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

convenes the

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

VOLUME II

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Holiday Inn on the Hill, Washington, D.C., on Wednesday, January 23, 2002.

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C O N T E N T S

VOLUME II
January 23, 2002

Legend of the Transcript:

(phonetic) = Exact spelling unknown
— = Break in speech continuity
(sic) = Exactly as spoken

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

(By Group, in Alphabetical Order)

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National Institute of Occupational Safety and Health

JAMES NETON, Ph.D., CHP
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P R O C E E D I N G S

8:05 a.m.

DR. ZIEMER: Good morning, everyone. I'm going to call the meeting back to order this morning. I hope all of you had a restful night and ready for another hard day of work.

One of our members, Jim Melius, is going to join us a little later this morning. He had to return to New York last night and flew back late in the day, and then is flying back this morning. So we're expecting him to join us before very long, but we are going to go ahead and begin the session.

I have a few announcements or housekeeping matters to mention. First of all, for the guests, the members of the public and others who are here as observers, if you wish to have copies of the minutes – the minutes, not the transcripts but the minutes – of the meeting, there is a sign-up book out in the foyer, and you can request copies of those minutes and they will be sent to you as soon as they are available.

Secondly, if any of you wish to make comments today – that is, any of the public, the observers – if you wish to make verbal comments,

and you see on the schedule that that is scheduled for immediately after lunch today, that — again, there is a sign-up book in the foyer. We ask you to sign up for that. We need to know who wishes to speak so we can schedule the time. I may actually schedule one of those just before lunch, because I believe we had one gentleman who did request a few minutes, and to accommodate his schedule we may try to do that just before lunch. But please sign up, in any event.

Lunch, again you will be on your own today for lunch. That's both the Board and of course the rest of you. So if you need a list of restaurants that are in the nearby area, I believe there's still a supply of those on the table or at the front desk.

And then finally, there is a noon checkout time. And you may have an opportunity, if you haven't already checked out, to do that when we recess for lunch. But if you do need a late checkout, you need to request that from the hotel. I'm not sure how long they will extend the checkout time, and you need to work that out individually.

Let me ask the staff if there are any other

announcements that need to be made right now of a general nature. It appears not, so we will proceed.

We're going to begin this morning – we have what is called an administrative orientation, and that's going to be presented by Corrine Homer, or known affectionately as Cori. And Cori is with NIOSH, and is going to lead us through this administrative overview.

Please, Cori.

MS. HOMER: Hopefully you can hear me, and you may not be able to see much of me.

I'm going to bore you a little bit more with more orientation information. And some of you already are aware of this process, as you've served on advisory committees or boards before. But for the rest of you, I wanted to provide you with some information to make the administration a little less confusing to you.

As you are already aware, the White House appoints or commissions the members for this Board. This is the only Presidential advisory committee that HHS has.

CDC/Committee Management Office provides Federal advisory committee policy and guidance to

NIOSH, and reviews confidential financial disclosure reports and determines if waivers are necessary, which you've all been through that process as well.

What NIOSH does, at least at the administrative level with myself and other staff, we prepare personnel actions, arrange and prepare travel orders and vouchers, request salary reimbursement. We plan the meetings and provide committee support.

In terms of personnel actions and issues, we prepare and forward the personnel forms to you, the members, for completion. That was that thick packet of forms that you had to wade through and return to us within a very short period of time, which I can't tell you how much I appreciate it. We assemble those forms and forward to the Human Resources Management Office that makes you a Special Government Employee. We also maintain your status as a Special Government Employee. You have one-year appointments, and we renew those appointments every year based on notification from Human Resources Management Office.

In terms of your travel, we let you know of

meeting dates and location. We contact you directly and arrange for your flights and lodging. We prepare your travel order as allowed by policy and regulation. We forward your travel documents and forms to you prior to the meeting, and we make requested changes to your flight and lodging arrangements.

For voucher reimbursement, which is — this is where you haven't quite gotten to yet — you return your original receipts and completed expense sheet to us for voucher preparation. You should have received an envelope that you should return all of your documents to us. We go ahead, based on what you've returned, and prepare your voucher. We forward the voucher to you for signature and return. We forward your voucher for approval and reimbursement once it's been returned, signed and dated by you.

Salary reimbursement, you're reimbursed $250 per day less taxes. When you receive that in your bank account or with your financial institution, it will not amount to $250 a day. It's going to show less, based on your taxes. We record your attendance at the meetings and request salary reimbursement for attendees upon

return to Atlanta.

We also compensate you for other time spent, at the discretion of the Executive Secretary. Now as a request to you, your preparation time for this meeting was fairly significant. If you can let me know individually, or let Larry know what your specific time spent was reviewing the documents and preparing for the meeting.

MR. ELLIOTT: Cori –

MS. HOMER: Yes, sir?

MR. ELLIOTT: If you could just – before we leave today, before you depart, if you could just write down on your little note pad how many hours you spent and give that to me, with your initials or signature so I know who gave it to me, and then I'll pass that on to Cori to get it taken care of. So hours spent in preparation of the meeting.

MS. HOMER: We do that fairly quickly upon return. We do want to make sure that your voucher is paid and that your salary is reimbursed as quickly as possible. We don't want delays any more than you want delays, which returning your voucher information – if I can backtrack a little bit – returning your voucher

information to me as quickly as possible helps me keep my records, and helps you be able to pay on your credit cards for the trip.

In terms of your salary, please check your accounts to ensure receipt of your reimbursement. We've actually had a record of members on committees and subcommittees that just assumed they were getting paid and never checked, and years had gone by — literally, years had gone by. We were receiving the appropriate documentation that was saying they were paid, and they actually had not been.

Meeting planning: We arrange for the meeting and lodging space. We arrange for member, staff and vendor travel. We take care of writer/editor, court recorder, AV equipment services, and light refreshments. We provide conference support. You've seen Nichole, myself, Martha DiMuzio, that the support for you has been strong, and we will continue that. The staff may change, but the support will not.

In terms of your meeting packets and supplies, copying materials, you should receive all that material prior to the meeting. There may be occasions that you do not. We do try to

prepare that and have that to you within a week or two before the meeting so that you have time to review that.

Points of contact: Your travel and vouchers, at the moment, will be prepared by Nichole. I believe you'll be returning your voucher information to me, but since Nichole has prepared your travel, any questions that you have can go to either Nichole or myself. Salary, personnel, administration, travel and vouchers, any questions that you have at all, please don't hesitate to call me. My current number is not listed here as we're moving this week. As of Monday my number will be what's listed. And I believe you already have my current telephone number.

If you have questions regarding your travel forms, the expense sheets that I've provided, any questions about your current travel or changes to your flights that you need to have, please let me know before we leave today, and I'll do my best to answer whatever questions that I can possibly answer here.

Any questions at all? Yes, sir.

DR. ANDERSON: Calendar?

MS. HOMER: We'll be addressing that in a few minutes.

DR. ZIEMER: Yeah, we'll get to the time calendar shortly.

But any general questions on the administrative issues that Cori has covered here?

Gen.

DR. ROESSLER: Mine's not a question, but I've already tested your system, had to have flights changed and stuff, and you're doing a really good job.

MS. HOMER: Thank you.

DR. ROESSLER: So it works.

MS. HOMER: I'll make sure Nichole knows.

DR. ZIEMER: Thank you. Other comments or questions?

Please, Larry.

MR. ELLIOTT: Let me segue off of what Gen just offered. If there's a travel situation that occurs for you in trying to get to a meeting where you might — in like Gen's case, she has another meeting – you're off to or going to be off to —

DR. ROESSLER: The next meeting.

MR. ELLIOTT: The next meeting – we can

accommodate that if we know. So please articulate what your needs are, and if we can we'll certainly take care of that and accommodate it. If we can't, we're going to tell you that.

DR. ZIEMER: You mean if you're working two meetings, then, back to back? Is that what you're talking about?

MS. HOMER: Um-hum (affirmative).

MR. ELLIOTT: That's right.

DR. ZIEMER: Right, okay.

Okay, thank you very much, Cori, for that information.

We'll proceed right on to the next item of business, which is the Board work schedule. Incidentally, I failed to mention, particularly for our visitors, there are copies of the agenda on the table. If you didn't get the agenda they should be on the table.

So this is called Board work schedule, and Larry, if you would take us through that.

MR. ELLIOTT: Well, we do need to schedule the work of the Board. I think you have a sense of the responsibilities of the Board and what work you have facing this group. And we have our next meeting scheduled for February 12th – or

excuse me, 13th and 14th.

We need to see what we can get accomplished here today toward, if possible, providing comments on probability of causation rule by February 6th, at a minimum. We need to discuss and talk about future meetings beyond February 13th and 14th, if we can, so that we can get some dates locked in. I don't have any specific proposal, other than I think we need to figure out availability here.

Doesn't March — we've tapped your availability for March, and it doesn't look like there's a time in March when all members can be present. And that's okay if that's what the Board wants to do, if they want to continue their business without a member or two present, as long as we have a quorum.

I don't know if there are questions about the timetable of expectations that the Department has. Maybe I could go over those, but I tried to give you that yesterday. We'd really like — we have a goal of finalizing both rules by April.

We plan to submit the SEC procedures to you progressively over the course of the next couple of meetings. It's not certain how much

information on the SEC procedures we'll be able to convey to you in February, but we'd also like to see those guidelines put before the Board and see some advice and comment on those fairly early this year. So probably April or May we really need the Board's attention to the SEC procedures.

As far as review of dose reconstructions, I would propose to you that we need to give ourselves a little bit of time to see NIOSH complete some of those dose reconstructions and have a set of dose reconstructions that could be sampled from. And I would propose to you that in my mind it makes sense to try to target a review of dose reconstructions around July or thereafter.

So just to give you a sense of order of business here, we really need POC reviewed and commented on first; dose reconstruction rule, if we can, second; and then attend to the business on Special Exposure Cohort after that.

So that I hope gives you a little bit of clarity of the work before us, but we need your assistance and your discussion on how to go about completing that work.

DR. ZIEMER: Larry, on the issue of March,

were there any time slots where there would be one day where we could, if needed, have a telephone or teleconference meeting if there was a pressing matter?

MR. ELLIOTT: We certainly could. Just have to identify –

DR. ZIEMER: The problem was finding, what, a two-day time slot where everyone –

MR. ELLIOTT: We did not see a two-day time slot where everybody could come in. We were going to miss somebody or more than one somebody.

DR. ZIEMER: So I'm wondering if it would be of value to go ahead – of course, the February meeting is already scheduled – to find and identify a time slot for March where we could schedule a teleconference – it could be cancelled if not needed – and then go ahead and get a meeting in April.

Wanda, you have a comment?

MS. MUNN: I guess I have – I feel, especially during these early months when – I don't know about everyone else, but I feel as though I'm going to take two or three meetings to get my legs under me and really feel comfortable with the process. I would much prefer for us to

bite the bullet in March, and even though we have to meet without a couple of members, try to go ahead and have a March meeting.

DR. ZIEMER: What if one of the members is you, Wanda? Then –

MS. MUNN: If one of the members is me, then I'll – if we can do something like a teleconference, there's a possibility that I could call in and listen in then. That would be very helpful, I think.

DR. ZIEMER: Let me ask, then – well, how do others feel? Do you want to go ahead and schedule a March meeting, if we can find a day where maybe only – what's the best we can do in terms of loss of members?

MR. ELLIOTT: Maybe the way we can do this, you've got this calendar before you. If we can look at March – and I'll let Cori start off here with her availability, because she has four other committees she's dealing with besides this one.

And so Cori, what days are you not available here that we should black out?

MS. HOMER: The first two weeks of March, starting at the 1st through the 8th, I'm not available. My best availability is probably the

13th on.

DR. ZIEMER: Okay. So do we want to go around the table, then, and – well, you've already collected people's schedules for March, or have you?

MS. HOMER: I have, but that's back at the office.

MR. ELLIOTT: We failed to bring it.

DR. ZIEMER: Okay, so we need to –

MR. ELLIOTT: I can tell you that I'm not available the week of the 18th, so that narrows it down a little further.

DR. ZIEMER: Anytime the week of the 18th?

MR. ELLIOTT: That whole week is out for me.

MS. MUNN: What do we do, 13, 14?

MR. ELLIOTT: I'm out 13th and 14th.

DR. DeHART: I'm not available the 13th. I am the 14th and 15th.

DR. ROESSLER: Do people not like –

DR. ZIEMER: Are Saturdays out?

DR. ROESSLER: Yeah, that's what I was going to say.

MS. HOMER: Saturdays are –

DR. ZIEMER: Not desirable?

MS. HOMER: – not desirable.

DR. ZIEMER: Okay.

DR. ROESSLER: Not even for travel?

MS. HOMER: Travel's okay, if you don't mind traveling on Saturday, but some folks do.

DR. ROESSLER: I don't mind traveling on Saturday.

MS. MUNN: I don't, either. That's fine.

DR. ZIEMER: Well, looks like the week of the 11th is pretty well out.

MS. MUNN: Did someone say they weren't available the 18th and 19th?

DR. ZIEMER: The 18th is out for Larry. Larry has to be here, under the rules.

MS. MUNN: Oh, that whole week you're out?

DR. ELLIOTT: That whole week I'm out.

DR. ZIEMER: That puts us into the week of the 25th. For whom is that a bad week?

MR. ESPINOSA: Are we limited on the Board just to two days a month, or is there any way (inaudible) to get some of the agenda done?

DR. ZIEMER: Yeah, Rich, just repeat the question.

MR. ESPINOSA: Are we limited on two days a month, or is there any way we can go like three days to get some of the agenda done?

DR. ZIEMER: I don't think we're limited, as far as I know, are we?

MR. ELLIOTT: The only limitation would be how much preparation we can put together in that amount of time to keep you actively employed at the meeting.

MS. MUNN: I don't know if my brain can handle three days.

DR. ZIEMER: That's true.

MS. MUNN: Immediately after Easter, then, or Palm Sunday?

DR. ZIEMER: Well, where do we stand on –

MS. MUNN: 25th, 26th?

DR. ZIEMER: For the week of the 25th, who has conflicts that week? No one?

UNIDENTIFIED: I have one on the 27th.

DR. ZIEMER: You have one on the 27th. And Chris (sic), we don't know Jim's schedule, either, do we?

MS. HOMER: No, we don't.

DR. ZIEMER: So we may have to –

MS. HOMER: And he's fairly difficult to pin down.

DR. ZIEMER: Okay. We actually may have to defer completing this till Jim gets here to get

that information.

MS. HOMER: Well, we can always connect by teleconference.

DR. ZIEMER: Right.

DR. ANDERSON: What's the 25-26th look like?

DR. ZIEMER: Is 25-26 good for everybody that's here today? Can we pencil that in as a tentative?

UNIDENTIFIED: What's the date for Easter?

DR. ZIEMER: Easter is the 31st.

MR. ELLIOTT: 25-26 is – okay, tentatively that.

We spoke yesterday about – I think there was a suggestion about having a teleconference scheduled after each Board meeting in case we need it. We should perhaps think about that and go ahead and schedule it. Is that the desire of the Board, or – to close up loose ends left over from the meeting or – and we can always cancel it if there's nothing, no business to conduct. But it puts us through a bind to announce in the *Federal Register.* We have to do that so many days in advance of a meeting, even a teleconference meeting.

MS. MUNN: But it doesn't create a problem

with the *Register* for us to cancel?

MR. ELLIOTT: No, it doesn't create a problem if we cancel.

MS. HOMER: Well, I do have to amend the order cancelling that, but —

MS. MUNN: But no public hoo-hah?

MS. HOMER: Well, it depends on how late the cancellation comes. Because we are limited on — there's just a schedule that must be kept in terms of any kind of administrative —

MR. ELLIOTT: Prior announcements.

MS. HOMER: Yeah.

MS. MUNN: I guess my thoughts in that regard are — I would think in most cases it would be difficult to know till we actually got to the meeting, till we got to the conclusion of our meeting, whether we really were going to need a follow-up or not.

DR. ZIEMER: There's a fair chance we may need to have something for February, roughly 4th or 5th, to complete what we work on here today, sort of final version of our comments. So it seems to me it would be prudent to get that on the schedule.

UNIDENTIFIED: Agreed.

MR. ELLIOTT: And we would need to announce that as soon as we get back to the office.

MS. HOMER: I would probably have to prepare it tomorrow —

MR. ELLIOTT: Right.

MS. HOMER: – and have it approved.

DR. ZIEMER: Because that's only two weeks off.

I think we've been asked to submit our comments by the 6th. Is that correct?

MR. ELLIOTT: Yes.

DR. ZIEMER: And how is the 5th for a teleconference?

MS. MUNN: That's great. That's the anniversary of the Constitution. That's appropriate.

DR. ZIEMER: Any problems with the 5th? We'll have to find a suitable — any bad times?

DR. DeHART: Does that give enough time for final preparation and anything we formally have to do on those minutes for them to have them by the 6th? That's only a day.

MR. ELLIOTT: Well, it's the — what will be going forward would be a letter from the Board. It's not the minutes, per se.

DR. ZIEMER: Would be the Board's comments, which would be based on work we do yet today, put in final form. And I assume it would be in the form of a letter from me.

MR. ELLIOTT: Yes.

DR. ZIEMER: Is that correct?

MR. ELLIOTT: Yes.

DR. ZIEMER: Which could be –

MR. ELLIOTT: As approved by the Board.

DR. ZIEMER: – after approval could be transmitted electronically to NIOSH or HHS.

MR. ELLIOTT: And I would think that in an hour teleconference, anything that comes out of that we could take care of and get the thing turned around by the next day, if we have to spend the whole night doing it, which we would.

DR. ZIEMER: So can we leave it for your discretion as to finding a suitable time? Keep in mind we have some people in different time zones, so we don't want it at 8:00 in the morning, I presume.

MS. HOMER: Perhaps if you let me know what time. How much are we going to need to discuss this? That's where I need to start.

DR. ZIEMER: We need to have – block off a

minimum of an hour.

MS. HOMER: A minimum of an hour?

DR. ZIEMER: Do you have to put —

MS. HOMER: Yes, I do, I have to announce times and amount of time.

DR. ZIEMER: Oh.

MS. MUNN: I would request that you not start before 10:00 a.m. Eastern Time.

DR. ZIEMER: Okay.

MS. HOMER: That's reasonable.

DR. DeHART: That sounds like a good time.

MS. HOMER: 10:00 a.m. Eastern? 10:00 to 12:00?

DR. ZIEMER: Would you like to revise your suggestion?

MS. MUNN: No, no, that's quite all right. This is not a video conference.

DR. ZIEMER: Okay, block it in at 10:00 to 12:00, then.

MS. HOMER: 10:00 to 12:00?

DR. ZIEMER: Yeah.

MS. HOMER: Okay.

DR. ZIEMER: We can always shorten it if needed.

MS. HOMER: That's right.

UNIDENTIFIED: And that's Eastern time?

DR. ZIEMER: Eastern time – 10:00, 9:00, 8:00 – that's 7:00 on the West Coast. But – let's see, you're on Mountain Time?

Okay, any other – now do we need to find an April date as well, Larry?

MR. ELLIOTT: We could either tentatively block off a time now and not – won't have to announce it, and then see how we proceed and whether we want to use it, but we'd ask people to hold out whatever time we block off.

UNIDENTIFIED: I would recommend that.

DR. ZIEMER: Okay.

MR. ELLIOTT: And I don't know that we need to go farther than April right now, at this point. In February we can look at May.

DR. ZIEMER: Well, let me ask you this. Would it be sufficient for people simply to list their bad dates in April and turn those in to Cori now, or –

MS. HOMER: Just send me an e-mail.

DR. ZIEMER: We don't need to verbally go through –

MR. ELLIOTT: Or you can mark on these and turn them over to Cori right –

MS. HOMER: Write your name across the top so I know who it is.

MR. ELLIOTT: Write your name across the top, mark your availability for April.

DR. ZIEMER: And then they can work on April.

MS. HOMER: April and May might be good, as well.

DR. ZIEMER: April and May?

MS. HOMER: Yes.

DR. ZIEMER: Okay.

MS. HOMER: So that I have a month advance.

DR. ZIEMER: Okay. So the request is to mark in April and May your bad dates, and —

MS. MURRAY: Excuse me, is the teleconference for February 18th? Those two days after the meeting, is a Saturday?

DR. ZIEMER: No, the 5th of February at 10:00.

MS. MURRAY: The 5th, okay. Thank you.

DR. ZIEMER: Okay. Larry, do you have further items on the work schedule?

MR. ELLIOTT: I do not. I appreciate the Board's accommodating this.

Are there questions? I'm sorry, are there

questions about the work we have before us, or —

MS. HOMER: Can I just ask one quick question? We are having all these meetings in Washington, or are we going to have them in another location?

DR. ZIEMER: That's a good question. Well, let's address that for a moment. Prior to this meeting there was some exchange from members to the staff about whether or not it might be desirable to have some meetings at other locations, particularly to accommodate members of the public from other locations, perhaps around DOE sites. And we can certainly do that.

One has to think about both the convenience of the location and how you would decide on one site over another. We've also talked a bit — some Board members have indicated a desire to visit sites themselves, although it's not clear if you did visit a site exactly what it is you would look at, and how that would help in carrying out the duties of this group.

But nonetheless, we can open that issue of visiting sites or locations near sites — for example, if the site were Los Alamos, would you go to Santa Fe or would you go to Los Alamos or

Albuquerque, that kind of thing. Gen.

DR. ROESSLER: I think it's a little premature to talk about sites right now. I think we need to have a couple more meetings to really get out feet on the ground and know what – where we're going, because once we go to a site we're going to get questions from the public dealing with that site.

DR. ZIEMER: Site-specific issues, yes.

DR. ROESSLER: Yeah. And I think really that puts more of a burden on the Board and the staff to prepare things that we're probably not ready for yet. We're still trying to get up to speed on what we're supposed to do.

DR. ZIEMER: Thank you.

Other comments, pro or con?

MR. ELLIOTT: I think Gen's point is very good, and I've been thinking about this since we polled the members as to their pleasure on having meetings at sites and the comments that came back.

I think it's pertinent to perhaps visit a site if you have a set of dose reconstructions that you're reviewing or have reviews being presented to the Board, and you want to

understand better what activities went on at a given site, or if we have a – you're evaluating an SEC petition once we have the procedures in place, and you want to have a better sense of what occurred at that site and why this class of employees wants to petition for the SEC. In my mind, that's what would trigger having a meeting at a site, to inform the Board.

DR. ZIEMER: Any other comments? Wanda.

MS. MUNN: Well, just for the record early on, I'm from way out in the Tooele brush. And I am conflicted about this issue simply because I'm aware of the fact that two-thirds of the nation's defense waste is stored at my site, and the processing and storage of that is the basis for most of the claims that we will get from that area.

On the other hand, my guess is my site will be probably one of the lowest in per capita claims for a variety of reasons, not the least of which is that the individuals who might be eligible for submitting claims feel very strongly that they have looked after their own welfare.

But I want you to know that both the site manager and other members of the DOE staff there

have offered whatever services they can provide if you choose to make this horrendous trip out there, which you really can't get there from here, but I can help you get there if you want to. I just wanted that out for you.

I do believe that we're correct in assuming that we don't really and truly know what we would want to look at at the site yet.

DR. ZIEMER: Thank you, Wanda. We'll interpret that as a kind invitation to visit Hanford when the time is appropriate.

MS. MUNN: If you need that.

DR. ZIEMER: Yes.

Welcome back.

DR. MELIUS: Thank you. Pardon me if I am off-track here, but I think we're talking about the issue of site visits.

DR. ZIEMER: Yes.

DR. MELIUS: And I would just add two things, and again I apologize if these have already been stated.

One is that for members that are from the West Coast, I think it's — I mean, I'm on the East Coast, and it's great for me to come down to Washington and so forth. But I think there is

sort of an element of fairness to other members of the committee that we don't hold all our meetings in Washington, that some of them be held elsewhere. Second — towards the West Coast.

Secondly, I think it's important for the visibility of this program and for the people that are potentially impacted by this program that we do hold some of our meetings at some of the sites. I think it's important that the people that are affected by this program have some access and appreciation of the process, and some time for input into this committee through the public comment period during our meetings and so forth.

So I would urge us at some point to start holding meetings at some of these sites, as difficult as they may be to get to. And I've traveled to many of them.

DR. ZIEMER: Thank you. Other comments?

MR. PRESLEY: Oak Ridge has already offered their willingness for the support, DOE and NNSA.

DR. ZIEMER: Thank you.

It appears that there's a desire to at some point visit some sites, that perhaps it's premature. And I think we can agree that at

least for the next two or three meetings we will continue the pattern here, if this is – if one meeting is a pattern, to meet here in Washington till we get past the initial sort of orientation of this group and the initial activities that we have to engage in.

If I hear no strong objections to that, I understand from *Robert's Rules* I can take that as a consensus opinion.

MR. ELLIOTT: We are locked in in the February meeting to holding it here, and that's by a departmental requirement where if we travel five or more people to a meeting we have to have advance notice of that and approval of that. We could do something for this March date you've selected of 25th and 26th, Dr. Melius, if you're available. And we've also asked folks to fill out their availability for April and May and turn that in to Cori. But we could in March, if you wished, hold it in a more central location to everyone, or whatever the Board's pleasure is on a site.

DR. ZIEMER: But that doesn't have to be decided today.

MS. HOMER: It does have to be decided soon.

DR. ZIEMER: Soon, though. Like when would be the —

MS. HOMER: Like I need to know by next week where you want it.

MR. ELLIOTT: Well, so we need to decide today.

DR. ZIEMER: Well, okay. Well, is there any strong feeling that we should be moving out to the sites by our third meeting? Or maybe not the sites. Maybe it's Chicago. I was thinking Lafayette, Indiana. You can't get there from here, either.

MR. ELLIOTT: Cincinnati would welcome you.

MR. ESPINOSA: I'll agree with Cincinnati during the baseball season.

DR. ZIEMER: We need you here in the meeting. Wanda?

MS. MUNN: For some of us it's not necessarily a matter of where it is, it's a matter of where the planes fly to. So Washington, D.C., remains a good option.

DR. ZIEMER: It's pretty easy to get here, yes. Thank you.

I think I will exercise the prerogative and say we'll meet here in March, unless I hear

strong objection.

[No responses]

DR. ZIEMER: Now we're going to move into a working session of the Board. This is a working session on probability of causation.

Before we do that, I would like to have us look at the procedural rules that a working group worked on last evening. And let me begin by thanking Tony for the work he did on developing sort of the straw man version of this document.

This is a document that we discussed yesterday, really our working rules on how we will approach agreeing on recommendations to go forward to the Secretary of Health and Human Services. This is a simple, brief working document. It's basically a one-pager. It deals with the issue of what constitutes a quorum, what constitutes a majority vote, and there may have been – oh, some matters dealing with the appointment of working groups and subcommittees.

