing Brush-Wellman. When Brush-Wellman was sued, DOE would reimburse Brush-Wellman for some of its legal costs and for settlement costs because of contracts that indemnified Brush-Wellman as a vendor, and in some cases as a contractor. And so the DOE felt it wanted to include exclusive remedy to protect the vendors as well because they were being sued and it was really -- they were acting as an extension for the government. But that was only in some cases. It became very controversial which ones.

RECA. And RECA, as you know, is a lump sum payment. It's exclusive remedy in that you can't sue the government. And it was sort of -- it's sort of based on this idea that someone was in the wrong place at the wrong time when the government did

something they probably shouldn't have done, either, not tell people about radon exposures in the mines or they were living in say St. George, Utah when some of the detonations in the Nevada test site went bigger than were expected.

RECA is based on the presumption for a list of cancers. If you have one of those cancers, you are then -- you receive a lump sum compensation and the compensation levels are different depending on your category within RECA. We added bone cancer because of the transuranic exposure. That wasn't in there otherwise. And we put in that someone had to work in a radiation-exposed job for at least one year before 1992 when we judged the radiological controls were then -- were improved to the point where this wouldn't be necessary. And the payment was $100,000 lump sum, no medical coverage, was the original proposal.

As things developed, we then gathered information around the country. We held public meetings to hear from workers. We met with contractors. National Economic Council's staff reports task force has continued. We came up with a second proposal, putting together essentially an extensive program in response to that requirement from President Clinton saying essentially look at all the issues and figure out what to do with them.

The basic model in this other proposal is we would have a Federal program for those uniquely nuclear conditions. And this was a discussion internally within the Administration on should we go past -- what's the implications of Federalizing all occupational illness, and there was a back and forth between a lot of agencies. The decision was made that the program would cover only conditions that were uniquely nuclear -- in this case, they were decided to be radiation and beryllium exposure, even though obviously neither of those are unique to nuclear weapons but they're predominant in nuclear weapons -- and have a state-based program administered by DOE for everything else because an asbestos exposure at Hanford is no different than asbestos exposure down the street at an aluminum plant. And we can discuss later why that decision was made.

So the decision essentially covered cancer and chronic beryllium disease and beryllium-sensitivity. The radiogenic cancer model you've spent a tremendous amount of time thinking about and commenting on really, as you know, was based in the radioepidemiologic tables that National Cancer Institute originally put together for RECA but were never used in RECA, and there's an interesting paper by an NCI Fellow named -- Fellow with a capital F,

not a -- at -- name Mark Parisgondola on the history of RECA, which if you want to read -- talks about how NCI put these tables together but they were never used because the community never trusted the government enough. And they fought it congressionally and Senator Hatch agreed with them. However, these tables were used by the VA in the Atomic Veterans Program, and I thought very impressively.

We looked at this and we felt -- we didn't want to break new ground, but we were trying to essentially graft other programs that the government had already decided worked into this program. So we looked at that program and we said this really does work, and so it was modeled on the VA Atomic Veteran Program. We'll get to that -- a little bit more about that.

The Paducah proposal was expanded to include all three gaseous diffusion plants. We'd done investigations at all of them. We felt we couldn't really -- while things may have been a little different or worse at Paducah, we couldn't distinguish between the three of them. It was poor rad protection across the board. And also for political reasons we couldn't separate them out. So we were willing to essentially extend that lump sum payment to all three gaseous diffusion plants, but

we didn't have the concept of Special Exposure Cohort. That came a little bit later.

And then this DOE-based program for all other conditions, essentially to eliminate the barriers in state comp programs for the remainder, and we'd already started doing that. The Office of Worker Advocacy at DOE had started -- I was the acting director. We were working with our contractors, primarily Oak Ridge, trying to get people into this system and we were successful with a number of cases. And Kate Kempen and Jeff Eagan worked very hard on that, and we thought that model would be useful -- would work.

It was based on the model at Fernald where there's a -- there had been a settlement made where there's a panel of three physicians that review cases of alleged work-related illnesses. There are three nationally-renowned physicians who see these cases. We talked to them, we looked at their statistics. They accepted about a third of the cases. They got to know that plant very well in terms of industrial hygiene. They looked at all the cases. And where they found cases to be work-related, they say okay, this one's work-related, let's get them into the comp system.

We thought that's a great model, and so that's -- we thought the DOE -- if the DOE really

tried hard, they could make this work, and so that was the -- sort of the other conditions.

And finally we were pretty clear about including what are now called atomic weapons employers. Before DOE built it's whole complex, it was using private firms around the country. Some of the big ones you've heard of obviously -- Mallinckrodt and Lindy and Harshaw did big work, but there were smaller plants as well. They should be included, too.

The Atomic Veteran Cancer Compensation Program was our model, as I was saying, for the -- what we call here the -- essentially the radiogenic cancer part of the program. This compensated veterans with cancer exposed to radiation from the products made by AEC-DOE, the nuclear devices or, in the case of Japan, the nuclear bombs. Veterans who had been compensated include veterans who had been exposed because they were on-site in Hiroshima and Nagasaki shortly after the detonations. They were in the south Pacific. They were at the test site. There were even veterans who had been compensated whose exposure was at Hanford as a result of being exposed from the releases at Hanford. So we felt also this made sense because the government already had made the policy to do this. These were -- we're now talking about contractor employees who have the

same exposures to the same devices, and they should be compensated in similar ways.

It was a science-based program. Probability of causation was estimated through this NCI-developed radioepi tables and we knew the NCI was updating them and we were expecting a new version fairly soon.

Now the Atomic Veteran Program actually is far more generous in some ways, or more lenient, than this program. There are certain presumptions in that program. If you're in certain cohorts and you develop say multiple myeloma, you're compensated. It doesn't make any different what your dose is, and there are a number of different diseases. We require doses for everything, but that program is more lenient, I guess, liberal. But as -- you know, for all VA programs, the benefit of the doubt goes to the veteran and that's where the as-likely-as-not language comes from. If it's 50 percent, you know, the benefit of the doubt goes to the worker -- the veteran, so it's not more likely than, it's as likely as not. And the VA uses the system that is in the legislation that you've all looked at, more than you probably ever thought you'd have to, around the 99th percent confidence intervals is -- comes right from the VA, and that's their language and they provide that. That's what

they do and this just parallels what they do. They don't have it in their legislation, but it was felt by Congress that it would be worth putting into this legislation just to make it permanent.

So we were trying to follow that, doing the same thing, giving benefit -- you know, bending over backwards to give the benefit of the doubt to the worker, using these same systems that the government had already opined on that worked.

