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Department of Health and Human Services

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)

Advisory Board on Radiation and Worker Health

VOLUME I

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P R O C E E D I N G S

(12:30 p.m.)

DR. ZIEMER: Good afternoon, everyone. I'd like to call the meeting to order. I'm Paul Ziemer, Chairman of the Advisory Board on Radiation and Worker Health. This is the sixth meeting of the Board. It actually was -- we had a sort of prelude. Our working group on dose reconstruction actually met yesterday and this morning, and now the full Board meets here this afternoon and all day tomorrow.

The Board members are all present. If you are an observer and wonder who the various people are who, their placards are by their seats so you can identify them. I'm not going to go around and introduce all the Board members at this time, but I would like to introduce two new Board members who are not yet seated at the table. They were approved just within the last couple of days by the White House, but the government bureaucracy is such that the White House approval is not enough to get them at the table here for some reason. There actually are some red tape issues that have to be taken care of before they're formally seated, but they are here today both as observers and they're certainly

welcome to speak at any time.

Let me introduce first Mike Gibson. Mike, stand up so we can see you.

MR. GIBSON: (Stands)

DR. ZIEMER: Mike is president of the PACE local union at the Mound facility. Mike's from Franklin, Ohio. Welcome, Mike. We're glad to have you here.

And then Leon Owens, who is in a similar position with the PACE local, president of the PACE local at the Paducah facility. And again, Leon, we welcome you, and both of you are certainly welcome to participate in the ongoing deliberations here today and we look forward to having your full participation once all that bureaucracy is taken care of.

I wanted to remind everyone here, Board members and observers, members of the public and other staff to be sure to register your attendance. There's a registration book at the table in the rear. Please do that, if you haven't already, sometime during the day.

And then also, members of the public who wish to address the Board during the public comment session, there is a notebook page for you to sign up

on so that we can have some idea of how many will be planning to speak and we can adjust the timing accordingly.

The agenda has been distributed. It's been on the web site, but I believe there are also copies of the agenda, as well as other handout materials, on the table in the back so members of the public and others who have not already done so, if you need copies of those, please help yourself to those, as well.

We're going to proceed with the agenda items, the first of which is the approval of the minutes of our last meeting, and I'm now going to move back to my seat for this. Let me comment first that the draft minutes are rather lengthy. They are 40-some pages in length. Some -- although they were on the web site, some of the Board members were in travel status and may not have gotten them before they arrived. Some Board members just arrived this morning and may not have had a chance to even look at those, so I'm going to give the Board two options. One would be a motion to approve, the other option is a motion to defer action until tomorrow, which means if you make such a motion, you're committed to reading these tonight before we

return tomorrow, so no goofing off tonight. But I do want to allow that option if you want to defer action on these until tomorrow, if -- I don't know how many have had a chance to read these or not.

Does anyone wish to defer action?

(No responses.)

DR. ZIEMER: No motion to defer action. If not, I'm going to ask for corrections or additions. Now let me preface that by saying I'm not going to ask you for typographicals because -- and there are some. We will simply feed those back to the staff and they can make those. I'm looking for changes of substance, either incorrect statements or comments or things of that sort. So -- and -- okay, Mark Griffon, you can start.

MR. GRIFFON: It's just a -- on page three, kind of a technical point.

DR. ZIEMER: Is this three of the --

MR. GRIFFON: Three of the body --

DR. ZIEMER: Three of eight?

MR. GRIFFON: Three of eight --

DR. ZIEMER: Which is the executive summary.

MR. GRIFFON: Yeah. It's the third to last paragraph, starts with any suggestions. The line (reading) This could be the reasonable uncertainty.

Was actually -- it should be: This could be the uncertainty combined with the central estimate that is then cancer specific. That was my proposal there. And that appears again on page 16 of the main body of the report.

DR. ZIEMER: So your suggestion is that the word "reasonable" be deleted and that it simply say: This could be the uncertainty, combined with the --

MR. GRIFFON: And replace "mean" with "central estimate". And that appears again in the main body on page 16.

DR. ZIEMER: Also on page 16. Are there any objections to this change? Let me move on and ask for others, I'm not going to vote on these one by one. Let's get them all before us and then we'll take action.

Other comments or corrections? Wanda, you're next.

MS. MUNN: A minor point, perhaps, on page ten of the main body, the next to the last paragraph when we're talking about the Board advising the Department before it decides not to evaluate the petition. I don't recall how much conversation we had, but I think there were a couple of comments about whether we needed to specify the basis for our

decision. And I don't know that we captured that. I don't know whether it's of major importance, but --

DR. ZIEMER: I believe the context here is that this is Mr. Katz's explanation to us of how he understood the wording or what he understood the wording to mean.

MS. MUNN: Yes, and --

DR. ZIEMER: And in fact, some of that includes things that -- where we had some differences and I think would be taken care of by our comments later, perhaps.

MS. MUNN: Okay, I didn't --

DR. ZIEMER: I believe this is Mr. Katz's explanation.

MS. MUNN: It was, yes, but I didn't see that we caught it elsewhere. That's -- as I said, no major issue for me. I just felt when I read it that it didn't quite --

DR. ZIEMER: This isn't necessarily what the final rule will say --

MS. MUNN: Right.

DR. ZIEMER: -- is what I'm saying. This is -- yes.

MS. MUNN: Yeah.

DR. ZIEMER: Okay. Thank you. Other comments? I'd like to ask a question on the footnote on page 4/8, that's the executive summary, and I think this appears elsewhere, too. (Reading) Two dose levels produced a 5.25 threshold.

And maybe I can ask one of the staff, is that 5.25 -- is that intended to be rem? Do we -- what is that number, the threshold? Is that a dose threshold?

UNIDENTIFIED: Yes, I believe it is.

DR. ZIEMER: Is it rem? Is that -- okay, if we could add the word "rem" there then.

There was -- I have a question on page 5/8, and this is part of a public comment. I think the commenter's here, and perhaps the statement is correct. It talks about a wish to reinstate DOE's retention of historical records. I guess my question was, have they -- is there an official policy that they not retain historical records? I guess perhaps I shouldn't ask for this to be corrected. I think that probably was the statement. I think it was your statement.

UNIDENTIFIED: What was it again? I was --

DR. ZIEMER: That -- the commenter wished to reinstate the DOE's retention of historical records.

UNIDENTIFIED: Yes, I made that statement.

DR. ZIEMER: Okay, then that's fine. Okay. On the top of page 7/8, the first paragraph -- again, I can ask -- maybe address this to staff. The third line from the end of that paragraph says (Reading) These assumed, except for breast and thyroid cancer, a quadratic dose response.

Could that be a linear-quadratic?

UNIDENTIFIED: It should be linear --

DR. ZIEMER: So it would be linear-quadratic dose response.

UNIDENTIFIED: What page was that?

DR. ZIEMER: It's the first paragraph on 7/8. It would be line -- line five. It should be then linear-quadratic.

On page six, item two -- and this has to do, Mark, with I think your report. And in the bullet under item two, it talks about the need to do a strategic sample. I'm wondering if that perhaps is supposed to be a stratified sample.

MR. GRIFFON: A stratified sample, yes.

DR. ZIEMER: A stratified sample?

MR. GRIFFON: Yes.

DR. ZIEMER: Okay. Thank you. I think the others that I have are mainly editorial and I'll

feed those back to the recorder.

Let me ask this question -- it's on page 32, the very last line, we have the 5.25 threshold again and so we'll insert the word "rem" there. And then in that sentence it says (reading) The average of 1.5 and 9 produces a 5.25 threshold -- rem threshold for health endangerment.

I'm wondering if -- I think this is Mr. Katz's material. I don't want to necessarily put words in his mouth. I think I'd be more comfortable if we said health effects. I'm not sure we endanger health.

MR. ELLIOTT: That comes from the language of the statute.

DR. ZIEMER: Okay, so we'll have to leave it. Okay.

DR. MELIUS: What about putting quotes around health endangerment. That way we know it's a term and it's not a statement of --

DR. ZIEMER: That would -- thanks, that would help, right.

Are there any other additions, corrections, modifications? If not, I'll ask for a motion to accept the minutes with the changes that have been noted.

DR. MELIUS: I so move.

MS. MUNN: Second.

DR. ZIEMER: Moved and seconded. All in favor, aye?

(Affirmative responses)

DR. ZIEMER: Any opposed, no?

(No responses.)

DR. ZIEMER: The motion carries, the minutes are adopted. Thank you very much.

Now we have an opportunity to review past action items and Larry Elliott's going to take us through that. There also is a -- in your booklet there is a section called action items.

MR. ELLIOTT: Well, it's good to be here with you all again on a very short turnaround. Seems like just yesterday and only about 40,000 air miles ago we were together, and hope that your visit and stay here in Cincinnati is going to be very enjoyable for you. And if it's not, let me know and I'll get this right 'cause I'm trying to move us along.

Certainly a lot of work the Board has accomplished again in a short amount of time, and a lot of work ahead of you. If you recall, I think it was the third meeting in Washington where you all

suggested and we thought a good idea, and this has also been practiced in other boards, as well, to carry on a list of action items and show the status of those items. As you can see, these -- we kind of started providing lists of these efforts back in February, so we wanted to touch base at this meeting on where we're at with some of these things, show what we consider to be the status among the staff and make sure that you're in agreement with that status or if there's remaining work to do or some other spin-off that you feel needs to be added to this list, we get that accounted for.

So as you see here -- I'm not going to go through each one of these, but just to highlight -- you wanted to hear about the history of this legislation so we brought Dr. Michaels in in May and provided that to you.

We -- I think this first one here should say clarified at 5/02 meeting commitment to provide consultation to this body as you deem it necessary and appropriate. We'll have to add some kind of language to that 'cause I think that's an ongoing effort. When you identify a expert that you want to hear from, we'll bring them to you, as we did with Dr. Lamb to discuss IREP issues.

We're going down through what list we acquired in May and you're going to see a lot of spaces there. You see the status as we see it, and I would ask for your comment on that. But I'd also ask you to help identify what the priority should be for this Board, what priority of action you want to take, recognizing that some of these items are not timely to act upon, that there needs to be certain things put in place before we can take some action on them.

For example, let's go down to identifying research gaps. I think that's something that we do need to engage on and work on, but I'm not so sure we're at a juncture right now where it makes a lot of sense for us to pick that up ahead of let's say explaining the records request process. So that's the kind of thing I'm asking you to take a look at and help identify for us what you want to hear about.

We're going to talk briefly tomorrow about our experience with the Town Hall meetings on the SEC, but we lay claim here that we completed those as of last week. We certainly don't have the last two transcripts up on the web site. And Mr. Ray Green, who went on the west coast trip, is somewhat

in a complicated situation trying to finish those up and pull this one together, as well. Right, Ray? So he's assured me we're going to get those soon and I've given him a little bit of breathing time to do so. We will give you the summary of what happened in those meetings, however, tomorrow, so -- let me see if I'm on the right track here.

You have this also in your books, the dose reconstruction working group meeting, so you need to take that into account. And I'll leave you with this last one on the action items that we think are the Board's action items specifically. So it's up to you to --

DR. ZIEMER: Maybe there is some question -- one of the items up there is -- it says (Reading) If no MOU -- this is a DOE MOU -- by next meeting --

Is that this meeting? -- then update status. If now's the time, I can direct to that or --

MR. ELLIOTT: I can't remember.

DR. ZIEMER: We didn't have that as a separate item, did we, on the --

MR. ELLIOTT: It's not an agenda item on this. There's no program status report on this agenda for this meeting.

DR. ZIEMER: But maybe if you might comment on the MOU.

MR. ELLIOTT: Surely. The MOU has now been interchanged several times between -- at staff level and is now at the Deputy Secretary's level being negotiated.

DR. MELIUS: One other update, the dose reconstruction status not detailed.

MR. ELLIOTT: Sure. That -- the award for that dose reconstruction contract is at the best and final stage of negotiation. We expect an award to be made very shortly.

DR. MELIUS: Could you just --

MR. ELLIOTT: Follow up.

DR. MELIUS: -- government jargonese, but best and final's changed since the last meeting and hopefully --

MR. ELLIOTT: In the competitive process of awarding a contract, there's been one proposer that has been deemed ready to negotiate for a final award out of all those proposers that competed.

DR. MELIUS: Thanks.

MR. ELLIOTT: So we're just going back and forth on --

DR. ZIEMER: Sounds like a name has gone

forward up the channels, perhaps.

Other questions for Larry or comments on the list right now?

(No responses.)

DR. ZIEMER: Thank you very much. Larry, you're going to report on the visits to the public meetings later. Right?

MR. ELLIOTT: Yes, we -- Ted Katz will be giving you a summary presentation on that at the start of your agenda item tomorrow morning, discussion on the SEC NPRM.

DR. ZIEMER: Thank you.

DR. MELIUS: Can I just --

DR. ZIEMER: Jim?

DR. MELIUS: One procedural question. The agenda that was on the web site I think listed Owen Hoffman as being on the agenda for tomorrow. Is that just a misprint or --

DR. ZIEMER: I don't think Owen -- Owen --

MR. GRIFFON: Yeah, I noticed that, too.

DR. ZIEMER: -- was on the August agenda?

DR. MELIUS: Yeah, on the one that was posted on the web site.

DR. ZIEMER: I wonder if that's something that didn't clear from the previous agenda or

something.

MR. ELLIOTT: Well, Owen was on last month's -- or last meeting's agenda.

DR. MELIUS: It was a misprint.

MR. ELLIOTT: He's not on this agenda. He had no plans to be here. I hadn't even -- I'm sorry. I'll check that out.

DR. ZIEMER: Unless you were looking at last month's.

DR. MELIUS: Mark and I -- Mark was on the phone --

DR. ZIEMER: Oh.

DR. MELIUS: -- trying to figure out which agenda we were looking at.

DR. ZIEMER: At the last meeting we approved -- in fact, take a look at the very last page of your minutes, which is addendum two or attachment two, dose reconstruction review work group recommendations. You recall at the last meeting we actually approved these recommendations. They were, in a sense, sort of the first step or first cut from the working group as to what they felt should be our direction, and basically we've adopted these. They are broad and somewhat general. That working group was tasked with visiting -- in fact, the reason

we're here in Cincinnati was to couple with the work group's visit to the facilities to look at how the paperwork is being handled, how the dose reconstructions are being done and to get a kind of a better first-hand knowledge of what it might entail for us to oversee, in a sense, the dose reconstruction processes. So Mark's working group met all day yesterday and this morning, and Mark's going to report to us.

Mark, if you would include in your report a bit of a description on what all your folks did while you were here and then you can give us at least a preview of what your thinking is as we move forward.

MR. GRIFFON: Yeah, I will do -- I can do that and one thing I was going to ask, though, on the schedule -- I don't see any time today for Special Exposure Cohort and I was wondering if -- because this report back probably for me right now probably is going to take 15 minutes, at most. I was wondering if we might want to have -- or if we can make room for a preliminary discussion and maybe continue tomorrow for the SEC.

DR. ZIEMER: Without objection, we can introduce the preliminary report of the exposure

cohort group, as well.

MR. GRIFFON: My name is Mark Griffon. We -- yeah, the dose reconstruction review working group met yesterday and today. We had agreed at the last meeting that to get a better handle on the task that the Board is responsible for in reviewing a percentage of the dose reconstructions that are done by NIOSH, we felt that we really needed to get a handle on what was involved in doing a case. And since NIOSH has initiated the process or actually gone quite far with the data collection phase of it and actually has completed a number of dose reconstructions, we thought it was beneficial to come out to Cincinnati a little early and get the tour.

And we did that yesterday. We had a -- Jim Neton and his staff took us through the whole process from when a claim comes in -- or from when they get a package from the Department of Labor, walked us through the whole system, including the database, and did some pretty extensive reviews on some of the cases that they've completed. And it was very instructive, and I should also note that the few staff that Jim has have done a lion's share of work in terms of getting all this data and

getting the system up and running. It's pretty impressive to see how far they've gone in this short time.

This morning -- that was mainly yesterday. This morning we spent a couple of hours trying to fine-tune, as Paul pointed out, the recommendation from the last meeting where we had sort of begun to construct what is this review going to involve. And we had a review panel, how were we going to do case selection and then sort of the scope of work are the three areas. And this morning we continued that discussion, mainly on those three items.

I'll review a little bit of what we discussed. I'm also going to offer that I'm going to try to construct some sort of a -- more of a draft that we can circulate tomorrow so it'll have more of the details in and would ask my working group colleagues to maybe help me out on that one, but we'll work on that tonight.

We discussed the panel makeup. We discussed questions on the procurement process and how the Board can be involved in -- in the selection process, and we went over the ways that the Board can construct criteria for the contract and to assure that the expertise of these independent

reviewers is appropriate. And we're going to try to draft some of that language tonight in terms of how can this -- how can we construct the language for the criteria for these experts that will do the independent review.

We're also going to turn to NIOSH's RFP for the dose reconstruction. We could probably look at some of that language there for the RFP to do the dose reconstruction to help us out in that language.

For case selection, we talked about how are we going to select which cases the Board's going to review. And we talked about possibly stratifying along NIOSH's efficiency process, and this is the process they're using when cases come in where they can sort of -- they group them by sort of complexity of cases. It's not quite that simply defined, but when I type this all out you'll see it more specifically. And that would create certain groups of -- or categories that we'd be interested in. And then we could do a selection within those categories, keeping in mind certain strata that we're interested in, such as geographic strata, chronological strata and one was raised today, gender. Certainly we should pay attention to that.

And then we also agreed that we have to,

sooner rather than later, get a pretty good handle on the number of cases and the expectation on how long it would take to review an individual case so we can get a sense, not only for the independent reviewers, but also each independent review panel that's set up is going to be comprised of one independent reviewer and two Board members, so there's a burden on the Board members, as well. So we wanted to get a handle on just how many we expect to select and how long we expect the review process to take.

We threw around some numbers. We may or may not include that in -- you know, I don't know if we're that far along, but we have a better sense from yesterday in terms of just what the workload will be for the review.

And then we spent a large majority of the time this morning talking about the scope, and some issues we discussed -- and I'm going to frame that way right now and hopefully I can better flesh them out for tomorrow -- included the depth of review. One thing we are certainly -- we believe the Board should certainly pay strong attention to is that the claimants -- from the claimants' standpoint, we want to make sure that we do the best job possible to

make sure that NIOSH had adequate data to do the dose reconstruction and that they made every effort to make sure that data they used in the dose reconstruction was adequate to make a determination for causation. And that's different from refining the dose perfectly, as we know.

We talked about how we can review the completeness of the data. That's a phrase that was I think in our original scope, that we wanted to make sure there was a completeness of data. And you can see where that could put -- you know, there's scenarios where that could be a never-ending -- you know, data always pops up, so we had to sort of -- we're trying to grapple with how can we define an end to this, but also make sure that we meet that criteria of it's a complete record.

We discussed also looking at the consistency. We thought consistency on many different levels was something that this review panel can have value added into the process. And by that I mean that there's going to -- the subcontractor's likely to do many of the dose reconstructions. NIOSH is reviewing all those dose reconstructions, from what I understand. By the time it gets to this independent review panel,

errors in mathematics or errors in calculations are unlike -- you know, less likely. Where we thought more value will be added is to make sure that the data used to calculate the dose is consistent across many different levels. And when I say that, I mean it's consistent with the interview -- interviews conducted or the allegations made by the potential claimant. It's also consistent with the site profile which NIOSH is building for that site. For example, if certain exposures occurred in certain buildings according to the site profile, then they're in some way reflected in the data that's used in that case.

And also that there's some consistency or fairness across co-workers. The way this was raised I think was that certain individuals -- and we saw this, looking through some of the records. Certain individuals have done a heck of a lot of homework and they've sent NIOSH a lot of very interesting documents, which has helped NIOSH to track certain things down. But that shouldn't work against those that didn't have that information, so we want to make sure that there's some fairness to co-workers, is kind of how we framed it.

And I think that was the main focus of our

discussion. We're going to try to better draft language around the scope of work -- and certainly anybody from the working group can add if I'm missing a big thing that we discussed. But I think we're going to try to refine some of that language around the scope of work particularly for tomorrow, and I think -- all in all, I think the trip to NIOSH's facilities was helpful for us to get a sense of -- you know, from the time the Fed Ex package is received with the data to the time they can put it -- you know, what's happening in there, how much data do they have, how long might we envision these reviews to take and what -- you know, drawing some end points to this review. And I guess that's it.

DR. ZIEMER: Thank you, Mark. And your group actually looked at the dose reconstructions for what, five cases that have been completed?

DR. NETON: Six cases.

DR. ZIEMER: Six cases?

MR. GRIFFON: Right.

DR. ZIEMER: That ran the gamut of sort of doses and kinds of events and exposures?

MR. GRIFFON: Right, six cases, and actually this efficiency process that NIOSH has is -- the cases sort of went along the efficiency process that

they're using wherein they showed us some -- they categorize them by low potential for external exposure, low potential for internal exposure. And at the other extreme, high potential and high potential, and I guess generally those six cases they tried to give us to show us some of the different categories that way so that we'd have a sense of what was involved on either side of the -- and actually one thing that they impressed upon us, which I think surprised some of them even, was that the low/low were some of the harder cases because they wanted to make sure they looked at every possible exposure. The high -- highly exposed, once they had enough data to say that they tripped the threshold, there was no reason to go -- you know, to proceed with much more detail, so --

DR. ZIEMER: The low/lows are often cases where people worked in areas where perhaps monitoring wouldn't be required normally because they are presumably not restricted areas, so it makes it more difficult than -- 'cause there's typically not monitoring data. Is that correct?

MR. GRIFFON: Yeah, that's the notion I -- generally, yes.

DR. ZIEMER: Now your review of these six

cases was more along the lines of an acquaintance with the process. You didn't formally evaluate these six reviews --

MR. GRIFFON: That's right.

DR. ZIEMER: -- so you're not saying yea or nay on those, but was there a gut feeling amongst the working group that the -- what you saw made sense to you in terms of how the assumptions were made and so on?

MR. GRIFFON: Well --

DR. ZIEMER: Maybe I'm putting you on the spot. I'm just sort of --

MR. GRIFFON: Yeah, I mean --

DR. ZIEMER: -- getting an early reaction to sort of the process, what they had available in terms of data and so on.

MR. GRIFFON: Right. My personal reaction was that they -- you know, it was the easier cases and so there weren't many surprises.

DR. ZIEMER: It was pretty straightforward, uh-huh.

MR. GRIFFON: I guess I'll leave it -- there weren't many surprises. I think at least one of them was a fairly well-publicized accident with very high exposures and, to no one's surprise, that was a

compensable --

DR. ZIEMER: Right.

MR. GRIFFON: So I think what's going to be the challenge will be those mid-level cases where the data is incomplete and those high-level cases where the personal monitoring record tripped the threshold, then I think everything was fine. But I did -- I guess I still have this question about consistency, and I don't think that they had to do much of this, but comparing the -- right now what they're getting from DOE and what they're requesting from DOE is personnel monitoring records. They're also, on the other parallel track, they're building these site profiles. But from the personnel standpoint they're just requesting the personnel records, and in these cases I think for the most part they were good enough to make a decision. But that may not be true in the future so I think that might be one question.

DR. ZIEMER: I wonder if any of the other working group members have any additional comments or observations. Gen Roessler?

DR. ROESSLER: I was impressed with the case where it was a low/low, because I think what the group is finding out is that these, as Mark said,

might not be all that easy, that when there's a real lack of data, then one has to try and come up with what could be the upper limit. And that impressed me with some of the -- I don't know if creative is the right word, but the ways that they developed for coming up with this upper limit. And I think overall, those cases that we saw show how this efficiency process can really be beneficial and I think that's one of the developments they've made in this whole process that I'm sure will be picked up by other groups when they do this sort of thing.

MR. PRESLEY: Larry, I have one comment -- Bob Presley. I'd like to thank Jim and his group again. They did an excellent job of hosting us. But the thoroughness -- you know, a lot of us had a question, what it took to do a dose reconstruction. And the six cases that we went through, the thoroughness of the case, what you all did to make sure that you took the data that you were given and left no stone unturned, and then also the fact that we've heard a lot of comments in some of the town meetings about people not caring about the people and things like this. And this morning we had a opportunity to hear one of the interviews, and the gentleman that did that I want to say did an

excellent job. I was very much pleased with the way he conducted hisself (sic) and the way he conducted the interview. Your staff is to be commended.

DR. DEHART: To give those who weren't there some kind of insight into what the datasets are that we're looking at, one case, for example, had over 700 pages of historical data information, interviews, letters and dose records. That one case consumed, obviously, a bit of time. And in doing the calculations, one individual spent nearly a week or more actually working that case and fine-tuning the dose calculations that were necessary. And in fact in one case the final determinate does was considerably higher than the dose of record because of some of the factors related to the kind of exposure that wasn't appropriately taken care of or not well documented, perhaps, in the records that were available. So a lot of work, a lot of time. And for the members of the Board, it indicates that we're going to be very busy trying to review these cases, even with an external expert going through because we're being -- we're proposing that there would be two of us with each one of these experts, going through literally hundreds of records as we proceed through the perhaps 8,000 records that would

be reviewed the first year of the contract.

DR. ZIEMER: Jim?

DR. MELIUS: In your review did you have a chance to get a feeling for how this process would work as you would gear up to deal with hundreds of cases and thousands of cases that are sort of pending out there and how this would -- sort of what would be the -- not necessarily the time frame 'cause that's hard to say, but how that process would work. For example, I would think like with the low/lows that you're going to -- it's going to take a -- where there's not much information, it's going to take a while to build up an inventory of site profiles that would be specific enough to different work areas and so forth to be able to deal with those cases. And at the same time, you have others that -- with the 700 pages of monitoring records which are just going to take a while to wade through. And is there a sense of how that part of it would work? And I'm thinking in terms of how we, in doing the reviews, take the sample from that. Maybe this will be clearer when you present tomorrow, Mark, in terms of how we're going to sample the cases, but --

MR. GRIFFON: Maybe. We did talk about some

possibilities for how to sample and maybe -- we talked about quarterly, and then we talked about the cases that we want to -- in that first quarter we may have all high/highs, you know, I don't know. And we may have all from one site. But maybe we just go -- proceed and sample those cases and then continue to track to make sure -- and establish sort of a matrix to make sure that we still complete our sort of geographic and chronological requirements as we proceed so that we cover all the sites and all the time periods of interest. They may not come up, like you said. We may have an even number of low/lows and high/highs in the first quarter, so we may have to adopt to that just to keep the process moving. If anybody else can add to that, I --

DR. ZIEMER: Let me add to that and then we've got Henry and Gen. I did sit in and observe the working group and learned a little bit of some of their thinking. And it's pretty clear, since they'll be looking at dose reconstructions that are, in essence, already completed that -- and this becomes a kind of audit -- that they need to develop a standard operating procedure as to what the audit is and perhaps say okay, are the assumptions that the staff made reasonable and appropriate. You

know, a list of issues that you -- every time you look at a reconstruction, you ask certain questions which have to do perhaps with completeness of information, validity. And I think the group is working toward developing this 'cause that will also tell us a little about how much time will be needed both by the Board members and outside consultants to do a proper audit job. And part of this has to do with what percent of the total reconstructions will we look at.

DR. MELIUS: Just to follow up on that point, seems to me that with a 700-page one, then it's a question of calculations and different types of exposures and so forth is going to be the focus of any review. With a low/low, the real question's not going to be how the calculations were done as much as the completeness of the records and how do you avoid a false negative and miss a significant exposure, which may be a -- you know.

MR. GRIFFON: And I would just add to that that I hope that with that -- while I'm impressed by the amount of data that NIOSH has collected, I've also got stacks of data, and I hope that we don't fall into that trap where we just say there's a lot of data so this will be the focus of our review and

it must be just some calculations we have to look at. We do want to look at consistency across those other factors.

DR. ANDERSON: Yeah, I kibitzed this morning, as well, but I -- and I looked through some of the records and it's a numbing exercise to go through some of the scanned documents which are difficult to read. I think it was very helpful for the group to look at that so you know what the dose reconstructor's doing, not just on a one-afternoon basis, but on a day-to-day and day out for a long time. And you can kind of get a sense of well, where's that system likely to break down. And I think we talked about there being maybe different levels of review, one which would be actually going through and looking at all of the documents. What's good in the system is up on the top of the report. They list which of the exposure information they actually used out of the whole document. So one can then, as a review, go through the documents, see if they missed something or omitted something that might be valuable.

I think the other issue we talked about is having, despite the attempt to make it very objective, there are subjective decisions and

choices that are made and that would be one thing that we want to keep track of, as well. So one of the points we thought that would be a good -- at least one level of activity would be there's some detailed information in the interview and being sure that in fact the issues raised by the interviewee in fact is addressed or if they indicate well, I had this kind of an exposure and then you look and there's no data on that, well, how was that issue resolved. Those I think are sort of qualitative issues that I think'll be important because they're going to be addressed systematically. And if they're not applied in a uniform manner, we then thought there may well be the same people working next to each other that different assessors go through their records and they could come out with a different result, causing again consternation. So those are the kind of issues that we thought may well be a focus of some types of reviews, but not do every one overly comprehensive. And so I think there's work yet to be done, but I think the framework, it sounded to me, was starting to flesh out. We still have a little time left.

DR. ROESSLER: I just want to pick up on Jim's comment about developing site profiles because

I think that's something that I became aware of when the low/low dose one was brought up. And I think that's really going to work and will save time is once you develop a site profile, at least in this kind of a general case, then it's something that they can go back on. And so I think it's important for us -- and I'm sure they've realized it -- to emphasize just what you said, the importance of having those site profiles.

DR. ZIEMER: Further comments then?

(No responses.)

DR. ZIEMER: Mark, your group then is going to do some refining this evening and perhaps have -- well --

MR. GRIFFON: Yeah. Yeah.

DR. ZIEMER: This is an ongoing thing. I think nobody is feeling like we know everything we need to know, now we can just draft up some kind of a document saying what's going to be done. But at least you're ready to take the next step and start to flesh out a little bit and define perhaps what it is we're looking for in the way of professional consultants to work with the Board and so on. So we have on our agenda tomorrow some time to get some additional feedback then from the working group.

Then if it's agreeable, we'll very briefly introduce the topic of Special Exposure Cohort. This is actually on the agenda for 8:30 in the morning, but it would I think be useful if we at least introduced to the group the straw man document that was developed since our last meeting. I'm wondering if copies of this were run. I know that Cori was --

(Pause)

DR. ZIEMER: What we're going to distribute to you -- first of all, if you recall -- and you can look in the minutes -- there was a lot of discussion last time about the nature of the comments we would make. And so I distilled those into the document that I think is the first two pages of the handout here. This is the straw man group of comments that I distributed to the others in the working group. And then attached to that is some feedback from Tony and from Wanda, I believe -- and I haven't even seen Wanda's yet since I was in transit before that went off. And we did not have a conference call, so this is just feedback e-mailed back and forth.

But let me point out to you -- and we don't -- I'm not proposing that we discuss it even now. I think, Mark, your -- I assume your point was perhaps

it would be useful to have this to look at overnight before tomorrow morning's discussion. So the primary comments were dealing with sections 83.1, 83.5, 10, 13 and 15. And then on the last two pages, which are feedback from Tony, Tony's suggesting I think I comment under 83.7, so that would also need to be inserted and some other massaging on mine and then Wanda, I haven't even looked at yours, but we'll take it home tonight and see how we can nail these all --

Now the ultimate document that would go to the Secretary of Health and Human Services would be in the form of a letter that would point out the activities of this Board since our last communication. So we've had -- this would have been our third meeting since we last communicated, so I think the cover letter would point out how hard we've been working since the last communication, and then would point out that we are commenting on this rule-making and then the actual detailed comments would be in the attachment to the letter. That's what I would propose.

DR. ANDERSON: I just wanted to -- since I'm not going to be here tomorrow, unfortunately, I think it's good to have these out, but I know a

number of us have gotten calls subsequent to the public meetings by individuals raising issues. And I guess what would seem to me to be very helpful is if those that got those or have some new thoughts get them down in writing and maybe get them exchanged today so people can think about it so that we're not -- those of you here tomorrow are not kind of thinking off the cuff on the comments it would be helpful 'cause I think there's a number of people that I've heard from that had some suggestions that we need to get into this. And the sooner we get some language so we're not crafting tomorrow, unless there's going to be some possibility that NIOSH would extend the comment period that would give us more time. I know I just got some of the minutes from the meetings and not all of them are on the internet yet, so other than the people who called, I don't really know what was actually said there. So it could be a one-sided conversation. So I don't know if -- is there a thought on the basis of the turnouts, and I think some groups wanted to have a meeting in their area and things like that, is what I've heard, and it would be too late if you're thinking of going to one of the other sites if -- is there any possibility of getting an extension on the

comment period, to keep it open a little longer?

MR. ELLIOTT: Well, at this time the comment period closes August the 26th and that's -- as of today, that's still the Secretary's desire, to see this put in place as soon as possible. So -- but that's certainly -- we've not had in our input in the Town Hall meetings requests for extension of the public comment period.

DR. ANDERSON: Okay.

MR. ELLIOTT: So -- and the last two transcripts will be on the web site very soon.

DR. ANDERSON: Okay.

MR. ELLIOTT: We just couldn't get them turned around, since we were there last Thursday.

DR. ANDERSON: I know.

MR. ELLIOTT: But tomorrow you -- you'll miss it tomorrow if you're not here, Dr. Anderson. Ted Katz will give a short summary of what we benefitted from in our experience.

DR. ZIEMER: And keep in mind, we don't necessarily have to be able to incorporate those things into our comments because they are comments that they will have to respond to anyway. So -- unless there's something that are so pertinent that we think we need to include it or add to it.

MR. ELLIOTT: Absolutely. Transcripts are going to be added to the regulatory docket and each of the Town Hall meetings -- everyone was encouraged multiple times to provide their written comments to the docket before the expiration of the public comment period, so we hope to see them there.

DR. ZIEMER: Rich?

MR. ESPINOSA: Yes. Has there been input in from other sites that didn't get a Town Hall meeting, like Oak Ridge or anything like that requesting for a Town Hall meeting?

MR. ELLIOTT: Yes. I have taken a couple of phone calls and one of those phone calls was from Oak Ridge requesting a Town Hall meeting. There was just no way that we could work it into the tight schedule that we had, and I'm sure that those sites are -- and in fact, Denver was the other call that I took and I explained that we had just been there with the full Advisory Board and talked about this and they had missed an opportunity. But I think it also speaks to the Board's interests to go around and hold these meetings at different sites and the benefit to doing that.

MR. GRIFFON: I just -- I'm just scanning the e-mails back and forth so maybe I'm not seeing

everything, but -- and looking at this for the first time, but I recall in the last meeting in our discussions that we had sort of turned over some issues that we wanted the working group to discuss. And I wonder if -- maybe it's not reflected in the e-mail or it didn't make it to the comments or whatever, but did you all have a chance -- I know you didn't have a conference call or anything, but did you have a chance to discuss -- some that come to the top of my mind are some of those definitional issue that I was focused on like sufficient accuracy or how the endangered health was defined. Did the working group discuss those or --

DR. ZIEMER: No, and we -- we may not have had -- "we", me, I guess, may not have had complete enough notes so that if there are some of those that simply fell through the cracks, I'd be very pleased to have those. Maybe you can remind me. I'll get my notes back out, but maybe you can remind me of those sometime before evening and try to incorporate that.

I knew when I sent this out I hadn't really -- I know I hadn't captured all of Tony's ideas, either, and probably missed some other folks's ideas, so --

MR. GRIFFON: I mean I think there's even some ones that just -- just glancing at the New York minutes, I mean I think there's some that are sort of potential gaps in the current regulation that really need to be addressed. The particular one I'm thinking of is that someone, if they're put in a class and they are not eligible for non-SEC cancers and they cannot apply, and it -- you know, I guess my question along those lines would be if they had exposure, say -- say a certain class is defined for a certain building over a ten-year span and they have reconstructible dose before and after, you know, in that kind of situation it seems to me that they would still be eligible to go forward and submit for a non-SEC cancer. And I was trying to understand the interpretation, but I didn't see it that way and -- in the New York meeting.

MR. ELLIOTT: I may be confused by your comment, Mark, but they wouldn't be excluded. They would be certainly eligible to file and proceed through dose reconstruction. I think the issue would be if at the end of the completed dose reconstruction the PC came out to -- in that upper mid-range right below compensability, what do you do then? How do you react to the particular situation

in that case? You see where I'm --

MR. GRIFFON: Uh-huh.

MR. ELLIOTT: -- leading this to? So maybe what we need is to have some clarification in language to assure that if you have monitoring or records that would support dose reconstruction for other periods of your employment and your work history, that doesn't exclude you from filing a claim and going through dose reconstruction.

MR. GRIFFON: And then I guess --

MR. ELLIOTT: Nor should it exclude you as a member of that class --

MR. GRIFFON: Right. Right, and then the question on either side of that is in making a decision on defining the class, you know, this hypothetical scenario comes to mind where you're defining -- you're defining this potential class. It's not a certified class yet, and you come up with your worst case dose estimates and you come up to 48 percent and therefore it's not an authorized class, a certified class.

MR. ELLIOTT: That's a different -- yeah, that's a different issue.

MR. GRIFFON: However, they've worked ten years before that and had exposures, some of them --

maybe not all of them, you know -- they've worked ten years after and then --

MR. ELLIOTT: So what do you do with that --

MR. GRIFFON: -- reverse -- reverse that and say they've got exposure on either side, for ten years in the middle they're in this class. They don't have that type of cancer.

MR. ELLIOTT: Right.

MR. GRIFFON: If we only use the dose from either side, they don't trigger the threshold, but we can't assign the dose from the class 'cause that's not an individual dose.

MR. ELLIOTT: Both points --

MR. GRIFFON: So that's the --

MR. ELLIOTT: Both points made lead us to the same dilemma, and I think that dilemma would be evaluated and the research and recommendation on how to handle that would be accomplished within what we would do in evaluating the petition. That's the research that we would examine, part of the research effort that would go into evaluating the petition.

MR. GRIFFON: Okay, well --

DR. ZIEMER: Mark, I'm looking at my notes here and then get to Jim. Let's see, one of the -- last time when we had some general questions raised,

one of them -- there was questions on definitions, one of which I jotted down as ill effects. I guess that's what you were referring to then, what the definition of --

MR. GRIFFON: And I have some of these thoughts written out which I can provide to the working -- but just the question of endangered health, whether -- you know, just this whole notion of trying to -- I mean we discussed this at the last meeting, the question -- you can't do an individual dose reconstruction, but somehow we're saying we have enough information to do a worst case estimate and then plug it into IREP and make an -- you know, make a sort of quantitative judgment on endangerment of health. And I just wonder if that's -- you know, I just wondered if the group had discussed that and whether there are other options that might be more appropriate.

DR. ZIEMER: Okay. And I'm not sure how we'll address that here, but if you have some ideas on wording, that would be helpful. Jim.

DR. MELIUS: Yeah, thanks. One is to follow up on that point. I do think it comes back to this issue of the criteria for when you can't do a dose reconstruction with sufficient accuracy, and we

talked about that last time. Some of the points I think Tony had made last time, also, and we've got to act. We've got this endangerment issue and now we've got sort of a third situation where this -- we've run into this, if we have someone with a cancer that doesn't qualify for SEC, has some history outside of the Special Exposure Cohort period, how do we deal with their dose. Is there a situation where we would take -- somehow take some of the information on their exposures during the SEC period and apply it to their individual other information. I mean it just -- I'm just uncomfortable just doing it always on a case-by-case basis 'cause I think we're going to end up with arbitrary and basically unfair decisions.

I've written up some comments which I think are being copied and will be circulated and I think we can talk about them tomorrow. I also believe that in the minutes for this meeting I captured particularly some of Tony's comments that -- from the last meeting that we can probably incorporate some of that language, also.

MR. GRIFFON: And just to pick up on Henry's point, you know, the transcripts did -- and I'd be very interested in the Hanford and Los Alamos

meeting 'cause you said that was -- both were very telling, very instructive, and I think one place this was picked up on was NIOSH staff response to these questions, so I think that would help the Board in wrestling with some of these issues.

DR. ZIEMER: Any other comments right now on Special Exposure Cohort?

(No responses.)

DR. ZIEMER: Let me ask the members of that group if they're available for a while this evening to look at the input. Tony? Gen, you're involved.

DR. ROESSLER: Wanda is.

DR. ZIEMER: Wanda was. Sally, were you?

MS. GADOLA: The working group?

DR. ZIEMER: The working group.

MS. GADOLA: You're talking the working group on the --

DR. ZIEMER: The SEC working group -- Tony, Wanda -- who else was involved? Sally. Robert, were you in there?

MR. PRESLEY: No.

MS. MUNN: As long as I'm well-fed.

DR. ZIEMER: As long as you're well-fed. Perhaps we'll go ahead and take our break right now so that the speakers will have their --

MR. GRIFFON: Paul --

DR. ZIEMER: A question first?

MR. GRIFFON: Paul, can I ask -- is -- if you -- I'm sorry.

DR. ZIEMER: Oh, I'm sorry, Mark.

MR. GRIFFON: If you can maybe let us know when the working group might be meeting or where you might be meeting 'cause if I have some written up stuff I can drop it with you.

DR. ZIEMER: Sure.

MR. GRIFFON: Okay.

DR. ZIEMER: Okay, let's take a 15-minute break and then we'll reconvene.

(Whereupon, a recess was taken.)

DR. ZIEMER: We're going back to order. We're going to switch the agenda slightly, simply because we have some problems loading one of the slide sets onto the projector, so we're going to start the paper by Michael Schaeffer and then we'll back up and pick up the presentation by Jerry Steele.

Mike Schaeffer is a senior health physicist. He's had -- at the Department of the Navy -- well, Department of Defense. He's had 22 years of experience at the Department of Navy in designing

and deploying and maintaining dosimetry and radiological instrument systems and programs. For the last 11 years he's been at the Defense Threat Reduction Agency. That was formerly the Defense Nuclear -- well, Defense Nuclear Agency and Defense Special Weapons Agency, I guess.

He's been involved in reviewing a lot of the nuclear test personnel information in the registry for atmospheric nuclear test veterans, also manager of DoD reclamation and experiments command center. Is that the right title?

MR. SCHAEFFER: Radiation.

DR. ZIEMER: Yeah, I'm trying to read somebody's handwritten notes and they're -- it's not my writing. Is it radiation experiments command center?

MR. SCHAEFFER: That's correct.

DR. ZIEMER: I guess I could read that as radiation. It's -- but Michael is going to talk to us about the dose reconstruction work that relates to the atomic veterans program. We're all interested in sort of how they're doing that insofar as it might give us some ideas in terms of how we review some of the records that we'll be facing ourselves. So Michael, we're pleased to have you

here and please, if you would, take the podium.

MR. SCHAEFFER: I appreciate the opportunity to come here today and discuss the dose reconstruction program of the atomic veterans. Atomic veterans is a term that applies to those folks that were exposed during atmospheric nuclear testing, mainly from the period of 1945 to 1962.

What I'd like to do for the short period today is explore a unique opportunity to understand dose reconstruction within the context of our nuclear test personnel review program. Before dose reconstruction, we need to of course set the stage for some other things.

For whom was this program started and what are the influencing factors of the program that have affected the conduct of business over the last number of years? And of course how does the program operate? And I think that's of great interest to this panel because there's a lot of comparison and a lot of contrast between what you're engaged in starting to do and what we've been doing for over 20 years. And of course, how does dose reconstruction fit and what are the significant issues of dose reconstruction that have risen over the particular years? I think those items you're going to find

quite fascinating in that you're probably going to have to grapple, as a advisory committee and also the other factors, the other agencies in the program are going to have to grapple with some of these very, very similar issues somewhere along the lines. And of course then there'll be a brief summary at the end.

Program serves almost exclusively veterans, maybe less than 1,000 civilians. The gender of the population is almost exclusively make, perhaps a few hundred females in this particular population. The U.S. atmospheric testing from '45 to '62 encompasses 20 test series and in total approximately 235 individual nuclear tests. The particular operational period for these tests extend through somewhere between as short as three months over nine months, and then of course it covers a period of participation six months thereafter, because there are activities engaged with the testing.

We also -- later on the population of post-war occupation troops at Hiroshima and Nagasaki were covered. Basically these are people who were within a ten-mile radius of Hiroshima and Nagasaki, and also were there a six-month post period from the actual occupation period. Also covers certain POW's

that were around during the time when the detonations occurred.

We also use the Department of Veterans Affairs definitions to decide who the test participants are and who they aren't, and Jerry Steele and Neil Otchin will talk more about those particular definitions in their presentation.

There's 13 public laws in all that govern the program. The one important one is Public Law 98-542, enacted in October, 1984, important from two aspects. As you'll see when Jerry Steele gives his presentation, there are a number of things that came about during that period of time establishing specific compensation programs for veterans exposed to radiation, not only nuclear tests, but other radiation risk activities within the DoD. Also the very important thing that it did for our program is it established a requirement for our coming up with standards for dose reconstructions for atomic veterans. It will become clear to you in a short while as to why dose reconstructions are important for this group of veterans.

Other programs that are covered, Department of Justice over on the right-hand side, that reflects the Radiation Exposure Compensation Act,

which I believe you are familiar with. And also another mention of the dose reconstruction standards. We went through extensive *Federal Register* comments, much like you did with 42 CFR part 82. We also, in addition to that, we vetted those reviews with the National Academy of Sciences before we actually published the final document for dose reconstruction standards.

The program as we know it today started in 1978. Vice Admiral Monroe, who was the Director of Defense Nuclear Agency at the time. There was a lot of Congressional interest in radiation exposures to people in general, namely the military and people in DoD. It was right during the era that was just on the heels of Three Mile Island, so there was a lot of public focus on radiation issues. And basically Vice Admiral Monroe promised Congress that he would start a program that would establish a registry for atomic veterans and try to establish the maximal dose as to which this cohort of people was exposed to. And basically our program has the Veterans Outreach Program as a result of that where we have people who could call in to us through an 800 hot line number. The basic information we provide is -- can be summarized in two questions. Was I there?