So we're going to put the text before you now here on the screen, and we'll have the opportunity to look at this, and if everybody is prepared to do so, to have a formal motion to adopt this as our operational guidelines.

So it consists of I think three main points, one of which has some subpoints. Is it three — well, okay.

MS. HOMER: There are three.

DR. ZIEMER: Yes, okay. Let's look at these, first review it point by point, and then I'll ask for a formal motion to accept this document. And once it's moved to accept, we can amend it if needed.

So on the definition of a quorum, it says we'll implement HHS's definition of a quorum, which is the — half the membership plus one, basically. We expressed it that way rather than saying six, because if additional appointments are made to this committee and the number changes we don't want to have to go back and amend this. So it's half the membership plus one. Currently that is six.

The Board will issue formal recommendations only after a majority opinion has been reached by voting — through voting by the eligible members, and here's what's meant by eligible members: Members that have not been required to recuse themselves from participating in discussions — and I think that would include voting, I guess,

the matter in hand; those who've not abstained from the vote — if somebody abstains the voting number changes, and so what a majority — what constitutes a majority changes; and then thirdly, those who may not be available to participate in a vote.

Now there is a notation here that all reasonable efforts would be made to obtain the vote – that is, trying to not take actions when members are absent, or if they are to try to have them vote, be on board by phone. But it's conceivable that there could be cases where one or more members were absent, in which case the total number voting changes, and therefore the majority changes.

And then the statement that the Board can form subcommittees — and this, incidentally — our charter does have a similar statement, and this simply puts that information into the working document here — that subcommittees and working groups can be formed at the discretion of the Chair and the Executive Secretary, and the provision for outside technical experts, if needed, to participate in those activities.

There's a difference between subcommittees

and working groups. Subcommittees fall under FACA guidelines in terms of meeting, and typically those subcommittees have ongoing responsibilities. For example, a subcommittee dealing with dose reconstruction would be an example. Whereas a working group is simply a group formed for a specific task, such as we had last night. It simply has an immediate task to take care of. It is not – a working group cannot act on behalf of the committee, but it can do work for the committee. It brings it back for the committee to act on as a group.

I believe that's it. I entertain a motion to adopt the rules. Okay, Roy, are –

DR. DeHART: I move the adoption.

DR. ZIEMER: Move the adoption. And is there a second?

MR. PRESLEY: Second.

DR. ZIEMER: Second, okay. Now discussion. Yes, Jim.

DR. MELIUS: I would propose a modification to number one that would be similar to the statement we have down under the end of number two, but a statement to the effect that in scheduling the meetings every attempt will be

made to have all Board members present so that we're not scheduling for a quorum, we're scheduling to the extent possible to make sure that the –

DR. ZIEMER: I certainly – I would interpret that as a friendly amendment, and we don't have to formally act on that. Without objection we can add a similar statement?

[No responses]

DR. ZIEMER: Thank you.

MR. ELLIOTT: You want me to add that right now?

DR. ZIEMER: You can add that right now. Other comments? Discussion?

MS. HOMER: Every reasonable effort shall be made to –

DR. MELIUS: Ensure that all Board members are available for meetings, something to that effect. Or scheduled such that every reasonable effort shall be made that meetings are scheduled to ensure that all Board members are available.

DR. ZIEMER: Might have to word-smith that a little bit, but I think we have the intent.

Any other items of discussion, questions? Are we ready to vote on the operational

guidelines?

[No responses]

DR. ZIEMER: I see no objection. All in favor will say aye.

[Affirmative responses]

DR. ZIEMER: Any opposed, say no.

[No responses]

DR. ZIEMER: Any abstentions?

[No responses]

DR. ZIEMER: Motion carries. It appears to be by unanimous consent. Thank you.

Now we're ready for the working session. And let me outline or propose — and I'm only proposing this, because this Board is so free and independent it can do as it wishes, in a sense — but I do have a proposal as to how we proceed, and let me try this out on you.

We have three questions that we have been asked to address. Those questions — this is on probability of causation — are delineated on the first page of 42 CFR 81, and you can turn to that tab. It's the probability of causation guidelines, or interim guidelines, I guess they would be called. And there are three questions we have been asked to answer. We actually talked

about those three questions yesterday.

Now what I am proposing is that we break into three working groups of three individuals each. This is carefully chosen so that the Chair isn't working. I would actually float from one to the other, crack the whip and make sure you're staying on schedule. But, no, the three working groups, one for each of these questions, to answer that question.

Now in answering that, I'm suggesting the following: That not only do you consider your own views and opinions relative to the items as spelled out in the interim guidelines, but I ask that you take a look at — I think you've all read through these — number one, the comments by the scientific or technical experts who've addressed this. There are seven of those.

Do you all have copies of those with you? We can bring them up on the screen, but it may also be easier if you have a hard copy to work with in the subgroup.

But insofar as the technical experts have raised issues, I think it would be appropriate to ask yourself are those issues ones that we are concerned about in terms — because we're asked to

judge whether or not appropriate use has been made of current science and medicine, and we have some technical input on that from others, and it seems to me appropriate that we make use of that.

Furthermore, there are public comments that you have copies of, some of which also address the scientific and medical issues. I'm not suggesting that we respond to public comments. I am suggesting that insofar as an issue has been raised that rings a bell for you and you think it's something you want to raise, that's fine as well. Simply be cognizant of those. Obviously there's some comments that are not pertinent to what we're doing. Someone who says I just hope the process proceeds quicker, something like that, that's not an issue we're dealing with, at least not directly.

So I'm simply suggesting that we be cognizant of the public comments insofar as they may have raised questions that we think are appropriate, and to particularly pay attention to the medical and scientific experts who have raised issues on the rule-making as well.

Then what I suggest you do is simply jot down items. This can be sentences that serve —

this will serve as a jumping-off point — of points of agreement about — for example, if you're talking about appropriate use of current science and medicine, you can break it down into, for example, the risk coefficients. Has appropriate use of science and medicine been used in that part of the order, and on through the various aspects.

Now this is a little sketchy, but it's a jumping-off point. Now let me open the floor. If someone has a different way of approaching this, I'd be glad to hear it and share it and so on.

Oh, yes. Each of the groups, there are the technical staff — and let's identify precisely who's here and what issues they can particularly talk to, so that if you want to have one of those technical staff come in and answer a question, why is this done this way, or could you clarify this and so on, so — and we'll identify those in just a moment.

Let me also make a comment for the observers. I would say that observers are free to listen in to any of the groups. We're not asking the observers to participate in the

discussion, and it would in a sense be inappropriate for you to do that at that point. But you're certainly free to listen in to deliberations, and if you want to wander around and help me make sure they're doing their work, that's fine. And we only have this room available, so what you may need to do is just move to a couple of corners of the room. We might be able to use the foyer out here.

But let me see if somebody has an alternate idea that they want to propose on how we proceed. I mean, we can operate as a committee of the whole, if you prefer, or we could in fact spend some time as a committee of the whole to start with. In fact, I actually thought we might spend about a half hour and see if there are some technical issues that you want the staff to address as a whole before we break up. But — Roy, you have a suggestion?

DR. DeHART: You had mentioned points of agreement. There also may be points of disagreement.

DR. ZIEMER: Well, sure, yes, of course.

DR. DeHART: And I think we need to keep that in mind as well.

DR. ZIEMER: Right, right.

Now our job is not to respond to the comments of the scientific reviewers or of the — certainly of the public. That's the job of the staff folks to do. So I'm only suggesting that those be used as resources to stimulate your thinking about issues that may be out there.

Yes, Jim.

DR. MELIUS: A procedural question in terms of the — we would break up into working groups for how long, and then get back together? Is that — what's the —

DR. ZIEMER: Oh, yes. Actually we have a working session this morning. We have a working session this afternoon. I don't have a good feel for how much time is going to be needed or how much progress we'll make, but we can see where we are toward the lunch break. And incidentally, there's not a formal break on the program today, so in your small groups you take breaks as you need it.

But depending on where we are, we certainly come back together and see what it looks like, committee as a whole; share with each other because we don't want this to be done one group

in isolation. So this is just a way to proceed to get sort of some straw man ideas out on the floor so that we can all react to. I would anticipate if we make good progress this morning, we operate as a committee of the whole this afternoon and refine what has been done. But to the extent to which we make that progress will determine how we proceed.

Yes.

MR. ELLIOTT: I'd like to make one comment for the Board's information. The subject matter experts, the technical/scientific reviews that we've facilitated and sought and Dr. Ziemer mentioned a moment ago, are centered on two documents primarily: One on the IREP itself, and the IREP is certainly mentioned in this rule. It is prominent in this rule. It's the underpinning for this rule.

So just keep in mind that five of those commenters were asked to truly evaluate the IREP and the risk models associated with that. And two other commenters were asked to provide commentary on the dose reconstruction documentation for RBEs that are used in the IREP. So when you're looking at those scientific and

technical comments, that's the background.

DR. ZIEMER: Some may not apply to this.

MR. ELLIOTT: Some may not apply directly to this rule.

DR. ZIEMER: But the IREP is – takes off from this, the probability of causation foundation here. So insofar as it's of help, that's fine. Okay.

Yes, Wanda.

MS. MUNN: My apologies to other members of the committee who are not as paper-averse as I am. I did not download those comments, so I'm hoping that someone has a hard copy for us to look at.

DR. ZIEMER: I have hard copies. Who else? Roy does. We have several hard copies available, so –

Is the committee comfortable in proceeding in the manner described? Roy.

DR. DeHART: Paul, I would suggest that we get together a few minutes before the lunch break just to get a sense of where we are.

DR. ZIEMER: Yes, good idea.

Otherwise, are we comfortable in proceeding? Jim.

DR. MELIUS: I am. Just have a similar aversity, as Larry knows, to carrying large amounts of paper around with me. For future meetings, if we're going to be discussing specific things, could we make them available at the meeting? You seem to have a lot of stuff with you, but not some of the stuff we need now. So it would be easier, that's all.

MR. ELLIOTT: We can get copies of these made, I believe. We can get copies of these subject matter —

DR. ZIEMER: Well, and certainly at the time that the agenda was made, none of us had in mind how we were going to proceed here. And in fact, this was simply an idea that I generated last night out of the blue, I guess you'd have to say.

DR. MELIUS: That's why I said for future meetings.

DR. ZIEMER: I hope that’s not in the record.

No, no, thank you, Jim. That's certainly a good suggestion.

Okay, let's take some time — let's see how we are — it's just 9:00. Let's take some time and see if there are some either general comments or questions, particularly questions that might

be addressed to the staff.

And let's see, Larry, can you identify who's available here and remind everyone of their area of expertise?

MR. ELLIOTT: Surely. Well, Mary Schubauer-Berigan is here again this morning, research epidemiologist that really did a lot of work on this probability of causation rule and the IREP.

Russ Henshaw is also here, epidemiologist. He knows IREP and the rule as well.

We have Ted Katz, who can talk to you about the policy implications of the two rules.

We have Jim Neton and Grady Calhoun, who — you didn't meet Grady yesterday other than a brief introduction, but he's a health physicist, as Jim is. So if you have questions on the dose reconstruction aspect or what is the inputs to the IREP, they can certainly help you in that regard.

We do have — I will go into the audience here to a certain extent, too. We have David Richardson here, which he's one of the subject matter expert commenters. I'm not sure that it's fair to really tap him, given we don't have the other subject matter experts here.

And we certainly have — David Michaels is here, if you have questions of — we have Josh Silverman – if you have questions from DOE. If you have questions about perhaps the intent of Congress on why we were given this or what their intent was to come from this, maybe Josh may help us out in that regard, put the onus on Josh.

So that's kind of, as I view them, your subject matter experts at your hand.

DR. ZIEMER: Thank you.

DR. MELIUS: Can I ask one other procedural question? I don't know to what extent there were any comments from reopening the rule-making, but I don't believe those have been posted yet, nor have we seen them. So I don't know if they're available or what the status of those are.

MR. ELLIOTT: I have not seen them myself. Dave Sundin's here, who is my Deputy, and I think he has read through them. Can you —

MR. SUNDIN: (Inaudible).

DR. ZIEMER: You need to use the mike so they can —

MR. ELLIOTT: We're going to get you on the record.

DR. ZIEMER: Get you on the record here.

MR. SUNDIN: There were only two that I recall seeing. They should be up on the web very soon.

MS. MURRAY: Name, please?

MR. SUNDIN: Dave Sundin.

MS. MURRAY: Thank you.

MR. ELLIOTT: Is it possible we could have them loaded up this morning?

MR. KATZ: I have them with me. We can make copies.

MR. ELLIOTT: We have them with us. We can make copies.

DR. ZIEMER: Okay. Henry has a question.

DR. ANDERSON: I don't know if it's a procedural question or what. Specifically in the proposed rules on page 50971, in the middle under *Updating NIOSH-IREP,* it specifically mentions the Board here, and it says improvements may also be directly recommended by the Advisory Board, which is us; and it also in the next paragraph talks about substantive changes will be submitted to the Advisory Board for review. I guess my question is our comments at this point, are those considered to be the review? Are we going to be getting your revisions?

MR. ELLIOTT: For the IREP?

DR. ANDERSON: For review? I guess it's —

MR. ELLIOTT: That'll be at a subsequent meeting.

DR. ANDERSON: Are we review and approve, or what is the process for subsequent changes? I mean, a lot of this is — in the rule is fairly non-specific. It lays down kind of the approach, but doesn't get into the specifics. And really my question is how easy will it be to make changes? Or will you have to go back through a rule amendment process, or — clearly, as you gain some experience and we track that as a Board, we may be making some recommendations on some of these issues. And I just wasn't clear as to what was going to be our role in that versus our role at this point, which is kind of a — leading a public comment. Are we still just in a public comment thing subsequent, or do we have a special standing of some kind?

MR. ELLIOTT: Well, your role today is to review and evaluate and comment on this rule.

DR. ANDERSON: Yeah.

MR. ELLIOTT: And this passage that you've quoted from this rule, as I take it — and I'll

look at others to help me out here – if there are changes to the IREP that we're going to make, that's separate from this rule. They will be brought before this Board so that you can evaluate, review and comment on those substantive changes to IREP. Does that –

DR. ANDERSON: Okay, I see.

MR. ELLIOTT: Does that answer your question? We don't have anything to present to you today on modifications to IREP based upon comments we've received.

DR. ANDERSON: Right, okay.

MR. ELLIOTT: Okay? We may make minor changes to IREP that won't be presented to this Board. And I think one of them that I could give as an example, Gen Roessler's come up to us, and we've had other comments about this, too, on the little pie charts, the little –

DR. ANDERSON: Yes.

MR. ELLIOTT: – you know, the pieces of the pie don't look proportional to the percentages. We'll make that change, and you're never going have a chance to say anything about it, I think.

DR. ANDERSON: Okay.

MR. ELLIOTT: But if it's substantive in

nature, yes, we'll bring it here to the Board.

DR. MELIUS: Can we go into that, I think maybe a little bit, because I'm still a little bit confused, Larry, on this process, because changes in IREP are going to have an impact beyond — it's more than a minor technical change. They obviously could affect a number of claims and retrospectively lead to changes in how claims have to be reviewed again, and so forth. And has anybody sort of thought through the process for that and a timing for that? We keep making a series of adjustments, or is it going to be every six months? I mean, obviously to some extent that's dependent on new scientific data and so forth down the road, but —

MR. ELLIOTT: We have had a little discussion about this, and we recognize that we need to address it and manage it to the point where we're not constantly coming forward with new changes. We need to be clear on the criteria that we use to say there is a change or a modification to IREP that we believe needs to be made, and here's why. What pieces or what points of criteria does this fit to justify a modification to IREP? And we would present that

to you.

We don't envision coming to each Board meeting and saying here's a new twist, a new tweak of IREP, or here's another change in dose reconstruction methodology. We think we need to have very clear justification and good scientific basis to make certain changes.

Does that help? That's not a very clear answer, but that's about all we can give you right now.

DR. MELIUS: That helps. What I would propose, because I think it affects how we work in our subcommittees and how what we comment on today, is that as we think about subject matter for future committee meetings that we devote a considerable amount of time to sort of background on the model IREP and so forth, hearing from NCI, hearing from others about that, and that we do that as sort of a series of briefings. Therefore, when it comes up to time to consider a change, we will be sort of prepared for that, and not have to push it into one meeting or whatever.

MR. ELLIOTT: That's a good point, good comment.

DR. MELIUS: Also that we don't then have to

get into, spend a lot of time dealing with those issues in terms of commenting on the rules today.

DR. ZIEMER: Right, right.

DR. MELIUS: That's the corollary.

DR. ZIEMER: No, the focus today is on the Part 81 itself, which is in a sense independent, although –

DR. MELIUS: Yeah.

DR. ZIEMER: Okay. Okay, let's proceed. Other questions or comments of a general nature?

[No responses]

DR. ZIEMER: Let me ask if the committee wishes as a whole to discuss any of the three questions before we break into groups? Or do you want to raise any technical questions with staff at this point?

[No responses]

DR. ZIEMER: There appears to be no urgent questions.

DR. ANDERSON: Do we have a copy of the rule for the – address question two?

DR. ZIEMER: This is the rule, this –

DR. ANDERSON: No, no, no, but I mean, if we're asked to compare it to –

DR. ZIEMER: Oh, I'm sorry.

DR. ANDERSON: — the atomic veterans, is it consistent with —

DR. ZIEMER: Oh, good point. Does the proposed — does the proposal appropriately adopt compensation policy as it has been applied for the compensation of veterans with radiation exposure. Help us with that one a little bit.

MR. ELLIOTT: In the technical presentations you got yesterday, there was mention of our evaluation and understanding of the precedent that's been set by the other compensation program for atomic veterans, and what we could use and build upon from that.

We don't have a report to share with you on that. We can bring that in. I think maybe the Government Accountability Office review report of that program is on our web site. I don't know if anybody printed that off. We could get that for you.

Certainly Mary or Jim or I could talk to in more detail about what we know to be their experience, and I think — is Mike Schaeffer here? – Defense Threat Reduction Agency is not here today, but he could have perhaps answered a question or two.

But essentially what we tried to do was get an understanding from that program as to what their experience has been and what their concerns or criticisms might have been from their constituents, from the workers who were being — or the veterans who were being compensated under that program, what were the good things and limitations that they experienced in that program. And we tried to address those as we could. We didn't spend a lot of time yesterday going through that for you.

Is there anything that Jim or Mary would like to add on that?

[No responses]

DR. DeHART: If there is someone here who could go into it in more depth — I was going to wait and find out which — one, two or three — I was going to get involved in before addressing that particular issue. But since it may touch on any of us or all of us, if there is someone that can provide more depth background on that, that would be helpful, I think, at this time, since all of us would be interested in this.

DR. ZIEMER: Okay.

DR. ANDERSON: We can't put a list up there

and a list, compare it and say it looks pretty close.

MR. ELLIOTT: This is a good question you raise, because this is a difficult question to answer without having more detail, which you're asking for.

DR. ANDERSON: And we recognize what you said, that you tried, you made every effort. And we can say — but it's hard to independently verify that. I guess that's how I see the question.

MR. ELLIOTT: Sure.

DR. ZIEMER: It's certainly a valid point to raise, so in fact it may be very difficult for us to really deal with that effectively.

DR. ANDERSON: Maybe we could just respond by saying we can't comment.

MR. ELLIOTT: We don't have any real hard-copy information other than the Government Accountability Office report, and we can certainly pull that up on-line. Maybe we should do that for you. That might give you a little more insight.

DR. ZIEMER: Larry, give us a little background on the question itself. Is there a

stipulation — I'm trying to recall if there's a stipulation in the public law itself that says that you have to appropriately adopt your policy to —

MR. ELLIOTT: Well, in the Act the ancillary supporting influence from this other compensation program would be the IREP.

DR. ZIEMER: Mary, do you have comment?

MR. ELLIOTT: That's one of the things we were charged with using, and that's used in the veterans — atomic veterans compensation program. We tried to talk through the experience of NCI's development of that IREP with you, and what modifications we sought and felt needed to be made to IREP that were applicable to the work force for the energy compensation program.

The Government Accountability Office was — report was critical in one aspect with regard to transparency in having an advisory body review their efforts, their work, their program. We felt we had that addressed with you all being appointed.

Does that help here?

DR. SCHUBAUER-BERIGAN: If I could just make two comments. I don't have the rule in front of

me, so I can't tell you exactly where it is, but it does refer to the use of the 1985 radioepidemiological tables to determine probability of causation, and then it adds as they are updated from time to time.

Another point I would like to make is that the draft NCI report, which I believe is part of your briefing book — Larry, did the committee receive that briefing book that you have in front of you?

MR. ELLIOTT: No, they did not receive this briefing book.

DR. SCHUBAUER-BERIGAN: Did they receive the NCI report?

MR. ELLIOTT: (Inaudible) web site.

DR. SCHUBAUER-BERIGAN: Okay, that actually is available, and we could get copies to you. But that has the NCI's justification for the development of the new software program, justifying the need for the changes and describing some of the effects of the changes.

The final NCI report, I believe, will go into even more detail about comparisons between the new tables compared to the 1985 radioepidemiological tables, but I don't believe

that's publicly available yet.

MR. KATZ: I'm sorry, Ted Katz, too.

Let me just add the other sort of major point in terms of adapting VA policy, was that as we discussed yesterday, in our case we basically gave DOL guidelines that were entirely objective, cut-and-dried decisions on their part; whereas Veterans Affairs has an element where in the case of an illness that's not covered, they have a decision, a judgment that's made, that's not written down on paper anywhere in terms of what the decision logic is for coming to that answer. So that's really the other major diversion in terms of the probability of causation rule. And then there are some differences with respect to the dose reconstruction rule, too. But that really covers it.

And I would just suggest that this is — this actually – this question is probably a lighter question, if you're thinking about dividing into three groups, there's not as much really discussion, I think, to be had on this question as the others. So you may want to consider that in terms of how you divide and conquer.

DR. ZIEMER: Exactly. It seems to be

leading in the direction of saying we may not have anything right now to say on this. It appears that we would need, as a minimum, some kind of a side-by-side evaluation, or something we could say here's what the veteran's policy was, and here's how we've adopted it to this. I'm envisioning something where we can actually — we need some information to answer the question.

Wanda, did you have a comment?

MS. MUNN: Yes, and the background that's given — granted, there is considerable background with regard to the development of the tables, et cetera. However, it sounds to me as though perhaps the GAO report may have condensed the VA program into a manageable piece of information. I don't know whether we have either the time or the willingness to do the kind of line-by-line comparison that perhaps some of us envision when we read this, does it fit. But at last the GAO report might be helpful for us.

DR. NETON: My recollection of the GAO report — I could be wrong on this, though — is I think it was primarily oriented at a review of the dose reconstruction efforts under the VA program that are conducted for DTRA, Defense

Threat Reduction Agency. So I don't sense that it would shed much light on this broader policy issue of the adaptation of the IREP, of the probability of causation tables. I might look at that closer, but I really don't think there's a lot of substantive information in there on that.

MS. MUNN: There must then be somewhere in VA.

DR. NETON: Well, I think there's a VA rule. I mean, there certainly is a — the VA has published a rule on their dose reconstruction — I mean, on their probability of causation.

MS. MUNN: I guess what I'm really grasping for is an executive summary of how the VA rule was applied and whether that was appropriate.

MR. ELLIOTT: I have the NCI report, draft report, and the National Academy of Sciences review, and this — and we can get you copies of that. I can pull up the Government Accountability Office report from the web site, and we can show that.

I don't believe there is a document that will enable you to go line-by-line and make a point of comparison. We don't have anything like that. We can pull the rule. We can get a copy

of the rule, perhaps, for VA. But I think you're going to find it doesn't match up to our rule in any shape or form. It's presented entirely different.

MS. MUNN: I'd expect the NAS report to have much of the information I'd hope to see.

MR. ELLIOTT: It's on the IREP. That's on the IREP.

DR. ZIEMER: Okay. Tony.

DR. ANDRADE: Paul, based on the comments from around the table this morning, I think I'm coming to the point where I think I'd like to suggest an alternative approach to dealing with those three questions, whereby we deal with these three questions at the end of the day for both proposed rules.

I think that the best that we're going to be able to do, given the time frame that we have, is to go paragraph by paragraph, as a committee of the whole, and request comments, questions, and/or issues that Board members may have with respect to IREP or questions regarding the origin of some of these tables, the applicability of some of the scientific methods that have been used.

Example, the dose reduction factor, other things. I have some general questions about how the physicians used criteria on screening. Did they take into account, for example, latency periods, or did the health physicists here use those things, use those types of data in IREP? I don't know if physicians did that beforehand, or you all are doing it in IREP. So that's a technical question that I have.

And then at the end of the day we summarize what questions we have, what questions this Board will be addressing, and in general how we feel about those three very high-level questions.

DR. ZIEMER: Okay. That certainly is a useful suggestion. Actually, the idea of going through this initially and asking for general questions is really along that same line, and maybe the issue is how much time we spend on that. And I think you're suggesting we operate for a while as a committee of the whole and get all of those questions out on the floor. And we can certainly do that, sort of paragraph by paragraph, and take as much time as we need on it.

DR. ANDRADE: Exactly. And some of the

paragraphs are trivial.

DR. ZIEMER: Sure.

DR. ANDRADE: They just state the obvious, and so those we can go quickly through.

DR. ZIEMER: Any other suggestions?

[No responses]

DR. ZIEMER: Certainly willing to proceed in — seem to be strong feelings one way or the other, but it's a good suggestion. And I think we'll be able to, by the end of that, see where we are, as you've suggested. At which point we can break into what probably will not be three groups anyway, if we need to break into it, because we're not going to be able to deal with that second one. We won't have any volunteers, right?

Okay, let's see how we're doing time-wise. Let's take a brief comfort break, and then we'll proceed with questions then. Fifteen minutes.

[Whereupon, a break was taken from approximately 9:29 a.m. until 9:51 a.m.)

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DR. ZIEMER: Now the path that we've agreed upon is to go through 42 CFR 81 more or less

paragraph by paragraph or section by section, and allow the Board members to raise questions or ask for clarification and make any appropriate comments they wish. So let us get the material before us, 42 CFR 81. We may come back to the section on comments invited where it has the three questions, because we have an alternate framework for question two, I think, which we can raise at the appropriate time that is a little more clear on exactly what is needed there.

Is there any – so let's go to Section III, I guess, which is called Background. III.A. is Statutory Authority. Are there any particular questions there that need clarification? Yes.

DR. ANDRADE: I'm not sure if the committee –

DR. ZIEMER: Use the mike there, Tony.

DR. ANDRADE: I would have assumed that the Board had had an opportunity to read the background section, and we just really optimize our time by looking at the proposed rule itself –

DR. ZIEMER: Okay.

DR. ANDRADE: – which is only two or three pages. And that way I think we can plow through it very quickly, and then refer back to the

background if necessary.