This then went to Congress. We actually never finished a written legislative -- the second proposal never actually was submitted by Congress to the -- by the Administration to Congress. That's a long interagency process to get signed off on the legislation. While we're doing that, Senator Thompson from Tennessee and Senator Bingaman from New Mexico took this on. They had both held hearings on this issue and were extremely interested, Senator Thompson holding a hearing of the Government Affairs Committee, actually Senator Bingaman going to a -- doing a meeting in Hispaniola. He's got another one I think coming up next week.

They put together a proposal which they introduced as a stand-alone bill. It was very similar to the second proposal. They obviously changed it in a number of ways. It was not the

Administration proposal. The Administration never formally endorsed it. We went back and forth on it. A number of notable differences between our proposal and Thompson-Bingaman -- the first was mandatory funding, which we now see makes the program work. And the reason for mandatory funding was in response to what I call the RECA-IOU debacle.

If you weren't following it at the time, there was a just outrage that was occurring throughout the United States with -- when sick workers or more often widows and children of sick workers applied under the RECA program and -- I know this personally 'cause I have a good friend who applied under this whose husband died, was in some of the detonations -- they would get a letter saying yes, we find you eligible for compensation. But the program is out of money. Essentially people got IOU's because this was an appropriated program and Congress was way behind in funding it. It was basically Justice Department and no one at the Justice Department at a high enough level really cared about it enough to get full funding for it, and so you had the government sending out letters saying yes, we owe you $100,000. Which, you know, this is not supposed to happen. It looked terrible, and it was an embarrassment, and everybody in the government felt this couldn't continue.

In fact, as a result of our getting -- once this passed, the Justice Department immediately went to OMB and said can't we make RECA mandatory as well and OMB said of course. It was one of -- you know, they talk in Washington a lot about the unforeseen consequences, and that's generally thought about as being a negative, but in this there are plenty of positive ones, that being one of them. And as a result of all this -- not just as a result of all this, but also the outrage about this, RECA, while it's not fully funded, it's very close to fully funded. It's not yet an entitlement, but they put I think $400 million into it this year. It's not yet an entitlement, I don't think.

Silicosis was added, and this was obviously done by the Nevada delegation. The Administration did not include silicosis, but Nevada felt that the work that was done in digging the underground -- the holes, which are the equivalent of mines where the detonations took place, were done without the proper protection and people deserved to be covered, so silicosis was added.

The GDP proposal was converted and it was called the Special Exposure Cohort, and this is obviously very important for you all, the thinking behind this.

Thompson-Bingaman did a couple of things.

One is while they listed the three -- the Thompson Bingaman Bill listed the three gaseous diffusion plants, they said there has to be a mechanism to expand it based -- and this was really based on the members of Congress hearing all over the country that the rad protection programs were poor, but more importantly that people's radiologic exposure levels or records were inadequate or, in some cases, fraudulent or lost. And we heard every sort of allegation you can imagine where came -- many of them document -- you know, people would -- brought in saying look, I have zeroes here while I was working in this place. How can that possibly be because there were places where things were zeroed out. There were all sorts of concerns and so Thompson-Bingaman both felt that we needed a mechanism -- they needed a mechanism to expand it, and came up with this language that you saw, which doesn't necessarily reflect the original Administration proposal which was really rather egregious behavior, and so that shift took place. And the Congressional intent around this was much more around if people are exposed, we can't figure out what they were exposed to. And there was certainly a lot of discussions about the fact that you probably can't measure some of these things because our records are so bad, and that's really

where that came from.

Thompson-Bingaman set the benefit level at $200,000 plus medical, but they included the wage-loss option, so you could take the $200,000 in cash or wage loss, but you would get medical coverage either way. DOL was assigned to be the lead agency and HHS and DOE were to assist them.

In the passage of that through the -- that was then introduced as free-standing legislation. It had wide bipartisan support from Ted Kennedy to Strom Thurmond, an equal number of Democrats and Republicans were on board. Originally what that reflected was the interest and the importance of this legislation locally, obviously. This wasn't of national concern, but in South Carolina or in Alaska or wherever it was, this was a very important piece of legislation and got very strong support from some key members of Congress.

It was introduced into the Defense Authorization Bill. You may recall -- well, it went through virtually unanimous -- this went through as a voice vote, and then the Bill itself was virtually unanimous in passage. I think it was 97 to three. This legislation, it's important to remember, at the time was seen as a compromise. There were several other pieces of legislation out there with also strong bipartisan support which were far more

generous, and the Administration, and me in particular, was out there trying to limit them and -- it was an interesting position to be in.

The Voinovich Bill essentially had that same benefit level, but for every occupational condition. There was a similar Bill in the House that -- there was a Whitfield Bill, there was a Udall Bill. The House Bills we never focused on as much because it was clear the action was in the Senate, but the Voinovich Bill was really -- which had a number of these same co-sponsors, would have been much more costly and expansive. Marcy Kaptur from Toledo introduced a bill to extend the provisions of beryllium to the DOD, to the Department of Defense, which used a lot of beryllium and that caused some heartburn at the same time because the Department of Defense wasn't ready to take that step. So all these were going on at the same time.

The Thompson-Bingaman Bill became sort of the compromise vehicle, and the big fight was over whether or not to limit it to the uniquely nuclear exposures. And my role, among others, was to make sure that all these other conditions didn't get Federalized. And the government made a real commitment to making sure to take care of those other conditions in a way that made sense and was fair to workers.

The House passed their authorization act earlier and did not get anything -- I think it was earlier -- but they had a sense of the House Resolution saying something should be done was in there, but there was no actual language or any spending.

It's important to remember the time that this took place. This was sort of the halcyon time of budget surplus. And while this seems like an expensive program, this is loose change in that Bill. That Bill included the expansion of tri-care, essentially Medicare for life or tri-care for life for veterans, which I think was -- came in -- the first estimate was $40 billion, was the CBO estimate and it went up from there.

There was some discussion at the very beginning from the leadership of the Senate, which was Republican at the time, not to put mandatory spending on this. Once the House came in, and Steve Byar from Indiana was the -- you know, pushed for this tri-care for life. Once that came in, the floodgates were opened and this was one of the things that went on that. There were mandatory spending, which normally don't go on a Bill like this, but that was -- once you were maybe spending tens and tens of billions of dollars, what's a couple of billion more in putting this on. So it

didn't have to go through the normal mechanisms for mandatory spending, which there are all sorts of Senate and House provisions on how you have to do that and you have to get various waivers, and this went through because these other things also went through at the same time.

