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

+ + + + +

ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

+ + + + +

SUBCOMMITTEE ON PROCEDURES REVIEW

+ + + + +

TUESDAY
NOVEMBER 17, 2009

+ + + + +

The meeting convened in the Zurich Room of the Cincinnati Airport Marriott Hotel, 2395 Progress Drive, Hebron, Kentucky at 10:00 a.m., Wanda Munn, Chair, presiding.

PRESENT:

WANDA MUNN, Chair
MICHAEL GIBSON, Member*
MARK GRIFFON, Member*
PAUL ZIEMER, Member

ALSO PRESENT:

TED KATZ, Designated Federal Official
NANCY ADAMS, Contractor
HANS BEHLING, SC&A*
KATHLEEN BEHLING, SC&A*
ZAIDA BURGOS, NIOSH*
STUART HINNEFELD, OCAS
EMILY HOWELL, HHS
JENNY LIN, HHS
JOYCE LIPSZTEIN, SC&A*
STEPHEN MARSCHKE, SC&A
SCOTT SIEBERT, ORAU*
MATTHEW SMITH, ORAU*
ELYSE THOMAS, ORAU*

*Present via telephone

P-R-O-C-E-E-D-I-N-G-S

(10:02 a.m.)

MR. KATZ: This is the Advisory Board on Radiation and Worker Health. This is the Procedures Subcommittee. My name is Ted Katz, and I'm the Designated Federal Official for the Advisory Board. And starting with Board members in the room, roll call.

CHAIR MUNN: Wanda Munn, chair of the Subcommittee.

MEMBER ZIEMER: Paul Ziemer, Subcommittee member.

MR. KATZ: And on the line?

MEMBER GIBSON: Mike Gibson, Subcommittee member.

MEMBER GRIFFON: Mark Griffon, Subcommittee member.

MR. KATZ: Okay and then NIOSH ORAU team in the room?

MR. HINNEFELD: Stu Hinnefeld, Interim Director of the Office of Compensation Analysis.

MR. KATZ: And on the line? NIOSH ORAU team?

MS. THOMAS: Elyse Thomas, ORAU.

MR. KATZ: Welcome, Elyse.

MR. SIEBERT: Scott Siebert, ORAU team.

MR. KATZ: Hi, Scott.

MR. SMITH: Matt Smith, ORAU team.

MR. KATZ: All right, SC&A in the room?

MR. MARSCHKE: Steve Marschke.

MR. KATZ: And SC&A on the line?

DR. BEHLING: Hans Behling.

MS. LIPSZTEIN: And Joyce Lipsztein.

MR. KATZ: Hans Behling, Joyce Lipsztein; is Kathy Behling on, too?

MS. BEHLING: Yes, Kathy Behling, I'm here.

MR. KATZ: Okay, sorry, you got squashed out by other affirmations. And HHS and other government officials in the room?

MS. HOWELL: Emily Howell, HHS.

MS. LIN: Jenny Lin, HHS.

MR. KATZ: And on the line?

MS. ADAMS: Nancy Adams, NIOSH contractor.

MR. KATZ: Any other federal officials or contractors on the line?

Okay, and any members of the public on the line? All done, okay, Wanda?

CHAIR MUNN: I hope all of you have received the email communications that were flying back and forth yesterday, several of which are pertinent to what we are doing today. The first two things I'd like to have us make a decision about is where on the agenda we want to address the information that Ted sent us with respect to PERs, and secondarily, the comments with respect to the letter that Paul provided as our second annual report to the Secretary. I hope you received my comments on that, some concern about the very last paragraph on the first page of that

letter.

I'd like to address both of those items fairly early before we actually get into the nitty gritty of our action item list. Does anyone have any concern about our doing that first, and which of the items are the items you would prefer to address first?

MEMBER ZIEMER: Whatever you want is fine with me.

CHAIR MUNN: Thank you. Not hearing any concerns one way or the other, let's do address the issue of the PERs. Ted had suggested, I think quite appropriately, that the request of briefing from SC&A as to how they anticipate addressing the PERs, and Ted provided a set of specs that he had suggested.

I would ask of Steve Marschke, who I assume is going to do that for us -- right? Is that your --

MR. MARSCHKE: Probably Kathy or Hans will probably do the -- your addressing

of the PER question.

CHAIR MUNN: Okay, very good.

Before we do that, I guess I'd like to make sure that we are aware of where we are with our database, even before we get to that. Steve has a report for us with respect to our status with items, as well as where we are with the database itself. Apparently, we are not yet where we need to be with the electronic version. Steve, do you want to bring us up to date?

MR. MARSCHKE: Yes, NIOSH has been bringing the database over from the ORAU computer to the CDC computer. And last week we got access to the database and were able to -- we had write access to the database, so we were fat, dumb, and happy last week. But then when I started preparing for this meeting and preparing the summary sheet which I like to send out, either myself or Nancy Adams usually sends out, when I was preparing a summary sheet I realized that we were going backwards,

and that the database was reflecting the database as it stood prior to the August meeting, and it did not reflect any of the changes that were made during the August meeting or during the October meeting.

Now we knew it wasn't going to include any of the changes during the October meeting because during that meeting we were not live. But we had anticipated including the October changes -- including the August changes because during the October meeting we weren't able to -- it did reflect those.

So I emailed the Subcommittee, and I emailed NIOSH; I forgot to email Nancy, I apologize, and basically I stopped updating the database at that point because I didn't know what we were going to do, whether we were going to try to replace the current database with a newer version from the ORAU machine or whether we were going to try to update it by hand. So basically now we are kind of waiting now to take the next step. We have -- the

electronic database as it is available currently on the NIOSH computer or the CDC computer does not reflect the latest changes. And as to the latest email I sent out, I think there are about 14 open issues that during the August meeting we had dispositioned one way or the other. Another, I think, four or so in progress issues that we had dispositioned one way or the other, and the database does not reflect that.

So I guess there are two options to go. One is somebody sit down with the minutes of the August meeting and try to update the database. The other one is to go back to the ORAU version that would show up there and bring it over again and try and update it that way.

But that is where we stand, and then once we get it to the end of the August meeting, then we have to do the update by hand for the October meeting, and we probably do -- any updates that get completed today will

have to be entered by hand as well. I don't know if we want to update the database today, how it gets reflected.

CHAIR MUNN: That is an extremely tedious process. I would hope that we could in any event be able to bring over the database which was complete after the August meeting. Even if we have to enter the October data by hand, that is tedious, and --

MR. MARSCHKE: The October data, we always knew we were going to have to do that by hand. And if we have to do the August data, that would be quite a bit of a job, and -- just to make sure that we got it correct because I looked at the August transcript and it's 300 pages long. So that would be a very tedious job for someone to sit down and go through there and make sure, but those are the options.

CHAIR MUNN: Do we have anybody from that side of the house that can give us a feel about when they might be able to -- since

we at one time had the database, following the August meeting.

MR. MARSCHKE: Well, that was on the ORAU side. The updates, remember in the August meeting, everybody at that meeting was still looking at the database on the ORAU.

CHAIR MUNN: Right.

MR. MARSCHKE: We did have it during the October meeting, and we were on the CDC machine on the October meeting. And it was up to date at that point. So it might be already over on the NIOSH side. It'd just be pointing to the wrong file, data set, someplace.

MR. HINNEFELD: Once they find the right files, it won't be -- that is the key element, is finding the right version of it. And I don't know how they distinguish these. It might be that they have modified dates on the properties in the files or something, I don't really know. But if Tom is coming down here, I don't know that he's going to be able

to do that today, but he might. He has a lot of access to computer servers.

CHAIR MUNN: That would be great. Do we have any feel for when Tom might be here?

MR. HINNEFELD: No, I didn't know he was coming. He was sick yesterday, and I didn't know for sure he was at work today.

CHAIR MUNN: But we think he is going to be here?

MR. HINNEFELD: Nancy said he's on the way.

MS. ADAMS: This is Nancy Adams. I got an email from Leroy last night because I sent him an email about the database. And he said Tom was coming over this morning. I emailed Tom, and I tried to get hold of him, but I've been unsuccessful. So I don't know when he might be there.

CHAIR MUNN: Well, we'll just hope that he might show up, and when he does, perhaps we will stop whatever we are doing at

the time and give him an opportunity to do everything possible to bring us up to date.

Yes, Paul.

MEMBER ZIEMER: I have one question. Steve, can you tell us are the numbers we used, the statistical numbers that we used in our report, up to date as far, if you go back to the slide you just showed, are we up to date on the numbers we provided for the Secretary's report, relative to the -- I thought we were.

CHAIR MUNN: We were up to date as of the time the letter was drafted, which was just before the October meeting.

MEMBER ZIEMER: Right.

MR. MARSCHKE: Before the October meeting, yes. I'd say those numbers were good --

CHAIR MUNN: They were good through August.

MR. MARSCHKE: Through August, right.

CHAIR MUNN: Correct.

MR. MARSCHKE: Correct.

MEMBER ZIEMER: They didn't reflect October changes?

MR. MARSCHKE: They did not reflect October changes.

MEMBER ZIEMER: I sort of recall you sitting here in the meeting and changing the numbers on the chart.

MR. MARSCHKE: In the August meeting, I did that. In the October meeting, I don't recall doing that. I don't think I did that because I don't think we had -- it was not -- the database was on the CDC machine at that time --

MEMBER ZIEMER: I meant the summary sheet you just showed us.

MR. MARSCHKE: The summary sheet that I just showed --

MEMBER ZIEMER: Didn't you update that while we were in the meeting?

CHAIR MUNN: Yes.

MR. MARSCHKE: The summary sheet that I just showed -- well, I've lost it now, but that summary sheet -- that was the end of August. That was a summary sheet that I generated yesterday, and that's the database as it stands right now. And it basically is the same as it was in, at the start of August.

If you look at this graph here, you can see that this line, the November line that is shown here, is virtually identical to the August line, whereas the October line is different. And this, going from here to here is the update that was lost.

MS. ADAMS: This is Nancy Adams. Steve, the number that I have written on my -- the total findings of 538.

MR. MARSCHKE: Yes.

MS. ADAMS: And then open was 105, which was different from July which was 118.

MR. MARSCHKE: Well, yes, we had 104, 105 in October, and now we are back to 115 open items, or --

MS. ADAMS: And 38 in progress, 86 in abeyance.

MEMBER ZIEMER: Well, I just wanted to cross check what we used in the letter. I thought it was the October data.

CHAIR MUNN: It was the October data, yes.

MR. MARSCHKE: At the start of the October meeting data, the start of the --

MEMBER ZIEMER: Okay. Remember, we left the blanks, the letterhead blank for the numbers, and we were going to fill them in after the meeting.

CHAIR MUNN: Yes. Originally we had intended having more numerical data there. We were going to give more numbers and agreed that that was overkill.

MEMBER ZIEMER: But we had a couple of percentages.

CHAIR MUNN: Yes. Yes, and the percentages were correct as of October, when we wrote the letter.

MEMBER ZIEMER: So we are probably okay on that.

CHAIR MUNN: I believe we are.

MEMBER ZIEMER: Percentage won't make much difference.

CHAIR MUNN: No, and it's such a small -- any change would be so small that it wouldn't affect the percentage by any more than one point at the very most, I'm sure. They were all significant numbers.

All right, well, we'll wait to see if we can get back to where we need to be sometime later today. In the meantime we'll have to work with what we've got. The tracking system status that comes up for me shows currently the total findings of 538; open, 115; in progress, 40; in abeyance, 79; addressing findings, 15; transferred, 39; and closed, 250. That's what comes up on the current base.

And that's it, only one or two single items away from where we were. That's

just about what we were using as our calculator. So yes, I think we are fine, Paul. I can't see this would be a problem.

Now next item, the PERs. Steve, do you have --

MR. MARSCHKE: A count? Well, I can just say -- I can introduce it a little bit. Yesterday the Subcommittee and the Board, actually, should have received an email from SC&A in which we transmitted two documents. One of them was the protocols to review NIOSH Program Evaluation Reports. And that is exactly what its title indicates. It's our draft protocol that we propose to utilize to review the PERs.

And it was written by Hans and Kathy. I have a version of it here on the screen that I can put up, and if Hans or Kathy, if you want to basically take over the discussion at this point, that would be good.

DR. BEHLING: Okay. This is Hans.

First of all let me apologize

because I wasn't really aware until yesterday that this would be on the agenda for today. And I had it in the hands of people at our SC&A home office and was hurriedly trying to get it into your hands before this meeting. So I apologize, but I do hope that members have had a chance to review it and understand what's in it. But let me briefly go over what it really involves.

MEMBER GRIFFON: Hans, can I interrupt for a second? This is Mark Griffon.

DR. BEHLING: Yes.

MEMBER GRIFFON: Where did that email come from? I can't seem to find that.

MR. MARSCHKE: It went to your CDC email address.

MEMBER GRIFFON: Oh, that explains it, thank you. I'll look on there. Thank you.

DR. BEHLING: At least we know that some of us, some of the Board members, may have not had a chance to look at it. But

just in brief, let me go over what I did here.

Among the things that was apparent at the October 23rd Board meeting was that we had really lost track of what happened to PERs. So the first section in the report tries to go back in time and explain what has happened to PERs. And one of the things I tried to do here was remind people of previous discussions we had in the form of attachments, some of which are obviously part of the report, and others are strictly referenced.

In past meetings we have had discussions about PERs, and to date we have done two PERs that try to track somewhat with the protocol that is being outlined or proposed here.

The first PER that was done in accord with this type -- with this basic procedure was the lymphoma PER, and following that one we had a discussion, and I think it was Mr. Katz's recommendation to at least eliminate one of the sub-tasks. Initially we

had six sub-tasks, and as a result of the recommendation to eliminate the first sub-task, we are at this point with five sub-tasks.

MR. KATZ: Hans, I'm sorry, this is Ted, but let me just clarify, that is not a Mr. Katz recommendation. That was a decision of the contract evaluation panel. That's where that came about. It was during the review of the new SC&A contract that the panel recommended that that first step be eliminated as unnecessary.

DR. BEHLING: Okay, we will obviously make a correction here to the report to reflect your comments here.

But even beyond PER-0012 and 0020, which were done basically in a format that is being proposed here, there were previous other PERs, and, in fact, I was reminded yesterday, and I guess it was Steve who also recalled that in addition to the four PERs that were done early on, there were an additional two

PERs, so we've done several PERs not by this protocol but basically under the protocol that was identified for review of procedures and OTIBs. So at this point we have really done a total of six PERs that were done initially under the protocols for procedures, and then two were done under a modified version of what's being proposed here. So that is the history behind it.

And one of the things that you will see if you go through this writeup is that the outstanding issue to date is the fact that we have yet to do any review of dose reconstructions that reflect these PERs, and that has been the topic of discussion on several occasions of previous work group meetings as well as full Board meetings. And I think this is a thing that needs to be looked at today.

Initially if you look at some of the attachments of previous meetings, we had proposed to do the, perhaps, three DRs that

have been modified or reassessed under the existing PER, and then in behalf of this particular draft report, I look back and say, is this really reasonable? And I think this is the thing that needs discussion today, is that who is going to basically decide what the number of PERs should be and whose responsibility should that be.

For those who may have the report and have it available, the existing proposal is to essentially follow sub-tasks one through five as defined on page six of the report that you may have available at least electronically.

MS. BEHLING: Would you like Hans to go through those sub-tasks, since many of you may not have had an opportunity to read through this?

MEMBER ZIEMER: Yes, that would be useful.

CHAIR MUNN: It would be helpful.

MEMBER ZIEMER: Before you start,

Hans, just to make sure everyone has the same report, the title of it under the SC&A transmittal is called Draft Transmittal, Draft SCA TR PR2009 0002 Rev 0 Restricted.

That's what it's under, what Judy sent us, so just for the benefit of those who are looking in there.

MS. BEHLING: To your CDC email.

MEMBER ZIEMER: Right.

DR. BEHLING: Okay, if you have that report, on page six is really the identification of the five sub-tasks that we are proposing to use in fulfillment of our PER review.

Sub-task one, and I'll read it verbatim so that -- for those who don't have it will get some understanding. Sub-task one states SC&A will assess NIOSH's evaluation/characterization of the issue and its potential impacts on DR. Our assessment intends to ensure that the issue was fully understood and characterized in the PER.

And that is basically just simply going through the steps that NIOSH will normally follow in establishing a PER. And that obviously includes certain discussions, writing up a PIP, and the writing of the PER that reflects what the technical issues are that prompted this whole issue.

Sub-task two, assess NIOSH's specific methods for correction action in instances where the PER involves a technical issue. SC&A will review the scientific basis and/or sources of information, ensure the credibility of the corrective action and its consistency with current/consensus science. And that is nothing more than, again, going over all of the technical information that NIOSH has cited on behalf of the PER, verifying the sources, and making sure that the PER truly reflects that information, in addition to perhaps going outside those sources and seeing if the technical sources that are cited by NIOSH are consistent with

the scientific literature at large.

Task three, evaluate the PER's stated approach by identifying the universe of potentially affected DRs and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation.

The second step may have important implications in instances where the universe of DRs is too large, and for reasons of practicality NIOSH reevaluation is confined to a subset of DRs.