DR. ZIEMER: We certainly can do that. Much of the — there's a fair amount of technical information in the background section, so I think if there are questions on that it might be appropriate, however, to — but you're suggesting that we jump to —

DR. ANDRADE: Page 50974.

DR. ZIEMER: – page 50974.

Let me just ask if anyone wants to raise any issues on the background section. Let's give the opportunity at least. If not, we'll jump immediately to the main body. Realize the background section has a fair description of probability of causation and IREP and related matters.

[No responses]

DR. ZIEMER: If not, we will then skip to the rule itself.

The main guidelines, then, begin on 50974, and there's an introduction there with background information again, very brief; purpose and authority and provisions concerning the rule, and then definitions.

Okay, first question.

DR. ANDRADE: Let me start the questions.

Under background, Section 81.0, there are two paragraphs that establish categories of employees with cancer for whom PC must be estimated or determined, and in particular in paragraph (b), the category that is noted is the Special Exposure Cohort.

Now given that the Advisory Board is to suggest additions if we consider it appropriate to the Special Exposure Cohort, is there a subject matter expert here, either on the Board or in the audience, that can address at least very generally what methods or guidelines were used to establish the Special Exposure Cohort so that we might be able to use either similar methods, if applicable?

DR. ZIEMER: Larry, can you help us on that?

MR. ELLIOTT: If I understand your question, Tony, you're asking why was the Special Exposure Cohort established, or how was it established?

DR. ANDRADE: Not so much why, but how.

MR. ELLIOTT: Okay. Well, that's – let me try to answer your question, but before I do I would say that this category here under (b), what that is specifying is that those individuals who

are a member of a Special Exposure Cohort who are seeking compensation for a specified cancer as defined, that DOL will have to use these regulations to apply to that – no, not to apply to that. Not for the specified cancers, that's the second category. The first category is all of those other than that.

Now the Special Exposure Cohort, how was it established? Well, it was established to include the three gaseous diffusion plants, primarily because of what happened at Paducah. Unless somebody in the audience has something they wish to say about this, I do not believe that there was any scientific basis, any scientific basis for establishing the Special Exposure Cohort. It was an accommodation given to those individuals who worked in those facilities.

David is here, so let David Michaels speak to this.

DR. MICHAELS: Can I rescue Larry here? I'm sorry, my name is David Michaels.

I'm here – I'm a private citizen here on two accounts. One is I'm interested in this, but also I'm a consultant to the Department of Labor in putting this together. I'm on the faculty at

George Washington University School of Public Health, but probably more importantly I was the Assistant Secretary of Energy for Environment, Safety and Health during the period this was put together, and so was there at the conception and probably even before that, that flirtation period of this legislative proposal.

The Special Exposure Cohort – I could give you a little bit of history about it and how the categories that are in there were chosen. Congress actually decided – the Administration proposed including Paducah and then eventually other sites as a Special Exposure Cohort. The Senate came up with this concept of how to expand the legislation and the categories slightly differently from the Administration proposal. I'll try to give you a sense of both of those, if you don't mind.

The Special Exposure Cohort originally was designed, as Larry said, around – to address some of the issues that were detected at the Paducah gaseous diffusion plant. What we determined, after a great deal of investigation, were two things. One is exposures occurred to levels of two – not merely the uranium, which was what was

everyone thought there, but there was exposure to some of the transuranic materials because recycled uranium was used, which will come as no surprise, I think, to many people here in the audience. But it was a surprise to many of the workers in Paducah, and certainly to some of the other interested parties.

What we discovered, though, at the same time was there was an effort made over the course of the decades when the gaseous diffusion plant was in operation essentially not to determine what the levels of exposure were, and not necessarily take the proper precautions.

There is, for example, there's a memo from somewhere in the 1960's saying -- this is from — among the contractors at this point, saying that there's a new bioassay for neptunium and we have exposure, significant exposure to neptunium, and that has been well documented. There's a new bioassay; we should probably use it. There are about 300 workers who should be tested. On the other hand, if we test — if we use this new bioassay the union will ask for hazard pay. And so there was no — the bioassay was never employed.

So the history of that sort of activity led the administration to propose that we establish essentially a category within this legislation that looked very much like the people covered by the Radiation Exposure Compensation Act, which is legislation passed by Congress some years earlier, which covered, as many of you here know, people who lived downwind from the Nevada Test Site, uranium miners, and some of the on-site test participants.

In that legislation there are categories of people covered — for example, people live in southern, parts of southern Utah, or people who were on the test site who were not adequately protected from the exposures. And it was determined by Congress that if any of these people who were, we'd say, in the wrong place at the wrong time developed one of a list of diseases, they would be compensated with a lump sum compensation.

This was sort of an attempt to fit Paducah and then the other gaseous diffusion plants onto that model. And with a little bit of jimmying it sort of fit in, and then Congress then added — the official proposal, by the way, from the

Administration was merely Paducah. That was then expanded both by the Administration and Congress, and then Congress at the last minute added Amchitka to that.

The basic idea of the Administration proposal was to deal with this sort of egregious lack of information. Congress, however, looked at it a little differently, in that Congress said in putting this together — and this was really in the Thompson-Bingaman process — I think the members of the Senate said how do we know if there are other groups who are like the Special Exposure Cohort?

And in their thinking, they didn't really want to address the question of egregious misbehavior. They said, are there people who just have the sorts of exposures that we cannot figure out, and that we — and they really meant did we not do a good job, but they never said that. And then you certainly can't — I believe they were thinking about that, but there's certainly no record of that Congressional intent. So I wouldn't say that — I couldn't tell you that that was the formal Congressional intent.

But they said there must be people who have

significant exposures, exposures enough to possibly give them cancer, but we can't – this dose reconstruction process that we've been talking about here can't address that issue. And therefore we need to have a safety valve, a way to say these people should be in a Special Exposure Cohort. They were clearly exposed. We don't know what levels they were exposed to, but we need to have a way to take care of them.

DR. ANDRADE: Great, thank you very much.

DR. MICHAELS: Sure. I'm sorry I was late today, but –

MR. ELLIOTT: Thanks for the bailout.

DR. ANDRADE: That's exactly –

DR. ZIEMER: Thank you, David.

Continue, and then Jim.

DR. ANDRADE: That's exactly the type of answer that I wanted, because if there are other circumstances or we identify that there are facilities or situations in which that sort of activity has occurred, then clearly that would be the type of guideline that we would use to add or consider adding a group of people to the Special Cohort.

DR. ZIEMER: Jim.

DR. MELIUS: Just to continue on this issue, I don't know if I can tell from reading it because it's a bit confusing even to me, but I think that second sentence refers – there are – the list of cancers that are covered for Special Exposure Cohorts is different than the list that's covered in the general rule. So there would be – I believe this is trying to refer to Special Exposure Cohort members who have a cancer that isn't covered under Special Exposure Cohort. Is that – am I –

MR. ELLIOTT: The first category is anyone who presents with a cancer.

DR. MELIUS: Right.

MR. ELLIOTT: The second category is a member of the Special Exposure Cohort who presents with one of the specified cancers.

DR. MELIUS: Okay. Okay.

MR. ELLIOTT: So if a member of a Special Exposure Cohort comes forward and presents with a cancer not on that list of 22, they're in category one.

DR. MELIUS: Yeah, okay.

DR. ZIEMER: Okay, additional questions on Section 81.0? Gen.

DR. ROESSLER: Just a real quick one. I'm not that familiar with gaseous diffusion plants. What are the other – in addition to Paducah, what are the other plants that come under this, and Amchitka.

MR. ELLIOTT: Portsmouth Gaseous Diffusion Plant at Piketon, Ohio; K-25 site in Oak Ridge; and of course Paducah.

DR. ZIEMER: Any questions on Section 80, or comments on 81.1, Purpose and authority?

[No responses]

DR. ZIEMER: 81.2?

[No responses]

DR. ZIEMER: Then we come to Subpart B, Definitions. Any questions on the definitions?

DR. DeHART: The only question I would have is that there is no defining time to indicate employment. I assume that in the calculations used that that is considered, that somebody must have been an employee for more than X.

DR. ZIEMER: There's a minimum number of – it's two years or something – there is a – Larry.

MR. ELLIOTT: Well, the employment is verified. Before a claim would come to NIOSH, Department of Labor would verify the employment

through the Department of Energy, and also DOL would verify the diagnosis, either through a death certificate or a physician's report. So by the time we see it, by the time this rule would be used, the employment has already been verified.

To get a little more specific in answering your question, the Special Exposure Cohort members would have had to have worked 250 days.

DR. ZIEMER: Is that only in the Special Exposure Cohort, the 250?

MR. ELLIOTT: Yes, I think so.

DR. ZIEMER: No limit on the others?

DR. DeHART: In calculating exposure, the dose over time is considered, so —

MR. ELLIOTT: And it's dose at first employment through their dose at time of diagnosis.

DR. ZIEMER: Tony.

DR. ANDRADE: I must confess that the one piece of — the one document that I did not have time to read with great care was the paper that was presented on RBEs, Radiological — Radiation Biological Effect on these factors. Are we still using a definition that is based on the effect of

a different type of radiation as compared to, say, 200 keV, low-LET radiation photons? Is that basically still the technical definition?

DR. ZIEMER: We've got a subject matter expert here.

DR. NETON: I'm sorry, I'm not sure that I clearly understand the question.

DR. ANDRADE: Okay, I'm asking for clarification on RBEs, and how they are currently defined and being used in IREP or in your own calculations.

DR. NETON: RBEs are, as defined in ICRP 60, are the radiation weighting factors, which are essentially for purposes of compensation interchangeable, are the ones used in ICRP 60.

DR. ANDRADE: So they are relative to the effects that would be produced by low-LET radiation. Is that correct?

DR. NETON: Right, although there are some modifications for low energy X-rays that are different. Is that — Mary may have to help me out on the low energy X-ray section.

DR. SCHUBAUER-BERIGAN: Actually, the reference — I think Jim's referring to the RBE factors that are used in the dose reconstruction

process. But referring to the document you mentioned, which is written by David Coker and colleagues, the RBE is actually calculated — referenced to the high-energy photons.

DR. ANDRADE: High-energy photons.

DR. SCHUBAUER-BERIGAN: Yes. They're a separate set of factors for each of the different energies below what's considered high-energy photons.

DR. NETON: This brings up an issue that I was talking about yesterday, that when we do the dose reconstruction we will use the ICRP 60 radiation weighting factors to report a dose to the claimant that is somewhat similar to what they're used to seeing as far as applying these weighting factors, the radiation weighting factors.

But when IREP is run, essentially what happens is the weighting factor is removed, and then the RBEs in the Coker paper are applied with their uncertainty distributions about them. In most cases it's almost — it's comparable, very close. In certain cases there are some differences, and — in those weighting factors as they're applied in IREP.

DR. ANDRADE: Okay. And in IREP, then, if you have the distribution function of a weighting factor, then do you sample that distribution function as part of the mathematical technique to come up with — or do you come up with a weighted average or something?

DR. NETON: No, it's calculated just as if any other uncertainty in the IREP program. It is Monte Carlo calculation run-through sampling the distribution as defined in the Coker paper.

DR. ANDRADE: Okay.

DR. NETON: Whether it's a triangular distribution or a lognormal or whatever, it would run the calculation the prescribed number of times, a thousand iterations, sampling that distribution probability density as defined.

DR. ANDRADE: All right, thanks.

DR. NETON: It has the effect of adding to the overall uncertainty, because the RBEs are not known with discrete — constant uncertainty as defined in — as used for radiation protection purposes. When you apply an RBE of 20 for alpha, it is assumed for radiation protection that it’s known without error, and in IREP it pulls that out and accounts for that uncertainty in the

program.

DR. ANDRADE: Great, thank you.

DR. ZIEMER: Roy.

DR. DeHART: Looking at (o) just above, where we're talking about the radioepidemiological tables, and I was wondering if Mary could comment on this. David Richardson talked to the linearity of low dose. Could you comment on that, as well as the effects of age?

DR. SCHUBAUER-BERIGAN: We've received similar comments to the ones that Dr. Richardson brought up yesterday, as both part of our subject matter expert review and as part of the public comment. So I can't address how we believe that the program should be modified, if at all, to incorporate revisions from these comments.

But our thinking when creating IREP initially was where it was possible and made scientific sense, that we ought to rely on methods that had been reviewed by scientific panels. And the NCI document actually had been reviewed by an NAS panel which deliberated on those issues, whether the appropriate, relevant models were use for age at exposure, and for the application of a dose rate adjustment factor,

DDREF.

We felt that there was good evidence beginning to be brought out about differences or variations from these assumptions of DDREFs that had been used by NCRP and expert panels throughout both the U.S. and internationally. So it was our sense when developing this, the modifications to the NCI program, that greater evidence — greater weight should be given to a DDREF closer to one. And we tried to work with NCI to modify this distribution for our software, and I believe that we agreed with them in the end about the appropriate distribution to use. It gives slightly more weight, I believe, to a DDREF of one, and it includes a very — a small probability that there's in fact an inverse dose-rate effect and that the DDREF is less than one.

A place that we could look at this, if you really wanted to take a look at the distributions that are used, it's not — it is available on the IREP demonstration software, but you'd have to kind of delve deeply into those details, the model details. And we can set this up and go through that and show that to you, what the eventual distribution looks like. We have — the

software does not have modification for incorporating the possibility of enhanced susceptibility at older ages of exposure, such as the one that Dr. Richardson mentioned.

DR. ZIEMER: Any other questions on the section on definitions? Yes, Roy.

DR. DeHART: One other question. In the list of 22 cancers, historically I'm familiar with the sensitivity of many of those tissues to radiation, but not all. What are we looking at here, the various sources of radiation? Because some of these are not common certainly to gamma, so we must be looking at various sources.

UNIDENTIFIED: Where are you? What should we be reading?

DR. ZIEMER: You're looking at the list of –

DR. SCHUBAUER-BERIGAN: Yeah, this is the list of specified cancers for the Special Exposure Cohort. And again, that was established by Congress.

DR. MICHAELS: Let's – David Michaels again. That list only applies to the Special Exposure Cohort, and it has no relevance for dose reconstruction. It was chosen, though – it's simply the list that was taken from the Radiation

Exposure Compensation Act list, cancers that were passed by Congress, and then lung and bone were added because of the transuranic exposures. And that's simply – it was simply a political decision. There was no scientific discussion of that. Oh, and renal then was – right, renal then was subsequently added in the – by Congress to reflect also that that was in the – it was in the original Radiation Exposure Compensation Act list, but was not included in the EEOICPA initial legislation. Thank you for –

DR. ZIEMER: Thank you, David.

Roy, does that answer your question?

DR. DeHART: One other question. Because of the circumstances of aging in males, I realize that prostate is not normally considered. How is that handled in the reconstruction?

DR. SCHUBAUER-BERIGAN: Prostate is, as a non-specified cancer, is covered in the IREP software, so there is actually a prostate cancer model. You, in the dose reconstruction process, would have to calculate dose to a relevant organ, and Jim can speak to that. But then you would simply apply that dose calculation to the models derived from the Japanese atomic bomb survivor

data.

I believe that is collapsed into a larger category with other male genitalia, if I'm not mistaken. And this is one of the cancers that I believe has not been shown in that study to be significantly elevated. However, because of the range of uncertainty about that risk estimate, and given the nature of this software which samples from that distribution, there is some dose at which you could conceivably be compensated for that cancer.

DR. DeHART: So it's unlike chronic lymphocytic, which is excluded.

DR. SCHUBAUER-BERIGAN: Right, yes.

DR. ZIEMER: Okay, thank you.

DR. DeHART: Thank you.

DR. ZIEMER: Further questions, comments on that section? We're still in definitions.

[No responses]

DR. ZIEMER: Okay, Subpart C, Data Required to Estimate Probability of Causation.

Personnel (sic) and medical information, 81.5. No questions? Yes. Okay, Henry, then Tony.

DR. ANDERSON: My question is in the

race/ethnicity, is that now going to use the new race/ethnicity categorizations from the current census, which is quite a bit different than previously? And how is that going to be covered, because it won't necessarily deal with — for skin cancer it's pigmentation, not ethnicity —

DR. SCHUBAUER-BERIGAN: The categories that are used in the skin cancer models are based on, you're right, on old definitions. At this point we don't have incidence data for cancers for these different classifications, and so it would be very difficult to make use of those.

So this is a subject of some obvious debate about how to actually enact this when a claim comes in. And our recommendation is that the claimant self-identify as one of the categories that have been included in the IREP software, which are, I believe, white — and that's divided into Hispanic, non-Hispanic — African-American, Asian, or Pacific Islander and Native American. Those are the categories used. And if a claimant were to identify as more than one race, then the calculation should be done several times and the higher value used. So the burden is on the claimant to identify, self-identify race and

ethnicity.

DR. ANDERSON: Again, generally the risk is related to the amount of melanin in the skin. Are you going to – is there any process here for the physician or somebody to deal with skin color actually, or the pigmentation? And I could see somebody identifying their race, but – and that might exclude them, but they could be very light-skinned.

DR. SCHUBAUER-BERIGAN: Actually, the way that the software operates, there are no – there are not different risk coefficients for the different ethnicities or race groups. The only variance in the program is in the background incidence rate, and this affects how the risk coefficients are transferred to the population.

DR. ANDERSON: I gotcha.

DR. SCHUBAUER-BERIGAN: It would be very difficult – we don't have any incidence rates for people with different levels of – it's a very crude level of categorization that has – that the data exists at.

DR. ANDRADE: My question, I –

DR. ZIEMER: Use the mike, Tony, please.

DR. ANDRADE: My question, again – I

mentioned this earlier – had to do with the use of latency periods to establish whether or not a given diagnosis was a credible one. Are those latency periods determined in the initial screening, and/or are they used in the IREP software?

DR. SCHUBAUER-BERIGAN: Let me answer the second part first. They are addressed in the IREP software, and each cancer has a set of risk models that adjusts for latency. There's a factor that's applied to all cancers as a default, which I believe assumes at least somewhere between three and five years latency required, and there's a step function that goes between three and five years. Other cancers, such as leukemia, have different latency functions because the risk across latency is very different for that cancer than for a cancer with long latency, such as lung.

To answer your first questions, I believe there is also in the Department of Labor program some requirement that the cancer have occurred at least five years after they began work – is that not right? Only for Special Exposure Cohort, okay. So if you're in the SEC, there is a

latency requirement built into the DOL's program. When a claim comes in that has to be verified. But for the IREP software, that would be handled on the calculation of the probability of causation.

DR. ZIEMER: I'd like to ask for further clarification. Does the program consider only the exposure window that meets the latency time period? In other words, subsequent exposure that's more recent is excluded in the calculation, or how is that handled? Do you understand my question?

DR. SCHUBAUER-BERIGAN: Yes. Certainly exposure after the incidence of the cancer is not considered.

DR. ZIEMER: No, no, I'm talking about exposure after the – after the latency –

DR. SCHUBAUER-BERIGAN: Yes.

DR. ZIEMER: – period.

DR. SCHUBAUER-BERIGAN: Yes. So that is not –

DR. ZIEMER: More recent, but after – but prior to the –

DR. SCHUBAUER-BERIGAN: Yes, you're correct.

DR. ZIEMER: Okay, it does do that.

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: Pardon me? I'm not talking about another source. I'm talking about exposure that occurs — say the latency period is five years, and the start of exposure was ten years ago and the person's been exposed for ten years. Does it only consider the exposure that you would say logically contributed toward the cancer as the dose of interest?

DR. SCHUBAUER-BERIGAN: Well, you would input the doses throughout the entire period, and the program uses the Monte Carlo simulation to select basically the latency for that exposure. And so exposures that occurred in between that selected latency — say it was two years. Exposures that occurred less than two years prior to the diagnosis of cancer would not contribute to their risk estimate.

DR. DeHART: Smoking is indicated as an adjustment on lung cancer, but the relative risk for smoking for upper respiratory problems — cancers — for bladder, for pancreas, are also significant. Were those considered in any way?

DR. SCHUBAUER-BERIGAN: That is also a point that was raised by several reviewers, and at the

time we recognized that that's true, and that lung cancer is the only cancer that has an adjustment, although other cancers are related, obviously, to smoking.

I think the sense of NCI when they were developing initial software is that the only cancer for which we had both information about association with lung cancer and information about the interaction between radiation exposure and that cancer risk and smoking is lung, trachea, bronchus and lung. And so that issue would, in our minds, have been tabled to future versions of IREP when better scientific information is available.

DR. DeHART: Thank you.

DR. ZIEMER: Sally.

MS. GADOLA: I also have a question that has to do with date of the diagnosis and with latency. Many cancers are not diagnosed for many, many years, like multiple myeloma. And I know that we talk a lot about the uncertainty as far as the doses of radiation, but it seems that there is a great deal of uncertainty in a clear diagnosis and the date of the diagnosis. And I would like to hear other comments from other

Board members and the experts here to clarify this, if possible.

DR. SCHUBAUER-BERIGAN: That's a very important point, and it's not one that we considered directly when we were developing IREP. That problem exists in studies on which these risk estimates are based, and it's sort of a ubiquitous problem throughout the medical community.

I would say, though, that the effect of that delayed diagnosis of cancer would be, I believe, to increase the claimant's chances of getting a favorable result since you would be excluding less of their dose. There are some exceptions to that, obviously. If you've missed a leukemia, since leukemia has sort of a wave-like function after exposure in the risk — the risk goes up very steeply for a few years after exposure, and then it tends to decrease. So if you've misdiagnosed a — if you've delayed the diagnosis of a leukemia, then that could be to the — add to the effect — to the detriment of the claimant. But we really haven't, I don't believe, got a way to address that at this point.

MS. GADOLA: Thank you.

DR. ZIEMER: Okay, we will proceed then. We have next 81.6, Use of radiation dose information.

DR. DeHART: If there is a mixed exposure, do you plot each source or each type of exposure independently in a mixed exposure situation – X-ray, neutron?

DR. SCHUBAUER-BERIGAN: In the IREP software there's a component for every type of exposure for each period of time. So if one were – had four exposure periods and were exposed to three different types of radiation, there would be twelve exposures for that person, and you would enter the year that each occurred and the dose distribution, et cetera. And those excess relative risk estimates are developed for each exposure, and then added together to produce the final probability of causation estimate.

DR. ZIEMER: Okay, we'll move on to Subpart D, Requirements for Risk Models Used to Estimate Probability of Causation.

81.10, Use of cancer risk assessment models. Henry.

DR. ANDERSON: Actually I want to just briefly go back to the dose, and just ask –

you're going to be gathering exposure information through interview and a variety of information. Do you have a process for how you're going to reconcile differences? I mean, you're going to get some qualitative information from the worker, from other coworkers, that may contradict what the measurement data is, and —

DR. NETON: Right.

DR. ANDERSON: — what's the strategy?

DR. NETON: That's an issue that we touch on briefly in the dose reconstruction rule.

DR. ANDERSON: Okay.

DR. NETON: I don't know if we want to get into that here or not, but —

DR. ANDERSON: Never mind. Never mind.

DR. NETON: Okay.

DR. ZIEMER: Yeah, when we get to part 82, that deals specifically with dose reconstruction.

Okay, use of the cancer risk assessment models?

DR. ROESSLER: Are we on (a) or (b)?

DR. ZIEMER: Well, we're just kind of skimming through. We'll start with (a), and if nothing on (a), we go to (b).

DR. ROESSLER: Okay.

DR. ZIEMER: Gen Roessler.

DR. ROESSLER: The word in here that catches my attention is change, and that's what I want to address. At this point in time, after hearing the presentations and hearing the answers, there's no question in my mind about the NIOSH using the best science. That's been reconfirmed in my mind over and over again at this time. And I think basing the best science on decisions of panels is very appropriate. They can't look at every little individual paper or something that comes up, so I think that's all appropriate.

My concern is how change is handled. There's going – there are a lot of things that are coming up, new studies, new information on bone cancer, on some of the things Roy pointed out where they're going to update. And that, again, is appropriate. When there's sufficient information to update the information that goes into these calculations, it should be done. I'm wondering how that's going to be handled – and I think Jim brought this up this morning – what our input is going to be. I think that we should have input into it because that has a great impact on the claimants.

These uncertainty bounds that I brought up yesterday, when they're so great in certain cases now, certainly is in favor of the claimants. As more information is acquired and incorporated into this, this could change. And my question really is, how are those changes going to be addressed with time?

DR. ZIEMER: I think maybe Larry, you need to — okay, you got one of your people to — the change master.

MR. KATZ: It's Ted Katz here.

Yes, and we address that in the preamble, actually. So those changes, before they are effectuated, will be proposed to you, will be proposed publicly because they will be part of the *Federal Register* notice for the Board meeting that's coming up. So they'll be explained in that meeting and in the *Federal Register* notice. They will be proposed to the Board. The Board will have an opportunity to deliberate over those changes before they are effectuated, and they'll know the results. So there'll be a public process, with you right in the middle of it, for deliberating over those changes.

DR. ROESSLER: Okay. Then my follow-up

question is how do you define changes? I'm assuming that this only — you only have to go through this for really major —

MR. KATZ: Exactly, and that's what we discuss, is this process — you'll actually have information whenever we make changes, but you won't have to deliberate over, as Larry explained earlier, over changes that don't have consequence for claimants.

DR. ZIEMER: Jim.

DR. MELIUS: Is there a reason that the process is not reflected in the regulations? Why is it in the preamble and not in the regulations?

MR. KATZ: It's in the preamble because — because — well, I'll just say because HHS believes that that's the appropriate place to address those procedures.

DR. MELIUS: Can you elaborate on —

MR. KATZ: Well, that's really — it's really very simple. HHS made a very clear determination that those — that procedure should be part of the preamble.

DR. MELIUS: Is that a legal recommendation, or is that a policy —

MR. KATZ: I think it’s a — it's a

combination of legal and policy, but this comes from HHS. This was a determination made by HHS, that that belonged in the preamble.

DR. MELIUS: That's not a very satisfactory answer, Ted.

MR. KATZ: It's a completely frank –

UNIDENTIFIED: It's honest.

DR. MELIUS: I didn't say it was dishonest, I just didn't say it was very satisfactory.

MR. KATZ: – unabbreviated, unedited answer, is all I can say.

DR. ANDERSON: What are the consequences, I think is really the question.

DR. ZIEMER: Well, do you have a concern that if it's not codified in the rule itself that it somehow can be bypassed?

DR. MELIUS: Yeah, that was sort of the question I'm trying to get. How was this procedure –

MR. KATZ: The legal consequences of it being in the preamble – exactly right – means it's not binding by law. It's not binding. It's – because it's in the preamble it's still within the discretion of the agency to apply that procedure. But I think the thing was, you put it

in the preamble, you make the procedure public, and the public will hold you accountable to that procedure.

MR. ELLIOTT: It is certainly something the Board can comment on. I think if you –

MR. KATZ: Right. This is – it's open to comment, absolutely.