The Conference Committee -- and this was really one of these things where you sort of wish they could have done a little bit better job. There was a Conference Committee which negotiated this, and the differences between -- that were negotiated were not partisan differences at all between Democrats and Republicans. It was purely a House and Senate difference. The Senate had the Thompson-Bingaman Bill, and that was -- they had strong Democrat and Republican support for that Bill. The House -- in this case only the House Republicans were involved in the negotiation -- just didn't want to see it, or there were few who wanted to see it, and wanted to limit it. And equally importantly, they wanted the program to look like RECA, because the House committee that was given jurisdiction for this was the Justice -- the Judiciary Committee, and they have RECA and they know RECA and they wanted to do RECA. And so you had this negotiation that took place without anybody from the Administration there because it was between, at the time, two Republican-

controlled houses and they didn't really ask our opinion and they didn't ask for help writing it, which is why we're in -- you know, some things need to be cleaned up because the Labor Department was always available to do technical draft of any issue people wanted on any side to make sure it's written well, but no one bothered asking in the conference.

The dispute included the nature and the size of the benefit. The House wanted a RECA-type benefit, which is a lump sum payment without medical. The Thompson-Bingaman Bill was wage loss or lump sum, plus medical. And the compromise -- I think -- yeah, the compromise -- they dropped the wage loss provision. As a result of that, they didn't want to make -- it couldn't be an exclusive remedy. And it was very clear -- and I remember speaking to the staff people about this, saying you understand that by doing this people will be able to go into the state worker's compensation systems to get wage loss in addition to the lump sum. They said absolutely, that's what we want. We just thought that was terrible policy, but that's what -- you know, when you talk about Congressional intent, this was overt Congressional intent 'cause they wanted it to look like RECA. They wanted the Justice -- the Judiciary Committee to have jurisdiction. They wanted it to be a RECA program.

Not surprisingly, $150,000 was the compromise because originally we had come -- there was a $100,000 Bill floating around and this was $200,000.

The Judiciary Committee really wanted the Justice Department to be lead. The Justice Department, needless to say, had no desire to be lead on this, but the Judiciary Committee wanted them to be lead so they would have jurisdiction, I think. So no lead agency -- the compromise was, there was no -- the President's going to do it all, so that led to the Executive Order of December 7th, needless to say because someone had to do it.

Again there was a compromise on silicosis. Some silicosis was covered, and this was the 1/1 provisions. I don't know if you've looked at that. Silicosis is -- can be diagnosed using an International Labor Organization scale. It's a -- 1/0 being sort of the lowest level of overt silicosis, and then it goes up; 1/1 would sort of be mild. And so they cut the -- they drew a distinction between 1/0 and 1/1, which HHS at the time opined was ridiculous, but it didn't make a difference. And there was a provision that said the President could take it out. It would stay in unless the President decided to take it out. And it was given enough time that whoever the next President was would be the decision-maker on this.

And so this is the decisions that were made.

The other -- the RECA survivor definition, even though it referred to various FECA laws, the way survivors were chosen to be compensated used some RECA definitions, which meant adult children would not be covered, and this caused a great deal of problems later on down the line and this was fixed in the later Defense Authorization Bill.

There was equity for uranium miners, which is something no one had ever discussed but it came up at the last minute because these same people who were giving me a lot of problems with some of the situations at the Judiciary Committee also felt very strongly if we're going to take care of the DOE contractor employees, uranium miners should be taken care of the same way. DOE was perfectly happy with that, as was the Justice Department, so the uranium miners, who originally had gotten $100,000 lump sum payments, now got an additional $50,000 plus prospective medical. They were put in the same pot.

It causes some confusion because you've got two different agencies providing benefits to the same people, but... There was a RECA attorney fee provision, but it was actually only a -- they only took six out of eight lines and left out a very important line, so that then had to be fixed later on, but that comes out of RECA.

So as a result of that, we had an Executive Order in December which was also put together through an interagency task force, essentially returning to the Thompson-Bingaman model for agency roles and responsibilities. And while the -- so for example, this Advisory Committee, which is appointed by the President, is an Advisory Committee to HHS. There's no need for the President to get your advice on this, but HHS needs your advice. But that wasn't in the Bill. That's --

HHS has a very important role, and let me just take a moment here to talk about the phenomenal job I think HHS has done. I had never -- I didn't have any idea of who should actually do this dose reconstruction. Congress was the one who put in HHS as being the -- in charge of dose reconstruction rather than -- I knew DOE shouldn't do it, but I thought the Labor Department could find a contractor to do it, and Congress felt HHS should do it. And Congress -- the people involved in that knew NIOSH and they thought NIOSH could do it and I know NIOSH was uncomfortable, but NIOSH has done a phenomenal job. In my wildest imagination I couldn't have imagined the amount of care and thought and success in the two sets of regulations I've seen, the probability of causation and the dose reconstruction. It really -- it shows remarkable

work and I'm grateful to NIOSH and to all of you for your participation in that. It's really a great piece of work and I know that there are people -- you know, they get hit from all sides. When I'm out in -- going out to sites, people say how come that dose reconstruction program hasn't started yet, or what's going on? And what I tell people is it may take a few months longer than anyone would want, but it's -- five years from now we're going to look back on this and say boy, thank God they did such a good job on this 'cause we won't have to redo it, and it's great and I think -- I'm very grateful to Larry and his crew for doing this.

It established the interagency working group, which sometimes -- which sort of exists now. People do get together and talk, although it formally says that HHS, DOL, DOE, DOJ, OMB and NEC are supposed to get together and talk about this stuff.

DR. MICHAELS: Well, OMB is not, that's right. Then needless to say, this was amended. And as many of you know, in the subsequent Defense Authorization Act, this survivor definition issue had to be clarified and it was easily clarified.

The attorney fee limit, which was essentially an incentive not to have reasonably -- reasonable attorneys get involved, was changed to

actually look like RECA because by choosing only the lowest level from RECA but not the level of -- the higher amount of pay when an attorney has to do a lot of work would have excluded good attorneys and just left really bad attorneys in the system, and the Labor Department was certainly concerned about that.

They changed some litigation provisions, which I don't need to go into, and directed NIOSH to study the effect of residual contamination in a couple of different places, and that was -- I guess NIOSH is doing that now.

So what's the lesson of this? You've all heard the adage, a camel is a horse designed by a committee. If I had found clip art with a four-humped camel, I would have used it, but I couldn't find one. This Bill does not reflect 20 brilliant scientific policy minds coming together saying this is the best program. This reflects a lot of thinking, a tremendous amount of historical work and sort of saying we're not going to recreate the wheel. We began by saying FECA for everybody. We looked at the RECA program. It's pieces of programs that Congress had already enacted and that were running well, other things that were political compromises, some new areas that we're just trying out, seeing if they work. There's no one

comprehensive cohesive vision, and I often think historians or journalists or anybody looking at this ten years from now saying well, what were they thinking when they put this together? Well, there was not any one person who thought about putting this together. This is a -- this Bill is a reflection of scientific, historic, political forces that all came together and this is what it left us to work on. And I know that sometimes causes some frustration, but it's what we have and that's the great part of the American system.