On behalf of sub-task four, SC&A will also evaluate -- actually, that should be sub-task three. On behalf of sub-task three, SC&A will also evaluate the timeliness for the completion of the PER. And that pretty much is nothing more than trying to assess the database under which these potential DRs may be selected for reassessment, and as I'm currently doing, I'm reevaluating -- or I'm evaluating -- PER 12, and here we are, we are essentially looking at, in this case, at all

facilities in the DOE complex, including AWEs that may have, in the case of high-fired plutonium, be affected by this PR. And then understanding how that universe of claims can potentially be reduced to a more manageable system by applying certain screening tests. And, again, you will see later on when you read in my report how that is done, those two, not necessarily review all of the potential claims in this universe, but select those that will only be affected by the PER, and that is most likely driven by the Probability of Causation. If the corrective action on the part of a PER will not come even close to the 50^{th} percentile of Probability of Causation, we can certainly reduce the number that would require reassessment. And that's really the central theme of task three.

Under sub-task four, conduct audits of DRs affected by the PER under review. And that is really the step that needs a substantial amount of discussion by

the Work Group. And we have up to this point come to the conclusion -- or at least I have come to the conclusion -- that the initial proposal to perhaps only limit our review of DRs to three may not be appropriate, and that was somewhat prompted by my current review of PER 12. And I explained why or what are the basic mechanisms by which we may have to increase the number. And that number may be variable and PER-specific. And as you will read in this particular protocol here, in the case of PER 12 there are any number of changes to the reassessment of dose reconstruction that may require a certain minimum number of DRs to be reviewed, and that is driven by the -- and in the case of Super S plutonium, that is driven by not only the facility that may be affected but the type of tissue or the organ, the target organ in question, and the methodology that was used to originally reconstruct doses, that is the type of bioassay that was used. In the case of

plutonium Super S the corrective action as defined under OTIB-0049 is based largely on the bioassays that were used to reconstruct the original dose.

And so if you go through the original report, and I won't go through the details here, you will realize, on behalf of PER 12, the potential number of variables that affect dose reconstruction are driven by the type of organ and the method by which the original dose reconstruction was determined.

And my feeling is that to really assess at least each and every one of the permutations by which a dose may be reassessed under PER 12, you may have to assess as many as 12 DRs as a minimum. And that really is basically what I think are the issues that need to be discussed here, and the real question is who should make the decision in terms of defining which DRs need to be assessed from the universe of DRs that are potentially available for us to review.

CHAIR MUNN: Hans, it would seem to me that PER 12 and the high-fired plutonium issues are probably among the more complicated of the PERs that we have before us. Is that not correct?

DR. BEHLING: Yes, it is. As I said, Kathy had put out a table, I think it's Table 1, that sort of looks at the complexity by which a PER will be used in terms of redefining dose reassessment. And this one turns out to be, perhaps, a little more complex. For those who are familiar with OTIB-0049, there are obviously a host of issues by which a dose reassessment has to comply with the OTIB-0049. And I think you are correct, Wanda, that not all of these PERs are equally complex. And perhaps the number of DRs in behalf of those PERs will vary considerably from perhaps as few as two, three to perhaps quite a few, and as I said, I haven't gone through all of them obviously, but in the case of PER 12 it appears that we

would probably want to look at maybe perhaps 12.

And if you read through the report I have basically stated that we would like to do the following: review the various documents under sub-task one through three and then prior to identifying and reassessing those reconstructions, is to present our findings to the Board, and make a certain -- make certain recommendations that, as I've just explained in the case of PER 12, we would go through it and say, in order to assess all of the different protocols that may be applied, and they do significantly vary based on the target organ that is assessed and also based on the methodology that was initially used on the original DR, we would then for instance propose to the Working Group what we would consider maybe a minimum or an appropriate number of DRs. And of course that would clearly involve a dialogue with NIOSH because as I also point out, there may not be any

claims that necessarily reflect each of the protocols that are stipulated in OTIB-0049. So we would have to obviously assist -- get assistance from NIOSH to say, okay, from the universe of DRs, they screen certain DRs down to those that will be affected by PER 12, and then make a selection based on certain features that will at least identify as many of the potential 12 permutations as possible, not necessarily meaning that all permutations that I have identified are necessarily part of the pool of, in this case, 1,720 claims that may be required to be reconstructed or reassessed for dose.

And I would assume that our recommendations would then go to the Working Group who then in turn would, like they normally do for our assessment of dose reconstruction, make a selection as they see appropriate.

CHAIR MUNN: My apologies. Hans, I now see for the first time scrolling down

through that entire document that you have already done a great deal of evaluation with respect to the complexity and scope of each of these PERs. That should be very helpful to us, once we've absorbed it. I don't know if anyone else has had an opportunity to really absorb this or not. Ted?

MR. KATZ: That is the material that was presented to the Board at the last Board meeting. You've actually received and may have reviewed that at the last Board meeting, full Board meeting.

MEMBER ZIEMER: Which material are you referring to?

MR. KATZ: That's the SC&A sort of analysis to identify some potential high priority PERs for consideration.

CHAIR MUNN: And very frankly I scanned it and did not really and truly absorb it, and without this briefing this morning would not have realized that I have seen it before.

What's the feeling -- yes, Paul.

MEMBER ZIEMER: Well, if I might make a couple of comments. And I appreciate the document that has been provided and the work that Hans and Kathy have done on this to kind of outline in more detail the approach.

I have just a couple of questions, Hans. Number one, on the various sub-tasks, particularly on the first -- well, the fifth one is simply to write the report, so that is a no brainer, I guess.

But on the first two you talked about assessing and the third one is evaluating. And what I'm wondering is how you actually do the assessment. I'm not asking for an answer now per se, but it is certainly, we want to assess it, but there's got to be some sort of assessment criteria that are used to characterize things to ensure the issue is fully understood.

Well, I don't know what that means exactly. But you must have in mind some

assessment tools that would indicate whether or not you believe that NIOSH got their arms around the issue.

Also I think I understand the assessment of the methods outlined in the second sub-task. You're just going to look at the technical materials that they used and see how representative they are of the scientific literature, I guess.

But it seems to me it would be helpful if we actually had you try this, and you sort of have already on some other ones, but here you are formalizing it, to try this with a particular PER, maybe not one that is overly complex, and not one that is overly simple, and show us what these assessments look like. Is there some way that you are going to score things, quantify things?

DR. BEHLING: No, I think --

MEMBER ZIEMER: How subjective and how objective can it be? That's what I'm getting at.

DR. BEHLING: Well, to quantify something would be very difficult.

MEMBER ZIEMER: No, but I'm trying to get a feel between subjective and objective assessments because I think it's difficult.

DR. BEHLING: It is very difficult, and I think it's very DR specific.

MEMBER ZIEMER: That's why I said I'd like to see what an assessment looks like. I think as you get into it you will have some criteria against which you make the decision. For example in sub-task two, you would, for example, say, okay, we have reviewed these technical documents and they are or they aren't representative of the consensus of the scientific literature, or some particular document has been ignored. And I think you can get at it pretty easily in sub-task two.

Sub-task one, it seems to me it's difficult, and I'm not sure on -- well, I guess on sub-task three -- I just don't have a feel for how you would approach it.

DR. BEHLING: Well, as I said, I have at least tentatively scanned the different PERs, and I realize the approach will probably vary and be tailored to the specific PER. But in the case of -- we have already done two cases, two PERs, one which was reviewed by the Work Group, namely, that's PER 9, the lymphoma issue. And then there is PER-0020, which is the Blockson. And in the case of, for instance, lymphoma, there was obviously some lengthy discussion about early diagnostic tools and so forth, and I think we have a transcript of the discussion that was held in behalf of my writeup for the lymphoma PER.

In the case of -- and that was a very medically-oriented kind of thing where I went back into the medical literature, my own pathology textbook, and we had a fairly lively discussion with NIOSH over that issue. And it was a very different and unique situation.

In the case of Blockson, it was

basically a revision to the TBD, and many of the changes that occurred, that was the genesis for the PER. So it's going to be very difficult for me to tell you precisely how it's done, but each one will be different. In the case of the current PER, Super S plutonium, again, will be an assessment that looks at the data that were used to come to this conclusion, namely, what was prompted obviously was the discussion and the SEC petition regarding Rocky Flats, that there were plutonium fires. These were very highly oxidized, plutonium oxide, highly insoluble materials. And the realization was that post-mortem studies and others involving exposed individuals showed retentions in their lungs that far exceed type S as described by the ICRP test group, lung model, and so on and so on.

So I don't know if there is a generic protocol that I can point to that will identify the method, and I haven't gotten to

the Super S plutonium. Obviously, Dr. Lipsztein, who is on the line, was very central to that whole discussion. But we will probably go back and assess whether or not there are any other data that could potentially trump the information, which is not likely, but it appears from what I have done at this point is that NIOSH took a very conservative approach by looking at the two most restrictive cases involving data, human data, that are available, and coming up to the various recommendations for this PER.

And as I said, I don't know if there is a generic protocol for me to point to and say we will follow this protocol. I don't want to box myself or paint myself in a corner by writing a protocol that may not apply at all. I believe each of these PERs will be very very different in terms of assessing the technical basis for it and simply following the methodology that NIOSH has supplied in coming to some understanding of whether or not

that was technically sound, claimant favorable, et cetera, et cetera.

MEMBER GRIFFON: But, Hans, this is Mark Griffon. If I understood you right the PER-0009 and PER-0020 reports that you did were done based on this protocol, so theoretically your reports should include a description of sub-task one through four and what you did.

DR. BEHLING: Yes.

MEMBER GRIFFON: So, Paul, maybe that would be something to start with in terms of getting an example of how it looks.

MEMBER ZIEMER: Yes, that's a good point. And, Hans, in those reports do you actually identify these as issues? Can we put them one to one against these sub-tasks?

DR. BEHLING: Yes, absolutely.

MEMBER ZIEMER: Okay.

DR. BEHLING: The report is essentially broken up by sub-tasks. And as I said, the difference between PER-0009 was that

there was an additional sub-task that has at this point been taken off as Ted Katz had pointed out, it's no longer part of the protocol that we intend to use and was not part of the protocol that was applied in behalf of PER-0020.

MEMBER GRIFFON: Can I ask another question on the document you sent around?

DR. BEHLING: Yes.

MEMBER GRIFFON: Under sub-task four, I think that probably is something we might want to discuss a little bit. I certainly agree with the criteria you listed. I guess it goes into section four, actually. But I was noting the three bullets in the beginning of Section 4, page 7 in the document. It seems to me, and PER-0012 or OTIB-0049, I guess, would be a starting point in my thought process, it seems to me that at least overlapping criteria would be the site where -- that was affected by the PER. Because I think in the case of high-fired

plutonium, we certainly -- it affects more than one site. So that is not listed in your criteria, although it sort of is underlined there I guess.

And then the other criteria -- and, again, this may be sort of underlining also -- is the Probability of Causation of the cases, just as criteria to consider when we select these cases for review. I don't know if others have thoughts on that, but I think this is an important part, where the Subcommittee or the Board sort of is brought into this, into the fold here.

DR. BEHLING: Again, Mark, this is so different among the PERs. In the case of PER-0012, it was here that for instance the recommendation to use a factor of four for the highly insoluble would allow a very quick and dirty approach at least for the urinalysis portion if the original dose reconstruction was performed by way of urinalysis, then the factor four, which is one that says, okay, if

we have to apply that, then we can clearly identify the threshold level of PoC, which turned out to be under OTIB-0049 16.57, or something like that, as a threshold. And that is clearly understood when you realize the corrective factor for Super S plutonium involves four. So that however is not a constant; it's a very critical variable, and it always comes into play when you try to screen out certain claims that are part of the universe initially, but then by way of a screening factor you try to reduce it in order to obviously maximize the effort in affecting only those claims that will truly have the potential for exceeding the 50^{th} percentile PoC value. But that will, again, change from one PER to the next.

MEMBER GRIFFON: I agree. I just thought that in that section you were listing criteria that may be considered in the selection of cases. And certainly the site is not going to affect many of the PERs because

they are site-specific.

DR. BEHLING: Yes, and in this case I think I did mention the fact that a site, in the case of even the PER-0012, we realize there is one additional correction factor that may be somewhat site-specific, and that is the particle size for Rocky Flats, we've assumed that in a fire, in an instance of high-fired plutonium that is the result of an actual fire, that the particle size may go from the default value of five microns to 0.3 microns, and that may be highly site-specific. Not to mention the fact that in attachment A of PER-0012 we do list the various sites that will be potentially affected by the Super S plutonium. I didn't necessarily -- I tried to be more generic in my writeup.

MEMBER GRIFFON: I agree with that. I think the other complication that I mentioned at the Board meeting that I thought we might want to discuss more here is that when we select these cases for review, you

know, the cases that fall under a certain PER, and Stu, we've certainly discussed this either at this Subcommittee or the other Subcommittee, I'm just not sure we will go about the reviews because oftentimes when NIOSH modifies a case or goes back and makes corrections to a case, they will not only do corrective actions based on PERs but may actually end up reworking the entire case based on more current procedures that are out there. Is that correct, Stu, if you are in the room?

MR. HINNEFELD: Yes, that is correct.

MEMBER GRIFFON: So I don't know how that complicated things when we go back to audit, but you know, to look at this, but it may complicate things is my impression.

DR. BEHLING: Yes, and you've mentioned one, and in fact if you look at OTIB-0049 they make a strong statement about identifying not only the universe but then

whittling down, and there will be a subcategory of claims that will not only be affected by PER-0012 but by others including for instance in the case of a lymphoma that may involve lymph nodes, thoracic lymph nodes, they will be affected not only by 12, but by PER-0009 and by other factors. And also there is the issue of was the original dose reconstruction one involving a best estimate or a maximized? If, for instance, the original dose reconstruction was a maximized dose, well, there will be certainly revisions to the dose reconstruction that reflect PER-0009, but NIOSH may elect to go back and say, well, we gave you a lot of gifts here as a maximized dose reconstruction that we will withdraw now, and so the whole idea of the dose reconstruction audit involving the PER is very complex.

MS. BEHLING: That's what we tried to discuss under sub-task four, if you read through that, we identified that.

MEMBER GRIFFON: And I guess that's my point is it could complicate the selection process for us because if you just look at sort of descriptive statistics and information like that, you may not be getting the full picture of what you're, you know -- because other changes could have been made, they could have -- well, I guess we just stated it.

DR. BEHLING: And, Mark, not even the least of which may be the fact that a dose reconstruction may actually have been audited under task three, and there may be outstanding issues that have yet to be resolved by your Work Group. And so -- I mean, under task four, so we are dealing with a very complex issue here, and that is why I have elected to basically make this into a two-step process, which is we will go through sub-task one through three, and then make a certain recommendation to the Work Group, and then allow the Work Group to discuss it, and then

select the cases that you may want to have as part of the audit.

CHAIR MUNN: Ted.

MR. KATZ: I'm sorry, I just wonder, because this discussion came up when we were reviewing the contract as well, the contract evaluation panel, but I don't know if this simplifies things, Mark, but I mean the point of these PER reviews is to review the adequacy, appropriateness, scientific quality of the PER action, and not really to evaluate other factors with respect to the redo of a dose reconstruction, and if it were just another dose reconstruction review. And I wonder if that doesn't simplify things in a sense. Because really you are only looking -- the point of these reviews is to determine how well was the PER constructed and then implemented, not any other sort of coincidental consequences for a particular dose reconstruction that you would address in a normal dose reconstruction review.

MEMBER GRIFFON: Yes, I think it's only complicated in the selection. I'm just trying to think this through, Ted, but I mean in terms of the selection you may see something that for instance using my PoC example you may look through all the potential cases and say, oh, let's look at this one because it's 48 percent or 47 percent, and when they read -- when they rerun it or reran it, it may have gone over 50 percent, but in fact it was a maximizing case, so then all those generosities as Hans just alluded to are taken out when they had to redo it, when they redid it with the PER corrective action. So you may not be selecting -- I think it affects things more in the selection process than in the actual audit process.

MEMBER ZIEMER: That is correct because in the audit process obviously they will have to consider those other factors. And you won't a priori know, I don't think, in the selection process how those will impact.

But it seems to me that one way to handle this is to include in the document the fact that SC&A would work, I think, with the Dose Reconstruction Subcommittee in the selection. I don't believe this Subcommittee would get involved in the selection. I mean if we approved this as an approach, we wouldn't be involved, would we, in selecting cases?

CHAIR MUNN: In selecting the cases, I wouldn't think so.

MEMBER ZIEMER: And so in making the decision on criteria for case selection, I don't think that is unilaterally SC&A's decision. Mark, wouldn't your Subcommittee be involved if it's a particular PER situation, or group of cases? Wouldn't you be involved in that decision, under number four?

MEMBER GRIFFON: Yes, I would, either this Subcommittee or the DR Subcommittee.

MEMBER ZIEMER: Well, I would think it would be the DR Subcommittee. All

you are really saying here is that this is a procedure that should be followed to audit some DRs that are affected, but the selection of those, it seems to me, would be done in collaboration with the Dose Reconstruction Subcommittees, though SC&A would need to -- well, they would need to be tasked or sub-tasked by your Subcommittee. So I don't -- I think these are criteria that they have identified, and it doesn't seem to me that your Subcommittee is necessarily restricted to consider only these things, but other related issues as you see it, it would seem to me.

MEMBER GRIFFON: Yes, and I think they do state, SC&A's document says that the selection will be up to the Board.

MEMBER ZIEMER: Right.

MEMBER GRIFFON: And I agree.