And what was my radiation -- what radiation dose did I receive by being there?

Of course as we've gone along the program we have supported Congressionally-mandated scientific studies conducted by the National Academy of Sciences. Two that have been most important in the program have been the study of crossroads participants. That was the Navy participants, Operation Crossroads, in 1946, a cohort of about 40,000 Navy participants. Also we did later on two studies, a basic and a follow-on study of what we call the Five Series Participants. Those were participants that were at [Greenhouse Castle, Upshot, Knothole, Plumb-bob and Redwing]*, so those are the five series. That's why it has the name Five Series.

Right now we don't have any work under way with the National Academies looking at mortality studies of atomic veterans.

There's four ways veterans can make contact with the NTPR program. One is by filing a VA claim, another by filing a claim with the Department of Justice. They can also reach us through their Congressman, and most of them of course reach us individually since early on in the program we

publicized widely in many newspapers, veterans' magazines, what-have-you, the 800 hot line number, so they know where to get ahold of us. And I'd have to say the traffic today, about 60 percent of the traffic comes by way of veterans affairs claims. The bulk of the rest of the business is from individuals who call in to the program or write in to the program. We also receive Congressionals on the order of two Congressional inquiries a month at this particular point in time. Traffic into the program is about 100 -- or 80 to 120 transactions per month, to give you an idea of the traffic we have.

As far as transitting through the process, it takes anywhere from 90 to 120 days for a request to transit the process. The metric that we use that we know that we get the best customer satisfaction is if we can turn around answers -- 75 percent of the transactions in 90 days, we generally have a good customer satisfaction rate, and we're running above that at this particular point in time.

The difficult cases take longer. I heard some of you talk about difficult cases where you can get stacks and stacks of information. We have those. Some of those can take longer than the 90

days, some of them can go up to six months, depending upon the complexity. Most of that complexity is driven by the fact that we can't put the person there behind some kind of record, and we just keep digging and digging and digging for the eventual record. If we can't find it in their personnel record, we know what military unit they went to. The fortunate part about our cohort is we can track people by military records, which are very, very robust. You have the name of a military unit a person says they were in. If we can't track that personal record, we can get the report from the military unit and track them through alternate means. So we go through a rather exhaustive means of trying to put the person at the -- connect the person with the particular event.

The research that we do is answering the basic question of who, what, when, where and why in terms of trying to put together the information to back up before we do the dose reconstruction.

That goes next to the dose reconstruction process, and I'll point out to you that the archival search and the dosary* search is actually done by two separate contractors. We do have them united by a teaming arrangement, but basically there's some

objectivity and distance in bridging the process between archival search and dosary search.

That all culminates together in a package of the outgoing letter, which comes to me. I'm the final review authority that checks off to see if there's an adequate research done, adequate time spent in drawing the conclusions. Did we draw on all the references that we have in the program for doing the dose reconstruction. Once that's done and I sign off the package, then it's mailed to the veteran or mailed to the Congressman or mailed to the VA.

Then of course we database all the information we gathered during the process. And it's very, very important later on because when we see a veteran that performed common activities to the veteran we just processed, it's good to have that history of the research that we're not re-inventing the wheel again, and also from the standpoint that the next veteran may give us something that adds to the experience of the first.

This gives you an idea of the traffic coming in to the program over the last ten years. Basically the demands on the program are driven by events outside the program -- new laws, new

Executive Department initiatives. There are also some unpredictable trends, just what our veterans feel about the program. For instance, in 1994 we had the emergence of the President's Openness Initiative on Human Radiation Experiments. And even though atomic veterans didn't, by definition, fall into the program, you can see it caused a lot of awareness and a lot of writing in to our particular program, even through the Radiation Experiments program, so you see traffic was very high in that one year. And you can see the peripheral years around it, as well.

We go down further to 1998, that was driven by our publishing the availability of a very limited bioassay program, and this caused a lot of veterans to write in to the program to queue in the line to make themselves available for urine bioassay.

And now we go to 2002 and you can see that that's almost twice the number that we received during calendar year 2001. The driver for that is the Department of Veterans Affairs Secretary established a program and a tiger* team in Cleveland, Ohio to process some of the older veterans' claims more efficiently and kind of took the one bite out of the elephant of looking at that

factor of claims of veterans older, dying for some reason whose claim has been laying in the queue for a long period of time. So the folks of that team -- we've gotten much more traffic from the tiger team.

Basically historical information document collection is very crucial before you can do a dose reconstruction. And basically when a veteran writes in to us, we want to focus on what are the questions that the veteran has, what are the issues the veteran wants treated. Basically when we go back and answer the veteran, we try to keep the information brief, to the point, answer the questions, only augment to understand. We find that over the years if you get into a long and involved discussion of the underlying science, you basically confuse them and perhaps lose their confidence in what you're trying to do in concentrating on the basic questions.

The main records sources we use are the Personnel Records Center in St. Louis and also the Coordination and Information Center in Las Vegas, Nevada, and that's the biggest collection -- hundreds of thousands of pages of documents chronicling what happened during the nuclear test era, all stored in a repository in Las Vegas which

DOE and Department of Defense jointly funds. Basically this culminates in all the document research that was done early on in the program, for the first ten years of the program, since 1978.

Now again, as I was saying before, we look for special orders for people if we can't find information, personal records. Again, we collect it anyway. We want to collect as much as we can on the person. We also conduct extensive interviews with the person if the person's still alive, and in the case of the person being deceased, we will talk to the family member who wants to correspond with us. Of course that information is a bit sketchy, but it's part of the information-gathering process. And this all culminates again in establishing participation, and once we know what the person did -- basic who, where, when and why questions -- we construct a dose if needed. In some cases, as Jerry Steele will explain, there's presumptive compensation, very closely akin to your special cohort group, that can receive compensation presumptively without needing a dose reconstruction.

So we pull all this together for the veterans. We provide the fact sheet for the program, any of the personnel records and other

source records that actually zero in on the person's participation. We make this available to the veteran and to the VA if the VA wants it.

This kind of gives you an idea of the technical data that we also collect during the exhaustive search. I believe our job is a bit easier than the job that you have before you in that we're just worried about nuclear test participation. We're not looking at multiple sites. We're only looking at tests done in the Pacific, tests done at Nevada test site, so basically our job is easier. We only have two sites versus -- with a large population versus the job that you've undertaken with your smaller groups of people having done many tasks at many sites.

But some of the basic information we want to collect in establishing participation is where was the person? You know, what did the person exactly do when they were on the test site? Where did they go when they went from point A to point B? What were the -- what was the weather? Was it raining? Was it blistering hot? Did it rain later on? Were there winds -- wind directions and so forth, so all this information is very key, as you'll find out later on when we get to the dose reconstruction

process.

Also lots of information on fallout intensity and duration, lots of survey information that exists in historical records. One of the most important pieces of information we have is shot-specific radiochemical data. We had cloud samplers who went up and actually took samples of the radioisotopes that were in the debris of the nuclear tests that provide some very, very key health physics information in determining the abundance of the up to a few hundred isotopes that can be in the debris, you know, both fission elements as well as transuranics.

And again personal exposure data, there's an abundance of film badge data -- not in the early days of the program, but later on as time goes on, we'll talk about that issue. And of course lots of after-action reports that were written that chronicled the various different things that happened at the test site.

This block diagram summarizes everything that's in our *Federal Register* description of the procedures and methodology for dose reconstruction. We actually start with trying to gather film badge data. And if we find the film badge data are not

complete, we look at other people in the same cohort. These are people doing the same common jobs as the person under question, and we look at the film badges and radiological data for the other people. And again, we ask ourselves the question, especially in the early days of the program, do the film badge doses account for all of the potential for radiation exposures. In a lot of cases we find that it does. So again we have to go and gather the radiological data for the environment in which these people worked and relate it to the particular duties that they did.

One of the particular features in putting dose reconstruction together is how to validate those dose reconstruction. Early days, what we did is wherever we had robust film badge data on personnel, we went ahead and reconstructed the doses anyway, just from a priori radiological data, and compared those two results and that allowed us some means of calibrating film badges -- actual film badge dosimetry that was known to be good in the later periods of the program with actual reconstructions from other radiological data. And this gave us the means of calibrating the dose, and of course in all this data that you're collecting

during the time, there's scientific uncertainties that were reported with these results, even by contemporaneously, including the instruments used and so forth and the military fare very good. We can go back and actually dig up older technical manuals and calibration procedures to know how accurate instruments were or how inaccurate they were back at that particular period of time. So this is what allows us to actually put together the external dose for people engaged in the testing when film badge data is either robust or in some cases completely lacking.

This is a very, very important slide in that it tells you the one radiation environment that we are concerned with for all of our nuclear test participants. On the right-hand (sic) side is immediate -- is at the time of detonation. If you were at a test at the time of detonation, you can be exposed to prompt gamma and neutrons. The time to the right side of the chart is delayed. This is some time after the detonation goes up or weeks, months, hours -- actually hours, weeks and months later. And these are people who, at least on the other side, are exposed to activation products. This is where if you were close enough in, the

neutrons could actually activate the soil. We also have descending fallout. If the test of course were close to the ground, ground shots brought up a lot of dust and debris in the fallout cloud.

We also have tests that were done in close proximity to one another and also close proximity in time, so you could have troops exposed to fallout that's on the ground from a previous test. And also you can have fallout that is deposited on the ground from all of these sources of course that get lofted into the air and resuspended, so there's another opportunity for exposure.

To give you an idea in the immediate range, that's -- you're talking about being 5,000 feet or closer at the time of detonation. And I can say, at least from our population, is no one was closer than 2,000 feet. We have about 1,000 out of the few hundred thousand that were between 2,000 and 10,000 feet. About one-quarter of the population, 50,000, were up to six miles away, and then the rest of the population were further away and exposed basically to delayed sources of radiation.

We have two types of dose reconstructions in the program, the generic dose reconstructions. These were done early in the program when we defined

cohorts of people engaged in common military activities. We performed dose reconstructions based on a unit engaged in common activities, what was the worst case dose that these people could have received if they were engaged full-time in the activity from start to finish of an operation. And again, it provides a maximal upper-bound dose for any military unit that was engaged in a particular operation. And this was the goal of the program in the early days as envisioned by Vice Admiral Monroe was let's determine the worst case doses people were exposed to, and I think that was a worthwhile goal during that period. This is before any movement came along to say that we were going to be engaged in compensation programs. And as you can see, later on that provides a little bit of a tension that's been created in the program over the years.

As time went on, with the emergency of Public Law 98-542, we shifted from group reconstructions into individualized dose reconstructions. These are uniquely constructed based on the actual activities of the people. We perform them only upon receipt of the inquiry on a person. It's based on the actual activities and the anecdotal information they give us in terms of

trying to resolve the inconsistencies. You talked a little bit about that in your process, and I can't add any more to it except that we struggled in the same way that you do in terms of trying to reconcile the information. It's very difficult for these folks 50 years hence to remember all of the details they were involved in.

What we generally do, if they say they were -- we say they were engaged in activity A and we know they went to activity B and they say well, along the way I did this, if it consistent with the movement where they went in moving from one point to another, we're going to give them the benefit of the doubt and include that activity. Furthermore, if we have any kind of military history that says well, they did another event along the way that they didn't remember, we're going to credit them with this information, as well. And they may come back to us and say well, I don't remember ever having done that, I don't know why you're putting this in the dose reconstruction. I guess comically sometimes they fight about this, say why are you adding this to me? Actually, we say, we're trying to give you some more dose that is consistent with the military records, so that happens in the

process.

And sometimes we have to use the first type of group dose reconstructions to fill in those activities. If we don't have the specific details, we'll give them the maximal dose for something that they plausibly could have been involved in and they didn't remember.

Building the participation scenario, very, very important to dose reconstruction because it establishes time and place in a radiological environment. And very much like your process, we construct the tentative scenario based on information we have from the military records. And again, there's some incompleteness there and what we do is do a careful triage between the two contractors in terms of what do we know from the records versus what we don't know from the records. What are other plausible activities that could have resulted in exposure to sources of radiation. Again, we work in the experience of the veteran, if the veteran is alive. If the veteran is not alive, this is where it really gets sketchy. And I haven't heard that during some of the discussions of your Board meetings here is what do you do for folks that are not living? I'm presuming that they can still

file a claim and you'll still have to do a dose reconstruction, but how do you work around the fact that you may not have a prime source of anecdotal evidence?

Again, after this is all done, we construct the final activity scenario. We identify the sources on certainty from the historical records and we provide this to the dose reconstruction team as a result of the triage of activity and the compilation of the records.

These are some crucial technical data that we must gather for each -- device output spectrum is very, very important. It tells you the radioisotopes in the cloud and it tells you the relative abundance of them. Very, very important for constructing internal doses, and we'll have some -- we'll talk more about that.

Also if we have the folks who were exposed to prompt neutrons. Again, during the time, we didn't have neutron dosimetry to measure this important component of radiation exposure, and if they were close enough, they're certainly there. And we use our conventional transport codes to come up with neutron doses.

We have to normalize field measurement data

because it's taken at different points in time. If you read a lot of our text, you have terms like H plus 1, D plus 1. That's hour plus one. Day plus one, that's talking about time elapsed since the actual shot. We want to normalize to something like the first hour after the shot. We want to bring all the data back to that normalized position.

Next we look at free-air exposures occupied at shot time, the troops that were -- the few troops that received neutron exposures that were in trenches. So then of course we use time, distance and shielding in terms of what would have been the neutron dose if they were partially shielded, chest-high out of the trench, so that's also added in there.

Then again all of the associated uncertainties with the scientific techniques we use of course are overlaid onto the process.

So that's the initial environment. Now we shift to the residual radiation environment, and again there's a wealth of radiological data that's been collected at the time. There've been contours drawn and basically it's take all this data and normalize it to one particular time component so we have a standard frame of reference. And again,

we're trying to overlay the participant walking through these contours of radiation -- varying radiation levels to integrate the external gamma dose. And at this particular time we look at environmental data to say what were the potentials for internal exposure, either through ingestion, inhalation or absorption through the skin, although that becomes a very small component.

So again this particular point, once we understand the external exposure for the residual environment -- residual dose environment, then we start to think about how we're going to do an internal dose.

Now for each shot, in order to conduct this calculation, we have to look at the decay rate, and that's been empirically determined for many of our particular tests. If you look at the -- again, the radiochemical mix, there's been plots of how the radiation measurements decay over time. Most of them decay by T to the minus 1.2. In some environments it's minus 1.3 and then some -- if the -- you've got weathering involved, it could be minus 1.4, but all of these are well-established from empirical measurements. So we have to apply that factor to a particular situation.

Again we have to normalize it back to a time base, an hour after the shot, then we draw maps of whatever the isopleths of radiation that were at hour plus one. And then of course we identify the uncertainties associated with applying these factors.

Of course what we have is you had some troops involved in a couple of days of the operation. You have multiple surveys done in space and time. You have troops marching in where the radiation is not only varying by contour, but it's varying by decay. We do linear regression on the [level wealth of this data]* to decide what's happening in terms of walking out from ground zero, what type of radiation levels you could expect. Then we characterize that field in surface and time, just what's going to happen with it, and we overlay on that the actual marching of the troops, going through some defined maneuver that you can find in the military records across this varying radiation field in space and time. And again, using computer models and so forth, we can come up with an integrated dose for a troop activity, marching through a couple of days of varying radiation fields.

This is a very, very key chart for dose reconstruction of internal doses. The block in the middle, activity concentration, is the main quantity that one must have in order to honestly do a internal dose reconstruction. And if it weren't for the radiochemistry and film badge data, it would probably not be possible to do an internal dose reconstruction. And what we do there in mating those two pieces of data together to make this possible is if you know the relative abundance of the isotopes in the cloud, you know the gamma emitters from all of those isotopes, you have a film badge on a person who is being exposed to the gamma component of these isotopes in space and time, you can go back and actually calibrate what the radiochemistry should give as far as some kind of absolute output.

Once we do that particular calculation, then we go back and we can derive an actual activity concentration corresponding to that particular time, like going back again to the relative abundance of all the other elements of the alpha, the beta, the gamma and all the radioactive constituents and construct an activity concentration. After we've done that, then we enter it into all of the internal

dose models that we're accustomed to using. In our particular program we originally started with ICRP-30 and we still, for the most part, use ICRP-30, and I'll explain why we're not using more modern models today. I'll just give you a reference point. We use organ dose factors that -- also from ICRP-30 to move from the activity to the dose for the particular model, and also we check this through consistency with other radiological measurements to make sure again that we have some reference calibration to film badge data. And this is, in short, how we do the internal dose estimate.

Again, before I showed you the radiochemical analysis, very crucial to this. Also the conditions, what kind of winds did you have ongoing? What kind of surface level measurements did you have? What kind of resuspension did you have at the particular time? This is where we get into the realm of making some assumptions.

As you know, resuspension is a factor that is very, very hard to tie down, even from all of the literature data. The best you can tie resuspension down is perhaps by order of magnitude by a factor of ten. Most of the resuspension factors we use are ten to the minus six, ten to the minus five, ten to

the minus four. We do have some special situations where it could be minus three or minus two. But for the most part, if we're going to err on the side of the veteran here, if we have a choice of picking say ten to the minus five or ten to the minus four, we're going to pick ten to the minus four, just for making sure that we're not underestimating the radiological condition.

Again, we have external doses to calibrate everything back to. I think that's a very, very crucial point here. If you have a situation where you have good dosimetry at some point in your program, that allows you to do that.

Urine bioassays, early on in the program there were small cohorts of people had urine bioassays. We haven't found them to be of too great a help because they are gross measurements. They're also -- did not have the accuracy in those days. We find a very difficult time correlating bioassay measurements back to doses. I guess the factor that works best for us here is the bioassay data usually complements the film badge data, so really they were not of any necessity -- it doesn't help us very much in doing a dose reconstruction. I think they were taken at the time to provide, at the time, high

exposure cohorts to see what kind of internal exposures they might have had.

But we've also done some modern-day bioassays, plutonium bioassays, and I can say from the limited experience we had in doing a pilot study is it's really not given us any kind of data that we can rely on for a dose reconstruction. In fact, most of the uncertainties in the process are such that it just doesn't give us the degree of sensitivity in looking at internal doses by some alternative means, although we've tried very hardly (sic) to try to get that to work.

But again we take a conservative selection of some of our assumptions. We talked about resuspension. Breathing rates, if the troops were marching at a kind of fast rate, we're going to use a breathing rate out of ICRP-26. Now I think it's been updated to ICRP-123. That is conservative with respect to the stress of the activities that they were undertaking as a marching troop into a fallout -- or a deposit fallout field.

Also the duration of the exposure, if we can't tie down precisely how long the person or troops were in a fallout field, we're going to assume that they were there for the longer period of

time.

Activity fraction of each isotope, we're going to make the most conservative of the estimates there if we don't know. Particle size kind of comes into that equation. One is if we can't determine what the particle size is, we're going to assume that it's a ten micron particle size with the following exception that if we know that there's a larger particle size that would promote a larger dose to a specific organ, we're going to use that. In case of lung, we're going to use a 20 micron particle size because that maximizes the dose to the lung for the particular veteran who needs a lung dose. So again, we're always working on the maximal side.

What we try to get out of the internal dose is a 50-year dose commitment to a specific organ. That will become clear to you why we picked that as the dose.

Once we've done the dose reconstruction, now it's the reporting requirement. Under 32 CFR 218 we have to come up with an external dose that's based on the alpha, beta, gamma. We also have to come up with external neutron and we have to report the range of uncertainties for the doses. And of course

if you look at the standard, it's not very specific on what type of internal dose that you're supposed to report. It doesn't say whether you're supposed to report a total effect dose equivalent, an effective dose equivalent or dose equivalent just is very, very open.

And what do we do in that case? Well, we go to our customer, the VA, and say well, what is it that we must provide to the VA in order to fulfill the requirements of a claim submitted by a veteran? And in doing so we provide a total external dose with a 95 percent upper bound in rems. We also provide an internal dose to a specific organ and -- that corresponds to the VA-claimed disease. The internal dose we do not provide a range of uncertainty on. It's inherently high-sided for some of the reasons I mentioned before. If we're going to pick resuspension factor, it's going to be on the high side. If we're going to pick a breathing rate, it's going to be on the high side. So every internal dose that we provide because the assumptions is inherently high-sided.

Of course if there's an eye and skin dose needed for a particular VA claim, we provide that when there's a related disease for the eye or the

skin, such as your basal cell carcinoma.

The veteran-provided doses we do something a little bit different. We give them the total external dose with the upper bound. Internal organ doses, we don't provide it, and the reason we don't provide is that particular time when a veteran corresponds with us, it's unclear to us whether there's a specific disease process involved yet at that point, or the veteran may just want some baseline information, trying to make up his mind as to whether he wants to submit a claim to the VA or Department of Justice. And if we provide of course a total effective dose equivalent internal dose, that's going to clash and be confusing with transmitting the dose to the VA later on. As you'll see, an organ dose is not going to correspond to a total effective dose equivalent internal dose, so we don't report that for the mere fact that we don't want to promote some confusion in passing out radiation information. Lord knows from the myriads of letters we receive from veterans, it's very confusing just to explain basic radiation units and principles to them, so we try to keep this at a simple level.

And of course we very, very much stress to

the veteran that even though we're providing them some basic dose information, he doesn't need to have this information in order to file a claim, and that will become evident to you when Jerry Steele and Neil Otchin talk about the VA regulations. One of the common myths is the veteran believes that he has to have a delineation of radiation dose in order to file a VA claim. In fact in some cases I think they have to have proven participation information. And again, none of these of course would prevent a veteran from filing a claim. If they don't have participation and dose information, they can still file a claim. VA, by their regulations, of course are bound to come to us and get that same information all over again, so again, you can see this process is doubled up somewhat in the minds of the veteran.

Next course of slides I'm going to get into some of the special issues in the program that have arisen over the years, and I think you want to pay particular attention to these in terms of some of the things that have caused us heartburn over the years.

First is reporting film badge doses. We believe that the film badge doses you report have to

mirror what's in the record. And in our particular program, film badges weren't widely worn by folks. When I say widely worn, in '56 there was a policy that said we'll put a film badge on every person that goes into the test area. Of course the reason for that is through the 1940's and 1950's, film badge dosimetry was still an emerging dosimetric technology. Not all the bugs were ironed out in it. Of course there were manufacturing problems and because you couldn't mass-produce film dosimetry at that time, there were a lot of people who were engaged in radiation risk activities that didn't have badges, and those were kind of operational decisions made at the time. But as we get later on into '56, the technology was not much better. Again, the drawback is it only measures the external gamma component. And also the benefit of film is many of the films that atomic veterans wore, we can actually go back to our repository at Los Vegas, recover them and actually look at the image on the badge.

We found for a few of our test series -- in 1956, for instance, Redwing; in 1962, Dominick* -- that some of the badges suffered environmental damage -- heat, humidity, light leakage. Again, we

were just learning how to mass package dosimetry and put it on people in a very, very damp and oceanic environment in the Pacific, and so we had to learn the hard way that film badge dosimetry en masse was not that simple. And again, you can go back to the records and pull these out.

In terms of doing uncertainty analysis on film badges, because we -- Crossroads, perhaps only ten percent of the total dose commitment was done by film badges, the rest was done by dose reconstructions, and we had various different productions of film over the years, we engaged the National Academy in a study to characterize film badge uncertainties. And it's done specifically by series in terms of bias, processing errors and what have you. It doesn't depend on whether you were in the Pacific or whether you were in Nevada test site. It depends on whether you were doing dosimetry for a few months or for nine months.

And what we found out in the study -- scientific study is it provided us a very, very good basis for doing statistical uncertainty. In fact, we use it quite extensively in our program, and if you haven't seen this particular monograph, you ought to get a copy of it because it's invaluable in

terms of the sources of error.

But one of the factors that came out in this, it said if you want to get true deep dose equivalents, we're going to have to divide our doses by a factor of -- or multiply our doses on our film badges by a factor of .7, and that was a little bit troubling in the program, as even though that's a good scientific answer, has a lot of good backup as to why the recorded image should be lowered by .7 -- again, when we dealt with the public in trying to put that information out, we got lots of information back that you're lowering my dose. It doesn't match what I have in the record. How can you take good science, I don't care if it is the National Academy, you're lowering my dose. That's the dose that's been in my record for the last 30 years. How dare you come along and change the particular dose in the record.

We also ran into a discussion of what do you do with damaged film badges. As you know, when a film badge is damaged by heat and humidity, you get a darkening of the image, which relates to perhaps a higher radiation exposure. That I could explain away a little bit better in the program in that when we employed dosimetry you had people side by side

who had good dosimetry next to people who had bad dosimetry, so again you could establish some parity in terms of knowing that a darkened image from humidity actually did erase what your radiation dose was.

So those are kind of the factors that we had to deal with in communicating film badge information to veterans, and we finally abandoned using the factor of .7 and we used the actual dose of record that's on the film badge, unless of course health physicist in examining the badge says we have a compromised image and a dose reconstruction would be in order. So again the public perception in trying to apply good science on film badges is we're lowering their doses, and it's not a good position to be in so I just want to pass it on to you as you engage yourself in looking at lots of film badge records and I'm sure you're going to run into in the energy cohort.

As film badge dosimetry technology emerged through its development, we also had changes over time in terms of radiation limits. Back in Crossroads the radiation limit in '46 was a tenth of an R per day. As time went on, say to the era where we had lots of film badges in the late fifties and

mid fifties, it was 3.9 R in 15 weeks, and some of you who have been around the radiation trade can relate to that if you take -- that's a quarterly dose, which if you take times four gives you 15 rem per year limit that we had as our national radiation occupational exposure limit.

And of course during the times where we had high accidental exposures, there were special physical exams done on folks, bioassays taken. And we also know from 1956 when we tried to put film out there en masse that it's just -- you just can't put it in a holder and hang it on somebody and go out in a wet environment. It doesn't work that way. So we've had to learn through other lessons learned. But we do have a supplement with a wealth of other extensive monitoring data to back us up.

And of course a lot of the things you're going to come across in a business that's done over a number of years where the radiation standards get stricter and your practices get better as you learn more about lessons learned is the information-gathering process, the public's going to want you, along the line somewhere, to admit that the government did them wrong. And of course that puts us in a very precarious position in the NTPR program

in that we're only the fact-gathering people in terms of, again, was I there and what dose did I get. And again, we do that by seeing what the records chronicle, without any judgment as to whether there were less strict practices, let's say, in the forties versus the fifties versus the sixties. Certainly you can see how things evolved over the years, and it's quite amazing that despite the changes and practice that, again, the wealth of data helps us go back and chronicle what really happened in terms of what exposures these people received.

So again, we report doses based on the facts. You know, the facts and nothing but the facts. Again, we place no judgments over radiological practices, but that's something that you're going to be faced with in terms of people submitting claims is they want the government to admit fault to the radiation dose that they received.

What you'll probably run into, does better science always help us in terms of working compensation claims? No, it hasn't helped us at all. It's gotten us into some really heavy quandaries.

If you go back to 1985 when we established the program, we used the best ICRP NCRP standards at the time and, again, we used ICRP-30, ICRP-26. Now as dose conversion factors have changed over the years and we looked at better biokinetic models, have we put them into the programs? No, we haven't. We looked at them very carefully and said if it's going to lower the dose to any degree, we're going to leave the old science intact. By the same token, if any of these case-by-case situations raise the dose to the person by applying the modern science, the newer, up-to-date science in dosimetry, we will put it in on a case-by-case basis.

So basically our tightrope that we walk is reviewing the new science. If it's going to lower the dose, we make that acknowledgement and then don't put it into effect. If it is going to appreciably raise the dose, we will put it into effect on a case-by-case basis.

Again this all kind of contributes to the public perception that science is not helping them. In our cases, if you -- in putting science into effect that lowers people's doses over time as the program matures, people are going to become less and less sanguine with the science, even though we know

it's best science, as some of us who are scientists in the room know. And the public perception is you're lowering my dose again and you're helping produce an answer that is not going to help or get me compensated. So you're going to be of course paying attention to that time and time again as your program matures over the years.

What I believe is what that's led to the very last bullet on the chart is as the public perceives less and less science helping them with compensation, more and more there's socio-economic solutions such as presumptive compensation that Congress feels the need to come along and award compensation benefits through other means. So you can see how this evolved over the number of years.

Here's one that I think really threw the credibility out the window on the NTPR program. We've been engaged since 1978 in coming up with the maximal doses to cohorts of people. Again, Congress came along and said we're going to do individualized dose reconstructions, so when you move from maximal doses to units to individuals doing specific things over specific periods of time versus an entire operation, doses are going to go down. Even though we know an individualized dose is going to be a

better dose for that person, in the minds of the person who say wrote in to the program in the era between 1978 and 1984 now submits a claim because there's a VA program, the dose is going to go down. And this happened -- this happens time and time again in our program. We see people writing in accusing us of lowering their doses.

Of course if you really look at all factors considered, when we went to individualized doses we also were required to account for periods of exposure that weren't covered by film badges. So actually doses kind of go in both directions as doses not only go down from the generic dose, but if there have been specific instances that are not covered by any of the information we have, the dose can climb back up. Again that leads the public to believe when they write in as we have gained more and more historical information over the years that we really don't have a handle on what the dose is. And as time has gone on when we've gotten better and better information both from historical records and for other veterans engaged in the other activities and their buddies write in, we get a better definition of what they did. And when you get a better definition of what you were engaged in, the

doses generally are going to go down. So it's one of these perceptions that the veteran feels that there's no net gain here at all in learning more about the process as time has gone on.

And of course this has redoubled over the years, despite the fact that we've had NAS look at our dose reconstructions. Again, the public regards dose reconstruction in our program with very, very high suspicion, and this is the area of our program that carries, still to this day, the highest controversy with any group -- Congress, the general public, veterans at large.

Another misconception is accuracy of doses. You have to really view accuracy in terms of what the program's intended to do. We started these programs with the idea in mind -- at least we knew from the direction of Congress that we're going to support compensation programs. The need for accurate doses can be very, very highly misunderstood. If you're supporting a compensation program, are you really interested in taking a yardstick that's 36 inches long and precisely trying to come up with a limit around 36 inches. Or do you find measuring 40 inches on the yardstick's good enough and you move on. Again, in terms of working

with the VA programs, we're trying to give benefit of the doubt to the veteran. We view accuracy not in terms of how accurately can you measure 36 inches in the yard, but if we, through the information, can only get 40, 42 inches of the yard, that's good enough for the veteran, provides some margin of error and benefit of the doubt.

In 1985 and 1995 the National Academy of Sciences took a hard look at our dose reconstruction program, '85 when we first started it, '95 when we were doing the mortality studies, and they recognizes (sic) that high-bounded doses are good for compensation program, but any -- anything that we're doing in terms of central tendency valued doses, we really aren't a program that's doing that to any degree of accuracy, so one can get the misconcept here that NTPR doses are not accurate. Scientifically they're not accurate. Are they high-ended in terms of serving the compensation program? Surely they are, and that was the intent for our performing dose reconstructions.

Independent oversight, that's a very, very important issue. The Energy Workers Employee Compensation Act started off with this advisory panel. This is a very, very good thing. We didn't

have this in the NTPR program in the early days, or we had it in some kind of fragmented fashion. In 1985 and '95 the NAS of course looked at our doses. They said they're not accurate enough for epidemiologic study, and certainly I would not take our doses and our database and submit them to any review for epidemiologic purposes because they're high-sided. And I think you all know high-sided doses are going to produce low-sided risk estimates. For the fact that we have a gamut of doses that could be accurate to high-bounded, you're going to have risk estimates that are off to the same degree. But they are adequate for supporting compensation programs, and I think one of the early-on comments to your program is how do you wed the two together. Can you wed compensation with the goals of doing scientific epidemiology later on.

I don't think you can. I think if you're going to pick one goal versus the other, you're going to get there from here. If you pick epidemiology as your goal, you're probably going to get very, very expensive dose reconstructions. They're going to be highly accurate. They're going to serve the purposes, but again, are we going to serve the public by sparing that expense. If you go

to supporting a compensation program, which some of you I see in reading your *Federal Register* is you've got some connection that if your dose in the worst case is never going to get you to a good probability of causation number, finish the work and walk away from it. Or by the same token, if the dose is very, very high and already gets you there to the answer, are you going to go the extra yard to get the rest of the radiation dose. If that's your main content of your program, I don't think you would be able to really look at doing epidemiology, so it's something that you all need to consider, that you're probably going to have to sacrifice one for the other.

GAO of course came in and looked at our program in January, 2000. They confirmed the previous NAS finding that we're doing high-sided dose estimates. They also said there's no better alternatives to dose reconstruction. This was even taking a look at our preliminary results on our plutonium bioassay. But they did note that we did not have an independent review process, that apparently the Academy, in looking at the program twice in ten years and the GAO later on, five years hence, is this is not considered an oversight process, and said when the finding -- the big

finding -- the only finding they had in the GAO report is that the NTPR program lacks an oversight process. It lacks an independent review process for dose reconstruction. And of course the action item was, DoD establish such a thing. And of course that got us into a Congressionally-directed NAS study that's ongoing at present to look at this very, very important question.

The major issues that we have, and some of you have read the statement of work for the NAS study we're talking about -- accuracy and so forth. To put this in the words of John Till*, the Chairman, the major issues here are the doses right. Again, we're not using the word accuracy. Are they right, are they serving the compensation program. And are they fair, and that's sort of the same questions I'm hearing you ask here today. And we'll see that report in the spring of next year.

Again, Congress asked them to recommend what kind of permanent system of review should be put in place, if any. So that's another public policy question that's going to get answered during the course of the study. And what they're doing in our study -- and Mark, you'll find this of particular interest -- they are basing their review on a sample

of 99 dose reconstructions that have been stratified by series, by numbers of people involved in specific series, also whether they had internal doses, whether they had high doses and there's some other discriminators there that figured into their stratification of these 99 dose reconstructions. They also run the gamut of the program from the early days before we were supporting compensation programs and well into the era of today where we are supporting heavily VA claims. And of course you'll see this process or these results released in April, 2003.

Interfaces with the Department of Veterans Affairs. We provide the participation in dose information to the VA. We don't interact with the process. Again, we provide in accordance with our *Federal Register* requirements. We don't receive any feedback as to what the VA does with the doses. We don't get involved in benefits review decisions that Jerry Steele will talk about or the medical review that Neil Otchin will talk about, or the final decision as to whether there are merits for grant of an award. And also we don't receive any feedback on the process on individual veterans as to whether they successfully worked through the process or not.

So this is a complete unknown to us.

What I can point out is, as far as oversight is concerned, is the VA, by Public Law 98-542, has an oversight process. We don't have it in our program, but the VA has it through the VA Advisory Committee on Environmental Hazards, and they oversee the process of the VA review of radiogenic diseases, probability of causation, all those particular issues. But again, that doesn't factor back to DTRA's program.

As far as our relationship's concerned, we're very much engaged in managing the process. And what I mean by that is making sure that when we get information from the VA that we have a proper citation of a disease so that we can gather the information and go forward. We have the veteran's claim and specific statement of claim that we get all of the information the veteran has provided to the VA, so this helps us put together our package, and making sure that all the boxes are checked up front as to having all the information that one could get from the VA in order to move forward in our process. So we do most of the time managing to make sure this happens. We're one place in DTRA. The VA of course has 57 regional offices across the

country and, again, we need to make sure that that process is monitored, that we get the information uniformly.

The one important thing that Jerry Steele is going to concentrate on, the very last thing, is VA can grant benefit of the doubt. One of the questions you'd asked is once they get through our process, the veteran gets the dose, he doesn't get the grant of the award, is it the end of the line. No, the veteran can come back and contest the dose to us. We go through a very extensive question and answering process in trying to satisfy the veteran's issues over the dose. And oftentimes we're not able to and, you know, when does the process end. And I think if you looked at your *Federal Register* process, it's kind of open-ended and at some point, you know, you have to say that the answer is the answer. But through the VA, if we had issued a decision to say that we could not put them at a particular event, the VA can look at the preponderance of evidence -- we look at the records only -- and say as a result of other evidence, if the person was at a particular test, they can concede the person's presence at the test, come back to us with a hypothetical scenario for

reconstructing the dose and we reconstruct the dose. So again, the veteran does have a benefit of the doubt process.

Another means of benefit of the doubt concerning the dose reconstruction is the veteran can bring a second opinion dose into the process. And if that dose disagrees with our dose by more than a factor of two, the VA by law must go out and contract with a third party to provide some reconciliation of the two dose estimates, and whatever final result comes out of the independent dose estimate is finally what results in the dose assigned to the veteran.

In summary, our dose reconstruction supports high-sided doses, thus we support compensation programs. We try to support benefit of the doubt to the veteran. Over the years we've had to compromise the science in order to interface with administrative and public policy issues and we talked about some of those at length at the end of the brief.

The PC process is totally independent of ours. Basically it's an interface with the VA without interaction. And again, independent oversight has been sporadic with the program and

some remedial action I'm sure will be recommended with the issuance of the National Academy report in April, 2003.

Questions and discussion.

DR. ZIEMER: Thank you very much, Michael. Yes, the floor is open for questions and discussion.

Mike -- or Mark.

MR. GRIFFON: I think -- I was just wondering and I think I've seen this -- I either talked to you or some of your staff at various times and got some of this information off the web site, but I was wondering if the scope of work for the NAS review is available. I think what's on the web site is probably the full scope. And then also if the NAS panel has developed protocols or procedures for review in the cases and if those are available.

MR. SCHAEFFER: The first question concerning the statement of work, they actually condensed it down to the two basic issues with the concurrence of the Veterans Affairs staff who they worked with in terms of are they right, are they fair.

As far as the other question of the actual protocol developed to review, again, due to the nature of the National Academy of Sciences in doing

an independent investigation, they have not shared the development of this protocol with us or actual procedure they're using to conduct the review. And I would be quite certain -- I don't think I'm making any presumptions here -- if you were to ask them today, they probably would say that they can't make them available to you or to anybody. But it might be a question you want to ask after April, 2003 when the ink is dry on their report.

DR. ZIEMER: Doesn't the Academy now have to operate under a process that very much looks like the FACA process where their deliberations of their committees open and so on? Wouldn't that --

MR. SCHAEFFER: It's certainly true they're under FACA, just as you are here. However, the actual work products that take place outside the public forum, they can tell the public what the bottom line is in terms of what they're doing as a result of the development of the protocol, but they can't tell you exactly what they're doing as far as looking at the dose reconstructions. For instance, we know they're looking at 99 doses, and why they're looking at 99.

DR. ZIEMER: And I think that's the kind of information we're talking about here. We're

interested in the methodology, not the details of the doses and so on. You know, is there some logic -- is it -- yeah, the rationale for -- how many total dose -- 99 --

MR. SCHAEFFER: They looked at 99 doses.

DR. ZIEMER: Out of how many? What's --

MR. SCHAEFFER: Individualized dose reconstructions out of 4,000 or 5,000.

DR. ZIEMER: 'Cause we were thinking about a two to three percent.

MR. GRIFFON: That's the same.

DR. ZIEMER: Is that where the number came from?

MR. GRIFFON: That's where that number came from.

DR. ZIEMER: Yeah.

MR. GRIFFON: Yeah.

DR. ZIEMER: Okay.

MR. SCHAEFFER: And what they're doing in terms of the internal review, they've not shared that in public with anyone. We do know that from time to time they come and gather records from us. We have to provide redacted records to them. What they're actually going and what content they're drawing from those records, I don't think anybody

knows. But we know from the statement of work that the -- whatever has been done in the process, such as what you're talking about, Congress has asked that they report exactly how they conducted this process, so that will become a matter of the public record when the report's issued.

DR. ZIEMER: Whose decision was it to use old science when it benefitted the claimant and new science when it benefitted the claimant? In other words --

MR. SCHAEFFER: It's been in the process --

DR. ZIEMER: -- there's almost an issue of fairness here. You could say well, I'll use whatever, old and older and new and newer. I mean --

MR. SCHAEFFER: If newer results in a dose that's --

DR. ZIEMER: Yeah, I understand what you're saying, but who -- is that a policy decision or --

MR. SCHAEFFER: It's been a policy decision throughout our program from the time even before I joined the program, and I've not changed that policy in any degree. It does work against the science, of course. And you know, it begs the question again is if you were to put that into place and what do you

do about compensation to folks that perhaps would not have been given compensation years ago. Also begs the question on the other side is what do you do if it -- there's often a more favorable award today, how do you go back and back-check that in the system. Again, since the VA process is not married to our system, it's hard for me to conjecture on that one.

DR. NETON: If I might -- this is Jim Neton. I'd like to ask a question, Mike, on that issue. Maybe some clarification on what you were saying. My understanding is that you based the program initially on the current science, the best science at the time.

MR. SCHAEFFER: That's correct.

DR. NETON: But then you were just reluctant to change to a more current model if it would --

MR. SCHAEFFER: Lowered --

DR. NETON: -- be detrimental to the claimant. So an instance, in 1985 ICRP-2 was the standard in effect for regulatory purposes, but you nonetheless chose to use the ICRP-30 models.

MR. SCHAEFFER: Uh-huh.

DR. NETON: So they were the best models available at the time of the program inception.

MR. SCHAEFFER: That's correct.

DR. NETON: Okay, so I think that's an important point.

MR. SCHAEFFER: And that's going to loom heavy on anyone who runs this -- you know, looking back at the program 20, 30 years hence, what you do about that issue. I don't know the answer to it. The fact that you all are starting a program afresh, you might have a better idea on how to handle that so we can learn from you.

MR. GRIFFON: Just one more thing. Are there any provisions for this whole Special Exposure Cohort -- I know you have presumed causation for certain subclasses. Are there provisions when you can't estimate a dose -- I'm going to use the words from our regulations -- with reasonable certainty where you would consider -- have you had that situation, first of all, where you can't estimate the dose -- a reasonable estimate of the dose. And secondly, are there provisions for adding those individuals or classes to the presumed causation group.

MR. SCHAEFFER: The answer to that question -- the first question is what do we do if we can't perform a dose reconstruction. I don't think we've

ever faced a situation where we couldn't assign some dose value. And basically gets us back to the chart where it's fairly well-defined, the activities for atmospheric nuclear testing and post-war occupation of Hiroshima and Nagasaki. By the same token, we are blessed with military records. The military kept very, very robust records of what people did and where they went, except in the cases of we do run into some frustrations with Hiroshima and Nagasaki where people went on excursion trips apart from their regular duties and they never got recorded. That's not to say if we can't get the record and VA concedes that they were there, again, we're still able to assign a dose to that particular process. Whether they were at the ten-mile limit of the two cities or whether they were inside the city or even just traveling around 20, 30 miles away, we can still assign some maximal dose value.

Now you had a second question, special cohorts.

MR. GRIFFON: Right.

MR. SCHAEFFER: The special cohorts in our program have been the Congressionally-mandated decisions to grant individuals in the same population -- atomic testing, Hiroshima, Nagasaki --

presumptive compensation just for being present. And it's been done for certain classes of diseases, other special categories which Jerry Steele will talk about in terms of the complexities. But it is possible in the course of the VA program where a veteran can file under both programs. And are there any advantages -- lots of pros and cons on that that it's too complex to answer.

DR. ZIEMER: Okay. No further questions? Then I thank you again, Michael --

MR. GRIFFON: I just want to add on that the pros and cons that are difficult to answer might be of interest for our Special Exposure Cohort working group because I think that's a similar issue with the pros and cons of petitioning to get in the Special Exposure Cohort.

DR. ZIEMER: Thank you very much. Next we'll have a presentation dealing with adjudication of claims through the atomic veterans. The presenter is Jerry Steele, who's with the Department of Veterans Affairs. Jerry began his work with VA regional office in Montgomery, Alabama several decades ago and then transferred to the VA central office in the mid-eighties. Jerry did his undergraduate studies at the University of

Mississippi, his graduate work at Troy State University in Montgomery, and currently Jerry is a consultant and advisory -- I'm trying to read this writing -- consultant for the advisory review staff, compensation and pension services. Is that the correct title?

MR. STEELE: Yes, sir.

DR. ZIEMER: Good, I want to get it correctly in the record, even if I get it wrong here. Thank you. Jerry, if you would, please.

MR. STEELE: I know the schedule had me on before Mike today, but as it turns out, Mike pretty well taught my presentation. Are there any questions?

(Laughter)

MR. STEELE: No questions? We will address exposure, the regulations under which the Department of Veterans Affairs can compensate a veteran or a survivor of a deceased veteran for a radiogenic disease, a disease due to radiation exposure. As one veteran pointed out in a claim, he says hey, I was 19, I was -- nothing could harm me. He said Hell, I could eat it and it would not hurt me. But we're finding out ten and 20 and 30 years later that that is not the case.

We'll look at Public Law 98-542 which was enacted by Congress, the Veterans Dioxin and Radiation Exposure Compensation Standards Act of 1984. Now I gather that is where you are at this point, standards or evaluating standards. My job is easy because the standards are set by Mike Schaeffer's group at DTRA for the atomic veterans and by Dr. Otchin for the other types of radiation exposure cases. Anyway, my job's a no-brainer. I process papers and get the radiation dose assessment from DTRA, from Mike's group, and then I -- we transfer -- we write it up and send that over to Dr. Otchin for an opinion as to whether it is likely, unlikely, or at least as likely as not that the veteran's now diagnosed prostate cancer is due to exposure to whatever dosage of radiation that DTRA established.

This is landmark legislation, actually, establishing standards. I hope I don't get in your way here, I sort of move around. This established not only radiation, which is kind of the focus of your interest now, but also dioxin. What is dioxin? Dioxin is a part of certain herbicides used in the Republic of Viet Nam.

So I was talking in the hallway on break.

The issue was prostate cancer and how that would impact the NIOSH realm. Well, with prostate cancer and the veteran who is diagnosed with that having served in-country in Viet Nam during the Viet Nam era, it is presumed -- it's a no-brainer. You have service in Viet Nam in-country, you're presumed to have been exposed to herbicides containing dioxin. Prostate cancer is one of the presumptive disabilities.