So that's the history as I remember it. I hope that was useful. I'll take any questions you like now.

DR. ZIEMER: David, thank you very much, a very enlightening presentation. Let me kick off our question period by asking you if you can address this. There has been off and on concerns by -- from members of this Board about the language that's used in the original Bill expressing the, quote, intent of Congress. It includes --

UNIDENTIFIED: The sense of Congress.

DR. ZIEMER: Yes, the sense of Congress. I'm sorry, not the intent, the sense of Congress, which makes certain statements about dose-effect relationships, about the adequacy of radiation protection standards and certain things like that,

and maybe some are wondering how -- if you know even how that language arose. It looks like once this thing got underway, Congress took off with it.

DR. MICHAELS: Yeah, that's -- I mean that was in Thompson-Bingaman. The Administration never put -- I mean our original letters that went with the Bills, we didn't have findings in our Bills. Our letters, I can certainly provide, were much more general, but the Congressional -- the members of Congress and their staffs obviously who had attended a lot of these meetings and who had heard from some of their constituents took that language because they felt that reflected their understanding of the Administration. That was not part of the original Administration proposal, but certainly reflected what some of the members who were really pushing this felt -- but this -- you know, it's based on hearing and third-hand information, obviously. But that's certainly how they felt.

But you know, findings of -- my understanding is findings at the beginnings of Bills, while they're interesting and important, they don't tell you what to do. It's the provisions of the Bill that say this is what you have to do. But it's important to under-- I think that reflects very well, though, the feeling of the members of Congress who put this together and their concern about this,

which is why -- you know, the Labor Department had the Congressional briefing during the last recess, just to fill people -- members of Congress --or their staffs, obviously no members were there -- on where the program is. And more than 40 offices sent people. We were shocked. The interest level's that high because these are important issues back home. People are getting money or not getting money and there's long concern, there's press interest and so that interest remains there.

DR. ZIEMER: I'd ask for other questions or comments. Yes, Roy DeHart.

DR. DEHART: I was surprised to see a legal fee imposed there. I don't see this like a worker compensation system where representation's required.

DR. MICHAELS: You mean the attorney fee?

DR. DEHART: Yes.

DR. MICHAELS: Well, the way the attorney fee provision -- the original Administration proposal did not have that fee in it at all. RECA has a -- RECA acts -- is set up like a tort system in that an attorney gets a percentage of the settlement and they get up to -- the way RECA's written, the -- RECA was amended just before this Bill came to the floor, a few months before, and there was -- actually the only fight they had over the amendment was around the attorney fees, and the

RECA provisions are the attorney gets three percent of the settlement -- two percent of the settlement and they get ten percent if there's an appeal and there's real -- there's more work about it. The first -- the initial filing is not a lot of work so that's only two percent. This Bill took just the two percent. And it sort of works on the lump sum provision. It says you can -- since everyone's getting $150,000 and no wage loss, it's reasonable to take a percentage of it to an attorney.

At the Labor Department there was some difficulties in figuring out did they mean to apply this to medical costs, because some state worker's compensation systems, lawyers are actually paid a percentage of the medical costs and that would not work in this case, so that's one of the reasons we're very happy that it was amended the second time to make it clear that the percentage only comes off of the lump sum. And if an attorney really has to do some work and get involved in appeals, they should get a larger percentage because that will require some work. And the feeling from the Labor Department, as well as many people, is that if it's limited to two percent, you're not going to get a good attorney willing to take it on. You'll get people who just do sort of millwork and -- to the detriment of the system and to the workers involved.

But that provision -- but worker's comp provision wouldn't look like that, but this isn't a worker's comp bill. I mean it's a -- it's neither fish nor fowl. That was the -- this compromise.

DR. DEHART: It just appeared, as we've gone through this, that everything is being done for the benefit of the claimant -- to get a filing and everything -- without having to go through an attorney at all.

DR. MICHAELS: That was the basis -- that was -- the basic idea from the Labor Department is we'll set this up, and Labor really pushed this from the beginning, we don't need attorneys in the system. But once it became a RECA system, then we took the RECA provisions and that's one of these strange things. It's unfortunate 'cause it's not a cohesive system with a philosophy behind it. It's a schizophrenic system.

DR. MELIUS: What about the fee for the Advisory Board, that's far more important.

DR. MICHAELS: Exactly.

DR. MELIUS: The Special Exposure Cohort, could you speak to that? There's really sort of two criteria that are included in there. I'll quote, (Reading) Not feasible to estimate with sufficient accuracy the radiation dose that the class received and reasonable likelihood that such radiation dose

may have endangered the health of...

Can you speak to how that language came about?

DR. MICHAELS: Yeah, I think what that reflects -- I think it's poorly crafted, but I think they were just -- this was the first time out. And you know, many pieces of legislation get multiple shots at being passed and get perfected before they're passed. This was one time around. I think the basic idea here was that -- and certainly hearing this from Senator Bingaman's staff -- they had heard, as many of the members had heard, of people coming forward saying I don't believe my dose records; they're wrong. They can't -- they can't be measuring right because I know what I was exposed to. And I believe in many cases that people were lying to me. And so I think the Congressional people took sort of our GDP concept and said well, this should be in that same -- if people are exposed and they weren't even keeping records or keeping good records, people should be allowed to get compensated, but we don't want to compensate the guy who walks in who's just -- was just refilling the Coke machine. So how do you -- how do you draw the line? And of course they didn't have any idea, and I don't have any idea, either. I don't mean to criticize them. I don't think I would do it any

better. -- on how do you figure out if someone was exposed, but -- you know, that -- the rad protections in Paducah, the dose records weren't done right. And so that's essentially -- they did it as well as they could and they threw it on you to figure it out. That's why you're paid the big money here to do it.

DR. ZIEMER: Other comments? Oh, I'm sorry -- Wanda?

MS. MUNN: Dr. Michaels, I have to thank you for a fascinating presentation. For those of us who live out in the boonies, the way things work inside the beltway is an absolute astonishment, so just following that was an exercise in concentration, believe me.

I'd like to go back to what was touched on earlier with respect to the sense of Congress statement. The thing that is of concern there is even though it is not a part of the Bill, when a statement is made that is so extremely misleading that any non-political person just reading it as a casual observer would be misled, it's kind of a problem for those of us who like to believe that Congress is capable of doing better than that. I refer specifically to item number six in the Bill. It has only two sentences in it, and the two sentences are simple. The first one is very

straightforward, (Reading) While linking exposure with the development of occupational disease is sometimes difficult, scientific evidence supports the conclusion that occupational exposure to dust particles or vapor of beryllium can cause beryllium sensitivity and chronic beryllium disease.