MEMBER ZIEMER: And it basically says -- I don't think this is stated that these are restricting considerations, but let's see how it says -- it includes the

following, it doesn't say it's only the following. So there can be other factors as you described, it seems to me.

MEMBER GRIFFON: Okay, I agree.

MEMBER ZIEMER: Or maybe they would say include but are not restricted to the following.

Hans, I think you said there were a couple of other minor changes you were going to make anyway, right?

DR. BEHLING: Right, but, Dr. Ziemer, let me just point out in my summary conclusions I clearly state that SC&A will not be the people who make any primary decisions. We will only make recommendations.

MEMBER ZIEMER: Right, that's why I'm saying I think the listing of the three is not intended to be restricted at all; it's just examples of issues that may affect us.

MS. BEHLING: And it's to guide you as to how many cases you might want to consider soliciting.

DR. BEHLING: And the diversity of the different cases. Like I said, it would be, in the case of PER-12, we would probably want to select -- under PER-12 we select -- or there are four different classes of target organs or tissues, the lungs, the thoracic lymph nodes, all other organs, et cetera. So we would probably say or recommend to the Subcommittee or Work Group, whoever, whether it's Wanda's group or Mark Griffon's group, a pool of criteria by which to select those. And then of course the Work Group or the Subcommittee would then make a final decision as to which ones they would like us to audit.

CHAIR MUNN: And, ultimately, no matter how prescriptive we attempt to be in establishing criteria, the bottom line is it's going to involve some technical judgments. We will have to have an agreement on items that are not as proscribed as we perhaps would like them to be, often.

DR. BEHLING: And as I said, it

would be really our input, SC&A's input, in behalf of sub-tasks one through three, that would provide the committee or the Work Group with the basic information on which they would then make a decision as to how many and which type of DRs we should then be looking at for a reevaluation of dose.

CHAIR MUNN: That recommendation would be welcome. It's very difficult for people who do not work with the cases and each of the procedures on a daily basis to make the kind of evaluations we're asking you to make.

DR. BEHLING: And in this case, I think, we have the blessing of Mark Griffon who is obviously a member of both committees, chairperson of the Dose Reconstruction committee. So certainly we have the ability to communicate well with the people who are well-versed in the issues of dose reconstruction and the audits of dose reconstructions.

CHAIR MUNN: So how do you

perceive our next step in this process as going?

DR. BEHLING: Well, I guess -- I hope that the Work Group members that are in attendance today will look at the writeup, and, as I said, I apologize that you didn't have a chance to review it and then perhaps make certain recommendations, whether they be by way of email or otherwise, so wait for another Work Group meeting to commence.

At this point I'm going to go ahead and conduct my audit of PER-0012 without, obviously, committing myself to any particular format. There is a lot of background work that needs to be done, but I will continue, and then I will await your final decision as to whether or not the basic methodology as provided here in our draft report will stand, and I still strongly feel that we should follow basically a two-step protocol that will allow SC&A to assess the PER under sub-task one through three, provide

a draft report on behalf of those findings, and then recommend to the Work Group or the committee a list of DRs, the -- or qualify the DRs based on an understanding of what the PER intends to do, and then allow the committee to select those cases which we will then review, and then we will write a final report.

MR. MARSCHKE: Could I just ask how this is going to work? I mean to me, listening to all this, this is kind of the first time I've listened to all this, but listening to all this it seems like there's going to be a breakdown between Subcommittees, and task one, two, and three is going to be done kind of under this Subcommittee, the Procedures Subcommittee, and then we are going to get a report -- SC&A is going to generate a report, and then it is going to go over the fence to the Dose Reconstruction Subcommittee to really do task four, sub-task four, under really the DR Subcommittee.

I'm a little wondering about the

logistics, or maybe it's too early to worry about the logistics of how this is going to be --

DR. BEHLING: Well, we anticipated that as an issue, and in our writeup we referred to it as the Subcommittee versus the Work Group because it tends to be basically an issue that I think needs further discussion, who will ultimately then undertake the role of reviewing our audits of selected DRs. Would it be Mark Griffon's group or Wanda's group?

CHAIR MUNN: Stu.

MR. HINNEFELD: Well, I have an unrelated question, if you want to talk about that. I mean it's related to procedure, but not that specifically.

MR. KATZ: I have a related question which may complicate things a little bit, but depending on which PER it is, when you have a site-specific PER I would think you would want that, if there is a Working Group for that site, that that Working group would

be the one to oversee the PER review, not really this. But that's a question, that's not an assertion. So if it's a PER for NTS, you would think the NTS Working group.

MS. BEHLING: I think from a conflict of interest standpoint we really need to move in that direction. And also I'm not sure -- why can't we treat the PER assignments similarly to how we treat receivers where there is a transferring mechanism from this Subcommittee to the appropriate Working Group, or even the DR Subcommittee. So that at least then we can track what happened.

CHAIR MUNN: I need to think about that.

Paul, you had a comment?

MEMBER ZIEMER: Yes, let's say that there is a particular PER of interest, let's say it's, I don't know, high-fired plutonium, it cuts across a number of sites in some cases, or you may have a site-specific one, what we would be approving initially is

the approach, that's this. Once that is in place, the Board can assign -- the Board can assign -- well, I guess we would be tasked to pick out PERs to review.

CHAIR MUNN: I would think.

MEMBER ZIEMER: That's the question.

MR. KATZ: That's a big question that was raised at the -- I raised at the full Board meeting. It's the actual selection of the PERs that will be reviewed. I had argued at the last Board meeting that that should be done by the full Board because of conflict of interest trouble with putting it with a narrow Subcommittee.

CHAIR MUNN: But by the same token if the recommendation from SC&A comes with a similar recommendation from this body, it seems to me that would be helpful for the full Board to make that decision.

MEMBER ZIEMER: Well, at the front end we have to decide on what PERs to review.

And so we have this list, and I think they are all in the document here, most of them, or all of them I guess are in the document, and we looked at the first several on the list last time.

But I think what we were struggling with, and maybe counsel was as well, is what can we discuss and maybe do we know the answer to that, in full Board when we have the whole list, other than making motions? The fact that some -- let's say someone from Hanford makes the motion that we do an Oak Ridge PER. Well, in a sense they are doing that to the exclusion of the site that they are involved in. So can they really do that, see? Can everything be on the table at startup? I have a lot of problems with how we make the selection. Once the selection is made, then I think it's fairly straightforward. Then SC&A can start their tasks, reviewing the thing, and they have to work with the Dose Reconstruction Subcommittee

to select doses, I guess, test and review, and task -- sub-task four.

But the front end of the whole thing, it seems to me, is --

MR. KATZ: I mean there are two -- I mean before the selecting dose reconstruction cases, I mean it's the oversight of task one, two, three of the PER procedures, as Hans laid out, and I would think the Work Group, if it is a site-specific one, I would think, again, the Work Group that is responsible for that site might be the logical one to oversee steps one, two, and three that they laid out here.

MEMBER ZIEMER: Once the full Board has made that --

MR. KATZ: Once the Board has made that selection. But let me just go back. I mean, I don't think OGC wants to be committed at this point since there are still issues with HHS about this. I think I as a DFO don't mind that, I don't mind being strung up later

if I am. But I think that the only thing that makes sense -- again, there are practical limitations on what we can do to deal with this conflict of interest problem because there is no way that I can imagine -- and I've given this some thought -- for breaking up the Board in ways to be able to deal with the question of selection piece by piece to avoid conflict, and I think the only thing that is practical, even though it's imperfect in the view of HHS with respect to tasking and conflict of interest, I think the only thing that is practical is for the list to come before the full Board, and those people -- people's conflicts, they simply stay silent on their conflicts. They can make recommendations unrelated to their conflict. They can contribute to discussion unrelated to their conflict, you know, the conflicted site, but they stay silent on those, and obviously they don't vote on those.

And I just think that is the only

workable way to do it.

MEMBER ZIEMER: So what you are talking about is that in full Board, suppose we select five PERs to review and say, okay, here's these five. Then we would take them one by one and say, okay, here's the Hanford one, the Hanford people say, how many vote to task this.

MR. KATZ: Right.

MEMBER ZIEMER: And here's an Oak Ridge one, the Oak Ridge people have to sit out. If we have one that is across the complex, then we will need some decision from counsel on how that would work, I guess, or maybe we have it. But it seemed to me there was some sort of feeling that if it's bigger than a certain amount it becomes more universal. If it's just like two sites, those people have to sit aside, if it's five or six or something, there's some point at which everybody -- am I understanding this correctly? Or maybe it's too early to say.

MS. HOWELL: I mean, I definitely think that that was what I conveyed during the October Board meeting. But it hasn't been finalized because it's a question that has to go beyond our team. And certainly we recognized the importance of it, and we have been in conversations with not only the other HHS folks, but also Dr. Howard is well aware of the concern, and Ted's working with us. So I'm hopeful but not -- can't promise that maybe we will be able to address it on the December 8th call.

MEMBER ZIEMER: Let me ask you another question. Are we meeting again before the full Board meeting? Is this Subcommittee meeting? I would like to see this document in some form approved. I sort of feel like it's -- in spite of the questions I asked earlier -- I suspect it's about what we are going to end up with, with a few minor edits. But I'm wondering if we would be prepared, at a full Board meeting, to recommend that this be

procedure, recognizing that it already in practice, number one, has been used. I think it pretty well reflects the original contract tasking for this activity. Although that didn't have official Board approval, I think, it was approved through the contracting process by those who were involved. And I think all we were trying to do is formalize that with the full Board in our last meeting, or that's what generated this.

MR. KATZ: So you are speaking about the December 8th meeting, conference call?

MEMBER ZIEMER: No, I'm talking about the February meeting. I think the conference call would be a little too early. I think we need to have a full discussion.

MR. KATZ: So we can certainly have this on the agenda for February.

MEMBER ZIEMER: I mean, I certainly am willing to -- to recommend that we approve this or whatever the document with

minor edits might be.

MR. KATZ: And then maybe, given that we have until February, maybe we can work hard at least to try to get clarity about this issue of when you have a PER that cuts across a few sites, how do we deal with that numbers problem? Because we are going to have to have a practical solution to that.

MEMBER ZIEMER: And even if we don't know the answer to that, we could still have a general approved procedure.

MR. KATZ: Right. Right, but it would be nice to settle it all at the February Board meeting, and we will work towards that.

MS. BEHLING: This is Kathy Behling. I would also recommend that maybe the Subcommittee go back and review PER-0009 that we've already done which is one of the -- which is a PER that crosses a number of facilities, and also PER-0020 which is site-specific. And, again, as Hans said, you will see in those PERs that are already completed

how we've followed the sub-tasks that are laid out here.

The other thing you might want to think about for future meetings -- I don't know if it has to go to the full Board meeting -- but as Hans mentioned, both PER-0009 and 0020 -- in fact PER-0020 I don't believe has been reviewed by this Subcommittee, and it would be a good example of where do we want to review that, that's Blockson PER, and we haven't selected any -- there hasn't been any decision on the number of cases or the cases that should be selected for PER-0009 which is the lymphoma issue. So those are also things you might want to consider for future meetings.

MEMBER GRIFFON: Can I make one comment?

CHAIR MUNN: Yes, please.

MEMBER GRIFFON: Paul -- I agree with Paul that I think we should probably -- this procedure looks very reasonable and looks

appropriate to follow, and we should probably at some point vote to approve the use of this or however that process has to work.

As far as the handling of the cases, I'm not sure, I can sort of follow the logic of the site-specific questions, but then I also have to reflect back on the fact that the DR Subcommittee has been looking at cases from all sites throughout its history, so if this is a -- really this is a dose reconstruction question, probably, and might be a lot easier if we just keep it between two Subcommittees, instead of farming it out to every work group and -- I'm just envisioning that process being very difficult to track, and really the work groups have been looking more at site profile and SEC issues, rather than does reconstruction issues.

Although they certainly overlap, I understand, but I guess if I had -- I guess it's my thought on that, that it would be a lot easier to manage if it were between the

two Subcommittees.

And then the final point is really a question. I was wondering if Hans or Kathy can elaborate on, in attachment one of this procedure, the -- I understand, in your level of complexity I understand how you ranked, or I can certainly envision how you ranked the science factor as medium, high, or low, but can you explain -- just explain a little bit on how you arrived at these selection criteria, high, medium, and low for the various PERs that you looked through in the table.

MS. BEHLING: This is Kathy Behling. Yes, in some cases, in some PERs, the selection criteria for NIOSH can be something very simple. I think John Mauro might have mentioned this at the last Board meeting. But something as simple as saying, if it's less than 50 percent we are going to look at everyone that is less than 50 percent, and there is not any additional criteria or

protocols that they use to select which cases are actually going to reevaluate, but in the case of the PER-0012, as Hans was mentioning, they are going to go back to cases, and they are going to say, we are going to look at this if -- depending on what the bioassay was and what the PoC was, and there is a calculation that they do for determining what the minimum PoC was, and so it becomes a much more complex process for determining who they are going to actually select in order to reevaluate their dose reconstruction. Does that make sense?

MEMBER GRIFFON: Yes, thank you, Kathy, this is Mark Griffon again. That makes sense. And let me just for clarity purposes, in that last column, the selection criteria, high, medium, and low, that is based on NIOSH's stated selection criteria, or is this sort of SC&A's independent opinion on how difficult it will be to select?

MS. BEHLING: No, I think that on reading through the PER and looking at NIOSH's

selection criteria.

MEMBER GRIFFON: Okay, so you may -- and in your steps one, two, three, I guess part of that would be to assess if the criteria is getting at what they need to?

MS. BEHLING: That is correct, absolutely.

MEMBER GRIFFON: All right, so this is really an unstated criteria.

MS. BEHLING: Yes.

MEMBER ZIEMER: These are SC&A's evaluations, though, right? When you say medium, Kathy?

MS. BEHLING: Yes, those are my evaluations. But those evaluations were based on NIOSH's selection criteria as stated in their PER.

MEMBER ZIEMER: Right, but they are somewhat subjective.

DR. BEHLING: Yes.

MEMBER ZIEMER: When does it go from medium to high, in other words.

CHAIR MUNN: Well, that is always going to be there. Stu?

MR. HINNEFELD: I apologize, the -- this is Stu Hinnefeld. I'm interested in sub-task one and two, exactly what does that mean? And to keep in a specific example, let's talk about PER-0012, high-fired plutonium. Presumably sub-task one is that we correctly identify the issue, and I guess the issue, loosely speaking, is that there is this high-fired plutonium out there at a number of sites that the behavior is not described appropriately by the existing ICRP models. That's the issue. So the corrective action we did here was we wrote an OTIB, which was, I think, 0049, and OTIB-0049, then, was our method to address that issue and apply that to the -- to the populace, to the subject population. So in sub-task two then, SC&A proposed review of the scientific basis -- or essentially, is that -- it sounds like it's the review, assess our methods for the

corrective action, in other words, assess OTIB-0049.

DR. BEHLING: Yes, and, again, there is some redundancy here, and --

MR. HINNEFELD: Well, it sounds exactly redundant to me because there is an OTIB-0049 review already.

DR. BEHLING: Exactly, and I think we have that review. And, again, that was Dr. Lipsztein's work that we used in OTIB-0049, and it's basically trying to pull -- and I have to say much of this has been done. And so what we are oftentimes tasked to do is to pull all the little strings together into a single report because we realize not everyone has been involved in, for instance, the review of OTIB-0049, and so part of this review of the PER goes beyond just PER-0012 because that is a relatively short document and it only summarizes and only references critical documents. The most critical document for the evaluation of PER-0012 is really OTIB-0049.

MR. HINNEFELD: So then if this -- well, it sounded to me like it was essentially another review of OTIB-0049 is what it sounded like.

DR. BEHLING: Yes, it is. Yes it is.

MR. HINNEFELD: And that's what you want to do?

DR. BEHLING: Well, I will review it, and, again, I will heavily rely on Dr. Lipsztein and perhaps sort of audit the auditor.

MR. HINNEFELD: So is that what you want to do, do another review of a document we've already reviewed? Now to me this PER -- and in fact I believe our findings on OTIB-0049, which may still need to be resolved, which may result in changes.

DR. BEHLING: And I think Dr. Lipsztein is on the phone, so she can make a comment as to what is outstanding.

MR. HINNEFELD: Before we do that,

I'd like to finish the thought. The PER process was a process -- that's what we've adopted, when we make a technical change in how dose reconstructions are done, we adopt this process to go back and reevaluate things that were done under the previous method. In this case our change was we published OTIB-0049 that specified the kinds of claims that that applied to. So in this case we've done this PER-0012, we have been -- have selected a population. The rest of this I think is absolutely good stuff to evaluate -- did we select the right population, all that stuff, that's good. We selected that, and then did we appropriately apply OTIB-0049 to the dose reconstruction? If in fact there are flaws with OTIB-0049 and that has to be revised and so the dose reconstruction method is changed yet again, then that is another PER, and that would have to come later.

I mean, to me reassessing the adequacy of our fix is essentially a review of

a technical document that we have already changed, and that technical document that we have already changed is the basis for the PER that we did.

CHAIR MUNN: And it's the response to the PER, yes.

MR. HINNEFELD: So I mean to then go on and further evaluate the PER process based on a new review of our resolution is going to bollix this -- this PER-0012 is going to get all bollixed up.

CHAIR MUNN: Agree.