MR. ELLIOTT: – if you feel strongly that that procedure needs to be clarified and outlined and presented in the rule, not in the preamble, that's where you should make your comment.

DR. ZIEMER: Okay. Tony.

DR. ANDRADE: I'd like to agree, and to back Dr. Melius' suggestion that somehow we consider the question of including language within the rule, even if it's simple, for the sake of transparency to the public that changes may occur, and that these changes, when substantive, will come to the attention of the Board, and therefore will be published in the *Federal Register,* et cetera. Again, for the sake of transparency.

Also, although this is not one of my concerns, certainly Shelby – the person who spoke to us from the Department of Labor yesterday –

DR. ZIEMER: Shelby Hallmark.

DR. ANDRADE: — Hallmark, was very concerned that changes could bring compensation levels down or up. And I feel that that's really — whether they go up or down shouldn't be so much a concern to us as making clear to the public why these changes have occurred. And therefore I think there's a good basis for having — for including language there.

And I would propose that the Advisory Board submit this as a comment on this proposed legislation.

DR. ZIEMER: Are you proposing that at this time as a formal action?

DR. ANDRADE: Yes.

DR. ZIEMER: So you can certainly do that, and —

MS. MURRAY: Could you repeat that, please?

DR. ANDRADE: I don't know if I can repeat it, but let me try.

I would like to propose that the Board comment to HHS that we include language on the probability or the possibility that compensation levels may change as a result of new science being added into the modeling process that is

used to determine those – the probability of causation.

DR. ZIEMER: If I might, Tony, Henry has pointed out that there is language to that effect in the preamble, and the issue would be to move the –

DR. ANDRADE: To move it?

DR. ZIEMER: – language into the body.

DR. ANDRADE: Yeah, I think that's –

DR. MELIUS: Yeah, they mention change in the regulation, they just don't mention the process. We want to move some sort of process language –

DR. ZIEMER: So is that the intent of your motion, is to move that language into the body of the –

DR. ANDRADE: Yes.

DR. ZIEMER: – the rule itself?

DR. ANDRADE: Exactly, and clarify these two points. One is that some general comment about process should be included, and I think that that language is there. However, it should also be noted that changes in compensation levels as a result of changes in science, and therefore PC –

DR. ZIEMER: Right, and those words are in the present language.

DR. ANDRADE: — may occur.

DR. ZIEMER: Yeah. So the motion, I want to hear a second on that.

DR. MELIUS: I'll second.

DR. ZIEMER: And to second it is to recommend to NIOSH that that language dealing with change be made a part of the rule itself so it's very clear that it's a requirement.

And just parenthetically, I might add, we're not talking about, for example, changes in IREP that make it easier to use or make it prettier or whatever, make the pie charts right. We're talking about things that affect the outcome.

DR. ANDRADE: Yes.

DR. ZIEMER: And did we get a second to the motion? Jim, you seconded.

DR. MELIUS: I seconded.

DR. ZIEMER: Is there further discussion on that? Yes, Wanda, please.

MS. MUNN: I would suggest we be very careful in the wording of that particular statement. I personally would not use level of compensation. That would lead people to believe

—

DR. ZIEMER: Yes, the compensation amount is a fixed amount.

MS. MUNN: It's set.

DR. ZIEMER: The awarding of compensation is the issue.

MS. MUNN: So one — yeah, yeah.

DR. ZIEMER: And I believe —

MS. MUNN: The probability of compensation.

DR. ZIEMER: The words are on page 50971, middle column, second full paragraph. It says substantive changes that would substantially affect estimates of probability of causation . . . will be submitted to the Advisory Board on Radiation and Worker Health for review. It also goes on to talk about public comment. I believe that's the language.

Is it — would that — if that's the language that we're talking about in the motion, would that be suitable, Wanda, as you understood it?

DR. ANDERSON: Just put after substantive changes, changes which would affect.

DR. ZIEMER: And it says here, changes that would substantially affect estimates of probability of causation calculated using NIOSH-

IREP.

DR. ANDRADE: That certainly addresses my concern. I'm not sure if that completely addresses —

DR. MELIUS: No, it does.

DR. ANDRADE: — Jim's concern.

DR. MELIUS: It does.

DR. ZIEMER: Then by implication it affects the award if it affects the probability of causation. We don't have to say the awarding of compensation.

MS. MUNN: No.

DR. ZIEMER: Is it still the same motion? I think it is.

MS. MUNN: I think so.

And I'm still — I don't think this needs to be incorporated in the language, but a procedural issue for my own edification. I'm assuming, then, that any substantial change which would affect a category of claimant would then be pulled out for review after the fact. For example, had a claimant already been rejected at the 43 percent level, say, and this new information might affect that individual, do we then retroactively look at that claim again?

MR. ELLIOTT: Yes. Yes, we would.

DR. ZIEMER: Parenthetically, what if the new data would have invalidated an earlier claim?

MR. ELLIOTT: No, we don't.

DR. ZIEMER: We send the collectors out to –

UNIDENTIFIED: You can’t get it back.

DR. ZIEMER: Further discussion on this motion?

Ted, please, you have a comment pertinent to this?

MR. ELLIOTT: We have had discussion on this. I think it would be helpful to –

DR. ZIEMER: Go ahead, yes, please.

MR. ELLIOTT: This is a concern we do have.

MR. KATZ: So yes, that's an obvious issue. That’s an issue that concerned us.

And I believe – and Pete's here, who could speak more specifically to the DOL rules – but I believe under the DOL interim final rule now, a claimant has a time period to bring back a claim that's been denied as a result of new information. This is exactly that sort of new information, so there's that opportunity. Also, the Department of Labor has its own authority,

with no time constraints whatsoever, to review a claim, to reopen a claim on the basis, for example, of new information.

DR. ZIEMER: Okay. We're ready, then, to vote on this motion. And if this motion passes, this will become one of our specific recommendations. This will require at least six votes.

MS. MURRAY: May I have a clarification for the minutes? Is the motion now in effect to move this, verbatim, into the body of the rules?

DR. ZIEMER: Yes, and thus have the effect of becoming part of the rule.

DR. ANDERSON: And the Board becomes (inaudible). The first action of any board is to (inaudible).

[Laughter]

DR. ZIEMER: Okay, are you ready to vote? And a vote of six or more will cause this to pass.

All in favor say aye.

[Affirmative responses]

DR. ZIEMER: The Chairman is also voting aye. And all opposed say no.

[No responses]

DR. ZIEMER: The motion carries. Again, a sort of unanimous consent, it appears.

DR. DeHART: A procedural question on the motion, basically. If this is published, as it will be, any change in the *Federal Registry* for public comment, I assume the Board will be provided all public comments to review.

MR. ELLIOTT: Oh, you mean if we have a substantive change?

DR. DeHART: Yes.

MR. ELLIOTT: Yes. Yeah, we will, as we have on these rules here, any further effort to change the rules or to change IREP or the SEC guidelines when we present those to you, we'll share all those comments with you.

DR. ZIEMER: Okay, thank you.

Let us proceed. That was 81.10, subset (b). Anything else on (b)? There are several subparagraphs there numbered (1) through (5) under (b).

[No responses]

DR. ZIEMER: Okay, we'll move on. We can always backtrack if something pops into your mind. Let's move on then.

Now we come to 81.11, which is the use of

uncertainty analysis in NIOSH-IREP. Paragraph (a), the use of uncertainty in the calculation.

I do have one question on that. In the calculation, for example, for photons, I think you end up using acute exposures for external photons – and someone can help me if that's not correct – that's true. Is that a default position, or can you in fact use chronic if you have information that would – or is it automatically acute?

DR. NETON: Unless information's available otherwise, it would be acute. But the chronic scenario would be available as an option if it were obvious from the records that that were the case.

DR. ZIEMER: I hadn't tried it, but I wasn't sure whether the program mandated –

DR. NETON: Oh, no, no. It's not a default within IREP itself. It's actually imbedded within our technical guidelines for dose reconstruction for input, for creation of the input table that would go to the Department of Labor for probability of causation calculation.

Although, that being said, I'm not sure that I can envision with current personal monitoring

programs, how would we be able to ascertain a chronic exposure scenario.

DR. ZIEMER: Well, I don't know the answer to that, either, and that's sort of a dose reconstruction issue.

DR. NETON: Right.

DR. ZIEMER: My only point here was that it does affect what kind of distribution appears, and then that affects the uncertainty analysis as well. Okay.

DR. ANDRADE: Could I ask a question?

DR. ZIEMER: Tony, please.

DR. ANDRADE: That is taking a more conservative stance as well, isn't it, in the sense that at least for low-LET radiation when you have a chronic or – I mean, acute exposures, research has shown that the dose response relationship is higher. So it is a more conservative approach to –

DR. NETON: Well, it is to apply an acute exposure that was instantaneously delivered for the dose-rate effectiveness factor, that's correct. I may be stretching my limitations on my health physics knowledge, and Mary may have to help me out here, but there's also – it is a

DDREF, so it's dose and dose-rate effectiveness factor. And I believe as was pointed out yesterday, for exposures under 20 rem, I think is the way it was developed, the factor is – it wouldn't make any difference, I don't think, in the DDREF if you applied it as acute.

Is that correct, Mary?

DR. SCHUBAUER-BERIGAN: Not exactly.

DR. NETON: Okay.

DR. SCHUBAUER-BERIGAN: It's very complicated. And really, without looking in detail at the NCI's model documentation, it's very difficult to explain what happens.

But at some dose, some theoretical low dose, even for an acute exposure, there is applied the chronic DDREF factor. That acute dose, that acute low dose, though, is sampled from a distribution of possible low doses. And if Charles Land were here, he really developed that with NCI and could speak to much greater detail about how that's done. But that's documented in the NCI's revised software. That dose value ranges from – that so-called low dose value ranges from .03 to .2 sievert, so that would be 3 to 20 rem.

DR. ANDRADE: Thank you.

MS. MURRAY: Was that .03 to .2 sievert?

DR. SCHUBAUER-BERIGAN: Yes.

MS. MURRAY: Thank you.

DR. ZIEMER: Are we ready to go on to the next section? Okay, Subpart E, Guidelines to — no, I'm sorry. Yes, Subpart E, Guidelines to Estimate Probability of Causation. Required use of NIOSH-IREP, 81.20.

[No responses]

DR. ZIEMER: Okay, 81.21, Cancers requiring the use of NIOSH-IREP.

DR. DeHART: A question related to carcinoma in situ, which is sort of an interesting conundrum because the diagnosis in fact is going to imply treatment. It is not a metastatic disease; therefore the fact that you found it, you've cured it, in all probability. What was the rationale for including it?

DR. SCHUBAUER-BERIGAN: The rationale for including it is — this was a topic of some discussion as these regulations were produced. The justification was that as cancer screening techniques have improved in this country — and I'll use breast cancer as an example — carcinoma

in situ is frequently the stage at which cancers are caught and diagnosed and treated. And treatment, in many cases, is identical for a carcinoma in situ as it would be for early stage metastatic cancer.

And so it was felt that that – making that distinction between carcinoma in situ and a malignant early stage cancer could in fact punish somebody for finding a cancer earlier. And that is the application of a policy decision that was made, similar to decisions – when faced with an unknown like that, the decision should be made in favor of the claimant, which would be to consider that. And that's certainly something that is – should be considered as the Board makes its decisions.

One other factor I should point out is that for some cancers like breast cancer, the risk factors for carcinoma in situ are the same as for early stage breast cancer itself. And so one could argue that it's likely that radiation might cause those cancers or those carcinomas similarly as for malignancies.

DR. ZIEMER: Okay, we'll move on to 81.21, general guidelines for use of NIOSH-IREP.

Yes.

DR. ANDERSON: I notice there's a couple of places it says DOL will calculate probability of causation. Who's going to be actually doing this? Are you —

MR. ELLIOTT: The Department of Labor has that responsibility. That's part of their final adjudication of the claim. They will use our rule. They will use this rule and the information that we send them from a dose reconstruction report and the IREP to do that calculation.

DR. ANDERSON: So they'll basically get the table saying 53 percent, and they'll look at that and say meets the criteria, and that's — no?

MR. KATZ: They'll actually operate the IREP.

MR. ELLIOTT: They'll actually operate the IREP.

DR. ANDERSON: Okay, so they'll be doing all of that.

MR. ELLIOTT: Yes.

DR. NETON: Yes, it's our intent that they will receive essentially an Excel spreadsheet that will contain the detailed dosimetric

evaluation that we do, and then they will import that into IREP and actually execute the program and generate the results.

DR. ANDERSON: I see. So you'll just calculate or generate the dose.

MR. ELLIOTT: That's right.

DR. ZIEMER: 81.23, Guidelines for cancers for which the primary site is unknown.

I'm just reminded that that includes Table 1 as well, so if there's questions on Table 1. It's not very clearly identified, but it's the table right at the bottom. The Table 1 heading looks like a paragraph right under 81.23, but I think it is the heading for the table. Okay?

And we've already been informed as to how this will work in terms of multiple cancers and multiple calculations, and selection of the highest probability in adjudicating the claim.

81.24, Guidelines for leukemia.

[No responses]

DR. ZIEMER: No questions? Okay, 81.25. I have one question on 81.25 on the calculational method. Is there some assumption about the independence of the cancers where you have multiple cancers and do the combining of the

probability of causations? Or maybe a better way to frame that is the independence of the risks of those cancers.

DR. SCHUBAUER-BERIGAN: Yes, those are assumed to be independent probabilities for purpose of this calculation, and that is the derivation of that equation.

DR. ZIEMER: And if the two cancers are not independent – I'm not sure if I even know what that means in medical terms – is metastases in one organ – or primary/secondary situation, is that – or does this arise in that case?

DR. SCHUBAUER-BERIGAN: Here we're not referring to – obviously to a secondary cancer arising from a primary. But for example, if you receive – if you had colon cancer and skin cancer, it's likely that those are two independent processes leading to those two diseases. So that was the thinking in setting this equation up.

DR. ANDERSON: An interesting question, because skin cancer's going to be involved. Is the time relationship between the two cancers come into play at all? It would seem to me somebody could apply for, under the – getting an

early skin cancer, then since most of them will survive go on to another 20 years, develop a colon cancer, or a woman a breast cancer or something.

Now if they'd already applied and been denied under the earlier, would that still count in the subsequent one as opposed to having two cancers that occur within — simultaneously? Now part of this would be going — historically you look at people who are already deceased and they died of the second cancer, but their medical history suggests they had — and again, skin is relatively common and treatable.

UNIDENTIFIED: Combining helps them.

DR. ANDERSON: Yeah, combining helps them.

DR. SCHUBAUER-BERIGAN: Right.

DR. ANDERSON: Is there no statute of limitations, was really the question.

DR. SCHUBAUER-BERIGAN: No. This calculation could apply to cancers that — primary cancers that occurred decades apart. And you would compute each probability of causation independently for each cancer, and then apply this equation to combine the two.

DR. MICHAELS: May I just add one point just

for informational sake – David Michaels. Claimants would be eligible for only one lump sum payment though, even if they had multiple cancers. However, it's of interest to the Labor Department to determine which cancers are causal, because medical payments associated with each cancer have to be determined.

DR. ZIEMER: Let's see, we were at guidelines for leukemia. Were there any questions on – no, we're – I'm sorry, I passed that. We were on guidelines for claims including two or more. Any other questions on that section?

[No responses]

DR. ZIEMER: Okay, 81.30, Non-radiogenic cancers, including the tables.

DR. ANDRADE: Just out of general interest, I'd ask the physicians here on the panel if they are aware of any research that is indicating any other type of cancer that may be considered or that may possibly be non-radiogenic.

DR. ZIEMER: Roy.

DR. DeHART: I don't know of any absolutes, and in medicine that's very hard, even for chronic lymphocytic. There are certainly, as we

all know, various tissues that are more sensitive than other tissues, but I couldn't give you a tissue that would be non-responsive to radiation.

DR. ZIEMER: Henry, did you have any other comments that –

DR. ANDERSON: No.

DR. ZIEMER: Okay. It appears that that brings us to the end of the rule itself.

DR. ANDERSON: Oh –

DR. ZIEMER: Oh, another question?

DR. ANDERSON: When the ICD changes – it's happening as we speak – are you just going to update the tables? Are you going to have to go through a rule process? You need to put in here somewhere so that you don't have to go through this rule-making process –

MR. KATZ: Yeah.

DR. ANDERSON: – when the codes change.

MR. KATZ: I think this falls – and I don't remember the term – but these sort of technical, non-substantive changes can be done without going through a rule-making process.

DR. ANDERSON: Well, just be sure that you can do that because it saves you a lot of headache.

DR. SCHUBAUER-BERIGAN: We actually considered — ICD-10 is in effect right now. However, the risk models on which —

DR. ANDERSON: Are all based on —

DR. SCHUBAUER-BERIGAN: Yeah, are based on ICD-9 classifications.

UNIDENTIFIED: Say that again.

DR. SCHUBAUER-BERIGAN: To repeat, the risk models are in ICD-9 codes, and therefore — you can still code any cancer, incident cancer or case of a death in any of the ICD revisions. So it's not a requirement for this program that they be done in the most current revision of ICD.

DR. ZIEMER: You're talking about the — adding to the list mainly, or are you —

DR. ANDERSON: Well, the numbers have changed, yeah. Some of the —

DR. ZIEMER: Oh, the coding numbers themselves, oh.

DR. ANDERSON: – broken down into different types that would otherwise have been included in this, now they'll have a separate category, so they might – you can always back-code your numbers. Generally you can translate backward, but it's more problematic going from 9 to 10.

DR. ZIEMER: Okay. Now opportunity for any other general questions on the rule, proposed rule.

[No responses]

DR. ZIEMER: Then we have completed that review. We actually even have at least one recommendation, made sort of progress.

We do now have an opportunity to frame out question two of the preamble, and we're going to distribute the rule for Veterans Affairs – not overly long. And then referring to question two, I'm going to ask Ted – maybe some of his colleagues can frame what the real intent of question two is, and it really has to do with the use of the POC tables.

MR. KATZ: Yes, sure. There's really, I guess, two more specific questions under that question which you could address. And the first is are the categories sort of possibilities for changes to IREP the appropriate ones, because that is an adaptation.

DR. ZIEMER: That is changes of IREP from its use in the other –

MR. KATZ: Right, and those are specified – I don't have the section number in my head, but

you have it. You reviewed it actually just now. You went through that section as well, and you said you might return to it. But it's the section of the rule that describes what possible changes would be made to IREP. So that's the first question.

And the second question in terms of adaptation pertinent to this rule is our approach to in effect objectifying decisions where we're dealing with unknowns – for example, not knowing the primary cancer, or for example not having necessarily a best, single best model. Is that appropriate, using that objective approach versus what is applied at Department of Veterans Affairs when you have, for example, a disease that's not included, is you have in effect an expert judgment being applied. So it's not a consistent – it may be – the expert judgment may be consistent, but it's not laid out objectively and cut and dried.

DR. ZIEMER: Larry, do you have anything to add to that, or any of the other staffers?

[No responses]

DR. ZIEMER: So this question would really take the form of does this rule appropriately

adopt the IREP model to this work force? Is that a fair way of –

MR. ELLIOTT: I think that is.

DR. ZIEMER: And the primary changes on that adoption are what?

Henry, did you have a question?

DR. ANDERSON: Yeah, my question is some of these things in the Veterans Affairs issue, like the referral to independent experts, if they're to reconcile, which is kind of one of the questions I had, how would that be done? Is that something that will be in the Department of – since basically you're not going to be doing it, you're going to dose reconstruct, it's how do you – I guess my question is where does Department of Labor come in in this? When they make the determination, do they have a process that's somewhat qualitative rather than strictly quantitative?

I mean, like that's kind of what the VA has here. If there's an issue needs to be decided, it can be sent to, as you say, for expert opinion; where here what you have is basically a model. You fit the data you have into the model. The only thing would be when we get to dose

reconstruction, if you say you can't do it, then the question is is it your responsibility to come up with an alternative process? Or do you just leave that to Department of Labor, and they would decide whether the person would go into a special group or be handled in some other way?

MR. ELLIOTT: That's where our Special Exposure Cohort guidelines –

DR. ANDERSON: And that's coming later, okay.

MR. ELLIOTT: – come into play, and that's coming down the pike. We don't have that –

DR. ANDERSON: Okay.

MR. ELLIOTT: – ready to present to you today.

DR. ANDERSON: Because it seems you're just – most of your rule is the mechanics.

MR. ELLIOTT: Yes.

DR. ANDERSON: And therefore, once you have the program on-line, you can put something into a field. But you can't add fields, you can't – your choices are relatively –

MR. ELLIOTT: As Jim Neton mentioned earlier, it's our intent to deliver a dose reconstruction report to the claimant, to

Department of Labor, and Department of Energy. And what Department of Labor's going to get in that dose reconstruction report is an Excel spreadsheet that has all of the input parameters for the IREP from that dose reconstruction. It takes out all of the subjective interpretation on their behalf to provide a very objective, specified parameters to plug into the program. And then all they have to do is hit that one –

DR. ANDERSON: Yeah.

MR. ELLIOTT: – submit data button and put the calculation, and they have the recommended decision based upon that.

DR. ANDERSON: If it goes into the program correctly.

MR. ELLIOTT: Yes, if it all meshes together correctly.

DR. ZIEMER: Any further questions or comments of a general nature?

Okay, I want to look at the schedule here for a minute.

DR. MELIUS: Can I just ask one question?

DR. ZIEMER: Yes, Jim.

DR. MELIUS: Are we going to comment on the three questions? I'm a little confused

procedurally.

DR. ZIEMER: Yes.

DR. MELIUS: Okay.

DR. ZIEMER: At least on two of them, and maybe three of them.

DR. MELIUS: Okay, because I have some comments about how we'd want to go about doing that, but I think if —

DR. ZIEMER: Right.

DR. MELIUS: — you go ahead, that's fine.

DR. ZIEMER: I just want to look at the schedule here, and just alert you we have a public comment period after lunch blocked off for an hour, but we will only have one person after lunch who's asked for one minute. And we have another one before lunch who needs five to seven minutes. We actually have a third one now, okay, David Richardson. We need to do at least one of the public comments before lunch. We can do the others then as well, with the permission of those commenters if they're willing to do them earlier, and then talk about how we proceed on answering the three questions.

We have basically one presentation this afternoon on dose reconstruction, and the rest of

the time is then available as a working session.

If it's agreeable, we could go ahead with the public comment period now and take a little break from this line.

Then let me ask Robert – is it Tabon?

MR. TABOR: Tabor.

DR. ZIEMER: Tabor.

MR. TABOR: Tabor.

DR. ZIEMER: Yes, Tabor, yes. Okay, I read the R as an N, thank you. Robert, are you prepared to proceed? Could you use the mike in the front, please? Robert's with Fernald Atomic Trades and Labor Council.

MR. TABOR: I'll try to be as brief as I can and hold it to the time limit that I indicated. I have a couple of items here I'd like to share with you.

For the record, my name's Robert G. Tabor. I go by Bob Tabor. I only mention the Robert G. because we have a Robert C. at the site as well. I'm the only one, though, on the e-mail. I appreciate the opportunity that you're giving me to do this outside of your normal agenda there.

Let me give you just some brief background. I'm a 21-year veteran at the Fernald site. I'm a

journeyman millwright by trade. I've been in this labor business for about the last 17 to 18 years, have held a number of positions throughout our council.

And I guess I find myself mostly on special assignments interfacing with a number of folks in our organizations across the network, a number of folks at Washington in your health and safety field, which is principally – a lot of what I do is associated with that. I've interfaced with Dr. Neton and Grady Calhoun a number of times in various types of committees or programs, or things that we do at our site that involved their expertise. I know a number of you folks that are here.

I've met a number of labor folks from across the country at other organizations. I've been to every site, the primary cites in the nuclear network, with the exception of maybe Pinellas, which I believe is closed, and Weldon Springs, which I believe is closed. And the only operating site that I think I haven't been to – I haven't been to any labs – but the only operating site I haven't been to is maybe Pantex.

And I take a minute to give you that

background because there's many of folks out there like myself that have a lot of interest in the things that you're doing. And I've followed this program pretty much since its conception, maybe not as closely as Dr. David Michaels, where he mentioned he's been involved since the flirtation of the idea, but have made a number of trips. And I'm pleased to see that we have an organized Board, and I am happy that — or I should say I'd like to compliment you on the fact that you've gotten this far this fast.

Let me step off the track here a second and make a comment in the form of a question. As Dr. Mary Schubauer-Berigan — I hope I pronounced that correctly — as she was dissertating (sic) yesterday, a thought or two came to my mind. And I began to write a question that I had, more so as food for thought for you folks, and I wrote it down. So I'm just going to read what I wrote — if I can read my own writing, that is.

When new methodologies or technologies or better practices are discovered or employed with respect to the probability of cause, determining the probability of cause, and those new tools help to maybe render a decision more clearly,

what impact may this make on previous cases that possibly a lesser accurate methodology or technology may have caused a determination to be negative as opposed to a favorable positive determination that you might now get with an updated technology, inasmuch as a decision made on a case today with whatever tools that you have to determine or make those decisions might be a little different five years from now?

And as she was speaking — you learn as you listen — it came to my mind that, what if? And I guess as an example, if a new methodology more clearly helps to render a positive decision as opposed to an old methodology that may have had a negative impact, what consideration will be given to those previous determined cases that may have been denied?

Now I know we've talked about there's a lot of latitude designed into this program that — what do I want to say? I don't necessarily want to say weighs in favor of the applicant, but it certainly gives some latitude there for error or whatever. I think you know what I mean. And — but you may have cases that are very borderline, that today fall one way that tomorrow may fall a

little differently under the same set of circumstances for the most part.

So I'd like to offer that up as food for thought if you haven't considered that, and what that might come to as far as some decision-making from the Board in the future, keeping that in mind.

Now on a whole other note, I'd like to talk a little bit about the structure of the Board. As indicated, I said I compliment you on how far you've gotten so fast. I certainly appreciate the fact that we have a brother on the Board here who is a labor type. But I'd also like to piggyback some comments that Richard Miller made yesterday about the structure of the Board and the balance.

Let me put it in these words — and this is not exactly criticism; it's just simply comes from some experience that I've had. I didn't mention the fact that I'm on the Fernald Citizens Advisory Board, and I've been on that board since its conception. I'm also a member of FRESH. I don't know if you're familiar with that organization, but that's the Fernald Residents for Environmental Health and Safety. They're a

public activist type of a group that follows a lot of health effects, things that go on throughout the country, and attend a lot of meetings and are quite in tune with these type of things.

And I also — not as a member but as a participant from the audience — have attended the Fernald Health Effects Subcommittee when it was in session, and am following up on participating in another committee to continue with some of the efforts of that committee. So I have a big interest in this particular area.