I think everybody recognizes that. There isn't much conflict around that statement.

The second sentence says (Reading) Furthermore, studies indicate that 98 percent of radiation-induced cancers within the nuclear weapons complex have occurred at dose levels below existing maximum safe thresholds.

UNIDENTIFIED: Ninety percent, well --

MS. MUNN: (Reading) Ninety-eight percent of radiation-induced cancers within the nuclear weapons complex have occurred at dose levels below existing maximum safe thresholds.

Now the first time I read that, my first -- I got through the first three words and thought what studies? I've never seen any studies like that. And after I'd read the sentence three times, I realized that this statement can probably be made about the general population. Why radiation-induced cancers, assuming that they are the radiogenic cancers that are identified elsewhere, is what they're talking about. If you make that assumption,

then this probably can be made clear of anyone who's walking around. But the casual reader would take that to mean my word, 98 percent of all radiogenic cancers have occurred in our workers who were unduly exposed because of inadequate regulation, and that's -- that's the sort of misleading and almost outrageous statement that does nothing for either helping come to good conclusions in dose reconstructions or helping sure -- making sure that people who should be compensated are compensated. It simply muddies the water and if that is in fact the sense of Congress, I'm assuming that it's the sense of some staffer who works for someone in Congress, but if that -- since it goes in -- to a specific part of our national law, it becomes more than just a simple -- a casual mis-statement made by someone in addressing this issue.

I guess I'm a little curious --

DR. MICHAELS: Well, it's worth thinking about that. I mean I can only respond -- I think I have two different responses. One is, given my understanding of the exposures -- you know, most workers in the DOE complex were not exposed to anywhere near the radiologic limits.

MS. MUNN: No.

DR. MICHAELS: Correctly. In fact, and if we believe through the (inaudible) threshold, it may

actually be true that 98 percent of radiogenic cancers, even though they may not be identifiable, in fact are caused by exposures below the limit because we have a large -- hundreds of thousands of people exposed to relatively low does. But that aside, putting aside accuracy to talk about process, in putting together this proposal -- this presentation, I went through hundreds of pages -- mostly not very interesting ones -- of the interagency review of the Thompson-Bingaman Bill because three times a week there would be something that would go around, and for some reason I saved a lot of them, with commenting on different lines and the -- you know, Labor Department would say this and then HHS would say that. And I mean everybody here saw those, and in not one of them did we ever discuss the findings, the sense of Congress at the beginning. They were totally ignored. And we looked at that Bill -- you know, no one cared about them.

Now maybe it's a problem that you think people are reading them, but in fact -- I mean the sense of the Administration is no one cared what was in there. If Congress wanted to say that, that was fine, but what we cared about was what they were telling us to do. And so there was no comment on any of that. And I couldn't even tell you what was

in there. I mean I'm glad you read it to me, but that's -- you know, I don't know if that's a -- what that means, but that we just ignored that.

DR. ZIEMER: And part of the concern here is that it is claimed to be based on scientific studies --

MS. MUNN: Yes.

DR. ZIEMER: -- and I don't know of anyone who's aware of any such studies that would make such a claim. Richard Miller says that he has some information on that statement. Richard --

MR. MILLER: Sure, I'd be --

DR. ZIEMER: -- can you add to that?

MR. MILLER: -- glad to. And by the way, Ms. Munn, you are right. There was a Congressional staffer involved in it and for -- as Dr. Michaels properly reported, neither the Administration nor the public had any role in the conferencing process. We were -- it wasn't even a fishbowl where you got to look in the windows and see what was going on. We'd occasionally get FAXed pieces of pages of a draft with talking points. So when the things like finding came out, what the Thompson-Bingaman Bill initially had in it and what was finally reported, as you just read it, are very different. And in fact, some of us have -- who have thought about doing some amendments have thought about a technical

correction to precisely to that very clause, and maybe I can illuminate because I agree with you, there's some concern about that finding.

What happened was, when Bob Nordhouse was the general counsel for the Department of Energy and Tara O'Toole, the successor to Dr. Ziemer, was the Assistant Secretary, they commissioned some folks at MIT led by Nick Ashford to undertake a study of the DOE worker compensation system. So some of the thinking that's leading to this had been going on well before Bill Richardson's tenure. And in the study -- and I can't -- I don't have the exact title of it, but it's -- oh, I don't know, about a foot thick, which looked at both the epidemiology that had been done in the DOE complex, had looked at the experience of the worker compensation system. One of the conclusions that they drew was with respect to what's called the doubling dose. And the question was, what is the likelihood, based on the epidemiology that had been done in the DOE complex, that individuals who sought compensation for radiogenic cancer -- or cancers arising out of the course of employment from exposure to radiation more broadly, what was the likelihood that they were going to be able to meet the doubling dose criterion. In other words, how many of those cancers would actually fall over the doubling dose.

And what the report said -- and it's a public document and so -- as a matter of fact, if you'd like, I'll get a copy of it and give it to the committee --

DR. MICHAELS: It's on the web site.

MR. MILLER: It's on your web site? Okay. And what that report said, and others who have read it should correct me if I inaccurately state this, but I think it's right, was that with respect to the doubling dose somewhere between one and two percent, depending on whether it was cancer death or cancer incidence, will fall above the doubling dose level. In other words, individuals who received in excess of two percent, and so therefore, inversely, 98 percent of all occupationally-related cancers which -- do you follow me? Okay. Ninety-eight percent of all occupational cancers will fall below the doubling dose, below the doubling dose -- okay? -- which is the legal standard of causation under most state worker's compensation programs. And if you look at the Thompson-Bingaman Bill, it specifically -- and I will get you actually the Thompson-Bingaman as it was added to the Senate Defense Authorization Act -- you will see specifically that's how it's quoted. All right? That it falls below the legal threshold for causation under compensation systems. It had nothing to do with the safe threshold.

So when this thing came out of conference okay? Need I say more? -- it -- whoever was involved at the staff level had never bothered to pick up the phone to say what was intended by this? And people were much more engaged in the fight over the silicosis standard, over which agency was going to be implementing this program -- Do you see what I'm saying? -- and we were all much more bogged down on the outside about that, and we never even looked at revised findings. And so I can't imagine what -- I don't know whether it happened on the Judiciary Committee, whether it happened in the Labor Committee, whether Speaker Hastert's office, who was involved in drafting this, did it. I have no idea, 'cause the Senate staff sure knew exactly what this was about 'cause everybody had seen this Ashford study. So it has to do with the doubling dose. It has nothing to do -- and your concerns are entirely proper, and there is a study to back that up.

