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

convenes

WORKING GROUP

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

PROCEDURES REVIEW

The verbatim transcript of the Working Group Meeting of the Advisory Board on Radiation and Worker Health held telephonically, on April 2, 2008.

STEVEN RAY GREEN AND ASSOCIATES
NATIONALLY CERTIFIED COURT REPORTERS
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C O N T E N T S

April 2, 2008

TRANSCRIPT LEGEND

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

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-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

-- “^” denotes telephonic interruption.

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

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P R O C E E D I N G S

APRIL 2, 2008

(1:00 p.m.)

OPENING REMARKS

DR. BRANCHE: I'm Dr. Christine Branche, and I have the pleasure of being the Designated Federal Official, as well as the Principal Associate Director of NIOSH. I'm the Designated Federal Official for the Advisory Board on Radiation and Worker Health. And this is a meeting of the Procedures Working Group.

If the Advisory Board members could please announce their names, please.

MS. MUNN: This is Wanda Munn. I'll chair this meeting.

DR. ZIEMER: Paul Ziemer.

DR. BRANCHE: Are there any other Board members?

(no response)

DR. BRANCHE: Well, so far we don't have a quorum of the Board so we can continue. Would the NIOSH staff please identify themselves?

MR. ELLIOTT: This is Larry Elliott, Director of OCAS, NIOSH.

DR. NETON: Jim Neton from NIOSH.

MS. ^: ^ from NIOSH.

MR. HINNEFELD: Stu Hinnefeld from NIOSH.

DR. ULSH: Brant Ulsh from NIOSH.

DR. BRANCHE: Will the ORAU staff please announce their names?

MR. SIEBERT: Scott Siebert, ORAU team.

MS. THOMAS: Elyse Thomas, ORAU team.

DR. BRANCHE: Would the SC&A staff please announce their names?

DR. BEHLING: Hans Behling, SC&A.

DR. MAURO: John Mauro, SC&A.

MR. MARSCHKE: Steve Marschke, SC&A.

DR. BRANCHE: Would other federal agency staff please announce their names?

MS. HOWELL: This is Emily Howell with HHS.

DR. BRANCHE: If there are any petitioners or their representatives, would you please mention your names?

(no response)

DR. BRANCHE: Any workers or their representatives please?

(no response)

DR. BRANCHE: Any members of Congress or their representatives please?

(no response)

DR. BRANCHE: Are there any others on the line who would like to mention their names?

(no response)

DR. BRANCHE: If we could please acknowledge telephone etiquette. We are all participating by telephone so if you would please mute your lines while our discussion goes on so that the speaker can be heard by all parties especially our court reporter. And when you're ready to speak you can unmute your line. If you do not have a mute button, then please use star six to mute the line. And then when you're ready to speak you can use star six again.

One more time for Mark Griffon?

(no response)

DR. BRANCHE: Michael Gibson?

(no response)

DR. BRANCHE: Robert Presley?

(no response)

DR. BRANCHE: Okay, Ms. Munn, it's all yours.

INTRODUCTION BY CHAIR

MS. MUNN: Thank you. With the concurrence of those of us who are online, I'd like to

propose one mild addition. I think it's not a mild one; it's a big one. When I sent you a reminder yesterday, I reminded you about the primary document that we want to attack which is SC&A's review of our procedures and methods, PER number nine.

I also mentioned a quick run down of the action list, whether we need to do anything between now and next week. One item I failed to put on, and that I do want us to touch upon, I'd like that to be the second item today, is the draft that Steve Marschke has provided us of the overview of the summary results of the first set of those 33 procedure reviews.

We've seen that material before in a slightly different format, and it does not appear to me that there will be a very large amount of discussion here other than I have a number of comments to make with regard to format and have not gotten those to either Steve or to Paul. So I'd like to discuss that after we've attacked PER-9 if that's agreeable with everyone here. Am I taking us too far afield from our primary objective or is that

okay?

DR. ZIEMER: Let's give it a try.

MS. MUNN: Very good.

DR. ZIEMER: That's Ziemer speaking.

MS. MUNN: Thank you, sir.

DR. BRANCHE: Ms. Munn, this is Christine. Just one more item. I just want to let you know that off line I am trying to get in touch with the remaining Advisory Board members.

MS. MUNN: Excellent, appreciate that. Thank you.

PER-9

Let's take a look at what Hans has prepared for us as their review for PER-9. This is a very heavily technical document which requires a significant amount of attention I think for more reasons than one. I'm sure that NIOSH has had an opportunity to take a look at this now.

And if it is amenable with you, Larry and Jim, I'd very much like to get some reaction from you before we begin our full-scale discussion on the contents of this document. I do hope that all of us have had adequate time to absorb what's here because

it's going to impact quite obviously a number of dose reconstructions.

Larry or Jim, do you have some comments that you'd like to make before we go further?

MR. ELLIOTT: Ms. Munn, this is Larry Elliott. I'm going to start off here and turn it over to Brant Ulsh who is going to carry most of our water on comments regarding this review. What I'd like to start with though is that I want to set the record straight, the history here a little bit straight.

I'm a little bit concerned that this review that has been developed by SC&A portrays or presents the issue of this change and how we go about assigning a target organ for lymphoma as being driven or initiated by a prior SC&A dose reconstruction report review.

And that is, you know, I do appreciate all the hard work and all the effort that SC&A puts into their reviews, but the reality and the facts are that we were well aware of how we were handling lymphomas and other things like this. And that started actually with a NIOSH-sponsored meeting on CLL probably -- I

don’t have the timeframe completely down in my mind. But, okay, well, I do now.

MS. MUNN: It was a number of years ago.

MR. ELLIOTT: July 21st, 2004, there was a meeting in D.C. on CLL, and that’s where the OCAS scientific staff started thinking about are we assigning the correct organs for lymphoma dose reconstructions. And so that’s where we started picking up this line of inquiry. And certainly the review of the dose reconstruction case confirmed our efforts and reinforced our efforts to try to do a better job for lymphoma claimants. But I just want to take a little bit of exception here that it was not SC&A’s review that started us down this scientific trail of making sure that we’re giving full advantage in our dose reconstruction on lymphoma claims.

MS. MUNN: It’s a point well taken. I notice there was a reference very late in the report about that early concern over CLL and the meeting that was held. But --

MR. ELLIOTT: I don’t mean any disrespect, Hans, to you or to SC&A. But I just want to make sure that we’re all clear in our

understanding of how this all started off.

DR. BEHLING: And let me just point out if there was any prior discussion, this was something that we were not aware of --

MR. ELLIOTT: That's absolutely correct.

DR. BEHLING: -- at the time when we reviewed the first set of cases, and one of which was a Hodgkin's lymphoma, this was something we weren't aware of. And as I showed in my Exhibit 1 on page ten of the report, I guess in 2005 the Board action number three says SC&A for that particular case stood fast on the issue of not necessarily making a change to that.

DR. NETON: I think, Hans, by our current methodology we probably would do that case the same way because that's a Hodgkin's lymphoma.

DR. BEHLING: Well, it was among the 528 cases that was subject for review.

DR. NETON: That's what I'm saying. In that particular response I think our response would stay the same, that the Hodgkin's lymphoma would be defined by the site of diagnosis for our physician's examination of the facts. It's not inconsistent with what we responded

there. But it's true. We did not go into any length at the time to talk about our activities behind the scenes --

MR. ELLIOTT: We were pre-decisional at that time. We were doing our own research into this. Doing our own scientific fact-finding and trying to arrive at our position. And you're correct, Hans. We had not shared that on the outside, and so you were unaware of that, and I appreciate that. I just want to make it clear to folks on this phone call that we were working this problem back in, late in 2004.

MS. MUNN: And I do remember the discussions, some of the discussions that took place. I'm not sure I was present at all of them, but I recall that having been an issue that we were well aware of on the Board. Perhaps this can be resolved by the simple insertion of a sentence somewhere in the Executive Summary or near the beginning of the report to indicate that all of the parties involved had been concerned about this for a significant period of time, and that although SC&A had not been directed to do so and was

not aware of the information, NIOSH was working on it.

MR. ELLIOTT: I think that's up to SC&A and how they want to treat the report in that regard. Let's put that aside now. I think Brant and Jim have several other comments that are more pertinent perhaps to our deliberation and discussion today and moving us forward. If we could return to that, I think that would be beneficial for all.

MS. MUNN: The technical issues appear to be the tough ones here, and I'm assuming that's going to be Brant's bucket.

DR. ULSH: Yes, it will, Wanda. If it's the Board's pleasure, I'll start going into the technical issues here. First of all, let me acknowledge that I am not a hematologist. I don't think anyone on the call is. And for that reason once those concerns were expressed to NIOSH, and we started looking into this issue, I did some preliminary research. And it quickly became clear that we would need some hematology expertise. And so we contracted with Dr. Mark Crowther at McMaster University.

Dr. Crowther's a very well qualified hematologist. He has Board certification, a master's degree in clinical epidemiology as well as an M.D. in hematology. And we engaged Dr. Crowther as a contractor to review our selection of target organs for lymphoma and for leukemia.

And we had several conversations with Dr. Crowther throughout 2004, and it culminated in his report which Hans has attached as an attachment to the SC&A report. At one point I sat down on a phone call with Dr. Crowther and asked him to give me kind of an educated layman's view of this whole issue. And that might be helpful if I relate that to you all.

Basically what we're talking about when we're talking about lymphoma, or there's a couple of broad categorizations. Mainly, if you think of the lymphatic system as a system of, well, a plumbing system, pipes that run throughout the body.