With Public Law 98-542 we're getting way down the road, though. When it was initially established, the only disability that was service-connectable was coracne*. I gather that's a skin condition. I defer to the medical experts. But I personally, in 30-something years of VA, have not seen an allowed case of coracne. That's not to say they don't exist.

So Public Law 98-542 -- and in your handout I think I had that listed as 3.311(a). It's in the definitive handout, not the slides -- 3.311(a). You can kind of skip over the (a) part because that's not the subject of my address today. But if you would go to 3.311(b), which is the radiation issue, radiation standard that was established September 25, 1985. The Standards Act of 1984 gave VA lead

time of what, 300 days to publish regulations establishing standards for dioxin and radiation cases. We almost made that deadline, because the effective date of our regulations is September -- well, we may have made it -- September 25, 1985. Maybe we missed it by about 30 days. But at any rate, we probably had published in the *Federal Register* proposed regulations. The final -- final effective date or the effective date of the final regulation was certainly under a year from the date of enactment of Public Law 98-542.

Our other law under which we consider radiation -- well, this is it, isn't it? This is the (a) and (b). The (a), dioxin, for the (b) is radiation. In 1994 Congress took the 311(a) and codified that at 38 USC 116 -- 111 -- whatever, 1016, so they renumbered 311 -- it used to be weird. If you're familiar with the way statutes are listed, we have a 311(a),(a) for subdivision (a) under dioxin. Then we had a 311(b),(a), so it was strange.

At any rate, in 1994 the Congress took the herbicides and placed them under 38 USC 1116. That's -- we caught that in the regulations, 38 CFR 3.313, so anything under 3.311 now is radiation.

The Public Law 100-321 took -- well, what did it do? It established a series of disabilities for which all we needed to know was that the person participated in a radiation-risk activity. Radiation-risk activity was defined as atmospheric testing of nuclear weapons, or the occupation of Hiroshima or Nagasaki before July 1, 1946. So if the veteran served on the American Occupation Forces in Hiroshima or Nagasaki prior to July 1, 1946, then that veteran met the definition of having participated in a radiation-risk activity. That meant the veteran was a radiation-exposed veteran.

And for the -- how many was it, 13 disabilities, 13 diseases, if any of those diseases were diagnosed, then we simply had to have from Mike Schaeffer's group confirmation that the veteran participated -- review of historical records confirm the veteran's presence in VA-defined Nagasaki area. That was good enough.

You might ask what is a VA-defined Hiroshima or Nagasaki area. By definition under statute, that is within a ten-mile radius of ground zero, Nagasaki or Hiroshima. Within ten miles. And that's important. We get letters of -- letters from DTRA that say the veteran is shown to have been assigned

to whatever unit at Kobe, Honshu, Japan, 125 miles from Nagasaki. So that veteran is not radiation -- does not meet the definition of a radiation-exposed veteran. That veteran does not meet the definition of participating in a radiation-risk activity, meaning the veteran -- official military records do not place the veteran within the VA-defined -- in this case, Nagasaki -- area.

So we're faced with -- this is a particular case I have on my desk now, someone writing to the Undersecretary for Benefits, to Admiral Cooper, asking for his personal attention and to the case. Since the veteran cannot be established by official military records as being in a VA-defined Nagasaki area, we will have to go back to DTRA, Defense Threat Reduction Agency, and say that since official military records do not establish the veteran's presence at or absence from Nagasaki, a site at which radiation exposure is claimed, then VA concedes that the veteran was there. So Mike will have his folks at DTRA come up with a radiation dose assessment on this particular case, which we will then -- doesn't fit under the presumed, does it, under 100-321 because the veteran is not a radiation-exposed veteran. Right? Did not

participate in a radiation-risk activity. So -- but he does fit under the 3.311 criteria, so we'll have to refer the case over to Dr. Otchin for an opinion as to whether the veteran's exposure to whatever dose -- it will probably be less than one rem -- whether the veteran's exposure to that one rem is likely, unlikely, or at least as likely as not to have resulted in the now-diagnosed prostate cancer. Okay?

We've been talking about 3.309. That's the regulatory -- the VA regulation for Public Law 100-321. Okay? That's the presumed -- actually, 3.309 -- you know what that is? It's the chronic diseases, chronic diseases for which service connection will be presumed if diagnosed within a certain period of time; 309(d) addresses the radiation diseases -- the diseases for which service connection is presumed if diagnosed at any time after service in a radiation-exposed veteran. We have a handout, probably is page 9 of the definitive handout that compares the diseases listed under 3.311 and those listed under 3.309. We'll get to that later.

How can a veteran be exposed to radiation? Could be exposed through participation in American

Occupation Forces in the VA-defined Hiroshima or Nagasaki area. Right? Can be exposed from participation in atmospheric nuclear testing, nuclear weapons testing. Occupational exposure, on the job exposure. What types of military occupations would result in occupational exposure? X-ray technician, perhaps?

UNIDENTIFIED: Nuclear weapons.

MR. STEELE: Nuclear -- occupational exposure? Right, nuclear weapon --

UNIDENTIFIED: Technician.

MR. STEELE: -- technician, changing out warheads and so forth, that would get it. What would be another one?

UNIDENTIFIED: Nuclear subs.

MR. STEELE: Nuclear -- nuclear -- let's call it nuclear propulsion, which would include subs -- we have some surface vessels, don't we, that are -- okay. These cases we -- the regional office might accidentally send an inquiry to Mike, but someone there screens them there pretty fast and lets the regional office know that that's -- that's not the proper agency to request radiation dose assessment for occupational exposure.

For a nuclear propulsion -- for a Navy

nuclear propulsion person or a claim involving Navy nuclear propulsion, the source would be the Naval Dosimetry Center at Bethesda, Maryland. Captain Paul Blake would look at his database. The Navy Dosimetry Center maintains a database for Navy and Marine personnel occupationally exposed to ionizing radiation and then would send us or send the regional office a statement showing periods of exposure, perhaps ships to which assigned when exposed, and then the -- they do it -- they show a CDE -- they list neutron, gamma, gamma and X-ray combined, and I think they show a beta. But at any rate, those beta columns and neutron columns are typically zeroes. Practically everything we get would be under the X-ray and gamma.

We would take Captain Blake's statement of exposure, and he would typically tell us that all exposures are whole-body -- probably means something to -- but so that's what we -- when we refer it over to Dr. Otchin for an opinion, we say -- you know, we just repeat what Captain Blake may have said, that all exposures are whole-body, for example.

There's another -- our manual is -- I didn't write this particular part, but it says on occupational exposure if the service records contain

DD form 1141, record of occupational exposure to ionizing radiation, if -- no, it -- how is it worded? If it does not contain that, then go to the Naval Dosimetry Center if it's Navy or to the address -- the Redstone Arsenal if it's Army, Bowling* Air Force Base if it's Air Force. Anyway, the different service addresses are listed. If I had written that I would say in addition to, you know, any documentation of exposure on DD form 1141, go to the Naval Dosimetry Center and ask for any other records, so that we would have a complete -- everything that any database might have as far as radiation exposure, and then send that over to Dr. Otchin for an opinion.

I think what our slides -- what this series of slides is addressing is the 311 case, the one that we're not going to presume, we're going to get a dose estimate. The first factor to be done is to determine that a specific disability is claimed. And this is weird, 3.303 just addresses service connection, so if it's not a presumptive disability under 3.309 and it's not listed under 3.311(b), notwithstanding the regional office should consider service connection -- well, that just means going through all the service medical records and ensuring

that no early manifestation of the disease was diagnosed in service because if it were, then that's service-connected on a direct basis. That's service-incurred. Okay? That's what 3.30... Okay.

Okay, here's what we're going to do if it's not listed. Wait a minute, am I getting ahead of myself?

UNIDENTIFIED: I think you skipped a bullet.

MR. STEELE: Did I skip one?

(Pause to reset)

MR. STEELE: If the disability is listed, okay, all right, there we go. If it's actually a listed disability, then we do the following. And here's where we're -- we ask that the regional office, before they go to DTRA -- because that's 90 days that we don't know that need to be expended. We need medical evidence establishing the claimed condition in fact exists. Okay? If it is a radiogenic disease or a presumptive disability that can be service-connected based on radiation exposure, then we go to the Defense Threat Reduction Agency. Why do I have a (b) on that? I should have eliminated the (b). It's just 3.311. Okay? (b) is a part of that, but it's -- okay.

Now what's the difference between the one

that I did before -- what's the difference between the 3.309 and the 3.311? 3.309 is the presumed list. Right? The 3.311 is the one that we have to get a radiation dose assessment from Mike Schaeffer's group, Defense Threat Reduction Agency. Or if it's -- if it's other occupational exposure, then we have to go to the appropriate service department -- Naval Dosimetry Center for a nuclear propulsion person, Army for a warhead -- nuclear warhead technician, Air Force for whatever Air Force is exposed to. X-ray technicians, dental technicians would have to go to whichever branch of service that person worked. Okay?

Once the regional office has done the three items here, then they contact my section and -- Compensation and Pension Service. I guess they do that to ensure that everything's been done, all the T's crossed -- crossed and -- I's dotted and T's crossed. We then -- we continue to log the cases and ask the questions to make sure that everything's been done before they send the case in to us. Maybe that lessens the cases we have to send back before they -- you know, for them to -- the regional offices to finish their development of the case. And if their development was correct up to the time

that it's called in, we ask them at that point to go to DTRA. I don't know if that lessens the number of requests that Mike gets or what, but...

Overall, for the -- these figures were correct the first of the year, or as correct as figures could -- you know. They were reported to Congress as accurate, probably couched in this is the best we can do right now -- 21,135 total radiation compensation claims; 2,582 grants of service connection. Of those -- of this number, 500 or 515 are grants under the presumptive -- the presumed disabilities under Public Law 100-321 under 38 CFR 3.309, and of those 515 what, almost two-thirds are based on atomic testing and then one-third on occupation of Japan.

UNIDENTIFIED: That's all you've got.

MR. STEELE: That's all I have.

DR. ZIEMER: Of all of those claims -- let's see, the 2,582, do those require dose reconstruction, the service connection -- those must. Right?

MR. STEELE: No, 515 did not require a dose reconstruction, but they required a letter from --

DR. ZIEMER: No, the 515, I understand that --

MR. STEELE: The 515 --

DR. ZIEMER: -- but what about the 2,582?

MR. STEELE: This number is included in here, so we would be looking at --

DR. ZIEMER: Oh, I see, okay.

MR. STEELE: -- 2,000 -- somebody that's good with math --

DR. ZIEMER: Okay, about 2,000. Now --

MR. GRIFFON: But how -- I think -- my question -- maybe Paul's going to ask the same question, is I thought I heard a number of 4,000 to 5,000 dose reconstructions done, but there's 21,000. Is that 2,500 a subset of the 21,000 --

MR. STEELE: Yes.

MR. GRIFFON: -- claims, and then there were only 4,000 or 5,000 that had dose reconstructions done, is that correct? I'm trying to connect the numbers from the previous presentation.

MR. STEELE: My presumption would be that the majority of the 21,000 would have had -- well --

DR. ZIEMER: Seems like most of those would have had dose --

MR. STEELE: Most of those --

DR. ZIEMER: -- reconstruction because you pull out the --

MR. STEELE: Yeah, right.

DR. ZIEMER: -- presumptive ones right off the top. It seems like everything else would have to have a reconstruction then. Am I understanding that correctly?

MR. STEELE: Yes.

MR. GRIFFON: But the -- previously we heard 4,000 or 5,000 dose --

MR. STEELE: Right, right, but --

MR. GRIFFON: -- reconstructions.

MR. ELLIOTT: Mike Schaeffer's not in the room right now -- maybe we can get him back in -- but I think you've got to remember that they do dose reconstructions for veterans not with a claim. Sometimes a request for dose reconstruction comes to them from the veteran without the veteran filing a claim and they go ahead and do it to respond to the veteran's need.

MR. STEELE: Also Mike's group is only going to do the, quote, atomic veteran. Is that true? The atomic veteran. Now what -- how did Mike define those? Occupation of Hiroshima and Nagasaki or atmospheric nuclear tests. We have other exposure claims, although I would not have thought 17,000 from that, so there's some disconnect there, yet.

DR. DEHART: Are those numbers in total with the law for the last what, ten years?

MR. STEELE: Yes, sir. They're cumulative as of the spring of this year. Okay? Any questions?

(No responses.)

MR. STEELE: Thank you.

DR. ZIEMER: Thank you very much. Then we're ready to hear from Dr. Otchin, and he's going to talk about probability of causation determination for the atomic veterans. Dr. Otchin is an MD, studied at Duke Medical School. He's Board-certified in internal medicine. He's program chief for clinical matters in the Office of Public Health and Environmental Hazards in the VA's central office in Washington, D.C. So Dr. Otchin, we're pleased to have you here with us this afternoon. Thank you.

DR. OTCHIN: Certainly. I should also mention I did my undergraduate work at the University of Florida since we have a professor emeritus from the University of Florida here.

(Laughter)

DR. OTCHIN: While we're getting ready, I might mention that essentially the whole text of my presentation is in your handout. The draft has been

revised very slightly, but those that don't want to listen certainly can read the presentation at your leisure. Also the overhead transparencies are also included in the handout, so if I can't get the overhead transparency working properly, you'll have a copy of that, also.

Can you hear me all right?

(Affirmative responses)

DR. ZIEMER: Are you going to move back and forth?

DR. OTCHIN: No, I'm just going to stay here.

As mentioned, I'm a physician with the Veterans Health Administration, which is the part of the Department of Veterans Affairs that provides health care and operates the VA hospitals and clinics. Our office, the Office of Public Health and Environmental Hazards, is responsible for providing medical opinions to assist in the adjudication of some compensation claims to veterans exposed to ionizing radiation when requested by the Veterans Benefits Administration, VBA, the component of the VA that is responsible for disability compensation and various other benefits programs.

Basically I'm on the part of the VA on the

left-hand side, which is primarily the hospital and clinic system of the VA, and Jerry Steele is part of the VA on the dotted side of the table of organization, so basically then send the cases over to our side and we send the medical opinions back.

I would like to stress that while our office provides medical opinions, it does not make the actual compensation decisions, which is the responsibility of the VBA. Also there is an extensive process through which a veteran may appeal an unfavorable compensation decision.

And if there are any technical questions regarding the adjudication process, I would defer them to Jerry Steele because his office actually is involved in the detailed adjudication process.

I'd like to now go into the issue of so-called radiation-risk activities. Participation in radiation-risk activities for VA purposes includes approximately 195,000 veterans who were involved in the occupation of Hiroshima and Nagasaki, as was mentioned; some former POW's with similar likelihood of exposure to radiation in Japan; and approximately 210,000 veterans who participated in atmospheric nuclear weapons tests. Also recently some veterans stationed at nuclear weapons facilities now

controlled by the Department of Energy and some veterans who participated in underground tests in Alaska were included in the definition of radiation-risk activities, effective March 26th, 2002, to ensure equity for veterans in light of the DOE/DOL compensation program.

Veterans who were exposed in a so-called risk -- radiation-risk activity have enhanced eligibility for VA health care -- including free VA health care for any malignancy or other condition that the VA recognizes as potentially due to radiation, as well as compensation -- compared to veterans who were exposed to radiation in other circumstances. For instance, nuclear submariners or dental techs in the military or X-ray techs or whatever.

As was alluded to, there are really two separate compensation programs available for radiation-exposed veterans. The presumptive program is limited to veterans who were in the -- in a defined radiation-risk activity who develop one of the diseases on the VA's presumptive list, which includes 21 different forms of malignancy. And hopefully the next transparency will point out this. This is the same as one of Jerry Steele's.

So in order to be eligible for a presumptive compensation, essentially a veteran would have to be -- have been exposed in a, quote, radiation-risk activity and have one of the diseases on the presumptive list. And five of the conditions on the presumptive list, those with asterisks, were just added effective March 26, 2002 -- again to ensure equity for veterans compared to civilians eligible for compensation in civilian programs, both the RECA amendments and the DOE/DOL program.

For presumptive cases, medical opinions are not needed and so ideally or theoretically the cases would never come to me.

The other program is the non-presumptive program, and the types of cases that are included in the non-presumptive program would be a veteran or veterans who were exposed in a radiation-risk activity who develops a disease on the non-presumptive list; or veterans who were not in a radiation-risk activity but were exposed to radiation in some other circumstance like a nuclear submariner or a dental tech or X-ray tech who are not eligible for the presumptions; or veterans who have another disease and for whom a expert opinion is provided by their physician or somebody else

supporting the fact that those diseases might be due to radiation, even though they're not on the formal list of diseases that the VA officially recognizes as related to radiation. And these cases, all the three cases I just described, are compensated under the non-presumptive process and they do require a medical opinion by our office.

And then the last of my transparencies -- this is sort of a flow diagram that shows the sequence of adjudicating a non-presumptive radiation claim that would come to our office for a medical opinion. Now this particular flow diagram is specific for an atomic veteran, the type of case that would go to Mike Schaeffer's group for a dose. If it's an occupational dose, rather than sending it to DTRA, it would go to the service dosimetry office or some other source of information for a dose, but the general process of how the claim is managed and how a medical opinion is requested by our office, the Office of Public Health and Environmental Hazards, is obtained and then the opinion goes back to the Compensation and Pension Service and an advisory opinion is then sent to the VA regional office. And it's really the VA regional office that makes the final compensation decision. And our

office does get about 200 to 250 medical opinion cases per year relating to radiation.

For a case adjudicated under the non-presumptive program, the veteran's estimated dose is considered in formulating a medical opinion on the likelihood that the radiation was responsible for the veteran's illness. VA regulations specify that when a range of doses is reported, the highest level of the dose range is to be utilized. And as Mike Schaeffer said, for instance, they'd give us an upper bound dose and so it would be the upper bound dose, not any of the more detailed doses cited in their letter, that is ultimately used by the VA.

For veterans involved in the occupation of Hiroshima or Nagasaki or those who participated in atmospheric nuclear weapons tests, the DTRA is mandated to provide the radiation doses, and the VA does not review or vet or analyze the DTRA doses independently. Essentially DTRA is mandated by law to provide the doses and the VA accepts them at face value.

But as was said earlier, a veteran who disagrees with an official military dose may submit an alternate dose from a so-called credible source, and this would include a person certified in the

field of health physics, nuclear medicine or radiology. And if one dose is at least twice the other dose, then a independent expert can be -- or is utilized to provide an independent dose estimate to resolve the disagreement.

Now for an occupational dose, in lieu of using the DTRA dose, we would get information from the file, such as the DD 1141 form which is the form that most veterans had that were an occupational exposure, report essentially incremental exposure throughout their military career. Also as was alluded to, each service has a dosimetry office that maintains a dosimetry database, and those are ordinarily queried to see if they have additional dose information available on the veterans. And in some cases, if there seems to be a disagreement between what the veteran says he did in the service and in the absence of a recorded dose or the dose seems inconsistent with what the veteran says he did, sometimes our office actually contacts the military dosimetry offices and asks them to research the case further. In some cases, as most of you probably already know, the VA does have probably the country's largest health care system, and we do have our own health physics program in the VA and

sometimes we actually send cases to the VA's national health physics program to try to come up with a dose estimate in the absence of any recorded doses or if there appears to be inconsistency between what's recorded and what the veteran's statement describes in terms of his activities.

Currently the VA compares the veteran's doses to screening doses developed by the Committee on Interagency Radiation Research and Policy Coordination, or CIRRPC, to assist in formulating medical opinions when applicable. These screening doses are based on the 1985 NIH radioepidemiological tables and were intended to satisfy VA criteria of "no reasonable possibility" and "at least as likely as not" and to be consistent with the VA's "reasonable doubt" policy.

The screening doses were determined so that they correspond to the upper-bound credibility or confidence value for the probability of causation of 50 percent. The VA utilizes the most lenient of the CIRRPC screening dose tables, which is based on the upper 99 percent credibility or confidence limits.

For non-presumptive cases, VA regulations also require that other factors besides dose be considered. These include the sensitivity of the

tissue and specific pathology to radiation, the gender and family history, age at exposure, time lapsed between exposure and onset of the disease, and exposure to radiation and other carcinogens outside of military service. Some of these factors are incorporated into the CIRRPC screening doses. For instance, specific pathology of some conditions, the age at exposure and the latency period.

In 1994 our office requested that CIRRPC update and expand its screening doses to reflect more current scientific information and to address additional diseases that the VA recognizes as potentially radiogenic. We were informed by CIRRPC that new screening doses could not be provided until the radioepidemiological tables themselves were updated. A request therefor was submitted to the Director of NIH referencing the requirement in the Orphan Drug Act for updating of the tables.

In 1995 the presidential Advisory Committee on Human Radiation Experiments recommended that serious consideration be given to "reviewing and updating radioepidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing..."

Subsequently the VA and HHS have co-

sponsored a project to update and expand the radioepidemiological tables and provide the results in the form of a computer software designated as the Interactive Radioepidemiological Program, or IREP. As with the CIRRPC screening doses the IREP software incorporates some of the factors to be considered by VA in addition to dose. A committee of the National Research Council has provided oversight review for this project.

At present our office is using the IREP in a test and comparison mode since it has not yet been formally approved and issued by HHS. the NIOSH version of the IREP is used in the same way for cases not addressed by the NIH IREP. Based on my discussion with Dr. Charles Land at the National Cancer Institute, it is my understanding that the current NIH and NIOSH versions of the IREP are identical except for bone cancer and malignant melanoma.

The VA's Veterans Advisory Committee on Environmental Hazards has advised us to defer use of the new system for actual formulation of medical opinions until it reviews the IREP further and recommends its use. We also plan to ask their advice regarding use of the NIOSH version of the

IREP for cases not addressed by the NIH IREP.

I will be happy to try to answer your questions. Thank you.

DR. ZIEMER: Thank you very much. Questions?

(No responses.)

DR. ZIEMER: I might ask -- I'm curious about the possibility of outside consultants coming in and challenging the established dose records. On what basis do they do that? Are they given information from the site that would allow them to say well, the --

DR. OTCHIN: Well, it's a difficult issue and I'm not sure I can address it, but some of the people that have done it have been experts that have been familiar with the DTRA program by virtue of having been on some of the NAS advisory committees that have reviewed some of the work in the past. Part of the problem -- you know, maybe Mike can comment on this further -- is the issue of classified information. I'm not sure how much access a person coming in totally unknown to the DoD would have access to the information upon which to generate an alternate dose. But basically this is -- and the other issue of course is cost. The

feeling is that the average veteran might not know whom to turn to or might not have the money to pay for an independent dose estimate, so there are some uncertainty of whether this is a meaningful alternative, but it is contained in the VA regulations and recently I did discuss -- not with Jerry Steele but with some other members of the staff in his office -- about sending a letter to NIH to seek additional names of people that could be contacted about providing at least a tie-breaker third dose, so there must be some -- you know, some veterans that do take advantage of this option. That's as much as I can say.

DR. ZIEMER: I could understand if there were some old records where there was a question about say the quality factors or radiation weighting factors for neutrons and something like that. Maybe that's the basis of it. It just seemed a little strange.

MR. ELLIOTT: Neil, I thank you for being here, as well as Mike and Jerry. My question -- I must have lost the point or didn't understand the point you made about using the VA's health physics staff. Could you go over that again for me, just so I understand when you engage them and why you would

and why you engage them versus sending it over to DTRA.

DR. OTCHIN: Well, these are not DTRA-mandated cases. To give you an example, we had a case recently of a Navy veteran that was stationed in the Puget Sound area where he claimed that he was involved in -- he was stationed where he'd had -- involved duties on a super-fund away site that involved radioactivity, as well as various chemical carcinogens. And there was no record, as I recall, or a very low dose on his DD 1141. The military service had no record of any doses in their dosimetry systems. But because the person claimed it, I sort of felt we should see whether the VA's own health physics program could contribute anything, and it turned out that the VA's health physics program is based in Little Rock and sort of the second in command of that is a former Navy -- nuclear Navy veteran himself. And by virtue of sort of knowing about this particular circumstances and that particular site and so forth, using sort of worst-case estimates, was able to actually come up with a dose. And in lieu of any other dose, we then used that dose. So this is an unusual -- this is not routinely done.

But another example, sometimes a veteran will claim that -- these again are not Mike Schaeffer's types of cases, but a veteran will claim that he was in a chemical -- the NBC* corps and they had to go out and do field tests to see if they could detect radioactive sources and so there would be radioactive sources hidden in the field and they would have to try to spot them. And because the military felt this was a low-risk activity, they weren't badged and so there was no doses and so forth, so --

But again, based on assumptions of distance and time and shielding and other health physics type concepts, actually in some cases we have managed to get a dose estimate. So the bottom line I think, without wanting to be too -- to sound too much like a Pollyanna, I think we do make a bona fide effort to get doses. If we can't get recorded doses, we do at least make an effort to try to get estimated doses. But those are unusual cases. They're not frequent.

Another problem at the moment, which I mentioned to you over the telephone, is veterans who were stationed at Hanford or Los Alamos or other places where they weren't badged, and it's been very

difficult to get dose estimates for those kind of veterans. And so again our health physics people in Little Rock have worked with me to try to -- using things like CDC draft report on on-site exposure information at Hanford, to try to use that as the basis for estimating doses so we have something to plug in so we can give a medical opinion. If we don't have a dose, we can't give a medical opinion. So that's sort of in a -- more than a nutshell.

DR. ZIEMER: Thank you. And it also appeared that outside doctors can sort of declare cancers to be radiogenic if they're not on the list --

DR. OTCHIN: Well, the way that came about -- and Jerry Steele may want to correct me -- is that for a long time the VA used these two lists, which is not up there right now, as an exclusive list. And then the court system declared that these lists were an added mechanism for veterans to get their cases compensated, but they didn't negate the ordinary mechanism for veterans to have any claim that they wanted adjudicated. And as I understand it -- maybe Jerry can amplify it -- this led to additional diseases being accepted, but only if some credible medical source issues a statement that they

think that that condition was related to the radiation. Jerry?

MR. STEELE: You're exactly right. You're right, Dr. Otchin. Congress enacted the -- after *Combee v. Brown*, which held that the 311 list wasn't an exclusive list. The VA position prior to *Combee v. Brown* was that the diseases listed under 3.311 were exclusive and therefore if one had a disease not listed, then it was denied at the regional office level as not being a radiogenic disease. 3.311 was amended to say that -- or to read, provide that VA will nevertheless consider a disease not on the list if the veteran has submitted competent medical authority -- competent medical evidence to establish a relationship.

Now we have historically used liberality there. We go with say a chief pulmonologist stating that this pulmonary condition is as likely as not due to radiation. So then we will accept that, although it's not a cancer, and we'll send it over to Dr. Otchin for an opinion as to whether the exposure to radiation at whatever level was -- is likely, unlikely or at least as likely as not to have resulted in this intersticial whatever fibrosis. Thank you.

MR. GRIFFON: Yeah. I just wanted to ask a question along the lines of the presentation from DTRA on the notion of not moving to more current models in cases where it wasn't going to benefit the claim. And I wondered and I've talked to you before about this on the phone. You said you were now reviewing or considering the IREP model and it -- in the recent report we got from NCI they did a comparison of this CIRRPC 99 percentile causation values versus the IREP model and it seems that that -- it will lower the amount that will be compensated, and I wonder if you're considering a policy rule there and --

DR. OTCHIN: Well, as I mentioned in my presentation, Dr. Land has made several presentations to the Veterans Advisory Committee on Environmental Hazards which was alluded to several times and I actually gave them at one point a table showing cases without names on them but ones that would pass muster with the CIRRPC versus pass muster with the IREP versus pass muster with both. The ones that weren't addressed by either I didn't put on the table. And it does look like the CIRRPC is an easier barrier to jump over or whatever you want to call it. And actually I've discussed it with the

General Accounting Office when they were doing a review of some of the dose issues and they felt this was not surprising given the fact that we -- the science is more robust, if you will, now than it was in 1985 and so the uncertainty intervals have shrunk down. But the outgoing chairman of the Veterans Advisory Committee on Environmental Hazards, Dr. Yanders*, and Dr. Warren Sinclair*, who's one of the eminent radiobiologists with -- who is on the committee both advised me not to utilize the IREP until the committee has had greater opportunity to consider it. And unfortunately, the committee is somewhat in an interregnum period because they're in the process of appointing replacement members, but my intention would be to present the official NIH IREP package and radioepi tables package when it's officially released by NIH as an official, endorsed publication. And they already know the implications in terms of how this is going to affect compensation claims. And I think obviously I'll await with interest what their recommendations will be. I think one doesn't have to be a rocket scientist to think of what various possibilities might come to mind. But at this point the committee is not meeting and the IREP is not released, so we've got

these two things that have to happen before it will be discussed.

DR. ZIEMER: Thank you again for sharing with us today.

We have opportunity for public comment now on our agenda. I have requests from two individuals to speak. First, Richard Miller. Richard, if you want, you can use the podium.

MR. MILLER: Good afternoon. My name is Richard Miller, Government Accountability Project. I feel like we all meet each other in hotel lobbies and hotel rooms like this regularly. It's our fifth opportunity to meet in a hotel. We should stop meeting like this.

I'd like to touch on at least today three different topics, the first of which is I was very encouraged to hear from Larry about -- in his presentation today that soon we will have a contract. Obviously some unfortunate circumstances have led to this delay. But one of the issues that we have raised in earlier advisory committee meetings was this concern about the population set of contractors that are going to be bidding on this work and the potential for conflict of interest. And now that you're in the BAFO stage, or maybe

you're in the give-us-your-real-BAFO stage, it seems to me it would be very helpful for the advisory committee to provide some guidance. Maybe, you know, it's inappropriate, but I don't think it is. You know, you're not getting involved in procurement-sensitive issues to make recommendations any more than you were when you reviewed requests for proposal and could have commented on it. I mean the RFP does discuss the conflict of interest and invites a plan from the bidders.

The degree and extent to which the potential for conflict arises is so broad in terms of the potential for companies, for example, who are bidding or who get awarded the contract actually would be reviewing their own company's work product elsewhere, or professionals who work for one company may be reviewing their former colleagues or even their own work product at other locations. Or they may have current contracts or expect future contracts that they're bidding on involving sites where they could be reviewing dose reconstruction. And so, you know, for claimants to have some sense of transparency that knowing that the individual -- not necessarily the company is 'cause you've got this problem. I mean you're in a box. It's a

shallow pool. There's a limited number of bidders, you know. You can -- you know, people are going to drink from the stream if they want to. But if there's some possible way to try to have a dialogue about what constitutes an appropriate level of disclosure to the claimant so that they know at the end of the day that the individual or group of individuals working on their claims do not have a potential for conflict of interest, given all of the -- shall we say subjective and judgment-specific calls that have to get made along the way by these individuals. I think that would be very, very helpful. And this is in no way a comment on the integrity of people that NIOSH itself has on staff, but I worry about who these contractors might be.

Which sort of brings me to the next point, which I suspect is going to get raised again, but just -- by others, but just we're pleased to see that the Senate Appropriations Committee took it upon themselves to put some nice language in commending NIOSH for their fine work on this program, particularly encouraging the Centers for Disease Control to think about allocating some more Federal staff so that Jim Neton has a little bit more help over there over than four health

physicists reviewing this sea of paper. I would not sleep well at night if I had to think about how much paper four people have to review, and I think it'll create a huge logjam and maybe the committee can address that in some way.

And then the last is really specific to a policy question regarding the special cohort rule and which I would really like to see the committee take up. And I just want to read you a statement that was made at one of the meetings -- field meetings. It was made on the special cohort, you know, four -- one of the four field meetings. And one of the NIOSH officials stated -- and I'm just going to quote from the transcript here, if that's okay. (Reading) And the last point I just want to make is that the decisions to add a class to the cohort are really in a sense grave decisions, and we view them as grave decisions. They are important consequences because if you add a class to the cohort, the members of that class can then only be compensated for the 22 cancers that are specified cancers, as allowed by the energy employees act -- allowed by law. And if you have a different cancer, you cannot be compensated under this program. For example, if you have prostate cancer or skin cancer.

So when we make decisions to add a class to the cohort, it's a grave decision. It's an important decision that has real implications for some members of that class, in all likelihood, because some members of a class are likely to have skin cancer or prostate cancer.

So the question is, what do you do about the non-SEC cancers. Mark Griffon I guess and others maybe raised this a little bit earlier, and I want to just sort of walk through what I think are the outlines of the problem or the contours of the problem and whether to suggest perhaps this needs to be addressed in the rule in some way, shape or form, perhaps. And so let me just lay out what I think the policy questions are and then perhaps a remedy.

The policy question, it seems to me -- and again, this is not laid out in the rule -- blocks anybody in a Special Exposure Cohort class from seeking -- in effect, if that statement as it was made is accurate -- for non-SEC cases, non-SEC cancers in all circumstances.

Now classes, as -- in the rule are defined by time and exposure. And you can imagine circumstances where individuals -- by definition if you can't reconstruct their dose and they have a

non-SEC cancer, they're out of luck. And it's by definition that's the case. The question is, what happens to doses -- as Mark was mentioning perhaps earlier -- that bookend. So say you worked in -- and one of my favorite facilities recently has been Numec* and Apollo*, Pennsylvania, in which, you know, there were clearly periods of time where there were very hazardous conditions and it looks like pretty shoddy exposure assessment work. Might be a candidate potentially for special cohort, say between 1960 and 1980, but in 1980 to 1985 there might be adequate dose records.

So then the two policy questions that arise are this. One, will people who have non-SEC cancers be able to apply for the '80 to '85 time period. And the second question is, and more difficult in the rule, is can any of the dose that was received between 1960 and 1980, which by admission you can't estimate except that you come up with a potential dose to go into your endangerment algorithm into IREP. Can any portion of that dose be applied to that non-SEC cancer, or even an SEC cancer -- doesn't matter which cancer it is, really -- between the periods 1980 and 1985. In other words, is -- is by virtue of having declared that you can't estimate

the dose between 1960 and 1980 in this example mean that therefore none of that potential dose can be added to the '80 to '85 period. That's one question.

And if you can, then the second related question is what would it be? Would it be that potential dose that you use to plug into the IREP models or do the worst-case or worst possible potential case or -- I don't want to characterize it 'cause it's not what the rule says, but sort of the potential dose estimate. Then you have a corollary problem 'cause it's already sort of clear on that one example, sort of -- kind of that puzzle that has to -- and then the question is can the -- and can the rule deal with that. And I think there may be practical solutions to this.

This one's a little harder, but it's the corollary to this if you turn this one upside down, and that's if you accept the endangerment criteria that's been established and proposed at least in this rule, which is the -- come up with a potential dose estimate and then you try to somehow fathom what cancers might be caused by that. I mean I don't know where all the biokinetic models are going to come from that are going to assign particular

isotopes to particular organs because they don't all exist, but somehow that's going to happen. And then you'll figure out whether the most radiosensitive solid tumor is going to make you eligible or if it's leukemia then you split the difference. I mean it's this sort of algorithm you have there.

But let's think about this. What happens if you go through that endangerment algorithm and you only come up with a 40 percent probability of causation for the class. You've concluded you can't estimate the dose, but when you get to the endangerment question and you've only got 40 percent -- you don't get over that 50 percent or 51 percent threshold in the IREP model -- can you account for dose those individuals, say in the same case, might have received between '80 and '85 to push them over that 40 percent, or can you only consider the dose within that cohort time frame.

Now this gets tricky because then you're going to say well, wait a minute. Between that 1980 and '85 period, some people may have been working. Some people may have been new into the work force. Some people may have not been in hazardous working environments. Some people may have been very well-protected and some may not. And so the definition

of the cohort between '60 and '80 may be different than the difference between '80 and '85. But nevertheless, what you've got is this puzzle. You've got this sort of interesting question about can you include any dose received outside the time and space of the Special Exposure Cohort, 1960 to '80 in this case, that you could then supplement -- it's sort of the inverse of the puzzle.

Now how to deal with this. Maybe there's an easy answer to all of this and -- and I'm wasting my breath, but I didn't see it in the rule. And the more I thought about the comments that were made at the public hearings, the more provocative this got because it gets messy. And I think what would be helpful is if NIOSH staff could come up with sort of an options paper on how to deal with this. That's one idea. And let the Board look at the options paper and then make a recommendation on which one to incorporate in the rule or as modified. Right? However y'all want to deliberate, it's your challenge. But -- but that's one.

Another is that your working group, your SEC working group come up with a solution to this, in which case you all deserve a pay raise, and -- or maybe it just ought to be debated out here. But I

don't think this rule is ready for prime time until you grapple with this because I think you'll deal with this whenever you have an SEC that doesn't cover the entire history of a facility. Or at least a huge period of time.

And then the question becomes, if you have a non-SEC cancer at a gas diffusion plant, how do you deal and can you impute any of the time periods between when the plants opened in 1992 when it's presumed the dose can't be reconstructed or are you just going to go ahead and reconstruct those. And what I think I've heard from NIOSH on that is they're just going to go try and reconstruct them.

But where you've actually made a physical determination through examination of records and your best analysis that you can't reconstruct that dose, and you're going to then posit some potential dose for inclusion in the IREP model, is that going to be a useful estimation process for helping and can any portion of that dose then be applied to other claims that fall outside that time period. So that's sort of the policy question that I see.

I think that sort of summarizes it 'cause I think --

DR. ZIEMER: Thank you, Richard. Let me ask

if any of the Board members have questions for Richard on the comments he just made.

DR. MELIUS: I just have a follow-up. I believe we've talked about this conflict of interest issue before and I think Larry deferred it because of the contractual situation, but if the contract is awarded by our next meeting, I really think we should have a presentation, some discussion of the -- of that issue. And I think Larry will be -- then be free to talk to us about it. So I'd like that on the agenda for the next meeting, or whenever the meeting is following the awarding of the contract.

MR. MILLER: Does that -- let me just ask a rhetorical question. Isn't that closing the door after the horse has left the stable?

DR. ZIEMER: Since that's a rhetorical question, it doesn't call for an answer, but we're all pondering it heavily here. Henry?

MR. MILLER: Just may the record reflect a pause.

DR. ANDERSON: A quick question, Larry. Do you see the dose reconstructions kind of being anonymous or will whoever did it have their name attached to it so that the claimant could see that this is the person that did it and here's their

credentials and have some sense that they know that they could do the -- their concern about any conflict of interest, or is it going to be anonymous?

MR. ELLIOTT: As I've said before, completed dose reconstructions are NIOSH work. They will come across to the claimant as a NIOSH product, using NIOSH letterhead and a NIOSH report to transmit that information.

I didn't answer your question. I hear somebody saying that. I did answer the question. No, you will not see the name of the individual dose reconstructionist from the contractor on the transmittal of the report. Whether we have it -- I think we will have it on the individual draft dose reconstruction report and on the final. Am I correct, Jim? That's the way the current reports are set up so we know who conducted -- who was the dose reconstructionist. We know who was the reviewer. We know who reviewed the reviewer's work.

DR. NETON: That's correct.

MR. ELLIOTT: But again, it's a NIOSH product. We take -- we are the ones held accountable for that.

MR. MILLER: So does that mean the claimant

will never have access to that information?

MR. ELLIOTT: Again, the claimant will get a NIOSH letterhead transmitting the dose reconstruction report that will indicate who the dose reconstructionist was.

MR. MILLER: Okay.

MR. ELLIOTT: Who the reviewer of the dose reconstruction was and who reviewed that reviewer's work.

MR. MILLER: Okay. So they will get --

MR. ELLIOTT: They're going to see all three, but they're not going to have access, per se, to that individual dose reconstructionist, if that's what you're seeking.

MR. MILLER: Well, I guess the question is will the resumés of those individuals be available to claimants.

MR. ELLIOTT: I'd have to defer and -- I don't have an answer for that question at this time.

DR. NETON: I think we're getting into issues that are related to our contract negotiations, really.

MR. MILLER: Oh, so that's great, so you're dealing with this. Okay. Thank you.

DR. ZIEMER: Thank you, Richard.

MR. ELLIOTT: I can't let that go. Yes, we are dealing with this. We're very serious about this conflict of interest and certainly your comments are well-taken and they have from the very start, Richard. And once the contract is awarded, the conflict of interest plan that's been negotiated and put in place will be available, and I think that's a key document. That's more of a key document to your understanding of how we're addressing this than the individual dose reconstructionist's name and resumé.

DR. ZIEMER: We have another public comment from Joseph Carson. If I read this right, Joseph is Department of Energy. Is that correct?

MR. CARSON: Correct.

DR. ZIEMER: Thank you.

MR. CARSON: Well, good day, Dr. Ziemer. I think it's about ten years since we've last spoken.

Anybody know who I am? Joe Carson, DOE whistle-blower, prevailed eight times? I don't want to belabor points.

I'm a safety inspector in DOE nuclear worker safety. My background, Navy scholarship to college, six years an officer on submarines, worked at commercial nuclear power plants in the eighties,

joined DOE in 1990, so I didn't grow up in DOE. I was hired to be an OSHA NRC inspector.

Following the Chernobyl reactor accident the National Academy of Sciences did a review -- I'm from New York, as you can probably tell, and I want to talk quick so you can get out. Okay? -- review of safety of DOE reactors. One of the recommendations was DOE should mimic the NRC, which following Three Mile Island has placed resident inspectors at all commercial nuclear power plants so that the NRC and headquarters would have another way of getting safety -- as opposed to getting it from the utility, could also have their people providing another insight into the safety conditions at the plant.

So at that point in time, you know, DOE is still self-regulating in both worker safety and nuclear safety. I was hired to be a headquarters safety inspector, primarily in Oak Ridge, but I reported back to headquarters. Dr. Ziemer was the Assistant Secretary. Not initially, I think he became Assistant Secretary sometime in '90 through the Bush administration, so he was my first Assistant Secretary.

At the time DOE was very -- and still is

very dependent upon support service contractors. You're talking about your contractors here. I was working alongside primarily support service contractors, and I found that it was kind of like a Persian court where the viewing manager would be the caliph, the support service contractors would make about $200 an hour, would be kind of fawning down because the manager had complete control of how much work they would get, and the DOE employees were at the back of the bus.

I voiced concerns about the use of support service contractors and basically, to make an example out of me, they started throwing my safety findings away so they could fire me for cause. And I said -- you know, not only -- this -- and this happened about the time when Dr. Ziemer was still there. I said not only -- you know, you're going to go after me, but what about all the people you're putting at risk? And this is DOE self-regulating safety and you're the regulators willing to roll dice with people's lives to go after me, so I dug in my heels and here we are ten years later. DOE has now paid over $400,000 in my legal bills.

The sickest thing about the whole entire process is when you prevail as a whistle-blower,

nothing ties it back to where the safety concerns get addressed. It's kind of like when you're a victim in a crime, you know, the victim gets kind of ignored sometimes. The safety issues that motivate a whistle-blower, at least in DOE, they're often -- I could win 100 times, they could pay millions of dollars, but DOE will actually turn around and say we were not ordered to address your safety issues, so we won't.

Well, MSPB is there to fix -- you tried to fire him, you can't fire him. You tried to reassign him, you can't reassign him. What is MSPB going to say about safety issues? All they have to do to prevail as a whistle-blower is show they're reasonable, so MSPB doesn't order DOE to address the safety issues. DOE turns and says we weren't ordered to, so we won't. So I'm -- it's like Groundhog Day. I go back and say well, I'm a licensed P.E. My options are resign, blow the whistle or both. Well, here we go again, yeah, and it's been going on for ten years.

So what does that mean to you? A couple of things. One of my initial findings that was suppressed by EH -- off course EH had a responsibility for it -- by Peter Brush*, who was

the principal deputy to Dr. Ziemer -- and this is all in writing -- was that DOE's accident investigation program was totally broken -- in Oak Ridge, at least. I identified that approximately 80 accident investigations -- serious accident investigation fatality, a serious injury, a serious workplace exposure, a release to the environment. There'd been approximately 80 -- of course Oak Ridge didn't exactly know how many, but in the eighties and early nineties, not once for any accident investigation was there any verification of any corrective action. Not once. So what'd happen is, people who knew this, when they would go out to do an accident investigation, they would basically phone it in. Nothing's going to get fixed anyway. And when I tried to document that because EH had a responsibility for the follow-up or the tracking of the accident investigations, because I was embarrassing my own management, they suppressed it.

I said what about safety? As a licensed P.E. I have a legal obligation to hold paramount the health, safety and welfare of the public and the workers in the performance of my professional duty. So I said to DOE you knew I was a P.E. when you hired me. I'm just being a P.E. and I'm required

legally to blow the whistle when necessary. I'm just doing my lawful duty.

I'm named after a New York City fireman. I'm wearing my grandfather's ring. I guess came to view the wrong set of values.

All right, so let's talk about the sick workers. My contention is DOE treated these workers as expendable, and what I handed out to you today is DOE in a microcosm. In 1994 I was involved in investigating a fire at a reactor at Brookhaven National Lab. During the fire there was a measurable release of radiation to the environment. A number of the first responders were contaminated. The interior of the reactor building was contaminated. DOE later claimed that no safety violations had occurred at the fire, which I knew to be a complete lie, so I told my -- I did point -- Dr. Ziemer had moved on. I told my supervision. They tacitly agreed with me, but when the report came out, no mention of the safety violations. When you have a fire and you have people risking their lives as first responders to put the fire out, and there are safety violations that cause the fire and there's a cover-up of the safety violations, you're treating those first responders as if they were

expendable, and that's what DOE did.

And that -- in this case, here we are eight years later. I have gone all the way to the President with this issue and DOE's representation is it wasn't a nuclear facility because the uranium that was used in this experiment, before it was irradiated with neutrons or exposed to neutron flux*, wasn't that hazardous.

Well, that's true, just like new nuclear fuel is not that hazardous. If you have it in your garage, you're not going to have a problem with it. But if you put a spent nuclear fuel rod in your garage, you're going to be dead pretty quick. And this experiment would take neutrons from the reactor and irradiate a fissile target of uranium, creating basically fissions in that uranium. So this experiment was surrounded by heavy shielding walls. When the experiment was done, the target was treated as high level nuclear waste, and now DOE has represented to the President it wasn't a nuclear facility because before the target was exposed to the flux it wasn't that dangerous.