What I might say with respect to structure of the Board is that if you really want to optimize your effectiveness or optimize your success, you really need to consider balance here. And what I'm talking about is other labor types on your Board. For instance, my friend right here, he's a representative of the labor type speaking for himself, maybe not so much for his constituency, because obviously that's the role that you need to play on the Board; and he comes from a laboratory.

Most of these claims that you probably will have before you are going to be claims from

workers at production type of sites. Yet you do not have the flavor of that element on your Board. And it could be quite helpful to you folks.

It's just a rule of thumb that I always use when I'm either chairing a committee or chairing a team to do something, the first thing I ask myself, what is it that I'm about to do; how does it — how and who does it impact? And when I identify that, I be sure that who it impacts is at the table for input, because it's going to render my decision-making a lot more thorough so I can do the right thing the first time. And it certainly helps when you're — to take that into consideration.

So I might suggest that if you have an opportunity to expand this Board that you consider getting some other flavors of labor from some of the production facilities, or at least somebody out there that's familiar with that. And as the gentleman pointed out yesterday, probably a lot of our sites are one of the largest bodies that's represented out there is OCAW, which is now, I believe, PACE, and also you have the metal trades. I belong to a metal

trades organization myself.

There's some advantages to that, and I would suggest that you take into consideration a couple of things. I'm sure that not just scientific data may or may not factor into your decision-making, but a lot of times operational experiences may have an important role in the decision-making.

A good example would be, in discussion with a friend yesterday, was telling me about an experience of one of their workers who had what is referred to, I think, as a shine. There was just — this person was radiated intensely and developed a cancer, a malignancy that normally doesn't metastasize itself in the pathway in which this did. But because of that particular little pinpoint zone that got radiated in the — by the nature of the way they worked, it may not even show in his dose reconstruction, on his dosimeter.

Well, how do we deal with those kind of cases? Those will be things I'm sure you may run into. And operational experiences will be vitally important to some of your decision-making. Having someone at the table that can

share in those things or has some insight could be really helpful.

Then there's another issue I'd like you to take in consideration. I come from a closure site. Part of the thing that the current CAB is looking at in the realm of stewardship — and I'm on the stewardship committee, as well — is our record-keeping.

Now I know Federally there are probably some laws that are in place that account for how we keep medical records, and those requirements will — the retention of those records will be protected. But there's other records out there that maybe are not laws from operational experiences that you may wish to say, hey, we may need to look at some of these things.

Well, keep in mind that just recently, especially at my site, there previously was a moratorium on records and record retention. That moratorium is being lifted. On closure sites this information is going to be going away, or it could go away. That may be an area that you may want to consider to look into as far as information that you may need in order to be thorough in some of the decision-making and the

processes of determining whether a claim is valid or not.

So I present you some food for thought with respect to that, with respect to the balance of the structure of your committee. And let me see here, in looking over my notes, is there anything I've missed? I don't believe so. That's all I've got to say.

DR. ZIEMER: Thank you very much, Bob, and your remarks will —

MR. TABOR: Do you have any questions?

DR. ZIEMER: — be included in the record, the transcripts.

Yes, are there any questions that any of the Board members have?

[No responses]

MR. TABOR: Thank you.

DR. ZIEMER: Thank you, Bob.

Next we have Fay Martin, LOC/CAP. Help me out, though, Fay. What is that?

MS. MARTIN: That's what I was going to explain. I'm Fay Martin —

DR. ZIEMER: And she's at Oak Ridge. I think you gave us those acronyms yesterday, and I forget what they are. Sorry.

MS. MARTIN: I'm Fay Martin, representing the Local Oversight Committee and the Citizens Advisory Panel of Oak Ridge. The LOC's composed of elected and appointed officials from the City of Oak Ridge and the seven counties surrounding the Oak Ridge Reservation. The CAP reviews and provides recommendations on DOE's decisions and policies.

Now long, long ago and far, far away there was a group called ACERER. That's the Advisory Committee on Energy-Related Epidemiological Research. As a member of their subcommittee, the citizens – and we have been led to believe that we as citizens should be involved and have input into what the government is doing on our behalf.

So I'm just here to ask a question. Are you going to have a citizens group appointed to work with this Advisory Board on Radiation and Worker Health? Does anybody know?

DR. ZIEMER: We'll let Larry answer that.

MR. ELLIOTT: Fay, there's distinct responsibilities this Board has, and those responsibilities were outlined yesterday. We certainly respect the interest of workers who are going to reap the benefits of this whole program,

and want their participation and their involvement, their observation of our work. We do not deny the public that opportunity as well. We encourage that. There is, however, no envisioned plan or need to incorporate a citizens advisory subcommittee to this body, though.

MS. MARTIN: Okay. It's just that I've been talking to some of the citizens, and they were wondering is $150,000 enough money to compensate for all the suffering they've had. And they have lots of questions that they'd like to bring to the Board. So I think their voice should be heard, also. Thank you.

DR. ZIEMER: Thank you, Fay. And again, your comments will be in the record.

David Richardson has asked to speak again today, and David, are you – yes. UNC Chapel Hill.

MR. RICHARDSON: Caught me a little bit ahead of time. But yeah, I'd like to again raise two points, two new points.

The NIOSH-IREP program that we've looked at – it's been up on the screen; it's kind of, again, a computer black box – has as its foundation a set of numbers that are coming from

a study of atomic bomb survivors in Japan.

I think it's important to stress — and I want to talk a little bit about that study as the basis for this first point, again from the perspective of an epidemiologist – and say imagine for a second the conditions under which that study began. Atomic bombs dropped on two cities. There are tens of thousands of people who died in the first weeks from injuries, from burns, and then subsequently from infections and the consequences of destruction of infrastructure.

So I think for workers and for the public it raises the question, which has been a question that’s been going on for decades with the life span study of atomic bomb survivors, is there selective survivorship? Or putting it another way, when you're studying the effects of radiation on a group of atomic bomb survivors, it's necessary that the effect of radiation on the survivors is the same as the effect of radiation in the general population you want to extrapolate to. So you don't want selective survivorship to bias the results.

As I said, this has been an issue that's

been raised by a number of critics. It was raised early on by the Atomic Bomb Casualty Commission as a consideration, could they even conduct such a study? In recent years, however, there's been several papers that have tried empirically to investigate this question – that is, looking for evidence that selection among atomic bomb survivors might bias dose response relationships.

And of particular concern it's been the hypothesis, which I think is a reasonable question, are the people who survived in the high-dose areas — that is, people who were close to ground zero — those people who survived now at least a minimum of five years to enter the study — they had to be alive in 1950 — were they robust people? Were they — when you have people exposed — and then you can think about this in lots of settings where people who receive high dose radiation exposures, some people are going to die and some people are going to have the constitution to go on living and survive the infections, the consequences of the burns — and then you begin studying those people, a robust group of survivors selectively picked out in the

high-dose areas, as in the low-dose, the far outreaching areas around Hiroshima and Nagasaki, there's less selection going on because radiation doses diminish with distance.

I would just like to draw the committee's attention, then, to a series of papers that have looked at that, including RERF Report 12 that was published in *Radiation Research* in 1999. There was an earlier study in *Health Physics* that came out late in 1990. And in 2000, I believe, in *Environmental Health Perspectives,* Stewart also investigated that question.

So now turning to IREP, I think a lot from looking at the way the IREP's dealing with the problems of — and this, I'd say, primarily is a question of bias, but also it's a question of uncertainty – there's some question about whether the study of atomic bomb survivors does have bias in it. So there's questions of bias and uncertainty due to selective survivorship.

And the IREP program's drawn heavily on NCRP Document 126. And the NCRP in that paper really does a good job of going through sources of uncertainty in radiation risk estimates. They come from the life span study, primarily focusing

on uncertainty in the radiation dose estimates, which I think is really valid.

There's a — and I would stress here again for the committee to remember that unlike workers who are wearing badges, the atomic bomb survivor dose estimates are derived primarily — and this is important to say — primarily from questionnaire data. And so people who have been participating in questionnaires know that there's questions, aside from uncertainties about neutron dose estimations and those things, questions about the validity of information that people give in questionnaires. That information gets put into a mathematical model and generated quantitative dose estimates for atomic bomb survivors.

But so there is — IREP has adopted many of the recommendations by the NCRP in Report 126 on how to deal with some of the uncertainties in radiation dose estimates in the life span study. There's a separate section, though, in what's called epidemiologic uncertainties in the life span study, and here selective survival is one of the issues that they raise, they address, and they recognize. And in fact, they point to the

Health Physics article in 1990. I believe the NCRP report came out before subsequent literature that's also been reported. But they conclude that there's evidence that there's bias, that the dose estimates from the life span study are probably biased downwards because of selective survivorship, but the degree of bias is probably fairly small, and they go on to focus on the dosimetry problems.

I would recommend to the committee two, at least two issues for consideration. One is there's a recognized small source of downward bias, and that's something that could be easily incorporated with using the same methodology as has been used for the other sources of uncertainty in the life span study.

The other question, though, is not just bias, but is uncertainty. Here you have another uncertainty factor, and it's something I think the committee can bring forward. Not just that the estimated degree of bias is small — and here we're talking about something like ten percent or — I'm not sure. For compensation purposes I think those are important factors. But then there's also uncertainty around that, because

it's to date not adequately quantified.

So I'll leave that as my first point, to take a look at NCRP Document 126 and consider bias and uncertainty arising from selective survival, which has been a point that's been raised in the literature now for decades. And I think the last decade has been very fruitful in documenting a negative dose response, particularly in the first 20 years of the A-bomb study between all-cause mortality and radiation dose. People with higher doses tend to be much healthier than people with lower doses, and that's evidence of selective survivorship in that population.

The second point that I want to talk about is a set of comments that I guess it's maybe — I'm going to make comments before the presentation has happened on dose reconstruction, and that's given the ordering of the agenda, the comments period is preceding the presentation. So I'm going to base my comments on a review of the handouts that are available over there on the side.

And just — I would like to point out for the committee's attention really the issue of neutron

dosimetry, which I don't see, except for the first slide, I don't see addressed, at least in the handouts. And I would argue that it's important for two reasons, the first reason being the biological effectiveness of neutrons and the uncertainty in the RBE factor for neutrons. And I'd argue that that uncertainty's largely because there's not been adequate — there's not been an opportunity to do a lot of epidemiologic research on the health effects of neutrons. And so necessarily, these RBE factors are uncertain. But the general consensus is that the biological effectiveness of neutrons is relatively high.

The other side of that is that the dosimetry for neutron exposure in the DOE complex ranged from non-existent to very poor for a long period of time. And it was an acknowledged limitation, and it was labor-intensive work. So there was limited neutron dosimetry that involved visual inspection of films. And so I think that's going to raise, again, an important — I think it's an important issue for the committee to consider, how to deal with periods where neutron exposures are uncertain, and the biological effectiveness of them is also uncertain.

Thank you.

DR. ZIEMER: Thank you very much. Could I ask – let's see, the RERF-12, was that the RERF report? I just – getting those references. Is that the '99 report?

MR. RICHARDSON: Yes.

DR. ZIEMER: And then the HP journal, do you know off-hand who the author on that one was?

MR. RICHARDSON: It's Little and Charles.

DR. ZIEMER: Little and Charles, thank you.

MR. RICHARDSON: First initials, M.P., Little, Charles, M.W. And the title's *Bomb Survivor Selection and Consequences for Estimates of Population Cancer Risks, Health Physics,* 1990, Volume 59.

The other – the RERF report was published also in the literature under the title *Non-Cancer Mortality, 1950 to 1990,* and *Radiation Research* in 1999, Volume 152.

DR. ZIEMER: Thank you.

Any other questions for – sorry – for David?

[No responses]

DR. ZIEMER: If not, Roger Shaw, McCarter and English.

MR. SHAW: Thanks, Dr. Ziemer.

A couple of points. Just a little bit of concern. I know that the Board, as it goes forward, will look at the meshing that we're having here of policy and sound science. It's something that we have to do. You can't separate the two completely, especially in this type endeavor. In fact, the way that the Act has been written, we – there are certain policy issues that are written in, and there is no changing that. That's understood.

But I think there's a lot of room, especially as we listen to IREP-NIOSH and what that constitutes, and the technical bases for that is very – there's a lot of complex issues in there, technical issues that hopefully you'll take a look at. There's very good people working in that, as we've witnessed, from NIOSH and other agencies through NCI, very good people working on these issues. But there are many issues within – just, for example, the use of that program – that need to be looked at very, very closely. And I would just say that we need to watch some of those applications.

I want to mention just two things. There

are new studies that go beyond where we've been with the primary risk coefficient bases, which have been the life span study of the Japanese bomb survivors, as David Richardson has mentioned. There are a number of studies that are going on at DOE, et cetera.

There's also a study that's due out later this year that many folks in this room have been associated with, including Larry Elliott and Dr. Richardson and actually myself, and that should be coming out at the end of the year from the International Agency on Research on Cancer. They're a national agency for research on cancer, IARC. There is a DOE, Department of Energy, cohort that's part of that study. There's also a commercial nuclear reactor cohort that's part of that study.

It's a 16-country study — was 17, now 16 — and it includes — it is the largest study of nuclear facility workers in the world. There's over 600,000 people within that cohort. Some of those people, a large majority of that dose is low-LET, not high-LET. There are flags for internal dose. There are flags for neutron, to separate people out that maybe you don't want to

mix apples and oranges. But I do want to make sure that you're aware. I know that Dr. Elliott will make you aware of that as part of the Board's activities. Hopefully that will be out by the end of the year. But I do want to mention that there are these issues of comparing populations like Japanese bomb survivors. These are actually nuclear workers, very large study.

The second issue I just want to mention again is — I'll let it go — but the DDREF and the DREF issues. We're applying it — it seems that we're applying for alpha an inverse DREF of a factor of four. In other words, we'll increase the risk from the dose if it is chronic dose, which it would be if it's internal exposure to transuranics. We are going to increase that.

On the other hand, it seems we're moving towards a DREF pretty much of one for external low-LET exposure. And again, that directly affects the risk. That directly affects the PC. Maybe not in a one-for-one — it's not completely, 100 percent proportional. But there is a proportion of it that does affect it, and as we saw with the pie charts that we went through with the program, you can see that — what the effect

is to varying degrees.

So that's really the two points that I wanted to mention. And I also say it, just for the record, I'd like to say I make these comments as also a Cold War veteran within DOE complex.

Any questions for me? Thank you.

MS. MUNN: I have —

DR. ZIEMER: Wanda has a question, Roger.

MS. MUNN: What's the 17th country that dropped off the list?

MR. SHAW: Germany, and someone can help me, but Germany could not get their data in on time, was the last update that I have. And I see a couple of nods. I can see David nodding.

MS. MUNN: Okay, thank you.

MR. SHAW: Germany couldn't get their data in.

DR. ZIEMER: Thank you.

Finally we have comments by Jim Ellenberger. Jim's with Pace International Union.

MR. ELLENBERGER: Thank you very much, Dr. Ziemer. I apologize for not being here yesterday during the public comment period. I had requested an opportunity to speak, and I unfortunately had a conflict and had to leave.

So I appreciate this opportunity this morning.

I want to thank the members of the Board for your participation in this effort. This is an extremely important part of the process that was established by the Energy Employees Occupational Illness Compensation and Prevention Act, and we have tremendous interest in this. I work as a consultant for Pace International Union. I have been doing that since June of last year. Prior to that I served almost 30 years with the AFL-CIO, and worked very closely with all of the affiliates of the AFL-CIO in the enactment of this legislation.

The legislation was very specific about the Advisory Board on Radiation and Worker Health. It required that the President appoint the Board 120 days after the enactment of the Act. And obviously that didn't occur, and that has caused some of the problems in terms of backing up the process. And this is obviously not the responsibility of this Board. You had no role in that, thankfully. But it is something that you have to deal with, and there are literally thousands of workers who depend on your work and are looking with great interest and anticipation

to the outcome of this process.

The other requirement in the Act that my brother Tabor had mentioned earlier, and I'm sure it was raised yesterday, was the requirement in the Act that there be balance on the Board reflective of scientific, medical and worker perspectives. And as I mentioned yesterday in the introductions, Pace International Union is the union that represents the single largest number of workers in the nuclear weapons complex, and it is an organization that is not represented on this Board. We have made a number of efforts with the Administration to try and get worker representatives from the production sector on this Board, and that has been unsuccessful.

I would like to point out a similar activity that you may be aware of; I don't know. The Department of Energy created an advisory committee to the Office of Worker Advocacy, which was also established by the Act. This committee was put in place a year ago. And its function is to advise the Department of Energy on the application of the law, and to provide advice and assistance to the Secretary when it comes to the Office of Worker Advocacy in that portion, very

difficult portion of the law which deals with diseases that are not covered by the Federal portion of the Energy Employees Occupational Illness Compensation Act.

I happen to be a member of that committee, and it's comprised of a lot of the most distinguished and knowledgeable experts in the United States on worker's compensation. Right from the very first meeting we realized that that committee lacked balance. We did not have in our initial meeting any representation from contractors. And we acted to advise the Secretary that that shortcoming should be addressed, and the Secretary did appoint representatives from the contractor community who now sit on the advisory committee at DOE.

As we proceeded with our work in that committee we realized another shortcoming. Particularly when you deal with state worker's compensation laws — there are, as you know, one for each state — and the forms of insurance coverage that employers have, either self-insurance or insurance through a state fund, or insurance through commercial carriers – we did not have any insurance representation on the

advisory committee. And we have again made a recommendation that the committee be expanded to include those interests. And the Secretary is in the process — Secretary of Energy is involved in a process right now to expand that committee to make sure that those interests are represented fairly in that process.

So I offer that for your information and perhaps your consideration. I think undoubtedly the work of this committee would be strengthened immeasurably, and you would gain an important element of trust from the public by making sure that you are reflective, as the law requires, of interests that are affected by this law.

Thank you.

DR. ZIEMER: Thank you very much, Jim. Are there any questions for Jim?

[No responses]

DR. ZIEMER: Thank you.

We are approaching the noon hour. We had actually blocked off 12:15 to 1:00 for lunch, but our experience yesterday was that may be pushing it, particularly since we may have to go off-site to get something. So we will recess at this time and then reconvene at 1:00 o'clock. We'll see

you then.

[Whereupon, a lunch recess was taken from approximately 11:53 a.m. until 1:08 p.m.]

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DR. ZIEMER: We need to call the meeting back to order, folks. Henry Anderson has to leave at 2:00 o'clock, and we want to finish much of what we do before 2:00. We won't be able to finish it all, but some key things we need to finish.

Before we do that, I'm looking for Nichole – where is Martha, and where is Cori? Martha and Cori aren't here. They're not out there? Okay, we'll catch them. I wanted to officially thank them for their work in arranging this meeting, and we'll just delay that a few minutes. They've done an excellent job, and we want to acknowledge that and show that in the record as well — Cori Homer, Nichole Herbert, and Martha DiMuzio.

We're going to continue at this point with the working session of the Board. I'm going to take my seat here momentarily, and we'll focus on answering the issues that have been raised, the three questions.

But before doing that, in talking to a number of you sort of on the side, just to see where you thought we were and so on, I sensed that there was a lot of sentiment on the Board toward acknowledging the issue of balance on the committee in some way. And it would seem appropriate that we do that.

Obviously this committee does not control its own membership. That is controlled by the Administration and the White House. Not even HHS controls that. On the other hand, it would not be inappropriate for us to reflect the need for that balance that has been mentioned by a number of our observers at various times here in the last two days. So I've asked Roy if he would prepare for us a motion that we might include in our recommendations.

Roy, are you prepared to do that?

DR. DeHART: I am. I would like to put before the Board the following motion:

The Board recommends to the Secretary of Health and Human Services to urge the President to provide balance to the Board's membership by the addition of a nuclear industry worker.

DR. ZIEMER: Is there a second to the

motion?

DR. ANDRADE: I'll second that.

DR. ZIEMER: A friendly amendment, could we say another?

DR. DeHART: I can — I said the addition of.

DR. ZIEMER: The addition of — okay, addition of another.

Did someone second that? I'm sorry.

DR. DeHART: Yes.

MS. MURRAY: Dr. Andrade did.

DR. ZIEMER: Thank you.

Now discussion. Wanda.

MS. MUNN: I guess I need to make my position on this very clear. Granted, I'm a degreed engineer, and I have an advanced degree. And granted also that I am not a union member. I nevertheless have made great effort during my professional career to see that I was never in a management chain, because when I received my technical degree I did so so that I could be on-the-ground, hands-on kind of engineer. And throughout my entire professional career, that's what I did.

So to have me considered as something other than a nuclear worker does not set well with me.

I consider myself a nuclear worker. I have never been management. I have – my policy-making activities have always been in the civil area, not in my work place. So from my perspective, this Board has on it at this time one-fifth constituted of nuclear workers who have not been involved in management decisions and are nuclear workers.

Now I don't know whether Rich sees me in that same way or not, but that's the way I see myself. And therefore I am not enthusiastic about this particular proposal.

DR. ZIEMER: Thank you for those comments. Part of this, of course, is always perception, and that's what we're speaking to here.

Yes, Rich.

MR. ESPINOSA: For the record, I don't believe the perception of this should be union/non-union.

DR. ZIEMER: No.

MR. ESPINOSA: It should be reflected as for the workers, whether you're union or not. And I agree with the motion that's made, and I do believe that should be amended to represent labor on the next appointees.

MR. PRESLEY: Dr. Ziemer, I'd also like to address this.

I am definitely a nuclear worker, having been at Oak Ridge and worked at Y-12 for 35 years, where I started out really as a — on the bottom of the rung, and have worked myself up working in all aspects, all the way up from a dispatcher to an engineer, and then into management and then back into the technical field of it. So I feel like Wanda. I feel like that I'm definitely in the category of a nuclear worker.

DR. ZIEMER: Thank you very much for those comments.

I might add that I suppose that probably a good portion of us would be in that category at least part of our career. I myself started out at Oak Ridge certainly in no management position, low end of the totem pole, as a worker. And I don't think Roy's motion is trying to deny that fact. It is, I think, an attempt to deal more with the perception from outside on the representation here, because most are seen more as professional engineers and physicians and scientists. So it's more that issue. I agree

with what you say, but I think it's that perception.

Tony.

DR. ANDRADE: I'd also like to add for the record that I agree with your comments, that I think most of us have gone through a period in which we were floor engineers. I was out at the test site. I did all sorts of work in my tennis shoes and gloves, and I took doses just like other people did. However, I would also like to stress the point that Richard made, that this is not really an issue about organized labor versus non-organized labor.

I think the motion would help to address two important issues. One is that we recognize the fact that there are representative bodies for portions of the complex that existed that had single-function missions. For example, we had facilities that dealt with gaseous diffusion. We had facilities that dealt strictly with plutonium and plutonium metal works. We had uranium facilities. Those facilities are not represented on the Board.

Richard is an excellent representative for the types of laboratories that we currently have

on board, and those are the national laboratories like Livermore and Los Alamos, that uses a spectrum of crafts to work our mechanical problems at those laboratories.

And so from that point of view I think that having somebody from those older facilities, many of them that are now going into shut-down mode, would be a prudent action to take. Again, not as organized labor versus non-organized, but just as a representative of those facilities that existed and were really in full-mode production during the period of time that we're looking at.

DR. ZIEMER: Other comments? Henry has called the question.

Quit looking at your watch, Henry.

That's not a formal motion to close debate, so I haven't recognized it. I want opportunity for further comment before we vote on the motion. Do you need to hear the motion again?

You want to repeat the motion, read the motion back

MS. MURRAY: Dr. DeHart moved that the Board recommend that the Secretary of DHHS urge the President to provide balance to the Board's membership by the addition of another nuclear

industry worker.

DR. ZIEMER: Are you ready to vote on the motion?

All who favor the motion say aye.

[Affirmative responses]

DR. ZIEMER: All opposed say no.

[No negative responses]

MS. MUNN: I'll abstain.

DR. ZIEMER: One abstention.

I declare the motion approved, and that will be included as one of the recommendations, then, to the Secretary of Health and Human Services. Thank you.

We actually have two items already to send forward. That's great.

Now I'd like to have us, if we're able to, to address at least two of the three questions on the list. We'll deal with –

MS. MURRAY: I'm sorry, Dr. Ziemer. Did you vote?

DR. ZIEMER: I voted for the motion, sorry.

MS. MURRAY: Okay, thank you.

DR. ZIEMER: The question we'll try to deal with first is, one, does the proposal make appropriate use – the proposal being the rule –

make appropriate use of science, of current science and medicine, for evaluating and quantifying cancer risks for DOE workers exposed to ionizing radiation in the performance of duty?

The other question, does the proposal appropriately and adequately address the need to ensure procedures under this rule — to ensure procedures under this rule remain current with advances in radiation health research?

We'll deal with those two questions. If we're able to deal with the third one that we were somewhat vague about before, we'll go to it after that. But let's see if we can deal with these.

As a minimum, it would be helpful if we could agree on a statement or recommendation on each of the two. We could have more. We could have none. But if we were in a position to make a statement — and more than a yes or no, does the proposal make appropriate use, yes/no — I think if we can develop a statement.

And to do that, I think rather than calling for a formal motion at this point, I'd like to have the opportunity for people to just surface some ideas or surface your views on that first

question, the extent to which this rule-making makes appropriate use of current science and medicine for evaluating and quantifying cancer risks.

Yes, Jim.

DR. MELIUS: Given the circumstances of our review, and the fact this is our first meeting and the limited time period to meet and review the entire procedure involved, I would like – I think it would be more appropriate if we sort of caveated whatever statements we make with some statement to the effect that we've had very limited time; that we've not done a complete review of the IREP and some of the other assumptions being used as part of this process; that we intend to go into more detail with that at future meetings, but we really have not been given the opportunity, given how late we were appointed and so forth.

And then go on from there to say something to the effect that in general we're in agreement with the approach that NIOSH has taken, and sort of make a positive statement from there in general to the extent that it's reflective of these regulations, again knowing that in future

meetings we would go back and discuss and talk in more detail about many of the assumptions and other — in fact, many of the issues that have been raised in the comments on these regulations, which really deal more with the model, not with the application of the general proposed regulation, the application here.

But I feel fairly strongly that we have not been given — not that it's anybody's, necessarily anybody's fault — but we've not been given an opportunity to really fully answer that question. It just — and certainly not to come to a consensus.

Now we may have individual opinions on that and had time to review it individually, but certainly as a committee – and the normal process for a committee, at least most scientific committees or advisory committees I've been on, you're presented a question, go through a series of meetings, and then try to reach a conclusion. And we're sort of — come to the first meeting, and, well, we'll give you an extra few days if you want it, but that's it. We're not even going to be given another meeting, another chance to meet. And I think we have to say that up front

in terms of our comments.

At the same time, I think we can – at least I feel comfortable giving support to what NIOSH and the Department has done so far, to put forward that the basic framework here is a good one and is sound, and address that question in a positive way.