And lymphomas can be broadly categorized into two different types. One is cancers, solid tumors, of the plumbing system

itself, the pipes, the cells that make up the lymphatic system. And those are one category. The other category is cancers that occur in the lymphatic system as a result of what flows through the pipes. Now we're talking about circulating lymphocytes. They get trapped out in particular lymph nodes and develop tumors where they are trapped out.

Now as Jim mentioned earlier in the discussion of the case that Hans cited, Hodgkin's disease falls into the category of cells or cancers where the cancer occurs in the pipes, in the material that makes up the piping system itself. And so on that basis Hodgkin's disease and a couple of other types of lymphomas, well, there's a couple of other, yeah, lymphosarcoma, for instance, and a couple of others.

Those can be, it can be inferred from those that the site of original radiation injury is the site where you see the tumor. So, for instance, there is a mass of lymph nodes in the groin area, and if you see a tumor in the groin area, lymph nodes in the groin area, you can assume that that's where

the radiation interacted with the cells to later become a cancer.

Now contrast that with the other type of lymphomas, and these are primarily non-Hodgkin's lymphomas. These are cancers of the material that flows through the pipes. And so they're circulating all through the body, and the radiation interaction could have occurred anywhere in the body. And they get trapped out in a particular lymph node. Now for those the site where you find the tumor is not informative about where the original radiation injury occurred.

And so for those cases we decided, with the advice of Dr. Crowther, to consider a claimant favorable estimate. What could be the highest plausible location that we could give? And we had originally, I originally -- because I wrote the first TIB -- went with LNET, the lymph nodes at the extrathoracic region.

Now I want to make it clear that these distinctions are internal dosimetry. They're health physics distinctions. They're not based on hematology. So when Dr. Crowther

reviewed the first version of the TIB, he said, yes, this was, our report basically reflected our discussion about these two different types of lymphomas.

Subsequently, to get an expert health physics review, we submitted our report to Keith Eckerman, who is a very well known internal dosimetrist. And Dr. Eckerman suggested that we consider the thoracic lymph nodes instead of the extrathoracic because they gave a higher dose. And so we made those changes. But that was not in contradiction to the advice that Dr. Crowther gave us. Rather, it was from a different perspective, a health physics perspective.

But the bottom line is this report as it exists now has been vetted by, well, I would say one of the world's foremost experts in hematology and also one of the world's foremost experts in internal dosimetry. And both of them have agreed with the way this report currently stands.

Now I'll let Hans speak more about SC&A's concerns. I don't want to paraphrase and perhaps misstate what their concerns are.

But it does concern me that the references that are cited in support of that are a 30 year old hematology textbook.

I mean, there's a lot of advances as I think everyone will agree not only in hematology but in medicine in general. And the cases that we see today, the ICD codes are assigned today by the Department of Labor based on the medical records that come with the case. And so they reflect, you know to the best that we can, today's medical knowledge.

And so while I certainly appreciate the difficulty in making ICD diagnoses, that's not something that NIOSH does. That's not our role. That's the Department of Labor that does that. And claimants always have the option of questioning that and appealing that to DOL if they feel that the ICD designation is in error. And frequently, actually, when we notice that an ICD code might be in error, we raise it with the Department of Labor.

But in this case I just don't see that we can actually agree to SC&A's recommendations because they go against the

advice of the experts that we've consulted. And quite frankly, the way that we have this TIB right now, it is extremely claimant favorable.

And if we were to take SC&A's advice and throw in the other types of lymphomas, the ones that are cancers of the piping system themselves, and make them the target organ being the thoracic lymph nodes, it would lead you to a situation that doesn't mesh with reality here. And what I'm talking about here is Hodgkin's disease, for example, is, well, quite frankly, there's not solid evidence that it's even related to radiation now.

Of course, we take the uncertainty into account and so allow for that possibility in the risk model. But if we were to assign thoracic lymph nodes as the target organ for Hodgkin's disease, that would make it one of the most compensable, or probably the most compensable, cancer in our program. And this is for a cancer that there is no evidence that it's even radiogenic. That is an illogical outcome.

And, I mean, numerous epidemiological

studies have examined Hodgkin's disease, and there's simply not been observed any relationship that would suggest that we should pursue this course. So I'm concerned about that.

MR. ELLIOTT: If I may, as I understand it there's a recommendation from SC&A here to revisit a large number of claims that they feel is affected by their review comments. And I think we need to, in Brant's comments about that, I want to point out that we don't think it's necessary to revisit those claims. And we're worried here that this is going to cause this report and this particular comment/recommendation is going to cause further and more frustration on behalf of these claimants.

DR. ULSH: To sum it up I think we've faithfully, well, I know that we have faithfully reproduced or incorporated the advice from the experts that we consulted in our TIB. I think the program evaluation, that report that we conducted in association with this TIB, accurately reexamined the cases that were affected, and the outcomes are accurate.

So I just don't see any need to, as Larry said, go back and revisit these cases yet again. I'd be happy to --

MR. ELLIOTT: That's just kind of the bottom line of where we're at. We certainly can get into the weeds on the technical issues presented here, but I just want to make sure that you Board members are aware of our concern here.

MS. MUNN: Yes, my primary concern in going through this once I overcame my resistance to extremely technical language which is necessary in a review of this kind, was the suggestion that such a large number of cases might need to be reviewed.

DR. MAURO: This is John. I'd like to offer a perspective that may be a little different than what I heard. And that is we actually were not able to complete all the different subtasks that made up this report. Because the last step in our scope of services was to select three cases and actually do a ground truthing, so to speak, related to how, in fact, the PER was implemented and in light of the concerns that we raised regarding

diagnosis. What really came out of Hans' report -- and certainly, Hans, you can step in here and correct me --

DR. BEHLING: Yes, I'm waiting my turn here, John.

DR. MAURO: Yeah, I know, but I just want to say that I think that we really were looking for some help in that we believe that if, given the landscape of the problem, we felt that there was a potential for incorrect assignment of ICD codes to particular, for some cases given the nature of this problem and given the fact that many of these diagnoses were performed many years ago.

So given that as a valid perspective we felt that within the 400 or so cases that were denied, it would be helpful for us to complete our work to find a way to identify those cases within the ones that were denied to see if it's possible that some of these potential missed diagnosis issues were, in fact, real.

And so the way I understand it, we were at a point where Hans didn't recommend revisiting the cases but recommended a process

where perhaps we can select -- we proposed three in our original work plan -- cases amongst the ones that were denied that might be the final proof of principle that, in fact, the methods that were used to assign ICD codes to those denied cases are ones that would be good test cases to see, in fact, if the potential problem that we identified was real or perhaps wasn't for the very reasons that you just gave, Brant.

So I think that that's how I saw, the purpose of this call was to see first of all if there was a general agreement that the scope of our work would include doing some cases, and also, seeking some help and given the nature of the problem in identifying the cases that we would look at.

MS. MUNN: And, John, I was under the impression that this work group would indeed identify some number of cases for you to review again. However, my concern at this juncture is with the process that was suggested to provide us with a list from which to make this choice. It's very difficult for me to imagine the amount of work that would be

necessary for NIOSH to be able to provide a list of the types that were suggested here.

DR. ZIEMER: Wanda, this is Ziemer. Could I ask and maybe direct this to John Mauro.

John, are you talking about a determination of whether the code was assigned correctly?

DR. MAURO: It's really related to, as I understand the problem, the assignment. In other words in revisiting, in this PER, one of the things that was done is say let's revisit all of these denials. There were 500 or so as a result of the PER. And in the process of revisiting it there were assignments made as to what cancer type each of those 500 or so cases should be appropriately assigned. Some of them were assigned to thoracic lymphomas, cancer of the lymph nodes of the thoracic region and some for other organs.

And what happens is there was a sorting process. And as a result of that sorting process, as I understand, there were a number of cases where the dose was reconstructed and there was, and people were granted where formerly they were denied. Our

only concern was that amongst those that were denied, our argument was that we think that in making the determination of the proper assignment --

MS. MUNN: I'm hearing serious telephone break up. Is that John?

DR. MAURO: I will speak directly into my headset. Is that better?

DR. ZIEMER: Yes.

DR. MAURO: Okay, I'm sorry for that.

DR. ZIEMER: There is some background noise as well.

DR. MAURO: Oh, okay.

MS. MUNN: I'm hearing muddled conversation. Is it my phone?

DR. ZIEMER: I'm not hearing that.

DR. BRANCHE: I'm not hearing that, Wanda.

MS. MUNN: Now, there's something going on. Is it my phone?

DR. BRANCHE: Well, it wasn't your phone before, but I just want to let you know that Michael Gibson has joined the line and Mr. Griffon will be joining soon.

Those of you who are on the line who are not speaking if you could please mute your

phone, we would appreciate it. If you don't have a mute button then please use star six. And you can use star six again to unmute your phone when you're ready to speak. Thank you.

MS. MUNN: I was getting --

DR. BRANCHE: I'm still hearing something, but I think it's just background telephone noise. I don't think it's conversation.

MS. MUNN: All right. I was hearing Larry fading out badly for me and so was, I think, Hans was trying to speak. I was getting nothing but static from what I thought was Hans. Was I the only person who was getting that?

DR. ZIEMER: Apparently.

DR. BRANCHE: I heard Hans clearly.

MS. MUNN: Well, then it must be my hotel phone here. I'll just try to get by.