DR. ZIEMER: Thank you for that clarification and --

MS. MUNN: Yes.

DR. ZIEMER: -- although it's quite true that the sense of Congress stuff is not the law, per se, the concerns I think that Wanda has raised are certainly real in terms of what this says to the public. And it may be at some future point that

this Board may in fact wish to comment on that. In one way it's sort of outside what our immediate responsibilities are, but on the other hand, it's a concern that could be in some way probably appropriately raised as a concern on what it says to the public in trying to properly educate people about all of the issues surrounding not only this compensation program but other aspects of radiation effects and health effects and so on.

MR. MILLER: Excuse me, Dr. Ziemer --

DR. ZIEMER: I want to thank Wanda for raising that.

MR. MILLER: And if you'd like, I'd be pleased because we have some language right now that's been prepared to amend that particular finding that we've sent up to the Hill to alleged counsel to have prepared, and we'd welcome your commentary on that language because it has not escaped our attention, either. It is a commonly-shared concern.

DR. ZIEMER: Okay, thank you.

MS. MUNN: And I guess I would like to also comment that not only is there great concern from my quarter with respect to what this says to the public, there is also great concern with respect to what this says about Congress and its sense about what we're looking at, so thank you.

DR. ZIEMER: Do we have additional questions for Dr. Michaels? Yes, Roy, and then Jim.

DR. DEHART: If we could return to the Special Cohort, the enthusiasm that you described that was occurring, or certainly a bandwagon of support across the country, as the activities of this committee and the review of complainants or claimants for awards occur, some will not receive benefit. They will fall under the criteria. There will be a lot of questions raised by claimants about the accuracy of dose, regardless of the science that goes into that. Where do you see the Special Cohort concept going? Is it going to be a bandwagon in itself, because there's already letters to Congress -- or from Congress to the Administration regarding this.

DR. MICHAELS: I don't know. I mean I'm quite confident that if someone has a reasonably good dose record or -- I'm quite confident that the dose reconstruction probability of causation modules that Congress and the Administration originally came up with and have been developed and perfected and hopefully implemented soon by NIOSH, if explained properly to workers, will show that even if there are inaccuracies in their individual dose, if they're close to being compensated, they're going to be compensated because it -- you have a 99 percent

confidence interval. I mean it's really set up in a way that ought to cover those people, and that's the idea.

Are there whole populations, though, which -- where there were overt activities and egregious overt activities of exposure and lack of record-keeping, they would sort of fit into the Special -- and we -- you know, take them a case at a time. We don't know. And I don't know how NIOSH is going to rule on that or how they're going to think about it, but to me, that's -- those would be the ones to think about. It's not the ones where just -- you know, there are no records, because I think it's reasonable to think you could figure out what people -- you know, the more -- the ball park. It's where you have these situations which people just didn't care, didn't control, didn't make -- didn't sort of protect people should be the ones that sort of get more scrutiny. I don't know. I mean I haven't followed it too carefully since then. I'm actually trying to get out of this and do some other things -- trying to get a new job.

DR. MELIUS: Along this same line, though, in terms of -- we're not out of it, so we've got to keep -- we're trying to keep you in it so that we -- at least to get some information and help. This issue of reasonable likelihood that radiation dose

may have endangered, was there any thinking in terms of -- a certain criteria in terms -- such as an epidemiological study or anything like that --

DR. MICHAELS: I don't think there was. I think they really felt like -- and the staffers who wrote this I think were very -- were not the ones who said let's just write something down. They really thought about this a little bit and said this is the best we can do at this hour, and we know there are good people in the government who could figure this out. I mean I think -- I believe that's what they really felt. And it's nice to see you all today.

DR. ZIEMER: Further questions?

(Pause)

DR. ZIEMER: Dr. Michaels, thank you again for sharing with us today. It's been very helpful.

DR. MICHAELS: Thank you all.

DR. ZIEMER: We're now going to move to the public comment period. We have one individual who has requested time to make comments, Robert Taber. Robert, are you here? Please.

MR. TABER: Yes, I am. I'm here. I'm Bob Taber. I attended this session back in January. I worked at the Fernald facility and my background basically is I'm a millwright by trade and I've been employed there since 1981, and I'm happy to see that

the citizens of the United States and our government is finally addressing some of the things that should be addressed.

I want to be somewhat philosophical here just for a moment and say that I'd like to remind everybody that doing the right thing right the first time is really an opportunity. And what I mean by that -- and I say that a lot to workers and I say that a lot to management because we can do the right thing right, we can do the wrong thing right, we can do the right thing wrong, or you can do the right thing right. And if you want to drive a little efficiency into it, maybe try to do it the first time around. Of course that's not the normal way we do business it seems like a lot of times in the world that we live in.

With that in mind, I would -- I have written down some thoughts that I had. Mostly I like to speak from an impromptu perspective, but I think this is worthwhile reading and eventually I will get to my specific point. I had some thoughts and what I wrote here was I would like to encourage this Advisory Board to stay focused, to not forget the intent of the Act; to remember that like many Americans who gave their lives in combat in the name of freedom, that many Americans, the Cold War veterans, sacrificed much to maintain that freedom.

Many Cold War veterans have died and others are inflicted with illnesses due to the work-related environment. The people of this nation, as well as our government, have a responsibility to make things right. This law, this Act is just one effort to meet that responsibility. To do anything less than the right thing right, hopefully the first time, is, in my mind, unacceptable.

Now let me be a little bit more specific. I would say that therefore -- you know, I would challenge you to see that the program is properly structured, specifically with respect to the evaluation criteria for dose reconstruction in order that these cases be fairly adjudicated. I guess what I have in mind to say there is that it appears to me that maybe -- I don't have the scientific mind that you folks do, but I get the inclination that maybe we might not be comparing apples to apples and oranges to oranges when it comes to the criteria for developing this dose reconstruction.

When I was listening to -- his name doesn't come to mind right now, from the NIC -- I mean NCI --

UNIDENTIFIED: Dr. Land.

MR. TABER: Dr. Land, thank you. And when I think about all the various types of worker studies that are out there, I'm not so sure that the kind of

statistics that we've accumulated in the past, especially to gain some insight as to how the worker's impacted by the environment that he works in, that the things that we have accumulated from maybe Japanese folks who survived the Nagasaki and Hiroshima bombs and the studies that we've done on those folks -- I mean, you know, in my mind, common sense tells me that the strong survive and the weak perish. And if you're only doing studies on those who survived, you're doing studies on those who were strong enough to survive. And I can't exactly say that I would think that those particular types of studies on those people would necessarily compare to what a worker in the nuclear network has seen over the years.