MEMBER ZIEMER: Agreed.

MR. KATZ: Just from a contracting point of view, this is for the Work Group to decide. It's something you decide, but it doesn't make sense to pay twice for a second review of a document that SC&A -- in some cases SC&A may not have reviewed the Technical Basis Document perhaps, but in a case where they have already reviewed it, you would think that would stand on its own.

MR. HINNEFELD: And my fundamental issue here is that the technical change that led to the PER is complete. It is done. It was the publication of OTIB-0049. So to then include a further evaluation of OTIB-0049 into the evaluation of this PER introduces a whole other set of possible upset conditions that were not a part of the universe that was faced in the completion of the PER. You are introducing a confounding factor into understanding whether the PER was done correctly or not.

CHAIR MUNN: It's a circular process that is really not what we want to get into.

MEMBER GRIFFON: Stu -- this is Mark Griffon -- Stu, I definitely agree that we should --

(Telephone interruption.)

MR. KATZ: For the record, Mark agreed with me, and then someone cut him off. So everyone else is still on the line?

DR. BEHLING: There are others still on the line.

MR. KATZ: Okay. He'll dial in.

DR. BEHLING: Let me just fill in the gap here while Mark is trying to reconnect here, and I understand that this is somewhat redundant, and what I was really hoping to do under sub-task one, two, and three is to basically consolidate and summarize what has been done. I am not going to go through the effort that Dr. Lipsztein had gone through in assessing the credibility of OTIB-0049. I will accept her comments and perhaps maybe add just a few comments and look at the PER-0012 in terms of, for instance, in the case of the PER-0012 there are certain criteria which are not necessarily addressed in OTIB-0049, and that is how to select the dose reconstruction screening methods one and two --

MEMBER GRIFFON: Wanda, I'm sorry, this is Mark Griffon. I think I cut myself off accidentally.

MR. KATZ: I credited it to agreeing with me, Mark.

MEMBER GRIFFON: Yes, you liked that ending, right?

The only thing I was going to add on, and I think it's still pertinent, is perhaps we should consider this as part of our selection process. Like in the case of PER-0012, I would say maybe we shouldn't review PER-0012 unless OTIB-0049 has been completely through our process and all findings are closed because if we end up disagreeing with fundamental -- you know the OTIB-0049 in any substantial way, and that has to be revised, then I would say hold off on reviewing the PER-0012 at all. So I guess that would possibly be a way to look at this, we don't want to do the work twice, and I don't want to review cases that are under a PER that we have sort of fundamental disagreements with on the basis of an OTIB change or something like that.

MEMBER ZIEMER: Well, I think the issue here is whether the task of, I guess it's sub-task one, assess the evaluation of the issue and potential impacts -- is that what -- what sub-task is assessment?

MR. MARSCHKE: Three.

MEMBER ZIEMER: No, three is how you identify the dose reconstruction.

CHAIR MUNN: Yes.

MR. HINNEFELD: Assess NIOSH's specific method for corrective action. In this case that would be assess OTIB-0049. In this case it might be as simple as just saying enough has been done.

MEMBER GRIFFON: But my point is that if it's under review still, I think I would hold off on moving any further until whatever entity is done reviewing it, if it's the Procedures Subcommittee or if it's another Work Group.

MR. HINNEFELD: Yes, I don't have a particular strong opinion on that.

MEMBER GRIFFON: Wait until it's finished. We don't want to duplicate the effort in this process.

MR. HINNEFELD: I understand. But understand that the PER-0012 is done, and if in fact there are subsequent changes to OTIB-0049, there would not be a new PER-0012, there would be a PER-0036 or whatever the number is to evaluate those.

MEMBER ZIEMER: Mark, you're talking about the OTIB, right? Mark, are you talking about the OTIB?

MEMBER GRIFFON: Yes, my point there was, and I understand Stu's point, but our bottom line is we want to eventually see that cases are done appropriately and have the correct scientific basis. If OTIB-0049 is still -- and I don't know the status of it -- but assume there are still some outstanding findings, I would say let's wait until we close those out in the procedures review because if in fact we end up or NIOSH ends up

revising OTIB-0049, then they come out with a PER whatever, 40 or whatever number, that replaces PER-0012 sort of. I don't know that we want to review different -- we might not want to review PER-0012 right now if we are not in agreement with the scientific basis underlying PER-0012. It would just cause us to review the same sort of issue again in PER-0040, if that makes any sense. So I'm saying wait until it's closed out.

MR. MARSCHKE: Mark, just to give you an idea, the current status of the review of OTIB-0049 is that SC&A had identified two issues, and currently those two issues are being shown as being in progress.

So that means that there are still, I guess, still outstanding issues to be resolved between NIOSH and SC&A and the Subcommittee here. So what you say is very true, that depending on the resolution of these issues they could involve a revision to OTIB-0049.

MR. HINNEFELD: You can do like you want. I mean we don't have a horse in the race, in terms of how this Subcommittee decides to do this. Just from my standpoint from the review, you have a complete set of actions from the publication of PER-0049, a PER to implement that, that OTIB. Okay, and that gets us to a certain spot where we are today, and then we have a review of OTIB-0049 that may result in some changes, may result in changes to OTIB-0049. Those changes, then, may cause us to reevaluate some of the claims again. That will be from where they are now; that will not be from where they were before PER-0012. And so it's like step-wise. Now you wait until the end and say, okay, when everything is done then we'll review it, then you have essentially two PERs to review at that time, one, 12, which is first, and then the number 40 or whichever it is that comes later.

MEMBER GRIFFON: And I'm saying

that we may decide, if that all happens that way, Stu, we may decide we don't need to look at 12 at all; we can just look at 40. That is just what I'm thinking in terms of the selection.

I mean what I certainly want to avoid is having us review the OTIB-0049 issues in two places. I think that would be very complicated.

MEMBER ZIEMER: Mark, the other side of the coin is that anything reviewed at this point, say with 49, it still has a couple of open issues, any changes that occurred in terms of compensation, those are in place. So if a change comes later, those aren't affected by it because they've been compensated. So those drop out of the review process. Understand what I'm saying?

MEMBER GRIFFON: Yes, that's true. That's true.

MEMBER ZIEMER: So if you want to assess whether NIOSH is correctly applying the

PERs, it seems to me you look at them as they are being applied, in any cases that are affected by those, otherwise you are not going to see -- even though you say, okay, this particular OTIB is not completed yet, nonetheless we have a PER that is in effect, and we are asking, in essence, SC&A to see whether -- how they are applying that, I think. Isn't that what we're trying to achieve here?

MEMBER GRIFFON: Then you are not addressing the underlying science.

MR. MARSCHKE: Basically you're not doing sub-tasks.

MEMBER ZIEMER: That's exactly the point, and I think I understand the point Stu is making. We are applying the science as we have it today based on an approved PER. And we are asking if it's been properly applied.

MEMBER GRIFFON: Yes, I think there are two steps, and all I'm -- I think we should review the underlying science, but we

shouldn't do it in two different places, you know. So if the underlying science ends up being documented in a revised TIB, and we are already reviewing that in the Procedures Subcommittee, then we shouldn't also have Hans do it in this PER review process. I don't think we should skip reviewing the underlying science.

MR. MARSCHKE: Can we make -- when the PER review is assigned to SC&A, can sub-task two be optional? I mean basically not optional, but I mean the Subcommittee in the assignment says the PER review has to look at the underlying science or sub-task two has already been done under separate review of, in this case, OTIB-0049, and therefore sub-task two under the SC&A review of the PER review does not need to be implemented.

MEMBER GRIFFON: That makes sense to me, Steve.

DR. BEHLING: And I think that is correct in the sense where not every PER has

the technical backbone that corresponds in the case of PER-0012, too, and OTIB-0049, and so you are absolutely correct, and I certainly wasn't planning on spending a lot of time rehashing things that have already been done or are currently in progress.

On the other hand, PER-0012 and OTIB are, you know, it's a marriage bond between the two; one basically is based on the other. And yet there are certain factors such as the selection criteria by which the PoC, the threshold PoC, is driven by a value that is defined in OTIB-0049, and so one has to go back and say were the selection criteria that identifies the universe, and then the screening criteria number one is defined in OTIB-0012. Is that appropriate? Is it consistent with OTIB-0049? The two are very difficult to separate out entirely. It's clear that OTIB-0049 trumps the technical basis for PER-0012; there's no question about that. But yet there are still issues that are

not yet necessarily specified under OTIB-0049 that should be looked at in behalf of PER-0012.

MR. KATZ: But, Hans, those come under sub-task three, the selection criteria, et cetera. I mean those come under three. So sub-task two does not need to be done where you already have a review of an OTIB as a basis.

DR. BEHLING: Yes.

CHAIR MUNN: So it sounds as though we all need to have some thinking time around this before we come to any specific instructions to SC&A. Except that Mark's point is certainly well taken. It would seem to be redundant and in many ways adding to confusion if we continue down the path right now of spending a great deal of time and effort on PER-0012.

DR. BEHLING: Well, Wanda, can I just make a comment, for instance. It was never my intention, and as I've said, I have

only started to look at PER-0012 in context with actually using or applying this protocol to it, and clearly at this point I would not have obviously spent a lot of time on this sub-task two. I would have probably used Joyce Lipsztein's comments and review comments and other things as an attachment and simply defaulted to them, so when we think about, oh, we're being redundant, we are paying for the same thing twice, no, I don't think I would expect to spend a lot of time writing up sub-task two that would potentially cost man hours in behalf of this particular task. I would simply default to what has already been done.

And I think this whole thing sort of summarizes the complexity of PERs that no two PERs are going to be identical, and each one has to be treated on its own merit, depending on what information is available, what has been done, have OTIBs been already issued, in which case some of these sub-tasks will simply be a reference to what has already

been done, and we'll simply brush over it. And that's really the difficulty in writing a generic protocol.

CHAIR MUNN: That's true. We recognize, Hans, that you were simply using PER-0012 as an example and probably a very good example since it has generated this kind of discussion.

DR. BEHLING: And the reason I used it, Wanda, is first of all, it is obviously on the table, and people are already familiar with it, and the real emphasis was not so much on task three but on the selection criteria of DRs. And it provides a perfect example how this selection criteria and the total number of DRs that may want to be audited are defined. But what is the method by which the Subcommittee will make the selection. And I used PER-0012 for that reason because people are familiar with it, and they can go to OTIB-0049, look at Table 1, and say, oh yes, these are the number of

permutations that you may want to look at that will affect the methodology for dose reassessment, and on the basis of that we will select certain numbers and certain types of reassessed DRs for auditing.

CHAIR MUNN: Well, we appreciate that, and my instinct is to follow Mark's recommendation that we -- I assume that was a recommendation, Mark -- that we actually not pursue the PER actively until we have in fact closed the OTIB-0049 issues. Am I stating that correctly?

MEMBER GRIFFON: Yes, that was my feeling on that one, yes.

CHAIR MUNN: That seems appropriate to me. The point that was brought up earlier with respect to getting something done before the next Board meeting is probably one we should think about at this juncture, to see if we can get further through our own process with these issues prior to that Board meeting. We don't have a session scheduled

for this Subcommittee prior to that time. And my calendar would put it in any case toward the end of January if we assume that we were going to have a meeting before the Board. If we want to bring something to them, then we probably should pursue this further and especially take a look at what's outstanding on OTIB-0049 and make every effort to try to close those, if at all possible, during that period of time.

I doubt that anyone will be able to spend much time on any of these individual items that we have before us over the next month or so. It's going to be difficult. But perhaps January would offer an opportunity for that to occur. I don't know how other people's calendars look for January and whether the last week of January is something we can look at. But when we -- is it your desire to take a look at that now, or would you prefer to wait until the end of our session later in the day and look at calendars

then?

I see Ted nodding his head.

MR. KATZ: You might as well see what else you have on your plate by the end of the meeting in deciding about scheduling this, unless we are going to lose some people between now and then.

CHAIR MUNN: I would hope not.

Let's keep that in the back of our head as a very good reason for us to consider a Subcommittee meeting prior.

Yes?

MEMBER ZIEMER: I still have a concern about the idea of waiting until everything is closed because, Mark, I want to just bounce this off of you. Let's suppose that something arose on the unclosed issues, maybe on this one or something like it, where it became evident that some completely new model was going to be developing and so on that might take a year or more to come to closure. I mean some of these thorny issues

get passed around and around. But in the meantime, NIOSH has gone back and are redoing -- at least on this PER, right. You are not sitting by, waiting --

MR. HINNEFELD: We are not waiting. PER-0012 --

MEMBER ZIEMER: Because I think it's possible on almost every issue that new information can arise and a new PER can develop. And if we say that we want to wait until sort of closure on everything, I still have a concern about how we assess those reconstructions that are done under the current PER.

MEMBER GRIFFON: Paul, I guess I should clarify it. I guess I just wanted to make sure that we consider that issue, that we -- if as we are selecting the ones we want to review, I think we should consider that status.

MEMBER ZIEMER: Oh, okay, you are not saying automatically eliminate because

there is an opening.

MEMBER GRIFFON: I wouldn't say automatically eliminate it, but I would also say that like in this case, PER-0012, we may say, you know, it is under review in the Procedures Work Group; it is not closed. But, however, we want to look -- but then I think we have to say we are going to look at the application only. The application, the PER as it -- because obviously we have to assess how the PER applied TIB-0049, we can't -- but in other cases where there is no sort of TIB attached, I think we look at the underlying science and the application.

MEMBER ZIEMER: I understand that.

MEMBER GRIFFON: So I'm not saying exclude it, I'm just saying make sure we -- because I can just see the situation where we start talking about the underlying science in this process as well as in the OTIB-0049 review , and I think we can't really -- we have to look at the application only in this

instance, I would think.

MEMBER ZIEMER: I suppose you can go to the open issues and get a feel for whether you think there is a likelihood they will have any significant impact anyway, or sometimes things are just not closed because there is some sort of administrative thing that hasn't occurred yet, or you are waiting for revised wording in the upcoming document or something, so it's in abeyance or something like that.

MEMBER GRIFFON: I guess I didn't mean it be exclusionary. I meant just that we take that into account or be aware of it when we're selecting.

MEMBER ZIEMER: Okay.

CHAIR MUNN: It's only logical, and it underscores what Hans has said several times. Each of these will require an entirely different set of criteria for evaluation, and we can very easily see why.

MS. BEHLING: This is Kathy

Behling. I just want to be sure I understand that we should then continue with our work on PER-0012. You are not telling us not to continue that work, I assume.

MEMBER GRIFFON: I think that has already been tasked, hasn't it?

MS. BEHLING: It has been, just based on this discussion. I wasn't sure if -- but we will just elaborate all of that in sub-task two as to the status of OTIB-0049 and continue on with our work.

CHAIR MUNN: That seems reasonable at this juncture.

MS. BEHLING: Okay, just wanted to clarify that.

DR. BEHLING: This is Hans. I'm looking at basically a summary of what changes will impact the reassessment of dose, and those are pretty much summarized in Table 4-8 of OTIB-0049, and we really have only a number of things that will involve dose reassessment, that is the factor of four, I assume, is not

being challenged, and I don't think Super P is going to be challenged for adjusting doses based on urinalysis.

Is there anything that is outstanding that would grossly affect the central methodology and values as defined in Table 4-8 that would affect dose -- the reassessment of dose? Are there issues that are outstanding, maybe more semantics or things that would not necessarily affect the methodology and the quantitative elements that are going to be used in the dose reassessment.

I am not familiar with where we are on OTIB-0049, in essence, what specific issues are outstanding.

CHAIR MUNN: Does anyone have the database up?

MR. MARSCHKE: It's here.

CHAIR MUNN: Can you actually read the two outstanding issues?

MR. MARSCHKE: First issue is basically a clarification issue. The issue is

some paragraphs need clarification, but in general it presents the data in a logical understandable sequence. Some of the sources of information in the document are not referenced. And then NIOSH's response is basically it does not appear that a specific response is going to be provided to this comment. If SC&A wishes to elaborate it more specifically on what sources of information are not referenced, then NIOSH can address this in page changes or future revisions of this document.

MEMBER ZIEMER: That is like an abeyance thing.

MR. MARSCHKE: Then basically the SC&A follow up was, NIOSH -- again, I don't know how far this goes on. Let me just scroll from here. There is a whole series of SC&A responses. The NIOSH response of the OTIB-0049-1 Part A does not satisfy the SC&A concerns. SC&A agrees with the NIOSH statement on page 41 Appendix C that the acute

scenario does not produce adjustment factors that are fairly consistent -- I don't know how much you want to go through all this.

CHAIR MUNN: Just wanted to have a good feel for what the actual outstanding issues are.

MR. MARSCHKE: I can send these to Hans when I get back and make sure that he has -- he is aware of these when he does his work.

CHAIR MUNN: It would be helpful, I think, for Hans and Kathy to have the entire history of OTIB-0049, what the issues were, what's been closed, and where we are with the two that are in progress.

DR. BEHLING: Well, I remember the writeup that Joyce submitted, and based on that it was a fairly strong technical endorsement of OTIB-0049. I don't think there were any major issues that she raised in her review.

DR. LIPSZTEIN: Let me insert -- Joyce Lipsztein -- we didn't read the last --

we didn't reveal the last version of OTIB-0049, and there were some changes made. One of the things that applied to both OTIB-0049, the last one and the initial one, that we need some specification or clarification on some of the application of OTIB-0049. It's not the period that is problematic. The problem is how to apply it if someone has two exposures or someone has three exposures. There is no clarification on what to do, and that is, I think, the issue that would be important for PER-0012.