MR. GRIFFON: Wanda, it's Mark Griffon. I just joined, too, just to let you know.

MS. MUNN: Hi, Mark, good.

MR. GRIFFON: Sorry for being late.

DR. ZIEMER: Wanda, my question was, well, maybe Larry can help on this, too. The coding is done by DOL. Is that not correct?

MR. ELLIOTT: That is correct.

DR. ZIEMER: To what extent -- and you use that code, but the dose reconstructor then, in terms of this issue, if they decide that the -- who decides whether the cancer is in -- I'll use Brant's words -- the plumbing or the circulating cells? Does the code tell you that?

DR. ULSH: Dr. Ziemer, if I could answer that perhaps. This is Brant. The ICD code is set by the Department of Labor.

DR. ZIEMER: Right.

DR. ULSH: NIOSH has nothing at all to do with --

DR. ZIEMER: Right, that's why I was concerned about an audit that was going to look at the assignment of the code because then we're auditing DOL.

MR. ELLIOTT: This is Larry Elliott. We do go back -- when our folks here see something of question, we go back to the claims examiner and ask them to revisit that code. I don't know how many times we do that. And it may not be ^.

UNIDENTIFIED SPEAKER: ^

MR. ELLIOTT: No, we don't make a point of checking it, but if it, Stu was saying we don't make a point of checking that. But when we do see something that seems untoward to us, we go back to DOL and ask DOL's claims examiner to revisit it with -- I don't know if Jeff Kotsch is on the line or not -- but DOL has a medical person on call or on retainer that deals with these kind of questions for them. They look at medical diagnosis or the medical history information. And they're the ones that help us find the ICD-9 codes.

DR. ULSH: But I do want to make it clear though that this process where we revisited this issue did not involve seeking changes in any ICD codes. Rather, it involved what happens after we get a case with the ICD code assigned. What do we do? Well, we pick which target organ is appropriate for that particular ICD code. And that is what has changed.

UNIDENTIFIED SPEAKER: As prescribed in TIB-0012.

DR. ULSH: Right, as prescribed in TIB-0012. And that was based on our updated

understanding of the latest scientific evidence about what target organs would be appropriate for which ICD codes.

MS. MUNN: Because those changes were the ones that were made as a result of both Dr. Crowther and Dr. Eckerman's reports, correct?

DR. ULSH: That is correct.

DR. NETON: This is Jim, and that kind of confused me as to what John Mauro was talking about in terms of looking at the ICD-9 codes.

DR. MAURO: And I may have been incorrect. My only reason for stepping in at this point was I felt that in order for us to finish our job we did need to pick some cases out of the 400 or so that were denied in the PER process. And one of the areas that we would particularly look at would be for that particular case if, in fact, the correct organ was selected for dose reconstruction.

I think it's my understanding that the protocol that you folks used is fine. The question really was if the benefit of the doubt, if there was some uncertainty, we were going to be looking toward whether or not the benefit of the doubt was, with regard to what

organ was in play, if there was some uncertainty, I would say a legitimate uncertainty from a medical perspective on which organ you would pick.

We would be looking to see if, in fact, you picked the organ that would give the highest dose. And so we were going to try to work with you folks to identify those three cases, because that's all we really limited ourselves to in our scope, that would test that question.

And at that point I think I'd like to back down a bit and let Hans speak because I didn't want to go too far without, you know, just let everyone understand I'm looking at it from the point of view as being able to complete an assignment. And we're looking for some help regarding completion of that assignment in light of the work that we have completed so far.

MS. MUNN: Let's do by all means hear Hans' comments here, but please very strongly Board members keep in mind the comment that Dr. Ziemer made earlier in case you weren't on line yet. He expressed a concern that is a

strong concern of mine, if the code number is assigned by Labor and not by us, then the question arises whether or not we have any legitimate reason to be questioning their codes other than the kind of question that's been returned to them in many cases by NIOSH when they had some question arise. Whether this particular audit should be addressing that issue is a real concern, I think, in terms of how the program's going to be administered.

With that in mind, I'm sorry. Go ahead, Hans.

DR. BEHLING: Yeah, let me back up and start at the end where John started to point the issue to the selection of cases. What we were hoping to do is if we're going to audit any dose reconstructions that have been completed, it should be one, the selection probably should be one that focuses on the best cases. Obviously, at this point there are 348 cases that have been denied as a result of the PER-9. And some cases were, obviously, it's a no-brainer for them to be rejected for any number of reasons.

So what I had hoped to do is to perhaps engage NIOSH in looking at the table that I included at the end where we would have some understanding of which, what these cases really represent with respect to, for instance, whether or not the original dose reconstruction was based on a best estimate as opposed to a maximized. The issue of what if the original POC with the target organ that was, in fact, now used to reassess it under PER-9 specifically for the internal target organ.

There were issues -- let's see here -- a number of other issues that are very important in selecting those cases that may very well prove to be the ones where we would want to look at it very carefully in saying was this reevaluation done properly including the new POC. And also an issue we haven't discussed -- I'll talk about it in a few minutes -- the issue of smoking as a variable that has not been addressed and so forth.

So we were hoping that perhaps NIOSH without a whole lot of effort would be in a position to provide us with that matrix of 348

cases that have been denied under PER-9 review and provide us with certain parameters that would give us a best chance of selecting only those DRs -- and I think we're only talking about three -- that might best be able to answer whether or not the PER-9 did what it was intended to do.

MR. HINNEFELD: This is Stu Hinnefeld, and I don't think there'll be -- well, I'm a little concerned that it will be a lot of work to develop this table from all of the potential cases. And the potential cases, in my view it's going to be 260. And the reason I say that, I say that is that a number of these claims that we did the reanalysis indicated the compensability is still below 50 percent.

A lot of those cases have been returned to us by the Department of Labor anyway. When they provided our analysis of the, essentially, the new dose reconstruction was entirely, dose reconstruction report, they provided that to the claimants, and the claimants raised some objection because now they didn't have a dose reconstruction that reflected their case. So the Department of

Labor returned those to us to do a dose reconstruction. So in a sense it mirrors that evaluation was done.

So I guess about eight of those have been returned for that reason and would not have been re-adjudicated yet. And since they're not adjudicated, I believe what the rules are, is we don't, the Board doesn't review cases that are not completely adjudicated. So the population's going to be I think 260 rather than 348.

Now having said that, most of these pieces of information are data based, and therefore, can just be written onto a table with very little effort, the ICD-9 code, and because of that, the target organ can be generated automatically. The POC, certainly, the new one is available. The original one is available. It just may take a second look because application has a couple of versions before the latest version. We'd have to make sure we got the one we're interested in.

Cancer diagnosis here is data based. Smoking history is data based if we have it. On a lymphoma case we won't necessarily have

it. And so I would also suggest in the smoking history column rather than just say yes or no, we would say, yes, we have a history or, no, we don't know whether the person was a smoker.

MR. ELLIOTT: We're not required to get a smoking history on anything other than lung cancer.

MR. HINNEFELD: That's why we don't have it. So there may be some that have for some reason we got it or for some reason, maybe they also have a lung cancer we might have it.

MR. ELLIOTT: There may be something in the medical file.

MR. HINNEFELD: But it won't be data based. So what I'm talking about is what is data based. And so we are not likely to have a smoking history to know one way or the other whether the person smoked. We can put that column down there and say either we don't know or we do have a history, and this is what it said, and there are about four categories that could be there. So we can do those things relatively easily.

But when you start to identify the DR

method, that you'd have to look at the dose reconstruction to determine. And for the, so that would be two dose reconstructions to look at, both the one before the PER evaluation and the one that was used in the PER evaluation. And then the exposure to alpha emitters similarly. You have to look at the dose reconstruction report to know that.

So for that reason that's a lot of work to do for 260 cases. And so I was hopeful that we might be able to get by with a selection of, if you're only going to two, maybe 20 or 30 of these cases and prepare that table for 20 or 30 of the cases to select from.

DR. BEHLING: That would be fine. As I said, I just don't want to have an audit of a lymphoma case that within seconds of looking at it you realize why it was rejected.

MS. MUNN: This is Wanda. I have already expressed my concern about the amount of effort that would be necessary to generate the kind of table that was suggested here and the kind of information. The other, one other topic that's been touched on is the smoking

issue. And this is, I think, a thorny one and an appropriate place for us to talk about it.

It's been understood, I think, by all concerned that smoking or non-smoking is not what we're looking at in this program. Only recently has a lung issue been factored into it. But there is a real question as to whether or not we are appropriately expected to go there. Am I incorrect in my understanding that the smoking issue is a problematic issue that Labor has to address and not one that we, as the Radiation Advisory Board is addressing?

DR. ZIEMER: This is Ziemer. I think -- and Larry kind of referred to this already -- since that information is not generally available for these cases, I mean, it could be inadvertently in a sense, as Stu suggested, but in most cases I don't think we have the information. So I don't see how we would be in a position to address that variable in this particular case even though it may be, you know, Hans has raised certain concerns there. But it's sort of one of those issues not unlike some chemical issues that as important

as they may be, actually fall outside of our, either our jurisdiction or our authorization to address.

MS. MUNN: It has always been my understanding from the outset that our charter was specifically radiation, and we are --

DR. ZIEMER: Smoking was considered for lung cases.

MS. MUNN: -- yes. We all understand that, of course, smoking affects what happens with radiation. We recognize that. But it's always been very clear to me that that's outside our specific charter.