I can recall the day and age when I went to work in 1981, I was one of the fortunate type that went to work later on in my life, and respiratory equipment and PPE at that time was not mandatory -- at least not at my site, but it shortly became a way of doing business. Some folks, it was an optional thing, and some of us would go ahead and say hey, it's a good idea to put on a half-mask, good idea to put on a respirator. I can remember when many a times that you would go to the showers in the afternoon and your white uniform would be totally green. There was no white showing. And my arms

were covered with green salt that were soaking into the pores, you know, from where you had sweat and you could see this stuff caked on you. And it was common to see black oxide all over the place. Many a times I have serviced a reactor -- not that kind that you have to stay away from, so to speak, like plutonium, but a reactor in making feed material that would be going out to Hanford and down to Savannah River. Then you would have to maybe do a fix on that particular reactor and we would open up that vessel and it would just burst black oxide out and people would stand there and poke away to try to un-jam it. And they're inhaling these type of things. Now just think about doing that for years. And this is before we used the kind of science that we have now to monitor people. And I guess that's why probably you have some of this Special Cohort groups because there's no way of saying that these people were not inflicted by that.

But I have seen many of my fellow workers die in the past years. I've been there just 21 years May the 11th, in fact, and I know that what we're doing now is really important. So I would really encourage you folks to take advantage of the opportunity that if this program has any holes in it, that we're not comparing apples to apples and that we're not comparing oranges to oranges, that we

take this opportunity to take and make things right and that we do it right the first time. What you don't want to have happen -- and you don't see a lot of people like myself who have the interest in seeing that justice is done in behalf of our workers. These folks don't understand the same things that you understand, but after a while they'll begin to understand that. If they suspect that we haven't done the very best job that we have the opportunity to do, let me tell you, you will hear those outcries later on. And they will get their representatives and those folks involved. So while we have the opportunity to do this thing right, I want to encourage all of us to take that opportunity. And if there's some holes that need to be plugged, especially in this area of the SEC and especially in this area of the criteria for which to maybe do these evaluations to the best of our ability. And I do compliment the work that NIOSH has been doing and I compliment the work that you folks do as well. I'm just suggesting that it doesn't appear that it's a perfect world and that we can make it better and that there's some opportunity here and I would like to see us take that opportunity.

And I think with that -- oh, there was one other item I had on my mind that I wanted to remind

us of. Last time I was here I said something to the effect about record-keeping. Lookit, folks, a lot of these sites out here, especially that of Fernald, are closure sites. They have lifted the moratorium on records. Now I know medical records are required to be held, but there's a lot of historical knowledge that will be probably utilized in maybe making some determinations about these cases. If you folks haven't stepped up to the plate and spoke up to whoever it is we need to reach out and get that message to about record retention, let's not forget that. Closure is right around the corner and some of this stuff is going to get archived, if not disappear. It may be very, very pertinent to seeing that there's some justice for some specific individual cases, simply because we overlooked the fact of sending the message -- hey, hang onto some of this stuff.

I can't think if there was anything else other than that.

I have a big interest in the Special Exposure Cohort, I guess because Fernald is not in that. I don't quite understand why not, but I'm not going to go into that at this time. I guess I'll just kind of track that as things go along and hope to see you sometime in the future. Thank you.

DR. ZIEMER: Thank you, Mr. Taber, and that

certainly is a good challenge to all of us to -- both on the Board and staff people, to do our best to do things right.

Now let me ask if there are any other items to come before us today before we adjourn. Yes, Jim?

DR. MELIUS: I have one little follow-up to what Mr. Taber said. In actually reading the legislation, we are mandated in the legislation to review the quality of the dose reconstruction efforts and I think we -- it's really imperative at that next meeting, presumably in early July, that we develop a plan and action to go forward on that 'cause I -- it is going to take some time. It's not something we can sit in a meeting and do, I don't think, and so I really urge that we make sure that's on the agenda for next time and that we leave time to discuss and develop that plan.

DR. ZIEMER: Thank you, Jim. And not only will that be on the agenda, but I'd like to ask Board members individually between now and then to think about those issues in terms of what might be a practical scheme to -- for us to carry out our role. And that means, for example, how do we want to evaluate the datasets that are being looked at? How do we wish to review the process itself, the mechanical process of dose reconstruction and any

related -- and how much of the actual caseload do we wish to review? So there are a number of questions that we have to ask and then think about ways that we can carry that out.

I was thinking last night a bit on just the datasets, and I know the staff has given a lot of thought -- it's not only getting the data, but saying how good is the data and is there enough of it. And I think we want to get some feel, for example, for what that looks like ourselves, and not just be looking at sort of well, how do the final calculations look but delve back in here and there. But those are some issues that I think it will be worth all of us giving thought to between now and the next meeting so that when we come together to discuss this, we might have some creative ideas that could be brought to the floor as to how we might proceed.

DR. MELIUS: Would it be appropriate to have a subcommittee that would at least maybe do a conference call or something in between now and the next meeting to discuss or come up with some ideas, hopefully?

DR. ZIEMER: I'm certainly open to that. I'm never quite sure exactly what we can do in terms of formal activities that don't involve -- you know, can we do conference calls and e-mails and so on or

do all of these have to be out on the web site and so on. I mean not that we shouldn't do that, but there's an efficiency factor, too. Maybe Jim -- or Larry or somebody could help us on how we might be able to do some of this between now and then and have a group do a little sidebar brainstorming and come up with a straw man approach that might be used.

MR. ELLIOTT: You can certainly have a working group established to meet by teleconference and exchange e-mails. We'll put those e-mails on the web sites so that all the members of the committee and the public can have access to them. We can set that up. A subcommittee is --

DR. ZIEMER: As opposed to a working group?

MR. ELLIOTT: Yeah, a subcommittee has a distinct function and life cycle and a working group can go on and on and on here, so...

DR. ZIEMER: A subcommittee is more of an ad hoc committee. Well, and certainly --

DR. MELIUS: No, there's nothing really -- I think it is the other way. I'd shared some other boards and I think it's the other --

DR. ZIEMER: It's the other way around.

DR. MELIUS: A subcommittee is a formal --

DR. ZIEMER: Then the working group is more correct, okay.

DR. MELIUS: For us, working group would be --

DR. ZIEMER: Whatever it is we're talking about, we know what it is. Right?

Well, let me ask if there are those on the group that would be willing to participate in such an activity between now and our proposed meeting. Okay, Henry's volunteering, Roy is volunteering, Sally's volunteering, Gen's volunteering, Mark's volunteering, Tony -- we almost have the full group. Okay, and Richard's volunteering.