DR. ZIEMER: Roy.

DR. DeHART: I agree with Jim's comments, and I think a couple of sentences up front. But I would then say, however, we have had the opportunity to read the documentation provided to us both in written form in our workbooks and on the web, and that we have had technical presentations and an opportunity to question those who represent the technical formatting. I think we need to give some kind of information about what we have done.

DR. ZIEMER: Gen.

DR. ROESSLER: I have a little different perspective, because – probably because I work with the concepts that have been presented almost on a daily basis. And I have been, as I said earlier, impressed with the current science that the group is using.

However, I do agree with your caveat. What I would suggest we do is put the positive statement first –

DR. MELIUS: That's fine.

DR. ROESSLER: – and then put the however next, because it really protects us, I think.

DR. MELIUS: I think again individually we've looked at this and have expertise in this area and viewpoints. But if we're talking about sort of a committee consensus statement, usually that involves a committee process, and we just haven't had time to do that.

We've all – I've been on committees with many people here, and I know you all served on other committees. And normally out of that process we may have some disagreements, you learn something from other members, you change your viewpoints on certain things, you understand things better. And that's how you come to some sort of a statement or consensus, and we just haven't had that opportunity here.

And I don't think we should – I think we should make – very careful that we do say that. I think we should try to – I agree, we should state our comments as positively as possible,

again not to find fault with anybody or whatever in this process.

DR. ZIEMER: Go ahead, Henry.

DR. ANDERSON: I was only going to put a statement at the end, saying that we look forward to working with NIOSH, reviewing the comments. And in either number one or number three, we need to build in that if we have our role in the rule, that then we look forward to being able to (inaudible). And I think we need to recognize that we'll continue to work with this, we'll see the experience and review it over the course of the time. And I don't want anything we say to delay the thing moving forward. But on the other hand, I totally agree that we haven't — we just have to state that we haven't had that in-depth review.

MR. ELLIOTT: Let me address your comments and your proposal.

I think that would suffice for what the Secretary's interested in seeing. My comments yesterday, I hope were taken as I intended them to be, not — that is, that we're not ram-rodding this through; that in the general context that's what this rule presents, the general context, the

general direction that we have set for probability of causation. That's what we're asking of you now, is to provide your general viewpoints about this rule.

Certainly we are going to get into a myriad of details in the IREP as we proceed, and bring back to you the IREP with the modifications as we make them, as we change them per public comments and subject matter expert comments. And you'll have time at that point to get far more ingrained in the details and the complexities of the technical aspects of IREP, as you will the technical guidelines that will support the dose reconstruction rule.

So all we're asking for February 6th is on the surface of these two rules, these two draft proposed rules, give us your general comments with regard to their direction and what limited amount of substance they present to you. Does that clarify anything, or does that help give you a sense you're on the right course?

DR. MELIUS: That's what I was saying, also. I mean, the pressures are the pressures of a delayed appointment of the committee, and there was a change in administration and might have

been expected. And secondly, the fact that there is a need for the program to move on, and we don't want to needlessly delay people or inappropriately delay people from getting compensation because of this.

And frankly, if I thought that waiting a week or whatever it would be to the next meeting would substantially change what our comments would be, then I think I would certainly suggest that, but I don't. I think we can reach an agreement on — a consensus on a general statement before — without the need for another meeting. And frankly, whether a week one way or the other would make much difference, I don't think so, because I think you can busily work on the final reg anyway.

But I just don't think we would change our opinions much by — or have done enough, had enough committee meeting time to really go into the detail that could be implied by that. And I think it's a little confusing, because many of the comments we're getting from the outside and some of your expert review have to do with the details, not with the general regulation. And I don't imply whether we agree or disagree with all

those comments, but we'll have more time to spend on that as a committee. And given their technical nature, that's probably more appropriate.

DR. ZIEMER: Thank you.

Any other feedback? I think I'd like to reach a point where we feel like we all sort of agree on the nature of the statement. Then it'll have to be drafted, crafted or drafted or both, so that we have specific words to react to. But if there are views that are sort of contrary to what already has been here or a somewhat different direction, I'd like those as well. I don't want to interpret any silence as being necessarily agreement. If you feel the urge to say that none of that makes sense, here's what we ought to say, then let's hear it.

[No responses]

DR. ZIEMER: I don't hear strong objections to what's already been put forth. I'm not asking for any votes at this time. I think what we'll do is take this, and we'll have a working group craft it into words, and probably will not finalize it until our phone call because Henry's going to be leaving here before we know it –

DR. ANDERSON: We didn’t talk about giving (inaudible).

[Laughter]

DR. ZIEMER: Well, I think we did.

UNIDENTIFIED: Henry has a lot of time on the airplane this afternoon to write this.

DR. ZIEMER: That's your assignment on the way home.

[Laughter]

DR. ZIEMER: Okay, so we have sort of a framework for answering the first question.

Richard.

MS. MURRAY: Would it be helpful if I read you the notes of what I took of what people said to see if you could develop something now, or do you –

DR. ZIEMER: I don't want to sit here and craft it now, but we'll use those notes later to actually do the crafting. I don't want us to try to compose right now. I just want to sort of get a sense of the Board.

Was there another comment? Do you have a feel for sort of that's sort of the framework or the ball park for the first statement?

[No responses]

DR. ZIEMER: Let's go to number three, does the proposal appropriately and adequately address the need to ensure procedures under this rule — to ensure that procedures under this rule remain current with advances in radiation health research? Any comments on that one?

DR. MELIUS: I would just say that I think we can combine that into a single statement for both — of general support for number one and three, so to speak, that would just be an additional sentence or so to that, rather than try to start all over again, have two statements.

DR. ZIEMER: That could certainly be done. Are you confirming, though, that you agree that there is a level of adequacy that you are comfortable with?

DR. MELIUS: Yes.

DR. ZIEMER: Henry.

DR. ANDERSON: And what I was suggesting is we take the very first proposal that we did, and say — and that would — it would be strengthened, were there to be a clear role for the Board written into the rules.

DR. ZIEMER: In other words, move that — this part of the recommendation, the thing we

already approved this morning. Right?

DR. ANDERSON: Yeah, because the — yeah. I would think the Board's role would strengthen if you could be assured that —

DR. ZIEMER: Certainly strengthens the change issue.

DR. ANDERSON: The change issue. That's the hook I would suggest we put in.

DR. ZIEMER: Other comments?

[No responses]

DR. ZIEMER: Does that silence mean, again, agreement, or did you have a big lunch and I need to rap the gavel?

DR. MELIUS: Anybody that speaks too much will get volunteered for this.

DR. ZIEMER: Those who didn't speak will be on the working group. Right?

Okay, so as I'm hearing it now, the framework would be one broad statement that would cover both questions, as well as the issue of moving that — those comments into the rule-making part.

Boy, we're just moving ahead here so rapidly I'm going to have to start speaking slower to stay on schedule.

Does the proposal appropriately adopt compensation policy as it's been applied? Now this is that issue of the adopting – not adopting, more adapting, I guess – adapting the veteran's proposal to this application. Does the Board wish to speak to that issue, And if so how? You have the document, the veteran's thing, now before you.

DR. MELIUS: One question, and you may have stated this morning – maybe Larry or who can answer this – but have you received any comments on this question? Has anybody commented on question number two? I don't recall any, but I –

MR. ELLIOTT: Ted, you want to help us out? Ted has been working on reacting and thinking about how we're going to address the comments, so –

MR. KATZ: We did – I think we just received one comment on this.

DR. ZIEMER: There was only one person that understood what the question was.

MR. KATZ: No –

DR. ZIEMER: It would be helpful for the committee.

MR. KATZ: And actually, and the comment was

actually along the lines of how this committee has responded, which was they're not sure what – it was a bit unclear to them what the metrics were, and what the advantages and disadvantages of adapting VA policy were, as well.

MR. ELLIOTT: If I may, I think what this really gets at is have we taken the right steps in what we've learned from the VA's experience in making changes or modifications in our rule, as well as the IREP that will be used in this rule, to – that are – those modifications that are appropriate and applicable to the work force under this compensation program. That's what I think we're after here. Are we doing the right thing, learn – building upon learned experience from the VA, and making changes appropriately for this work force.

DR. MELIUS: The committee finds no evidence that you have –

MR. ELLIOTT: No evidence that we've done that?

DR. ZIEMER: No, no evidence that you haven't done it correctly.

UNIDENTIFIED: However, a caveat –

DR. ZIEMER: Well, this is one of those

questions, I suppose, where the proof is in the pudding, as the old saying goes. You don't really know till you see the outcome. But would it be appropriate if we included a phrase or two that said that as best we can determine it appears that they are – because this has to do with direction, that this rule appears to be appropriate for the DOE work force for whom it's focused, something to that effect.

DR. MELIUS: Yeah, certainly I think we can say that NIOSH has considered a number of factors for this – the DOE work force would differ or program should differ for the DOE work force than for that covered under the VA program, and appear to be appropriately taking those factors into account. And if you go through the rule, particularly under the – they talk about uncertainty issues and some of the scientific issues, some of the parentheses, the examples they use, I think, are evidence of that. They're just issues that wouldn't come up in – for the VA rule.

DR. ZIEMER: Wanda, please.

MS. MUNN: We can either make a very bland statement along the lines that we're talking

about, or we could use this as an opportunity, if this body feels it's appropriate, to point out that there's an enormous difference between the two types of compensation. As best I understand the compensation in the Veterans Act, all one had to prove is that they were there at the time and have one of these cancers, and they were then compensated.

What we have before us here is an effort to face the reality that simple exposure to radiation does not automatically assume the development of disease. I don't know of any other place in this particular rule where we would have an opportunity to make that kind of statement, but it appears appropriate to me that we would be wise to make that distinction in our comment, and again applaud NIOSH for the efforts that have gone into identifying and reducing the uncertainty in making these kinds of decisions.

DR. ZIEMER: Good point, opportunity to make – let me get some reaction to that from around the table.

UNIDENTIFIED: We have a comment from Ted.

DR. ZIEMER: Ted has a comment here.

MR. KATZ: Can I just clarify? They do

actually, with the atomic veterans, they do dose reconstructions, and they do calculate probability of causation. Does that —

MS. MUNN: In some.

MR. KATZ: Excuse me? Okay, I'm sorry. I just —

DR. ZIEMER: Okay. Any other reflections on the point that was just made? Sally.

MS. GADOLA: I have a question.

When I initially read this, I had the impression that it was the spirit that was behind Congress when they enacted this – and maybe I'm wrong – but to me it seemed like because this was dealing with the Cold War veterans, the people that were working in the nuclear plants, that this was one of the reasons that this was also included and this was used as a guideline — not just the scientific, technical aspect, but I felt that there was also an aspect that dealt with the spirit and the reason for it.

And maybe that should also be addressed. Maybe also we have some comments or some of our experts have some comments on that.

DR. ZIEMER: Okay, thank you.

Do we have any reflection on either of the

comments that Wanda or Sally made?

[No responses]

DR. ZIEMER: Okay. Thinking about it. Yes, Tony.

DR. ANDRADE: I want to ask a question of Larry.

When was the Radiation Exposure Compensation Act passed?

MR. ELLIOTT: October of 2000.

DR. ANDRADE: October, 2000.

MR. ELLIOTT: Oh, RECA. You're – RECA, Radiation Exposure Compensation Act.

DR. ANDRADE: Right.

MR. ELLIOTT: I'm sorry. It was 1990, ten years before the one I just mentioned.

DR. ANDRADE: Right.

MR. ELLIOTT: I'm sorry.

DR. ZIEMER: Now we – let me see how we're doing on time. It's quarter to 2:00.

I am going to ask for a few volunteers to be a working group to put some words together.

Wanda, would you be willing to put together the words that express the idea that you surfaced –

MS. MUNN: Certainly.

DR. ZIEMER: – a couple of sentences? And then let me ask for one or two volunteers to – and this is not going to be lengthy – to put together the sentences on – which will be sort of one or two paragraphs on the other issues. Jim. Do we have one other person?

DR. ANDERSON: If it isn't today, I'll help.

DR. ZIEMER: Well, first attempt is going to try to be today, Henry.

Notice how free he was to volunteer, knowing he would be leaving shortly.

Okay, Gen Roessler.

DR. ROESSLER: Well, I have to leave kind of like at 4:00 o'clock –

DR. ZIEMER: No, no, no. We want this all –

DR. ROESSLER: – but I'd be glad to work with Jim.

DR. ZIEMER: All we want is just an early rough draft. We will not act on it today. We'll act on it by – on our – February 5th. I think I'd like if – and see if you agree with this – I'd like to sort of see what we have before us, and then you can have something to take with you and mull over between now and then. And we will have some chance to polish in between by e-mail

exchange before we get to the final product, so everyone will have a chance for input. I just need two or three people. So we actually have three, with Wanda's main assignment being those sentences dealing – Tony, did you volunteer?

DR. ROESSLER: He's good at words.

DR. ZIEMER: Gen just volunteered you.

DR. ANDRADE: Thanks, Gen. I can work with Wanda.

DR. ZIEMER: What I'd like to do is take about a 15-minute break right now, allow you three or four to sit in the corner and do that. And then at 2:00, once Henry's gone –

DR. ANDERSON: Okay, rub it in.

DR. ZIEMER: We're scheduled at 2:00 o'clock to have Dr. Neton's presentation on the technical guidelines for dose reconstruction. And we'll have a little – we have another session – we have some time after that, at which time we might look at this early draft. And that would pretty much complete our agenda at that point.

DR. MELIUS: Are we going to go through, comment on dose reconstruction?

DR. ZIEMER: We'll have an opportunity to – to work – to do comments on dose –

MR. ELLIOTT: Yeah.

DR. ZIEMER: My understanding is that's not quite as urgent. Is that —

MR. ELLIOTT: Well, we still have the same public comment period, and then keeping the record open till February 6th for the dose reconstruction comments. But by statute, what we're forcing to happen here is your comments need to be in place in the docket on probability of causation. That's a responsibility this Board has before we can finalize that rule. We can proceed and react on our dose reconstruction comments as we take you through the technical guidelines, okay? And if we have to reopen the record for that to — you see, we've asked you to look at the dose reconstruction guidelines. You're required to look at the POC rule.

DR. ZIEMER: By statute.

MR. ELLIOTT: By statute. And we chose to ask you to look at dose reconstruction. So what we're trying to force here is your comments into the record on probability of causation.

DR. ZIEMER: And that's the priority.

MR. ELLIOTT: That's the priority. If we don't get through that on dose reconstruction,

we'll just proceed as we can to get those in. But —

DR. MELIUS: Can you reopen the record, though? That's —

MR. ELLIOTT: Yeah.

DR. MELIUS: Okay.

MR. ELLIOTT: We can reopen the record.

DR. MELIUS: I'm not sure it's necessary, but it may be.

MR. ELLIOTT: I'm not sure it's necessary on that, but it is necessary on a legalistic viewpoint that we have the record open for you to comment on POC.

DR. ZIEMER: We'll take a 15-minute recess as a full committee, ask the working group to pow-wow, and see what you can put together.

[Whereupon, a brief recess was taken from approximately 1:50 p.m. until 2:05 p.m.]

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DR. ZIEMER: I'd like to call the committee back to order again, or the Board back to order.

Just before we resume our deliberations, it's a good point in our meeting to formally recognize the work of three individuals who were

instrumental in doing all the ground work and arrangements for this meeting – Cori Homer, Nichole Herbert, and Martha DiMuzio. And here they are over here, and let's thank them.

[Applause]

DR. ZIEMER: Very well done, ladies, and you've set a high bar for future meetings to be right up there like this. This is great. Thank you very much.

Now the working group reports to me that they have the wording really all ready, but they're not going to share it with us today. They actually are going to e-mail it out, get some final word-smithing. But I understand they have pretty much agreed on what they think we should look at, but are not ready to sort of distribute it yet. So that will occur – and Jim is going to handle that. That's going to happen like the minute you get home, right?

DR. MELIUS: Not – the minute I get back to the office tomorrow morning.

DR. ZIEMER: Okay. It will happen soon, and –

DR. MELIUS: It will happen tomorrow morning, and then –

DR. ZIEMER: And then –

DR. MELIUS: – we should set a schedule.

DR. ZIEMER: – we'll each have an opportunity to actually look at that and provide some feedback. Let's agree to provide feedback. Jim, again, if you would collect that and then develop the final wording for us to use in our conference call. Okay.

Any questions on that?

Yeah, Larry.

MR. ELLIOTT: And the conference call is February 5th at 10:00 a.m. Eastern Standard Time.

DR. ZIEMER: Correct.

MR. ELLIOTT: And the purpose of this call – we have to have a purpose when we announce it in the *Federal Register.*

DR. ZIEMER: The purpose will be to approve the recommendations to be forwarded to the –

MR. ELLIOTT: Secretary.

DR. ZIEMER: – Secretary of Health and Human Services.

DR. MELIUS: Can you move that time? I'm giving a talk at that –

MR. ELLIOTT: We can move that time if it's the pleasure of the Board. You tell us what

time.

MS. MUNN: As long as it's later and not earlier.

DR. ZIEMER: Do you have a conflict at that hour? Is that —

DR. MELIUS: I'm giving a presentation —

DR. ZIEMER: Oh, well, I —

DR. MELIUS: — at that very moment.

MR. ELLIOTT: How does 1:00 p.m. Eastern Standard Time sound for everybody? And we'll let Dr. Anderson know.

DR. ZIEMER: Okay, so pencil that in for 1:00 p.m. Eastern Standard Time, then. Thank you.

MS. HOMER: 1:00 to 3:00?

MR. ELLIOTT: You want 1:00 to 3:00, or — and then we can — if we don't need the two hours —

DR. ZIEMER: Block it off 1:00 to 3:00. If we don't need the full time, we won't use the full time.

Now we're going to hear from Jim Neton again, and he's going to talk about the dose reconstruction. Here he is.

Jim, please.

DR. NETON: Good afternoon. I'm here to flesh out a little bit in somewhat more detail our approach to dose reconstruction under 42 CFR 82, which is a little shift in gears from the probability of causation, PC rule discussion we've had thus far, which is the priority of this meeting. But I'd like to try to lay the groundwork for some future discussions at meetings that are upcoming related to dose reconstructions today.

So with that being said, let's see if I can get this thing fired up there. So this is — there is some redundancy built in here, partly intentionally, just because the concepts are the same. And like I said, in some cases I'm going to elaborate a little bit more on the concepts, and some places I'm just going to provide what I believe to be some reasonable examples that might help solidify in people's minds the groundwork for the approaches we are taking.

I mentioned yesterday that we do have our draft technical guidelines issued. I am reviewing them now. I'm in the unfortunate position at this point that the people in my group are cranking out work faster than I can

read it, which is good, I guess. But by the time the Board convenes next time, we should have those draft guidelines available for review. Now that I've committed to it, I can see Grady is shrinking in his seat.

I'm going to start with external dosimetry, primarily because it's somewhat of the more analytically straightforward process. Internal dose, as we'll see, and for those of you who have been involved in internal dosimetry as a hobby or a career, we'll see there's much more art involved in that process. So I'll take what I believe to be the easier approach to explain. I can get warmed up at least with the external.

Not to demean anyone's intelligence in the room, but I'd like to talk about what we mean by external dose in terms of what we're talking about for compensation, and it's of course dose received from outside the body. But we do have to consider both what we consider a deep dose, a dose to the organs that are within the body that are radiated, as well as the surface dose, the skin dose, because as we're seeing already, a skin cancer is a fairly common form of cancer.

And indeed a number of the claims that we've

received already are presenting with skin cancer. In fact, much to my — not surprise, but I guess I was a little bit surprised to see the number of multiple primaries — you know, that formula that we talked about early on for the PC rule. It's not out of the ordinary to see a skin cancer coupled with a future solid tumor down the line. So we do need to concern ourselves with how skin dose is calculated.

Three primary sources — gamma and X-irradiation, photons and X-rays; neutrons are definitely a source of exposure in the DOE environment at many sites, and is something that we are taking a long, hard look at, and I will address that a little later in the presentation; and beta particles, which are primarily from an external exposure perspective only relevant for skin dose. Anything greater than one centimeter deep in the body, any irradiated tissue would not be exposed to the energy deposited by a beta.

And for purposes of compensation and in general for radiation protection, alpha radiation is not considered as a source of external exposure, although one can argue for certain — the average range of an alpha is about 50 microns

in tissue, so it's not going to get down to what's considered to be the 70 micron depth of the basal cells of the skin that would be of significance for the generation of skin cancer. There are some higher energy betas from (inaudible) case here is I think there's an 8.78 meV beta that I'll take a look at, just to make sure we're not missing something there. It may actually get down to 70 microns. Okay.

As we view it for compensation purposes, there are four components related to external dose that we need to at least evaluate for each claim, and those are listed here: The measured dosimeter dose, which we talked about yesterday, the dose that the film badge or the TLD badge receives, and some conversion that's required to convert that into an organ dose for the cancer that the claimant presents.

And then the missed dose, which we're going to talk a little bit more about today, which is the undetected dose that one needs to add back into a claimant's dose to ensure that we've adequately covered what his potential exposure was in somewhat of a realistic fashion. I mean, we're not going to blindly go back in and add

doses without doing some sanity checks here.

Occupational environmental dose is another area where, when it's possible and when available, we would like to consider the environmental exposure. And what I mean by that is exposures to workers who were not necessarily monitored in the plants, but just generally in the vicinity of the plants. This would be emissions from the stack that, whether it's particulate or noble gases that have photons emitted, it would irradiate the workers. We need to consider that. And this is particularly for people who were never monitored. There is a small component — I have an example later of what we mean by that.

And I talked yesterday about occupationally derived medical dose, which is these required medical X-rays. So the simple algebraic equation on the bottom is a total dose, is the summation of those four different types.

The hierarchy of external exposure, I talked about this yesterday. The personal monitoring film badge or TLD, we would put highest priority on using once it was evaluated for its adequacy for the monitoring program involved.

Pocket ionization chambers that were typically used at facilities that could — the little pencil dosimeters that people wear, they would wear in conjunction with a film badge typically. But those would be read on essentially on a daily basis, where you would go into a area, zero it, look at it and record your dose in some kind of a log book later on. Those are useful for establishing ranges, although their energy dependence is suspect, and we need to take a very hard look at that if we're going to use them for anything other than high energy penetrating gamma.

Group dosimeters also have been issued historically in the past, and that would be people who were working in a similar exposure environment. Historically in the past they would pick one person as representative of the group, and monitor — and look at the group's dose based on that.

And then we get into the work place monitoring, the area ambient air surveys. That shouldn't actually be air surveys for external exposure. Ambient area surveys is what's meant there, which is the general — the radiological

technicians will go out and map out an area to create a radiation work permit, or something to that extent.

And then the last in all of these is the source term analysis, which is — a simple example is if you have a point source of cesium 137 sitting ten meters away and it has so much activity, one can calculate what the bracketing range of exposures might be in that environment. And we can do some calculations using a computer program such as Micro Shield or something like that to come out with some estimates of dose using source term analyses.

Okay, I went over a simpler example for external dose yesterday, but I'd like to talk in a little more detail. This is a Hanford worker exposed from 1/3/51 to 12/19/51, so I think we have a dozen reads throughout the year. And these happen to be non-zero doses, so we're not talking about dealing with missed dose here. We're talking about things that were above the detection limit, the stated detection limit of the monitoring device, at least. And if we accept this monitoring device, particularly in the shielded window, which is the deep dose

equivalent on this dosimeter, these would be the readings that we'd be concerned with for looking at a dose to the organ.

We've taken and estimated the laboratory uncertainty for this, and essentially this was done based on an evaluation of what the Defense Threat Reduction Agency is doing in their program. The monitoring devices used back in this 1951 time frame are very similar in nature. This was a film badge packet that had similar filtration and properties and processing techniques. So our estimated uncertainty is about 14 millirem in this range of these deep dose equivalents, and the worker, if you add up all of his positive results, ends up with a 415 millirem total dose for that monitoring year.

If we take each of these 14 millirem and we run it through a Monte Carlo simulation program such as Crystal Ball – there's a number of commercially-available products out there – we could actually generate an uncertainty distribution about that. This is a fairly simple case. One could argue that we should just propagate the errors and come out with the estimated uncertainty, but you'll see as we –

later on this is going to be folded into the larger error structure of the external dose.

So if you put in each of those doses into a Monte Carlo program, add them up, and then each time sample this uncertainty distribution, you end up with essentially a probability density of what the potential doses were for that worker for that monitoring year. And you can see in this case the central tendency estimates, since this is normally distributed, the mean is 415 millirem, and at the 95th percent confidence interval the dose could have been as high as 513 millirem.

If this was the only uncertainty that we had about a person's exposure, this is what would go into the IREP program. It's a fairly simple example, but there's going to be more to it than this. But if this were the only uncertainty, this would exactly be it. We would input into IREP for 1951, high energy gamma, 415 millirem with a standard deviation of down here, 50 millirem, and that would be sampled as such.

Okay. The missed dose again — and that was for a person that has complete monitoring history. Now we need to talk a little bit about

how we're going to handle the missed dose. I'm going to talk a little bit more technical detail of how that's going to be.

Yes, sure.

DR. ANDRADE: Excuse me, did you mean 99 percent?

DR. NETON: Actually, yeah, it's confusing. For some reason we calculated for 95, and yeah, it would be — well, in IREP you put in one standard deviation, so this would be actually two standard deviations. It would be half of that which would go into IREP, right. It's one sigma is 67 percent confidence interval, two sigma is 95. So I probably should have been a little more consistent with the input on that. It's good catch, thank you.

The missed dose, of course I talked about yesterday, can be significant when the frequency of exchange was great and a relatively high detection limit. For instance, 30 millirem, .3 millisieverts, is not uncommon in the 1950s for a number of sites, and with a 52-week badge exchange, if a person works 50 weeks you end up with something like one and a half rem.

In the area of neutrons it's even much more

significant than this. We've seen detection limits for neutron monitoring. In the area of neutron monitoring we've seen at the – I don't want to pick on Hanford; we happened to look at that data in somewhat more detail than other sites so far – 80 millirem detection limit with a 50-week – a weekly badge exchange. There's a very large potential missed dose there. We're not suggesting that is the missed dose, but we need to take a long, hard look at that and determine what the exposure conditions really may have been.

DR. ZIEMER: Jim?

DR. NETON: Yes.

DR. ZIEMER: Question. Many facilities have a formal procedure for establishing missed dose – interview the person, check – as a standard operating procedure, and then they enter a number into the record at the time. If you go back and find those, does your group intend to accept the missed dose values that are established at the time, or will you still try to go through another procedure?

DR. NETON: Okay. I think –

DR. ZIEMER: Or do you know yet?

DR. NETON: Well, yes and no. I think there's two separate issues going on here. When I'm talking about missed dose, I'm not talking about a missed dose in which a worker, for instance, claims that he did not wear his badge –

DR. ZIEMER: Oh. You're just talking about the –

DR. NETON: The undetected dose –

DR. ZIEMER: – limited detection part of it.