MR. ELLIOTT: This is Larry Elliott. I'd really like to comment here. The only other risk factors that we are asked to examine under this law -- if you look at the law, this is where it comes from -- is smoking with regard to lung cancer and ^ with regard to skin cancer. And we have not identified, nor has the law identified, any other risk factors that should come into play.

I think we need to have a discussion about the comments, the review comments from Hans, on smoking. I think Jim's prepared to

do that later. But I think the first order of business here is to continue on. Stu was very clear on our desire to accommodate SC&A's review of specific cases and how we can go about that. We certainly can do it.

But I think I'd like to turn it over to Jim and have Jim speak about whether or not he sees merit behind doing that because really what we're talking about here I think from SC&A's review is a question are we using the right target organs.

DR. BEHLING: Well, no, it goes beyond that, Larry. Let me finish, and I guess I feel like I'm being cut off again. I just started actually discussing things and talking about the back end of the selection process for the audits.

But the issue of smoking is very different for lung cancer as opposed to the lymph nodes. In the case of lung cancer the issue of smoking only affects the POC calculation in the denominator meaning that people who smoke have a higher natural incidence of lung cancer.

In this case the issue of the

disruption of the mucociliary escalator, which normally clears, is being compensated by -- and if you read the very short, brief discussion I enclosed in the last section, six, the ICRP-66 publication notes that among smokers versus non-smokers, you have 14-fold increase in albumin macrophages, five billion versus 70 billion.

What that really translates to is a much higher transfer of radioactivity into the regional lymph nodes meaning that you can certainly be sure that this affects the radiation dose as opposed to the incidence of cancer that results from smoking. The two are very, very different mechanisms. One only affects the POC equation. The other one has a direct impact on the amount of radioactivity that's being transferred from the lung into the thoracic or extrathoracic lymph nodes and thereby increases the actual radiation dose to those tissues.

So we have to be very careful about understanding the difference in terms of assessing the smoking issue for cases involving lymphomas versus lung cancer. And

it’s very important to make that distinction.

MS. MUNN: That was very interesting information, Hans, frankly, rather shocking to a lay person.

DR. BEHLING: I would like to continue if I could.

DR. NETON: I would like to address that a little bit though, Hans. This is Jim. I think what you raised is a scientific fact, but there is no model that could be applied to make this adjustment even if it were true.

DR. BEHLING: Well, you can look at the mathematics, Jim, one or five micron particles are removed expeditiously by way of other mechanisms such as absorption, but if it’s an enzyme material that goes out. And if you have an impaired mucociliary transport mechanism that ultimately clears it into the EP-2 region and then from there into the gastrointestinal, you can look at it mathematically and say what is the potential impact if this is now cleared by the way of --

DR. NETON: I think we’re committed to using the best science available, and I’m not aware of any good science that’s peer reviewed out

there that we could use to make this correction. But let me add to that. I think that you need to look at the total picture here involving the lymph nodes as well. It is well known that cigarette smoking also causes an increased inhalation of natural radioactivity.

I have personally measured this in the laboratory for Thorium-230, -232 and -228. There is a considerable amount of additional intake that occurs there. So I would challenge your assertion that smoking does not affect the denominator in the calculation. It does. And, in fact, Polonium-210 is even more widely known as a natural constituent of cigarette smoke. So you have a natural increase of radioactivity that should contribute to the denominator where we're going to look at the scientific picture in total.

Secondly, if you've done like I have done and looked at lymph nodes of cigarette smokers versus non-smokers, they are much larger because of the collection of the inner mass of the material that's in the cigarette

smoke. That mass by making the lymph nodes larger tends to diminish the dose and the dose to the organ from the amount of radioactivity in there goes down considerably. So you have to look at that whole picture. It's not just a one-sided analysis. And I'm not sure any of those factors could be modeled appropriately to be sufficiently accurate.

DR. BEHLING: Not to belabor this issue, but when you increase the lymph nodes in size, you also increase the number of cells at risk so they cancel each other out.

DR. NETON: No, it's mass, it's transformations per unit mass, Hans. Energy per unit mass deposit in --

DR. BEHLING: I realize that, but when you have three times the number of cells, you have three times the number of cells at risk. And I know the dose would --

DR. NETON: Well, this brings me to another issue, Hans. Let's talking (sic) about the lymph node model itself. We are assigning a dose to the lymph nodes as if it was entirely, the entire lymph system. As you well know, the radiation risk model developed from the

Hiroshima-Nagasaki survivors is based on a uniform whole-body exposure.

We are treating our intakes as if that same amount of material in the tracheobronchial lymph nodes irradiates the entire lymph system. That by its very nature is an extreme over-exaggeration of the dose to the lymph system. So we feel this is an extremely claimant favorable analysis to begin with. To do it properly one should take and take the weighted dose to the lymph system over the entire lymph system and not just that one little piece.

DR. BEHLING: That's another issue for discussion --

DR. NETON: Well, again, one has to look at the total picture, Hans, not just a one-sided, scientific review.

DR. MAURO: Jim, I think that what I'm hearing is that we're dealing with a multifaceted problem, scientific problem, in terms of how do you come to grips with this situation. And the only reason why I would say that it requires the attention is we're talking about differences in -- for example,

in the simpler sense depending on the organ -- let's just put the smoking issue on the bench for a second.

Depending on the organ that was selected for doing the dose calculations, my understanding is that the difference in the dose, that reasonable people may come to different conclusions regarding what was the organ of concern in this diagnosis. And one choice would result in a dose that is several orders of magnitude, maybe three orders of magnitude as I understand, higher than the other organ. So if there is, so we're talking about a scale of things.

So if, in fact, Hans' concerns that there might be some ambiguity in selection of the proper organ and that reasonable people could differ on what the correct one is, and if judgments have been made in the process you just went through which perhaps did not always give the benefit of the doubt, we are talking about difference in doses to the organ of concern that could be on the order of a thousand or more.

DR. NETON: John, let me stop you right

there because I've got a question. We're kind of talking about two separate things here. One is the organ of concern. And the organ that is reconstructed is clearly tied in our TIB-0012 to the ICD-9 code provided by the Department of Labor. So we have no choice in that number. With the ICD-9 codes provided to us is what we use, and we have a look-up table.

There is no room for judgment on the part of the health physicist. If he sees an ICD-9 code of something-something-something-dot-X, he'll go to the table and apply the dose reconstruction to that organ. So there's no judgment involved here at all on the part of NIOSH.

Now, Hans has raised a bigger issue I think --

DR. BEHLING: Well, I would like to be able to make some comments here, and I'm constantly being cut off. And I'm not sure there's any point in my continuing on this if I'm not given a chance to even comment.

DR. MAURO: Hans, please go forward because I've been jumping in --

DR. BEHLING: I've been told to get quiet.

DR. MAURO: Please, go ahead, continue, please.

MS. MUNN: We definitely need to hear what you have to say, Hans.

DR. BEHLING: I'm trying very hard here.

Anyway, let me go back to a few things that were mentioned earlier. When we talk about Hodgkin's disease I concur with some of the original statements that were made. Hodgkin's disease is a very easily definable form of lymphoma, and it's something that can be done with an ordinary light microscope because the histopathologist who looks at a biopsy will look at it and identify what's called the Reed-Sternberg cell.

It's a very large cell. It has a morphology that is readily recognized by even a very novice-type person; and therefore, the diagnosis is one that is without question one that you can rely on. On the other hand the issue that even involved Hodgkin's disease is one of which lymph node was identified for biopsy.

And now we're talking about what is

the stage. If you have a Stage I Hodgkin's lymphoma, then that means there's only one tissue or one location by which that neoplasm exists. And so if you biopsy that, then it's true, then the tissue where you biopsy the tumor is also the location at which the transformation, the original transformation, took place.

On the other hand we all know that when you have most incidences lymphomas, if you read through the medical text, it usually is not something that is diagnosed at a Stage I level meaning that you will have Stage II, III and IV. At which point the biopsy may very well represent a location that is not the primary neoplasm but a secondary neoplasm. And therefore, the biopsy, the anatomical location for that biopsy has very little in telling you where that original transformation takes place. That's for Hodgkin's.

When we talk about non-Hodgkin's lymphoma the issue becomes even murkier because now we're talking about a host of different cell lines from which that neoplasm was derived. And therein lies the problem in

making a very definitive diagnosis. And what I tried to tell you is in my review, is that the ability to identify the cell line of origin has been a problem throughout the history of treating lymphomas. And it's due to the fact that when you talk about non-Hodgkin's lymphoma, the cell lines are extremely difficult, and they change with time.

If you read the statements that I extracted directly from my medical text -- it's true. It's 1979 -- but I also want to point out to you that many of these lymphomas I'm sure among the 500 and some odd were probably diagnosed prior to the introduction of the ICD-9 codes which now leaves you with a big open-ended question is how do you translate those particular medical records into a contemporary ICD-9 code.

And if you look even at Dr. Crowther's comments, there's a very brief, one-and-a-half page consultant report. He had some serious questions about that ability, and how do we go about making a diagnosis at this late in the day or in the year 2007 and assign an ICD-9

code from records that may be 30, 40 years old and at a time when many of these definitive methods that are currently in use, and most of these are immunological.

They look at cell receptors for the SC component that was set formation and other things that didn't exist until, in some instances, only very recently. So you have a very difficult time in looking at medical records, especially older ones, and somehow or other pigeonholing that particular cancer and saying we can assign with a reasonable degree of certainty an ICD-9 code. And on the basis of which we then assign an internal and external target organ. And that is the sum total of this whole report.