Well, that's a good-sized subcommittee. It's everybody but the Chairman. We would need somebody to be willing to sort of have the lead on it. Who are you pointing at? Jim.

DR. MELIUS: I didn't volunteer.

DR. ZIEMER: He hasn't volunteered. Mark, do you want to --

UNIDENTIFIED: All right, I'll take it.

DR. ZIEMER: This is just for -- just to have a point of contact, so Mark, if you will take the lead and you have the names of everybody who volunteered. Please keep me in the loop on all of your ideas.

DR. ANDERSON: Just -- this is one kind of informational point. If we're going to be doing specific case reviews, the issue of confidentiality

--

MR. ELLIOTT: You won't see the individual's name. There will not be personal identifiable information in these.

DR. ZIEMER: If we end up looking at data --

MR. ELLIOTT: It would be de-identified.

DR. ANDERSON: Yeah. What we need to know is what constitutes -- I mean you can't -- there will be very specifics in the work history and the age --

DR. ZIEMER: Right, right.

DR. ANDERSON: -- in the site that -- you know, you just need to --

MR. ELLIOTT: We understand that very clearly.

DR. ANDERSON: Yes.

MR. ELLIOTT: We have to protect -- it's our responsibility to protect the confidential --

DR. ANDERSON: Yeah, the issue I was going to raise is since we're tasked to do that, there would be some role and we are government employees as --

MR. ELLIOTT: That's right.

DR. ANDERSON: -- but what I'm trying to say is one option would be to have the specific reviews and the cases we choose reviewed in a non-open forum. The results of the review and our

compilation of that would be done in a public forum so --

DR. ZIEMER: Well, this is one of the items that you can consider as you -- let's not solve the problem --

DR. ANDERSON: It really becomes a NIOSH decision --

DR. ZIEMER: Right.

DR. ANDERSON: -- but it would seem to me that we could --

DR. ZIEMER: We can propose some ideas along those lines as a part of this exercise.

MR. ELLIOTT: Let me take you back just a second. Given that everybody, minus the Chair, is on this thing, it would have to be a subcommittee. And a subcommittee -- when you meet as a subcommittee you have to have the -- we'll announce it and public availability will have to be made. If you're a working group, we do not -- we would announce the working group, but we don't have to accommodate public participation. Just so you're clear on that.

DR. ZIEMER: Yeah, I think we decided that this was going to be a working group. It's ad hoc. It doesn't go on forever. It's for a specific purpose.

MR. ELLIOTT: The issue is is a working

group needs to be limited in number. If you have you're achieving a quorum here, and then you've got a subcommittee.

DR. ZIEMER: Let's do just that then, make sure we have not exceed the quorum, number one --

MR. ELLIOTT: I don't have a problem either way.

DR. ZIEMER: -- and other folks can be kept in the loop as far as information is concerned. Let's see again who was -- okay, Mark, Gen, Roy, Robert, Richard, Sally and Henry. Okay, now we're over the quorum so let's --

DR. ANDERSON: I guess what I -- I would like to see what's going on. I'd be happy to comment, but I don't necessar-- I mean if we want to cut down the numbers, I don't need to be officially on the work group, as long as everybody is in the loop and can comment.

MR. ELLIOTT: The other members --

DR. ANDERSON: But we charge the work group to do the compilation and keep the record, that --

MR. ELLIOTT: Members of the Board would be fully kept informed, no matter which way you go.

DR. ANDERSON: If I drop out you'll be at five, so you won't have a quorum, so that may be --

MR. ELLIOTT: That's six.

DR. ZIEMER: We're still at six.

MS. GADOLA: I can drop out.

DR. ZIEMER: Sally's dropped out, but again, you'll be in the loop and -- okay, one, two, three, four, five.

MR. ELLIOTT: So for the record, we need to establish who is on this and --

DR. ZIEMER: Okay. Mark Griffon will chair the work group, will include Genevieve Roessler, Rich Espinosa -- Roy, were you -- yeah, Roy DeHart, I think Robert and that's it. Right? One, two, three, four, five. Okay?

MR. GRIFFON: The only thing is, Tony didn't have the opportunity here. He might be interested in this topic, so I don't know --

DR. ZIEMER: And again, Tony will be in the loop and will have opportunity to comment if necessary, so -- I mean he didn't have an opportunity, but I don't think it's appropriate for us to volunteer for him at this point, so --

MR. ELLIOTT: And point of order for the record, we need to establish the charge to this working group.

DR. ZIEMER: Okay.

MR. ELLIOTT: Clearly.

DR. ZIEMER: The charge for the working group -- let me put some words out here and see if this sounds okay. The charge to the working group

would be to develop an initial draft of the process for this Board's meeting its obligation to -- now I want the words that are in our charge --

DR. MELIUS: Can I -- in the legislation it's (Reading) review the quality of dose estimation and reconstruction efforts.

DR. ZIEMER: Right, that's what -- the words we're looking for.

DR. MELIUS: Can we say have -- rather than -- why don't we have -- develop a draft, why don't we have develop options.

DR. ZIEMER: Yes, that's fine.

DR. MELIUS: I think that --

DR. ZIEMER: Develop options for how we would meet that requirement. Is that specific enough for -- from a legal point of view? Do y'all understand the charge? Mark, do you have that?

DR. MELIUS: And then to report back to us at our next meeting.

DR. ZIEMER: To report back at our --

DR. MELIUS: At our next meeting and then --

DR. ZIEMER: And to keep us informed as you proceed. And there are some specific words in the Act that pertain to what this Board has to do on that process -- assess the methods established and verify a reasonable sample of the doses established. So it's in that context. Thank you.

Now let me ask, is there further business to come before the Board at this time?

(Pause)

DR. ZIEMER: Staff, any additional housekeeping things we need to take care of before we leave?

MR. ELLIOTT: Just remember to turn in your sheets to me on your preparation time, and if you haven't turned in your -- and you want to, your photo release form, and I thank you again for all your participation and your effort in the meeting.

DR. ZIEMER: Yes, and let me echo that. Thanks to everyone for a productive time together. We look forward to our next meeting, probably on the dates indicated, perhaps in Denver. We'll see where we end up. Thank you very much. We are adjourned.

(Meeting adjourned at 11:30 a.m.)

C E R T I F I C A T E

STATE OF GEORGIA :

:

COUNTY OF FULTON :

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the 2nd and 3rd day of May, 2002; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 4th day of June, 2002.

STEVEN RAY GREEN,
CERTIFIED MERIT COURT REPORTER
CERTIFICATE NUMBER: A-2102