So but my issue is, DOE, why don't you just tell the President we don't need Yucca Mountain because the new nuclear fuel's not that dangerous,

either. So that's the kind of rigmarole I've experienced from DOE.

So what does this mean to you? I would have to question -- okay, additionally, the sick workers. Here now you -- you're the advisory committee. I'm going to make a contention, making this as a P.E. If you don't think it's accurate, please, file an ethics complaint against me. Please, because DOE will not address my issues. I want them addressed somewhere in some form. These sick workers are a workplace health and safety disaster of national scale. Just like Enron, WorldCom, Global Crossing, CPA and lawyer disasters, so to speak, which is financial, who has said where were the safety professionals when all these people were being exposed? Where were the people who had legal duties to hold paramount the health, safety and welfare, risking their jobs, risking their careers if necessary to do their duty by the health and safety of the workers? That's what all these Codes of Ethics say. That's what the law says. It didn't happen and no one is saying it. We're tacitly part of a cover-up and then we're turning around, saying to the same safety professionals, tell us what happened, without even saying you did wrong.

If you think I'm wrong, where are all the safety professionals now? I have won and won and won. You think they would be insulted. Oh, no, it's my personal problem. My personal problem. So they can go home, get their fat paychecks, get their pretty easy jobs and say well, it's just Joe's personal problem, just like the DOE will say he's emotionally unstable. He's a threat of workplace violence. Because it's like the politics of personal destruction at a retail level. If I could be discredited personally, you don't have to deal with the technical issues, do you?

Okay. I'm squeaky clean. I have a Q clearance. DOE has dirt on me. Where is it? It's going on for ten years. My life's an open book. My wife is the president of PTA. I teach Sunday School. Okay? I'm involved in leadership positions in a number of leading professional societies. Where's the dirt, DOE? When are you going to deal with the technical issues? I'm really right now at the point that one or more Senators going to put a hole in as DOE Deputy Secretary to persuade DOE it's not going to get away with it anymore. Just last week DOE said a settlement of my case is not, quote/unquote, legally warranted. Well, when is a

settlement ever legally warranted. Try to persuade DOE that doing the right thing is going to be politically warranted, or hopefully someone in the Senate will.

I'm saying that you can't trust any of those safety records. You can't trust the safety professional providing it to you. You may say I'm wrong. Well, let's address what -- are the sick workers a health and safety -- workplace health and safety disaster? If so, where was the breakdown in the Code of Ethics? Where was the breakdown by the professionals by their professionals, and let's try to get to the bottom of that aspect of it 'cause I think that will give some answers to how much reliability can be placed on the safety records by which you're going to be -- or you'll be advising the people who'll be making the determinations about claims for people.

So some suggestions. Acknowledge the possibility that the DOE workers are a workplace health and safety disaster and ask the appropriate safety professions and professionals to evaluate was there a breakdown in the Code of Ethics in their professional duty, individually and collectively. What should be done about it?

The handout I gave about this HFBR fire. I would request this advisory committee request the DOE do in fact a differing professional opinion as to whether I was right or wrong about that facility being a nuclear facility because if I'm right, it has EH implicated, the Office of Science implicated, the DOE IG implicated in a cover-up, right up to the Secretary -- or I should say the Assistant Secretary.

Discretionary function. One reason we're here is because discretionary functions have been used over the years by the courts to prevent workers from getting claims. I'm not an attorney, but I have to ask the question, does discretionary function allow DOE to suppress, as in my case, a licensed safety professional from doing their duty and then to punish them for it? Does the government have the discretion to do that, too? I don't think so, but I think that's a question the court should address.

Conflict of interest. I'm speaking about what Richard Miller said. I think one way to address conflict of interest is what things -- what do your -- and the dose reconstruction people, if they're certified as something or other, what are

their professional ethics? How are they relevant to conflicts of interest? What -- where's that professional accountability that might -- you know, if there's a conflict (inaudible) on one side, but on the other side, you know, this is where we rely upon professional ethics to try to bring things back to an even keel. What is the applicability of that?

Okay. Those -- that's my comments. I'd appreciate any questions you may have.

DR. ZIEMER: Okay. Are there any questions for Joe? Joe, you particularly expressed concern about the reliability of those records that we'll be depending upon. Are you suggesting that they may be altered or we're just not going to be able to get what we need or -- can you give us -- what's -- from where you sit, what does that look like? We've had some concern, number one, about getting full records. I don't think we've been so concerned that there's folks sitting there trying to doctor them, per se. But can you flesh out a little bit about your concern about those records or -- flesh that out a little bit 'cause I think we want to be sure we get full records.

MR. CARSON: Well, I'm going to speak first personally and I'll try to expand on it. As an EH

safety we had databases that we would keep our safety findings, and they were erased twice and we basically start all over. So my first question would be how complete they are.

My next question would be --

DR. ZIEMER: Now when those things occurred, was there a record made of the loss of information to --

MR. CARSON: No, that was one of the things I blew the whistle about and suffered the punishment for. No, there was not.

And these type A and B accident investigations, there is still records that these investigations occurred, but there's no record that corrective action was ever completed and they basically just kind of waved their hands over them I guess in the late nineties.

I would also have -- suspect if you're a industrial hygienist, a health physicist, and you were told don't find positive readings, that you may have readings there but they were not accurate readings in some -- to what people were exposed to. And I guess the phrase that came up three years ago at Paducah was midnight negatives, when they would vent the cascades to the atmosphere at night so no

one would see it and they would call it midnight negatives, you know, 'cause they wouldn't be keeping track of what was going up the stack.

It's some very stark realities in DOE. You know, DOE had security clearance, and I would not be here at this point had the Cold War not ended because they tried to pull my clearance. There is no due process for pulling a clearance. They can just pull it for any reason, and if your job requires you to have a clearance, that's grounds to terminate you 'cause basically for DOE or a DOE contractor, triple play. One, you know, you're fired; two, you're personally discredited; three, you're black-listed in the industry the rest of your career -- 'cause if you ever lose a clearance at one place, you can never work, at least in nuclear power, again. So it's pretty -- you know, pretty high odds, pretty -- you know, I'm -- be honest, that's -- you know. I served on submarines for six years. I was willing, if so ordered, to play an active part in the deaths of millions of people. It wasn't so I could just look the other way at what I saw wrong in DOE. But to --

So in trying to address your question, Dr. Ziemer, I would question the completeness, I would

question the accuracy, I would question -- you know, the -- again -- and this is the -- and another aspect of the bigger issue, how much -- you know, who are you going to trust? How much could those technicians -- you know, they -- were they in fact to some degree subject to biases, they make -- write them less than what they really are? And that's what I'm asking because some of the things in my case, it's talking by extract -- interpolation, but that's -- that's my -- that's my point.

DR. ZIEMER: Yeah. Okay, thank you. Additional questions? Yes, Sally.

MS. GADOLA: I was wondering just which facilities you were particularly talking about in Oak Ridge, if you could make that clearer, please.

MR. CARSON: Well, at Oak Ridge I was a headquarters resident so I went to all the sites at Oak Ridge -- K-25, X-10, Y-12 -- and I saw some similar issues in each. Like I would be looking at hoisting and rigging -- well, the accident investigation was cross-cutting. You know, there would be -- Oak Ridge, that would even be looking at reports from Paducah and Portsmouth, which at the time were reporting back to Oak Ridge, the Oak Ridge operations office. But in my field inspections, I

would be at all three sites. Am I answering your question? I'm not sure I fully understand your question.

MS. GADOLA: Yeah, you are answering. That was what my specific question was, and Dr. Ziemer also asked the other question that I had and that was changing safety records and reporting, which is something that I've expressed concerns about that I've seen happen in private industry and it's something that I've been questioning that -- that has this also happened in DOE facilities. So I appreciate your addressing that.

MR. CARSON: You know, there are two ways of -- you know, one lie is not write anything. Another lie is to say -- write something -- you know, sample where you think you're going to -- you're going to get what you want to find and not what you don't want to find. You follow me? There's a scale of gray, so to speak, as the poets would say. Someone actually went in and read A and wrote B, well, that's one thing that may have happened. But it's more -- I would think more likely either someone decided not to go in and read or someone didn't go there, they read somewhere else and said I think I was close enough. You know,

there's any number of ways to kind of nick it, you know.

MS. GADOLA: Right, and sometimes people have good intentions, but sometimes genuine mistakes are made, too, especially if people are not as careful as they should be.

MR. CARSON: Well, let me -- DOE, as you may know, pays the highest salaries in the Federal government. And when I say that, you're going to say how can that be, isn't everything by grade and whatever, whatever? Yes. And if you go to DOE, you're a grade or two above what you would be just about anywhere else. So you might think DOE gets the best and the brightest. My perception is no, you get people who put up with it because they get a little more money, and that's why they don't want to voice a concern because they can't get paid that much anywhere else. And they're saying that there's -- there's a greed and a fear that was at -- that was -- still -- still is today very much present at DOE. What you would think -- you would think, you know, 20 -- DOE I mentioned is self-regulating. Why are not all the engineers in DOE licensed professional engineers, at least to give some individual professional accountability. I would not

have experienced what I've experienced in the last ten years if these engineers were P.E.'s 'cause I would go after them through the state boards. DOE may reward them, but the state boards might take a different view of things. So just to -- I'm just trying to -- there's just up and down.

You know, and I'll point the finger at the safety professionals. In that handout you have a bunch of letters written in the last couple of months, AAAS has written letters about my behalf, NSPE -- and again, I don't want to be self-aggrandizing, but these are firsts because the bullets are still flying, legally. And these -- and the profession actually showing some cohesiveness -- Code of Ethics? Unheard of. So you know, you're seeing the pioneer at the frontier of engineering ethics. But you see DOE, I think, as the wasteland that happened with these sick workers because too many other people just basically said I don't want you to get sick. I'm not going to put it in people's heads, but push to shove, my economic well-being takes precedence over your physical well-being.

MS. GADOLA: Well, I'm sure we appreciate your comments and different people have different

opinions about what actually happened, but I think the more light that's shed on the whole picture, the sooner we can get more actual truthful information.

MR. CARSON: Yeah, I don't want to -- and it's not so black and white. It's a tapestry. It's complex. That's why I'm saying let's look at it from the perspective of was there -- was the Code of Ethics inadequate? Was the implementation inadequate? Was it both? Because if it was, what has changed to make it better now? If it's not -- you know, if you're going to trust the prescriptions, you have to trust the diagnosis. I'm saying that's part of the diagnosis that has not been evaluated.

MS. GADOLA: Right. Sometimes you need to re-evaluate the whole big picture again, and I think that's what you're getting at. Thank you.

MR. CARSON: Okay.

DR. ZIEMER: Okay, additional comments or questions for Joe? Okay, Joe, thank you very much for being with us today.

MR. CARSON: Thank you.

DR. ZIEMER: Were there any other public comments? I only have the two signed up, but -- that's it? Thank you.

There will be opportunity tomorrow again for public comments, if additional individuals wish to make such.

Tomorrow morning the schedule is as shown, beginning at -- 8:00 to 8:30 is really your chance to get here, grab a snack and chat a little bit. The actual gavel will hit the table at 8:30. The main things on our agenda tomorrow are discussions on Special Exposure Cohort and on the dose reconstruction work group's recommendations.

Let me see if there's any administrative things we have to take care of today. Any -- okay, the room will be locked, so you can leave materials here if you need to overnight. Anyone have any other -- oh, those that -- the working groups -- Mark, your working group is going to get together?

MR. GRIFFON: Yeah, I was just discussing -- I mean I'll offer to -- I'll talk with them after this, but I was going to offer to draft something tonight and then maybe meet a half an hour before the meeting. Is that okay?

DR. ZIEMER: Meet here?

MR. GRIFFON: Yeah, meet here, and I was going to ask the same, Paul, for your -- is your group going to get -- 'cause I was going to get some

-- the reason I don't want to meet right now is I have some written comments for the SEC that I'd like to get to your group and --

DR. ZIEMER: Right.

MR. GRIFFON: -- how can -- how can people do that if they wish to get written stuff to you?

DR. ZIEMER: Well, I'm -- again, I can compile it tonight if -- unless the group wants to meet briefly. But would you want me to compile it and then meet in the morning? We could meet at 8:00, go over it. Is that okay?

MS. MUNN: Okay.

DR. ZIEMER: You'd rather meet tonight, huh, Wanda?

Well, yeah, the thing is, 8:00 o'clock is what, 5:00 and --

MS. MUNN: Yes, it's 5:00 a.m., but that's all right. You don't expect much of me. Right?

DR. ZIEMER: Well, okay. We'll work it out. So we'll recess now and reconvene tomorrow morning at 8:00 -- 8:00 o'clock.

(Meeting adjourned at 5:35 p.m.)

C E R T I F I C A T E

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I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the 14th and 15th day of August, 2002; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 14th day of September, 2002.

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Presidential Advisory Committee

Department of Health and Human Services

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)

Advisory Board on Radiation and Worker Health

VOLUME II

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Hyatt Regency Cincinnati, 151 West Fifth Street, Cincinnati, Ohio, on August 14 and 15, 2002.

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P R O C E E D I N G S

(8:30 a.m.)

DR. ZIEMER: Good morning, everyone. I'm going to call the group back into session for our second day on this sixth meeting of the Advisory Board on Radiation and Worker Health. The record will show that all the members are present, although they're not all at the table.

DR. MELIUS: Except Henry.

DR. ZIEMER: Oh, Henry left. I'm sorry, Henry had to leave, so all members except for Henry Anderson, who was not able to be here for this second day.

Before we get to the agenda items, I'd like to make a couple of announcements. Number one, to remind everyone, including the Board members, to register again today your attendance here. They actually register for both days separately so everyone -- observers, staff and Board members -- please register your attendance in the book on the table in the rear.

Those who -- members of the public who wish to address the Board, please sign up there at the table, as well.

Board members, sometime before you leave

today, if you have preparation time hours that you need to turn in, turn those in to Larry Elliott.

Later on in the meeting we'll have some brief time for any additional administrative housekeeping items, but let's now move on to the agenda items. The first item is discussion on Special Exposure Cohort. This is in relation to the comments that we wish to develop and submit -- actually to submit to Secretary Thompson which will become our comments on the rule-making.

You need to have before you, as we discuss this item, three pieces of paper. The first -- or three items, there's more than three pages. The first item is the packet that was handed out yesterday called -- it says at the top Advisory Board on Radiation and Worker Health, comments on proposed rule 42 CFR part 83. That packet has five pages, the first two pages of which have some comments on specific sections -- draft comments, really; the third page of which has some comments by Wanda; and then the last two pages are some comments from Tony, so have that handy.

The second item which we will utilize as we go into discussion on this is a two-pager that says ta the top General Comments. You should have found

it by your seat there yesterday. It's not identified. It's a highly secret document. Actually it's authored by Jim Melius and so you can make a note of that and you can even date it 8/15, but it has five items on it and in a moment I will ask Jim to lead us in a little discussion of these items, which are some thought-provoking items which will mostly relate to this rule-making.

And then the third item is being distributed right now, and these are some comments that Mark Griffon has proposed that we consider, as well. And these are hot off the press so I've not had a chance to look at them, but Mark has prepared these comments as an outcome of our discussion at the last meeting, so there's some statements here regarding the issue of accuracy or what is sufficient accuracy, some information on clarifying the issue relating to non-SEC-listed cancers, and thirdly, definition of endangered health. So we'll take a look at those comments, as well, as we proceed here.

Now just to get us underway, on the first packet, the statements there are suggested comments to be made section-by-section. If we take Wanda's comment, which is mainly on one of the words, the word being, in section 83.1, "proactive" -- Wanda

felt that that word had certain connotations that might be undesirable and she's suggesting an alternate word. I think the word was "diligent".

And then Tony's comments were mainly to restructure 83.1 to provide an actual suggesting wording. It's a slight modification of the wording that was there, and we can come back to that, and then to add some comments for section 83.2. So those, all taken together, result in rather modest modifications to the first two pages that you have.

Now let me ask you to just put those aside for a minute because I think before we get into any details on wording anything, I'd like us to consider some of the related issues that have been raised.

First of all, let's take a look at Jim's document -- and Jim's agreed to lead us through this, and I've spent a little time myself and I think some of the others have in thinking about these questions and how they might possibly be addressed in some suitable way in the rule-making. But Jim, if you would lead us through your concerns there and then let me ask, as we proceed, that people respond to Jim's questions and give us input so we can get a feel for what others are thinking on these issues.

DR. MELIUS: The first comment concerns the relative balance between the two approaches to developing Special Exposure -- new Special Exposure Cohorts. And I think as we discussed at the last meeting and the NIOSH staff, in response to some of our questions, is that the emphasis in the current approach is -- a rule is on developing Special Exposure Cohorts after an individual has gone through the process and NIOSH has been unable to complete the dose reconstruction. And NIOSH envisions that as the major way of people entering new Special Exposure Cohorts being developed.

And my concern about that is that that's going to delay the process because a person has to go all through that process. It's going to be a difficult dose reconstruction 'cause you eventually get to the point where you can't do it, so -- but that's going to take some time and effort to determine that you can't do it. Then you have to go through the whole process of developing the Special Exposure Cohort, which is the petitioning process, the report and so forth. And that's just going to take a longer period of time.

Secondly, it's going to be sort of a difficult process from the claimant's point of view

'cause meanwhile one person's going to have submitted a claim, other people, maybe from the same work site or same area, are going to be submitting claims. They're not going to know what's going on and it's going to take a longer significant period of time to pull all that together. And I also don't think it's a very efficient approach to doing this. And given the large number of claims that are pending or that we believe to be in the pipeline coming down here, that I think a more -- I won't use Wanda's unfavorite word there, proactive, but an approach that relied more on the petitioning process would be more efficient 'cause it would allow up front the designation of some Special Exposure Cohorts, an active process to determine who would qualify, whether there was adequate dose information available to be able to do individual dose reconstructions on those in that group. And eventually, as those cohorts got designated, it would be a much more efficient process because there would be a larger number of Special Exposure Cohorts or you'd get there quicker, I guess is the -- is my feeling on that.

I think it's also much more understandable and easier for the claimants to interact with that

process, rather than waiting for the individual and not understanding very easily, it's not a very transparent process figuring out what's happening with your individual claim and whether you qualify and how much information is needed and so forth, that more emphasis on the petitioning approach I think would be a -- I think it's just a better overall approach and a more efficient approach and a better use of the available resources for this -- for the designation of Special Exposure Cohorts.

So I guess what I would be recommending is that they put more emphasis and make the petitioning process a little bit easier in terms of providing better guidelines and making that a little bit more direct for encouraging people to apply through that process than -- rather than waiting on all the individual claims to have gone through that process. I think we had some discussion of this last time, so that's not a new idea. It's something we did talk about at the last meeting.

Okay, do you want to discuss that?

DR. ZIEMER: Yeah, let's discuss them as you present them, while they're -- okay. Roy?

DR. DEHART: I don't recall that there was anything in the rule itself that prevents

petitioning and that worker representatives can prepare a petition for a group of workers, probably workers independently could prepare a petition. And would the fact that an individual in that petition have applied as a single individual for dose reconstruction in any way inhibit the process from going forward as a petitioned group?

DR. MELIUS: NIOSH would have -- I don't know of anybody's even thought through with it. There's a lot of complications to this process with this mix of individual claims and group claims going on at the same time. And we talked about yesterday with the non-SEC cancers, there's some situations out there with -- over different time periods of work within the SEC period, outside the SEC period. How do you define the course? That everybody in the cohort has to not be able to do dose reconstruction? You may not know that until you've done some individual cases. It may be that one person in that work group had great monitoring and nobody else did, and we know that the exposures were variable enough that one can't extrapolate from that one individual to everybody else very well.

I think if you look at the second and third comments here, particularly the third comment, I

think I just -- there seems to be more of a barrier set up in terms of the petitioning process and I think I would like to see it made a little friendlier process, and more emphasis put on that in terms of the outreach and the activities going on to encourage people to go through that process. And if I remember correctly from last meeting, NIOSH was saying they were emphasizing the opposite approach, through the individual one, so I think it's just a question of emphasis rather than a question of either/or.

MR. ELLIOTT: Ted had stood. I don't know if he has a comment.

DR. ZIEMER: Ted? Or do any of the staff have comments on Roy's question about simultaneous petitioning?

MR. KATZ: Sure. I didn't stand, I just sat upright.

DR. ZIEMER: Well, once you do that, you're in trouble.

MR. KATZ: I'm just teasing. Yes. I mean in either case, whether simultaneously someone's petitioning for a class and someone else has in a claim seeking a dose reconstruction who would be part of that class, in either case, however that

works, one of the first things we're going to have to figure out is whether we can do dose reconstructions for these individuals. And in that respect, I mean there's no delay incurred because we're going to have to figure out whether we can do dose reconstructions. If a class -- if you petition for a class to be added, we still have to answer that question. We still have to go through the work that we'd have to do with an individual dose reconstruction if it comes to us that way to determine whether we can do a dose reconstruction. And I don't want to belabor the point, just -- but there's no inherent delay here whatsoever because we have to determine that -- answer that question first anyhow.

DR. ZIEMER: Okay, thank you.

MR. ELLIOTT: I would like to add, also, that I truly don't believe we emphasized one approach over the other. We're offering an opportunity of two approaches. We weren't emphasizing that the individual claim and dose reconstruction being able to be conducted was the primary approach. What we emphasized was that an individual, once diagnosed, needs to file a claim immediately so that their medical benefits would

start at the time of filing.

DR. ZIEMER: Other comments? I suspect that part of the concern is more the appearance -- and maybe it's the wording that seems to put the burden on the individual petitioner, even though the intent may be to have it go either way. That was a concern that arose last time, that perhaps it appears that the petitioner must go through a certain process first before they can even think about this alternative.

Let's have some other comments. Yes, Tony. Tony and then -- oh, okay.

DR. ANDRADE: Well, I tend to agree with Jim. It's pretty clear that in 83.7(a) that groups of employees, one or more employees, can petition. However, there doesn't seem to be enough, as Jim states, emphasis that group petitioning could also -- that group petitioning might be the desirable way to get into the system. And it's only that it's a matter of emphasis, and it's not to emphasize one approach versus the other. It's just to bring out some clarity, some clarification. And I wouldn't mind suggesting a simple language addition that would say that, for example, a group of petitioners who believe they have collectively been subjected to

a special situation or something to that effect. And it could very well be pointed out in one simple phrase, I think, in 83.7.

DR. ZIEMER: Robert?

MR. PRESLEY: I also agree -- Bob Presley. But I have one comment. A lot of these people are deceased. They don't know that they're in a group, and I think it behooves us to be able to go back in and look at that and maybe have some input to be able to put those people in a group. And you know, we're working with people that don't have a clue of what their spouse did or their father did, and so I think it -- we need to look at that a little bit broader.

DR. MELIUS: Can I just comment? I think that's a very good point and I think if you wait until individuals apply, they're going to be ill and probably older. And getting the information from them, the burden on the families to try to provide some of the necessary information will be that much more. If the cohort's designated up front, then you don't have to go through that process and so forth to do that.

I think and agree with what Tony's suggestion was, too. And I think if you go to

number three suggestion down here, which is just one of the follow-ups to this, is that the way the rule's written now for the petitioning process, there has to be -- I forget the wording used -- a positive affirmation that the records don't -- exposure records don't exist, and that's a -- I think that's a question of wording, but that's a burden.

And then there's this thing, or. It's an or. It's not an absolute requirement. Or a health physicist or other dose reconstruction expert has to review the information and submit a report with it. And it's not an absolute requirement, but I think it certainly implies a heavier burden for the petitioning process. I think that could be taken care of in the rule by putting in a third "or" into that. That, one, yes, you ought to find out if dose information's available to the extent that that's possible to do, but also providing some sort of guidance for what other information. It may be it's some sort of internal report that's available or an outside review that's pointed out that this group was not monitored for a period of time and there was a potential for significant exposure, so forth. But not implying that someone has to go out and get an

expert to come in and help them do the job that I think people are expecting NIOSH to be doing as part of this process. I mean I can see the reason for the petitioning including some rationale for why it should be a special cohort, but I don't think one can expect the petitioner to do all the proving, so to speak, 'cause that's difficult. And I don't think this is what NIOSH intended when they wrote this, based on our discussions at the last meeting. But it certainly is implied in the language there and I think that's something we can fix with some other suggested phrasing in there.

DR. ZIEMER: Other comments? Yes, Tony.

DR. ANDRADE: Tony Andrade again. What I see here, Jim, is two issues that we're trying to work at the same time. And one is to try to emphasize to the public that, in a very balanced way, they can apply -- they can petition as a group or they can apply individually. And when they do apply either way, one of the comments that we have not yet discussed actually gives NIOSH some responsibility to help along that process, either for the individual or for the group that's doing the petitioning. And I think that that was the first comment that I had suggested but that it hasn't --

we haven't yet talked about it.

DR. ZIEMER: Okay. Any other comments now on the first item? I think we've -- pro or con.

(No responses.)

DR. ZIEMER: Okay. Then let's go ahead with the second one, Jim.

DR. MELIUS: Second one? Okay. And I should add that this comment ties somewhat to I think one of Tony's comments at least that was from the last meeting, and also one of Mark's comments this time, and certainly my major concern about this regulation is the fact that NIOSH has not provided any guidance or guidelines for how they will make the determination that there is not adequate information to do a -- so that it's not feasible to do a dose reconstruction with sufficient accuracy. And I think that's a major deficiency of the approach that's being proposed here, on several fronts.

One is the one hand they are doing the -- saying that a dose -- it is not possible to do the dose reconstruction, appropriate dose reconstruction. At the same time implying that in order to meet the health endangerment criterion that there is enough information in order to be able to

make that calculation.

Secondly is that one has these -- I mean there's different situations here and for people on the outside looking at this process, either as their own claims are being handled or as they are approaching the petitioning process as a group, they really do not have an understanding of what -- what do they have -- what information do they have to provide or what -- how will their information be evaluated to determine whether they qualify for a Special Exposure Cohort. How will NIOSH make the determination that there is not adequate data available to do -- I think as it says in the law -- to do a dose reconstruction with sufficient accuracy, it's not feasible to do that. And I really think that's a significant problem and I think the whole program would be better over the long term if NIOSH would wrestle with that question and come up with a set of guidelines. And I recognize it's not easy to do 'cause there's lots of different ways of doing a dose reconstruction and lots of different sources of information that one's pulling together. But it's so critical to this -- the way this rule is constructed that I think that there needs to be some guidelines provided. And my

preference would be those guidelines go for public comment because it is going to be such an important determination made on the part of NIOSH.

DR. ZIEMER: Tony?

MR. GRIFFON: Just a point --

DR. ZIEMER: Oh, Mark, I'm --

MR. GRIFFON: No, I just wanted to mention that my point number one on my comments is almost the same so we could probably discuss it at the same time.

DR. ZIEMER: Good, okay. Yeah. Just pull Mark's thing there and kind of put them side-by-side.

MR. GRIFFON: They're the same point.

DR. ZIEMER: Determination by NIOSH that it cannot complete a dose reconstruction for claimant. Thank you.

MR. GRIFFON: Okay, sorry.

DR. ANDRADE: I would like to point out that section 83.9 does indeed list guidelines that point out when a dose reconstruction might be found inadequate. And I would defer to the experts -- to Ted and to Jim -- to comment if they wish to on that particular section because it does list out general guidelines as to when dose reconstructions are

inadequate. So maybe they can help answer that. I felt that in general it did a fairly good job.

Now the specific question as to whether data are accurate to a certain degree, I believe falls into this as a subset -- as a question that would be one of the parameters that is looked at in determining whether a dose reconstruction is adequate or not. So I think we need to answer Mark's question -- and it's your question, as well, Jim -- but I think we would need to do so in terms of what's in 83.9.

DR. ZIEMER: Further comment? Okay. Mark, are you --

MR. GRIFFON: Can -- I'm just -- it's table one in 83.9, is that what you're looking at, Tony?

DR. ANDRADE: Correct.

MR. GRIFFON: Yeah. I don't think -- I mean from my standpoint, I don't think that answers my question. That is sort of what the petitioner would be -- would have to provide to get in the gate, so to speak. But I mean for sufficient accuracy, what I was -- and in my comments, and I've had dialogue on the side with NIOSH staff on this. I mean the question of is there a quantitative way to define this, I think that's difficult, to say the least.

Jim's shaking his head. Anyway -- but there may also be qualitative, and I can't say I've explored or exhausted options on this, but there may be qualitative metrics that would -- and for instance, and this is just a for-instance, you might consider whether all or a percentage of the TLD or film data was available for -- I'm thinking of it as -- for the class, all or a percentage, I'm not -- and bioassay data was available for all relevant radionuclides and -- let's see, and the data was consistent with the knowledge of site processes and NIOSH could complete -- I mean those are very sort of qualita-- and I'm not saying those are the ones, but that's the idea of you could lay out some qualitative metrics that gave a sense of the threshold that it's going to take to reconstruct sufficiently accurate. And I think I know the response I'm going to get, but Jim's standing up.

DR. ZIEMER: Yeah, and I think we want to hear from staff on this. I guess we've all kind of felt intuitively that one of the issues is that we don't really know fully what the parameters are. That sort of begs the question because if we don't know what those parameters are, then certainly the claimants won't and so what are the rules of

engagement is sort of what it gets down to.

DR. MELIUS: Or how do we review those.

DR. ZIEMER: Yeah. Jim.

DR. NETON: Thank you. Jim Neton. I actually agree with Mark to a certain extent -- surprise. I think we have to get away from the concept -- and I agree with the qualitative nature of this. The term "accuracy" means a lot of different things to a lot -- many people, but we have to couch this in terms of sufficient accuracy to be able to make, in terms of our efficiency process, a determination whether the person falls on the left side or the right side of the compensation bar. That's -- and so if we cannot determine something with sufficient accuracy, in my mind, all that really means is that we could not make a definitive determination using the efficiency process that it fell either to the left or to the right of the 50th percentile at the 99th percentile, of course. So you allow the efficiency process to work. You start with your low/low, low/high -- you know, what we were talking about yesterday -- and you keep working your dose reconstruction till you run out of facts, of factual evidence.

Once you run out and you realize, just like

Mark was saying, I'm still missing chunks that I can't fit into this puzzle, I have no idea what this person's dose was for 15 years; I can't find it and he's still on the low side of compensation. The only choice is either say the claim is denied or we just can't complete it. We just do not have enough information to make this claim complete. So it really -- it's a qualitative issue, but I don't think -- you know, you just know when you've exhausted all possibilities and a claimant still is not in -- possibly over the 50th percentile, you just have to say we can't complete it. It sounds squishy, but that's really the way it's got to work in practice, I think, unless someone else can come up with a better approach.

DR. MELIUS: Can I -- but that is the problem with this approach. I think you've wrestled well with this issue of do you make the 50 percent, and that is what complicates this issue. But at the other end, if you're looking at a group of people, they may have -- their dose may accumulate up with what information you have to different points, like ten percent, 40 percent, all over the place. Well, at what point do you then say there's not sufficient information for that group? Or are you going to

deny half the group? I mean how are we going to form a group out of this --

DR. NETON: Well, that speaks to setting -- determining the class. I mean if there's a class that you can really -- we need to do our job very well in defining that class down to its narrowest common denominator. Who falls in that class that we really don't have the information for. If we clearly have information for half of that class that we can do and -- they just won't be in the class.

DR. MELIUS: I just think you have to operationalize that into guidelines in some ways to have some consistency in the program, some transparency, some knowledge so the claimants understand they're being treated fairly in that process, and so we can review it. And I think that has to be written out in some way operationally how you're going to handle that particular issue. And I think that effort is really absolutely necessary to making this process fair.

DR. ZIEMER: Roy.

DR. DEHART: I think there's one other step, too, to consider here, which reinforces the idea of being as precise as one can in guidelines, and that is the appeal. As this stands now, it is so soft, I

wonder how a judge would assess this. And I would think that it's going to be harder to sustain a position under appeal with these kinds of guidelines, as soft as they are.

MR. KATZ: Can I just --

DR. ZIEMER: Yeah.

MR. KATZ: Can I just speak to that point? I really -- as is explained in the dose reconstruction rule, where we can't do a dose reconstruction, we have to lay out the wherewithal -- why it is we can't do that dose reconstruction very clearly in that report. So I mean that's what would come before a judge, that kind of information. What is the information lacking that prevents us from doing a dose reconstruction that the judge would evaluate. So they will get very clear information at that point in time when we make a determination that you can't do a dose reconstruction.

And I just wanted to address then the second point, Dr. Ziemer, that you raised -- that Jim raises that it's unfair to the petitioners if we can't tell them with more crystalline clarity when we can't do a dose reconstruction because then they won't know whether they're going to make it yet or

not, whether they're going to make it into the class. But we're not burdening the petitioner with actually proving that we can't do a dose reconstruction at all. I mean that's our burden. And they're free to petition and start the process, press the button for it to go, without making -- they don't have to make that case. So it is a problem in the sense that they won't know at the front end what the outcome of their petition's going to be because they won't be able to answer the question, well, can they in fact do a dose reconstruction or not. But they can get the process going. They can get us set to work on doing the work to evaluate that question. Thank you.

DR. MELIUS: Let me --

DR. ZIEMER: Sally and then Jim.

MS. GADOLA: I just had a question for Ted. Could you give us some examples as what you would actually write in that report as to why you couldn't do the dose reconstruction?

DR. NETON: Ted just tapped me on the shoulder, so I guess I'll come up with an example. I think it's sort of -- to complete what I was saying earlier, is if we did the dose reconstruction and we move so far and found maybe 75 percent of the

available information, found bioassay results, air monitoring results, all that sort of thing, but maybe the external dosimetry component was missing and we had no co-worker data, really no good source term to hang our hat on, we would say that this person's dose record is incomplete; it cannot be completed; we've searched high and low, there is no component that we can use to estimate his external dose and therefore we can't complete it.

Now that being said, it's possible -- and you know our efficiency process. We don't always have to have complete information. If a person -- based on the merit of just their internal results -- is over 50, we won't bother to even search for the rest of that information. But in those cases where the components that we do have do not put the person over the bar, we'll have to identify which pieces of those information are missing that we feel could add dose to their claim, to their case. So I mean I can't -- I could go on.

MS. GADOLA: I think that helps clarify a little bit, at least in our own minds, and maybe that's where some of this questioning comes from because that's still sort of vague.

DR. NETON: Right. But it really ties in

with our efficiency process again. We just keep going and pulling the thread as far as we can go until we run out of possibilities. But if we can't find all the possible sources of exposure and identify them, then that's when we pull the plug and say we can't go any further.

The other option's to deny the claim or send the claim to Labor with an incomplete dose reconstruction and unjustly have them deny the claim because we don't have all the information. But there's no very really good quantitative -- I mean we could describe this qualitatively is sort of what I'm sketching out here, and maybe that would help. I don't know.

MS. GADOLA: Thank you.

MR. KATZ: Can I just add to that, Jim, because something that I think I've already heard, and Jim will correct me if this isn't right, but this is sort of a simpler example to your question, what might be in that report. Well, say there's an incident -- a circumstance where a number of workers were around a pile of -- a pile, a swamp or whatever of radioactive materials, no one's certain what those radioactive materials were and in what quantities and so on, and that's all the

information. There's no dosimetry information, no personal dosimetry information, there's no area dosimetry information. I mean that may be a circumstance where again you say we don't have the wherewithal to estimate doses there because all we have is some possibilities for what sort of radioactive materials were in that swamp, and we don't know their quantities, either. I mean that's just another example, maybe simpler.

DR. ZIEMER: Jim?

DR. MELIUS: Two comments, one to one of Ted's earlier comments. I mean I don't think just because a person can apply for it doesn't mean there isn't some burden to let them know what they're applying for or what -- how they qualify. I can apply for Social Security disability. I don't -- or VA disability. I don't think I make it on a lots of grounds, but it doesn't stop me from applying for it. Fortunately there are guidelines on the application that sort of tell me whether I qualify, what's my military history, so -- I mean I think you have to provide some guidance out there.

The other corollary of this is -- the other part of when we're looking at this is that are the doses that you are reconstructing being done with

sufficient accuracy? I mean because when you say you can't do the dose reconstruction, well, are you -- which side are you erring on, so to speak? Are you erring on the side of doing a bad dose reconstruction, not sufficient accuracy? Or are you erring on the side of saying you can do a dose reconstruction, even -- you can't do a dose reconstruction and therefore a person's qual-- I mean it cuts both ways, and without some sort of guidance at that lower level, that level where you can't do it or you can't achieve sufficient accuracy, I think -- to me it's just very problematic. I think, Jim, you're articulating it better than you have when I've asked this question before 'cause I think there's more experience and that we've talked about it some more and so forth, but I really think that needs to get into a set of guidelines or something for us as a committee, for you as a program, to be able to do this with some kind of consistency and for people on the outside to be able to understand the process. And I agree it's not easy and it's going to take some time and effort, and it's not like you don't have other things to do, but in the long term it seems to me it would really be very -- very helpful and I think

it's necessary.

DR. ZIEMER: Incidentally, on this accuracy issue now, the way the thing is being bounded, it's not an accurate process. By favoring the client by assuming worst-case, you are actually being more inaccurate but more favorable to the claimant. Accuracy does not necessarily help the claimant. I mean if you -- if you tried to pin everything down -- I mean the cases we looked at, for example, the low/low case, they gave every benefit of the highest possible exposure, not -- I would say it was probably very inaccurate, because accuracy has to do with how close you are to the real number. All of these were over-estimates. You know, you say what's the highest possible dose the person could possibly have gotten under these circumstances, so accuracy doesn't necessarily help the client. So I'm not sure that that's what's being looked for on some of these cases. That's just a comment.

Jim Neton.

DR. NETON: I was just going to -- you spoke to the issue I was going to bring up, which is these are not accurate. As Mike Schaeffer pointed out from DTRA yesterday, they're not epidemiologic studies. They're -- the idea is to over-estimate

the dose, to quickly process it and if it still accurately falls on the correct side. I mean this is not mathematical accuracy. This is compensation decision accuracy that I think that we're speaking to here. And if we can over-estimate someone's dose by an order of magnitude or just be extremely generous and the probability of causation falls at 15 percent, then we've made an accurate dose reconstruction. We've accurately determined that that person falls on one side or the other. We haven't determined, we've actually decided that the dose is not going to be high enough to get over the bar.

So it may be instructive to go over a few dose reconstructions generically with the Board at some point to demonstrate that process. I know the working group has looked at them and has a sense now, but maybe in a future meeting we could do a few de-identified, very generic cases that would maybe shed some light on this issue.

DR. ZIEMER: Let me point out that in 83.9, as a starting point, the criteria for the Special Exposure Cohort -- there's two criteria, starting point, insufficient records and insufficient information leading to inability to do a dose

reconstruction.

Now in a practical sense -- and I'm just trying to now push the envelope a little bit -- it seems to me, Jim, that you're saying all right, what about the claimant, what do we tell him when -- if he's applying. Question one, do you have reason to believe that your dosimetry records are incomplete or insufficient -- or something like that. You're saying what are the series of questions you would ask that would serve as the parameters for somebody to even know whether they're in such a cohort.

DR. MELIUS: Correct.

DR. ZIEMER: What kind of questions would you ask?

DR. MELIUS: Uh-huh.

DR. ZIEMER: Is -- I mean just as a starting point.

DR. MELIUS: Correct, and how do you -- is defining insufficient and incomplete.

DR. ZIEMER: And what does that mean? What is -- incomplete, does that mean a film badge is missing? Not necessarily.

DR. MELIUS: Right.

DR. ZIEMER: Okay. Wanda --

DR. MELIUS: Could we just go back to --

'cause I think Jim Neton just sort of -- has been talking about what is sufficient accuracy for this process, and I think you articulate that well. But sort of going back to the opposite and what is insufficient, it's such that you cannot do the dose reconstruction for a group that they qualify as a Special Exposure Cohort. And I think that's what we have to wrestle with, when you reject that individual because there's insufficient or incomplete records or insufficient information like that. I think that's the crux of it and it's getting some explanation now. And it's not just for the claimant. I think it's for the program to have some consistency and for us to be able to review that program. I mean we're going to be taking a sample. We're not going to review every one, so looking at that consistency is by what rules you -- guidelines you follow in doing this on that.

DR. ZIEMER: Okay. Wanda.

MS. MUNN: It sounds as though the question is how do you prove a negative. If anyone here knows how to prove a negative, I would like them to step forward now because it's a question that's bothered me for a long, long time, and I suspect most of the rest of us.

When someone says that's all there is, there ain't no mo', how can I prove that there ain't no mo'? And I don't believe I can do that. I don't believe that I can contrive language that would make it appear that I'm doing that. It is, I think, incumbent upon us to try to see that the language is as reasonable as it can be. And this current language appears to be quite reasonable, unless you can somehow prove a negative.

If there are ways that we can define what constitutes the arrival at that negative point, then perhaps we can belabor this until we identify what that language is. I personally don't see that there's language that will suffice to do that. When we no longer, when the Agency no longer, when the individual can no longer provide further information, then that's all there is. So what language do we put into a rule-making that says when we've found everything that we can find, we can't find any more?

I guess I am at a loss to know how we can be more flexible, because really you do have to be flexible for each and every case. The amount of information that you're going to get is, in my experience, never perfect. We will have to work

with imperfect information. The decision's already been made. We will make every effort to see that the imperfection lies in the benefit of the claimant. I see no further step that we can take unless someone has magic language.

DR. ZIEMER: Thank you. Other comments? Wanda, let me just ask you. The question then, as I understand what you're saying, you actually then feel that the language that's in here now is sufficient to provide what is needed for both the petitioning process or is it just this issue of the guideline part -- that more detailed guidelines are not necessary, as you see it?

MS. MUNN: I do not believe that we can structure language which will provide adequate guidelines without unduly burdening the Agency and the petitioner to the point where we're asking for the impossible.

DR. ZIEMER: Other comments? Mark.

MR. GRIFFON: Yeah, I guess the other area -- and we're going to come up to this in one of the other comments, also, but the other area where sort of Jim's comment on insufficient butts up on this process, and a concern that I would have from the claimant's standpoint is you pull all the strings,

as Jim said. You do the most conservative possible estimate process for the dose reconstruction, and you determine that you can't do a dose reconstruction. And then -- but then the Agency is still able to do or calculate for that class a -- or for that potential class a potential dose to compare it to -- compare to the level of endangerment. And I think that is also going to be a -- that's why I'm trying to look for that line of where -- a point where you say you don't have data -- you've looked at everything and tried everything and you just don't have data to do an individual dose reconstruction, and yet you turn around and you can still do a class --

DR. ZIEMER: Which implies that you do know --

MR. GRIFFON: Huh?

DR. ZIEMER: Which implies that you do know enough to make that --

MR. GRIFFON: Right.

DR. ZIEMER: -- determination.

MR. GRIFFON: Right. And -- well, that's the question. And I know that they're distinguishing that by saying the class would be a potential sort of a worst-case dose, but it still --

you know, I guess that line's not anywhere described or there's no guidelines on how -- where that line is, even. And I guess that's what we're wrestling with.

MR. KATZ: Dr. Ziemer, can I -- can I just explain that a little further? 'Cause this is a concept that's gotten misunderstood a couple of times now, but that was closer to it there. So we're -- I mean the first thing we're doing is coming up with that benchmark, what dose would be health endangerment. The only question then that's put to the health physicist, the technical staff at that point is could radiation doses have reached that level or higher? They're not estimating what those radiation doses were, just asking the question could they have reached or exceeded that benchmark. And that is, I think, an exceedingly lower sort of burden in terms of what they have to do --

MR. GRIFFON: Than being able to --

MR. KATZ: Than being able to estimate --

MR. GRIFFON: -- complete the dose reconstruction. Than being able to complete a dose reconstruction --

MR. KATZ: Right --

MR. GRIFFON: -- that's how your defining

sufficient accuracy.

MR. KATZ: -- than being able to actually estimate what that dose was to those individuals. I mean there they can then draw on experience as -- throughout the DOE program as to what sort of doses can be associated with what little they know about the radiation source term in those instances, they can draw on all that experience to make a judgment as to whether doses could rise to that level. And just to make a -- and you know, analogies are always a little bit ham-fisted, but just to make an analogy, I mean if we're going to talk about the weather for a second here, and if we have the meteorologic records on a century of the weather, but in 1945 those were wiped out throughout the country, we have no records on the weather in 1945, say, you could reasonably have all that other data for 1945 for Atlanta in December, you could make a judgment as to whether it could have been 65 degrees in December or on a day in December, whether it could have been that high or higher. That wouldn't be estimating -- making a judgment that the weather was 65 degrees in December, which is what you're doing when you're doing a dose reconstruction. You're making a judgment as to what the dose

actually was. You're just saying could it have reached that level, and that's what the hump those assessors are doing and I think the -- there's a whole lot of information in this world about what sort of doses are associated with source term and so on, and to be able to make those rough judgments is well within their ability.

Then once they make that judgment, just to remind you, that judgment then comes before the Board and is open to public scrutiny. And if anyone else in the world can say then well, you know, I know of an instance somewhere where dose approximated that level associated with this sort of circumstance or whatever, that gets brought into the equation then. So it doesn't stop with our technical staff making that judgment, although they'll have a lot of information to draw on there. But it goes on to the public and others. So I just thought it'd be helpful to sort of clarify that for you because it has a bearing on this.

DR. ZIEMER: Is everybody clear on what the differential here? Yeah, Jim.

DR. NETON: I just have one more thing, and maybe there's another way to look at this. I've heard some -- Mark say a little earlier about we're

going to come up with this incremental dose, even though we say we can't estimate it. And one way to look at this is the way it's specified, is we're really trying to determine is the probability of causation able to get to 50 percent or greater, given that circumstance. We take that -- we could actually run IREP, for example, and determine -- it's an extra three rem of dose given that would be required in that cohort to exceed the 50 percent. All it would require NIOSH to do is to say is that plausible, given where the person was working, that cohort was working, that there was a potential for that additional three rem of exposure. We don't know what it was. All we're saying is is it even possible.