DR. ZIEMER: Could I comment?

DR. BEHLING: Yes.

(no response)

DR. BRANCHE: Hello?

DR. ZIEMER: This is Ziemer. I couldn't tell whether my mute is on or off.

I appreciate those comments. I just, it seems to me that, Hans, you're addressing an issue that's a DOL issue it seems to me.

Am I --

DR. BEHLING: Well, if it is, Paul, then I guess this whole discussion has very little purpose. I just brought it up from a purely scientific --

DR. ZIEMER: Yeah, I understand the point that you made, Hans. The concern I have is that assignment is made prior to us getting any, getting the case as far as I know. And I don't think we're in the position, unless Larry says that as they look at a case if something looks fishy, they can send it back, but maybe Larry would comment further. But my understanding is that we're not assigning those codes and are not typically auditing them.

MR. ELLIOTT: You are correct in everything you said there, Dr. Ziemer. It is a DOL issue.

DR. ZIEMER: The concern is a valid concern but not one that we're in a position to address I think.

MR. ELLIOTT: You say you're not in the position to address. We can only address it when we think there's something that DOL

should re-look at. And we don't look at, we don't examine them to that level of detail because we accept the, what's called the -- what do they call this now? The statement of facts, the statement of accepted facts associated with the claim. And it is not our responsibility. It's DOL's responsibility to provide those to us.

DR. ZIEMER: But then the issue is given that we have a code, is the follow-on question then are we using the right target organ? What is the next issue either Hans or John? What's the follow-on point?

Let's assume for the moment that the code was correct. I mean, certainly some of them are, but what's the follow-on issue from our end?

DR. BEHLING: It has repeatedly been told by both Jim Neton and Larry and Brant, we don't, NIOSH does not select the ICD-9 code. That's handed to us. And the ICD-9 code is very specific if you look at it. It identifies an internal target organ and external. And if at this point we have no authority over DOL, this whole discussion as it is basically an

exercise, an academic exercise that has little or no value if they can't change the DOL.

DR. MAURO: Except, would you agree, the smoking issue then? In other words it sounds like we're talking about two different issues. One dealing with is the right diagnosis to the organ of concern. And this sounds like it might be outside the purview of the Board. And the second part is if it was properly diagnosed, if, Hans, in your opinion is the smoking issue an issue in terms of can you, the numbers you threw at us, the effect that smoking might have on the biokinetics.

DR. BEHLING: Yeah, it truly will. As I said, if you have 14-fold increased in alveolar macrophages whose principal objective is to transport and clean the lung of particulate matter into regional lymph nodes, it's clear that you're going to increase the dose. Again, on the other hand there is no documented -- I looked at ICRP-0066, and while they made reference to it -- you can read it yourself -- there's no quantitative data that would allow you to make an adjustment.

DR. ZIEMER: Going back to the point Jim

Neton was making. We could certainly regard this as a long-term, scientific issue that hopefully down the road, I think that question would be of interest to the scientific community outside of even of this program because there are other factors for the smokers that come into play.

There are clearances, the lung clearance into the lymph nodes but the coughing and all of that affects the clearance and the GI tract doses. And then Jim raised the issue for the smokers of the added internal burden of natural nuclides that affects part of those equations. So it's very complex it appears to me.

DR. BEHLING: Yeah, and I'm not suggesting that this become a scientific investigation --

DR. ZIEMER: No, not for us, but it could be an issue that we tag as one of scientific interest in the future. For example, if NCI or some other group is looking at this, we would want to keep abreast of what's happening.

DR. BEHLING: But we did make, for instance, an adjustment when we encountered the Super S

plutonium and with limited scientific data, we essentially defaulted to an approach that acknowledges the difference between S and Super S, and therefore, the dose involving the lung. And so is it appropriate for us to perhaps in a very questionable, not questionable, but in a less than 100 percent scientific method approach this issue as sort of default to a value that gives the claimant perhaps an elevated dose if he's a documented smoker.

DR. ZIEMER: Well, if you could identify all of the variables. I think the Super S was a little more straightforward than this.

DR. NETON: I agree with Dr. Ziemer on that. It's not exactly a fair comparison.

DR. MAURO: I like where we are in this conversation. I think that we've really crystallized the issues. I don't think there's any ambiguity; I think we all see the same picture. Namely, there is perhaps a legitimate question regarding the selection of the organ of concern. But what I'm hearing is it's really outside the purview, at least right now, for investigation of the Board and

for its contractor.

In regard to the issue of clearance and the effects of smoking and how it might affect the loading up of the thoracic lymph nodes are actually extrathoracic lymph nodes, that is a scientific question that is certainly of interest. But what I'm hearing is something that really cannot be taken on at least at this time for this particular PER review. I say all this because if what I just said is in general agreement, it means that our job is completed on this particular PER review, and we really need not go into the last step, subtask, which is reviewing particular cases.

I'm trying to find a way to achieve closure on fulfilling our obligations to the Board. And I think that if what I just described accurately characterizes the state of affairs, you know, I think some very important things came out of this conversation, but perhaps they're not items that are appropriately addressed by the Board and its contractor at this time.

MS. MUNN: Well, they are certainly

important. There's no question about that. One of my questions is whether we even have any knowledge relative to Labor's consideration of the questions that have been raised here. I have no way of knowing whether these questions have been kicked around by the medical folks over at Labor, whether they have taken some of these or all of these questions that Hans has raised so thoroughly into consideration as they make some of their code assignments even.

DR. ZIEMER: Well, this is Ziemer again. Let me make a couple of comments, and I'll play off of what John said a little bit. We have this report. I would like to see a couple revisions. One is to take care of that early issue that Larry raised and recognize the work that NIOSH had been doing and also point out that unbeknownst to you, they were doing that and that you had also reached the same conclusion in your early review. So to be fair to both sides, you both identified the problem. So let's make that known.

Number two, the information is in there, a good discussion by Hans. I see no

reason why that can't still, it still will be out there in a sense. You might add a comment that in a revision that it appears that this is the purview of DOL so the Board will not need to address this further. And I think we have to leave it there.

In a sense the information that you have would be at DOL's prerogative to use or not use. We're not going to force it on them, send it to them or whatever I don't think. I think it's in the public record at that point and they can see it and use it as they see fit.

Let's see, was there a third --

DR. BEHLING: Smoking.

DR. ZIEMER: And the smoking issue seems to me, again, you could point that out as you have and indicate as well that there may be other aspects of this that you haven't, that would have to be considered including the impact of natural activity on the smoker and perhaps other clearance mechanisms besides the lymph node clearance. Hans, I think you probably mentioned the GI clearance would probably change with --

MS. MUNN: It was in --

DR. ZIEMER: Anyway, I'm just saying the information is in a sense useful to have for whatever we can use in the future. And you might mention that although we can't make that correction now, it's something that might, as we move forward, might reach a point where perhaps NCI or some other group will come out with a model.

I'm just trying to make, say we have the report. Let's get it in a form that identifies, recognizes everybody's concerns and then we can't do any more at this point I don't think as far as procedurally.

DR. BEHLING: If there is one recommendation, and again, I don't want to speak disparagingly of Dr. Crowther, but being a hematologist is obviously related subject matter that would perhaps give this person insight. But the person I would really consult is a clinical histopathologist and one who has a very, very working knowledge about the issue of identifying the cell type that would ultimately then give an understanding of the modality for treating that lymphoma which

is very critical.

And for that I looked at Dr. Crowther's background. He's really not a clinical person in that sense where he has a lot of experience in this particular area. You would probably want to look at somebody who worked in a hospital environment or a research environment that deals with this issue on a daily basis in looking at tissue biopsies and running various tests whether they're immunological tests, serological tests to make that ultimate diagnosis.

And those are the people that I would sort of look at and sort of say they're the best people to provide us with an understanding of whether or not the current ICD-9 codes are, with regard to the internal/external target organ, are they really correct.

DR. ZIEMER: Well, again, I think we're getting into that other territory. I don't know -- you don't want to put that in your report.

DR. BEHLING: No, I'm not.

DR. ULSH: I've got to take exception to

that. Dr. Crowther is the head of the largest, well, one of the largest hematology departments in the world. He has, I think, 30 or 40 interns under him. Hans, what might be tripping you up is that in the United States there really isn't a separate sub-discipline of hematology. Everybody is an oncologist.

That is not the case in Canada where Dr. Crowther is from. Hematology is a separately recognized sub-discipline. Dr. Crowther has over 125 peer reviewed publications. He's coming out with a textbook this summer, Evidence-Based Hematology. He has both clinical and research experience. He works at a research and teaching hospital at McMaster University.

He is eminently qualified. He is also internationally recognized. So to imply that he doesn't have the right qualifications to review this, I think, it's not accurate. There's no one more qualified to review this.

DR. BEHLING: Well, okay, as I said, I don't know him personally, and maybe that's what's lacking here. But if you read his consultant report, it does leave an awful lot of

questions open to interpretation which he himself acknowledges. There's very little hard evidence, scientific evidence, in the classification of certain lymphomas. I think that comes through loud and clear. So if you recognize him as your expert, he certainly has raised a few questions about the ability to assign ICD-9 codes in his very brief consultant report.

DR. ULSH: Actually, I'm looking at his report right now, and he did not ever address the issue of the adequacy of historical records in assigning contemporary ICD-9 codes. Like any prudent scientist he acknowledges where there's uncertainty, but he was specifically tasked by us to address where there are areas of uncertainty and to point those out.