MR. HINNEFELD: I remember the issue. It's multiple acute exposures, monitoring, and how do you interpret it in that instance. Those are the issues, and that goes on there. I don't know that we provided a response.

CHAIR MUNN: So, John, does that help you any with respect to understanding better where we are?

DR. BEHLING: I'm trying to

understand what Joyce just said. Joyce, are you implying that perhaps the Table D adjustment factors may not be appropriate for all cases of exposures? Is that what you are getting to?

DR. LIPSZTEIN: No, there is some clarifications because you don't know where or how you should apply it when someone is exposed, for example, in one year, and he is exposed again, for example, five years later. You don't know how to apply the table, that is all. So it needs some clarifications on what to do if someone has a chronic intake, if someone has one intake in year one and then has an intake 10 years later; we don't know what to do with the numbers on this table. It needs some clarification on how to apply OTIB-0049. Maybe what we should do is I can send you our problems with how to apply OTIB-0049, and I didn't read what you wrote about the PER-0012, so I was quiet because I didn't read it.

DR. BEHLING: Well, Joyce, for your information, so far my writeup is really not a strong technical evaluation that basically would compete, or even try to re-evaluate what you have already stated. Mine is not. So mine is a much more simplistic evaluation of PER-0012.

DR. LIPSZTEIN: And the other thing that might be important is that the new OTIB-0049 has some application of cycle samples, and we didn't review it. I don't know if it will affect PER-0012. But I was not involved in reviewing it.

What I was trying to say about the application that NIOSH has to clarify how to apply OTIB-0049 because I was trying to do a dose reconstruction for a worker and I had difficulty following NIOSH instructions. So I think it just has to be a clarification on how to apply 49, and that is what PER-0012 should be about, right?

MR. HINNEFELD: Yes, I think the

response to your comment will be explanatory and will not really be particularly substantive. But it will explain how your technique would apply; that's what I believe. And so I believe that the issues remaining are not huge in terms of technical rules. That is my belief. I've been known to be wrong.

MR. MARSCHKE: The summary of the -- or the SC&A summary of the issue or what we would see is SC&A would like a more detailed explanation of OTIB-0049 on how to calculate doses from multiple independent acute exposures and why the approach given by NIOSH is claimant-favorable. More examples should be given including the treatment of independent intakes. As such SC&A recommends the status of Part A of the OTIB-0049 issue 1 remain as in progress. So really it looks like it's asking for more explanation, more examples. They are not really saying that this was done wrong. We think that we need to do it this other way.

CHAIR MUNN: That's a very small number of issues that are even being debated any longer. So if Steve can send a full history of all of the OTIB-0049 findings and the resolutions, that would be helpful, I think, for Hans and Kathy in their approach to PER-0012.

MR. HINNEFELD: I was wondering, Kathy, have you used the database?

MS. BEHLING: Yes, I can. I was about to say that I can pull up all the data and go back and get a history. And we will summarize that as our sub-task in this particular case, in this PER review.

MR. HINNEFELD: I believe Steve has updated all the information from SC&A, I believe is on the database, so it's all on there.

MS. BEHLING: Okay.

DR. BEHLING: Stu, this is Hans. Can I ask just maybe for a little bit of clarification. Is it the intent of NIOSH to

basically review the recommended approach as stated in OTIB-0049 to see if the issues that Joyce raised are basically issues that will fall by the wayside because your protocol is a more bounding assessment that will more than adequately address any uncertainties that are being raised by Joyce. Is that what NIOSH intends to respond with?

MR. HINNEFELD: Well, my judgment -- and I don't have our response; the technical people should give the response -- my judgment is that the scenario that Joyce describes does not occur in our dose reconstruction. If we have essentially a positive bioassay with some years separation, unless there is very clear evidence that this employee was nowhere possibly exposed, the assumption on the dose reconstruction was that the person was chronically exposed during their employment, and the acute intakes are superimposed on the chronic exposure in order to match the bioassay that you have.

And I believe in that circumstance our judgment factor will still be favorable. That's what I believe, but that is strictly a judgment sitting here, and no one has told me that that is true. So don't everybody bank on that.

CHAIR MUNN: We had an action item for a technical call on this OTIB to try to resolve these last outstanding issues. But I have no evidence that that call took place.

MR. HINNEFELD: Well, no. In fact I haven't got a response. I would like us to be able to try to respond to this, just answer it without committing to a phone call first. If our answer is insufficient in some ways we can try a call.

CHAIR MUNN: All right, well, we will continue to carry the phone call, or we will change it when we get to that action item later on.

So are you okay, Hans and Kathy?

DR. BEHLING: Yes, one I'm trying

to look back and say, okay, the issues that Joyce raised -- and let me just get an understanding and ask for comments here. We are basically reviewing a dose reconstruction, will be reviewing a dose reconstruction that assumes Type S. Now we know perhaps in some instances it was Super S, so obviously acute exposures, chronic exposures, these should all have been addressed in the original dose reconstruction. And now on your PER-0012 we are simply going to modify that by applying certain adjustment factors, in the case, if the target organ was either the lung or the thoracic lymph nodes we would simply apply a factor four, it was based on urinalysis plus the yearly adjustment factors as defined in Table D. And that would be all the revisions to the dose reconstruction would encompass it, is that correct? And it would not necessarily go back and say, okay, what was the bioassay, the original bioassay? Did it consist of potential periods or intake regimes that

consist of an acute period of exposure or discrete -- acute exposures followed by chronic exposures? That would not be part of the reassessment, I take it.

MR. HINNEFELD: I believe you are correct, Hans.

CHAIR MUNN: I think you are right.

DR. BEHLING: So all these issues may not even come into play when we look for dose reconstructions that have been reassessed. I mean, we are basically saying, okay, for this individual where there was a potential for exposures, and the assumption was that it was Type S, we will then now apply Super S, and if in the case of lung we would apply the factor of four. If it's urinalysis based, and in addition to that the Appendix D yearly adjustment factors, and that would be the sum total of the dose readjustments.

CHAIR MUNN: Well, we may find that many of our concerns are moot once you

actually look at the data itself.

DR. BEHLING: Yes.

CHAIR MUNN: Is there anything more to be said about this before we go to lunch?

MR. MARSCHKE: Wanda?

CHAIR MUNN: Yes.

MR. MARSCHKE: I just wanted to say, while we have Joyce on the line, before we break for lunch, can we talk about the two-day sampling thing, item -- this item here?

CHAIR MUNN: Certainly.

MR. MARSCHKE: And then maybe we might be able to release Joyce from the discussion?

CHAIR MUNN: I can see no reason why not. We go to OTIB-0029, right?

MR. MARSCHKE: Yes. I wanted to specifically go through the action item on Wanda's action item list of data sources and transcripts regarding practices of OTIB-0029 on two-day sample issues.

CHAIR MUNN: We might ask if everyone received the data that was just sent by email with respect to OTIB-0029, yesterday or the day before?

MR. MARSCHKE: Yes, I did send out an email on issue 1 of OTIB-0029, we had an action item to clarify Joyce's comments and upload them into the database.

CHAIR MUNN: And so we have item 1 and item 2 were covered in that.

MR. MARSCHKE: So, yes, item -- issue 1 and 2 were covered in that, and what I did, the Subcommittee and NIOSH up until that point had not received Joyce's comments on the NIOSH responses. So those were sent out. And then there was a specific issue about this two-day hiatus, I guess, between the time that the sample is taken -- or maybe -- yes, between the time that the worker is exposed and the time the sample is taken. And I think we talked about this a little the last time we met, and it was mentioned that in some cases

this was done intentionally, and I guess -- this is an email that I always see. I'll put it up on this board here now, and unfortunately I did not send this to the total Subcommittee members. But it's basically an email that I received from John. And if we can just start with about the third sentence there.

It says, respect to my action item, that's the two-day -- I did look into the two-day hiatus issue and determined that the basis for our concern was the early years at Y-12 and virtually all facilities with widespread documentation that it was standard policy to deliberately have a two-day hiatus, so that only uranium we were looking at was Type S. NIOSH has already confirmed that this is true, and I believe that was done at the last issue, we talked about that.

MR. HINNEFELD: You mean here?

MR. MARSCHKE: In here.

MR. HINNEFELD: What I said was, I

recognize -- I remember when it was preferred to have the days off. I didn't intend to say that the samples were only collected with two days off. What I said was, because of lab capacity, we didn't normally, it's just that samples be collected.

MR. MARSCHKE: So it was -- I really confirmed that it was --

MR. HINNEFELD: Yes, I don't know that that actually --

MR. MARSCHKE: So this is a little -- the reason for that is that in the early days Type S and M uranium were not considered important contributors to the dose. NIOSH argues that later this policy was changed as evidenced by the fact that they see urine samples on Tuesdays, Wednesdays, et cetera.

During a site visit interview, Kathy DeMers found out that there was still a two-day break, i.e. workers took their two days off during the week. That interview is the basis for our concern.

That being said, this is a relatively small problem since most intakes are in fact episodic, which specifically reduces the significance of this issue. Nonetheless if you assume chronic intake, there could be a three to tenfold underestimate of the dose if you don't take this two-day hiatus into consideration if the exposures are primarily Type M and Type S.

And Joyce did a detailed analysis of this which has been provided to NIOSH. So I guess I wanted to -- that is what we at SC&A have really done on this -- on this action item, to query the data sources regarding the progress on the two-day sample issue.

So I wanted to put that out on the table and see what the next step is to help us smooth this along.

MEMBER ZIEMER: So is the suggestion that everybody had the two days off before the urine sample, regardless of which day of the week it was, it's always --

MR. HINNEFELD: That is our understanding.

MEMBER GRIFFON: That's what I was going to ask Steve. Is there any way you can provide -- you said in that statement, that email from John, it's been well documented for -- what I want to understand is, what does well-documented mean? Do you have the document? And the second part of that was in the early years. And then, again, how do you define early years.

And then I guess the last thing would be the interviews; was it one single person interviewed, or were there multiple interviews confirming this, and if there were, could we have the references for those? That would be useful.

MR. HINNEFELD: Yes. I don't have the answers to those right now, Mark, but those are very good questions. And I would like myself to know the number of interviews, and, again, defining early days is really kind

of subjective. But we can look into it and see if we can tie it down a little bit.

MEMBER GRIFFON: It seems like the only way we're ever going to resolve this is if we have some of these documents, documented things, if there are actual procedures and if you have interviewed former HPs that have sort of confirmed, yes, this was the policy up till whenever. You know, I think that is the only way we are going to resolve this.

DR. LIPSZTEIN: But also the NIOSH response to our comments was that 40 percent of the samples were not collected on Monday, and I don't know how this would change because 60 percent of the samples were collected on Monday, so why should we not use the Monday -- even if this was not two days absence, how do we demonstrate that 40 percent of the samples were not collected on Monday. This is not important anymore.

MEMBER GRIFFON: That is a good point. Sixty percent, if it was equally

dispersed between the five days, you'd have a stronger case -- NIOSH would have a stronger case.

CHAIR MUNN: So the action is for NIOSH to respond to the current comments?

MR. HINNEFELD: Yes, we will share that.

MEMBER GRIFFON: I will -- I would like SC&A to follow up on the specific questions I asked, too.

MR. HINNEFELD: And those were the number of interviews and what we mean by early days and what we mean by widespread documentation; is that it?

MEMBER GRIFFON: And the references to the interviews and the references to the documentation.

MR. KATZ: And another question Mark raised was, have HPs confirmed this was the policy.

MEMBER GRIFFON: Right, who were the interviewees, I guess.

CHAIR MUNN: So it actually is SC&A's ball right now.

MEMBER ZIEMER: Or both.

CHAIR MUNN: Well, it's hard for NIOSH to respond to the comments if they don't have the comments, clearly.

MR. MARSCHKE: It would be kind of important to know what the references are for the documentation.

CHAIR MUNN: Yes. So right now it's SC&A's problem.

DR. LIPSZTEIN: Actually, for most of the plant's history, the plant review and collection methods were a spot sample submitted Monday morning before entering the work area. But these were samples that were submitted at a minimum of 48 hours absent from the work area, and besides is it July 1 to December 31, 1961, it was stated that Friday evening samples should be discontinued in favor of Monday morning samples. That's somewhere in 14-5.

MR. HINNEFELD: What document was that, Joyce?

DR. LIPSZTEIN: That's from the TBD 14-5 on the I-12, the internal dosimetry.

MR. HINNEFELD: Okay, thank you.

MEMBER ZIEMER: What was the number?

MR. HINNEFELD: It was 14-5.

MEMBER ZIEMER: That is the same profile.

DR. LIPSZTEIN: Yes, yes.

CHAIR MUNN: All right, Joyce, do you have anything else to add?

DR. LIPSZTEIN: Not on this issue, but I have a big problem with TIB-0029. I don't know if we are scheduled to discuss this. But it's the data for '47 to '51. Because the first urine samples that are given in TIB-0029 is from '52, and the TIB-0029 states that from '47 to '51 they had very similar operations, and therefore they were modeled as one intake experience, but we don't

have any bioassay results in TIB-0029 before '52. So I don't -- we need more documentation on why this was --

MEMBER GRIFFON: Why it's appropriate to use that later data?

DR. LIPSZTEIN: Yes, yes.

MR. HINNEFELD: That is on our list of things to respond to, because we just got that at the last meeting. Isn't that right, Mark?

MEMBER GRIFFON: I think so, yes, but NIOSH still owes theirs.

MEMBER ZIEMER: Okay.

CHAIR MUNN: Anything else with respect to OTIB-0029?

DR. LIPSZTEIN: And also I don't know if that's appropriate here, it's why OTIB-0029 doesn't have Type S for uranium when the DVD 14-5 says that there were Type S, there was highly soluble uranium at the site also.

MR. HINNEFELD: Can you say that

again, Joyce? I didn't catch the first part.

DR. LIPSZTEIN: I said that in TIB-0029, there is only type M and type N, and not type S.

MR. HINNEFELD: Oh, I see.

DR. LIPSZTEIN: But if you go to the occupational internal dosimetry document, on Y-12, you have highly soluble uranium listed there.

MR. HINNEFELD: So why isn't it addressed in TIB-0029, is your question, right?

DR. LIPSZTEIN: Yes, why it isn't addressed at the Type F also. But for some of the cancers and internal organs, Type F would be the most claimant-favorable.

(Simultaneous speakers.)

MR. MARSCHKE: F as in Frank.

MR. KATZ: Okay, thank you.

MR. MARSCHKE: Actually I think it's covered in the issue or part of issue five under OTIB-0029. We raised a concern of

why Type F is not considered. And again I think we have been doing some back and forth. Again I'm looking at the database.

MEMBER GRIFFON: So that is in NIOSH's --

MR. MARSCHKE: Well, as I got it, what the Work Group directive says is NIOSH and SC&A should have a detailed teleconference to resolve this issue, Subcommittee members will be informed when the teleconference will occur. And that was back in March of this year, where that was -- that directive was given, and I guess nothing has really happened since then.

MR. KATZ: Stu, does that need a teleconference, or does that just need a response?

MR. HINNEFELD: I'll have to see. It would depend. I mean, you're using bioassay data to get your dose assessment. And you're assessing systemic organ doses. It really doesn't matter what the solubility

class of uranium was. What's systemic is systemic, and it's going to behave in set given models regardless of solubility. The solubility is lung removal, that's what that pertains to. So the bioassay essentially translates directly to systemic organ dose. Talking about non-systemic organs like lung and GI tract, there may be in fact -- be some difference, so I don't know.

CHAIR MUNN: Is it possible that I have an error on my reference to teleconference meeting, and that it is not--

MR. HINNEFELD: It might be this one. I don't know.

MEMBER ZIEMER: I thought you said you were going to check first and see if you needed a teleconference. That was my recollection.

CHAIR MUNN: That was our comment with respect to issue one, but this is not issue one. This is -- I don't believe, 49.

MR. MARSCHKE: No, 29.

CHAIR MUNN: Twenty-nine, 29? Really? I even specified the page, 29-1.

MR. MARSCHKE: Well, 49 is a different question. I don't know --

CHAIR MUNN: But this is 29.

MR. HINNEFELD: Twenty-nine is the Super S we had. OTIB-0049? That's the one we were talking about.

CHAIR MUNN: Right.

MR. HINNEFELD: I can't decide today whether a phone call is needed. We will determine in looking at the issue, we will determine, and if we do feel like a phone call would be beneficial, we will let the Subcommittee know, and SC&A know. We'll try to reschedule something.

CHAIR MUNN: All right. Anything else?

Shall we break for lunch? 1:30?

(Whereupon, the above-entitled matter went off the record at 12:21 p.m. and resumed at 1:30 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:30 P.M.)

CHAIR MUNN: Well, let's go ahead and begin. I think our first item is probably one that Mark probably wouldn't have a lot of interest in anyway.

MR. KATZ: Okay, just to make it official. So this is the Subcommittee on Procedures Review, Advisory Board on Radiation Worker Health, and we are reconvening after a lunch break.

CHAIR MUNN: Thank you. The first item that I'd like for us to get out of the way, since I think it's a fairly straightforward one is the transmission letter to -- of our report to Secretary Sebelius. Paul provided us with a letterhead copy of what we had agreed to in our last Board meeting as being our transmission letter. And with the exception of needing to remove the question mark from the first page --

MEMBER ZIEMER: Where was that?