DR. NETON: It's the design of the monitoring program in general, when I say missed dose. The other dose is unmonitored dose or some incident dose.

DR. ZIEMER: Thank you.

DR. NETON: But the answer to that question is we intend to interview the claimant, and where his assertions seem reasonable and cannot be refuted by other evidence, we would accept the claimant's assertions. We've seen a couple of cases already that there are some – it's going to happen. There's no doubt about it.

But we need to do a check on it and make sure that, for instance, if someone claims that they were over-exposed to plutonium in a facility, and the records indicate that that

plutonium did not exist at that facility until ten years after that incident, then we would have to question the veracity of that statement. So there are certainly what I call sanity checks one needs to do on this stuff. But it's going to be a difficult process to go through each of these, for sure.

For current day periods, it's relatively insignificant with modern day programs. Typical missed doses are less than 40 millirem a year, .4 millisievert. So we don't expect — we will certainly consider it and put this, add this back into the monitoring record, but it's not going to be anywhere near as large.

And I've got a couple of examples here I talked about. Missed dose can be one and a half rem for early time periods — which is interesting, ten percent of the occupational limit in the 50's, and now it's down to about two and a half percent of the current limit of five, which was in the 70's. So it's come way down. The technology has improved tremendously over the time.

Again, critical components, we've talked about this: The limit of detection, number of

badges. The central tendency of the distribution is going to be estimated, as I indicated, using this limit of detection divided by two methodology, which is fairly standard nomenclature in the literature for estimating missed dose.

We do intend, though, not to assume that this is a normal distribution, but our experience base with worker data, particularly some of the data that exists in the Health-Related Energy Research Branch's files, indicates that a lognormal distribution is more appropriate to the distribution of these data.

So if we take a similar worker who was exposed between '54 and '61, the limit of detection – and he had a certain number of zero doses recorded – 32, 52, 50 on his annual summaries – if we can obtain these. Now this is assuming we can obtain this information. The LOD over two is such, and then the LOD is, of course, twice that. But what I'm trying to indicate here is that we are going to assume that the 95th percent confidence level is the LOD. We've seen this time and time again, that the LOD over two in most circumstances is a biased estimate high

for the worker's exposure. And we believe that the LOD is a fairly decent handle to fix the upper limit of the possible exposure for that monitoring period.

So one can establish, based on those parameters, some lognormal distribution of the missed dose – frequency distribution of the missed dose in this particular case. And we see here that the geometric mean would be 210 millirem with a 95th percent confidence interval out at 4.2 millisieverts. So for this worker's range of exposures, he had no positive badge results whatsoever during these monitoring periods, but we would estimate and input into his IREP – input into the IREP file that would be run for probability of causation a geometric mean of 210 millirem to account for the possibility that he was exposed, or he or she were exposed to that level, and put in a geometric standard deviation based on the methodology I just described.

I'm real close to these analyses, so if I'm not clear, please speak up.

Okay, the next area I'd like to talk about is the environmental dose area, where it's unmonitored dose received from stack emissions

typically at sites. And it can be significant in the early years. Again, as the technology and exposure limits and air monitoring standards decreased, it's not as much a problem in the current days.

But in early years when production for weapons was high, they would do what they called green fuel runs, which is instead of allowing the fuel to decay for the short-term decay products to go away, they would essentially start dissolving these things fairly early to extract the desired material, whether it was plutonium or whatever. And that would result in a much higher emission of fission products, the iodines and the xenons, those kinds of materials that are present. A short half-life, but fairly significant dosimetrically shortly after production.

And we do view this for some groups of workers, such as construction workers, to be maybe their primary source of exposure. If a person's working out in an area of the plant where there is no monitoring, it's not considered a radiological area, this indeed may be their only source of exposure, albeit in most cases

fairly small, but certainly need to be examined.

Here's an example of some real data that we managed to pull out of the records from — again, I'll pick on Hanford here — in 1947. The area — this is a diagram of the Hanford facility or site, and you can see the 100 area, the 200 area, the plutonium processing areas. The doses in white here — don't let the units confuse you. These are old radiological units in millirep. For all practical purposes, those can be considered equivalent to millirem for our demonstration.

But you can see that there's quite a distribution of – this is the average 24-hour dose rate at each of these locations as measured in May of 1947. I believe it's for the entire month, average. So knowing that the average background radiation in the United States from just standing on a spot of soil somewhere is around ten microrem per hour, that equate, for 24 hours, to about .24 millirep for 24 hours.

So one can see that for some cases around here, the 100 area, it's fairly close to background. But here it's .7 millirep, so that's quite elevated above background, not quite a

factor of ten — not ten, point — here's a higher one, 2.2 millirep per hour. So there's a distribution, and it's almost — this is almost a factor of ten above what we would consider to be ambient, natural background. So this would — someone obviously working in this area unmonitored has a potential for some environmental exposure, would need to be added back.

I don't know and don't expect that the quality of data is going to be this good for sites, but when we do know it we certainly have to consider it and include it in the exposure profile.

The medical dose, I'll just touch on briefly again. Required medical X-rays, there are examples in the case files — not case files, but the dosimetry medical files of workers at some facilities, particularly in the early years where stereoscopic X-rays were taken — it's known as photo-fluorography, which is essentially a fluoroscopic examination of the chest with the fluoroscopic image transferred to film. They would take a picture of a fluoroscope, essentially. And I believe that was primarily

because you could do screening a lot quicker, or you could just take these pictures and then go review them.

The doses from those procedures, since they were fluoroscopically based, is quite large compared to current day medical X-rays, which are the order of 10, 15 millirem. There has been some research done into this, and especially dose to, for instance, red bone marrow has been determined from a fluoroscopic – or photo-fluorographic examination to be as high as 800 millirem.

So again, in some workers' cases, this may be their dominant source of exposure, occupational source of exposures, particularly if this was considered — was required for them to be employed at the site. So that's one of the main reasons we want to add these back in, because there are some out in the files, and we've seen them, some large doses that need to be considered and added back in from this means of exposure.

And as the little equation indicates, the occupational medical exposures, just a summation of the number of X-rays times N, although D_i may be somewhat difficult to obtain. We are asking

from the Department of Energy to provide us — most medical facilities won't know what the dose was, but if they provide us the manufacturer and the make of the X-ray machine and the kilovolt potential, those type of pieces of information, we should be able to get some sort of an estimate from them. There just weren't all that many types of machines out there.

Okay, conversion to organ dose. I talked about yesterday the ICRP 74 methodology. So we're going to either convert from ambient deep dose equivalent or the deep dose equivalent, and these are as defined in the ICRP terminology, $H^*(10)$ and $H_p(10)$. It's just — the H is, of course, dose equivalent, and the ten just refers to a ten millimeter depth.

As we discussed, the ten millimeter depth is not necessarily adequate to estimate the dose to certain organs that may have been exposed that are deeper in the body. And the factors that will affect this conversion are what the target organ is. An organ such as the thyroid that is very close to the surface is going to be very close to $H_p(10)$, or the breast tissue, especially for high energies.

When you get into organs that are dense and deep within the body such as red bone marrow, which would be the organ we would calculate a dose for leukemia induction, much significant corrections may be required. And also it's energy dependent, so the lower the energy, the greater the effect. And the exposure geometry, whether you are standing in a parallel beam of radiation or moving around in a circle, it makes a difference.

I just have a graph here that — it's a sort of busy graph, but it does depict what I'm talking about. And this is a specific example for a bone marrow dose conversion factor as a function of photon energy, and I've got it sketched out for four different exposure geometries.

So for example, if you look at the yellow line — not yellow, the dotted line here, the anterior-posterior, that's the AP. The beam is coming from the front, and you're working in a glove box or a fume hood or something like that, and you're wearing the badge right here on your lapel.

This is the ICRP 74 predicted conversion

factor that one would use as a function of various photon energies. You can see that it never really approaches unity, so it's always going to be some reduction. And we need to determine at what point we're going to not even bother with the correction. But you can see that if you get below 100 keV there's a dramatic drop-off here, which you'd expect because lower energy photons have less penetrating power through tissue.

So you get down into here, and if you're looking at 60 keV for americium — 20, 30, 40 — it's going to be less than a quarter of the dose that your badge had measured, particularly in the early days when they didn't correct. Essentially what the film badge was reading was roentgen air exposure, which doesn't account for any tissue depth penetration at all.

So we need to really be careful down in here. Plutonium X-rays are down in here around 17 to 20 keV. In some cases we can say that the badge probably can't even read what the bone marrow — or the bone marrow dose is not even — the badge may over-predict by a factor of 100 what the bone marrow dose is.

So we're going to be looking at this and where to apply this correction factor. Right now we've got it to be corrected across the board. But there are some instances where I think, especially in the efficiency approach that we talked about adopting, we may not even bother — like we'll over-estimate everything so we won't make any corrections, and if the claim is below — at a very low POC, we're not going to bother.

The good thing is this is all easily computerized. These are standard formulas that we can plug in and run.

The geometries that I presented here, the anterior-posterior, rotational and isometric, I don't expect that the posterior-anterior's going to be that common. That would be radiation coming only from your back. I can imagine possibly a medical exposure or geometry where a person's running a fluoroscopic machine with their back to the beam, I'm not sure. But for completeness it's in there. We can certainly deal with it if we have to.

And again, these are examples of different types of exposure geometries where – drum storage in a warehouse, certainly a person is being

exposed, most likely in a four pie essentially geometry; glove box or fume hood worker would be AP; and a reactor worker may be some combination of those two.

And the final uncertainty distribution is going to be determined — I didn't have time today, and I think at future meetings we can discuss some of the uncertainties about those other geometries. But the final uncertainty will include — I showed you a sample of how that Monte Carlo calculation would go for the dose for the badge result itself, and then we will do a likely — an uncertainty distribution as well for the missed dose, the environmental dose, and the dose conversion factor. And I've indicated here what our best guess is, our best estimate is for the distribution about those four types of components of the dose calculation. Perhaps at a future meeting we can go through those and some of the logic behind the assignment of those various distributions.

Let's switch gears a little bit now and get into something a little less analytical and a little more difficult to nail down analytically with one’s computer program, but I'd like to talk

to you about how we're going to deal with the internal dose issues, which more than likely are going to be — it would have the potential to be the largest component of dose in the DOE work force, particularly with the alpha emitters.

As I talked about, alpha emitters have a — are of no consequence from an external dosimetry perspective. It's the opposite. In the internal dosimetry world they're everything. An alpha has a quality factor of 20, so just by virtue of that you're — they're five MeV type emission cell, there's a lot of energy deposited, biologically-damaging energy deposit per unit emission.

So again I'll start with a fundamental definition, which is dose received from radionuclides deposited in the body, and we are considering four possible means of entry into the body, as standard in dosimetry. We can either inhale them, we can either ingest them, they can be either injected or absorbed through a puncture wound, or they can be absorbed through the skin, such as gaseous tritium vapor.

Radon exposure is evaluated not using a dose model within IREP. We didn't talk about this earlier, but the IREP model itself is purely

based on exposure in working-level months. And the National Cancer Institute has updated IREP to include the radon model that was used essentially, I think, for the — well, I don't want to say something not correct here. A lot of the uranium miner data was used to — the risk values established with the uranium mining was used to establish the working-level model in exposure for radon. So in this case we're not going to dose at all. We're going from exposure using epidemiologic data and going directly to risk. So what I'll be talking about today for internal dose does not apply to radon daughters.

Okay. To do the calculation we divide it into steps. One, the key component is to determine the intake, how it's transferred through the body, and then the excretion, because the excretion is pretty much the only handle that we have available to quantify internal dose after the fact. The 66 model is used for inhalation, and we intend to use ICRP 56, 67 and 69 that include these updated specific biokinetic models that I talked about. They're the recycling models that are not single, first-order rate kinetics with no recycling. They account for the

ability of material to be deposited in the organ, go back into the bloodstream, and then be redeposited. These new recycling models do not exist, however, for all nuclides. This is new technology, so where they don't exist we will use the default ICRP 30 metabolic models.

From an internal dosimetry perspective, this is what the human body looks like, a bunch of boxes with little arrows. I'm trying to indicate and make a little simpler by the things highlighted in red are modes of entry into the body. So as I discussed earlier, we can have an ingestion, inhalation, or a puncture wound coming into the body.

And we can also remove things from the body by various means. We can either have — we can either breathe something in, and some of it doesn't get deposited. As a matter of fact, most of what you breathe in doesn't become deposited. It comes right back out. Or – I like this – this is ICRP 66, has defined extrinsic removal, which is essentially blowing your nose, kind of a fancy way of saying nose-blowing. And of course we can eliminate material metabolically that comes out through the urine or material that passes

directly through the GI tract in the feces. This is an error on my part. I indicated sweat as a mode of input into the body. In fact, it is a removal mechanism. So one can sweat out tritium vapor, for example, tritiated material.

Yes.

DR. ZIEMER: Quick question. Likewise, aren't there examples where you can ingest – if I can use that word – tritium directly through the skin?

DR. NETON: Yeah.

DR. ZIEMER: So it could be an input as well.

DR. NETON: Right. I didn't mean to imply that that was the only means. It is a means. Tritium can also be ingested, inhaled or absorbed. It's one of the more metabolically easy to model, but difficult to figure out the entry mode.

So what we have here is the respiratory tract model, which this would represent the ICRP 66 model that really is – I don't know, it's about 20-something compartments. It's an extremely complicated model. I didn't show it for this meeting because I thought maybe we wouldn't have enough time. But when material

goes into the respiratory tract, it can be absorbed into what's called the transfer compartment here, which is essentially the bloodstream. So any material that gets into the bloodstream then can be deposited in any of these various compartments. And that in fact is what we were doing with this IMBA program. We have 36 possible organs with which to calculate a dose to.

One difficulty we have, though — I talked about this a little bit yesterday — is that the 36 organs, unless the organ is metabolically involved in the accumulation of the radionuclide, it's very difficult to calculate a dose to that organ. For example, the prostate gland does not really concentrate plutonium, at least to any extent that the ICRP would recognize.

So we are calculating the dose from adjacent organs irradiating the prostate gland that have material, but we are also considering this transfer compartment, since this — radioactive compounds are actually in the bloodstream and circulate through the body, we can actually calculate the dose to this transfer — the number of transformations that occur in the bloodstream.

And if we know the volume of blood that's in any of these other organs, then we can come up with some estimate of the dose.

It's going to be small, but for completeness sake, I think we probably ought to add that back. It's intuitive to me that it's going to be small, but I think we really need to document that, or at least document why it's small. So we're going to be adding that analysis in the future.

Okay, I've kind of beat this to death. It's the 66 model that was developed in '94. It really corrected some deficiencies. It allows for a much larger particle size range than the ICRP 30 model did. It allows for modeling the deposition and movement of gases in and out of the lung. It allows for much more latitude of applying shape factors to particles. The title volume of the worker can be modeled all the way from resting to active. There are age adjustment coefficients. I'm not sure that we're going to use all those, but the flexibility is built into the model. Thirty was the previous one, and I've already talked about most of that.

Okay. There are still two models that we're using, which is the gastrointestinal model, the E

model, which is a fairly old model. It is essentially a three-compartment model with linear first order rate kinetics through it, still works well for our purposes.

And the bone model. The bone model allows us to have two source organs, so essentially the bone is considered two organs. There's trabecular bone and cortical bone, and those both metabolically behave very differently. And those two source organs can irradiate two target tissues within the bone, which is red bone marrow and bone surface cells. And that allows us to calculate the dose to the bone surfaces and the dose to the red bone marrow, so therefore we can actually estimate a dose for either osteosarcoma, which would be a dose to the red bone cell surfaces, or leukemia, which would be a dose to the red bone marrow.

So it's a useful model. We certainly will be doing a number of those kind of calculations, and I don't see any reason why it needs to be replaced at this point. There really is no better model available, in my mind.

The absorption values specific for the GI model have been updated. Even though we're using

the old E model for the gastrointestinal tract, there's some newer information about what was known in the field as the F1 value – that is the amount of material that's absorbed across the gastrointestinal tract as it moves through. For some materials, such as plutonium, it's ten to the minus fifth, a very small fraction, so almost none becomes deposited in the body; whereas if you actually ingest cesium, it's considered to be 100 percent absorbed in the gastrointestinal tract. So those factors — we're going to be using the newer factors for those models, even though we're going to be using the old model.

The IMBA program, we're somewhat excited about this. This is a new program. It's never been used in the U.S. to my knowledge before. We have the first, I think, working version in the United States. It's a beta version, developed by ACJ & Associates. Some of you may know Tony James, who worked for a number of years out at the Hanford site — worked at Battelle, not the Hanford site, sorry — and in conjunction with the NRPB, the National Radiation Protection Board in England, specifically Alan Birchall, who is a — I guess it's not an exaggeration — a world-renowned

internal dosimetrist in his own way. He's done a lot of the modeling.

We've taken advantage of what's been done by the NRPB in the past, and they've essentially modified it for our compensation program's specific needs. And we continue to work with them to refine this model to make it more useful for our needs. Most of those efforts are being put into the area of automation. With these number of claims that we need to process, it is still a fairly manual entry process for us. And when we can get the front end where we can actually import bioassay files one after another, it'll be a nice addition.

This is just an example of the IMBA screen, and nothing new here other than just to demonstrate that it does allow for a number of different metrics. One can type in the — a number of different analyses. One can type in different measurement types. We're limited right now in the number of radionuclides, but we've targeted the ones that we feel are going to carry the bulk of the DOE exposures, those being radionuclides such as uranium, americium, plutonium. We do have a few fission products

modeled, but we're working to expand that distribution, the number of radionuclides that we're modeling.

One can put in there measurement type, and we can calculate the dose over a specified interval, which is extremely important for us. We can put in the date of initial employment and the date of diagnosis, and it will provide an annual dose, internal dose, for every of those years and fractions of years thereof to the 36 individual organs. Because if you remember we were doing multiple cancer – I mean, if there are multiple primaries, we have to do a dose for each primary.

And also, if the primary is unspecified, if you remember that table, if you're guessing – not guessing – if it's a secondary cancer you have to estimate what the primary is. In some cases that table in the IREP rule specifies six or seven different organs. That means the dosimetrist will have to calculate and provide the Department of Labor the internal and external dose for six or seven separate organs per case. So it's very important that this prints out – it doesn't just do one organ at a time. It'll do all of them,

and then we can work through that that way.

Some important features that we like about this program, of course it does handle acute or chronic exposure situations, and it's fairly flexible. We can modify just about any of the parameters we want to meet our specific needs, and we do expect to encounter a number of different scenarios. And it's also useful for us establishing what I talked about as the missed dose for the monitoring programs. We can put in the detection limits for certain bioassay frequencies and samplings, and run through this multiple times and generate what we ought to call missed dose profiles for a certain site over certain periods of time. So it'll be very useful for us to do that with acute chronic scenarios and different solubility classifications.

Right now there's four types of bioassay samples that are supported: That is a whole body count, and partial body measurements as well – whether you measure the lung or the whole body, it can account for that; lung measurement; urinary excretion; and fecal excretion. It doesn't handle right now breathing zone air samplers, which I'd like to add. A breathing

zone air sampler, in my mind, is essentially a device that measures intake, 20 percent of your intake that runs at one liter per minute.

And a little bit about the outputs. It gives total intake. We don't really need it for our purposes, but it will provide committed effective dose equivalent. I mentioned the committed dose for each of the 36 organs, effective dose, and the dose to each organ. So it certainly is capable of providing us what we need.

DR. ZIEMER: Jim, you indicated this was in the beta testing stage?

DR. NETON: Right. That's correct.

DR. ZIEMER: And when will it become available, and will it be on-line?

DR. NETON: I'll answer the second question first. I'm not sure we're going to be able to put it on-line. We certainly will do that if it's possible, but this – we are in an agreement with ACJ, and somehow with the NRPB as well. I'm not sure – our lawyers need to look into that issue, as to whether we can put it on-line based on our licensing agreement with ACJ.

When it'll be available in its full version,

I'm hoping that we have this available within the next few months to have something that we can say is ready to go, although that's not to imply that this is not a working version. It is a functional version. It does work. Most of all of the testing that needs to be done has been done on the modules themselves. There's been a lot of independent review on the individual modules. All that IMBA really does is assemble the I/O, the input/output, and reformat. That's one of the things we liked about it.

So I'm hoping in the next few months that we can get the more production version going — certainly before we have to do the — in the April time frame when we have to start running — we can start running them for probability of causation calculations.

If we're going to do a dose reconstruction, it is a detective game. It's somewhat different than the external dose world, and here is why. There's a number of reasons the red dots sort of outline.

The detection limit for the measurements vary all over the board. It's not as simple as a badge read. The type of radioanalytical

technique used historically varies widely from the early 50's to the 90's. There are now techniques with thermal ionization mass spectrometry that can measure plutonium that is orders of magnitude below anything imaginable even when I was in graduate school, which was probably longer ago than I care to admit. So we need to really find out the facility's specific detection limits, and that's going to require some detective work on our part.

We intend to go through and develop facility profiles, and fortunately many facilities have done this. Some of the larger facilities do have historical documents that have been put together that do outline a lot of this information.

We need to determine the exposure type. Was it an acute, one-shot deal based on an incident, or was this a chronic type exposure that occurred to the worker? Of course, the exposure mode makes a huge difference, whether it was inhaled, ingested, or whether it was absorbed through a wound.

The effect of previous intakes on results. For example, what you're seeing today, is that being influenced by something that was coming out

in the urine before that, and that needs to be considered. And of course, the estimate of the date that the intake occurred. If you have no knowledge of when the intake occurred and you have a positive bioassay result, almost the only recourse you have to do an estimate is to go back to the last time a sample was taken and it wasn't detectable. That can result in some very large missed doses, and so that all needs to be considered as part of this little detective game.

And of course, the physical characteristics of the source material. Just because you have a bioassay sample does not mean that it's interpretable because of the solubility of the material. If it's very insoluble uranium and it's in the lungs, a much smaller fraction's coming out in the urine per day than if it's extremely soluble uranium. So we need to develop again these site-specific profiles, so we know in which facility what type of solubility material was being used.

I alluded to this a little before, but here are the types of data that we have to determine dose. Particularly in the bioassay world, we have the in vivo results, the urinalysis, fecal

samples and breath samples. And by breath samples, I'm specifically talking about breathing — well, actually there's two — I mean two things by breath samples. There's breathing zone air samples that hang on the person's lapel that are a fairly decent indicator of at least the magnitude of the level of exposure.

But breath samples, of course there are some time periods for radium body burden analysis. I know at the Fernald site this was done where people were measuring radon emanating in the breath due to radium 226 imbedded in the skeleton. And there's a similar technique called thoron analysis that's analogous for measuring thorium depositions. There aren't a lot of those, but we certainly will look at those if they're available.

So we have these four techniques available to us —

DR. ZIEMER: I think we have a question here, perhaps.

DR. ANDRADE: Real quick question here. For your purposes and the way you're going to do your analyses, how do you differentiate between acute and chronic for internal —

DR. NETON: Right. It's going to be —

DR. ANDRADE: — for intake.

DR. NETON: It depends on what's available. If we have a fairly good bioassay program record — for instance, a person had a monthly bioassay sample — one can determine based on the level that's coming out in the urine over time whether or not that person was chronically exposed. If it was an acute exposure, one would see the subsequent samples dropping off rapidly, fitting — the drop-off consistent with the models that you would employ. You do need to know, though, facility-specific information.

DR. ANDRADE: Right, but again — and I think you talked about it yesterday a little bit — when you're talking about plutonium internal dosimetry, you're talking about plutonium that's going to be in your body for the rest of your life.

DR. NETON: Right.

DR. ANDRADE: So therefore, you're going to consider that a chronic exposure, is that correct?

DR. NETON: Yes. Yeah, maybe I misunderstood your question, but yeah. Once you

have a plutonium intake, it's going to be a chronic exposure over the time period from the — to the date of diagnosis, for sure.

DR. ANDRADE: Right. Now on the other hand, take the case of iodine, biological half-life of a few days. Is that what you consider an acute —

DR. NETON: No, that would also be chronic, because as we talked about yesterday, the definition of chronic for these risk models is something that happened over — the definition of acute is something that happened in less than a couple of hours. Chronic is like more than a few hours. And the half-life of iodine in the thyroid, I think, is somewhere around eight days. So that would also be a chronic exposure.

DR. ANDRADE: Chronic, okay.

DR. ZIEMER: But you distinguish between acute and chronic intakes?

DR. NETON: Right.

DR. ZIEMER: Which is not the same as dose.

DR. NETON: Right. That’s right, yeah.

That's what I thought your first question was alluding to, which is an acute intake where in the earlier production mode of operation at uranium facilities, a certain amount of ambient

airborne uranium was acceptable. One could say that as long as I stayed below ten percent of the annual exposure, the limit or the maximum permissible concentration in air, it was okay. So one was breathing about ten percent of the allowable concentration.

That would require us to use a different model on that person to determine his intake than if it were an acute exposure. Although one can argue that a chronic intake is nothing more than a series of continuous acute intakes, and it ends up being that way, approximating that way in the models. Either way you take it, it ends up the same way. But the chronic allows you to bypass some calculations.

Okay. We do intend to rely on incident reports. These are valuable for pulling up a lot of that detective information that we're talking about. If a person was involved in an incident — that was some off-normal event that happened where he was required, more than likely would have been required to leave a bioassay sample, names of coworkers would have been potentially recorded, what the person was doing at the time — those types of pieces of information would be

extremely helpful in nailing down a specific incident when they do happen. And we're hoping that we can retrieve those things in the person's monitoring files as we request them.

Airborne radioactivity concentrations, lacking any other bioassay information, of course are useful to a certain extent to reconstructing exposure. And those can be of several different types, whether it's breathing zone air samplers, general area samplers, or just estimates derived from gross contamination levels in a facility.

So I'm going to go through a couple examples of what we would do for bioassay data, how we would look at some airborne air sample data, and how we might approach a estimate just based on some first order – first principle source term analysis.

Although before I do that – I jumped a little bit ahead – I need to talk about missed dose a little bit. And we actually talked about this, is the dose that could have been received and been undetected. And it's a function of a number of different things as based on the detection limit of the bioassay sample and the monitoring frequency.

The solubility, as I talked about, is a major factor in this dose. And we've done a number of calculations using our IMBA program and putting in hypothetical exposure scenarios for what we believe to be the detection limits of the monitoring programs at certain sites. And for what's considered pure class S material – that's solubility material that is removed from the lung slowly. There's three classes of solubility: F, M, S – fast, medium and slow. For the ICRP 30 types that's equivalent to D, W and Y. For pure class S material, there could be a missed dose to the lungs that results in greater than a 50 percent probability of causation without any positive bioassay.