But we go with the best available science and the weight of the evidence. Dr. Crowther went through a very detailed review of the ICD codes that we asked him to and did exactly what we asked him to. He went through them one by one and told us what his recommendations are. Now I don't see a whole

lot of uncertainty there at all. It's very clear what he recommended.

DR. BEHLING: Well, it's a difference of opinion. I'm looking even the very first paragraph and it certainly raises a few questions in my mind. But again, this is an academic issue.

DR. MAURO: Yeah, I think that as I said before, we're at the right place on this. That is, we've expressed some concerns that obviously are really not, the last step in our scope of services in looking at cases, we walked away -- as I understand it, notwithstanding the issues we raised regarding smoking and regarding identification of the organ concerned, we found that the PER was a very good PER and was being implemented in a scientifically sound way.

That's what I walked away with when I read this. And the main concerns we have had to do with this, number one, appropriate diagnosis and to smoking. And the only reason we wanted to go on to the last step in the process was to look into those two particular issues to determine the degree to which they

may represent a challenge to a way in which the PER is currently being implemented. Without that I don't know if there really is a need for us to go on and do any of the three case reviews.

DR. ZIEMER: I agree. I think it's complete. In my mind it is. I don't know how the other Board members feel.

MR. ELLIOTT: John, this is Larry Elliott. You said something there that raised my eyebrows. You said that your report finds the PER to be well done and the work to be appropriate. But I don't read those words in this review.

DR. MAURO: Well, I'll let Hans speak to that.

DR. BEHLING: Well, as we just heard from Paul, he wants us to amend the report at three levels.

DR. ZIEMER: Well, I was expressing my opinion. I think it's -- and I want to hear from the others. I don't want to make decisions for the Board.

MS. MUNN: Well, you certainly expressed my opinion appropriately. My concern from the

outset was that the issues that were being raised were extremely valid issues, but I was not at all sure that they were within our purview. That was my concern.

DR. MAURO: And, Hans, please speak to --

DR. BEHLING: Well, John, basically, I still have some reservations, and I think everyone who understands the issue of lymphomas and their diagnosis, especially as we go back in time 20, 30 years, there's a big open-ended question. How accurately were these medical records reflected through a type of lymphoma and the source or the primary neoplasm and its anatomical location et cetera, et cetera.

DR. ZIEMER: And I'm saying that I'm not asking you to revise any of that. I think that's fine. I'm just saying we can't impose that on --

DR. BEHLING: No.

DR. ZIEMER: -- on DOL.

DR. MAURO: Yeah, and I want to go back to Larry's point because I want to make sure that I'm correctly representing my understanding. Except for the two issues that we just discussed which are outside the purview of our

mission so to speak, it's my understanding that the process that NIOSH went through and that given that there was not a smoking issue that we're concerned with, and given that we did not happen to encounter a PER where the ICD-9 or diagnostic issue came into the play, the process that they went through and how they implemented it, and how they selected the cases and did their dose reconstructions, it is my understanding that every part of that seemed to -- when we spoke last, Hans -- that seemed to be very well done until we ran into these two what I would call major issues.

DR. BEHLING: No, John, the ICD-9 code is not selected by NIOSH as you've been repeatedly told. So they followed the instructions of DOL. And if there is to be a change in how we assign ICD-9 codes, it cannot come through NIOSH. It has to be at the level of DOL. And so therefore, that issue goes by the wayside.

DR. MAURO: I'm not sure whether you're agreeing with what I just said. We happened to run into a PER, I mean, what we really have before us is the very first PER we were asked

to review is this one where the issues that emerged that we have concerns with really are outside the purview of the Board.

Other than that, if those issues were not there, and we were dealing with some other PER where those issues that emerged, I guess I would say that if those were unfair with by and large the process that was used to get to, the way in which the cases were -- for example, the way I've always looked at this is that there's a multi-step process where once the issue is raised, however it comes about, then NIOSH goes through a process of selecting the cases that could possibly have been affected by that issue. And then systematically go through a triage to identify the ones that will need to be reconsidered and then reconsider them. And then, of course, the compensation process goes forward. It's my understanding that that process, the front end of the process, was done well. And I think that was my understanding --

MR. ELLIOTT: John, this is Larry. Can I jump in here?

DR. MAURO: Sure.

MR. ELLIOTT: Because I want to hearken back to what I said at the start of this conference call. That I'm very concerned that this report will lead to claimants being further frustrated. And on page five of the Executive Summary at the last paragraph of the page, this phrase, the first sentence ends in a phrase, "nevertheless this contains significant deficiencies," does not match up with what I heard you say just now or a moment ago.

DR. MAURO: Well, of course, this is in light of what we've just learned about what's within -- what I'm hearing is there's a need to re-issue our report.

MR. ELLIOTT: I would appreciate that because the folks out there in the claimant world are going to hold this up and ask DOL to send claims back to us, and we're going to turn right around and say we have applied the best science possible.

DR. MAURO: But we do have a dilemma. And the dilemma being that, I mean, in a funny sort of way, hey, we think NIOSH did a great job with this PER; however, the Department of

Labor, we wonder whether or not that we have some concerns about, you know, the fundamental biokinetic models as applied to this class of problem which goes toward ICRP.

And, two, we have some concerns regarding the process that was used to identify the organs of concern, both of which are outside the purview of NIOSH, at least at this point in time perhaps, and the Board. So I don't know what we do at this point. I think we have something very important to say, but I'm not too sure how to go about saying it.

MS. MUNN: It appears to me that you've at least cast the outline of what has to transpire here. Clearly, the report needs to be reissued. Clearly, the issues that you have brought up are valid issues. They simply cannot be addressed here. I see no problem in identifying the issues. Does anyone else see any problem with that? It appears to me that it's only fair to identify the issues. It's just they're not, the issues are not applicable to this PER and --

DR. ZIEMER: Yeah, I think one of the

problems, for example, on the statement Larry just referred to on page five, it says the deficiency is in the PER. Well, actually, the deficiencies that you identified are really outside, they're not only outside the PER, they are outside the NIOSH fence.

So I think, John, you may need to think of some creative ways to indicate that there are these kinds of concerns, but under the current framework of this law, NIOSH is not in a position to address them. You could speculate -- well, I don't know if you could.

Part of this where you identify the coding issue I suppose you could point out that this is a concern that has to be handled by Labor. You don't know at this point, you don't know that Labor has not --

DR. MAURO: Yes, yes.

DR. ZIEMER: -- and so you have to be very careful and say this is a concern and that --

DR. MAURO: Could we say that? Maybe we could just say that.

DR. BRANCHE: This is Dr. Branche. May I make a suggestion? I think to be able to say, I think that Dr. Ziemer was leading along a

very wise path. But I think you could simply end by saying but this is outside the purview of NIOSH. You don't have -- and since we don't know or we can't ascertain explicitly in whose purview it is. And I wouldn't risk saying it's Labor only to find out it's somebody else.

DR. MAURO: I would go a step further. I wouldn't even be judgmental. I would say that based on what we reviewed, we see that there's a potential for a certain class of problem emerging in terms of diagnosis. Now, we're not saying that problem exists. We're not saying that it needs to be fixed. But at least from what we've seen, we see the very real possibility that that kind of problem could emerge on a particular case.

DR. ZIEMER: You need to make it clear that it's not something that NIOSH can handle. It sounds like --

MR. ELLIOTT: And I would offer that it's not, you know, lymphoma is probably the poster child for this problem.

MS. MUNN: No question.

MR. ELLIOTT: But it's not the only ICD-9

code that would have problem being assigned based upon rough, I mean --

DR. NETON: Fifty year old medical records.

DR. MAURO: Yeah, yeah, we've got to work -- I accept this challenge to try to craft words carefully to communicate something that might be very important, but do it in a way without being presumptuous regarding what Labor's doing and not doing, and not even point toward Labor. Just make the statement as Christine wisely suggested, this is outside the purview, but nevertheless it is a question that has come up that may require further investigation, that sort of thing. And then stop at that point.

DR. BRANCHE: This is Christine again, and the other thing that you have on your side is that the Departments of Labor and Energy do participate -- I don't know if they're participating in this call. I don't know if they've joined yet, but then the staff at NIOSH as well as SC&A would have a point of reference if this should come up later on. And you'd have documentation where you made certain that it wasn't pointing to NIOSH, but

there was an issue, a deficiency, that you uncovered.

DR. MAURO: Right, and we leave it that way. And I think it serves everyone's purpose this way. And at some point in the process the degree to which it's picked up by those organizations and individuals that feel it's something that needs to be picked up, great. If not, that's certainly their choice.

I feel as if that we've done something important here, but at the same time we have to function within the structure of the way business is done here. And we have to go gently, but nevertheless get the information out. We'll do that. And we certainly will put out another draft for consideration by all concerned to make sure that we strike that delicate balance that we're looking for.

MS. MUNN: I know you can do that, John.

MR. ELLIOTT: This is Larry Elliott. I think that is a very good thing that you have proposed to do there, John. And I encourage you, and I would offer my help if I can in any word-smithing that you would like help on. For the working group, I just want the working

group to hear my thoughts about review of PERs.

I was very excited that the Procedures working group was going to pick up an examination of PERs. And I was further excited by the fact that the working group assigned this particular PER for a first examination. And what I hoped to have seen out of that was how well we identified the scientific issues surrounding the change, and how well we implemented that.