CHAIR MUNN: That was right after February, 2009, and the second paragraph, almost the next to the last line. I had no issue except the first paragraph on page two, the last sentence. As some of you may recall, we originally had a rather lengthy paragraph there talking about our evolution of the current tracking system. We opted to take that out. But having done so, we are left now -- I didn't realize this until I read it through clean -- we are now left with a sentence that says: Initial meeting's findings and the result of process of addressing them was undertaken with a spreadsheet matrix tool for tracking progress. But then that leaves you with no feeling at all of what happened after -- initially. We certainly have gone a long way from that simple matrix that we first started with, and my concern revolved around the fact that it seems to be incomplete. I had suggested that it seemed to me that we still needed at least

a sentence there to essentially state that that tracking process has evolved into an electronic process for not only tracking but also archiving, and didn't feel the sentence needed to say much more than that, but did feel in view of the fact that we spent a considerable amount of time developing this database, and how we operate it, and in view of the fact that I anticipate it will be used extensively as time goes on, by more and more subgroups. Don't want to go on playing with this forever, and it's been approved by the Board, but I thought we ought to discuss my reaction to it, I don't know whether anyone else had that reaction or not.

Paul, do you see what I mean?

MEMBER ZIEMER: Yes, I do. It doesn't make sense, and we either need to add to it or change it or delete it.

CHAIR MUNN: Yes, it seems to me that it's -- one simple sentence would take care of it I think. But this probably means

that we'd have to take this back to the Board again.

MEMBER ZIEMER: I don't think it would change the intent, if you want to leave something in, you could say something like this, that these findings were tracked on an electronic database, it was established on a protected CDC site where access was simple for the agency, the contractor and the Board. And that would be it. It includes one of the sentences we took out. But I think as Ted said, we don't want to get into elaborate discussion of the tracking system.

CHAIR MUNN: No, no, I didn't suggest that we should. But it just seemed to me that we needed to at least indicate that we are no longer just tracking it on a paper matrix, which is what this suggests. Mike, do you have any problem with that?

MEMBER GIBSON: No, not at all.

CHAIR MUNN: Mark, are you back yet?

MEMBER GRIFFON: Yes, I just got on, Wanda. I'm sorry.

CHAIR MUNN: Okay, did you pick up on what we were talking about?

MEMBER GRIFFON: No, I missed that.

CHAIR MUNN: Okay, we are talking about the transmission letter to the Secretary.

MEMBER GRIFFON: Oh, yes.

CHAIR MUNN: Paul provided it for us. And I pointed out that the only problem I had with it was the first paragraph on page two, the last sentence leaves us hanging after we deleted that other full paragraph where we had originally described our evolution of the database in considerable length. Now that sentence leaves us hanging out in midair, and I was suggesting that we need at least another brief sentence just to make notation of the fact that it's evolved considerably and that it's a fairly sophisticated tool now.

MEMBER GRIFFON: That's fine with me.

CHAIR MUNN: So Paul is busily writing out a proposed sentence here.

MEMBER ZIEMER: The proposed sentence would be to delete -- or the proposed action would be to delete that sentence that says initially these findings and the resultant process of addressing them was undertaken with a spreadsheet matrix tool for tracking progress, and to replace that with this: to track these findings, an electronic database was established on a protected CDC website where access was simple for the Agency, the contractors, and the Board. And that would be it.

CHAIR MUNN: I would make one suggestion to your wording that would suggest that, instead of saying was established, could we say, has been developed.

MEMBER ZIEMER: Has been developed?

CHAIR MUNN: Just indicative of --

MEMBER ZIEMER: This wording is part of what was in there before, but that sounds better, if that is okay with Mark and Mike.

MEMBER GRIFFON: Fine with me.

CHAIR MUNN: So you want to read that whole paragraph through now?

MEMBER ZIEMER: The whole paragraph would state: findings and observations made from the technical reviews range from minor issues with no measurable impact on composition decisions to manage the scientific debate which may have complex-wide implications. To track these findings, an electronic database has been developed on a protected CDC site where access was simple -- that should say is simple for the Agency, the contractor, and the Board. Is it contractor or contractors?

CHAIR MUNN: Contractors, I

believe.

MEMBER ZIEMER: Yes.

CHAIR MUNN: Does that do what we need it to do, Mark?

MEMBER GRIFFON: Yes, that sounds fine to me.

CHAIR MUNN: Mike?

MEMBER GIBSON: Yes, that sounds fine.

CHAIR MUNN: All right, since Paul wrote it, I'm assuming that he agrees with it.

MEMBER ZIEMER: I don't think that changes the meaning from what the Board approved. It's an editorial.

MR. KATZ: Yes.

CHAIR MUNN: Does anyone else have any concerns with the letter, and our anticipated enclosures with that?

MEMBER ZIEMER: Could I ask Nancy, Nancy Adams, are you still on the line?

MS. ADAMS: Yes, I'm here.

MEMBER ZIEMER: Nancy, for delivering this letter, I assume we go through the same process as we do on the others, we go through John and then through the Secretary?

MS. ADAMS: Correct.

MEMBER ZIEMER: Okay, so I can provide this letter to you electronically, and that - as a modified letter - and what are the attachments?

CHAIR MUNN: The attachments are the status sheet that Nancy and Steve always - -

MEMBER ZIEMER: Okay, so you have the status sheet, Nancy?

CHAIR MUNN: It would be the status sheet, our most recent one, the one that is not up right now because it disappeared in the transfer.

MR. MARSCHKE: Do you want me to get you a new version of that, Wanda?

CHAIR MUNN: Steve has the version that we were using.

MEMBER ZIEMER: The numbers have to match.

MR. MARSCHKE: I can send you -- I think I have in my archive what I handed out back at the beginning of the October meeting.

CHAIR MUNN: Yes, and that's the one that we were working from.

MEMBER ZIEMER: The letter says, 538 findings.

CHAIR MUNN: Yes, 538 findings and the percentages were --

MEMBER ZIEMER: It says more than 80 percent.

CHAIR MUNN: That looks right.

MEMBER ZIEMER: And 49 percent.

CHAIR MUNN: And open, 21 percent.

MEMBER ZIEMER: This shows 49 percent closed.

CHAIR MUNN: Yes, 49 percent closed, and 80 percent having been deliberated on one way or another.

MEMBER ZIEMER: This shows 47, so that's a different chart.

CHAIR MUNN: Yes, that's fine.

MR. MARSCHKE: What are the percentages open?

CHAIR MUNN: He said the number --

MEMBER ZIEMER: In the letter, we have 80 percent, more than 80 percent deliberated on.

CHAIR MUNN: Which means, yes --

MEMBER ZIEMER: And 49 percent was the total that were closed. And so 47 -- so there is a discrepancy between the letter and the attachment. We need to make sure --

CHAIR MUNN: Yes, we need to make sure that's okay. And that attachment had the usual indications below it, what each of the categories meant.

MR. MARSCHKE: Yes, this one that I'm showing here now was one that I did by hand because I didn't have access to the last

list.

MEMBER ZIEMER: Well, you see more than 80 percent, so this percentage here must have gone down and the other went up. We must have closed something at that meeting.

MR. MARSCHKE: October. This is really where I think you want -- well, this only shows 48 percent being closed.

MEMBER ZIEMER: That's October 9th, but I think we changed that at the meeting.

CHAIR MUNN: Hopefully you can find that in your records. I'll check mine too to see if I have it. We anticipated sending that summary sheet and the chart, the bar chart.

MR. MARSCHKE: We have two bar charts, we have the percentage bar chart, which basically always adds up to 100 percent; and then we have the number of issues bar chart. I can send you both and you can pick whichever one you want.

CHAIR MUNN: No, I think we were going to do the percentage, weren't we?

MR. MARSCHKE: If you are talking in percentages in the body of the letter, it makes sense.

CHAIR MUNN: I think that's the one we had agreed we would use.

MEMBER ZIEMER: Okay, so maybe we were at the second to last one, it's more than 80 percent and now it's back down.

MR. MARSCHKE: Yes, that's because on October we went back because of lost data.

CHAIR MUNN: Yes.

MEMBER ZIEMER: So I need to change the numbers in the letter?

CHAIR MUNN: No, why don't we say as of October 1st, the numbers, then you wouldn't have to change anything. In the letter, if we said as of October 1, 2009 --

MR. MARSCHKE: I can send you this bar chart, which basically shows more

than 80 percent --

MS. ADAMS: This is Nancy. I have a PDF file that's October 14th, 2009.

MEMBER ZIEMER: Right, that is the one we're looking at now.

CHAIR MUNN: And that is the one we were using at the time we put the letter together.

MEMBER ZIEMER: You have the bar chart, Nancy?

MS. ADAMS: I do. It's all part of the same PDF.

CHAIR MUNN: Yes.

MEMBER ZIEMER: The numbers and the bar chart?

MS. ADAMS: Right.

MEMBER ZIEMER: Okay, so you have what we need?

MS. ADAMS: I do. I will forward it to you just to triple check that it's the right thing.

CHAIR MUNN: All right. I'm

fairly certain that it is, because it was the one I was using at the time we were putting the letter together.

MEMBER ZIEMER: If you will make a note that that will be the attachment, then, for this letter, also.

CHAIR MUNN: Those two things were the only thing we were going to enclose since we felt anything else would be extraneous and we agreed we would not send the SC&A report, as too voluminous.

All right, we know where we are going.

MR. KATZ: Just a note, though, we still need to collect votes from Dr. Melius and Mike Gibson to close that out before sending that letter, right? Mike, are you still on the line still?

MEMBER GIBSON: Yes, I'm here.

MR. KATZ: You got my email about your vote on this letter?

MEMBER GIBSON: Yes. I'm fine

with it.

MR. KATZ: Okay, well, can you send me an email formally just letting me know that you are voting in favor of the motion?

MEMBER GIBSON: Will do.

MR. KATZ: Thank you. That's one. So then I just need to get -- I've asked Jim for his vote too.

CHAIR MUNN: Good. Any other issues surrounding the transmittal letter?

MEMBER ZIEMER: And what they have is the draft we had at the Board meeting, not this. Because we voted on the draft.

CHAIR MUNN: Yes, that is correct. That is correct.

Shall we move on to our action items? The first item that we had was transferring the two procedures from our responsibility to Rocky Flats, that memo was sent, and it should now be in their hands. Is that not correct, Mark?

MEMBER GRIFFON: We have it.

CHAIR MUNN: Very good. That's done. And we just completed item number two, the draft of the report to the Secretary.

Stu is going to check with IT to verify how to provide PDF files.

MR. HINNEFELD: I don't have an answer yet, but I did get the question to them fairly recently, so.

CHAIR MUNN: Okay. That will continue.

OTIB-0029, is there anything there that we did not cover with our discussion this morning with Joyce?

MR. HINNEFELD: No I think we covered that this morning.

CHAIR MUNN: So we now have the action in SC&A's court to respond more thoroughly with respect to where the data came from that they are using for their comments; correct?

MR. HINNEFELD: Correct.

CHAIR MUNN: Next, query data

sources and transcripts on the two-day sample issue.

MR. HINNEFELD: They're the same.

MEMBER ZIEMER: Is that the same as OTIB-0029?

MR. HINNEFELD: That's part of OTIB-0029.

CHAIR MUNN: That's part of what we were discussing under OTIB-0029. So that's -- that's actually nothing -- well, my concern here is whether we have an open issue on the database that needs to be, that we need to follow up on. Do we have an OTIB-0068 open issue? I'm trying to get back to it, I keep losing it.

MR. HINNEFELD: We don't have OTIB-0068 in our database at all.

MR. MARSCHKE: OTIB-0068 was the two-day hiatus OTIB that never got published. But it's the same discussion we had in OTIB-0029. That's where we had that discussion.

CHAIR MUNN: Okay, since it never

got published, really and truly, it's actually covered under 29.

MR. MARSCHKE: Right.

CHAIR MUNN: We should probably stop referring to OTIB-0068, because it never got published.

And it seems to me that that is covered by our previous discussions with OTIB-0029, or am I mistaking it?

MR. MARSCHKE: I believe you are correct.

CHAIR MUNN: So we will eliminate that, and consider it closed by reason of the previous one.

Distribute a draft transfer of ID-43 and 07 to Surrogate Data Work Group, and that one I have not done.

MR. KATZ: We want to knock that off, because the Surrogate Data Work Group I think should be meeting soon.

CHAIR MUNN: Yes. I'll make sure.

Next item is revise two, identified changes in SC&A procedure used to review NIOSH procedures, and briefly revisit the entire text for other potential updates. This is another carry-over.

MR. MARSCHKE: We have done that.

CHAIR MUNN: You have done that?

MR. MARSCHKE: And there was, of the same email that transmitted the draft PER review procedure, also transmitted the revised draft of the procedure-review procedure, and the one thing we were going to change was on the -- or the one thing we were going to change in two locations was on the table checklist table, and was item 1.3, where we basically had a, in parenthesis, a statement for the reviewer to check and make sure that all the data was provided in the procedure itself, and none of the data had references, or was provided by references. And that was just not a reasonable expectation. So as you can see here, by item 1.3, we have deleted

that, the parenthesis, the statement that was in parenthesis, from the checklist table, and also from further on down in the report.

MEMBER ZIEMER: What page is that?

MR. MARSCHKE: That is on page 15, or 14.

CHAIR MUNN: On what date did you transmit that?

MR. MARSCHKE: That was transmitted yesterday. That was -- Judy transmitted that yesterday.

CHAIR MUNN: Okay.

MEMBER ZIEMER: With the PER report, they were both --

MR. MARSCHKE: -- both documents were transmitted in the same email.

CHAIR MUNN: I remember that now, okay.

MR. MARSCHKE: And then there was also, further on down I think in Section 3.4, the same phrase was in parenthesis under -- in

one of the bullets, under Section 3.4, where we did go in and we deleted from there as well. And then when we performed a more -- or looked at the procedure in its entirety, we found that much of the procedure was written geared towards the first set of procedures that were under review. And in a couple of occasions, under scope, and under Section 4, select technical issues, we have really geared those sections toward the specific procedures that were included in the first set of reviews. And we have gone in -- in this revision and tried to make those two sections of the document more general, tried to generalize those, as you can see under Section 2, under procedures to review, we kind of, before it had a list of the exact procedures that were included in the first round, and now we just included some general statements that these are the types of documents that will be reviewed, and so on and so forth.

And the other third type of change

we made was, this procedure referred to task three, which was a terminology under the original contract, which is no longer included in this new contract. So we have gone through and we have changed any reference to task three and put in more appropriate references to the current contract.

CHAIR MUNN: And how is it currently described? I know task three is incorrect.

MR. MARSCHKE: I can't think of where there is a good example. I'd have to get back to you on that one, exactly where that change got made.

MEMBER ZIEMER: You know what would be good on a document like this would be to enumerate the changes. I'm wondering if either -- yours have a page, I guess it's like the second page after the cover page where you -- let me look at that -- you indicate the effective date and revision number and so on.

MR. MARSCHKE: Yes.

MEMBER ZIEMER: I'm wondering, whenever there is a revision, if it would be -- would it be worthwhile enumerating how this document differs from the previous one, this document reflects the following changes, Section A, Section B, whatever it is? Or otherwise you have to lay it side by side and say, now what did they change here. It doesn't jump out at you. Or in the purpose, you add a paragraph that indicates that this is a revision of the earlier document that includes the following changes. I'm trying to think, I think to do it on that first sort of summary thing would be an easy way to do it.

CHAIR MUNN: Well, especially in light of the fact that most other governmental agency documents do that.

MR. KATZ: Stu's focus documents do that.

CHAIR MUNN: Exactly, and it's very helpful, especially if you are tracking.

MEMBER ZIEMER: Or you may sort

of want to review the changes.

CHAIR MUNN: Right. Right.

MEMBER ZIEMER: Now wait a minute. Where are they?

MR. MARSCHKE: So underneath this, we have this heading type thing, where we have all this on the front page, and then underneath this we can just list out --

MEMBER ZIEMER: The following revisions have been made from the previous version, page so and so, section such and such, has been revised to do something. It could be just a simple chart or something. This might be something whenever you revise a document, to indicate how does it differ from the previous one.

CHAIR MUNN: If you reference the NIOSH documents, you will see clearly how that is done.

MR. MARSCHKE: No, I know what you are talking about.

CHAIR MUNN: That would be very

helpful. So the questions like this one would be much easier to track.

MR. MARSCHKE: Let me ask the Subcommittee's opinion here. We are calling this document Revision 3 because it replaces this document which was Revision 2. But we've given it a different document name, a different document number, because we've changed the way we assign numbers, so it's really, in my way of thinking anyway, this is Revision 0 of this document --

CHAIR MUNN: I agree.

MR. MARSCHKE: And supersedes Revision 2 of this document.

CHAIR MUNN: I agree absolutely. Otherwise -- yes, any time we change the document numbers --

MEMBER ZIEMER: Yes, this simply replaces --

MR. MARSCHKE: We need to put down what we talked about earlier, we know this, and say, these are the changes that were

made.

MEMBER ZIEMER: Now what if you didn't change anything, but you were only changing the document number?

MR. MARSCHKE: Then you would put down underneath here no changes.

MEMBER ZIEMER: Right.