This is a serious limitation of bioassay monitoring programs that we pretty much knew going in. So it's possible that a person who breathed in soluble material, who was exposed in a facility with insoluble material, and was monitored even monthly in the urine for urine samples and never showed a positive sample, one could estimate that there was a potential for that person to have had a dose that was greater than 50 percent POC for lung.

And this speaks to the issue of whether one is monitoring an organ — one has a cancer of an organ that is a source organ that deposits the activity, or it's an organ that the activity doesn't concentrate in. So in many facilities solubility of material is really a mixture, and we know that. We've done enough examination that there really is no one type that fits all facilities, and we need to consider that.

If you get down to this class M material which is moderate solubility, it's going to be a small contributor to the dose, more than likely, or it is a small contributor. But it can result in very large bioassay results, so — bioassay samples. So really need to consider the solubility of material.

Okay, I'm going to go now and talk a little bit about this efficiency approach using bioassay samples, and this is the same example I had yesterday, but I have a little more detail on the screen.

If you remember the flow chart we had, we said, okay, let's pick the mode of exposure that the person was most likely exposed. So here we have a person who worked at a plutonium facility

and left bioassay samples between 1961 and '65 — this is real data, it's not made up — and you can see that after about '64 his bioassay samples popped up and was well above the detection limit, as I talked about yesterday, which was about .05 picocuries per liter, so it's down in here.

So he had some evidence of what I would call chronic exposure in this time frame, but nothing that really strikes you — what strikes out as obvious is this bump here. So if we were to say let us just assume that this intake that occurred here, that the bioassay results that are coming out in this time period were a result of an intake that occurred back here in 1961, we can estimate his dose using that intake scenario. And it will be a wild, a very large overestimate of dose. There's no doubt about it, because we're way above any bioassay sampling in this area.

And then we can calculate what his dose would be. There's annual dose, and let's assume that he started working in '61, and his cancer was diagnosed in 1969, so we'll stop the analysis there. And here the dose is to, say, three separate organs that we might be evaluating as

primary cancers. It's very obvious for the lung that there's pretty large doses in this column, and it peaks at about 15 rem in 1962. So what that represents is just a clearance of this material out of the lung over time, based on this ICRP 66 model. But if you look at — 89, I think it was 89 in the first year, so these are very large doses. And I'm fairly confident that when I put this into a probability of causation model I would have some fair confidence that this POC is going to be greater than 50 percent, particularly if the person were a non-smoker.

The liver's not as clear-cut, though. It does not contain as much plutonium, obviously, over this time period, but it still has fairly large doses. I would say that's still a fairly large exposure and a pretty high probability of compensation to the — because the plutonium moves out of the lung, and we know metabolically it concentrates in either the liver or the skeleton. Those are the three main deposition sites.

On the other hand, if the person presents with urinary bladder cancer, the doses are orders of magnitude lower for even this wild, high, overestimate of his exposure. Ignoring this

material here, but saying that this intake occurred way back in '61, this is well less than a rem exposure over that period, so his probability of compensation's going to be fairly low. There's no real indication here.

So again we start with our approach, and we say what did our overestimate look like? And here we have three examples of how we might proceed based on that analyses.

So then we said okay, let's do an over-estimate; now let's go do the other way and do a conservative — not an underestimate, but just take a conservative approach. Let's take a conservative approach and not include all his dose. So this is a blow-up of that graph, but I'm starting from '64, so this represents just that increased time period where he popped up in 1964. So here we're saying I'm not going to count any of these points, and I'm only going to model the dose as if it were — started here in 1964. So let's say he was exposed in '64. What is his dose, assuming this scenario? So this would be a low estimate.

If we take the low estimate, we still see a fairly large lung dose, which I suspect — and I

don't have the data to establish this yet, but that would result in a fairly significant probability of compensation. Or say it were a liver dose that is not as clear-cut, and the bladder, of course, is still low, and we in fact would not have even evaluated the bladder on the second pass because the high – the whole highest (inaudible) would have not even made it.

So this is an example of how we would go about using these bracketing estimates using internal dose models that we've established.

Yeah.

DR. ANDRADE: On each of those examples for input parameters into ICRP 60 methodology, do you also use Monte Carlo to select – to pick it from a distribution those solubilities or particle sizes?

DR. NETON: Not in this particular example, because these are our worst case upper limits. Essentially they would be the Monte Carlo upper end samplings without really going through a Monte Carlo.

DR. ANDRADE: Okay. So that would be equivalent to an ICRP 26 study methodology assuming Y class material and one micron type

particle size?

DR. NETON: It's analogous to that, but we're using the 66 methodology, which would be an S class solubility and five micron particle size default.

DR. ANDRADE: Thanks.

DR. NETON: Okay. If we don't have any of this nice bioassay data to hang our hat on, we need to go back and look at the work place data.

And this is a simple example of how we might use work place air monitoring data to – this is a simple example of say that we happen to have five air sample results for a particular work scenario and this is this red blob here. Here's an area where a worker, Work Area A, could have worked during his period of employment, and this other blob up here, let's call that Work Area B. And we're fortunate enough to find some facility monitoring records which we do have, at least at one facility, some pretty decent records of this nature.

And we have these five air samples that are distributed about the site – air sample one here, air sample two, three, four and five. I suppose I could have done a better job of numbering these

air samples, but nonetheless, we have five samples represented by these little blue dots. And these are the measurements that were received or detected at each of these air sampling locations in what's called like, say, 3 DAC, which would be three times the derived air concentration. Those values would be in microcuries per milliliter or becquerels per cubic meter. It sort of doesn't matter for this conversation, but these are all relative values of some level of the regulatorily allowable exposure air concentrations.

So how would we go about, for instance, estimating the intake, which is how much material, radioactive material did this worker breathe in in each of these operations? Well, one option is to take all five of these air samples and average them and apply them to each scenario, but that doesn't necessarily make the most sense. And in fact, if we looked at this — if we took Work Area A, I think that we would select half of the air samplers based on sample one and half based on samples two and four.

So here's air sample one for Area A, so we'll take half of the air concentration based on

that, and then we would half based on the average of these two to assign it to this work area. And in fact, we would end up using an average air concentration in that work environment of about one and a half DAC.

The other scenario —

DR. ZIEMER: Is that weighted also for the size of that area, or is it —

DR. NETON: No, it's not. This is a simple example. I'll agree with that, and I'm not sure we can get that refined. But it's a good point.

This other sample, though, we have an air sampler here and an air sampler here, and the source of airborne radioactivity up here. So clearly, if this is the source and it's pluming out in this direction with the ventilation direction in this manner, then we'd probably be best off extrapolating backwards and taking some interpolation of three, five — five, three and one, and going back here.

So it was two at air sampler five, it was four at air sampler three. And if we want to predict back here at the source, I think we would say — we extrapolate one, three and five back, we would predict that the results would be five DAC

based on that location. So — one, three and five, I'm sorry. So we go back this direction and extrapolate, interpolate backwards. So I don't know that we're going to have all this level of detail, but I know at least we are going to have some situations where we're going to have to do this.

And of course we need to do something with that result. We just can't report the worker's dose in air concentration. So we're going to convert the intake into — or convert that measurement into some intake using this formula that you see on the screen, which is the concentration times the breathing rate in milliliters per hour — that represents 20 liters per minute breathing standard of reference worker times the stay time – and apply any protection factors as necessary.

Now I should say a word about use of protection factors. It is our intent to be somewhat skeptical of respiratory protection factors. Historically they may have not either been worn as instructed, or the fit-testing program may have been adequate to qualify them as protection devices for the workers.

I think in more current environments we may be able to use that, and in fact we are going to be required to use that in situations where air sample results for breathing zone air samplers are taken here, are reported already corrected for respiratory protection factors. I know that's a routine practice at facilities, to take the BZ result and divide it by a factor of 50 if a person's wearing a full-face air purifying respirator, and record that as his intake.

So that's going to be in there. We need to be aware of that, and then we need to evaluate at that time whether or not that was appropriate. So we just need to approach this with some trepidation.

Okay. And the last of my examples is where we have nothing as far as air concentrations, no bioassay data. And this is a somewhat simplistic example, but it serves to point out that there are something we can do, given that if we know how much material the worker was — what he was working with and how much.

And let's take this example where there were no air samplers in the area, and a person was working in a hood and playing — working with

these uranium dioxide sintered pellets, and it was a grinding operation where he's taking certain amount of surface area off of the pellet, and they're a half-inch diameter by a half-inch high.

By the way, this is sort of an adaptation of the approach that's used in — those of you familiar with the new Reg 1400 document that talks about the need for air sampling in the work environment, we're kind of taking a backwards approach and said if there's a need, let's predict what — you have to predict what the potential air concentrations are to determine if you have a need for air sampling. So we've kind of worked this process backwards to come up with these type of examples.

Let's assume the fume hood has a face velocity of about 150 linear feet per minute, and the person's working with these pellets a couple of feet from his face with a high-speed grinder, and the velocity of these pellet — the grinding material is faster than the hood can remove it from his breathing zone, and the guy's average rate is about 20 pellets an hour.

So he's grinding these pellets. He's doing

about 20 an hour, and there's some potential for airborne generated in his work environment. So again we've assumed that he's removing a 1000th of an inch, and we know the density of the material since it's uranium, and we can calculate from that how much radioactivity is being generated into this airborne sphere of two feet diameter that's in his breathing zone environment.

And the predicted — based on that calculation, we can predict that the air concentration — conservatively, because we're assuming it's all ejected towards him — is 1.5 times 10^{-7} microcuries per milliliter. At 20 pellets per an hour, we come up with 5 times 10^{-8} microcuries per milliliter. And if one compares that to current — the derived air concentration for insoluble uranium, which this is, it's three orders of magnitude higher than what the allowable limit is.

DR. ZIEMER: You didn't say anything, however, about the particle size there. The fact that it isn't captured in the air flow implies a fairly heavy particle. What about the — sort of the mass median aerodynamic diameter —

DR. NETON: That's correct. It would be conservative for us to assume that this was a five micron particle. It's probably more dense than that. By definition, if it's five micron diameter, the density would automatically make it heavier than that, you're right. So this is a bracketing estimate to try to determine if there is a large potential for exposure in this case. So since he's three orders of magnitude above the limit, we could readjust the particle size and do a little more careful analysis, that's right.

One nice thing about the IREP program, though, is we are not constrained to point estimates. In fact, one of the allowable inputs is a uniform distribution, meaning I don't really know what this is, but I know it's between A and B. And when you sample the person's exposure, sample all those possibilities uniformly, which would be the most generous distribution one could assign. I'm not suggesting we intend to do that in all cases, but one could.

In a case like this – for example, if this worst case analysis came out very low, and we said it's very low, we're not really confident. We know we're within an order of magnitude, and

we know it's from – pick two numbers – one and ten. If that were used as the IREP input and the value were still extremely low, then again we've managed to make a determination regarding compensability one way or the other without really biasing the analysis.

DR. ROESSLER: I have a question about the word "we." This is – the word "we." This has kind of concerned me all the way throughout your presentation, which again I don't think there's any question about the science. What I'm trying to determine is when you say – all these things, especially with the internal, are going to be done, I assume, on a very individual basis. A lot of this, as you said, is art. It's interpreting, making best decisions.

I'm concerned about objectivity. I don't have any question about NIOSH, but I don't know much about the contractor proposals and who is going to be doing this, and who's going to be doing what. And maybe that's too big a question at this point, but that's it, is –

DR. ZIEMER: Maybe a preliminary answer would be appropriate, and also some indication of the degree to which you will be able to formalize

the methodologies that are used.

DR. NETON: Right. That was going to be in part of my response, and maybe Larry can kick in here at the end with some other discussion. But "we," meaning NIOSH, intend to document as much as possible how this process runs and provide this to the contractor. That would be through technical guidelines, and actually procedures as to how one flows through these analyses.

That being said, though, you are right. Internal dosimetry, we have to rely – allow for some latitude in interpretation. But where information is lacking and cannot be ascertained definitively, one should – one is almost required to default to some conservative assumption without any other information available.

We also intend to have a fair level of quality control involved over the contractor, where a certain percentages of the dose reconstructions that are performed will be done separately by us and compared to what the contractor does come up with. We intend to review all dose reconstructions that come out of there – not necessarily review all calculations, but at least they will be issued under NIOSH

letterhead and have at least gone over some level of review by a NIOSH representative.

I'm not sure I –

DR. ZIEMER: And likewise, is this not the sort of thing that you want this Board to take a look at, some of these actual reconstructions.

DR. NETON: Yeah. Oh, yeah.

MR. ELLIOTT: That was going to be my –

DR. NETON: And the Board, as well, I forgot.

MR. ELLIOTT: That was going to be my comment. It's NIOSH – when he's talking "we," he means NIOSH. It's our responsibility to provide oversight to the contractor who will be doing these dose reconstructions.

But I hope through these examples that he's shared with you this afternoon that you start to get a sense of how you might develop your sampling strategy in review of dose reconstructions, because we certainly have started thinking about that when we apply that, not only for the Board but for our own quality control interests that Jim mentioned – which ones we're going to target, which we're going to spend more time on, which we're going to spend less

time on. And he's right, we are going to look at every one they do, and we will spend more time on perhaps something like this until we're confident that we've got it down right.

DR. MELIUS: I have a related question. This probably jumps a little bit, but relates back to the proposed regulation also. And that's the issue of how is this going to be documented and then communicated back to the people involved.

You talk about what some of the steps are involved, but it really is not clear to me from the regulation, what I've seen so far, is what will be the documentation that will be communicated back to the worker or the claimant that would have a concern, as there's an appeal issue and so forth as the information goes forward. You have put in place a mechanism where the, quote, draft results would be shared and discussed, but it's not clear the documentation for that. And I'm particularly concerned in the case where there is incomplete data. In fact, the data can be so incomplete that you cannot –

MR. ELLIOTT: (Inaudible).

DR. MELIUS: So what will be the

communication in that case? And I think that also goes to this whole issue of how we do oversight on the process, and also deals with some of these – the appearance of conflict of interest issues in terms of people, potentially some of the people involved or whatever.

MR. ELLIOTT: Sure. Well, we certainly can't provide you an example of the communication today, but in a general sense I think these are going to be individualized.

And we are going to work with the claimant throughout this whole dose reconstruction process, from not only the point of the interview, but once we approach the claimant with what we consider to be a completed dose reconstruction, we'll consider how we articulate what was done in that dose reconstruction, what the limitations of it were, what issues we want them to be aware of associated with that.

So each one of these reports that goes back to the claimant as a draft, before they sign off and accept the dose reconstruction, is going to require a considerable amount of effort on our part to really communicate how we treated their data, if there was data. If there wasn't data,

what did we do to come up with these numbers.

DR. MELIUS: I think that maybe there's two separate issues. How do you document it? Because from the point of view doing oversight or sampling the documentation's important, and the second issue is what part of that or does all that documentation go back to the claimant? And it's — I don't think that's clear from your regulation.

MR. ELLIOTT: It's probably not clear. But the claimant will of course have a right to view their whole case file, which we will have added to along this trail of dose reconstruction, and we will walk them through that not only in the report, but actually as we talk to them over the interview and as we develop the dose reconstruction.

But this is a good point you're raising, and this is something we probably have not clearly articulated, as you say, in the rule, and we need to pay more attention to that; and when we promulgate the final version, we should address it.

DR. NETON: I think, if I could add a little bit to that, I think it's the intent that the

claimant actually receive a copy of the technical report, but on top of that technical report is going to be a one- or two-page summary that is a narrative of what was done in somewhat simpler language, so that a non-technical person could understand it. I do believe they have a right to the technical report that we use to determine their dose.

So two pieces of information actually will go to the claimant: A summary report, and then the actual dose reconstruction — not necessarily all the raw data that we've used, but which data that we ended up — we did end up using in the dose reconstruction. He's certainly also going to have a copy of his interview that we conducted with him, because he is required to review that and weigh in on that after we do the interview. And he'll be able to see clearly to the extent that we used the information that he provided versus the information that was provided to us by Department of Energy and monitoring programs, and why it was or was not used in his dose reconstruction.

DR. MELIUS: Is the claimant going to be made aware of the information that was not

available? For example, records were missing or unable to find that –

MR. ELLIOTT: Yes.

DR. NETON: Yeah, that'll be part of a narrative discussion, as to how the – what approach was taken.

Grady has a comment.

MR. CALHOUN: This is Grady Calhoun.

I just, in listening to some of this, in 82.26 it's somewhat detailed as to the type of information that would be included in that report and given to the claimant. And some of the very things you're talking about are listed in there as specific items that need to go in there. For example, if data information is given and we, for some reason, decide not to use that, we have to state in there we received it, we didn't use it, and here's why. So I just didn't know if you had read that section or not.

DR. MELIUS: Well, no, my question was to the – there was reference as to the documentation of some of the information, but not how it would be communicated to what extent would be available.

And secondly, in the – and maybe I've missed

it – but in the issue where you're unable to have adequate data in order to do a dose reconstruction, it's not clear how that will be – how your effort will be communicated back. What will the documentation be that will say, sorry, we couldn't do it, or we couldn't find it, or this is what records from those years were missing, or we have – it's a subcontractor, DOE had no records of or the facility had no records of your ever working there, things like that.

There's lot of possibilities there that I think are going to be important not only for the claimant, I think they're also to some extent important to the committee in terms of us figuring out – making recommendations for how this program should go and be improved.

DR. ZIEMER: Certainly under 82.26, which is really the guideline or will become the rule in some form, there will have to be some sort of SOP, standard operating procedures, as to how they're actually going to carry out the details. I wouldn't expect all the detail to be in the rule itself.

MR. ELLIOTT: No. But your point is well taken, Dr. Melius, on if we cannot do a dose

reconstruction, what happens? How do we communicate that, and what happens next to that individual claimant? And this proposed rule is fairly silent on that, and the reason why is you're going to see that come forward in this Special Exposure Cohort petitioning guidelines, in what we're suggesting there. You don't have that in front of you, I know, but —

DR. NETON: But we do — there is an inclusion in 82, though, that addresses if we cannot do a dose reconstruction, we can inform the claimant that it was not possible. And what you're saying is we need to detail why. That's not explained.

MR. KATZ: Can I interject, just because it — in fact, if you look in that section in the rule, it does explain exactly that we would be explaining to the claimant what information was necessary to do dose reconstruction and wasn't available. So it would be.

DR. MELIUS: But explanation, which as I read it was just part of the interview, is a little different than a document that —

MR. KATZ: No, this is the report at the end, not the interview. I'm talking about in the

report. It would be a documented explanation, with the documentation of what data was required to be able to complete a dose reconstruction and wasn't available – isn't available. Is that – it would explain how that information would be used, as well as what the information is that's missing.

DR. ZIEMER: Well, certainly the issue is noted. It needs – attention needs to be given to that as we proceed. I think it's an excellent point.

DR. NETON: I don't want to belabor the point, but there's another side issue to this, and it points to the fact that this report has to be fairly well crafted.

As we talk about doing these efficient – applying the efficiency process to claims, it works fine if a person presents with one cancer and that's the end of their story. But a claimant needs to be informed that if they present with a second primary cancer five years down the line, the dose reconstruction that was performed and provided to him is not necessarily the bottom line. If we run through and do this efficiently and say yes for lung cancer, we're

done, we have to go back again and re-evaluate how refined that lung cancer estimate, dose estimate was, because it may not be obvious that the person is qualified or not qualified for compensation.

Do you follow my logic on that?

DR. ZIEMER: So maybe rather than fairly well crafted, the report has to be very well crafted.

DR. NETON: Very well crafted, okay.

DR. ZIEMER: Right.

DR. NETON: Exactly. These types of issues need to be pointed out in this correspondence and report as early as possible, so that there's no mistake as to what happens down the line.

DR. ZIEMER: Jim, this has been a very informative presentation. We thank you. I —

DR. NETON: No, I have one last slide to go over.

DR. ZIEMER: Oh, I'm trying to turn you off here, but finish up, please.

DR. NETON: Okay, sorry.

This is just the last slide that talks about how we're going to handle the relationship between primary cancer and organ doses, and we've

envisioned four different scenarios.

As indicated in the IREP program, we're going to use ICD-9 codes to determine the primary organ that we need to do the dose for, but there's not always a one-to-one correspondence between the ICRP 30 — the ICRP available organ and the ICD-9 codes. In fact, there are many more ICD-9 organs than there are cancers or doses that we can calculate it for.

So what we intend to do is apply this strategy where if there's more than one ICD-9 code for a region, we will calculate the dose to the ICRP region that's described and assign a dose. So for instance, in the nasal/pharyngeal area we sometimes have more organs available to calculate a dose than the ICD-9 code applies. Is that right? Hang on. There's more than one ICD-9 code for the ICRP region, yeah. So if there's multiple codes, we'll just take that region and apply it across the board. That's an easy one.

One ICD-9 code describes organs associated with more than one region, that would be an example of, say, the gastrointestinal tract. If someone has intestinal cancer, we can calculate the dose to the small intestine, the large

intestine, colon. We would calculate the dose to all three, and then take the largest one and default on a conservative side for that estimate.

If the organ is not contained in an ICRP dose model, then we would take the dose from the highest exposed organ that's not associated with a known metabolic site. For example, for plutonium, if it — the liver, the lung and the skeleton are the organs that concentrate plutonium. Then we would take the organ just — the next highest organ that is not one of the three sites that's described in the metabolic model and use that. And that would imply that it's an overestimate of the dose because it's — of the 36 organs that ICRP has modeled, they're presumed to be the 36 highest exposed organs internally.

And when it comes to lymph cancer it's a little less clear-cut, but we only have a lymph node cancer model in the ICRP models. So if it's clearly a lymph cancer that's associated with the lung region we'd use the lymph model, but outside of that we would use the approach that we just described above for number three, and use that in the remainder organs, take the next highest

exposed organ and assign it.

It's claimant-friendly, but as you see from my earlier examples, organs that are not metabolically involved in the metabolism of the radionuclide are orders of magnitude below in exposure levels. So more than likely those organs will not be compensable cancers in those scenarios, but it is claimant-friendly. We'll pick the highest dose.

Okay, with that, I will conclude my formal remarks.

DR. ZIEMER: Well, the comments I made before your last slide still hold. We do thank you for that.

Let me ask if any of the committee members have additional questions before you're seated here.

[No responses]

DR. ZIEMER: Okay, thank you, Jim.

MR. ELLIOTT: If I could ask —

DR. ZIEMER: Oh, yes.

MR. ELLIOTT: I want you to be aware that we've kind of been feeding you information here, information yesterday about this dose reconstruction rule, a little more information

today about the technical aspects of internal versus external dose reconstruction. And in the next meeting in February it's our intent to present to you, in advance of that meeting so that you have time to review them, the technical guidelines for both internal and external dose, okay? So I just wanted to give you a sense of how I see this as progressively tasking the Board. So you're going to get more detail next month on this.

DR. ZIEMER: Jim, comment?

DR. MELIUS: Can I ask just in terms of the process here of obtaining the information, is there a formal agreement between NIOSH and DOE in terms of getting – making available the different types of information that will be necessary for this process?

MR. ELLIOTT: We are working on that. We have a draft Memorandum of Understanding in our department going through review. The Department of Energy is waiting for that to be sent over for their examination, and that's our intent. Much of this MOU does address the need and issues surrounding provision of data and information.

DR. MELIUS: Because I thought NIOSH had,

with the regulation, done a good job of outlining the various sources of information and might be used, but those are also going to have to be made available in order to use it. And it's not an inconsiderable burden to obtain this with a lot of difficulty, even in the best of circumstances.

DR. ZIEMER: Now I call attention to the agenda. We're overdue for a break, but I notice if we take the break then we are rapidly at our closing time.

I'd like to ask the committee – well, my feeling at this point is that we probably are not at a point where we want to or will be able to spend any extended time on looking through the rule itself this afternoon. We at best would have about 15 minutes and barely get into it.

On the other hand, my plane leaves very late today, so I can stay if there's just a great urgency or urge on the part of the committee members just to stay on for two, three more hours, why we can do that. But we actually have put in a lot of time today. I think it's been productive. And if there's no objection, we will continue the working session on dose reconstruction at the next meeting, where we will

get into the rule itself in more detail.

I do want to –

DR. MELIUS: Just one question, not saying this will be necessary, but I assume that Larry's offer to reopen the rule for comment still holds, the dose reconstruction portion of the rule?

MR. ELLIOTT: We're going to check on whether or not we actually have to do that to effect a reopening of the comment – the record to incorporate your comments, or if we can just add them to the record at the point in time they're available.

DR. MELIUS: Okay. That would actually be helpful, I think, for some of our future issues between now and – particularly between now and when the whole process becomes operational, when the rule becomes final. I think it'd be easier –

DR. ZIEMER: Thank you.

DR. MELIUS: – if we didn't have to do that, because I do think – the sneak preview of the Special Exposure Cohort process, I think, may affect how we want to say – it actually may affect how the rule would work, too, I think.

DR. ZIEMER: I'd like to remind the members of the Board to provide to Larry Elliott the

information on their preparation times.

MR. ELLIOTT: And your calendar for –

DR. ZIEMER: And your calendar, if you haven't already done that.

MR. ELLIOTT: I need to know – just write down on that little pad there, Jim, one page, how many hours or how many days you spent –

DR. ZIEMER: Your name and the hours of preparation time.

MR. ELLIOTT: – preparing. And don't be embarrassed –

DR. ZIEMER: I also would like to give members of the public, if there's anyone else here that did not have an opportunity to make public comment but wishes to do so, we can accommodate that at this point.

[No responses]

DR. ZIEMER: They're as anxious to leave as everybody else.

We do appreciate the input we've gotten from members of the public. Appreciate the good work of the NIOSH staff and others who have participated and supported the work of the Board, and certainly appreciate the effort of the Board. I think we made good progress in the last two

days, and we're off to a good start, and we commend you on that effort.

I'd like to ask if anyone else has any comments for the good of the order before we adjourn?

Okay, a comment from Larry.

MR. ELLIOTT: Unless you have one –

DR. MELIUS: Well, probably the same comment. Certainly thank our Chairman in doing an excellent job in –

[Applause]

DR. MELIUS: – doing this process and guiding us through the first meeting.

DR. ZIEMER: Thank you.

DR. MELIUS: You have to abstain from the vote, but –

MR. ELLIOTT: That was a little bit of my thunder. I was going to extend my appreciation to Dr. Ziemer, as well as to the Board members. I appreciate your time and your effort and the difficulty it was in getting you all here, and glad that we've had these two days together. I think it's been very productive, and it's been that because of the staff preparation time as well as your own preparation time. So I do

appreciate that. Thank you very much.

DR. ZIEMER: Thank you, and we then declare the meeting adjourned.

[Whereupon, the meeting was adjourned at approximately 3:44 p.m.]

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C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 128 pages, was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

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

WITNESS MY HAND AND OFFICIAL SEAL this _____ day of February, 2002.

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

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