MR. GRIFFON: I'm not sure I understand what you mean by an additional three rem of exposure.

DR. NETON: Well, or -- let's say we did -- we pulled the thread, as we said, and we looked at every possible avenue except the internal side. And the probability of causation for that dose reconstruction arrived at 25 percent, given the partial information that we had. We could actually back-run IREP and say what -- how much more dose is that person going to need to get over 50 percent,

and given the exposure scenario and circumstances surrounding that cohort, is it plausible at all that that exposure could have -- that exposure environment could have existed? I mean it's sort of a different way of looking at it, but we're not actually calculating a dose. We're trying to estimate what -- was there sufficient dose in that environment to endanger health.

MR. GRIFFON: But I guess you go back to the concern of if you didn't have sufficient information up front to do the dose estimate, then I guess the concern from the potential claimant's standpoint might be how can I be sure that they, even in the -- even in their worst-case scenario, sort of in trying to estimate whether there's enough dose there to push me over, whether they have the information -- enough information to even -- for example, you know, what if you assume that -- you know, based on all the process records you have, all the site profile information you have on a certain facility, they always handled the depleted uranium and actually the truth was that they had recycled uranium with hefty levels of transuranics that were accumulating in certain processes where some of these individuals were working, even on your worst-case scenarios

you're going to miss the boat drastically for your internal dose estimates if you only assumed uranium as opposed to neptunium, plutonium, other potential exposures --

DR. NETON: That's correct.

MR. GRIFFON: So the question is, you know -- I guess the question is, you know, how do you -- you know.

DR. NETON: That's a different issue, I think. I mean you're assuming we've done a bad job doing our homework there at that point, we've made a mistake. We have not identified all the possible source terms. I mean I think we have to start saying, with the SEC, that we've identified all possible source terms. I'm not saying we always will, but that's our job. And given that, is that transuranic contamination that was unmonitored sufficient to move that over into --

MR. GRIFFON: But I guess the premise for petitioners is that you don't have information. You know, that's one of the basic premises is that -- you know, for this group, this class, they already went over that hurdle where you couldn't reconstruct individual doses, so you already know you're looking at a class that you're lacking information on.

DR. NETON: Right, but hopefully by that point, though, we would know the potential source terms that were in the environment that were not monitored. I mean that's part of the dose reconstruction. It's like go out and identify all those source terms and then make the decision -- you know, a missing neutron dose is a good example of that, as well. I mean did they monitor neutrons properly? No. Okay, can we go back and reconstruct this neutron dose properly? If not, was there sufficient neutron exposure in this reactor environment to put that population over 50 percent? And we're not saying every claimant in that population was over, but it's not possible to assign a dose to any individual, so they would just all be over automatically.

MR. GRIFFON: Yeah, I guess I understand what you're saying.

DR. ZIEMER: Actually as you discuss it, you realize that the staff in fact has a scheme, and I think, Jim, you're saying that the scheme doesn't show up here.

DR. MELIUS: Scheme doesn't show up here, and I think the scheme has been articulated well for this issue of when there's not sufficient

information or the records are incomplete. I think it's a different -- maybe it's done by a series of scenarios or whatever as to how those will be handled. I think they're articulating it better than when I've asked the same question at earlier meetings, and better -- as well as I think they've given some thought to this issue with the endangerment criteria. And again, the endangerment determination is going to come to us for review, so there's a peer review system or a outside advisory review system built into that process. On these individual determinations, there's not. We have a sampling that's going on and I think that's where -- you know, with thousands of claims, we need some sort of -- a set of guidance for how you're going to handle those. And I think it can be done. I disagree with Wanda. I don't think we're trying to prove a negative, we're just trying to determine -- have some guidelines on how we will put things into different categories, given the basis of the information that we have, or don't have. And I think that ought to be written out in some way.

DR. ZIEMER: And somehow in the rule-making I think, taking both of those into consideration, one would not want the rule-making to be so

proscriptive that you lose the flexibility and therefore cut out some folks in the process. So somewhere between no guidelines and minimal -- or very proscriptive, there's a point where the guidelines perhaps are such that everybody sort of understands how things are going to proceed, but there's sufficient flexibility to handle those things that you didn't think about in advance.

DR. MELIUS: In my -- what I wrote up here, I recommended they go out for further rule-making on this 'cause I think it needs some public comment if it's something that -- I mean an alternative is to change -- clarify some of the language in here so it's better understood. And then develop an internal guidance document that comes back to the committee for review and discussion and that would be sort of the operational guidance for what they're doing that, which is how we've done this in other -- some of the other situations, dose reconstruction rule. Really the IREP is mostly in the background. It's not in the regulation other than its use, and so that may be another way of handling this situation. But I just -- I feel very strongly it needs to be in writing and it needs to be something that's gotten some input.

DR. ZIEMER: Well, as I've looked at 83.9 -- section 83.9, it appears to me that, at least conceptually, a lot of the information is there. It may need to be articulated in a somewhat different structure so that it takes the form of what might be more appropriately labeled as guidelines that would help both the petitioner and maybe even the Board understand the process. I have a feeling that part of this has to do with the clarity with which we think this is spelling out to people exactly what the rules are on this.

DR. MELIUS: Correct, and then how will the decisions be made? As I said, talking about thousands of claims, so it's not -- we're not going to be -- individually discuss these or -- and so I don't think the instances are going to be so rare that a case-by-case approach is going to be adequate.

DR. ZIEMER: Shall we go ahead and look at your number three?

DR. MELIUS: Number three we've really discussed already and --

DR. ZIEMER: Yeah, it's --

DR. MELIUS: I'm going to move to number four and five together and just -- let me do five

first 'cause then I think it backs into number four.

This was written before Larry updated us yesterday and DOE, but I mean it's clearly critical to this process that there be complete records made available, and particularly this issue of making a determination that there's not sufficient information available. And so access to the records and complete records are going to be really I think very necessary because if not, then it's going to be a very chaotic process if a set of records suddenly shows up three years later or whatever or delayed for whatever reason, and we've already determined a Special Exposure Cohort based on those records not -- thinking those records weren't available. I mean it's -- I don't know what the -- what exactly we'd do in that case. And I really think we need to go on record as a Board stating that this is critical and that this MOU with DOE has to be in place. I mean it's been a long time and I understand how hard it is. I don't want to put Larry on the spot with this. But I think we really need to say -- we've talked about it at other meetings, but I think we need to go on record with these -- with our comments on these rules that it's critical that this MOU be in place for this process to be workable.

DR. ZIEMER: I suspect in this case that such a comment perhaps would be apart from the comments on the rule-making, could be a separate comment of some sort to encourage the completion of the MOU, or at least to identify to the Secretary that the Board feels that MOU is a very important step that needs to come to completion. We recognize that -- at least from the NIOSH side -- they are working very hard for this to be brought about, and I don't think any of us thinks that the problem is on the NIOSH side in coming to completion on this thing. And we also -- I think there's some level of angst amongst us as to, even with the MOU, will all the records needed appear. And that's something that we'll have to work with very diligently.

One thing that perhaps is -- that sort of helps is as records are obtained, we see inconsistencies, that tells you that something's missing. So there will be opportunity to begin to compare records from groups and so on to see whether there is a consistent picture. There's been hints and -- maybe not just hints, allegations of adjusted records. But you know, you can't do that completely and have it go undetected. It's like juggling the books. You know, the threads go out and at some

point things don't match up and the bottom lines don't balance. So some of that could come to light, we just have to be diligent.

But the MOU is the starting point and certainly worth emphasizing the need for closure on that.

DR. MELIUS: Possibly in the cover letter with the comments, I don't know, or a separate letter.

But comment number four is -- may be premature, but I'm concerned about how long this process is taking and could take. And it may be that the rate-limiting step is going to be getting the records, and not knowing what's in the MOU is -- and how they've worked out time frames is difficult. But there ought to be some consideration to how do you do a time -- when do you -- when is it no -- when have you waited too long or is it taking too long to complete this process, because then it becomes I think very unfair to the claimants if this process drags on for years and years with that. And there ought to be some time frame involved -- and maybe this is tied in to the guidelines on determining when the information isn't available. If you're just not going to be able to do this and

complete this in a timely fashion, then I think there needs to be some determination made that this is complete and that the -- I think the claimant ought to be awarded if there's going to be inordinate delays in completing the process, doing that. And yeah, there are resource issues involved and so forth, but unless sort of a time line is -- frame and expectations developed in terms of how quickly claims can be going through this process, then I think it's going to become more and more problematic. And so we ought to be starting to pay attention to the time frame. I mean Larry has to get this contract awarded and get geared up. It may not be appropriate now, given this initial surge of requests and so forth, but there ought to be some expectation out there for -- that people will go through this process in a reasonable length of time on the NIOSH end and that we as a committee ought to be monitoring that in some way.

MS. MUNN: This issue of the MOU is of such magnitude, and I think should not be mixed in with our comments on the specific rule-making. In any case, the implementation of that MOU would fall into different hands than the individuals who would be working with the rule-making. I'd like to suggest

that we move forward with all due haste to prepare a letter suggesting that this Board urge the Department of Energy to work diligently at preparing and negotiating an MOU with our agencies to make that exchange of information possible quickly.

DR. ZIEMER: Wanda, I don't know if you were just making that as a comment or a formal motion, but --

MS. MUNN: I was making it as a motion.

DR. ZIEMER: Okay, a motion that the transmittal to the Secretary this time include a statement urging completion of the MOU as soon as possible.

MS. MUNN: A separate letter.

DR. ZIEMER: A separate letter. Okay, the motion is that there be a separate letter, separate from the comments -- or separate from the cover letter with the comments.

MS. MUNN: Right.

DR. ZIEMER: And that's a formal motion. Is there a second?

DR. DEHART: I second.

DR. ZIEMER: Second. Discussion? Tony.

DR. ANDRADE: Paul, I would like to propose that that letter indeed -- first of all, I'd like to

say that I wholeheartedly support that motion. However, I would also like to suggest that some of the words that Jim has used here, including those that allude to the timely availability of complete exposure records, should become part of what we are urging the Secretary to do. I think that is -- I think that is all-important. That forms really the crux of what we want and what is needed from that MOU.

DR. ZIEMER: The sentence that the MOU must provide an adequate assurance that complete records will be made available in a timely fashion. Is that the phrase you're --

DR. ANDRADE: That's correct.

DR. ZIEMER: And Wanda, do I understand your motion to include that?

MS. MUNN: Correct.

DR. ZIEMER: Yes. I knew she included that. Yes, Roy.

DR. DEHART: I simply would ask NIOSH if such a letter is -- would be deemed helpful, 'cause sometimes there are political ramifications of this sort.

MR. ELLIOTT: I appreciate that question, and I do believe that in this instance it would be

well-received by the Secretary as to what this Board's concerns are in this regard and kind of what your thoughts are about timely submission of information to us to help process the claim.

DR. DEHART: Okay.

DR. ZIEMER: Further discussion?

MR. PRESLEY: Bob Presley.

DR. ZIEMER: Bob?

MR. PRESLEY: Would that specify DOE as one of the -- or --

DR. ZIEMER: This would specifically speak to the MOU between NIOSH and DOE.

MR. PRESLEY: You might look into NNSA then because a lot of your records or stuff's going to have to come from NNSA.

DR. ZIEMER: But is not -- the DOE is the agency mandated under the law here to make the records available, I think even from their contractors. Maybe Larry, you can clarify that.

MR. ELLIOTT: You're both right.

DR. ZIEMER: Is there going to be an MOU --

MR. ELLIOTT: No, there's only going to be one MOU between the Department of Health and Human Services and the Department of Energy. But when it comes to classified information, the NNSA has some

purview. And the -- I can -- I'm not speaking out of school. The current draft that we have fronted speaks to that and includes NNSA. And at this point in this juncture, the DOE has in fact agreed to that and offered some additional language to that particular section that would -- that NNSA has to buy into and support 'cause they'll have a commitment under the MOU. So if that actually goes forward and goes through to signature, that will be existent in the document.

DR. ZIEMER: Further discussion? Mark.

MR. GRIFFON: Yeah, just along those lines, I think we might consider also asking a timely release of DOE records, but also the atomic weapons facility records. I'm not sure if that would be useful in this letter to actually -- because I know that's been a problem currently getting that --

DR. ZIEMER: Are you talking about the contractors?

MR. GRIFFON: Well, the MOU with DOE -- DOE to provide some of those atomic weapons facility records, as well -- the timely release of those records.

MR. ELLIOTT: Well, they're -- that's covered. That's covered. DOE's umbrella

responsibility covers not only the DOE-recognized weapons complex sites, but also those older AEC, AWE contractors. And whatever they can do to afford us entree and access and provision of information from AWE's, that has to be covered in this agreement.

MR. GRIFFON: I just got the impression that that was a particular issue in terms of what the role of DOE was as opposed to the role of NIOSH, you know, and I think that we might strongly recommend that DOE take on that task of getting those records and getting them to you. That's all I was...

MR. ELLIOTT: Certainly would welcome that assistance, yes.

DR. ZIEMER: Other comments? Before we vote, if this motion passes, I'd like to ask which two of you will volunteer to draft the language of the -- this will be just one paragraph to be inserted in a separate letter. Wanda, do you want to work on --

MS. MUNN: Oh, sure, I'd love to do that.

(Laughter)

DR. ZIEMER: Well --

MS. MUNN: That's fine, yeah.

DR. ZIEMER: Wanda, who made the motion -- and who seconded that motion?

(Laughter)

DR. ZIEMER: I don't want to penalize people for making motions. Actually, maybe Jim, you would be willing to work with Wanda to -- I think you can incorporate some of Jim's words, and it's just a few sentences.

MS. MUNN: Yes. Yes, it's brief.

DR. ZIEMER: And touch base with staff to make sure we've covered the bases.

MR. ELLIOTT: And we would gladly help you as much as we possibly can, without crossing the line. But I would suggest that you refer to the Act, and there's some specific language that you might want to incorporate to augment your argument.

DR. ZIEMER: Okay. Are we ready to vote on the motion? Okay, all those who favor the motion, say aye.

(Positive responses)

DR. ZIEMER: All those opposed, say no.

(No responses.)

DR. ZIEMER: Motion carries with -- any abstentions?

(No responses.)

DR. ZIEMER: No abstentions. Okay, thank you. So that takes care of that one.

Okay. Now Jim, I think we've completed the discussion on your items. I want to move to Mark's items. Mark, if you would lead us through your items.

MR. GRIFFON: Well, we've discussed number one, so I think we can just skip that. And I would recommend maybe just talking about number three first and then maybe -- maybe I would call on Ted to answer number two for the entire Board. We discussed this at breakfast, so he can answer pretty much every question. I think it would be useful for the Board to hear his response.

First -- number three is the definition of endangered health, and I guess the -- you know, this does tie in to what we were -- a little bit what we were just discussing. I guess I feel more comfortable on the sufficient accuracy definition if the endangered health definition were more like the original SEC. In other words, it was based on duration of employment of a class within a certain area along with monitored or should-have-been monitored -- and the reason I say that is just the discussion we're having back and forth with Jim Neton, you know, that -- I wasn't suggesting that NIOSH wouldn't have done their homework so much as

that if they had done their homework and had all the source term information and a number of these factors, even in the absence of personal records, TLD's or urinalysis, it seems to me they may be able to -- with the conservative assumptions that they've talked about -- make an estimate of individual doses. And you know, so the question is if you can't -- you know, if you've exhausted -- as Jim says, pulled every string and you reach a point where you say we cannot, for this class, define with sufficient accuracy their doses, their individual doses, I think that that next step to some I think is going to -- and even -- you know, I'm wrestling with it and I think -- I agree with Jim Melius that the explanations are clearer and the logic is clearer, but I'm still wrestling with this -- you know, it's a little bit counter-intuitive, but -- you know, even though you didn't -- you exhausted everything and you couldn't determine individual doses, but then you're going to come up with a number -- or -- well, back-calculate a number from IREP, a ceiling at which -- you know, and they try to see if there's any way they could have reached that ceiling, so to speak. And that's where I get a little concerned because if you've exhausted -- if

you've pulled all the strings and have all the data, I wonder where that line is between there when -- you know, that you couldn't do the individual dose reconstructions but you have enough to kind of generate a number, a worst-case number to get this sort of quantitative measure of health endangerment. And I wonder if it would just be more useful to go back to a more qualitative measure of health endangerment, and that's the issue, so...

DR. ZIEMER: Okay. I think it's very easy to articulate scenarios where you could have this situation. Let me give you one. I've got a group of workers who work with 15 microcuries of carbon 14. They are not badged, 'cause you're not going to be able to pick up the C-14 beta on a badge. They are not bioassayed because they don't reach the threshold for which it's required. So if you come back ten years from now or 20 or 30, you will find no records of dose for any of these individuals. You could not do a dose reconstruction. There's no information, except that they worked with 50 microcuries of carbon. So what would you do as a worst-case scenario?

You'd say well, okay, let's suppose they somehow had their beaker filled with their carbon

labeled something-or-other and they drank it and ingested the full amount, and you'd calculate a -- an internal dose and come up with a number. Say okay -- and it's below some value. That's really worst case. Now --

MR. GRIFFON: Well, let me -- this is great example, 'cause let me ask Jim Neton, in that situation do you think there's sufficient information to estimate individual doses with sufficient accuracy? Can you complete a dose reconstruction?

DR. NETON: You've got to go back to the efficiency process.

DR. ZIEMER: Upper limit.

DR. NETON: We could upper limit that and say the highest dose in that entire population was -- let's pick a number, 500 millirem, and therefore you're done. I mean the efficiency process --

DR. ZIEMER: You assume everyone did that, which they couldn't because they couldn't all consume --

DR. NETON: Right.

MR. GRIFFON: But those are individual dose reconstructions.

DR. NETON: But that is.

MR. GRIFFON: So you could do it, huh?

DR. ZIEMER: I don't know if that is.

DR. NETON: That would -- I would call that a dose reconstruction under the efficiency process that we applied --

MR. GRIFFON: People weren't required to be badged --

DR. NETON: -- in the worst-case scenario --

MR. GRIFFON: -- so if it was worst-case, they didn't trigger it.

DR. ZIEMER: Is that a dose reconstruction?

DR. NETON: Yes, that would be a completed dose reconstruction.

DR. ZIEMER: All right.

MS. MURRAY: Overlapping conversations, he can't take it.

DR. NETON: Maybe we could take that one step further, though, and it was five curies of carbon 14. There were 100 workers in the lab. We have no idea which worker did what in that laboratory and they all had access to the carbon 14. And a dose reconstruction -- a quick and dirty calculation would indicate that yes, it's possible that one person could have gotten sufficient dose to -- got a POC greater than 50 percent. A dose

reconstruction is not possible at that point. We don't know which worker was there, but yet there was sufficient magnitude of dose in that laboratory to have possibly endangered the health of that cohort. That, by definition, then would be -- a dose reconstruction can't be done. We don't know, and it's endangered their health, possibly. Not necessarily every worker. Maybe one out of 100, but we have no idea of -- we have no ability to assign any individual dose to any of those people.

MR. GRIFFON: Yeah, it's difficult to play these what-ifs on the fly, but I mean I would also -- you know, you might think of -- with a more hot lab like that, you might question -- you might have badged workers, to so -- these are what-ifs, but anyway --

DR. ZIEMER: Right, or you might have bioassays.

MR. GRIFFON: Right, right.

DR. NETON: Yeah, maybe that's not a great example, but let's go back in the DOE environment where we've had workers who have been exposed to large quantities of gamma out in the field that were contractors that we're aware of in some of our cases that were never badged. In fact, they were never

even registered as having been at the site, although they certainly, by affidavit and what-not, have been demonstrated to have been there. So similar circumstances, you have curies of radioactive material. A person is in that environment working there for four or five years. In that situation there's certainly potential, and we know they're not badged. We have examples of this already.

MR. GRIFFON: I guess for this I just turn back to the intent of the statute and I -- I do -- you know, I get the impression that a lot of these dose reconstructions are going to be completable, you know.

DR. NETON: I think so.

MR. GRIFFON: So --

DR. NETON: I felt that from the beginning.

MR. GRIFFON: So given that, I guess, you know, the intent -- going back to the intent of the statute, you know, that -- there's sort of an admission that we don't have the data to reconstruct your dose, a certain claimant's dose or a certain class's dose, I'm sorry. Then to go that next step and try to quantify the health endangerment, I guess that's where I'm a little concerned that okay, we already say we don't have adequate -- this is an

individual program. We're trying to come up with worker compensation decisions for individuals and if we -- if there's an admission that the records were not complete enough to allow us to an individual dose reconstruction, then why not just look at it -- okay, let's not -- you know, I think then you're taking the next step and saying we don't have enough to do the individual dose reconstruction -- here's where I get a little uncomfortable. We don't have enough to do the individual dose reconstruction, but we think that this -- somehow we're pretty sure that this source term and the information about the processes on the site is complete enough that we can do a worst-case estimate, and that's where I lose a little bit of faith, maybe, that --

DR. NETON: But also on top of that, we have no idea which workers were in those situations which would have received the larger exposures. You can imagine 100 workers in a facility where a large cesium source is not monitored, you don't know which ones were sitting maybe out in the hallway, somewhere else -- this is 50 years later. It's just not possible to reconstruct that. So your alternative is to just be extremely claimant-friendly and everyone that comes through just say

well, you were in a situation that would potential endanger your health and make -- do a dose reconstruction very favorable and pass them all through the process.

MR. GRIFFON: Yeah, I --

DR. NETON: I mean that's sort of the equivalent of having an SEC, in my mind.

MR. GRIFFON: Well, I'm not saying it shouldn't be a rigorous process to determine -- to narrow -- I mean I'm not arguing for broadening the class infinitely. I'm just saying that, you know, the examples of -- for examples, you know, with processes where you were working with recycled fuel, you know, process information shows that transuranics will be isolated or concentrated in certain sub -- you know, certain processes, certain buildings, and I think you can do a reasonable effort to determine what subset of workers were in those areas, and that's a work duration thing. You might say anyone who worked in that process area where the -- you know, that process was going on for over a year and should have been monitored for this stuff but was not, that is good -- you know, we couldn't calculate your individual dose. That's the precursor to all this is we couldn't calculate your

individual dose.

DR. NETON: Right.

MR. GRIFFON: And then the next thing is --

DR. ZIEMER: But we can get a bound then.

MR. GRIFFON: Right, let's make sure that -- you know, the check for endangerment of health would be just that you worked in those processes where -- you know.

DR. NETON: Well, you're suggesting that we wouldn't look at endangered health based on --

MR. GRIFFON: That's the --

DR. NETON: -- probability of causation.

MR. GRIFFON: That's the question, and I know it's a fundamental question.

DR. NETON: Well, I think the Act says that we have to determine if their health was endangered. That's a criteria. I mean that's one of the conditions that we're tasked with looking at. And endangered health is the fact that there was an unmonitored material -- that doesn't pass that test, I don't think. Unmonitored material doesn't necessarily endanger health to the definition which we've adopted which is to have caused cancer as likely as not.

MR. GRIFFON: Yeah, I don't have the Act

right here with me, but I'm not sure the Act specifies how you would define endangered health.

DR. NETON: No, it doesn't.

MR. GRIFFON: Or interpret endangered health. Right?

DR. NETON: No, but the rule does. I mean we've taken that approach, endangered health --

MR. GRIFFON: Yes, the rule does now, yes. But that's what I'm commenting on.

DR. NETON: If you believe in a linear, no threshold hypothesis, then any atom that wasn't monitored potentially endangered their health. You have to have some objective criteria to quantify that. I mean you just can't say because there was an unmonitored small amount of material, that that endangered health. There may be a one in 100,000 chance of endangering the health, but is that really what we're tasked with doing? I don't think so.

MR. GRIFFON: I see your point.

DR. MELIUS: I think what's bothering us with this is we've got this IREP model which is a very elegant model for taking into account uncertainty and given (inaudible) based on whatever is available in terms of epidemiological and other health information. And then we wed it up with this

situation that Mark is just describing -- I've gone through some examples with him -- and we do this very convoluted calculation -- leukemia and two different tumor types -- somehow imply a certain amount of accuracy to that process, I think more accuracy than it may deserve. And you worry that it would become sort of an arbitrary decision as to how you would make that determination. Then how do you then calculate how -- what's -- who is the cohort? What's the duration of people -- you know, how -- is it anybody that would have been in that laboratory over that period of time or is it they have to be there for 30 days, how do you make that calculation. And in a situation where we've already said there's insufficient data to do individual dose reconstruction and -- it just seems to be a very convoluted way of making this determination. I think it sort of implies that there's a stronger basis for the determination than we really have. I think -- use Ted Katz's analogy, it's like having him go outside and look at the weather one day and run in to this supercomputer that then will calculate what the average temperature's going to be in Atlanta that day, and you're sort of making -- you know, you ask Ted to come up with well, is it

going to rain or not and Ted runs in and presses the button and does all these calculations. But Ted's guess is -- sort of bothers me a little bit as how we're going to rely on that versus somebody else's guess as to what the weather will be that day. And then we do a calculation that somehow implies that that's a good guess. You know, I don't know.

MR. GRIFFON: I also -- I do understand and I appreciate Jim's response that -- and I don't think -- you know, when I go back to the statute, I certainly don't think the intent was to try to include people in the Special Exposure Cohort like vendors that were on the site once a week -- just an example, but just a vendor coming in once a week, wasn't badged, wasn't monitored, we didn't know anything about his dose and -- you know, but the chances are very small that he had any significant exposure. That's not the intent and so I appreciate your response that way, but -- you know, and I'm not sure how to -- I'm not sure how to put that other trigger on there, but I have a concern of just this notion that you can -- that you've exhausted all your possibilities for individual dose reconstruction and yet you're going to try to in some way quantify this endangered health aspect. So

I'm still wrestling with it myself, but that's -- that's the concern.

DR. ZIEMER: But it appears that the methodology is not one like the weather case where you're trying to predict the weather. It's more like what's the worst possible -- what's the hottest day you can have in December, and use that as the upper limit. So you can say well, it's unlikely, statistically, that some level which you have decided is out here somewhere -- that the weather will be hotter than some value in Atlanta in December. So we're working way out at the extreme of the prediction. Remember that these are prediction models. There still is a chance for error in any of these. There still is a chance that someone who has a cancer caused by radiation will not be compensated, but the chance is very small -- but not zero. Okay?

And I think in the way they're approaching this, it says basically we're trying to find worst case. We can't reconstruct dose, but we can bound it in a reasonable way that is fair to anyone -- it's not the Coke machine guy who comes in for a minute, but it's the worker who's in there. And usually on these cohorts you're specifying when they

worked there. And some may have been there a month and some may have been there a year, but they still qualify if they were there when certain things were there, which is set within the boundary of the cohort.

MR. GRIFFON: Well -- go ahead, Jim.

DR. MELIUS: I think there's two things, though, that are still a concern. One is that there's going to be situations where the information's going to be very weak. And that initial number that Jim and his staff is going to come up with is going to be -- have a very flimsy basis. Not their fault. I mean good judgment and everything, but just there's so little information. And then we're sort of plugging that number into this very fancy calculation. I mean it's --

And the second thing is why are we doing this, given -- knowing the fact that this is going to be, in many cases, a very weak number, based on judgment and so forth, all -- given that. Then we're doing this averaging between leukemia and some other cancer. I mean it just -- that calculation -- the two calculations and so forth just seem to me not appropriate, given the nature of the number we're doing. It seems to me it implies more

accuracy than -- the number than is probably warranted by the situation that this process is meant to handle, and I just think it's sort of an unnecessary step to take and tends to be arbitrary and why do that. But again, we're going to -- we, as a committee reviewing these -- the NIOSH report, we're going to be looking at the basis for that number. Now I mean that's really what we're going to be looking at and providing some input to that and so forth, so that may take care of this issue. But it's still -- I worry about the situations where there's just so little information and we're trying to make that information fit into this calculation.

DR. ZIEMER: Rich.

MR. ESPINOSA: Well, I also see a possibility to where there's going to be a lot of information provided, but the information might not be sufficient to do a dose reconstruction or possibly put these members on a cohort. For example, there's electricians at CMR in Los Alamos pulling wire. They're pulling wire through three or four different lab rooms a day to where they're exposed to four or five different isotopes, but they're not on a bioassay program, but they are badged with the TLD that's biased to one or the

other.

DR. ZIEMER: Roy?

DR. DEHART: Jim, I understand your concern. What is your consideration for the alternative? How would you do it, other than just taking the whole cohort and awarding?

DR. MELIUS: Well, you could either come up with, first of all, some duration type of calculations. It's not clear to me yet how they're going to consider duration and exposure. And I would certainly simplify this process of doing the two cancers and so forth. I just don't think that -- I just don't think it makes sense, given how weak this data is going to be. So I would get rid of that doubling -- that consideration of two different types of cancers and so forth.

MR. GRIFFON: And along those lines, Roy, the -- I mean I think where -- to get to this point, we've also seen that you've got to go over that first hurdle, that they couldn't calculate an individual dose with sufficient accuracy. And I think from what we've seen in -- I think they're going to -- even for the low/low cases where they -- you know, they're going to use worst-case data, worst-case estimates if they're nowhere near 50

percentile, they're not even going to reach that next hurdle of okay, we can't -- you know, they're going to give them the best, most -- you know, benefit of the doubt and try to do an individual calculation if they don't reach that hurdle. So I think that throws away that concern of are we going to be putting people in this class that really had no chance of any -- I mean that would -- that's my notion, anyway, is that you're going to lose those in that process. You know, those that had no significant chance of any significant exposure. Then once you've reached that, you say okay, but for -- you know, we can't define this dose. Then I think -- you know, I think that step of just a duration-based approach and -- you know, should have been monitored or were monitored approach might be adequate. That's my opinion, because I think those other ones are going to fall off before you get -- before you meet the first set of criteria, which is can you estimate with sufficient accuracy. And you know, sufficient accuracy is defined is complete the dose reconstruction for purposes of compensation. It doesn't have to be -- as we've said before, it doesn't have to be an accurate dose, it just has to be accurate enough to make a determination for

causation. So that, I think, could get -- you know, I hear the concern about well, we don't want to just be adding people to this class that really had no potential of any significant exposure at all. I think that's part of the reluctance to go to a qualitative measure for endangered health. But that would be my rebuttal is that I think that's -- those are going to fall off in that way.

DR. ZIEMER: Mark, where are we on your -- we did number three. Sufficient accuracy, we sort of covered that before, and do you want to -- we need to take a break.

MR. GRIFFON: We should take a break 'cause number two is very complicated and maybe Ted can look at number two during the break and step through those responses because --

DR. ZIEMER: Yeah. Let's take our break and recognize we also have to discuss the dose reconstruction recommendations yet, too. Fifteen minutes, folks.

(Whereupon, a recess was taken.)

DR. ZIEMER: We'll return to our business. I have one housekeeping item, and that concerns the minutes of the meeting which we approved, but I pointed out that I would like you to individually

provide your editorial changes or -- the mis-spellings or anything like that. I have a master copy -- this is Cori's master copy -- and anyone who has editorial changes we'd like you to mark them in the master copy.

How many of you have such changes? Let me see. Okay, I'm going to start this around with Wanda. Mark yours in and then pass it on to the next person, just as we go here. Just mark yours in there so that they're all in that one copy. This is in addition -- this does not include the actual substantive changes that we made yesterday. We already have those on the record, so these are just the editorial changes, any grammatical or spelling or whatever, that kind of thing.

Now let's return to Mark's document and the clarification of issue regarding SEC class applying for non-SEC-listed cancers. And Mark, before you get into this, I want to ask a question which I think is part of this and also I think relates to Richard Miller's question yesterday, the question about combining of the special cohort upper boundary dose values with other doses. And maybe Jim, you can help us answer this.

Under the guidelines and procedures, could a

person who has a period of work -- let's say they were Special Exposure Cohort period -- or potentially Special Exposure Cohort period, but perhaps didn't meet that criteria. Let's say that it was determined that their dose could have been no more than let us say ten rem. And then the calculations showed that it was not sufficient to meet the probability of causation for that situation. But in addition to that, at some other location perhaps, they had monitored doses and dose reconstructions could be done, and suppose it was found that they had another ten at one location and five at another. The question is, can they add in the hypothetical dose from the period for which dose reconstruction was not done, and add that as an upper bound to the other doses that could be reconstructed? I think that -- that's sort of the nature of what Richard Miller was asking about the --

MR. GRIFFON: And that's my question 2(c) here is exactly that.

DR. ZIEMER: Right.

MR. GRIFFON: Yeah.

MR. KATZ: Well, actually I think 2(c)'s different.

MR. GRIFFON: Is it?

MR. KATZ: But -- yeah, because that's asking for the class, would the class determination I think you're getting at there, can --

MR. GRIFFON: I think that's what he said.

MR. KATZ: -- dose is up.

DR. ZIEMER: But if they're in a class that's been approved, they're getting compensated already, so that's a moot point. Right?

MR. GRIFFON: No, potential -- go ahead, answer his question.

MR. KATZ: Potential class, they're not really in a class. Let me --

MR. GRIFFON: Answer his question.

MR. KATZ: Well, let me -- I'm going to go through all of these really -- why don't I just go through all of these, instead of starting at the end there.

An individual's in an SEC class but has exposures outside of that time period, location, et cetera that defines the class, and the question is can that individual apply for compensation outside of the procedures of the Special Exposure Cohort to the DOL. And that's already answered. That's actually not a policy issue at all. Right now and

always -- the Department of Labor, when they get a claim for a cancer that is not an SEC cancer, that claim will come to us for dose reconstruction. So there's no barrier for an individual who doesn't have an SEC cancer, a specified cancer, coming to us for dose reconstruction. There's no even decision or appeal they have to make.

MR. GRIFFON: And that question was put in there more as a clarification. I --

MR. KATZ: Right, so I'm clari--

MR. GRIFFON: -- was a little concerned about the statement that Richard Miller read yesterday from the transcripts in New York seemed to interpret things differently and that's --

MR. KATZ: Right, let me -- and that's -- you know, he said some Federal official -- it's me. I'm the responsible party. I'm speaking very narrowly in that case because I think people, for the most part, were understanding that with the atomic weapons employers that their whole facility and work experience would be -- comprise the class. But anyway, that's my -- if I had to do it over again, I wouldn't make a narrow expression like that. I did -- I did it. So --

MR. GRIFFON: That was just for

clarification.

MR. KATZ: So send me back to Buffalo.

(Laughter)

MR. KATZ: Please don't. So if so, can the dose assigned to the class be added to the individual -- that's, I think, the question Dr. Ziemer's raising just now. Can you take -- so say you don't -- say you don't -- I guess there are two scenarios here, really. Say the situation were you don't add a class. There's a petition for a class and you determine the dose wouldn't make that minimum threshold of possibly causing a specified cancer. And the question would be then so that you'd come up with some -- how high could it have been, the dose. You'd come up with some number there. Would you add that into the individual dose reconstructions. And we haven't crossed that bridge to -- we didn't think down this lane to answer that question. I mean it's certainly a question that's germane for our dose reconstruction procedures and we're going to have to answer it, but we haven't. So I can't stand up here now and tell you what -- we would take that dose or half that dose or not take that dose or what, but I agree, that's an issue. It belongs here with the Board as an issue, too, and

we'll have to resolve it.

But let's then take the other situation where you have added a class -- I'm sorry.

DR. ZIEMER: Let me interrupt, but nonetheless, if that person then -- if you were doing a dose reconstruction, that would be a period of time in their history for which you would have to do something.

MR. KATZ: Thanks.

DR. ZIEMER: Right?

MR. KATZ: Thanks, that's --

DR. ZIEMER: And the logical thing to do would be to do the upper-bound calculation that you would have done anyway for the class.

MR. KATZ: So that's an option, right. And that's something that has to be --

DR. ZIEMER: It's a kind of dose reconstruction.

MR. KATZ: Exactly right. That's an option. That's something that's going to have to be decided, but we haven't -- we never -- we didn't get to that question yet. Okay?

Then we have the situation -- the different situation of we've added a class. Okay? And that window -- some individuals -- in the same situation,

some individuals have exposures from other periods, and then they also have their experience during that period in place covered by the class.

MR. GRIFFON: Okay, I'm not sure your example's -- I think you're reviewing a potential class here. Right? And then you're considering --

MR. KATZ: Well, I mean --

MR. GRIFFON: -- exposures outside the window? Okay, go ahead. Go ahead.

MR. KATZ: If it's a potential -- I mean it really -- there are two -- if it's a potential class, we're going to have to resolve the issues of whether we can do a dose reconstruction and so on. I don't think that helps clarify -- I mean really there are two scenarios at the end of the day is whether the class is added or not. And the reason those are distinct --

DR. ZIEMER: If they are, the other doses don't matter then 'cause they're compensated.

MR. KATZ: If they are, for the other cancers --

MR. GRIFFON: And if they're not --

MR. KATZ: -- they're compensated.

MR. GRIFFON: That's the question, if they're not.

MR. KATZ: We've addressed the situation of if they're not --

MR. GRIFFON: No, no, no, no --

MR. KATZ: -- if the class is not added.

MR. GRIFFON: -- if the class is not added --

MR. KATZ: Then that's what I just explained, if the --

MR. GRIFFON: No, then for class determination, can you add previous exposures?

MR. KATZ: That's the third -- let me go to that last. Okay? That's the last of your questions and I promise I'll get to that.

MR. GRIFFON: I thought you were there. I'm sorry.

MR. KATZ: I'm sorry. Again, so we've answered the question of what happens if the class is not ultimately added. Then we have a decision to make, and the Board has a role here, too, I suppose, advising us on this.

But here's the other scenario. We add a class, and we just went through how we would do that, right, how we would make that determination. In that case, we don't actually have an upper-bound estimate radiation dose 'cause we didn't do a dose

estimate. All we answered was the question, could the dose have exceeded some benchmark, but we didn't put a cap on that. And in many cases, the cap may be -- you know, the sky's the limit, almost. Right? It could be exceedingly high.

So in that case we don't have the same material to work with in terms of what we would do for the individual who has a different cancer and has doses outside of the class. Right? What we will do there, again, I think -- I think we're going to need to consider that situation and the advice of the Board, but it's -- again, we did not imagine our way down that path, so that's why we don't have a procedure. But anyway, it's an issue for the dose reconstruction process.

So then the final question which Richard raised yesterday and you have raised again here, which is what about -- I think I have this right. What about considering the individual's doses outside of the class period as an element -- as facts to contribute to whether you add that class or not. Right? Do I have that right?

MR. GRIFFON: Yeah.

MR. KATZ: Right.

MR. GRIFFON: And this is kind of the -- you

know, this is -- and I don't know how often the situation might even arise, but it's the borderline case where you're reviewing a class -- a potential class --

MR. KATZ: Right.

MR. GRIFFON: -- and they don't meet that hurdle.

MR. KATZ: Right.

MR. GRIFFON: But maybe they've all had previous exposures or some of them have had previous exposures, significant exposures --

MR. KATZ: That were recorded.

MR. GRIFFON: -- do you take those into account when you're considering that class or not, and that's --

DR. ZIEMER: Or how does that differ from the first case?

MR. GRIFFON: That were reconstructable. Right, that were -- the earlier exposures were reconstructable.

DR. ZIEMER: That's similar to the case we talked about before then.

MR. GRIFFON: But --

DR. ZIEMER: You've got one part reconstructable, one part not.

MR. GRIFFON: Except in this case you're making a decision on the class instead of on the individual dose reconstruction. Right?

MR. KATZ: Right. The first case --

MR. GRIFFON: So you're adding the dose to one instead of the other -- you know.

MR. KATZ: Right. The first case is really simple because we're just completing the dose reconstruction. The second case, you're saying how do we -- and again, we did not think there, either. And I believe -- and I'll just have to say that vaguely because I'm not certain -- the way the regulation's written now, I don't think you could take the exposures outside of the time period and bring them into consideration of the class.

Now the problem -- I mean there may be circumstances like that where everyone had the same exposures outside that were monitored but then hence also had exposures within -- the issue that certainly has to be satisfied is that they all have to have a common exposure experience to be considered as a class, so we're going to have to satisfy that criterion.

DR. MELIUS: Could you define the class based on their -- in a way that would include a

criteria for additional individual exposure? That would be one way of approaching it.

MR. KATZ: I think the way you define -- I think you would -- I mean to get at this, I think you would simply define the class beyond the period when the records were inadequate, but including the period when records were adequate as well as the period when records were inadequate to come up with -- do you understand what I'm saying?

DR. MELIUS: Yeah, that's another --

MR. KATZ: And then -- but everyone would -- in the class would have to meet both of those -- in other words, elements. They would have to be during the period when records were adequate, as well as the period when records were inadequate. Do you understand? Does that make sense?

DR. MELIUS: That would be another option. I mean --

MR. KATZ: Right. That's the one I can imagine.

DR. MELIUS: I think there are a couple of options for doing this and it may depend on the -- probably on the particular situation. Pardon me if this is very convoluted, but...

DR. ZIEMER: Have we completed yours, Mark?

MR. GRIFFON: Yes.

DR. ZIEMER: Okay. Now I want to add one more thing into the mix here for Special Exposure Cohort, and that is to input into our sort of knowledge base the outcomes of the Town Hall meeting -- meetings, because they may be pertinent to know what the public comments were. So Ted, this would be a good time I think for us to hear your summary on some Town Hall comments. Is Ted still here?

DR. MELIUS: While Ted's returning to earth here, can I just make one comment on that --

DR. ZIEMER: Sure.

DR. MELIUS: -- last section?

DR. ZIEMER: Sure.

DR. MELIUS: I think one of our recommendations might be, as a Board, is that NIOSH review these regs to make sure that they don't preclude any of these options for dealing with some of these situations. I don't think we can ask them at this time to develop every possible scenario, but make -- try to go through this and make sure they haven't precluded some of the options for the future in terms of --

DR. ZIEMER: And that argues for flexibility, which was one of the issues that I was

concerned about if we became too proscriptive.

DR. MELIUS: Right.

DR. ZIEMER: Okay. Ted, are you set?

MR. ELLIOTT: While he's getting -- cutting the lights and all of that to present, I would just inform the Board that the transcripts from the last two Town Hall meetings should be up on our web site and available for anybody who wants a hard copy upon request the first of next week -- early -- perhaps Tuesday of next week.

UNIDENTIFIED: That'll be fun to read.

MR. ELLIOTT: I'm sorry?

UNIDENTIFIED: I said that should be fun to read.

MR. KATZ: Okay. So I'm just going -- I'm just going to give you a flavor for the comments we received, both on the rule and on other matters, too, because in fact we received a lot of comments and questions and so on on matters outside really the parameters of this rule. But it was very useful I think for us to be out there explaining things for lots of people who don't understand much related to dose reconstruction, and other issues, as well.

So one of the first questions we received everywhere -- almost everywhere, I'm sure -- was why

didn't Congress include us in the cohort. Why is the burden of proof higher for us? And sort of following along these lines, couldn't Congress have included us, for example, because we worked with the same radioactive materials that they used at the gaseous diffusion plants. Those came to us afterwards, so why aren't we there? Or because maybe our exposures are likely to be higher than they were there? But we heard this first.

DR. ZIEMER: What did you tell them?

MR. KATZ: Well, we explained that we don't have reporting really from Congress to be able to give them a clear answer as to how Congress decided on the locations that would be included originally in the cohort.

So -- and similarly, why aren't our illnesses covered? Why is cancer the only health outcome covered among illnesses related to radiation or radioactive materials?

Why aren't all toxic exposures covered? We had questions in Los Alamos about what about non-ionizing radiation, and we had questions I think at all locations about chemical exposures.

Why aren't employees of the AWE's covered who worked during periods when there was residual

contamination? We had a lot of questions about that, about the defined periods currently of the AWE's, and we explained to them what's going -- ongoing with our radiation -- residual contamination study that we're doing and what the status of that is.

And then lots of questions along Jim's continuing concern about how long it will take to do a dose reconstruction or determine that we can't; to obtain contractor support for the dose reconstructions; to decide the outcome of a petition. And there was concern about delay arising from the Congressional review period. I think everywhere that sort of raised consternation, sort of visible consternation. And you know, we experienced a lot of anger about the duration that's already -- the water under the bridge, how much time has gone by on all of this and their claims awaiting adjudication.

And questions about what's a class, how it's defined, how large or small it can be. Can it be a whole facility, so on. And we had recommendations at some of these meetings that their -- they believed their facility should be added as a class.

This is a question that we've actually dealt

with at length in this Board meeting already, so I won't go into it at length, but this is my statement, sort of drew this out. Can members of a class opt out of a class that's been added? And as I explained, they wouldn't need to opt out. They would automatically come to us -- this relates to situations where people have cancers that are not covered -- not a covered -- under the Special Exposure Cohort procedures and they would come to us for a dose reconstruction in any event automatically.

Can a claimant withdraw a claim before adjudication is final and submit a petition? I mean this -- presumably their concerned well, if they find out down the road that their dose is likely to be low, can they instead take another route and submit a petition for a class.

And just to answer that -- but I mean there's nothing -- there is nothing in the procedures that preclude them from doing that. They can, at any point, submit a petition. We don't limit them based on that.

Why does a claimant have to petition if NIOSH cannot do a dose reconstruction? This was sort of the question of why do we have to petition

at all in that case? Why don't you just simply go on about evaluating a class?

DR. ZIEMER: What was your answer?

MR. KATZ: And I'm sorry, the answer -- we've talked about that here, too, is as we read the law, the law requires a petition to start the process.

Why are the SEC procedures so complicated? And then we had we had a whole --

I mean -- there's a great quote from John Adams I could give here, but maybe I'll pass. Why are the -- do you want me to give that?

John Adams was asked -- this could not be recorded, but John Adams was asked by a Frenchwoman once why the American form of government was so complicated, and his response was well, you could take all the wheels out of a watch, but it wouldn't necessarily tell time.