And quite frankly, I have to say, you know, I'm not real comforted by on either one of those points here. I don't see that in this review, and I hope the revised review will speak to both the scientific basis for the change and how well the change was implemented. And any way we can help you in that review I certainly will stand up and do that.

DR. BEHLING: Larry, not to belabor the issue, but I think one of my concluding statements was that NIOSH fully understood the technical basis for this PER and accommodated, as I said, with the two things that I

identified here as potential problems are now not considered your problem.

And so as far as I'm concerned I was not harsh or hypercritical of anything that NIOSH did. Now that we're all of the understanding that this whole issue of ICD-9 codes is strictly something that is outside of NIOSH's purview, those two issues go by the wayside.

DR. MAURO: And I would --

MR. GRIFFON: John, this is Mark Griffon. Can I ask one thing?

DR. MAURO: Yeah.

MR. GRIFFON: Two issues, I agree with that one. That's obviously in DOL's camp. But the question of the biokinetic model I think is certainly a NIOSH issue even if it's a long-term science issue. I mean, and I agree with everything Jim Neton said that it's not only one side that you have to look at. But I think we should examine that. The ICRP-66 does have a section on that, but they're basically, from what I can tell -- Jim probably has looked at this certainly more than I have -- but it looks a little

inconclusive, the research, at this point. But I don't --

DR. ZIEMER: Not that there's as an issue, but they don't have a solution at this point.

MR. GRIFFON: Right, right, but I think --

DR. ZIEMER: That's what I was saying --

MR. GRIFFON: -- it is in NIOSH's --

DR. ZIEMER: -- ^ table maybe.

MR. GRIFFON: Yeah.

MS. MUNN: That can be said and at the same time maintain that NIOSH has appropriately handled these issues with the best science available which has done so. It's an outstanding question, but it's not a question to be resolved in this program.

DR. ZIEMER: Right.

MR. GRIFFON: Right. I'd have to look at the exact language, but I mean, I think that --

MS. MUNN: I don't think that the law gives us that prerogative, Mark. I really don't.

MR. GRIFFON: The law doesn't give us what prerogative?

MS. MUNN: The prerogative to weight these kinds of issues that go outside the standards

that currently exist.

MR. GRIFFON: What standards? This is ICRP. I mean, it's raised in ICRP --

DR. ZIEMER: But we --

MR. GRIFFON: -- papers in here that do make some conclusions. NIOSH is determining that all the literature basically is, there's no trend or there's no, you know, I think that's what the conclusion is. But I don't know that we've examined that or talked about that. I mean, I'm looking at the most recent one I could find was a '93 Kathryn paper which is referenced in there which is sort of suggesting some modifications to the biokinetic model. I'm reading while we're on the phone here.

So I don't know why we can't at least put that as a, you know, it seems like we're consistent, you know, ICRP is saying that there could be an effect here, a concern with smoking and lymph nodes, but currently they have no suggestion, but we're going to put it in the long term, you know, we're going to further look at that in long term science issues.

DR. NETON: Mark, this is Jim. I have no problem saying that this is a long-term issue that we should keep aware of.

MR. GRIFFON: Okay, maybe we're saying the same thing.

DR. MAURO: Yeah, I think we're in agreement on this.

DR. NETON: I would not argue that we shouldn't be concerned about it. I was just trying to make the point that at this point in time we have no consensus scientific opinion on this issue that we can hang our hat on.

MR. GRIFFON: I guess the one question I had, Jim, was do we have anything that says that your current approach where you didn't do any weighting sort of will bound any of the --

DR. NETON: Oh, absolutely.

MR. GRIFFON: -- most conservative factors being found in some of these studies such as Kathryn. I mean, --

DR. NETON: I think that's probably, that's something that's going to likely happen. This weighting thing all started when we tried to develop a model for CLL. And we actually are working on this weighted model right now. And

once that's done, it'd be easy to make that comparison.

MR. GRIFFON: I think that would be worthwhile just to have on paper. It certainly shows that you're aware of the current literature. You've considered it, and you still believe your calculations are bounding. I mean, I think that's good for all of us to have.

DR. NETON: ^ any of that right now. I guess we were here prepared to discuss this in light of the current PER and the scientific validity of what we've done here.

MR. GRIFFON: Yeah, that's fine.

DR. NETON: I do agree. We need to track and keep abreast of all the best science. And if we have to put it on a list, and I get reminded every three months as to my delinquency, that's fine.

MS. MUNN: Hans and John, will there be any problem in your issuing your revised report well in advance of the Procedures work group next face-to-face meeting toward the end of May?

DR. BEHLING: Yeah, I mean, there shouldn't

be any problem. However, I guess I'm still wondering if, in fact, the audit of at least two or three cases is still something that should be done in light of or in spite of this issue that we resolved this saying we won't question the ICD-9 code or even address the smoking as a variable, but strictly review the assigned doses that in the science based on bioassay data.

That is still an independent variable that goes outside the scope of these two issues, smoking or ICD-9 codes. I mean, this could be just another routine dose reconstruction audit that skirts the two issues that we've been discussing for the last hour, but it's nevertheless an audit that may have some potential value especially for POC cases where we're talking about revised POC of let's say between 45 and 50.

And now the focus will be on, well, how did the bioassay data contribute to this new assessment. This is going to be just like any other dose reconstruction except we're now dealing with lymphoma. I mean, you could look at this as two dose reconstruction audits or

three dose reconstruction audits that are very, very similar to the other ones that we do under Task Four.

DR. MAURO: And those can be picked, I guess, without this, see, the trouble we ran into is that we were trying to pick ones that would test the two issues that we were concerned with. Since those issues are off the table, we simply now have to, I guess, demonstrate that this process was, in fact, implemented on these three cases. I don't know how we would pick it, maybe just randomly.

DR. BEHLING: Yeah --

MS. MUNN: That was the first big word that I wrote on my notepad here when we were discussing it an hour ago, random, question mark, and why not.

MR. HINNEFELD: This is Stu Hinnefeld. If you're interested in cases where the new POC approaches 50 percent, why don't we just run the top ten, the ten cases that are still not compensable after rework that are available for review by the Board, sets ten of 250, and take the ten that have the highest new POC,

and you can select the three you want.

DR. MAURO: Send them over.

DR. BEHLING: The point here would be strictly to assess the assigned dose to the either thoracic or extrathoracic lymph nodes but evaluate the use of bioassay data that gave rise to that number.

MR. GRIFFON: Sounds good, yes.

DR. MAURO: Yeah, straightforward, it's a standard dose reconstruction audit. That's what it comes down to without these other issues at play.

DR. BEHLING: Yes, we will assert the issue of smoking and ICD-9.

DR. MAURO: Of course, you know we're going to be tempted to slip that in, but we won't do that. Please send us those ten cases, and we'll go ahead. And is it okay with the working group for us to just go ahead and pick the three we like, or would you like to pick those?

DR. ZIEMER: It seems to me we should pick them like we do the others if we're going to do it.

DR. MAURO: That's fine.

MS. MUNN: I think this is good.

MR. ELLIOTT: We will issue the top ten cases as Stu has described. I think this is appropriate. This goes to the implementation aspect that I spoke about a moment ago.

DR. BEHLING: And the reason I brought it up --

DR. ZIEMER: And once you do that then you can issue your revised report that will include what you did there.

DR. MAURO: Yes, we'll revise the report --

DR. BRANCHE: Excuse me. Excuse me. Ladies and gentlemen, I know how excited you are, but this is like the third time you all are talking over each other. It makes for a really bad transcript. Thanks.

MR. ELLIOTT: Do you want us to send the ten cases to the working group and let them select or do you want us to send it to everybody and you guys decide who you want to select?

MS. MUNN: Send it to the working group. We'll set up a very quick teleconference, and we'll choose three.

MR. ELLIOTT: Thank you.

MS. MUNN: And we'll get those three to Hans

and to John.

DR. BEHLING: And just to answer your question which precipitated this discussion in the last few minutes, the timing. If we were to exclude any dose reconstruction audits, May would be, obviously, I'd do it within a matter of days. On the other hand if there are, if this revised draft is to also address the issue of audits, then I think the time scale may have to be expanded a bit depending on when we get those cases and how soon we will be in a position to review those.

MS. MUNN: Then, Stu, what do you see as the timeframe for your pulling those ten and getting them to us?

MR. HINNEFELD: We'll probably ask ORAU for the pieces of information that are not data based. And it's going to take a custom query to build the table for the cases, for the information that is data based. So I think it might be a couple weeks or so, maybe --

DR. MAURO: How about a two-step process, Wanda? We could put out a revised report that gets to the delicate issues that we've been talking about. You'll have it in your hands,

and my guess is it may take a couple of iterations to get that down.

MS. MUNN: I would imagine so.

DR. MAURO: Yeah, and I'd like to get that right because of its sensitivity for the reasons that Larry clearly articulated. It is important that we get this language correct. And once we have that in place, that's going to be the important document that -- and right behind that some place along the line, of course, we'll get started on -- I would not want to hold that up because we want to work on the three cases. We'll supplement the report expeditiously as soon as the three cases are completed. But I think getting that first one out is going to be important.

MS. MUNN: That's a wise observation.

DR. BEHLING: So we're on for May to get the revision to this draft. And then however soon we can get to complete the dose reconstruction audits, we'll add those to the report.

MS. MUNN: Yes, we're set for, I believe, May 20th for our next face-to-face in Cincinnati.

DR. BRANCHE: That is correct.