MR. MARSCHKE: You would put down underneath, no changes were made to this document.

MEMBER ZIEMER: Just a new numbering system.

MR. MARSCHKE: What we need to add to our cover or our summary page, we need to add, down below here, we need to say, the changes that were incorporated were, and then --

CHAIR MUNN: Exactly.

MEMBER ZIEMER: And even if it's no changes, and it's just the document number.

MR. MARSCHKE: The document number and change the document, something like

that.

MEMBER ZIEMER: So what are you doing on document numbers? So this is SC&A, does PR stand for something specifically?

MR. MARSCHKE: Yes, it does.

MEMBER ZIEMER: PR stands for something.

MS. BEHLING: Excuse me, this is Kathy Behling, PR stands for procedure, and we do PR for a technical review, and so the PR is supposed to stand for procedure.

MEMBER ZIEMER: And then 2009 is?

MR. MARSCHKE: The year.

MEMBER ZIEMER: So it's procedure one of this year?

MR. MARSCHKE: Procedure one that was issued this year.

MEMBER ZIEMER: Thank you.

CHAIR MUNN: And in my personal opinion, Steve's comment about the numbering system is absolutely correct. This should be Rev 0 of this document.

MEMBER ZIEMER: Of the new numbering.

CHAIR MUNN: Otherwise we could get really confused.

MEMBER ZIEMER: But you would point out that it's not just -- it's not Rev 2 of the old system. It is a revision in Rev 2 of the old document. It doesn't supersede it; it was a revision.

MR. MARSCHKE: Oh, yes, all right.

MEMBER ZIEMER: Otherwise you could just say --

MR. MARSCHKE: -- a number change.

MEMBER ZIEMER: Right. A number change. I think that would be helpful as you go forward to do that. But I couldn't keep track of what you said all the changes were as you went.

MR. MARSCHKE: Okay, we will add to this page a list of changes, and we will change the rev to Rev 0.

CHAIR MUNN: Okay, so I'm going to leave this on the list so that next time we see it, we'll have the addition of changes shown on the introductory sheets. So that we can follow -- it is sort of difficult for us to discuss the changes that were made if we don't have them right in front of us.

MR. MARSCHKE: So the Subcommittee doesn't want to -- okay, we will add those and resend it.

CHAIR MUNN: And personally this member of the Subcommittee wants to have an opportunity to read through the new documents, which I haven't had an opportunity to do, being on an airplane yesterday.

MR. MARSCHKE: Well, I mean the other part of the question, does the Subcommittee want to give us any other comments that we might as well include when we issue another draft B, or should we just issue draft B and then wait for the Subcommittee to give us comments on draft B.

MEMBER ZIEMER: I'm not sure if you do what I just described that that is a new revision. That is just a new format.

MR. MARSCHKE: Right.

MEMBER ZIEMER: Unless we ask for other changes. If you reissue it with that identifying sheet, it's still --

MR. MARSCHKE: It's still Rev 0?

CHAIR MUNN: I think so.

MR. MARSCHKE: I think we should identify this as Rev 0, draft 1, or -- exactly.

CHAIR MUNN: Yes, probably so. That would be better.

All right, if you will do that for us, then we will have an opportunity to look at it after you identified what the changes are and where they are, and we can review those briefly at our next meeting, if that is agreeable with everyone. Anyone have a problem with that? If not, it will carry over to our next agenda, and we have a review, an

individual review to do prior to that time to be ready for it.

The next issue that we had was the Commonalities Report, the table. And so far as I know I was the only person who had any comments that went to Steve. Steve, did you have any other comments?

MR. MARSCHKE: No, I did not receive any other comments other than yours, Wanda, and again, yesterday around 1:00 o'clock yesterday afternoon, Judy sent to the Subcommittee the draft version of the Commonality Report.

CHAIR MUNN: Does everyone have that? Mike, Mark, do you have it on your CDC mail?

MEMBER GRIFFON: Yes, I do.

CHAIR MUNN: Good.

MEMBER GIBSON: Yes, I have it, too.

CHAIR MUNN: Good.

MEMBER ZIEMER: There is a more

recent version, a November version.

MR. MARSCHKE: This is one that came out yesterday.

CHAIR MUNN: It just came yesterday on the CDC mail.

MEMBER ZIEMER: Did you pick out -- there were some spelling errors in the first version.

MR. MARSCHKE: Yes.

MEMBER ZIEMER: I mean the spell checker picked them out, so I assume you guys would have also.

MR. MARSCHKE: Wanda picked up a bunch of my spelling errors, and Nancy Johnson, our proofreader or our technical editor, she went through it and picked out -- cleaned up more of my stuff, so any spelling errors are my fault. But we've had a couple of people go through it and look at it.

CHAIR MUNN: Okay, thank you. I see in Table 2.1, you clarified the wording there; thank you for that. I'm assuming the

other concern I had about those two tables turned out to be pretty much the same thing. This was very interesting from my perspective to see the common issues here. I'm not sure exactly what we want to do with them now that we have them, but I found it interesting to see what we have. Does anyone on the Committee have any feelings about how this information should be applied, other than simply to have it available for those of us who work across a number of issues from various sites? Is there a specific action that you need taken with respect to this?

I certainly appreciate the work Steve has done on it. This was no easy thing.

And it was certainly confusing to me, as I'm certain it was to other members of the Committee. Some of these cross-cutting issues were difficult to remember where they belonged. This will help greatly.

We can show this on our record as closed, then, unless someone has something

further they want to say at this time.

MEMBER ZIEMER: Well, I just wanted to double-check, now, we were only looking for consistency, weren't we, from one finding to another, for common findings?

CHAIR MUNN: That was the original concern that was raised.

MEMBER ZIEMER: And I don't recall that we saw any inconsistencies in this later, did we?

CHAIR MUNN: I didn't see any. Did Steve as he went through them?

MEMBER ZIEMER: I mean, you've looked through. Did you see any inconsistencies?

MR. MARSCHKE: No inconsistencies, no. There are some cases where this -- actually this exercise may be helpful in that some of the common issues were resolved for some of the procedures. We can then use those resolutions to resolve where that issue pops up on other procedures. So that may be

useful.

CHAIR MUNN: That's one of the reasons why I anticipate that this will continue to be a reference document for exactly that reason.

MEMBER ZIEMER: Do we need to approve the document then, or what do we need to do?

CHAIR MUNN: I would like to have a record of the committee having approved it, and if we are going to do that it may be that we need to give everyone a little more time to look it over, although we had more than adequate time to review the original report. The only changes that have been incorporated here have been explanations that Steve has marked with an asterisk underneath, a couple, three of the tables, just additional information identifying what the wording meant, where the words came from. I had indicated that it wasn't -- I didn't think it was clear to the casual reader where some of

the similar-issue wording referenced. It didn't seem to me that it was -- it didn't actually say that the wording was the same in both cases. But the asterisk information clarifies it, I think, quite well.

What is your desire? Do you want to take a look at this before we approve it, or are you willing to approve it now?

MEMBER ZIEMER: Well, I will start us off.

CHAIR MUNN: Thank you, Paul.

MEMBER ZIEMER: I think we should approve it or accept it or whatever action you desire. And then we should, in your report at the full Board meeting, we should share the outcome with the Board. And I don't know if you've distributed this, but it seems to me it's useful to make it available to all the Board members for reference.

CHAIR MUNN: I think we have not distributed it, not to my knowledge.

MR. MARSCHKE: And we did not

distribute it. When we sent the email, we sent the email only to the Subcommittee, as opposed to the other procedures email we sent to the full Board.

MEMBER ZIEMER: Well, it seems to me, maybe it's two motions, one is to accept the report, and the other would be a separate motion when you make the report to the full Board you keep them apprised that this has been done and to share with them a copy of the outcome.

CHAIR MUNN: It sounds like one motion to me, unless there are objections. If there is no objection, I will take that as a single motion.

Do I hear a second?

MEMBER GRIFFON: I will second that.

CHAIR MUNN: Thank you.

Any opposition? If anyone opposes, speak now or forever hold your peace. It will otherwise be recorded as a unanimous

vote of the Subcommittee to accept the report as written and to provide it to the Board as a part of this Subcommittee's report at the upcoming teleconference.

Hearing no objection, it is accepted, with commendation to Steve for a job well done. Thank you.

MR. MARSCHKE: You're welcome.

CHAIR MUNN: Provide more input on OTIB-4701 for Subcommittee members. Let's take a moment to get back to where -- through five other screens.

Let me have the screen back. Okay, 47-02. Extended radiation monitoring at Y-12. The OTIB states there were 240 distinct ID badges, but SC&A was only able to identify 229. And it looks like the last notation that I believe I have is a June notation, SC&A to provide discussion as to why they agree with the NIOSH response at the next Subcommittee meeting.

MR. MARSCHKE: I sent the Board -

- Bob Barton of our staff actually had looked at this issue, and we talked about this issue, and Bob was on the phone in the October meeting, I believe. And we've gone through -- issue two has got three parts to it, and I believe we are in agreement on the first and second part. Let me just make sure -- yes, the first part was how many individuals, workers, are represented in the database, and I think NIOSH eventually -- we agreed with NIOSH on the final number eventually, and so that issue was considered to be in abeyance.

Part two, the issue in brief was, were zero dose values included in the analysis for all four dosimeter types. And NIOSH came back and said, yes, and we agreed with that response, and basically that portion of the issue was closed.

The third part, the issue in brief was that the TIB would benefit from a more substantial discussion of why the RPRT-0032 values are more claimant-favorable than the Y-

12 external monitoring records. And NIOSH basically gave a rather detailed analysis as I'm looking at it here. And SC&A gave an even more detailed analysis.

Our concern on this one as I recall was that in the NIOSH analysis, they were utilizing what is essentially weekly monitor readings, and they are using them as if they were quarterly monitoring readings. And what we've done, besides redoing this analysis, was redo the -- what the analysis that NIOSH had done except multiply all the numbers by 12.5, which would be converting them from a weekly meeting to a quarterly meeting.

And when we do what we thought was a comparable analysis to what NIOSH had done, we have the results that are presented here on this table or in this file. And we get -- the conclusions are very similar. We get very few instances where the conclusions differed if we had any. But we just felt that the analysis

had to be done correctly, or differently.

CHAIR MUNN: So this is -- what you have on this screen, Steve, is your report?

MR. MARSCHKE: This I believe I sent to -- yesterday at eight o'clock in the morning, again on CDC mail, I forwarded this analysis that Bob Barton of our staff has done, and this is what I'm showing on the screen here now. This was -- yes, this was -- I sent this to the Subcommittee yesterday.

CHAIR MUNN: Oh, I see, we just got it yesterday. I missed it.

MR. MARSCHKE: This was an email that Bob Barton had sent to me back in July, and I just forwarded it to the Subcommittee yesterday. But we did discuss this in the October -- it may have been the August, but I think it was the October meeting -- and I remember we had Bob on the phone, and we did discuss this. And -- but I don't think we ever sent the attached files. So -- for NIOSH

to take a look at. And I can see that they agree with what we have done, and what they --

CHAIR MUNN: Yes, that jibes with the wording of the action item as I have it, that more information was required on this one. So is it possible for you to now send that data to NIOSH and to us?

MR. MARSCHKE: What, the analysis? I mean you're talking about what he just sent, right? Or what are you talking about?

CHAIR MUNN: We're trying to get a resolution of the concerns.

MEMBER ZIEMER: The thing you sent yesterday was from Ron?

MR. MARSCHKE: It was from Bob Barton.

CHAIR MUNN: But Bob wasn't the one who sent it?

MR. MARSCHKE: I sent it.

MEMBER ZIEMER: Right. I saw a couple you sent that were labeled Joyce, and

one that was labeled Ron. This was labeled Bob.

MR. MARSCHKE: No, this was labeled from, it would have been from Steve Marschke. That would be the email you look for in your CDC box.

MEMBER ZIEMER: Right.

MR. MARSCHKE: And there is a forward of a NIOSH OTIB-0047 issue two, was the subject of the email.

CHAIR MUNN: I don't see it.

MEMBER GIBSON: I don't think I got that email.

CHAIR MUNN: No, I can't see mine.

MEMBER ZIEMER: This was yesterday, right?

CHAIR MUNN: Correct. The 16th.

MEMBER ZIEMER: I got several from Judy and one from you that said --

MR. MARSCHKE: Wait a minute, maybe it did not go to your CDC mail, I'm

sorry. It went to your real -- to your regular account. I'm sorry.

MR. KATZ: It didn't go to me at all.

MR. MARSCHKE: It didn't go to you at all?

CHAIR MUNN: Okay.

MR. MARSCHKE: I'm sorry, it showed up on my CDC email, I thought I sent it.

MR. HINNEFELD: So the contention here though I'm guessing that -- and I am not a hundred percent sure of this, but in one set we have -- I guess it's in the CEDR weekly results, is that right?

MR. MARSCHKE: Yes.

MR. HINNEFELD: The database, that was a weekly result?

MR. MARSCHKE: Yes.

MR. HINNEFELD: And the TIB reports quarterly, is that it? And then the comparison somewhere, the comparison that was

done was, the data was used as if they were quarterly, and they are actually weekly. But there is not a thirteen-fold difference between your calculated numbers and ours, right, or do you know?

MR. MARSCHKE: Off the top of my head, I don't know.

MR. HINNEFELD: I would have to look at it more, because I remember the issue from last time, and it came up last time, and I remember it. It would seem that there is a little more to it. It was treated in some fashion, and inflated from weekly data up to quarterly data in order to getting them more close to each other. Or maybe we're not anywhere close to each other. But the TIB would be the direct -- that would be the coworker study that we would say, this is what -- this is the code word for population use for dose reconstruction, and the database then should support it for SC&A, but it doesn't exactly, because it is quarterly data and

being treated as quarterly data. But if we felt like each of those readings was a quarterly reading, and used the data, our number would come out thirteen times lower, the TIB number would be about thirteen times lower than the number that you guys calculated taking twelve and a half times those database numbers.

MR. MARSCHKE: You're saying that you would have assigned it as quarter, but it was only for the week?

MR. HINNEFELD: Well, if that's what it really was, there wouldn't be a thirteen times difference.

MR. KATZ: Nancy? I'm sorry, Nancy, or anyone -- is anyone still on the line? It's showing as if it's still live. Anybody hear us on the line?

MR. MARSCHKE: The issue in brief, if you read the issue in brief, it said the TIB would benefit from a more substantial discussion of why they used RPRT-0032 values

were more claimant favorable than the Y-12 external monitoring records. And then so -- then the NIOSH response generates these tables that you see there, table one, that you see there with -- where there is an attempt to show that the monitoring data was in fact -- that the e-values are -- the e-dose values on the right-hand side of the table are claimant-favorable versus the R-1 and R-2 and R-3 and 4 values, listed in the body of the table. What we think is the R-1, R-2, R-3, and R-4 values that are in the body of the table, those are generated on -- from weekly data as if that weekly data were quarterly data.

MR. HINNEFELD: When we were putting this table together.

MR. MARSCHKE: When you were putting this table together.

MR. HINNEFELD: Okay.

MR. MARSCHKE: And I don't think you have to go -- we are not really asking you to go back into the OTIB and change anything.

Basically this proof, if you will, that the R-32 values, the RPRT-0032 values are more claimant-favorable; this proof needs to be redone. But when Bob has redone the proof --

CHAIR MUNN: Hold up a minute, Steve. The reason I'm asking you to hold up is because we seem to have lost everybody on here, and I'm sure that Mark will want to hear this.

(Whereupon, the above-entitled matter went off the record at 2:31 p.m. and resumed at 2:34 p.m.)

MEMBER ZIEMER: See if Mark and Mike are still here.

MR. MARSCHKE: Mark, Mike, do we still have you?

MEMBER GRIFFON: Yep, I'm here.

MEMBER GIBSON: I'm here.

CHAIR MUNN: Let's very quickly tell them what we were talking about. Do you have Steve's email from yesterday on OTIB-0047 issue two, status rationale? Mark and Mike?

That's what we're discussing.

MEMBER GRIFFON: Yes, I couldn't find the email. And you say it didn't go to the CDC account, it went to the other one?

CHAIR MUNN: It went to your real account.

MEMBER GRIFFON: I will look on there.

MEMBER ZIEMER: There is an attachment, which is the document. And while we're looking for it, I want to point out that normally when there is an attachment, I file the attachments. But this attachment has no date on it and no authorship on it, so a year from now it's going to be hard to remember where this fits into the scheme of things. That's just a reminder. I think even a document like this -- it gets dis-attached from the email is my point, and therefore sometimes to put it into context, it's good to have a date on the document.

CHAIR MUNN: It's cumbersome to

do, but what I do when I personally download something like this is, I also download the transmittal message just as a transmittal with the same title as this. It is cumbersome, but it's to make sure that I have -- if there is anything said in the transmittal that is helpful, it is there.

How are you doing out there in radio land, have you found it yet?

MEMBER GRIFFON: I'm doing peachy. Actually while I'm trying to find it, I have a recommendation that may change the status anyway. From Steve's last document, the comparative analysis, along with these, the TIB-0029 and the TIB-0047 stuff, I'm wondering whether we should reform whatever we ever had in the Y-12 Work Group. But we certainly had -- because it was under that one large work group I believe at the time, we were handling Mallinckrodt and Y-12 and several issues.