And lastly, how will NIOSH reconstruct doses? There were lots of questions about how would you reconstruct a dose given this situation or that situation, given that records may not be complete, and so on.

But that -- I mean I think that's a decent flavor of what we heard on the road.

DR. ZIEMER: Okay, let's see if there's any questions for Ted on the issues discussed at these Town Hall meetings.

DR. MELIUS: Could you give us some idea of what the turnout was at the different meetings?

MR. KATZ: Yeah -- oh, yeah, I'm happy to. So the first two meetings, Buffalo was under 20 and Ohio -- just outside of Cincinnati -- was again under 20. And I think that is in part a product of the very little lead time we had between announcing the meetings and the meetings being convened, and the fact that newspapers hadn't gotten out a story in advance of the meeting and so on.

So -- and then out west we had really much better turnout. At Hanford we had about 350 -- I haven't actually seen the numbers, but I've heard that a number of times and it looked like that. We had to open up another room to fit all these people. They were going right out the hotel lobby and into the street. So there was about 350 at Hanford and then at -- near Los Alamos in Espanola there were approximately 50 to 60, I think.

DR. MELIUS: And in the Buffalo meeting, which is some of the older atomic weapons plants or -- was the flavor of the questions or the nature of

the questions different or did you get -- we really haven't talked a lot about dealing with those employers in this committee and I'm just curious as to are there -- given time periods involved and some of their eligibility issues, were there any particular things that came up that the Board should be cognizant of in terms of working with those employers?

MR. KATZ: Jim's standing up, I'll have him give --

DR. NETON: I think the key issue in my mind, we had a number of questions related to residual contamination and period of covered employment. I mean that was a good theme for a large part of the meeting, why they had to work in a certain defined time period to be eligible to apply and who set those time periods and are they going to be changed and that sort of thing. A lot of frustration from the people in that area.

MR. KATZ: Then the other sort of distinctive thing at Buffalo was -- I mean it was clear this would -- this makes sense probably to everybody, is that they had even less information than at the other sites about everything in general, and a lot of pent-up frustration related to that.

Go ahead, Mark.

MR. GRIFFON: I was just going to ask if Jim or Ted can expand on the residual contamination report -- from what I understand, their report was -- a study was required, is ongoing. I'm not sure where that stands now.

MR. ELLIOTT: I'll speak to that. The six-month progress report which was due to Congress at the end of June is going through inter-department clearance right now and OMB approval so that it can be sent over to the Hill.

DR. ZIEMER: Okay. Are there further questions?

(No responses.)

DR. ZIEMER: It appears that there are not. Thank you, Ted, for that report.

MR. KATZ: Thank you.

DR. ZIEMER: Now we're going to return to this topic of the Special Exposure Cohort after lunch. I will ask the working group if they would mind maybe sitting around the lunch table together and discussing the form of the document that we prepare. We want to get sort of on the table for us yet this morning the report of the dose reconstruction working group so that we have that

before us, as well. And Mark, if you could lead us through now your current -- I think there's a handout. Did everybody get it?

MR. GRIFFON: Did it circulate to everyone? I'm not sure.

DR. ZIEMER: We have a --

MR. ELLIOTT: It has been placed at each person's --

DR. ZIEMER: -- version 2.0 of the working group --

DR. NETON: No, we -- that was a draft that we distributed early for review by just the working group.

MR. GRIFFON: Yeah, we were planning on meeting at the break to go -- 'cause I --

DR. ZIEMER: Okay, so you don't want to sort of --

MR. GRIFFON: Well, that would be the question from me to the working group since I did a lot of this last night and they didn't have a chance to look at it.

DR. ZIEMER: I gotcha.

MR. GRIFFON: I don't know if they're ready to give it to the entire Board or if they have comments for me and changes that we want to make

first. I didn't have a chance to --

DR. ZIEMER: I'll leave it up to the working group. Do you want to have any input on this before -- are you --

MR. GRIFFON: They've had input, don't get me wrong. We discussed all this --

DR. ZIEMER: No, no, I know you have.

MR. GRIFFON: Yeah, yeah.

DR. ZIEMER: Go ahead, that would be my --

MR. GRIFFON: You think it's okay?

DR. ZIEMER: Yeah, I would --

MR. GRIFFON: I think we can distribute this then to the entire Board and I can go quickly through it. It's not that -- it shouldn't take that long.

(Pause)

MS. MURRAY: Dr. Ziemer, may I ask a question while he's distributing this?

DR. ZIEMER: Uh-huh.

MS. MURRAY: This afternoon when you go over the SEC rule, will that be the clarification of the answers to all these questions? Because frankly, from the discussion this morning and my notes, I'm not sure that I'm clear on what the answers were to all of them.

DR. ZIEMER: Right, I'm not sure that we're clear on what the answers are, either, but to the extent that we're able to address those and come up with some language, I think we're hopeful that many of those will be at least addressed in some way.

MS. MURRAY: Great. I just wanted to make sure I hadn't missed anything.

DR. ZIEMER: No, if your notes are confusing, they're very much reflecting the meeting, I think.

DR. MELIUS: The answers are yes, yes, no, maybe.

MR. GRIFFON: Should I give -- I mean people haven't looked at this. Do you want to --

DR. ZIEMER: Maybe you could lead us through it, huh?

MR. GRIFFON: Okay. It's not that --

DR. ZIEMER: Yeah, it's not that extreme.

MR. GRIFFON: -- different. It's version two of the last -- which we approved by vote of -- sort of an original scope of work for the dose reconstruction --

DR. ZIEMER: And remember, if you want to have the early version, it's the attachment two on the minutes --

MR. GRIFFON: Right.

DR. ZIEMER: -- so if you need that --

MR. GRIFFON: And for the most part, this is a redline strike-out type version --

DR. ZIEMER: Of that.

MR. GRIFFON: -- except for the -- it doesn't completely hold true 'cause of my edit. I didn't start doing that till mid-way through, but anyway, I'll point out where the differences are.

I tried to expand a -- based on what we were discussing yesterday and what we went over the last couple of days, we tried to refine, at least a little bit further, some of this initial scope for the dose reconstruction review. The independent panel section, we -- yesterday we did talk about establishing a criteria, sort of a professional criteria that we would look at or that we would draft for NIOSH then to do the -- go through the procurement process and hire these independent experts. We haven't -- we didn't have NIOSH's RFP and we wanted to look at that language, so we didn't really include that in there, but we're still planning on adding that to the independent panel section.

DR. ZIEMER: Mark, could I interrupt and --

MR. GRIFFON: Uh-huh.

DR. ZIEMER: -- maybe we can get some comments on each section as we go here.

MR. GRIFFON: Sure.

DR. ZIEMER: On independent panel, could you clarify the working group's -- how you envision -- when you talk about the two Board members and one expert, is my understanding you're envisioning this as not necessarily being the same two people for each review, but that this workload would be distributed in some way amongst the total Board members, including the newer people coming aboard, so we --

MR. GRIFFON: Yeah, that is correct and we need to -- we didn't -- we didn't know how to describe that, I guess. A rotating basis or something like that, but the intent is that the two Board members participating in the panel would rotate and hit everybody so we can spread the workload.

MR. PRESLEY: The panel will meet prior to the meeting so it won't be a separate meeting. It might be the day before.

MR. GRIFFON: Yeah, that was just another consideration that we had just to reduce the travel

burden on everyone and everything to try to -- for the most part, we see the independent expert doing the bulk of the work on these reviews, then pulling that in with the two Board members and giving the two Board members an overview and sort of a preliminary read on it, and then the next step would be to present to the entire Board. So that's kind of the sequence there. But we'll refine that language to reflect that it'd be a rotating -- two Board members would be on a rotating basis.

DR. ZIEMER: Another question here, Mark.

MR. GRIFFON: To be assigned by the working group. Maybe I'll add that in, too -- no.

MR. ELLIOTT: I'd like to understand this as best I can. So let's say if you had 30 dose reconstructions that you were going to review in -- from one quarter, the first quarter.

MR. GRIFFON: Uh-huh.

MR. ELLIOTT: As I understand this, you would identify two experts, let's say, and identify in that sample of dose reconstructions those which would require certain members of this committee to recuse themselves from, so you'd match up with that individual expert two members who were not conflicted.

MR. GRIFFON: Right.

MR. ELLIOTT: And you'd come in a day before -- everybody that's engaged in this, identified to be engaged in this would come in the day before a Board meeting, per se, and run through all the dose reconstructions with the individual Board members who were responsible for assisting or working with the consultant, and so you're going to have people I guess floating in and out of that. Is that the way you see it kind of working?

MR. GRIFFON: Yes, except that I think for any set of cases, the team will stay the same. I'm not sure if I --

MR. ELLIOTT: Oh, okay.

MR. GRIFFON: -- exactly understood your question, but I think that for -- say once you have -- once we select cases and they're assigned to an expert --

MR. ELLIOTT: So the three might have --

MR. GRIFFON: I think the intent --

MR. ELLIOTT: -- five of the 30 to look at.

MR. GRIFFON: Right, right, right.

DR. ZIEMER: And if I could insert again here, this current wording makes it appear that there are only two groups, two sets of two, but in

essence there could be three or four groups. It's even conceivable to me, depending on the workload, that you might have three or four subgroups meeting with --

MR. GRIFFON: That's correct, and --

DR. ZIEMER: -- the expert to handle -- you know, this group has five or six or ten dose reconstructions and another group and another group could even be meeting the same day and the same place.

MR. GRIFFON: That's correct, and that's a reflection of our last couple days -- I missed that on editing, but -- at 11:00 o'clock last night. Is that all on the independent panel section?

DR. DEHART: Let's carry it the one step further. The next day then, what we're envisioning currently is that the panel would present to the Board their recommendations. Let's say that the recommendations for 20 of the reviews are benign and they would be presented to the Board for approval by exception. That is, if Board members want to pull one out for more detailed review, that certainly could happen, but we would present a list of cases that we would -- hopefully would pass through the Board, but the Board would approve every one. And

then there would be a set, as well, that the group -- the panel felt needed the Board's review.

DR. ZIEMER: Full Board.

MR. GRIFFON: Right. Right, and we -- yeah, we discussed that a little. I didn't put that -- you know, I didn't get that far in our language there, but that's a reflection of our discussions.

I think also -- you know, I'm just thinking now, this is a personal opinion that comes to mind, is that the two Board members meet with the expert, you may look at ten cases. You may say -- the two Board members may feel that eight of those are ready to go to the entire Board and these other two -- they may have questions for the expert to go back and, you know, review -- so there may be a triage there before -- you know?

MR. ELLIOTT: That's great, it informs the question I was about to ask 'cause I'm trying to get an understanding of the realm of recommendations that might be coming forward from these panels. And it certainly could be without exception we recommend the Board approve. And here's another one with -- we have some exceptions or concerns about it and we want the full Board to review. And here's another category where the panel has looked at it and

advised the consultant that they need to go back and do some more work, some more research or some more evaluation of the dose reconstruction. Is that pretty much the realm of --

DR. ZIEMER: But let me insert here. Let's keep in mind that the Board is not approving every dose reconstruction. This is an audit sort of thing.

MR. ELLIOTT: That's correct.

DR. ZIEMER: I don't know if that's the right term, but it's a quality control step.

MR. GRIFFON: Right.

DR. ZIEMER: We we're not talking about the Board having to approve things before the -- in fact, in many cases the decision will have been made and perhaps the compensation paid. This is an after-the-fact quality control step.

MR. GRIFFON: Uh-huh.

DR. ZIEMER: It's like a tax audit that said did you do it right last year; if not, you've got to change something. So bringing these to the Board for approval should only have the connotation that we're bringing to the Board the fact that the procedure -- the audit procedure is -- on these has been done and we've -- the staff -- the quality is

sufficient. So it's only -- I think, only approval in that sense, not that it's okay now to pay this claim. Okay?

MR. ELLIOTT: Absolutely, and I appreciate that clarification.

DR. ZIEMER: Is that the right understanding?

MR. ELLIOTT: Yeah, because these would be completed dose reconstructions they're going to see and the decisions may or may not have been made at that point in time to DOL, but DOL has it in their adjudication effort.

DR. MELIUS: But I think we have to recognize that -- hopefully it will be rare; it may not happen at all -- that there could be a circumstance where there would be a systemic -- an issue with dose reconstruction that the Board would --

DR. ZIEMER: Right.

DR. MELIUS: -- disagree, would recommend that NIOSH change, and then there'd have to be a decision -- I think probably with NIOSH and DOL people involved -- do you need to go back and re-look at some of these.

DR. ZIEMER: Right, exactly.

MR. GRIFFON: Absolutely.

DR. MELIUS: I mean I don't think we can --

DR. ZIEMER: That's the intent.

DR. MELIUS: Right, but we're not -- yeah, okay.

MR. GRIFFON: Right, okay. Case selection -- ready to move on? Okay. In the case selection we just -- really just modified some wording. Most of this we've discussed already. The strata we modified a little to reflect NIOSH's own internal process, the NIOSH efficiency process which Jim has described, which sort of involves the way they're going to handle cases when they come in, whether they're very low potentials or very high potentials and in between, and we're going to sample along those strata. A simple explanation, Jim, I think that's fair.

And along with the site, time period and diversity were the other strata that we would look at. The other clause we added in there -- the second paragraph says that we're -- feel the appropriate sample size is approximately two to three percent. And this, as we've discussed before, is consistent with the DTRA approach. That's sort of where we got that number from with -- and we also

discussed of -- cases will be selected on a quarterly basis by the working group, so our working group will stay in existence with a small role, but we will stay in existence for the case of selecting cases on a quarterly basis, and the working group will continue to track those cases that are selected. And the tracking piece is important because we discussed the situation where the hopper of cases that are ready may all be from Hanford, and we want to get our reviews going so we randomly select, but the only cases available are from a limited number of sites, but we want to keep in mind that we want to cover all our strata of all the sites and time periods or a percentage of the sites and time periods. So we thought we could achieve that by this ongoing tracking, details of which I cannot answer right now, but that's the nature of -- the flavor of what we're trying to achieve there.

Questions on that part?

MS. MUNN: You stumbled across another one of my favorite buzzwords, diversity. What diversity are we diverting here? Are we talking about types of work? Are we talking about types of people? What diversity? I just -- the word is so confusing to me.

MR. GRIFFON: I'm going to defer this to a team member that came up with that.

DR. DEHART: Obviously we're going to look at gender, because gender plays a role. So you know what I'm going toward. It'll be race, ethnic kinds of issues so that it's a balance. We have reviewed some of a variety of backgrounds of individuals.

MS. MUNN: Well, it may surprise you to know that I think the type of work and the level of involvement in certain kinds of work is probably a more important diversity issue than either of those.

DR. DEHART: We're hoping that the site selections will pretty well take care of that. If we find that it isn't, we certainly will adjust that. But the diversity as used here is in terms of the personnel issue.

MS. MUNN: Okay.

DR. ZIEMER: Comment?

DR. MELIUS: Now you have me a little confused. But are -- what about the words you struck out, which were -- I was thinking of a diversity of claim decisions, which were awarded, claims denied, claims --

MS. MUNN: Uh-huh.

DR. MELIUS: -- non-reconstructed. Are you

going to look at that diversity, also, or stratify in that in some way in terms of doing your sampling, or is that what you're calling the NIOSH efficiency process?

MR. GRIFFON: We thought that was -- at least the intent is that the NIOSH efficiency strata, the categories, are going to achieve that same end.

DR. MELIUS: I think I agree with you --

MR. GRIFFON: Yeah.

DR. MELIUS: -- though I would prefer some language that's a little clearer 'cause I'm not sure that anybody outside of this table and the NIOSH staff understands what the NIOSH efficiency categories are.

MS. MUNN: I guess I might feel NIOSH decision categories might better identify, in my mind, what I think we're after.

MR. GRIFFON: Yeah, I -- that's actually the term that NIOSH -- I was trying to be consistent with their internal language on that, and they are calling it the NIOSH efficiency process. Yeah, I'm open for changes on that or if we can better clarify it --

MR. ELLIOTT: I would ask that we avoid

that, Wanda, because we don't make the decision. I don't want to confuse the claimant with that, that there's a decision being made by NIOSH. I'm sorry.

MR. GRIFFON: We're certainly open for -- you know, we --

DR. ZIEMER: I think the point is, as far as Jim's question is concerned, your intent is not to exclude those -- that spread of awards versus denials and so on, so that'll be included.

MR. GRIFFON: I mean we may --

DR. ZIEMER: And actually this is really -- presumably it's a statistical random sample. The random sample, by itself, to some extent should do the stratification except that claims may not come in randomly in the sense that they may -- some sites might be over-represented, so that's why they're trying to stratify, I think. Otherwise, a random sampling would cover the types -- the various types of claims, the -- all the things you're talking about --

MR. GRIFFON: Another possibility --

DR. ZIEMER: -- that's your random --

MR. GRIFFON: -- that might address Jim's issue is that the struck-out language, we might be able to leave that in and then parenthetically say

based on the NIOSH efficiency process -- you know, through the NIOSH efficiency process, 'cause I think we do get those categories, yeah.

DR. MELIUS: No, I'm comfortable with what you're doing, I'm just concerned --

MR. GRIFFON: I know.

DR. MELIUS: -- some of this is for -- is the credibility of the program --

MR. GRIFFON: Oh, yeah, sure.

DR. MELIUS: -- and we have to communicate -- you know, one of these drafts when we were -- got a document together -- communicate and I want to make sure that the claimants and people out there understand what we're doing, that's all.

MR. ELLIOTT: I'd like to make a couple of comments for your consideration. Maybe you discussed this in your working group. Did you discuss weighting? The only weighting you show here is weighting based upon number per site. What about weighting on this category of denial or -- compensability or non-compensability and weighting -- I'm thinking of -- if I were making this decision for you, I'd say the heaviest weight should be on that middle category that the most work is going to be expended upon, so that's one question or comment.

And the other comment that I would offer you for consideration is that to work in here a sentence on -- with language that says you reserve the right or you have the ability to change these -- the selection -- case selection criteria as claims come forward and time progresses. You may see a different mix that you want to achieve.

MR. GRIFFON: The first one we did discuss, and maybe I can massage some words there to have weighted into -- the intent was to weight on those NIOSH efficiency strata --

DR. ZIEMER: And you could --

MR. GRIFFON: -- just as you said. That makes sense to us, too.

DR. ZIEMER: Mark, possibly you could simply add "and other criteria that arise in the course of your evaluations" or -- you need a sort of a catch-all that would allow you the flexibility of considering other criteria that may not be obvious right now. I think that's what probably you're saying.

MR. GRIFFON: Is it? Yeah, okay. We'll try to do that. I also -- you know, I am mindful when we're doing this of having concrete guideline -- not too much -- you know, too much flexibility so that

we're vague in what we're doing, you know.

Any more on the case selection?

DR. ZIEMER: Go ahead.

MR. GRIFFON: The scope and protocol, the first paragraph there was in the last -- for the most part, in the last report. We modified one bullet there, in number one, slightly. And then the next page, on the top of page two, this was entirely new draft of sort of a protocol, so this is sort of -- the first piece being the broad scope and then this sort of a protocol on how the panel would conduct the dose reconstruction reviews. And we talked about the type of review, and this is just what we've considered.

Mainly in our discussions the last two days we talked about sort of a basic level and then advanced level, or a more comprehensive level I guess might be a better word, actually. And then in previous meetings -- and I added this in, going through my notes last night -- we did discuss possible blind reviews. And I should note that when I said -- so we have these three categories, basic, advanced and blind. And I would think that the blind -- we haven't put numbers or percentages on these, but I would expect that the blind reviews

would be a small percentage of the overall cases that the panels review. But we think -- yeah.

MR. ELLIOTT: I'm lost on blind. What do you mean by blind in this context?

MR. GRIFFON: Blind means -- no, don't put that in there. Blind means -- I -- just a blind review where NIOSH would provide -- and let me make sure I get this right -- the administrative record, everything NIOSH used to calculate an individual's dose and then the panel would themselves come up with the -- or generate the form that would feed into IREP, rather than be provided that up front.

MR. ELLIOTT: So you're saying blind to the inputs.

MR. GRIFFON: Right.

MR. ELLIOTT: I understand now. You would not see what the determination would be from the dose reconstruction.

MR. GRIFFON: Right.

MR. ELLIOTT: That's what you'd be blind to.

MR. GRIFFON: That's right.

MR. ELLIOTT: I understand now. Thank you.

MR. GRIFFON: Okay. So if you -- I'll just -- if I can go through this sort of broadly, a basic review -- A, B, C and D are in both the basic and

the advanced review and sort of broke it up into categories. Review data gathering. B is review interview and documentation provided by the claimant. C is the review of the internal dose estimates. D is review of the external dose estimates. And let's see, the main difference -- I guess people can read through -- I don't want to go through every line on this, but the main difference between the basic and the advanced is if you look at A, there's a number three that was added which says review the entire administrative record to determine if relevant information exists which was not considered by NIOSH. Whereas in the basic review, we would just look at what NIOSH used in doing the dose reconstruction. And as we learned in the last couple of days, Jim Neton said that on the database system, those records which NIOSH uses for the actual reconstruction will be at the top of the hyper-linked file so you'll have all the -- and they'll be distinct from the rest of the administrative record. So it'd be a less compre-- the basic would just entail looking at that as opposed to looking at the entire administrative record. The entire administrative record already for some of these cases is upwards of 300, 400, 500

pages of various records, so that's much more comprehensive review.

Also in C and D you'll see the expanded -- numbers four and five in both C and D are the same, but they're -- in the advanced version they're looking at the -- determine whether dose estimate is consistent with relevant radiological information within the NIOSH site profiles. And NIOSH is establishing site profiles for all the sites, and this is -- this is actually something we discussed at length in the last day or so, that this is a real place where this review panel can have value-added to make sure that -- 'cause this is one of the things that we hear in public meetings, et cetera, that -- you know, we want to make sure that this panel double-checks and make sure that dose reconstructions are not just being conducted based on personnel records, or at least those -- if they are done on those personnel records, they're checked to some extent against site profile data so that there's not major inconsistencies, that something's missing.

And five is similar along those lines, compare case information and assumptions with relevant co-worker case information and assumptions

for consistency. And that's the idea of having -- you know, of five or six operators from the Hanford 300 area, if you're looking at one with -- in isolation in the basic review and in the expanded review we might do cross-checks and make sure that similar assumptions were made -- were appropriate, et cetera. That sort of thing. And that's --

And then the blind, the last thing on the bottom after all my deleted things, is the blind dose reconstruction, which we just, to some extent, described there with Larry. And then -- you know, and then on the next page, which is sort of that the -- that would be the report -- reports results to the Board.

DR. ZIEMER: And so, Mark, you envision that every one of the reviews, the panel would have some sort of a documentation that said, for example, determine whether all assumptions used in dose determination are appropriate. Yes.

MR. GRIFFON: Yeah, this was sort of --

DR. ZIEMER: You would have a --

MR. GRIFFON: Along the lines of what --

DR. ZIEMER: -- written report and you'd report that to the Board, we determined that all assumptions are appropriate, that the data are

consistent, et cetera, down the list. Or if there's questionable ones, you would raise that and --

MR. GRIFFON: I think -- I expect that the expert would be going into this protocol and then the two Board member -- the panel would agree on that, you know, those conclusions. And then they would --

DR. ZIEMER: And there actually -- there would be documentation that --

MR. GRIFFON: Right.

DR. ZIEMER: -- of such an agreement and --

MR. GRIFFON: Right. This was -- this draft here of the protocol was done in the spirit of your idea of -- or several people's ideas of a checklist sort of concept, yeah.

DR. ZIEMER: Okay, any comments or questions?

DR. MELIUS: Yeah.

DR. ZIEMER: Jim.

DR. MELIUS: I think the working group did a very good job with this. I think it -- I have one question as to whether -- I guess this would be for the advanced reviews. One of the I think major concerns in terms of credibility of the process is the issue of what information is available that

wasn't -- was not made available or was not included or not considered in your review. And that you seem to be approaching that purely from a records review point of view. You're looking at the site profile. You're looking at the administrative record and so forth. Did you give any consideration, as part of the review, of going back to people at the site and asking some of the site experts -- and we can talk how to define that -- about should other information be considered for a person working in that area? And I think that -- I know that -- my understanding from NIOSH for their site profile are going to have that process, but I'm not sure that that -- when NIOSH does that that we're -- have a way of ascertaining whether or not -- how complete that site profile is. And would it be sort of value-added enough to make it worth the -- is the effort worthwhile to go back and talk to some people from the site and -- just to make sure that all relevant information is included, has been considered. I do think that could help the process some.

DR. ZIEMER: Let me respond as a -- first and -- it sounds on the surface like a good idea. I'm wondering about the practicality. That's a separate kind of audit. That's not an audit of the

dose reconstruction. That's an audit of the data-gathering thing, which may be a good thing to do. I'm not sure that's a burden we want to put on the dose reconstruction subgroup, so we may want to think about that as a separate question. How do we have assurance that, number one, it's not -- probably not a simple task for this Board to go on to sites and do that, but aside from the logistical thing, perhaps we need to think about is there a way to develop some level of comfort with the information that's used in the site reconstruction -- or the site profiles.

MR. GRIFFON: Yeah. I mean, you know, we certainly -- and this is my biggest issue since I've been on this -- but I guess what we were trying to do was to -- and I certainly have concerns about the site profiles and the -- NIOSH's staff power. You know, do they have the resources and are they getting the data to build these site profiles to be what we would like them to be. We tried to bound this dose reconstruction review to look at -- to tag into those site profiles, but also my feeling is that our Board needs to also push and make sure NIOSH has the resources to make sure those site profiles -- and a thought that I've been considering

is the idea of having some sort of site-specific boards or panels of professionals, workers that assist NIOSH in developing those site profiles. But that's a whole 'nother set of work --

DR. ZIEMER: That's my point. I don't think --

MR. GRIFFON: Yeah.

DR. ZIEMER: -- the dose reconstruction --

MR. GRIFFON: I think --

DR. ZIEMER: -- groups can do that.

MR. GRIFFON: Well, I think we -- in our scope we did say that we would review the quality of the data used for the dose reconstruction, and I guess I was trying to push that as far as I could and then -- but I -- and that's why I'm saying that that -- maybe to push this from two sides makes sense to make sure that these site profiles are beefed up as best as possible, and then actually the dose reconstruction review -- reviewers, the panels, will be reviewing those site profiles and they will have a lot of that substantial data that Jim might be talking about, but I don't know. Yeah.

DR. MELIUS: Well, it seems to me, though, that this is one of the opportunities to check on that. We're hiring a consultant. We've had the

site profile -- site profiles will have sort of developed a list of some of the experts, people that are familiar with the site and could be helpful and that some process for that consultant to go back and just check with those people for this particular work area where this person worked or case, was there some other information that should be considered in some way. And we're not talking about doing it on everybody. We're just doing on the ones -- you know, the second tier here.

MR. GRIFFON: Yeah.

DR. MELIUS: And I think it would provide one check on that process. I agree that the site profiles themselves may need some sort of review process, also, and we don't want to get this whole process bogged down in that. But to me, if we're going to look at dose reconstruction and the information -- I think it might be able -- possible to do that. I share concerns about the logistics and so forth and how complete that can be, but this seems to be the opportunity. We're drawing a sample. We're -- I don't know if that frightened you and you fell off the -- but it seems to me that if we beef this part of it up, it might be able to take care of that at the same time now.

MR. PRESLEY: I don't think you want to put that on an industrial hygienist or -- not an industrial -- but an HP's back, do you, because he doesn't know -- the people that we're going to be hiring to do this, the majority of them have had no experience into what the workers have done. You're going to have to have somebody go back with a little bit of experience to see that in the areas. I think you're going to -- that's why -- I'm like Larry. I think it's going to have to be a separate portion of this.

MR. GRIFFON: I think that's almost an argument for it.

MR. PRESLEY: Yeah, I agree. I'm arguing for it, but I think it's going to have to be a separate --

DR. ZIEMER: You're asking who should really do that. Right?

MR. PRESLEY: That's exactly right.

DR. ZIEMER: Well, certainly the quality of the information is still a part of this, and it may be that in the process that certain kinds of questions could be identified that might form the basis for developing a process for going back and doing what you're talking about. I think it could

be a fairly substantial task. To just ask the question on any particular site or any subset of a site, do we have the site profile for this operation at Hanford.

DR. MELIUS: Yeah. No, I understand that part. I just worry for the credibility of the process if we haven't done that and claimants are there concerned about well, they just didn't take into account -- they didn't consider the fact -- this happened or that happened or there was this exposure and -- that didn't come up and no one seems to be paying attention to that. And I think that could occur.

DR. ZIEMER: One thing we might think about, and this would probably be the subject of perhaps the next meeting, would be to say okay -- NIOSH is developing the site profiles and they've gathered information from various sources -- to say okay, let's look at that in some way. Let's start with an audit of what we got and how we got it, and then think about what strings do you pull or what the next -- I don't know that we can solve that here, but I think that might be an issue that we want to put on the issue board for future consideration.

DR. MELIUS: But can I just add -- if we can

have some way of going back and testing that site profile versus --

MR. GRIFFON: Right.

DR. MELIUS: -- these actual cases, is it -- are they helpful enough?

MR. GRIFFON: That's -- I just made a note to that effect, Jim. I think that might be something we can add in to test, even on a percentage of the advanced, maybe even, you know. Maybe it's not all of the advanced ones, right.

DR. ZIEMER: Larry has a comment and then I think Tony and then Roy.

MR. ELLIOTT: Just to make sure that we're all working with the same understanding, the site profiles are -- they're going to be developed, and right now I'd say they're fairly sketchy, and certainly you could spend your time looking at what a site profile might look like at this point in time. But I think you'd be better benefitted in spending your time, as we get to a point where it may make more sense, to expend the effort and the time to look at what the site profile speaks to.

Certainly I think it does make a lot of sense for the comprehensive review stage to take a sample or where you think it's appropriate to have

the consultant make contact with whoever is appropriate at a given site, ask that question. This is the information I've seen and used; is there anything else we didn't have that wasn't used, that should have been -- that you are aware of. And maybe we can -- we can make that happen, I think.

In the examples of the dose reconstructions you all witnessed this week, I think you also saw some instances where information was provided that was not used. And I would ask how do you account for the -- in the quality of a dose reconstruction, how that's been handled. I don't see that addressed here. You know, where in instances the claimant said I've got this information. I'm searching here to see how you handled -- in your review, in a quality of the dose reconstruction process -- that the claimant understood why it was not used or why it didn't make sense to use it. I think that is just as important -- you know, when a claimant comes forward with information that they've spent time, money and their own energy in collecting and assembling, and then they don't see it used, we're going to hear as many complaints on that side of the fence as we are on the other side of the fence, I think.

MR. GRIFFON: Yeah, I think we --

MR. ELLIOTT: And I don't see that addressed here.

MR. GRIFFON: (Inaudible) maybe not extensively enough -- and I'll remind that -- was drafted at 11:00 last night. I thought we tried to capture that in the review of the interview and documentation provided by claimant, determine whether NIOSH appropriately addressed all allegations made by the claimant and assure that the interview information is consistent with the data used in the dose estimate. And then in the first -- number three on the -- or A-3 on the advanced, the distinction between the basic and the advanced was that we're reviewing the entire administrative record, which from my understanding of how NIOSH is -- you know, the administrative record includes all the data they got. They may not have used some of that data and the independent expert and panel would be able to then -- then they have to go through all that administrative record, and if they found certain things that they thought were relevant to the dose reconstruction but were not considered by NIOSH, then they've have a -- they'd question it.

MR. ELLIOTT: Thank you.

MR. GRIFFON: So I think that's where we got it.

MR. ELLIOTT: I think it's covered then.

DR. ZIEMER: Tony?

DR. ANDRADE: I just wanted to comment that it's not entirely clear in my mind yet what comprises a site profile, but as the discussion has evolved I think I've got a couple of ideas and I think that eventually we're going to see that a, quote, site profile is going to come about and maybe -- how shall I say it -- even a technical area within a site profile will come about from many different avenues, one being the dose reconstruction process itself and the interviews that are done for that process; number two, well-known accidents that have been documented; and number three -- and this is true probably more so in recent years than in the early years -- the development of databases of incidents in which we know there have been updates or intakes of radioactive material.

And for example, at our plutonium facility we have developed a site profile that goes back fairly -- a fairly long ways that we use as a prior distribution for Bayesian* analysis or for looking at the possibility that a real intake has occurred.

So if we're going to choose to develop these things, I think we're going to have to develop -- we're going to have to realize the diversity of sources of data that we're going to have to use to build these as we go along.

Did Jim want to respond to that?

DR. NETON: I was just going to amplify on what Dr. Andrade said. It's true, a site profile is that and more. All of those things go in there. What I would like to say, though, is a site profile is a dynamic thing. And Larry's right, right now we don't have a volume of information in there, but they are growing as we do dose reconstructions.

In many cases, some of the simpler ones that the working group saw, we needed very little site profile information to construct a dose. We needed to know very limited things, like frequency of badge exchange and maybe the detection limit of a badge and what the badge consisted of and we could be finished.

In the more complicated cases, as we get into those middle ground cases where we need to pull out all stops, that's where the site profile's going to grow dramatically, where we have four classes of information in site profiles -- characterization of

the internal monitoring program, the external monitoring program, the medical radiation monitoring program, and the environmental monitoring program. There are four key areas that we're expanding on, and only in those cases typically where we go to a full-blown dose reconstruction would all four of those areas be exercised or utilized. So it is possible to have limited site profile information yet have dose reconstructions move forward, and I think that's what the Board would see now if they actually took a snapshot. But down the line I think it might make some sense where we start doing cases where we have no monitoring and we're going to rely on air sampling data and that sort of things that are -- that may be in there, environmental area surveys, that sort of thing. It might be better to -- down the line to look at those profiles.

MR. GRIFFON: I guess also in some way I'm not sure if this falls into internal and external, but I think some sort of process --

DR. NETON: Right, source-term knowledge, that sort of thing. I think you saw a good example of that on an AWE where we went out and really tried to pull all the stuff that was in there.

MR. GRIFFON: Right. But as everybody's

realizing -- I mean this is not a small task, and from what we could gather in our tour of the facility, the site profiles are, as Larry said, sketchy at this point. They're -- and there is a massive undertaking, I would say, to get those up to speed. And another concern I would have is that I know that dose reconstructions are going to feed into that process to help you fill out that, but I'd hate to have the cart before the horse -- is that the expression? I mean I hate to be -- you know, if we don't have a full picture and then we have to go back and redo dose reconstructions again for a lot of people because we missed something --

MR. ELLIOTT: We don't want to do that. And please understand that as soon as this contract's awarded, there's going to be a group in the contractor that we're going to sit down with and that's their primary responsibility.

MR. GRIFFON: Right.

MR. ELLIOTT: Start the research effort, put the site profiles on the table --

MR. GRIFFON: I understand.

MR. ELLIOTT: -- figure out what information gaps exist in those profiles and let's get them filled.

MR. GRIFFON: Right.

MR. ELLIOTT: Okay?

MR. GRIFFON: Right.

MR. ELLIOTT: Move on that, because it's going to aid the individual dose reconstructions as the individual dose reconstructions aid the profiles, and we need both -- we need to track these at the same time and put as much emphasis on both tracks as we can.

DR. ZIEMER: Roy and then --

DR. DEHART: I would caution the Board on expanding this audit activity. This is an administrative paper audit, if you will. And to make it an investigative audit, to go into the work site -- by phone, in person, whatever -- is going to complicate, delay -- and I'm not speaking in opposition of doing that, but don't do it with this process.

DR. ZIEMER: Thank you. Jim?

DR. MELIUS: No, Wanda had her --

DR. ZIEMER: Oh, were you up first, Wanda? Go ahead.

MS. MUNN: I almost hesitate to broach this because I recognize how involved it might become. But in the process of doing site profiles, would

there be a value to having that material, as it develops, be available on the web site for other individuals to provide data that perhaps might not be in the official record, which would be helpful? And I recognize, as I ask that question, that the quality of information that you get might be questionable and that the quantity of it might be overwhelming. But it's simply a question. Would that be of value in assisting to accommodate the goal of site profiling that you have in mind?

MR. ELLIOTT: Well, you know I'm a big web site person. I think we've got the best web site going, and I think this would be a certain beneficial aspect to see this information provided publicly. And the benefit I see in that is somebody out there may say hey, I've got a piece of information I don't see there. Have you not found this?

Certainly it's going to be problematic for us to do so, given -- you know, I can envision large amount of information -- we've already got a large amount of information on our web site, but this will take us to another whole level, so we'd have to evaluate that. But I think the benefit outweighs the difficulty.

MS. MUNN: Be ready for it.

DR. NETON: I do think that's a good idea. And we already plan on having this on our intra-net internally to use for our contractor. I would say, though, that certain pieces of it may not be able to go on the general web. We plan on having these drill-down menus where it will take you down to specific cases and classes of workers so that ends up being part of the profile information, so it would have to be generic monitoring information, not any claimant-specific type stuff.

DR. ZIEMER: But something to be considered. Jim?

DR. MELIUS: I would just add that while these site profiles are currently not very robust, I think it's all the more important that there be some process to check that now. And whether it's this working group or another working group, how we figure out that process, I don't know procedurally, but I think we need to consider that and figure a way that we're going to provide some affirmation of that information within the constraints of resources and time for doing this. And it may be that down the road when these profiles are -- you know, a few years from now when they're much stronger, then that

process -- that part of the process will be less important. But until then, I think -- I'm just real worried that people are going to question the results -- question our review of the results unless we find some way of taking that into account.

DR. ZIEMER: Other comments? We're approaching the noon hour and we have a public comment period. I have three individuals who've requested speaking times from up to ten minutes each, which means 30 minutes. So I'd like to ask if any or all of the three -- Bruce Lawson, Jerry Tudor and Bob Tabor -- we have Tudor and Tabor -- can any or all of you would be willing to wait till after lunch to speak? If it's a problem, we'll do it now.

MR. TUDOR: The only problem I have, I would like to -- if it would be first thing after lunch, that would be fine. I just don't feel like, you know, I need to stay that late.

DR. ZIEMER: Okay, let's have you -- we'll go right now. I just want to check with the other folks.

You're okay after lunch and you're okay after lunch? Okay.

Let's go then with -- let's see now, this is -- you are --

MR. TUDOR: Tudor.

DR. ZIEMER: -- Tudor. Okay, Jerry. Why don't you address us now then, Jerry. Do you want to use the podium, if you want to go up to the podium or --

MR. TUDOR: Nah.

DR. ZIEMER: -- either one? Right here, okay.

Jerry is with -- is from Clinton, Tennessee, USOL.

MR. TUDOR: Yes.

DR. ZIEMER: Thank you.

MR. TUDOR: Yes, I'm Jerry Tudor and I'm with USOL and that's United Sick, Oppressed Laborers, who's a sick organization, Oak Ridge, and I'm with CHE, who's the Coalition for a Healthy Environment. And we met with our Congressman in Oak Ridge yesterday, or his aides, and he informed us it'd be next year before any laws could be passed to change anything about this.

The problems I see with it is the amount of time to become a special cohort is ridiculous, you know, because -- I've already been applied a year, so should they determine that DOE don't have records, then I have to wait another year to year

and a half? Is that not the time limit?

DR. ZIEMER: There is a 180-day waiting --

MR. TUDOR: Yes, plus --

DR. ZIEMER: -- period after something is filed before --

MR. TUDOR: Plus --

DR. ZIEMER: -- Congress approves it, yeah.

MR. TUDOR: Plus you have 200 days to act on it after that. Okay.

DR. ZIEMER: Right, so there is a time span, right.

MR. TUDOR: And most people are sick, you know. I have fourth stage prostate cancer, and a lot of people are already upset with the amount of time it's, you know, been taking on this. And another problem I have with -- when I set at home and read the minutes of the meeting and the calls and whatever and May the 29th -- 8th on a teleconference call, y'all said that the majority of the claims would be denied. Well, that bothers me. And you know, looking at it from a sick worker, you know, if y'all are saying the majority of the claims will be denied already, before any dose reconstructions are done -- they're up to seven now -- you know, that kindly (sic) bothers me. And they

said there'd be a lot of mad people, and they will be, you know.

And another thing with -- problem with comparing me to somebody that worked in -- chemical operator, which that's what I was, you can't compare me with a person that worked at the other end of the room even because I done a job different from him. I might have been exposed to a bunch and he might not have been exposed to any. I might not have been exposed to any he's exposed to a bunch, you know.

And working at Y-12 all those years, I know records were inadequate. I also know that if a program had a bunch of money in it, they clocked my time to that program. I may have not even worked on that program. I may have been doing something over here -- cleaning -- sweeping the floor, cleaning up a spill or something, and was charged to a job that I didn't do, you know. And that creates a problem when you start doing dose reconstructions and you look -- say well, he done this this day. That is not the way it happens at Y-12. I'm sure some of you know this. And I just thought I'd come up today and, you know, try to get my two cents in.

DR. ZIEMER: Thank you, Jerry, for those comments. Now we always like to provide an

opportunity for the Board, if they have questions or want anything clarified, to see if there are any questions or feedback for Jerry.

(No responses.)

DR. ZIEMER: Okay. And your remarks will appear in the record, as well. Thank you.

MR. TUDOR: Thanks a lot.

DR. ZIEMER: Thank you very much. Let's now recess for lunch and right after lunch we'll hear from Bruce and Bob, and then we'll return to our session on the Special Exposure Cohort.

DR. MELIUS: What time?

DR. ZIEMER: We're due back at 1:30. We want to be prompt on that because I know starting at 3:00 some people have to start bailing out.

(Whereupon, a luncheon recess was taken.)

DR. ZIEMER: Okay, I'll call the session back to order. We would like to hear now from Bruce Lawson. Bruce is with PACE Medical Screening Program and is from Oliver Springs, Tennessee. And Bruce, glad to have you here to address us this afternoon.

MR. LAWSON: Thank you. And for those of you who don't know, Oliver Springs is a suburb of Oak Ridge.

As he said, I'm Bruce Lawson. I worked at the K-25 site at Oak Ridge, which is one of three DOE facilities in Oak Ridge. I was a craftsperson. I was there a little over 30 years. The last nine years I was the union health and safety representative for the site and just a couple of general comments. I'll keep this brief. I hate to be the first speaker after lunch. Everybody's wanting to -- anyway.

I saw first-hand what Joe Carson alluded to yesterday, some of the things he mentioned about records, and I saw exactly what he was talking about. I saw industrial hygienists, health physics people and safety people, professionals, silenced and their minds changed by a simple frown. It didn't take any pressure at all to get them to rewrite records, redo reports. As a matter of fact, they were under the onus to clean up reports before DOE ever saw them. So what -- most cases, what DOE saw, the final analysis was a cleaned-up or very much edited version of what actually took place.

I now work with the local worker health protection program, the medical screening. We -- very often we're the first point of contact for the claimants in this EEOICPA thing. We meet the

individuals face-to-face and we hear -- I could repeat, but I won't, a lot of the comments that you heard at the public meetings that was referred to earlier. We hear that every day, many times -- of course similar verbiage.

Most of our claimants are not -- I wouldn't say most, but a large portion of them are uneducated, almost to the point of being illiterate. Their spouse, be it a husband or wife, said very little, if anything, about what they did at work, what their job was, what their job duties, especially. So they know virtually nothing about -- they just know -- and in our case, we see people who weren't even sure which one of the three plants their husband worked at. And they were told, of course, you don't talk about what you did years ago, and they certainly don't understand this process. To them, it's much too complicated and they don't -- they're not -- they just don't understand dealing with bureaucracy and Federal procedures.

We -- a lot of them can't get their records from DOE, and a lot of them can't get their records from local physicians and hospitals. I know of one case where this lady -- and this is a person who is existing on Social Security. They wanted to charge

this lady $300 to give her her medical records. She couldn't afford it. She walked away. She came to us. We made some phone calls and was able to persuade them to give them to her.

But anyway, we've seen a lot of people throw up their hands and quit because they can't deal with the established bureaucracy as it is. They get a couple of requests for information, the claims office -- the DOL claims office loses their records and so on and they write back for more documentation, and they just throw up their hands in disgust and say I knew I couldn't do it anyway.

Based on what I've heard about dose reconstruction and the requirements -- record-keeping from DOE, we're very, very wary of it. We believe that more -- far more deserving claimants will be denied than actually paid. And there again, around the Oak Ridge area, all too often the word on the street is if you didn't work at K-25, you can forget it. It's -- you know, people have their claims in the pipeline for over a year, and the word is getting around. I talked to Dr. Bingham* yesterday and their business is way down. So is ours, not quite to the extent -- what she said, but it is down. But that's -- word of mouth in any kind

of business is the best advertising, or worst advertising you can get. And right now, we're getting some very negative word of mouth advertising, the entire process is.

I applaud your efforts, and especially what you mentioned this morning about streamlining the process, getting on with it, get -- get these claims moving, get them through. And I know you guys are bound by the law, but in the back of your mind, remember, these people were probably -- most of them were probably exposed to far greater hazards from chemicals than they were from the radiation exposures that they got. So don't feel the least bit hesitant to go ahead and push a claim through that's questionable in my mind because these people are definitely deserving. Most all of them are.

That was about it. I just jotted down some notes that I thought you might want to hear from the street, and that's where we are, street level.

DR. ZIEMER: Thank you, Bruce. Let me ask if any of the Board members have questions for Bruce.

DR. MELIUS: I have one.

MR. LAWSON: Sure.

DR. MELIUS: Thank you for your comments,

Bruce. What -- do you have any ideas on how we deal with this situation where the official records may not be truthful or accurate, accurately reflect people's exposures? Would we get -- be able to get that information from interviewing some of the people down there or how do you get at that? I mean I know it's not easy, but do you think people are generally aware of the issue when the records are not being -- have not been properly kept for a period of time or --

MR. LAWSON: Not in every case, certainly, but there are some that are. We did a lot -- I say we, I'm talking about our local union there and the international did a lot of risk mapping where we called the workers themselves. And there again, I heard reference to expert -- site experts. If there are experts at these sites, it's those guys who were out there every day -- and ladies, of course -- who were out there every day with their hands on. They knew what was going on in this area as opposed to -- someone mentioned earlier that you could be at the opposite end of the room doing an entirely different procedure, different process, which is true. But we gathered people together and -- with maps of the buildings, different areas -- what was here, what

went on and so on -- and from that we -- we have a lot of information.