MS. MUNN: Which would be a good time to address this. I'm hoping to be able to be there. I'm going to be having some surgery right after this Tampa meeting, and they're giving me another shoulder. I don't know whether they're going to let my shoulder travel by then or not, but May 20 is the day we set. So if it's going to be possible for you to get a revision to us ten days or so before that, John, it would be very helpful.

DR. ZIEMER: And remember, I won't be at that meeting in Cincinnati, but I would be there by phone.

MS. MUNN: Good, okay.

DR. BEHLING: So May 10th should be my target date.

MS. MUNN: If that's possible. If that's not --

DR. ZIEMER: Is it the tenth or 20th? Oh, ten days before. Okay.

DR. MAURO: May 10th, so that's our marching orders. May 10th, now, May 10th would be, what I'm getting at is though it sounds like that this document though is going to go through some type of process. And is it the May 10th

version that you would like to see having gone through the process whereby I would say us, with Larry and perhaps the working group having a chance to work it through? In other words right now we're talking, today's what, April 2nd? That's five weeks from now.

Hans, is this something we could put out within two weeks, get it into Larry's hands, get it into the working group's hands, Christine's hands so that they can see the language, the tone? And then we can maybe even go through an iteration before we actually have what I would call our official May 10th deliverable.

DR. BEHLING: Well, from my point of view it's a matter of spending a few hours of wordsmithing, but it's a question of how, you know, how diplomatic is my rewrite that will be acceptable to Larry and whoever else would be in line for the review. We may argue a bit here and there.

DR. MAURO: That's why I'm saying, I don't this is going to be a difficult thing to do in terms of us putting together the next straw man.

DR. BEHLING: No, and we spent an ample amount of time discussing why NIOSH is not responsible for the assignment of ICD-9 codes, and that smoking is an issue that is complex but without the documentation and scientific literature. I mean, this is not going to take me very long.

DR. MAURO: Wanda, how about we get it to you in a week, and we get it to Larry in a week?

MS. MUNN: That would be wonderful.

DR. MAURO: We'll get it to you in a week. We'll all have a chance to chew on it a little bit and do it again, and maybe even do it again. And by the time the tenth comes --

DR. ZIEMER: We'll be in Tampa in a week so --

DR. MAURO: -- oh, yeah, that's right. I forgot, two weeks. How about we get it to you within two weeks? That would give us two more weeks to fool with it and make sure we get it polished up so that on the tenth we've got ourselves a draft that we're feeling pretty good about.

MS. MUNN: That would be terrific.

DR. MAURO: Very good, very good.

MS. MUNN: That would be great. We'll look forward to that.

So we're all on that page? We're all happy with what we're doing with the PER-9 issue?

DR. ZIEMER: Right.

MS. MUNN: All right, very good.

OVERVIEW OF THE FIRST SET OF 33 PROCEDURES

Next topic, the rework that Steve Marschke got to us on the overview of the first set of 33 procedures. Steve, you're still on?

MR. MARSCHKE: I'm here, yes.

MS. MUNN: Good. My apologies for not getting my comments back to you and to Paul and Kathy. I think you've covered just about the waterfront here. It's what you sent is not in the format that I would prefer to see it. I still would prefer to see a very brief text, all of which you have here, but with most of the tables not as a part of the text.

If we can all stand the time element involved, I would like to have an opportunity to do a little cut and paste job of my own and

send it to you and Paul and Kathy for your sort of overview as to whether or not you think that's closer to what I had in mind -- it'll be closer to what I had in my mind. I don't know whether it'll be closer to what Paul had in mind or not. But if you would allow me to do that, I would certainly appreciate it.

For one thing, for example, I'd like to remove the review criteria and findings up into the part of your text that ends the first two paragraphs on page three. I'd like the criteria and findings to be up front. And then the contractor findings and status of findings that follow that can be, can easily encompass all of the material that needed to be done which removes a lot of the overview material back under paragraph four because we've already done it up front in the other table.

I think it will work just fine with a slight change in table or back at the back the one that we discussed in our e-mails earlier. We talked about how many columns should be added. At least Kathy and I, I assume you

were privy to that, about how many went under Table 4. And I think if we expand Table 4 just a little bit, put it in landscape format instead of portrait format, we can include the titles of the procedures reviewed.

And that would be everything everybody ever wanted to know right there in those two tables. They cover almost everything that's been done in this first set I think. I'll let you take a look at that after I put it together and will try to get that to you as soon as I can. I'm traveling right now and don't have access to the kind of equipment that I really need, but I think perhaps I can do that.

Is that all right with you, Paul?

DR. ZIEMER: Yeah, that'll be fine.

MS. MUNN: Is that all right with the rest of the group?

MS. BEHLING: Wanda, this is Kathy Behling. I just wanted to, excuse me just a minute because Steve was unable to be on the last conference call so I tried to incorporate the changes and apologize if I didn't capture everyone's suggestions. So Steve is not to

blame for any of the changes that were made, and I'm sure he's certainly in agreement with seeing any changes that you would like to incorporate.

MS. MUNN: Well, if it's not going to hold up the wagon too much, I'll do that.

DR. MAURO: This is John. I really appreciate that. That really helps. We can really get your direct perspective. That will be very helpful to us in finalizing this.

MS. BEHLING: And actually, the other thing I want to make mention of is because this was a report that we're sending to you, I obviously realize you would not probably want this format with the disclaimers and that kind of thing. Because currently it's a discussion piece that we're having between SC&A and the work group and NIOSH, but obviously this will be a report from the Board to the Secretary of HHS. And so it won't have the look and the format that is typical for SC&A. I just included that for this working piece during our discussions here.

MS. MUNN: I understand that, and I appreciate it. As I said, I think everything

we need is here. It's just a preference with respect to how it's presented I think.

Mark?

MR. GRIFFON: Yeah, I'm still on. I'm not too worried about format, Wanda, so that's fine.

MS. MUNN: Okay, that's fine.

Mike, any problems?

MR. GIBSON: No, that's fine.

MS. MUNN: Okay, very good. I'll try to get that to you hopefully before we go to Tampa, but I'm not at all sure.

DR. ZIEMER: There's not much time left. You can bring it with you if you want.

MS. MUNN: Yeah, that's one of the things we probably will end up doing.

DR. ZIEMER: I won't have a chance to do more on it before I leave anyway.

MS. MUNN: All right, then we won't feel like that's a big pressure thing, but I will try to get it to you.

I do not have on my list of action items that I have from our last meeting, I don't believe that I have anything that we were required to touch on before our PER-9

discussion --

DR. BRANCHE: Wanda, do you hear the music?

DR. ZIEMER: Yeah, I hear it.

MS. MUNN: I do hear the music. Somebody's put us on hold.

DR. BRANCHE: Yes, they have.

MS. MUNN: So we're hearing the symphony.

But is any other member of the work group aware of outstanding information that we had indicated we needed before the Tampa meeting?

DR. ZIEMER: I don't believe so.

MS. MUNN: I don't think so, and I didn't have any list unless someone else has some action item that I failed to record.

(no response)

MS. MUNN: That's fine. Then --

MR. GRIFFON: Wanda, one question. Where do we stand on the discussion of the CATI procedure review? I think it's 90, 92, one of those.

MS. MUNN: Ninety-two. We're going to use the new matrix to report on it at the next meeting which is, I'm not sure whether I meant Tampa. I don't think we did.

Kathy can you help me remember what we were, what I meant when I said we were going to use PROC-0092, the new matrix, to report where we are at the next meeting?

MS. BEHLING: Yeah --

DR. ZIEMER: You were going to report on the nature of the matrix for the full Board.

MS. MUNN: Yes, I know. That's one of the things I want to, when we finish here, want to very quickly ask Kathy to stay on for a minute and Christine to stay on for a minute while we talk about that for just a minute.

But, Kathy, were you planning on using PROC-0092 then as part of your presentation?

MS. BEHLING: No, I wasn't. I was simply going to give an overview of the matrix, what we're capturing, trying to show to the other Board members just so they have an understanding of. If they also want to have a similar matrix database put together for a matrix for their work group, I think it's probably a good idea, and it's as we discussed --

MR. GRIFFON: So, Wanda --

MS. MUNN: So when I said at next meeting,

in my mind I was saying at our next meeting in May. But I just wanted to make sure that from what Mark had just asked that I was not misinterpreting that.

MS. BEHLING: That's correct. In fact --

MS. MUNN: Do you have something else, Mark?

MR. GRIFFON: No, no, no, I just, you were asking about outstanding actions related to the tracking matrix and stuff more than the individual findings in the resolution of individual findings, correct?

MS. MUNN: Yes.

MR. GRIFFON: Okay, then I'll retract my question.

MS. MUNN: I thought one of the notes that I had underneath it was include three and five as being in abeyance. But I think it's a May item. That's what I'm thinking.

MR. GRIFFON: All right, thank you.

MS. MUNN: All right, then I have nothing else other than a conversation I wanted to have with Christine and Kathy. Does anyone else have anything we need to touch on before Tampa?

DR. ZIEMER: No.

MS. MUNN: Otherwise I will let everybody go back to work with the exception of Kathy and Christine if you'll two hang on for a moment, then I'll see you all in Tampa next Monday.

DR. BRANCHE: Everyone travel safely.

(Whereupon, the working group meeting was adjourned at 3:00 p.m.)

CERTIFICATE OF COURT REPORTER

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COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of April 2, 2008; and it is a true and accurate transcript of the testimony 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 7th day of Dec., 2008.

_____

STEVEN RAY GREEN, CCR, CVR-CM, PNSC

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