DR. ZIEMER: That suggests that perhaps there's another source of information that could be tapped into --

MR. LAWSON: There is, yes.

DR. ZIEMER: -- your risk mapping.

MR. LAWSON: There certainly is. Mark Griffon was involved in a lot of this, the sessions that we did.

DR. ZIEMER: And that is information that would not derive from requests to DOE, I assume. Is that correct?

MR. GRIFFON: That's correct, yeah. But this is -- I think medical surveillance program data was actually explicitly mentioned in one of the regulations or the -- yeah --

DR. ZIEMER: Right.

MR. GRIFFON: -- and this is all under the medical surveillance -- DOE medical surveillance programs.

DR. ZIEMER: So it is available via the DOE route, then, or not? This sounded like a separate --

MR. LAWSON: Probably if you request the

right document, would be my guess.

DR. BINGHAM: Well, I'm a PI on one medical surveillance project, and these are cooperative --

DR. ZIEMER: You need to identify yourself.

DR. BINGHAM: Eula Bingham, the University of Cincinnati College of Medicine, Department of Environmental Health. The PI, the -- I'm the PI on this one. These are cooperative agreements and because the workers were so concerned about DOE and its reputation and so forth, we were very careful. And we agreed not to give it to them. I mean if a worker decides to give it, that's their choice, and we have them read a confidentiality agreement and so forth. But the data belongs really to the project and it's only given in de-identified form. And theoretically that could be done by each of the projects, not by DOE.

Now certainly DOE could encourage the people who have the projects to do it, but they do not own the data. The only thing they would own that we have is if monitoring data for a certain facility, then they own that and that's covered under the Privacy Act. So I think you'd have to go to the different surveillance projects and ask that, and I think most people would be happy to share what they

have.

As a matter of fact, we've already shared some of the information with NIOSH on what we called institutional histories of some of the sites where we knew what the processes were and during what periods of time. Not perfect, but at least something.

So -- but for this, the actual owning of the information is for each project, but you know, you could never give up identified data. That's up to each worker. Is that right?

MR. GRIFFON: I guess I was thinking more along the lines of the summary reports, which are -- all the de-identified summary reports which capture -- at least may help in the site profile side of things. Certainly the interviews and the identified data, Eula's correct on that.

MR. LAWSON: And what we call the needs assessment documents where we had the initial meetings, in a generic form.

DR. ZIEMER: It seems to me we'd want to make sure those got into the system if they're --

MR. ELLIOTT: Yeah, let me speak to this a little bit, and I appreciate Eula speaking on it, as well. And she's certainly very accurate, DOE

doesn't own much of this information, and so we've been working with several of the PI's and in some specific situations regarding perhaps construction workers, we've been working for the Center for Protection of Worker Rights for -- trying to put in place a sole-source contract with that -- with a consortium under the Center for Protection of Worker Rights to get information from these different programs for five different sites, the work history-related information for construction workers. And also we should be aware that any one of the former workers who go through the program are given information back to them individually which should be part of their claim. They can submit it as part of their claim, and so that personal, individual information can be utilized as it comes from the individual. And we certainly -- every time we deal with a claimant and we identify that they were a member of a former worker screening program, we ask do you have this information and it certainly would be beneficial if you would provide it. And so that's one way we try to get around this issue of the individual information and not having a release form signed through the whole program.

MR. ESPINOSA: What are the five sites?

MR. ELLIOTT: Well, there's -- we're still working on the negotiation of this agreement, sole-source agreement with CPWR on it. I can't go into it at any more detail than that right now.

DR. DEHART: Again, thank you for your comments -- Roy DeHart. There was a point of clarification. You had mentioned that in Oak Ridge the word is that if you didn't work at K-25, forget it. Under the special cohort, the gaseous diffusion operation was covered. Did it cover anyone working in the reservation -- in the K-25 reservation itself, or just specific site and operational activities?

MR. LAWSON: Just the K-25 site. Of course we had a lot of workers who transferred between sites. That happened very frequently. But if they worked as much as 250 days --

DR. DEHART: In that building?

MR. LAWSON: -- at K-25, they -- we're a special cohort.

DR. DEHART: Okay.

MR. LAWSON: They would be considered.

DR. DEHART: And when you say K-25, you're talking about K-25, the building --

MR. LAWSON: The gaseous diffusion plant

itself.

DR. DEHART: -- the building.

MR. LAWSON: The physical -- physical plant --

MR. PRESLEY: No, no.

DR. ZIEMER: The site.

DR. DEHART: The whole site. Okay.

DR. ZIEMER: The site.

DR. DEHART: The whole site. Okay.

DR. ZIEMER: Other questions for Bruce? Thank you very much.

MR. LAWSON: You're very welcome.

DR. ZIEMER: All right. Now we'll hear from Bob Tabor. Bob's been with us before from Harrison, Ohio. Bob, are you here?

MR. TABOR: Yes. I'm Bob Tabor -- Robert G., for the record. I'm a member of the Fernald Atomic Trades and Labor Council. I work at the Fernald site, 21-year veteran there, millwright by trade and a labor representative. I spoke to you folks in the past and I guess the first thing I would like to say is I'm happy about the new members of the Board and glad to see that that issue's been addressed and the addition of those folks. I'm also happy to be able to be here again, you know, to

participate and listen to the Board's activities. Doing so certainly helps elevate the learning curve because without a doubt to say, this is a kind of a complex issue, some of these things are.

And I guess on that note, some of the things I'd like to talk about, it'd be really hard for me to reiterate those things in such a manner that I might get as detailed as some of you who really understand the science behind this. So some of my comments will basically be in reference and in general, because the things I've been thinking about the last few days that I would like to comment to have been explored by a lot of conversation and discussion here this morning, so I just want to reiterate the issues that Mark brought up and that Jim brought up, especially those on the issue regarding the SEC class applying for non-SEC-listed cancers and those particular issues there. I want to be sure that we give thorough thought to how to adjust or how to fix those type of issues and answers.

I mean I recognize that as this whole process evolves there's certain things that were not thought of in the beginning in the rule that have come up that need to be addressed. And I just want

to reinforce the fact that, you know, we need to do everything possible to fix those things so that we don't have a lot of black holes that complicate things as we go down the pike, you know, on making claims.

One of the other issues deals with -- let's see here. My concern over the fact that Fernald was unfortunate that we didn't get ourselves as -- identified as part of the original cohort groups, such as Paducah and Piketon. And in lieu of that, it leaves us in a position to possibly explore what is now before us, which is the Special Exposure Cohort, those particular avenues. And one of the things that bothers me a little bit is that the rule-making or the guidelines, if I'm expressing that correctly, that was set forth for the original cohort groups, that those same things are not true for that of the Special Exposure Cohorts, and so I have some concerns relative to the equity in that process. That's about the best way I can explain that I think we've talked a little bit about it here this morning in detail, but I want to reiterate that.

And then I guess in part of that thought process comes the issue that Mark touched on

relative to, you know, the endangered -- the definition of an endangered health. There seems to be some complicities (sic) there, in my mind, relative to how we're going to approach, you know, defining that with respect to maybe dose reconstruction of the individual and possibly what that might be -- you know, for the site or something to that effect. It's difficult for me to talk to that somewhat in detail, but I think Richard's touched on it, as well as we've addressed that issue here this morning. And I just, once again, want to reiterate those two particular areas that we need to work on for good clarification.

One of the other things that came to my mind this morning in some discussion and it came up a couple of times, and I'd like to touch on it again. Let me grab my notes here. There was -- you know, I had asked -- I was writing down some questions I asked -- I asked myself a couple of questions I guess I really knew the answer to, but let me just read those. I said to myself here, you know, some questions.

I said in doing the dose reconstruction, is the only category of collected data, you know, that of consideration for doing the reconstruction would

be that of just exposure records. Well, I got to thinking about that and said now, Bob, that's -- no, there's other things that are considered, as well. And then it posed a question in my mind, you know, does the nature of where you worked in an operation and what maybe the individual did and what they were exposed to, does that have bearing on the development of the dose reconstruction? And the answer to that is well, yes, it does.

Then my thought process went to the questions that were generated or the conversation that was generated this morning under the issue of -- let me think here a second -- the memorandum of agree-- I mean memorandum of understanding relative to what are we going to do about DOE and getting additional information, and what is that information going to be limited to. I think you've heard me speak a few times in the past over my genuine concern about the record-keeping processes, especially with respect to the record-keeping processes -- well, wait a minute, let me back up. Maybe not the record-keeping processes, but the retention of records at some of these sites, and especially of those sites who are kind of on the short list.

Now by the short list, I mean sites that are destined for closure in the near future. At one time here for a while there was this moratorium on the disposal of records, and I think I mentioned the last time that that moratorium has been lifted. Now a lot of those records are going to be on processes that we did at the site, the various types of, you know, things that went on -- you know, where the people worked, what they did. I was hoping that something that might be generated in addition to maybe a special letter which you folks indicate that maybe you should write to the DOE or Congress addressing the memorandum of understanding relative to information, that we might address the fact that maybe they should reimpose a moratorium on these records. Because as these sites close, it's going to be really, really hard to find these things. Without a moratorium, they can ship that stuff off to anyplace and it just gets hidden in a -- you know, in the closet. And then you have information that you may need, other than just the medical records on the individual to make certain decisions, obtaining that information gets only that much more difficult when you don't have availability to those records. And I have a big concern over that and was

disappointed in the fact that they have lifted that moratorium. So I would like to reiterate that aspect for your consideration and whether or not you would like to address that in your letter or if it ties into that or if it's something you should address, you know, independently, you know. Because Fernald's probably going to be one of the first sites, other than Weldon Springs, that's going to be what we call, you know, a closure site that's come to completion. We have a lot of retired employees right currently and, you know, and as these things -- as these issues crop up and these applications become more familiar with the employees and that they make application, you know, for compensation, the record issue might get real muddy. So I wanted to reiterate that.

So other than that, I believe I don't have any other comments for today. At least that's what I've jotted down.

DR. ZIEMER: Thank you very much. Again, let's see if we have questions -- yes, Tony?

DR. ANDRADE: Seems we don't have enough microphones to go around the table. Sorry about that, Bob.

MR. TABOR: Okay.

DR. ANDRADE: Bob, I haven't been -- truthfully, I haven't been keeping up with what's going on with moratoriums on -- moratorium on records-keeping. Do you know if this permits sites to actually destroy records or is it directing sites to send records to other facilities?

MR. TABOR: I'm not certain. It's not really totally clear in my mind. Moratorium means, you know -- in my mind means don't do anything with them, in the sense of like destroying, or you have to keep what you've got. I think when they lift the moratorium, exactly what the total guidelines are on what you can do with the records, quite frankly, I'm not so sure the DOE has developed a true, pure, good set of guidelines on what you can get rid of and what you can't.

Now let me give you just a far-fetched scenario. I think that probably you could destroy maybe cash register receipts from the cafeteria, and that wouldn't be any big thing. And they're not going to -- whew -- put that stuff out someplace in a big vault. But then there's this other set of delicate records that will have a greater meaning, you know, to -- you know, to our future citizens or our future society, certainly may have a greater

meaning to an organization like ourselves and the processes that you're involved in. I don't know exactly what their rule-making is going to be on how they're even going to approach this.

I've had some discussion with some higher-ups, at least at the field level, asking them since the moratorium has been lifted, what are your guidelines for how you're going to go about this, if you have a plan, and what specific records. Quite frankly, my impression is is I'm not so sure that they have guidelines in place to say you can do this to this extent or you can do that to that extent. I'm not really sure about that, if you want to know the truth. But I have concern about it because my impression is okay, if a moratorium is lifted, then begs the question what you're just asking, just what can you get rid of. And even to complicate things more, what you may retain, where's it going to go.

DR. ZIEMER: We have a comment from Larry and then from Bob.

MR. ELLIOTT: The moratorium on destruction of records for epidemiologic purposes has not been lifted.

MR. TABOR: That is correct.

MR. ELLIOTT: It is still in place, and so

in that regard, any system of records that has use, utility, benefit to epidemiologic studies and the understanding of exposure associated with health outcome, are protected. And NIOSH has, in the last 12 years, a long history of involvement in advising, arguing with, recommending to, working with DOE on making sure that those records are intact and retained and not destroyed. I know that the health-related energy research branch at NIOSH, which I was the branch chief for, has worked very closely with the people who do record reviews across the sites.

What I think you're very accurate and your point is very well-taken on, Bob, is what happens to those records that are protected when a site closes down, and where do they go and how do we find them. And that's been our concern for a number of years as to the finding aids and the systems of records that are protected for these purposes and how to make sure that they're not lost in a Federal archive somewhere and they are retrievable and traceable. And that's something we have commented on and been concerned about, and I think that's where I hear your point dwelling and hitting home with me very strongly.

But the moratorium on destruction of

records, in my understanding -- unless you have some memo within DOE I have not seen yet -- has not been lifted.

MR. TABOR: Well --

MR. ELLIOTT: It's still intact.

MR. TABOR: And I agree with you there, Larry. I understand that things like medical records, and then you framed it as epidemiological records and things like that, my impression is that yes, there's not a moratorium to lift that. I mean in other words, those things have to be -- stay intact. But you're right, the issue is where may -- you might find them in the future.

I think that what I'm also referring to here is things that might be associated that people would look at or you folks may look at in developing maybe probability of causation --

MR. ELLIOTT: But it's all records. We have been integral in deciding with DOE what systems of records -- and it's not only the medical records, it's not only the dose records, we have targeted the process records --

MR. TABOR: Okay.

MR. ELLIOTT: -- the processing information records, the changes in historical practices at a

given site, employee benefit records, the PSQ's --

MR. TABOR: Okay.

MR. ELLIOTT: -- we say don't destroy those --

MR. TABOR: Well, maybe that's not been clear to us in the past, but those are the things that I have concern about, you know --

MR. ELLIOTT: And if you go --

MR. TABOR: -- process records.

MR. ELLIOTT: If you go into DOE's routine use authority under the Privacy Act that gives NIOSH routine use authority to access those records, you'll see a long list of systems of records. And those systems of records, by their nomenclature, will give you an indication of the variety of information that's protected. And it's not only just medical and dose, it's a long whole list of -- there must be -- I recall like 27 different systems of records that we said we need to see. And we had to make some very strong arguments for why a certain system of records was important to --

MR. TABOR: Yeah, well, that would be my concern.

MR. ELLIOTT: -- research and understanding of exposure and health outcome.

MR. TABOR: Okay.

DR. ZIEMER: And let's see, Robert had a question or a comment.

MR. PRESLEY: I agree on some of these records. In the past three years that's what I've worked on extensively. And I know at Paducah there's stuff -- when the new company took over -- out the door. Or in a trailer. And we're in the process of going through some of that stuff.

The other thing is, Larry, I think what we need to do is send that letter out again, because a lot of the people -- the new companies are taking over. You've got the new contractors. They are looking at that old data as -- this is not mine, I have no responsibility. Then I put my people in the records center. They don't know the difference between a purchase order and a -- I hate to say it -- and a medical report. Those things get shoved in a box. They get sent to Atlanta with a destruction date and they're gone.

MR. ELLIOTT: I think you're absolutely right. I think -- you know, the point you make is different than what Bob was making earlier that -- where the record go is one thing, but acknowledgement of a contractor or the records

manager at a certain site, who's new to that site and new to DOE's process, may not have found that memo that said moratorium on destruction of records for epidemiologic purposes covers these systems of records. I agree, I think that would be a very important thing to articulate in your letter.

MR. TABOR: Well, a reminder would probably really help because the only thing that I can attest to -- you know, in these closure sites where clean-up is really I mean robust and it's in full swing, I will tell you that going through three contractors over 21 years out there that the closer you go and the faster the pace gets, it is a administrative merry-go-round, and I mean it is really, really hard, not only to find people that are responsible in those areas to figure out what's going on and where things are at that particular stage in time as opposed to where things were just a few years before.

So you know, what Robert had to say there, there's a lot of validity in that. I mean it becomes very difficult, so maybe a reminder like that would really be good and we need to keep our finger on the pulse of things.

DR. ZIEMER: Thank you, Bob, for a very

important point that you raised.

Now we have one more person who has requested time, and that is Mark Lewis. Mark is with PACE and from Waverly, Ohio. Mark?

MR. LEWIS: Thank you. Hi. First I want to thank everyone for putting the time and effort that you've been putting into this. It's very important to all of us nuclear workers and other people throughout the country at the weapons facilities and I applaud your efforts for that.

I have some topics I'd like to talk about as pertaining to site profiles, expert groups and record keeping. They all tie in together, what we're talking about.

First of all, the site profiles. I have the privilege of being the coordinator of the local worker health protection program in Piketon, Ohio -- dose screenings some of you guys were alluding to a while ago, Larry was, and the thing we found out about site profiles, a lot of the records that we needed to get ahold of through the plant exposure records, they were either incomplete or non-existent. And by getting ahold of -- we called expert groups of workers, former workers -- we got ahold of some former workers and we put together a

risk-mapping session. This risk-mapping session and focus groups. The risk-mapping session where I set people down at tables, give them a map and have them go back -- like taking a snapshot of the past of the plant.

We found out, just like you mentioned, some of the buildings used today for certain processes that weren't used for that process years ago. A lot of exposures -- you'd think a building would be clean. For instance, at our site we have a building we have shipping and receiving in. And years ago it was where they sampled high grade uranium. So within the walls of that building, inside with people working there, they was drilling or something in the walls, the maintenance man, they would be going through a space and time with some of that dust could have transuranics in it or whatever, you know. So we found that the workers were our experts at that time.

We got all the records we could from the plant, but that, mixed in with the workers, led us to know more of what to screen for today, you know, in our screening program.

The risk-mapping part is very important. I think, you know, if you went to a site to talk to

somebody, you know, they'd give you all the records they'd have from the company, you know, that's running the facility now. But don't forget to talk to some of the retired people.

And the dynamics of this risk mapping, too, is worthwhile because you get two or three people together that worked together for a while. You know, you want to get like with like people. You get process operators, for instance, at one -- one day. Get all the people who did welding at another time, and these people could be retired now -- most of them were. They'd see each other and their memories would click more. And the collective memory of those people was more valuable to us, really, than any hard data that we had. I just wanted to share that with you.

Also, pertaining to past -- I'm just going to talk about neutron exposure at our Portsmouth site. There was numerous studies done at the Portsmouth site -- gaseous diffusion site pertaining to, you know, exposures and all. But none of them ever did come back and say there was neutron exposures. Our own in-house -- the union activity, our safety reps and stuff, suggested that hey, we had some deposits in some lines and the potential

could be there for neutron exposure. And we asked specifically for NIOSH to come in and just do neutron exposure. And sure enough, that's what they found, we had neutron exposure that we weren't monitored before, see, before. So you know, just going by your past histories of safety studies at different sites may not clearly reflect what you have. I can't emphasize enough about how workers could be involved in it.

Now a lot of you may know that a gentleman, Jeff Walburn*, works at our site. The company has -- I heard was mentioning earlier yesterday something about maybe somebody forgot to do something or whatever, but there's cases -- in Jeff Walburn's case, and it's in Congressional records and the company's got letters, too -- where they said yeah, we zeroed your dose for liability purposes. And it's in Congressional records and in memos, you know. So there's a lot of vidility (sic) out there, you know, saying that it was done intentionally in some cases, so --

In my own record, I started working at the site when I was 21 years old in the fire department. I got into a serious exposure situation where I had high grade weapons material on top of my anti-C's*

from the fire department. And I ran out of air, went outside to get some more air in my bottle. A guy unzipped my suit, all the stuff fell down on top of my head -- maybe that's why I am the way I am today, I don't know -- but it all fell on me and eventually I got exposed real bad, you know. I had no skin left on my face for a long time and I went through a lot of hassle.

Well, in '88 I had some heart trouble and I thought I'm going to go get my records and just sit down and see what I was exposed to. Well, guess what? There's nothing there. Nothing happened that day or for them weeks that followed.

So I thought I wanted to at least mention those to you, and that's about all I had. Especially when, you know, you go to do the site profiles, don't forget the retired people -- all right? The retired workers and the risk mapping. That's all.

DR. ZIEMER: Thank you, Mark. Let me again ask if anyone has questions for Mark.

(No responses.)

DR. ZIEMER: Okay. Thank you for your input on that.

Now we need to return to the topic of

Special Exposure Cohort.

DR. MELIUS: Can I ask -- sort of figure where we are procedurally, I guess. We spent a lot of time this morning talking about this and I'm not sure where we're going in terms of getting comments in to NIOSH and how you want to proceed on that.

DR. ZIEMER: Well, what I'll do here is summarize. The working group met during the noon hour, and I'll summarize where we think we are and get some feedback from the Board members.

Just for planning purposes, Mark, does your working group have some further things that you're going to want to present today, or are -- I mean you're not under any pressure to come to a final document. You got a lot of input this morning for refining and --

MR. GRIFFON: Right. Not for today.

DR. ZIEMER: -- I think you can move forward with what you have, so --

MR. GRIFFON: Yeah, and we did mention that we might want to have a conference call in the near future --

DR. ZIEMER: Right, but --

MR. GRIFFON: -- to probably --

DR. ZIEMER: -- in terms of today's meeting,

I think we're okay on that. I had planned -- I thought we had put in the agenda, but I'm not seeing it, to at least have a little discussion relating to -- how can I describe it? Let me call it personnel issues at NIOSH. Actually an issue that was raised by Mr. Miller and perhaps we'll have time to at least discuss -- I think -- it has to do with whether or not the manpower is sufficient, particularly in dose reconstruction and so on. This is not an item that Larry has asked me to raise. It can be very -- it can be a little ticklish for the Board to get involved very deeply in hiring and manpower levels at the Agency, but at least some on this Board have raised concern about whether or not there's enough staffing to get the job done. And perhaps we can at least discuss that a little bit.

I do want to at least get us up to date on where we are on the Special Exposure Cohort. We're still shooting for having comments ready by the 25th, I think, of August. Is that the -- or 26th.

MR. ELLIOTT: The 26th is the last day.

DR. ZIEMER: The comment deadline. So let me tell you what we've done so far, kind of taking all of the input from this morning, Jim's comments, Mark's comments and the ones that we had prior to

that.

What we're looking at now would be a letter to the Secretary which included with it a series of comments relating to specific parts of the 42 CFR 83. Some of those were ones I described this morning.

That is, in section 83.1 to reformat the wording in the manner that Tony had suggested. That would be the first paragraph on that page. Plus utilizing Wanda's word for proactive, the word "diligent" in identifying and assisting employees; adding a section 83.2 with the wording that Tony had suggested for that section in his item two. That wording is that a section would be added to state a cancer claimant whose dose reconstruction was completed, but whose claim did not qualify for compensation, cannot reapply for or use the procedures for designating classes of employees as members of the special cohort as a route for appealing a decision, that it is not an appeal process. Section 83.10, as shown on the sheet, 83.13 as shown, 83.15 as shown.

Now we then looked toward dealing with specific things, and let me refer to Jim's comments -- and these overlap a bit with Mark's. First of

all, on the first comment where Jim has recommended NIOSH should modify the approach envisioned by this rule to place more emphasis on the group petitioning process. We note that section 83.7 actually identifies both the group petitioning process and the individual, so our thought here was to use the preamble -- and the preamble will be reformatted, is our understanding, so that there will be descriptive information pertaining to the various sections. So there would be a preamble that would have a portion relating to section 83.7. And our suggestion here is that there be language in the preamble that would sound something like this, and I'll give you the rough draft that the committee came up with this noon.

Quote, NIOSH should emphasize the group petitioning process, parentheses, as opposed to the individual petitions, and explain or describe possible types of groups that might consider petitioning; e.g., a group of workers who believe they have been subject to an undocumented exposure at a facility.

So basically then -- end of quote. So basically the preamble would be used to sort of emphasize the group petitioning process and give an

example, and that might be expanded on, but that at least was our initial recommendation for dealing with that.

On the second item --

DR. ANDRADE: Paul --

DR. ZIEMER: Yes. Oh, yeah, please -- and any of the working group can help out here. Tony, please.

DR. ANDRADE: Just a tiny suggestion. This is word-smithing, but nevertheless I think it's important in light of the fact that we're not trying to give higher weight to one process versus the other. Instead of using the words "as opposed to" I would suggest something like "vis a vis" or something along those lines.

DR. ZIEMER: NIOSH should emphasize the group petitioning process vis a vis --

DR. ANDRADE: The individual.

DR. ZIEMER: Okay, I gotcha. This is not final wording right now. This is our draft and we may have to have a conference call and at least get final wording out for -- and even do a phone vote later this month.

Now on the issue of guidelines, we struggled with that quite a bit. And where we landed on this

was to ask -- and our comment would suggest that the -- ask the staff, in the preamble again 'cause the preamble is more like a guide, to add some words to section (e) under -- I guess it's section (e). Section (e) on page 42964, that's the *Federal Register* page. And this would come in in the paragraph that says (reading) commenters asked HHS to define the conditions under which NIOSH would not have sufficient information.

And basically, Jim, I think your question was when do we know we don't have sufficient information.

Now as we read through the preamble, it was our feeling that to some extent they have described this, but it may be helpful to concisely put this all up front and say that by sufficient information we mean incomplete information on radiation source, incomplete information on processes and practices, incomplete information on source terms. So it would spell out what it is that we're talking about when we mean incomplete.

There was a feeling amongst our group that it would be difficult to go beyond that. If you drive down to the next question and say well, what is incomplete source information or what is

incomplete dosimetry information, we can't say it's one missing film badge or it's seven or it's 25 or something. So at this point we're saying the guidelines would have the nature of describing the types of things where the judgment is that there's not enough information in this category to complete the dose reconstruction. And that -- it seemed to us that that would allow sufficient flexibility so that it was not completely proscriptive to those doing the work, but still identified for those petitioning what it is that we're looking for or what it is that's missing. And one could even then have -- if it were an application that said are these pieces of information missing from your records and therefore you are petitioning on that basis. So that's where we landed on that one.

Item three we think now is being covered already by our previous section one where we are -- is it previous section one? Where we are asking NIOSH itself to be more aggressive, formerly known as proactive, more diligent in identifying and assisting employees. And again we ask the Board if that will address the issue, but at least that's where we landed on that.

And then finally -- of course your item five

we've already covered in a separate motion, and item four I think we -- we think we ended up this morning as realizing that probably we can't insert the time limit into this. Was that --

DR. MELIUS: Yeah, I think it's --

DR. ZIEMER: -- everybody's understanding? We discussed it and so our recommendation was not to include anything on that. So what I've just described now is the nature of what the recommendation would be and I think we'd like some feedback as to whether or not -- and it would have to be worded and we would do that together with a cover letter and distribute that for a final vote, but I want to at least get an early measure of level of comfort with such comments. Or if there are some major issues that remain undealt-with, we need to identify those.

I might also add, I believe that if individuals have issues that they don't -- and the Board is not able to, as a group, deal with, they could always be submitted as an individual's. Is that not the case, Larry? Nothing prevents Board members, as individual citizens, to submit comments, but -- and you may want to address that. Is that --

MR. ELLIOTT: No, you're absolutely correct,

an individual Board member may submit comments as an individual.

DR. ZIEMER: Right. We don't lose our citizen privileges.

MR. GRIFFON: Paul, did the working group address my -- you know, the three -- I know one of them overlapped Jim's, but the other two were --

DR. ZIEMER: Let me go back to yours here and see what -- you know what?

MR. GRIFFON: Ran out of time.

DR. ZIEMER: We missed -- was it the sufficient accuracy issue that you're asking --

MR. GRIFFON: No, that overlapped with Jim's, I think, but especially the number three, I guess the endangered health question.

DR. ZIEMER: Actually, we didn't. I'm sorry, I think we ran out of time and so that -- that does not imply that this was not important. What -- and maybe we can get some feedback right now. How can we handle that one?

Is -- I want to start -- let me ask Ted first. Ted -- or maybe Jim -- Jim's there? Whoever. Is it the staff's feeling that they have in fact defined endangered health in a manner that is fully consistent with the law? That is, it's

based on the law. He obviously has to answer that yes. Right?

UNIDENTIFIED: He'd better.

DR. ZIEMER: But you understand -- I need to rephrase the question. Have you stopped beating your wife, Ted?

(Laughter)

DR. ZIEMER: This says the current definition of endangered health relies on an estimate of potential dose and expresses some concerns. Does the -- we need to consider whether endangered health itself is fully and adequately defined in the draft here.

MS. MUNN: Well, it certainly -- I'm assuming that everyone is relying on the same footnote that I am for that definition, where the footnote says (reading) HHS interprets the statutory language, endangered the health -- see 42 USC 4384q(b)(2)* -- to mean there is a reasonable likelihood that the radiation dose may have caused a specified cancer. That's a quote from the statute.

DR. ZIEMER: That's the definition here.

MS. MUNN: Right. Since claimants cannot be compensated as members of the cohort for any adverse health effects other than certain cancers under the

relevant portions of the law. It appears to me that that's defined by the law already.

DR. ZIEMER: I believe this is how NIOSH has defined it, based on the law.

MS. MUNN: Based on the law, uh-huh.

DR. ZIEMER: Those words may not be in the law itself. Ted?

MR. KATZ: No, no, the law used the term "endangered the health". HHS had to interpret what that means, and what you're reading is -- it was HHS's interpretation of that. And you know, of course, as Dr. Ziemer said, we believe it's consistent with the law or it wouldn't have gotten out.

DR. MELIUS: But are you saying it's the only -- it's not the only definition that's consistent with the law.

MR. KATZ: It's --

DR. MELIUS: There are other ways of -- wouldn't you say there are other ways of operationalizing that that would be consistent with that, or are you saying that's the -- this is the only one?

MR. KATZ: I'm not precluding that there's a possibility of another way of operationalizing this.

I just -- we didn't come up with it. We didn't imagine it.

DR. ZIEMER: I think you could argue to some extent it is driven by the law itself. I mean I suppose I could argue that you could say that it's -- endangerment is 50 percent or more likely than not at the 50 percent confidence level rather than 99. I mean it's a definitional thing.

DR. MELIUS: Correct. But I'm just saying I don't believe that the -- the law is very vague on this and what they mean by endangerment, and I don't think this is necessarily the only way that that can be interpreted. In fact, I personally think that they're taking a relatively narrow interpretation of what is in the law and what my understanding is in the background, and it certainly contrasts with how some of the other Special Exposure Cohorts were designated. They were designated based on a duration of exposure and a question of whether or not they were monitored or should have been monitored -- facility, which I think sort of begs the question of a level of endangerment or level of risk in that. So I think there certainly -- the law implies some other approaches could be utilized.

DR. ZIEMER: At the end of the day, you

still -- you end up having to have some criteria, and it's a little difficult for me to see that you could use -- that it would be proper to use a criteria that's different from the criteria that are being used with the regular dose reconstruction 'cause that's --

MR. GRIFFON: Why? Explain your logic for that. Why would you think that would be improper since in one case you can estimate doses but in the other case you already said that you cannot estimate doses, so why would it be improper to use a different --

DR. ZIEMER: Because the way that they're doing it here does a group estimate and caps it and makes a -- it's not an individual dose reconstruction, but it makes a -- it makes what I would call a reasonable estimate that their dose is below the same bar. You're basically saying everybody in that group is either over or under that -- well, let's say if they're in the cohort, they're over the bar, that same bar that you're using.

DR. MELIUS: I don't interpret the calculation that's being done to necessarily -- in that way -- probably 'cause we have very little guidance for how that will be done. I mean what I

find to be illogical -- I don't know if that's the right term -- is just the basic fact that you're doing -- you've said you can't do a dose reconstruction, yet you're basing endangerment on a dose reconstruction of some sort, and the -- I'm not saying that's not an approach that can't be used, but I think it has some fundamental problems with it that concern me, and I don't think it's the only approach that's -- certainly not the only approach that's prescribed by the legislation. I don't think this is an easy issue, either, so I'm not trying to trivialize or say that NIOSH's effort wasn't an effort that should not be considered by -- I mean, for example, for the other -- some of the other Special Exposure Cohorts, it was working one year and being badged or working a job that should have been badged, I think is the terminology. Now concern that was is well, would there be -- would we encounter other situations where people may have been badged as a precaution, even though recognizing that very little likelihood they would have had exposure and in case would we be allowing them into the cohort inappropriately. I don't know whether it would be the cafeteria workers, I don't know what the right example is or -- Well, in that case, one

could argue that one would have enough information to be able to do a dose reconstruction enough to say that they wouldn't qualify. Are there situations where that's -- they're going to fall in between or be complicated from either of these approaches?

UNIDENTIFIED: Yeah, I think it's a --

DR. ZIEMER: So even the statement "should have been badged" has certain implications on both nuclides and doses and so on. I mean --

DR. MELIUS: Should have been monitored, I mean. Excuse me.

MR. GRIFFON: Monitored or should have been monitored.

DR. ZIEMER: Oh, should have been monitored. Well, either one of those.

MR. GRIFFON: Either way, yeah.

DR. ZIEMER: Yeah, so there are certain implications, as soon as you do that, that there are some levels.

DR. MELIUS: Yeah.

MR. GRIFFON: Right, right.

DR. ZIEMER: Mark, you had --

MR. GRIFFON: That there's some significant level, right. I mean I -- just to pick up on Jim's point -- I wish Jim Neton were still here, but I

think that we heard NIOSH's efficiency process is actually going to exclude those insignificant dose cases from getting over that first hurdle of sufficient accuracy. They're going to be able -- like Jim said, they're going to be able to do an individual dose reconstruction 'cause they're going to make all these worst-case assumptions and they're likely not to -- even with all the worst-case assumptions, they're not going to trip the 50 percentile, they're out of the potential class automatically, so that to some extent addresses that concern about just putting in -- potentially opening up this class for people that had very little or insignificant exposures.

And I think the other --

DR. ZIEMER: Well, but that still is dependent on that bar being at that same level that you talked about earlier. They're still comparing it with the probability of causation of 50 percent at the 99 level 'cause they're using the same --

MR. GRIFFON: But that's for individual dose reconstructions.

DR. ZIEMER: Right.

MR. GRIFFON: That's the way they do that, right.

DR. ZIEMER: Right.

MR. GRIFFON: Right. I'm not sure I followed your point on that. But anyway, if -- you know, the other reason for arguing for this definition of endangerment that's not tied to -- and I agree with Jim, this is a complicated issue, but the other argument for not tying it to an IREP sort of approach is just -- in addition to what I just said, the hurdle should catch those low ones, but also the secondary thing is that this sort of counter-intuitive nature, especially to the potential claimants, that they couldn't do my dose reconstruction but then they were -- they had enough data to reconstruct the class's dose and we still got booted out, you know. I can see that sort of scenario playing out. And then -- you know, so if you had another sort of criteria for endangered health, you may get to the same end as -- and in fact if your efficiency process works and you have another way of defining endangered health, we may end up at the same end point, but I think it would at least be more understandable to the public and seem less sort of counter-intuitive. I mean I still am concerned about that situation where you're trying to -- you're doing a sort of worst-case dose

for a class when you're -- when we're clearly concerned about the extent to which these site profiles can be built up and -- you know.

DR. ZIEMER: Yeah, Roy.

DR. DEHART: Endangering to health is almost a fatal error in this document. The definition -- many physicians would say radiation, per se, is endangering to health if you believe in the linear effects, so I think the definition is a poor choice to begin with. And what we're trying to do is turn a -- I guess a sow's ear into a silk purse with trying to box that in. It's an unfortunate definition to have to deal with.

MR. GRIFFON: Yeah, but I wonder if the author is -- intended that language for that very reason.

DR. DEHART: Politically, it may have been.

DR. ZIEMER: Other comments? Yeah, Larry.

MR. ELLIOTT: I think when we, within the staff, dealt with trying to address this issue -- and you're absolutely right, Dr. DeHart, this is an unfortunate piece of meat that we've been given that's full of gristle to try to chew and swallow, we were looking for a test of reasonableness. What's the test of reasonableness here? Endangered

the health. What dose would it take to have resulted in endangered the health? And achieve a balance of parity with those that would not -- that would have to go through dose reconstruction where dose reconstruction could be done, and I think that's how we approached this. So maybe -- I don't know if that helps or hinders your thinking about this or not, but perhaps if you had an alternative suggestion on another option for -- to be considered on how to define endangered the health in this regard and achieve a balance of parity in a test of reasonableness.

DR. ZIEMER: Tony?

DR. ANDRADE: After going through this proposed rule several times -- and there are several shortcomings and we are starting to deal with most of them, but this is a tricky one. Every time I tripped over this particular one, in my simple mind I felt that because this legislation deals with special circumstances under which somebody might be considered -- again, and not as an appeal, but might be considered again for compensation, given that new information has come to light about a facility -- a facility profile, if you will, whatever that may mean at this particular point in time -- about an

undocumented exposure which one or many people claim to have been subjected to, then my proposal would be to try to tie this definition to this new event that could potentially have caused additional dose to be added to the person's original dose. It's a simple-minded way of looking at things, but it is a way that a special cohort could be formed, logically. I'm struggling with this even as I speak, so if the experts can rebut what I said or give reasons why that would not make any sense, I'd appreciate it.

DR. ZIEMER: One possibility -- I think Mark has suggested, and let me read the words 'cause maybe this will help us. At the very least, this needs to be explained further within the regulation, and it's because of the counter-intuitive issue --

MR. GRIFFON: Right.

DR. ZIEMER: -- so it may be that we can raise this in the comment and indicate the concern that's reflected in the Board and ask the staff to explain it further within the regulation. Now I don't know what that would mean in terms of how that would play out unless we're at a point where we can suggest what those words might be.

MR. GRIFFON: I was just going to -- I was actually going to ask Tony if he could restate -- I

think I understood what you were proposing, but could you restate that? I'm sorry, I just want to follow your...

DR. ANDRADE: I'm just saying that process-wise, a person may end up with a, quote, incomplete dose reconstruction. However, if new information has come to light with respect to a situation that the person may have been in or that NIOSH has identified with respect to the facility that they worked in, that in itself will result in an additional dose than that that was originally considered in the first dose reconstruction.

And maybe it'll take IREP again to calculate what this additional dose is, but it may be that which could be defined as the additional endangerment or whatever this purports to be.

DR. ZIEMER: I'm not clear, though, how that helps in the definition here.

DR. MELIUS: Actually when I first interpreted what you said, it actually did help me and let me tell you what I thought you said, which is that if you -- if you think about this, it's going to deal with I guess maybe two situations. One is the unexpected has been found. Go back to the enrichment plants, the transuranics, we just --

nobody thought or not enough people thought or however you want to do that, and you have a surprise and what do you do? And you can't go -- you know, to go back and try to recreate and reconstruct, you can't, so that's one situation this should cover.

The second situation this should cover is when there just -- it's an old facility and they just weren't monitoring and -- just 'cause the means weren't available at the time and maybe all the records on sources aren't as good as they would be now and so forth and so on, and therefore we -- we're just totally befuddled in trying to do a dose reconstruction.

When I worry about the current approach that NIOSH uses to endangerment, I worry about the second situation, where there's just very, very little information and that they're just going to be making a wild guess at what -- at what would -- what number you put into that endangerment calculation that they're going to do. I don't think, for the surprise thing where you know it's a big exposure, that it probably matters. But it could be problematic when there's just very little information and no monitoring and no records. And we really are just going to be guessing at that.

The opposite situation we worry about is we don't want to include the trivial or non-exposure in this, so how do we come up with a definition that would exclude that, but not I think rely on what could be an arbitrary guesstimate at what their exposure should be. And maybe there's just enough different situations maybe there would be more than one way of approaching this. I don't know, I -- and we don't have all the examples, but I do think the endangerment is -- the Special Exposure Cohort is the surprise exposure and just the non-existent monitoring and records. And maybe if we distinguish those, it helps. Maybe it doesn't.

DR. ZIEMER: Wanda?

MS. MUNN: Well, I guess I still come back to the footnote again, and to the original rule-making where this term, endangered the health of the members of the class, is used just as it's beginning to identify what bases are necessary in order to establish the finding of a special cohort. And it includes a finding of short-term radiation health effects for other members of that class and identification of radioactive materials that they didn't know about before, as Jim was just saying, a description of shortcomings of radiation protection

measures. And all of the things we're talking about, it seems to me, are in the rule. And since this entire law is based only on radiation-induced cancers, then I guess, to me, that -- with that background and what's already here -- I understand that there is some concern there may be other ways of defining endangered the health, but this definition that's given here that NIOSH has developed, in this context, appears appropriate. Because what they're saying is there's a reasonable likelihood that this radiation dose may have induced the cancer and under these certain circumstances.

I guess if we have better ways of identifying exactly what that means, if it were -- if it were further unidentified, if these descriptions were not given here below, then I would have the same concerns that everyone else does, but -- what does endangered the health mean -- but the law says we're talking about only radiation-induced cancers and here are very specifics about what that endangerment might have resulted from. Are we beating a dead horse? I mean can we get any -- if we can get any better than this that would give our potential claimants broader consideration, then what is that?

DR. MELIUS: I think we're saying the alternative -- an alternative is, 'cause I think there are probably others, also, is that it would apply to a situation where NIOSH is unable to complete a -- it's not feasible to do a dose reconstruction with sufficient accuracy and the person has worked at least one year in a facility in a area where they were monitored or should have been monitored, and probably would need to flesh that out with some definitions by -- what means by monitored or should have been monitored.

MR. GRIFFON: And I mean I keep coming back to this point, but this is a two-pronged test, and sufficient accuracy is the first test. And if I give in on having a more precise definition of sufficient accuracy -- you know, the way NIOSH defines sufficient accuracy right now is they can complete a dose reconstruction and -- you know, an individual dose reconstruction. And we know -- I mean from our review of some of our cases, we know that for these likely low/low situations, to use the NIOSH efficiency process they likely have low exposures to internal and low exposures to external. They're going to take those through and give them every possible -- given the data they have -- worst-

case scenarios, individually test that case against IREP, as they should, and those are going to drop out, the very low, insignificant exposures. The ones that miss -- and that's why I'm focusing on it's a two-pronged test, you know, it's not -- they were just trying to define endangered health in isolation where -- it's a two-pronged test. They have to get over that first hurdle first.

DR. ZIEMER: But they're still testing it against IREP.

MR. GRIFFON: They're still testing the individual dose reconstruction against IREP. Correct.

DR. ZIEMER: Right.

MR. GRIFFON: As they should, as they do all the time. Correct. But the class against IREP is a different question.

DR. ZIEMER: Right.

MR. GRIFFON: Right. And then I'm saying -- you know, so you get rid of these insignificant cases by their own process by that definition of sufficient accuracy -- I would argue by such a broad definition of sufficient accuracy you're able to get rid of those insignificant or lower doses, lower dose cases. They won't be in that class. They

won't make that hurdle. And then since you're -- by not being able to calculate a dose with sufficient accuracy, can't -- I mean complete a dose reconstruction for these folks, I think you have to kind of say if they made that hurdle that far, he's -- we're really -- the data we have left, can we really use that data to kind of do the -- as Jim said, to kind of do this worst-case estimate to compare against that bar for the class in IREP or should we have just another set of criteria similar to the original SEC. And so I think of it as this two-pronged test.

And I would also have problems if I thought that a lot of the -- I mean I don't think it's equitable if a lot of the -- just because you can't reconstruct the doses but they likely had very insignificant exposures and they make it into this class, that's not equitable. That's not what we're looking for here. But I think we're -- the NIOSH efficiency process and that definition of sufficient accuracy protects against that. I think Jim Neton said that to me either on the record or on the side here earlier, so that's how I'm trying to grapple with this.

DR. MELIUS: If I can just add, I think with

the current approach they're using or proposing to use, that I take comfort in the fact that we're going to, as a committee, be reviewing those. Those will be part of the petitions that come to us. I worry about how we're going to make that assessment, evaluate the decisions that they've made because I -- again, we don't have much information and they're making a guesstimate of some sort in order to fit it into this -- to these IREP calculations that they're proposing, and how are we going to assess whether those are appropriate to do or how do we evaluate those? And I think we're going to be hard-pressed -- and particularly to keep them consistent from situation to situation so that we're treating everyone who would fall into a Special Exposure Cohort, or potentially would, in a fair manner, that we're making the same assessment for a cohort at Hanford that we would at one at Oak Ridge or wherever. And where we'll be dealing with some very, very different situations. Your laboratory example we talked about this morning as compared to a production facility and so forth. Where admittedly we don't have enough information to do a very good sort of quantitative evaluation of that risk.

DR. ZIEMER: I don't know what the process was on the original cohorts. I wasn't involved. But someone made a determination that there had to be a certain length of time and perhaps there had to be some -- there had to be some indication that there were certain types of materials around, even if it wasn't -- people weren't monitored. So there must have been at least a kind of group estimate as to what potential doses might have been, like the screening process, that says it's very conceivable somebody could have been there and gotten more than a few millirem -- pick the number. I don't know where -- somebody must -- in the thinking process, somebody must have had a bar that says they could easily have been up here somewhere. I don't know what the process was. But I mean where did these times come from? They can't be completely arbitrary. I mean how would they -- well, maybe they are. Congress did all this without any scientific input. All right.

No, I mean rationally speaking, there's still -- whether you explicitly say that there's some test, dose test or you do it more indirectly and say okay, even intuitively -- I mean I think I could intuitively take a number of -- say if

somebody's working with these things for a year and we weren't monitoring them, I can guess that there could have been situations where they got pretty high doses. I don't know how -- does anybody know how that was done and -- okay, please.

MR. MILLER: Richard Miller. I will only offer you this much, that this was an administration proposal when it came forward as the one year, but it had been based on discussions with the Justice Department about the RECA model which uses a working level month criteria for compensability. And so what they did was -- and they looked at the RECA amendments that were done in 2000, in fact, which had been passed as part of what was then S-1515, and in that legislation you will see actually foreshortened periods of time compared to the old RECA, so they -- the one year threshold was sort of -- the whole concept of using a time period, Dr. Ziemer, was derived from the RECA model of compensability. They used time or duration in the mines or in the mills or in the shipping and transfer operations as the criteria.

DR. ZIEMER: All right. But see, in general, that implies -- in the radon case it's a concentration times the time and you get a -- an

intake value, but indirectly, somebody is measuring that against some standard. But I'm at a loss as to where we really go with this. It's -- whether we specify it in terms of time or other parameters, we are either directly or intuitively saying that there's some point at which there's an endangerment. And maybe my endangerment level is different than somebody else's, but it's somewhere there.

And we're sort of -- we sort of end up, I think, saying it's the way NIOSH has done it, is that a reasonable -- is that one reasonable way to do it or is that completely unreasonable?

MS. MUNN: No, it's reasonable.

DR. ZIEMER: Obviously there's other ways to do it. Is there a better way? Is there -- or is the issue simply one -- but yeah, people don't quite understand this, or does it make sense intuitively, and I'm trying to grapple a little bit with -- I think, in principle, you end up doing the same thing. Wherever is you do it and draw some lines, you're doing sort of the same thing. So how do we do it in a way that is reasonable and also does not seem, for those out there, to be black magic.

DR. MELIUS: To reiterate the concerns on this one, to both, one is that it -- the current

proposal is, one, it's counter-intuitive. Okay? Which I think poses problems with people viewing it from the outside, a claimant, a group of claimants. Secondly is that I think it is quite arbitrary in terms of how the dose will be selected, and that also is going to cause problems -- again, from your -- someone applying for this program or evaluating this program or for us reviewing these decisions -- as to how it is being applied. I think the advantage of a time frame, albeit an arbitrary one, is that it's understandable, it's transparent, and it can be applied and we're -- you know.

DR. ZIEMER: Yeah. I was going to say that certainly the counter-intuitive issue -- I certainly agree with that. The other, I think, is as much arbitrary -- I mean whatever time interval you choose obviously is as arbitrary as any other, so -- so in any -- it sort of gets down to what is a reasonable way to approach it.

DR. MELIUS: Just one quick thing is that the 250 days has the advantage of being consistent with what's already being in the law. That's --

DR. DEHART: My question dealt more or less with consistency, as well. Is this the first time in a rule that this has been defined this way? This

is the proposed rule, so if there is to be a change, this is where it would have to be since it doesn't -- it isn't preceded by another...

MR. ELLIOTT: I'd consider that if you establish 250 days as the requirement, that might go counter, in some instances where the class may not have spent 250 days, or you may need more than 250 days to reach whatever criteria you use for endangerment of health, so that's why we stayed away from that. And in fact, we felt that it was appropriate to say that -- and here I would like to speak to -- comment about the arbitrary nature of what you were talking about, Dr. Melius. I think once you -- what we have not done clearly, in my mind, is articulate clear and well enough what we see happening here, and that is that the class definition that we bring forward for the Board's review would establish what the class -- the time frame that would be appropriate, in our mind, that would support the test for endangerment of health and is appropriate for the given situation that the class experienced. And I think you would see all of that laid out. We don't -- we should perhaps prepare a mock-up example of a class definition. I don't know if that would help or not.

And I think there's also a hang-up here -- I think Jim tried to speak to this earlier this morning, Jim Neton, about if the counter-intuitiveness here is based upon we can't do a dose reconstruction but we can put a dose in and determine whether or not health was endangered, you've got to come at that just the opposite way. You've got to come in from IREP and say okay, what is the most -- worst case likely scenario here this class experienced, which is the radionuclide most of concern, and what's the most likely answer that would result from that -- from an exposure to that? And so you don't plug in a dose number, you plug in the demographics of the class as it's defined into IREP and you see what the 50 percent at the 99th percent probability -- credibility limit dose is, and then that's the test of reasonableness that we've been talking about.

If that, on the face of it, looks reasonable, we're going to come forward and say we recommend that this class be added. But if it's not reasonable, we're going to say that, as well. So maybe that's where we've lost you all, or maybe where we're not understanding what you're talking about, or maybe passing by each other.

DR. ZIEMER: Okay, Jim.

DR. MELIUS: Yeah, just back to one comment. In trying to think through this -- and again, we don't know all the potential situations involved, but I don't think that there would be very many where there would be exposure less than 250 days -- a situation where you wouldn't be able to do the dose reconstruction in a way that -- have enough information to do that that would still pass this test, as you develop it. But I'm guessing, too, on that. We just don't know. So I think -- I'm not real worried about the false negatives in that group, but it could occur with this situation.

I also don't want to be -- repeat my soap box speech too many times, but I think this does go back to this issue which I'm going to talk about some more if I'm not satisfied with how we resolve this, is this whole issue of defining when we can -- how we're going to do these dose reconstructions, when we cannot do them, how it applies in different situations. And I suspect if we spent some time working on that issue and then came back and we're talking about this regulation and this situation, I think a lot of it would be easier to -- discussion would be easier for all of us. But we are dealing

in a vacuum and -- to a large extent 'cause we haven't really -- at least I haven't -- don't see the criteria there for when you will and when you will not be able to do dose reconstructions. I think you're starting to get away from case by case in terms of the presentation, but it's still, to me, very arbitrary. And I think it makes this discussion that much more difficult, also.

DR. ZIEMER: Any more comments?

UNIDENTIFIED: Why don't we take a break?

MR. GRIFFON: That's a good comment.

DR. ZIEMER: It's 3:15. Let's take a 15-minute break and we'll reconvene.

MR. ELLIOTT: I remind you all I need your preparation time.

(Whereupon, a recess was taken.)

DR. ZIEMER: In order to think about reaching some level of closure today, one of the ideas that has arisen during the break is to perhaps do two things. One is, on this issue of clarifying the definition on health endangerment would be to have the document that we send to the Secretary indicate that at least some of the Board members are concerned about NIOSH's definition. The other option would be to endorse the definition and vote

it up or down as far as the Board is concerned. My personal feeling is that it would be useful to at least have our document reflect the concern of those members -- and it could be a majority, actually -- but reflect both of those views by indicating, for example, that the definition that's being used in the document is of concern to some of the Board members. That doesn't address the issue of exactly what a better definition would be, unless we were to come up with something, or those who have expressed the concerns would come up with some alternatives.

And then the other issue, and Jim indicated just before the break that he was still somewhat concerned about how the guidelines are defined for the issue of determination of special exposure -- or determination of when you can't do a dose reconstruction. And I think has a potential way of addressing that, also, in the document that might be satisfactory to all concerned.

Jim, why don't you suggest that one first and then we'll back up to the other one.

DR. MELIUS: Okay. What if the Board makes a recommendation that NIOSH develop a set of guidelines for how they will be making the determination as to when a dose reconstruction

cannot be adequate -- completed with sufficient accuracy, et cetera, the verbiage that's in the regulation and so forth, and do that -- that would be presented to the Board for review. So it would not be part of the change in the regulation, per se, but it would be something that would come back to us as a Board to review so we would better understand, provide better guidance on how they do that. So similar to how we've done with the dose reconstruction. We have a framework that's in the regulations, and then we have a -- some implementation documents that we have reviewed at various points. Same with the IREP.

DR. ZIEMER: And so in the document itself, are you suggesting that in the preamble where these sort of broad guidelines are given that there simply be some words that suggest that the staff would develop operational guidelines for use, and they wouldn't be part of the rule.

DR. MELIUS: They would then pin -- we ask them -- I think we formally ask for that in our recommendations and that they come back to the Board for review.

DR. ZIEMER: And there could be a sentence inserted here saying that such guidelines would

exist, and I would simply ask Jim to construct a few sentences which we would insert in that section.

Okay. Now back to the other issue, the definition of endangerment of health, Jim, what is your feeling on having a statement in the -- I ask Jim and maybe Mark 'cause I think the two of you have this concern. What about having a statement in the document -- it might actually be in the cover letter, or it could be associated with the definition where -- that footnote definition, to indicate at least some of the Board members are concerned with that operating definition. I don't know what we would do with that at that point, other than --

DR. MELIUS: Well, I think if we had a statement that a number of Board members or some Board members -- I can talk about the wording -- have concerns about this definition and this approach that's being proposed by NIOSH and suggest that NIOSH -- and carefully review this approach and consider alternative approaches, and I think we've talked about one approach -- such approach.

DR. ZIEMER: I just bounce that off the group. We were trying during the break to see whether we could find a kind of -- I don't know if I

want to call it middle ground, so much as a way to comment and raise the issues, particularly -- including those which are of concern to maybe not the full group, but at least some members of the group. How do the others feel about that approach. Roy?

DR. DEHART: I agree with both points, but I would also add that there needs to be a sentence or two -- some kind of explanation of why there was concern on the definition.

DR. ZIEMER: Right, and you could even reference the definitions used in the other legislation or the statutes, yeah. And again, Jim, would you be willing to draft a few lines that we could insert there and -- yeah.

DR. MELIUS: Yeah, I'll draft Mark to pull something off his computer. I think he's written some of this.

DR. ZIEMER: Now let me ask the group overall -- and again, we're not voting today, but I wanted to see if we've -- have we covered -- with those two methods of handling those two issues and the other ones, have we covered everything that we would need to address in this document?

DR. MELIUS: Can I ask one question of --

DR. ZIEMER: Sure.

DR. MELIUS: -- Larry and -- when people write in to DOE requesting records -- I'm thinking in terms of the class petitions, and you have a requirement that people have one of two items, a letter from DOE saying those records do not exist, or a report from a health physicist or dose reconstructionist, I'm concerned that the burden of doing the second one is a lot for people to do. If they want to do it, fine. I think -- and you have it as an "or". I'm worried that -- I'd like to be reassured that the DOE does respond when they don't -- can't find the records and say they don't have this. My personal experience with FOI's is when you put them into an Agency and they don't find the records, you never hear from them 'cause they don't find them. And those are the most frustrating ones to pin them down. And I don't want people having to chase after a letter saying there aren't any records. It's Wanda's proving the negative.

MR. GRIFFON: And you're asking the petitioner to do that.

DR. MELIUS: Yeah, and in the petition you're asking them to do that. If they do it routinely, where we can assure that they routinely

-- fine, I'm not worried about it.

MR. ELLIOTT: I can't speak for DOE, but I can speak about our experience in listening to claimants and in public meetings, and it runs all over the board. It runs over the board from -- I got my information back, I didn't like what I got and I asked for more; I got it back, I liked it -- to I haven't heard a word. And it seems to me that it varies from site to site, for individual to individual. But I would also add this in my response to you, that our intent in putting that there was not to force -- I don't believe, and Ted can correct me if I'm wrong 'cause I wasn't privy to all of the discussions among staff in crafting this language -- was not to force an individual claimant to do one or the other or either. But if they had it, it certainly added credence to their petition.

MR. GRIFFON: That's not the way it's worded.

MR. KATZ: No. I mean it's a requirement, one or the other. Let me just clarify, the dose reconstructionist report or whatever -- I mean we especially had in mind, why that's there as an "or", is not for someone to go out -- and we didn't think -- we didn't imagine that happening, someone going

out and hiring themself (sic) someone to review DOE records, but really to address the situation -- some of this sort of work has been done already and someone could just grab, at hand, something off the shelf to make their case. And then -- I mean -- and you probably want to recall, too, you made a suggestion for something in addition to this, which is if there have been studies elsewhere, published studies, whatever, that address this lack of records for certain cohorts of workers or so on. That should be a third alternative. That's not in there right now so you probably want to comment on that, as well.

DR. MELIUS: But I guess my concern is that you've made it a -- the "or" is a requirement. Is required either to have the health physicist's report or -- we add a third one, or this outside report, or a response from DOE saying the records don't exist. And if they're unable to get that response, they can't apply.

MR. KATZ: Right. And the assumption we made is that DOE would have to respond to them when they make the request. And another assumption we made is that in cases where a petitioner is having no luck getting a response, we'd hear about it and

then we could help them -- put pressure on DOE to respond to their inquiry. 'Cause I mean most government agencies I thought are bound under Foyle* to respond, but -- so that's sort of a revelation to me that they actually can ignore a Foyle request 'cause that's legally binding, I thought.

DR. MELIUS: I would then -- personally, I guess I would suggest for that one that they have documentation that they've made a good-faith effort to obtain records and were unable to should suffice, rather than having them have to wait six months to get DOE -- I mean I don't argue with the need for them to have tried to get records if they do exist and not just to flood you with petitions for things, but they ought to -- you know, if they can give you the letter they sent and didn't get a response in 60 days or whatever.

MR. KATZ: Right, and let me -- Richard just reminded me that in the case of the AWE's you're not -- there's no government -- there's no government to be, but -- so that's a case aside, as well.

DR. MELIUS: I think we can take care of that specific language. I just want to --

DR. ZIEMER: Roy?

DR. DEHART: I haven't heard that we did

anything regarding the storage of records. We were going to comment on it, I thought, perhaps in the letter. Didn't we decide to do that with regard to the letter that was to be written on the MOU? The issue of record storage.

DR. ZIEMER: Actually when we did the MOU resolution, we hadn't talked about the record storage. The record storage came up today. I think that -- I think I heard that the -- Larry was talking about reissuing the reminder, but -- or --

MR. ELLIOTT: Well, it's not my job to reissue the reminder; it's DOE's. And I would encourage you in your letter about the MOU to speak to this. The storage of records, the archival of records, retention of records, the moratorium and resubmitting -- re-notifying across the complex that there is a moratorium and these records have importance -- maybe this is the leverage you really should apply is not only importance for epidemiologic research, but importance for compensation.

MS. MUNN: Yeah, that's easy.

MS. GADOLA: Can I just address that simply?

DR. ZIEMER: Yes.

MS. GADOLA: To reiterate the importance of

what Larry just said and of the Board addressing that issue is from hearing what I've been hearing from people who have been trying to obtain records in Oak Ridge. Some of the problems they have encountered is that due to the storage of different contractors, records are stored in different ways. Some were stored under people's last names, some were stored under years. Some of them they have no -- not been able to locate, but they know they must be there someplace. They have also found folders that have pages of medical records that have never been put in files because they said well, the files are here somewhere but we can't find them or we don't have time to find them. Some of them they discovered were put in with the personnel file in a different file. Like the medical file is in with about three other files that pertain to personnel records, then -- and other ones are in a separate box that has just medical records in it. So I think the more that you emphasize the importance of this, the better record-keeping we're going to have and people are going to get reminded. And it has changed hands because there are some people that do know the rules, some people that are professionals. As Bob knows, you encounter some people that

understand the whole process very well, and then you get others that don't have a clue.

DR. ZIEMER: Thank you. I think actually the memo to the Secretary will probably have to be limited to asking DOE to re-issue or to remind people about the storage issue. This is a whole additional thing on how DOE keeps its records or --

MR. PRESLEY: Right now this will be a great thing, too -- Bob Presley -- because DOE is in a process of trying to either upgrade or redo what they do with a lot of their records. They're right now in the process of redoing this, so it would be wonderful to get something out on this. This is the time to do it.

DR. ZIEMER: Is there a particular past memo that could be referenced to the Secretary that covers that, and then we can reference that and say the information that -- previously issued in memorandum such-and-so should be reissued? Okay, thank you. Staff will run that down.

DR. MELIUS: One other issue I think we talked about before. I just wanted to make sure everyone agrees it should be in our comments. That was from Mark's set of comments and it was number two, clarify the issue regarding SEC class applying

for non-SEC-listed cancers. I think what we were going to recommend and NIOSH said they were going to do was that they were going to work out procedures for dealing with these different situations. And then our recommendation for these -- for these set of regulations is that NIOSH review those and make sure that the current regulations would not preclude any approaches that might be used to deal with these situations. I think that's just sort of a technical legal wording issue. I don't know of any verbiage right now that might be a problem, but there -- I haven't looked at it from that point of view, but I think we ought to make sure that gets captured. And I don't think there's any objection to that.

DR. ZIEMER: What -- can you -- just so I have it in my record here, what section are we talking about? Is it on the regulation on the -- or the definition of the class and the listing of the --

DR. MELIUS: I think so, I just -- I don't want to pick on Ted, but I get worried if he misinterpreted or mis-spoke or got misquoted on it that -- was thinking of something and I'm just -- just want to make sure we're not -- I just hate to have to reopen the reg. just to deal with some minor

thing.

DR. ZIEMER: I think it would be the section that says the individual -- if they're determined to be part of an SEC class defined -- let me see. It's the issue of the non-SEC-listed cancers, is it not?

DR. MELIUS: Yeah.

DR. ZIEMER: And I'm looking for where that appears.

MS. MUNN: Well, the specified ones are listed in 83 -- is that --

DR. ZIEMER: Specified cancers, those specified cancers I guess is what we're talking about.

UNIDENTIFIED: Is it 83.11?

DR. ZIEMER: Section 83.11?

MR. KATZ: Can I make a suggestion? I think you're not going to find -- I mean I'm not sure what part of the rule we need to look at hard to make certain this concern is addressed. I think that's a real concern that Jim raised, and I think if you -- if it's enough that the Board specifies that -- their concern that classes of employees can be defined in such a was as not to preclude that sort of scenario, I think that'll handle it, and then we -- I mean it's going to take some serious looking to

see what, in the construction of this rule right now, might get in the way. But I don't think you're going to solve it quickly, flipping through the rule.

DR. ZIEMER: So this will be a general comment, not referenced to a particular section right now. Thank you.

Anything else?

(No responses.)

DR. ZIEMER: Now since all of this has been developed in the public meeting, can we then distribute the text to everyone and the web site prior to having a conference call? This no longer has to go through the working group, I believe would be -- okay.

So what I will do is collate all this with the additional verbiage that is provided and we'll get this distributed to everyone in preparation for a conference call, the time of which we will need to designate yet today. Is that agreeable?

Let's look right now at calendars, if we could, for that.

MR. ELLIOTT: And while you're looking for your calendars and your time, let me explain what will have to happen here. We'll have to announce in

the *Federal Register* that the Board will convene a conference call to deliberate and vote upon the language to present your comments on this notice of proposed rule-making. And we need to know today which day you want to have your conference call 'cause we're going to have to announce that early next week in order for it to be out there in time. And as we did the last -- the conference call back I think in February, we will allow the public an opportunity during that -- to listen in on that conference that you have and provide any comment at that point. Anything else, Cori, that I need to share with them on this? I think we -- we have to -- there are some things we have to put in place, like *Federal Register* notice. We'll get everybody lined up on a call-in number and get that out to you. But this should be the only real business you should take care of that particular day.

DR. DEHART: What's the earliest date, do you think, from your perspective?

MS. HOMER: From my perspective? When does this have to be placed by?

DR. ZIEMER: We need to have it by the 26th of August, and that's very -- probably very close to the earliest date that they can -- there's not a

whole lot of time. Today is --

MS. HOMER: Okay. Let's see if we can go for the 21st --

DR. ZIEMER: As the earliest.

MS. HOMER: -- or the 22nd as the absolute earliest.

DR. ZIEMER: Okay, let's just check timing, 'cause we need to also get stuff out to people for them to look at. How's the 26th itself, Monday the 26th?

DR. DEHART: Can you get that turned around to get it submitted then?

MS. MUNN: I don't think you can do that in a day.

MS. HOMER: Yeah, is it possible to submit it within a day?

DR. ZIEMER: If we agree on the telephone call -- who has to have it that day?

MR. ELLIOTT: It has to be postmarked that day. Postmark it to the Secretary and a copy that goes to the regulatory docket.

DR. ZIEMER: Okay, so we're better if we back it up a little bit, in case there's some changes.

MS. HOMER: What about the 23rd?

DR. ZIEMER: 23rd, Friday the 23rd -- bad? How many -- for whom is the 23rd not feasible? Not?

DR. MELIUS: Not. That's --

DR. ZIEMER: Not.

DR. MELIUS: -- good for me.

MR. GRIFFON: Not so good.

DR. ZIEMER: Not so good.

MR. GRIFFON: The 22nd is better, but I can do it if I have to.

DR. ZIEMER: 22nd? Is the 22nd okay?

MR. ESPINOSA: What time frame?

DR. ZIEMER: Well, in terms of New Mexico time -- we won't do it at 7:00 in the morning New York time.

DR. ZIEMER: Late morning? East coast time, late morning?

MS. HOMER: Late morning, early afternoon?

MR. PRESLEY: Early afternoon would be better for me.

DR. ZIEMER: Early afternoon? How is say 1:00 p.m. eastern daylight time?

MR. PRESLEY: On the 22nd. Right?

MR. ELLIOTT: About a week from today.

DR. ZIEMER: Is that enough time, Cori, one week?

MS. HOMER: Yes, that'll be enough time.

DR. ZIEMER: Can we get a recorder?

MS. HOMER: Ray?

THE COURT REPORTER: A week from today?

MS. HOMER: Yeah.

THE COURT REPORTER: Have this ready?

MS. HOMER: I'm sure we can get a reporter.

DR. ZIEMER: No, we don't need that ready.

MR. ELLIOTT: No, no, you don't --

The conference call, can you attend the conference call.

THE COURT REPORTER: Oh, a week from today?

MS. HOMER: Marie, how's your schedule?

MS. MURRAY: Oh, you want me on it, too?

MS. HOMER: Uh-huh.

MS. MURRAY: Hold on.

MS. HOMER: 1:00 p.m., how long do you expect the call --

DR. ZIEMER: One hour.

MS. HOMER: Just one hour?

DR. MELIUS: 1:00 p.m. eastern?

DR. ZIEMER: Is that okay for recorders?

THE COURT REPORTER: Yes -- well, she's checking. It is for me.

MS. MURRAY: Thursday's good. The 23rd's

not good. Well done, y'all.

DR. ZIEMER: So ordered. Open your e-mail just before the call. No, no, we'll try to get it out early in the week.

MR. ELLIOTT: We'll send an e-mail. We'll send it via e-mail and we'll also put it on the web site, and if anybody's in travel status or needs us to get it to them by Fed Ex or a hard copy somehow, we'll do our very best to accomplish that.

MS. HOMER: If you know where you're going to be ahead of time, I'm sure we can Fed Ex it to you.

DR. MELIUS: Can I ask one other --

DR. ZIEMER: You bet.

DR. MELIUS: -- quick procedural question. And this is something I don't understand at all, so hopefully somebody does.

We're talking about a number of changes to this document, and you're going to be developing a number of other guidance documents. You're going to be dealing with the issue of how to deal with the non-SEC cancers and so forth. Is there advantage to having this as a -- rather than as a final rule, as an interim final rule? Does that give you more flexibility in terms of being able to adopt some

other changes and sort of notify people that you're going to be working on this -- 'cause there are some things that aren't worked out here yet and...

MR. ELLIOTT: Go ahead, Ted, if you want to answer that.

MR. KATZ: Let me just explain what an interim final rule, issuing that would do. That would mean that you could operate and you could deal with petitions, but that at some point in the future you can produce then a final rule that changes things. Now I think you're still required -- if you change things substantially beyond what the public has had an opportunity to have input on, you would have to actually issue another interim final rule because you have to give the public opportunity. But -- so what it would -- the difference is, I guess, if we issue a final rule now and we want to change things, what we would have to issue later is a notice of proposed rule-making again and then go to a final rule. And the problem with that is the notice of proposed rule-making is not effective law. But I guess it'd be a -- you'd still be operating under your existing final rule while you were doing that, so you'd be changing an existing rule. So I -- I'm not entirely certain, you know, what the

difference would be, but certainly it would allow you to make changes in the future. Whether you'd have to issue another interim final rule or not would depend on what those changes were.

DR. MELIUS: But it just seems to me we're wrestling with a number of issues that we as -- being NIOSH, the Board here -- trying to determine this endangerment issue, how we'll make determinations in terms of there not being enough information, the issue of how do you do the non-SEC cancers and how we fit them into rule-making. And if there are advantages to doing it that way -- and plus at the same time we'll be gaining -- NIOSH will be gaining experience, we'll be gaining experience reviewing some of these situations. I think -- I can certainly see better information, more information coming from NIOSH as you're starting to review more petitions and recognizing different situations. Ted and I were talking at the break about acute exposures and which is the best way of handling them under -- in terms of looking at endangerment and I just think -- if there are advantages like that, I think it may be something that ought to be considered. Maybe we ought to recommend that it be considered as a way. And it

would also allow things to -- claims to be processed. At the same time it would sort of notify people that look, we're still looking at this and aren't -- you know, may make some changes down the road and are still considering changes to improve this process.

DR. ZIEMER: Any comments or reactions? It's -- Mark?

MR. GRIFFON: Yeah, I think that would also be -- I mean just the case history alone I think would be helpful to all the Board. You know, we're playing a lot of what-if games with different scenarios and how they're going to play out. I think it'd be useful for NIOSH, too, to see how this definition of endangerment is going to play out and how -- versus the sufficient accuracy side of things. So I would think that would be helpful to have it as a interim.

DR. ZIEMER: Wanda?

MS. MUNN: I don't know how I got on this see-saw with Jim and Mark on the other end. But aren't we in real danger of running up against time and energy limitations of both the staff and this Board every time we say oh, good, let's have another rule-making? Aren't we really creating some

potentially unsurmountable problems because of our concern over one or two issues that we would like to have very clearly delineated that possibly may never be delineated? I understand the rationale behind wouldn't it be nice if we could make this an interim, but I also foresee an enormous amount of time and public hearings and all that being done repeatedly, at great cost of both time and effort of everyone concerned. I don't want to shortchange anybody, but I have some real hesitation of saying oh, yeah, let's just make -- let's make this the in-between time and we'll think of a lot of good things in the meantime and have another rule-making. It seems like we're stretching ourselves and staff when we start thinking of not doing this in as crisp a manner as we can now. I know we're time-constrained now, but I can't imagine we'd be less so later.

DR. MELIUS: I guess I would -- if I understood the explanation why, it's to the contrary. This allows some changes to be made, certain types of changes, without having to repeat the whole rule-making process, so it should, if anything, save time and effort on the part of the staff and everyone else involved in looking at this, that there could be adjustments of this rule --

would allow the work to go forward, which we all want. We want this to go forward. At the same time it would allow some adjustments without necessarily requiring a full rule-making again. Now if they're going to make major adjustments, yes, that requires a full rule-making. But if they're going to make non-major adjustments -- which I think they may very well do --

MS. MUNN: Define non-major.

DR. MELIUS: Yeah, I know. It's sort of like a negative, you know, proving the negative.

DR. ZIEMER: I wonder if we could ask Ted, how difficult is it to make minor adjustments in a final rule, as compared -- what is the real advantage of an interim final rule, other than the nomenclature is --

MR. KATZ: Well, the final rule -- I mean I suppose it's not that hard if it's just a most minor technical adjustment, you can issue that pretty readily. But really otherwise, a final rule, you can't make changes without giving public notice and going through rule-making again. So again -- and I can't -- sorry about this negative bit thing here, but I can't tell you what the bright line is for what is substantial changes to the rule that the

public would not have been able to foresee, but I think there's language along those lines, really, that the public has to be able to sort of foresee how the changes arose out of what they were privy to, so -- that would trip it otherwise. So if you don't trip that line, then you can go from an interim final rule to a final rule that has changes in it, but they're just foreseeable changes, I think -- changes that arose out of what the public had to consider and the Agency had to consider previously.

DR. ZIEMER: It sounds like either way if the changes are substantial, then you still go through a much more extensive process. If the changes are not substantial, you don't have much process either way. So how does it differ?

DR. MELIUS: The advantage is -- I think the advantages -- I mean the technical change to the final rule are really minor things. You change the name of the Agency, and even sometimes that's gone to announced rule-making, but I think it's little technical things like that, or the decimal point missing or whatever -- you know, something like that. What we're talking, if there's adjustments to the rule that have been part of the public comment and have just taken some more experience to be able

to decide which is the best way to go and then you don't have to go through another process. So it has advantages for -- I hate to use this -- moderate changes as opposed to really minor.

MR. ELLIOTT: Well, I'm coming at this from a perspective of having to talk to the Secretary's office about this, and I know there's a considerable interest in the Office of the Secretary to put this in place to address the concerns of people across the weapons complex about wanting to petition. I would suggest to you that -- I don't know, I'm not saying this is what the Secretary would do, but I think the Secretary has some very conservative counsel that would speak in his ear and say until there is a final rule, you should not make a final decision on a petition. So if you're operating under an interim final rule and we need to be careful and cautious here about adding a class that we may wish we hadn't have added or it may not have been -- we have to go back and revisit that each time for everything that was -- every petition that came forward under the interim final and we took action upon.

I think that you have addressed this issue by making the recommendation about operational

guidelines. I think that's where -- I'm enthused by that. I think that's the appropriate place to handle these different changes that come forward. Those things -- those are the operational guidelines that you would see, you'd react to, you'd work with us on, and that's where we can -- I think we can gain some ground. But if you go forward, you want to go forward, that's certainly your prerogative as a Board to go forward with a recommendation. But I would just ask you to consider what you might be facing with the Secretary making a decision on a petition under an interim final.

DR. ZIEMER: I guess I would also be concerned about the public perception of an interim rule and what the implications of that might be with respect to how claims are handled, that it's kind of the picture that well, the system really isn't ready to go yet so how do I know my claim is really going to be handled the way it would or should be. I don't know what the perception would be out there. It may or may not be.

An interim final rule -- we're hearing a lot of -- you know, people are dragging their feet getting this system in place. It sounds like -- it sounds like the Agency's dragging along again.

That's what I'd be concerned about.

DR. DEHART: Roy DeHart. I think the potential downside from the political perspective could be severe here if they decided not to start allowing us to review petitions. We can't afford that. We can't -- we can't be seen by the claimants as being obstructive. We've got to move forward, I think.

DR. MELIUS: I think we can couch our recommendation -- we're making a recommendation. They can consider it. They -- it can be outweighed by counsel's advice that the Secretary shouldn't make a designation until they've got a final rule in place. We've gone from -- this was guidelines to regulation, and I -- so who knows where the right place to stop is and I think we put forward -- it has some advantages. If it has a serious downside like that, then I would hope that the Secretary would not listen to us. I suspect the Secretary wouldn't listen to us in that case. But we don't know that and I think Larry's speculating, probably on more facts than I have and more experience with this, but let's -- if it would help. I don't think it's -- if it's -- people see that things are being processed, then it won't be a perception issue. If

it's -- holds up processing, yeah, obviously people are going to be concerned. If anybody sat here and listened to us today in trying to -- wrestling with all this stuff, they'd probably be glad we get anything recommended and out, so...

DR. ZIEMER: Further comments on this?

(No responses.)

DR. ZIEMER: Again, I think this is one where there's a little bit of a split and the possible solutions would be either, one, to vote it up or down, or two, to indicate in the cover letter that some of the members have suggested that the interim final rule process be considered. Is that --

DR. MELIUS: Yeah, I think that's proper.

MS. MUNN: I'd prefer to vote it up or down.

UNIDENTIFIED: Make the motion.

MS. MUNN: I move that we vote up or down. I would prefer that this become a final rule.

DR. ZIEMER: That's sort of two motions. Are you making a motion that we vote on this issue or are you making a motion that -- what is your motion?

MS. MUNN: I move that we vote on this issue.

DR. ZIEMER: Okay. And is there a second to that?

DR. MELIUS: Well, are we going to vote on it today or at the telephone conference call?

MS. MUNN: No, now.

DR. ZIEMER: The motion is to vote on this now as to whether or not it appear in the document. Is there a second to that motion?

(No responses.)

DR. ZIEMER: I hear no second. So do I interpret that to mean that the others -- I don't know fully how to interpret that at this point.

Tony, did you -- are you making a motion?

DR. ANDRADE: Yeah, I'd like to make a motion here. I'd like to be as specific as I possibly can be. I'd like to move that we vote up or down on whether the rule go forward.

DR. ZIEMER: As a rule?

DR. ANDRADE: As a rule, with recommendations sent to the Secretary that have been adopted today. However, and this may be a different motion, with respect to the two -- I believe two issues that exist, that those issues be taken care of in language to be adopted in either guidelines or a preamble to the rule that will go forward. It's

complicated. It's a complicated motion, but it's -- I think it handles everything all at once.

DR. ZIEMER: As I understand the motion, which is not yet seconded, it's a motion to adopt all of the items that we've previously discussed, although we don't have the wording before us, which, if adopted -- I'm not sure what that does and we still are going to need the wording, right, for -- and we had already agreed to a meeting at which we would vote on this, but nonetheless, your motion is to adopt now those items that we had previously discussed. Is that -- and that did not include this issue of interim rule or was that part of that?

DR. ANDRADE: What is the best way to proceed?

DR. ZIEMER: All you've covered is everything but the interim rule, because the other items I think we've agreed on how we're going forward. We haven't agreed on the interim rule issue, so your motion would be to basically adopt the others. I think we still need to refine the wording though.

DR. ANDRADE: Okay. Then let's take it step by step. In which case, I move that we do not pursue a path that includes an interim final rule.

DR. ZIEMER: Okay. The motion to not pursue a path that includes an interim final rule is essentially a motion not to say anything in the document to the Secretary about an interim final rule. Is that -- is that the motion?

DR. ANDRADE: That's the motion.

MS. MUNN: Second that.

DR. ZIEMER: And that's seconded. Now discussion on that motion. Mark?

MR. GRIFFON: Well, I mean I think several Board members have addressed this as a possible -- this sort of resolution -- potential resolution to this problem of operating in a vacuum of how these cases or how these petitions are going to fall out. And I think that's -- that's part of the reason -- and actually Henry Anderson at the last meeting made this as a recommendation -- or I don't know -- you know, not a formalized recommendation, but he brought this concept up of a possibility of an interim final rule, so I think a number of us feel that that might be -- and you know, understanding -- and I agree with what Jim pointed out, that you know, these -- if there's downfalls, then the Secretary's going to consider both sides and, you know, make that decision. But there is at least

some up side to it. We feel there could be some benefit to that, or some members feel there could be some benefit to that.

DR. ANDRADE: That's precisely why I'm calling for a vote.

DR. ZIEMER: The vote -- if you vote yes, that will mean that the document does not say anything about an interim rule. If you vote no, that provides, if desirable, an opportunity to state that some members have this concern.

DR. MELIUS: I have a -- yeah.

DR. ZIEMER: It would not necessarily have to be a recommendation.

DR. MELIUS: I guess I have a procedural concern about our committee. We've operated by consensus and by adopting documents that reflect that consensus and not by voting on individual recommendations. And I think we're in a little awkward spot here because we had -- led to believe there would be a conference call -- a document produced and that we'd be reviewing and voting on -- agreeing on -- or reaching -- trying to reach agreement on particular language, and we really haven't completed that process. And just sort of changing our procedures and our approach and sort of

-- certainly has some implications for how long the conference call will be a week from Thursday.

DR. ZIEMER: The Chair is going to call a five-minute comfort break while you chat amongst yourselves.

(Whereupon, a recess was taken.)

DR. ZIEMER: Are we all comfortable again? Before we were so rudely interrupted by the Chair, I think that -- I think to some extent, Jim, what I heard you saying, through my discomfort, was that a sort of plea for operating on this issue in a similar manner to some of the others and maybe allowing the document to the Secretary to suggest that at least some members suggest that the Secretary consider this as a possible path to take, but if that were done, it would not have the weight of being a recommendation of the full committee but would at least raise the issue, I think is what you --

DR. MELIUS: I think that's correct. That's fair to --

DR. ZIEMER: And so I guess I'm interpreting what the outcome of a vote, if a vote is yes, to sustain the motion, then the note to the Secretary would not mention this issue. A vote to defeat the

motion would keep the door open for what you're sort of requesting, and that is to allow this to be mentioned as a sort of -- I don't know, minority report or something like that, or at least --

DR. MELIUS: Well, I'm trying to avoid minority --

DR. ZIEMER: No, no, no, it wouldn't have such words, just say some of the members have suggested.

DR. MELIUS: Right. Much as we've tried to make sure members who aren't here are available and get to participate and review things, I think this is similar to what's -- it should try to reflect what the committee has talked about. And there may be times when we do need to vote on these issues. I don't want to preclude that 'cause that's a way of evaluating how we -- what we believe and so forth. But at the same time I think if we can deal with it sort of through the wording and sort of reflecting what we've recommended, I think -- I'd prefer that, but --

DR. ZIEMER: If the motion were defeated, the issue would arise in the final document again in terms of the wording itself. Tony?

DR. ANDRADE: I just wanted to say that I

have no objection to continuing the discussion. And what I'm proposing here is really a two or three-step process that will be followed. Number one is determining whether this body believes that there is value-added in holding -- or standing up an interim final rule. That's step number one.

Step number two is to have our telephone -- our teleconference, during which time we will discuss the final language that we will be suggesting for the final rule, whether it exists in the preamble or in the body of the rule itself. And perhaps at the same time people will have thought through some of the questions that have been brought to -- brought up on the floor and maybe we'll have -- or somebody will have a clearer definition from the staff or from among our body.

Or we will decide at that time -- which might be step number three -- to address these I think last two issues that we're grappling with, which are difficult, but nevertheless I think handleable in the long run. For example, in guidelines that will be developed or some other vehicle.

So again, I'm not proposing to break up the way we've normally done business. It's just that

the only path forward that I can see at this particular point so that we can move on, allow NIOSH to begin its work as quickly as possible, and for us to get as much of those things that we are in consensus about into the rule as quickly as possible, is to go down this path --

DR. ZIEMER: To the final rule.

DR. ANDRADE: -- to the final rule.

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

MS. MURRAY: May I ask for clarification on the two issues, whether it's an interim final rule or not? Those are the two issues? What are the two issues?

DR. ZIEMER: The motion is to whether or not this committee would include in its recommendation to the Secretary that he consider issuing this as an interim final rule or not. The motion was that it be issued as a final rule, so voting yes for the motion is to preclude its being discussed in the letter as an interim.

MS. MURRAY: Gotcha. Thank you.

DR. ZIEMER: Is that everybody's understanding? So if you vote yes for the motion, you are voting to identify it as the final rule, in

which case nothing is said to the Secretary. Voting no doesn't -- it doesn't preclude stating that some members suggest it be issued as a final rule. Okay.

All who favor the motion, say aye.

(Affirmative responses)

DR. ZIEMER: All who oppose the motion, say no.

(Negative responses)

DR. ZIEMER: Okay, I'm going to call for a show of hands, so all in favor, raise your hand. One, two, three, four in favor.

All opposed, raise your hands. One, two, three, four. The Chair votes against the motion. The motion dies -- or is not carried.

Okay. Now I think we're back to where we were. We will vote on the full document at the telephone conference. I will ask Jim for an additional sentence or two on that interim rule issue. You still have an opportunity to wipe it out, if his words aren't good enough, at the final vote.

The time of the next meeting. Actually there is one other item that -- there's housekeeping issues. Maybe I will ask that we at least have on the record this item that was raised by a member of

the public raising concern about the -- not by a member of the public today, but by a member of the public in an e-mail to me -- concern as to whether NIOSH had sufficient staffing to actually handle the workload that is before them. This is a little bit difficult forum to discuss that because if you ask any manager in a Federal facility if they need more staff, that's an automatic yes. But on the other hand, it could be discussed in the framework of what the Board sees as the workload and a little bit of feeling now, at least by the working group, is the staffing level. And knowing that a contractor is to come aboard soon and help with the real dose reconstruction -- I guess I will only ask the Board, are you concerned about the workload and the staffing levels, from what you see?

DR. MELIUS: Yes.

DR. DEHART: Yes.

MR. GRIFFON: Yes.

DR. ANDRADE: Definitely.

MR. PRESLEY: Definitely.

DR. ZIEMER: Let the record show that virtually all the Board members expressed some concern about the staffing levels.

Now do I interpret that to mean that you all

feel that there's too many staff members?

(Laughter)

DR. ZIEMER: There is a general concern amongst the Board that the staffing may be pretty minimal for the job that's ahead. I'm not sure that it's appropriate for us to raise this with the Secretary as an issue at this point because I don't know that we have all the facts in terms of what the workload is. Perhaps when the contractor comes aboard very soon, we will have a better feel for this and can address it in the future. I at least, as a starting point, wanted to have it on the record. And perhaps we would even put it on our little action item as something we want to look at on an ongoing basis to make sure that the staffing level is sufficient to carry out the mandate of what is before you.

Again, I want to make it clear to everyone that Larry has not had any contact with me on this issue to ask me to raise this. This has come from a completely different source, member of the public, and I just wanted to at least see if that reflected everyone else's sort of perception of the issue. Anyone have any particular additional comments along this --

DR. MELIUS: Given the hour, I will try to make this very short, is that I think I would ask for the agenda for the next meeting to include an update on hopefully the contract's awarded, how that contract's going to be managed, how we stand in the claims process and what we foresee -- the staff foresees down the future to -- in terms of handling this program so that we can have some discussion.

DR. ZIEMER: Thank you. Okay, administrative housekeeping. Cori, what items do you have for us?

MS. HOMER: Well, most of you have at least sent in a voucher and it's been prepared. Not all of you have been reimbursed. I think there's one that I received --

DR. ZIEMER: Previous meeting, right?

MS. HOMER: From the previous meeting. There is one I received and was not able to get to, as it got to my desk the day before I left.

Salary issues, if anybody has not been paid, please let me know.

One more item 'cause the fiscal year is closing. I need your vouchers mailed back to me as soon as possible. I must have them on my desk within two weeks. We have to file an annual report

and that has got to be compiled -- the costs of the Board, including travel, has to be compiled prior to that report being prepared.

Also, roster changes. If any of your information has changed on the roster, if you would like to switch addresses from your home to your office or vice versa, please let me know so that I can update the agenda.

And if you haven't already done so, please let Larry know -- write down your time, preparation time and outside time getting ready for either the work group and/or the Board meeting, and let Larry sign off on that and give it to me so I can submit it for salary payment.

DR. ZIEMER: Okay. Thank you.

MR. ELLIOTT: I would like to add to Cori's list that if your employment status changes or anything on your OGE-450, you know what that thing is; that's your declaration of conflict of interest issues, we need to call for that again. So if any employment change happens or anything changes that would reflect upon that form, please file a new form and call me and we need to discuss it. Thank you.

DR. ZIEMER: Now time of the next meeting. We had blocked off -- at least according to my

calendar -- October 15 and 16 as a possible date. I think we had a back-up date, also.

MR. ELLIOTT: I think we had 14, 15 and 16.

DR. ZIEMER: And November 18th and 19th was also blocked off.

Okay, October 15th and 16th is basically two months from now. We are assuming, I think, that the dose reconstruction -- or the contractor will be up and running by then. We have some items on our master list to address. We have perhaps some dose reconstruction groups to be underway, perhaps, and test out the system and so on. Is October still good?

I had a note in my book that we were thinking about meeting in Santa Fe. Is that still good for y'all? Richard say oh, yeah. And do we know logistically, Cori, or staff, is that --

MS. HOMER: I actually have checked into a couple of sites --

DR. ZIEMER: Okay, so that's --

MS. HOMER: -- independent contracts on that basis.

DR. DEHART: Was there a holiday problem?

MS. HOMER: Yes, it was a government holiday on the 14th.

DR. ZIEMER: On the 14th.

MS. MUNN: Columbus Day. It doesn't keep me from traveling.

DR. ZIEMER: Is it a major problem?

MR. ELLIOTT: It's not a staff issue.

DR. ZIEMER: Right. Then we will proceed with those dates for Santa Fe. It appears to be still clear on everybody's calendar. I think we'll have plenty of items to address at that point.

Do you anticipate, Mark, that any of the working groups would meet ahead of that or --

MR. GRIFFON: The panels? No, we won't have a -- I mean we're hoping that we -- at least by conference call -- start to resolve and start the procurement process --

DR. ZIEMER: The procurement process and maybe --

MR. GRIFFON: I doubt that we'll have --

DR. ZIEMER: Okay, but you can work --

MR. GRIFFON: Right, right.

DR. ZIEMER: Okay. Any other comments on that? Then we'll proceed with that schedule, develop the --

UNIDENTIFIED: And the dates are?

DR. ZIEMER: The actual meeting dates would

be the 15th and the 16th, so many will have to allow the 14th for travel and the 17th for travel.

We do have on the agenda one last opportunity for any other public comments. I have not received notes that there -- oh, Bob? Okay, thank you. Bob, please proceed.

MR. TABOR: Can I do that from here?

DR. ZIEMER: Yes.

MR. TABOR: Bob Tabor again, for the record. Folks, all's I wanted to say is one thing, and it's not real specific upon me -- it's not real specific about the fine detail which you're involved here. It's kind of an over-arching comment. But at one of the meetings I pointed out that -- do not forget that we need to do the right thing right the first time and do the right thing right for the right reasons. If this stuff is not really clear and not clean and it's not ready, I would beg you, don't do it until it is. And if it requires extending or whatever kind of process you go through to say hey, we need more time, I think that from a worker perspective I would rather wait to have something right than to take and rush ahead just to show progress. You know, for whatever those words are worth. So if you need additional time, you know,

even in your public comment period, I know it's done many times in the government stuff. They set a date, but you find that there's a lot of interest out there in a particular topic matter and people will request -- we want more time to take in comment on this and work through this. And I'm just saying I know you're doing your very best. But you know, from a worker perspective, please, do the right thing right, as best you can the first time and for the right reasons. And if you need more time, take more time.

DR. ZIEMER: Thank you, Bob. That's basically measure twice and cut once. Right? For the tailors. Right? Thank you.

Any other items to come before us?

(No responses.)

DR. ZIEMER: Anything for the good of the order?

(No responses.)

DR. ZIEMER: If not, we're adjourned.

(Meeting adjourned at 4:50 p.m.)

C E R T I F I C A T E

STATE OF GEORGIA :

:

COUNTY OF FULTON :

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the 14th and 15th day of August, 2002; and it is a true and accurate transcript of the proceedings captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 14th day of September, 2002.

_____

STEVEN RAY GREEN,
CERTIFIED MERIT COURT REPORTER
CERTIFICATE NUMBER: A-2102