But I know, if memory serves me,

we were looking at the state profile issues too, and we had left several open. And Jim Neton brought this to my attention a while back, but we never did close out the -- we have remaining Y-12 profile issues. So I'm wondering with all these issues and the remaining set of profile issues, whether we shouldn't reform our Y-12 Work Group and take some of these things up there. Just thought I'd throw that out while I'm looking for the email.

CHAIR MUNN: Thanks, that should confuse the issue.

MEMBER GRIFFON: Glad to be at home.

CHAIR MUNN: It might be helpful for you to broach that during our teleconference, if you feel that is a valid problem. Because it seems to me that would something the Board should address rather than --

MEMBER GRIFFON: That's fine. I

just thought I'd -- I wonder what your thoughts are, too.

CHAIR MUNN: Well, my personal thought is if we can deal with it here, that's better. But and the only reason I say that is the more the Work Group and Subcommittees we have, the more cumbersome it is for everyone to deal with.

MEMBER GRIFFON: Yes, that was what I had originally thought, because we didn't have a Work Group and why create one just to deal with this. But after looking at several of this ongoing findings, I'm a little -- it's raising my concern that we might want to in some ways just key in on some of these issues.

CHAIR MUNN: Well, of course that's one of the reasons we asked Steve to put together the list of commonalities.

(Telephone interruption.)

CHAIR MUNN: All right, Mike, do you have the document?

MEMBER GIBSON: No, I have not found that one.

MEMBER ZIEMER: It is not on your CDC mail. If you are looking in CDC, it is not there.

MEMBER GRIFFON: Oh, I did find it, TIB-0047 issue two, that is the subject, right?

CHAIR MUNN: You're right, that is it.

MEMBER GRIFFON: I did have it.

MEMBER GIBSON: It's regular email, not the CDC.

CHAIR MUNN: Correct, your regular mail.

MEMBER GIBSON: I have it open now.

CHAIR MUNN: Okay. Have any of you got it?

MEMBER GIBSON: Yes, I found it.

CHAIR MUNN: Good. Do you have it open? Ready to go?

MEMBER GIBSON: Ready to go.

CHAIR MUNN: That's good. Then we'll ask Steve and Stu to give us a very quick thumbnail sketch of the discussion that was going on which is not yet complete, it was underway while you folks were offline.

MR. HINNEFELD: Okay, I will start.

CHAIR MUNN: Thanks, Stu.

MR. HINNEFELD: Steve, these documents that he sent yesterday -- and I think Part 3 is the one to talk about, Part 1 and 2 are essentially put in bed. So Part 3 is the one that I think we talk about, I think it just starts on page two of four of the Word file. Table 1 that he presents is reproduced from a NIOSH response where we said this should support our contention in the TIB that the TIB numbers, the TIB doses, are favorable compared to the actual dosimetry data which was in the CEDR database.

And as Steve has pointed out, or

the reviewer has pointed out correctly, the values, the R-2, R-3, R-4 values in Table 1 are potentially a quarterly read, I believe that's the contention. I'm not saying absolutely because I don't know for sure, but they say that it's a quarterly reading, and it's being compared to this table -- or I'm sorry, this is a weekly reading, R-1, 2 and 3 are a weekly reading, which are being compared in Table 1 to a quarterly number in the e-dose column, and the quarterly dose -- e-dose column is the number from the coworker TIB.

So really the comparison, we cannot compare weekly numbers, you should multiply that by twelve and a half and you get their Table 2 which is on the following page, and then that shows which of those one, two, three and four numbers get -- it's not necessarily some of those numbers are higher in some cases than the e-dose. Although yes, even in one case the total is higher for R-2.

Now as I recall there are some

complicating factors here. I think I recall that R-1 is the canceled dosimeter reading, and R-2, 3 and 4 are other, like filtered badge, or unfiltered badge readings. I don't remember which is which, so there are some things to consider there.

And the other thing I think that complicates this analysis, if I remember our original response, is that it's clear from the reporting of data, the CEDR data, that there are for quite a period of time the -- essentially all of the results are 30, which is the reporting level. So it appears during those periods of time, rather than reporting zero, they reported at reporting levels, 30. So it's a little more complicated than adding the numbers up, but it is a fact that the table that was presented in our response, Table 1 in this document, is not convincing support for our contention that the coworker approach is more favorable than the actual reading. That is a true statement, and it's

just going to take some more time to go back through and adjust and figure out what to say.

MR. MARSCHKE: I agree with what Stu said. In Table 2 if you look at the response from Table 2, it's basically taking the numbers from Table 1 and multiplying them by twelve and a half, and then Bob Barton realized, again like Stu said, that there are a bunch of 30s in there, which are really less than NBL values, so instead of using 30 you use 15, then you get the values which are really in Table 3, then I think the majority of them if not, maybe only one -- maybe only one or two, not very many if any, exceed the e-values. Our values are always less than the e-values except for maybe one or two. I can see 1949 the R-2 value that seems to be higher.

But again --

MEMBER ZIEMER: Well, the e-value is supposed to be yearly?

MR. HINNEFELD: Well, the e-value

is --

MEMBER ZIEMER: Is that quarterly or yearly?

MR. HINNEFELD: That's a quarterly value. E-value is quarterly.

MEMBER ZIEMER: Quarterly, okay.

MR. HINNEFELD: It's listed here by year, quarters one, two, three and four, and then it's the total for the year, it's listed.

MEMBER ZIEMER: E-dose is what?

MR. HINNEFELD: That's the number in the coworker table.

MEMBER ZIEMER: Right, is that the yearly value?

MR. HINNEFELD: Well, the bold one, where it says total, that's a yearly value. The 1948-1 is the first quarter of 1948.

MEMBER ZIEMER: Which table are you looking at?

MR. HINNEFELD: I'm looking at

Table 3 right now.

MEMBER ZIEMER: R-1, R-2, R-3 and R-4 are quarterly values, with calculated --

MR. HINNEFELD: Calculated to be quarterly, yes. In two and three, those are calculated to be quarterly from the weekly numbers, Table 1 has just the weekly numbers, in R-1, 2, 3 and 4.

MR. MARSCHKE: The first four lines of the table are supposed to be quarterly numbers, all the way across.

MEMBER ZIEMER: What's R-1, R-2, R-3?

MR. MARSCHKE: R-1, R-2, R-3, is different -- one of them is -- what is it?

MR. HINNEFELD: I think R-1 is the pencil dosimeter. I think R-2 is the open window. I think R-4 is cadmium filter. I don't know what R-3 is. But I'm just going from memory and I could be wrong.

MR. MARSCHKE: The different

types of doses that were measured?

MR. HINNEFELD: Yes, different dose quantities in the CEDR database.

MR. MARSCHKE: So really the concern was that these numbers here, R-1, R-2, R-3, are really weekly numbers.

MEMBER ZIEMER: I understand that.

MR. MARSCHKE: And we are carrying them over here to the quarterly numbers.

MEMBER ZIEMER: But when you redid Table 3, these are all lower?

MR. MARSCHKE: When we redid Table 3 was, we took the Table 1 numbers and just multiplied by twelve and a half.

MEMBER ZIEMER: That was for Table 2.

MR. MARSCHKE: For Table 2, and then for Table 3, up here like I said, we changed the zeroes, the thirties were changed to fifteen. And this is kind of like what Stu

is saying, is that more -- the Table 2 numbers are a simplification, and probably need to do more analysis than just that, and whether or not you have to do what's in Table 3 or something more or along those lines.

MEMBER GRIFFON: I tend to agree with Stu that it is more complicated. I mean I hear you saying that there were a lot of requisite thirty values, but also I'm reading in the database the response for finding 47-2 it says that although it was stated that zeroes were excluded from this analysis, it turns out that zeroes were not always excluded, and that the -- on April '48 through December '49, the 25^{th} percentile, dose for 11 of the 21 months were equal to zero. So I think there is -- I guess I tend to agree with Stu that a little more work needs to be done here to prove the case. I'm still not clear whether or when zeroes were excluded. Certain 30s were recorded in some years. Did the policy change? I'm not quite clear.

CHAIR MUNN: Well, in part two of this particular issue, the brief that we are all looking at, the summary NIOSH response says the analysis included all zeroes but removed entries listed as NR, and SC&A said they revisited and agreed that the zeroes were in fact included for all four cases, and that entrees listed as NR were not included in the analysis. So doesn't that answer the question you were asking, Mark, or does it not?

MEMBER GRIFFON: Yes, it shows -- yes, I didn't see that, so that's part two, it says that all zeroes were included. But then I guess the table -- I'm not sure where we stand, I guess is the question. I mean it sounded like Stu said he wants to go back and look further at this because of the recording of the MBL issue . SC&A may have in Table 3 offered a sort of a way to get around that, but I'm not sure that is their place to do, once again. But I've taken half the MBL, I mean, I don't know that NIOSH has said that

they are going to do that in their coworker models. So I guess I don't know where NIOSH stands with their responses to questions.

MR. HINNEFELD: There is a fairly long response that we wrote some time ago that -- sent in August that we haven't managed to get in the database yet, I haven't managed to get it in the database yet. Because it really needs to be linked. It's long, it's a long document, and it really needs to be a linked document, and that was one of the things that we had to fix when we read this over. It was just a linked document.

So there is some information that has been prepared that is not available in the database we used to get here. So I think there is a way out of this. I want to make sure in my own mind I understand R-2, R-3, and R-4, because our response does identify them as being from bad results, but it's not clear why somebody has three different film badge readings.

MEMBER ZIEMER: Well under each filter, maybe.

MR. HINNEFELD: I'm thinking it's different filters. And we have a TIB that describes -- there is a TIB that describes --

MEMBER ZIEMER: For the most part those numbers won't be very different.

MR. HINNEFELD: So I need to -- we need to on our side sort out what the -- what we know, and what the issues-- how to formulate this a little better.

MEMBER ZIEMER: Okay.

CHAIR MUNN: So we're left with an open action item for NIOSH to what, to organize and re-present the data that is already available?

MEMBER ZIEMER: The data or something else.

MR. HINNEFELD: Again in fact, the fairly long response I sent in August predates the document that Steve sent last night. They had the benefit of that document,

I think.

MR. MARSCHKE: I think that Table 1 came out of that document.

MR. HINNEFELD: Table 1 came out of that long response, so they had the benefit of that when they wrote the most recent, so it's probably going to be an iteration of us and them in the database, and then we go another round.

CHAIR MUNN: Okay.

MR. MARSCHKE: So Stu, do we have that long response document?

MR. HINNEFELD: I sent it in August, I sent it to the Subcommittee in August.

MR. MARSCHKE: Oh you sent it to the Subcommittee, okay.

MEMBER ZIEMER: Do you know what it was called?

MR. HINNEFELD: NIOSH responses to selected findings from third set ER review underscore to Subcommittee underscore August

20th, '09. And so I would think I sent it on August 20. And there are a series --

MEMBER ZIEMER: It's dated August 13th.

MR. HINNEFELD: There are a series of things that we added in there, but this specific one on 47-2 is in there, just one of the selected ones.

CHAIR MUNN: All right, so I'm going to keep this action item open. NIOSH is going to reorganize and present the material that already exists on this issue. For OTIB-47-01, and it's three segments.

MEMBER ZIEMER: It is 02, I think.

CHAIR MUNN: It's 02?

MR. HINNEFELD: Yes, 47-02.

CHAIR MUNN: What did we do with 01? I thought what we were looking at here was -- this was issue number 2. And there were three parts to issue two, and these are the three parts that we are talking about here.

MR. HINNEFELD: Yes.

CHAIR MUNN: So you are telling me that the open item ought to be -- okay. So issue one is -- what is the status of issue one, then? Why am I still carrying it?

MEMBER ZIEMER: You know in that document, Stu, that you just referred to, there is almost nothing on 47-02.

MR. HINNEFELD: Maybe it is 47-01.

CHAIR MUNN: Forty-seven oh one.

MEMBER ZIEMER: There is an extensive discussion of 47-01.

MR. HINNEFELD: That's the one where it didn't support --

CHAIR MUNN: So it's shown --

MR. HINNEFELD: That is dash oh one.

CHAIR MUNN: This is dash oh one?

MR. HINNEFELD: Yes.

CHAIR MUNN: That we have been discussing?

MR. HINNEFELD: Yes.

CHAIR MUNN: That's what I thought, but then you just told me no.

MR. HINNEFELD: Yes, and you were right.

MEMBER ZIEMER: No, it's 01.

CHAIR MUNN: And then 02.

MEMBER ZIEMER: Before we leave 01, I think --

MR. HINNEFELD: Well, the same finding, the same finding is number three in dash oh two, it seems to be the same as the finding in one.

MR. MARSCHKE: I think that is the key. I think we decided upon that last --

MEMBER ZIEMER: That was on one.

MR. MARSCHKE: Because 01 - when we resolved part three of issue two, we also took care of issue one. So it's kind of redundant on our part.

CHAIR MUNN: Okay, so that is why R-2 carryover item says check incorporation of

closure data in OTIB-47-02. But if 47-02 item three is the one that we are going to be dealing with under finding 47-01, then one of the two of them needs to say -- needs to reference the other, and be closed, correct? Should not 01 reference -- shouldn't 02 be closed, and reference that it's being dealt with in item one?

MR. HINNEFELD: The problem you have, Wanda, is 02 is a three-part issue.

CHAIR MUNN: Yes, I understand that.

MR. HINNEFELD: So you have -- I mean, you could say the third part of it is closed or is addressed in issue one, and the third part of it therefore doesn't need to be further chased as part of issue two. And then part one, I guess, of issue two is we do recommend putting it in abeyance and recommend part two, we recommend it be closed. So I guess issue two would then be changed in abeyance, that would be the most --

CHAIR MUNN: It would seem logical to me that we close one or the other of them, and if we want to track it through 02, as it's broken out into its three parts, then that is fine. But whichever we choose to do, it seems foolish to continue to track the same issue in both finding one and finding two. So which is most logical from the database-maintenance point of view?

MR. MARSCHKE: I think it's most logical to keep tracking one as a separate issue, and then basically issue two would then consist really of two parts, the part about the number of badges, and the questions about zeroes at the end included or not included. And I think we have a meeting of minds between SC&A and NIOSH on those key parts. So issue two would then be restatused to in abeyance or closed.

MR. HINNEFELD: Right, and for completeness, since we have been talking about part three, we can just say part three is

addressed --

MR. MARSCHKE: In the text. In the Work Group directives up in here, we would say part three of this issue would be addressed --

(Simultaneous speakers)

CHAIR MUNN: And we have already recommended closure of part two. So that leaves --

MEMBER ZIEMER: Well, SC&A recommended closure on part two, and in abeyance on part one, but we haven't actually formally accepted those yet, right?

CHAIR MUNN: Well, SC&A and NIOSH have agreed on part two?

MEMBER ZIEMER: Right. I'm speaking of Mark -- Mark?

MEMBER GRIFFON: Well, what is part two? Is that the --

CHAIR MUNN: Do you have your --

MEMBER GRIFFON: -- R-1 to R-3, any instance of zero was not included, but it

was included for all four, is that the one we're talking about?

MR. MARSCHKE: That is part two of it, yes.

MEMBER GRIFFON: And what is the conclusion, that all the zeroes were included for all four?

MR. HINNEFELD: The NIOSH, our response to the initial comment was that the analysis included all zeroes but removed entries listed as NR, which presumably is not read.

MEMBER GRIFFON: But it included all the zeroes for all R-1, R-2, R-3 and R-4?

MR. HINNEFELD: Yes, well at least two, three and four. R-1 was not a film badge reading.

MEMBER GRIFFON: R-1 was the pocket dosimeter?

MR. HINNEFELD: The pocket dosimeter.

CHAIR MUNN: I just don't want to

carry two issues forward if we have only one.

MEMBER GRIFFON: I don't think you have to carry that one forward. It's just a statement of fact, right; NIOSH has corrected that, that they in fact did include the zeroes?

MR. HINNEFELD: Yes.

MEMBER GRIFFON: So I guess that's fine.

CHAIR MUNN: All right. Steve is going to make this magically happen to our database, right?

MR. MARSCHKE: When we get the database back.

CHAIR MUNN: Whenever it occurs.

MEMBER GRIFFON: Did anyone look into this not-recorded question, I'm curious what percentage of -- how many NRs were there in the various fields, and why were they not recorded, or why were the field of NR be filled out for the damaged film, damaged --

MR. HINNEFELD: I don't know off

the top of my head. Maybe the person who monitored for that week or whatever, they weren't in the area that week. But the documents, the underlying documents, might say. I would need some time to find out.

MEMBER GRIFFON: Because to me, an NR could mean not recorded or not read, and those could be different, obviously. You could decide not to record a value because it looks like the film was overexposed, in advertently or whatever, or the pocket dosimeter was dropped, you know.

MR. HINNEFELD: Right.

MEMBER GRIFFON: But you could not read it because you just decided not to read all films. That's a very different circumstance. I was just curious.

CHAIR MUNN: So can we call it the original SC&A report where the findings should tell us that?

MR. MARSCHKE: I would think.

MR. HINNEFELD: I think the -- I

don't know.

MR. MARSCHKE: I am just looking -- again, part of the email that I sent out, there was a second file attached to the email that I sent yesterday, an Excel file, which is a Y-12 database, external dose database. And if you look in column N, O, P and Q of the Y-12 external database worksheet, you can see the NRs are -- those are the doses, those are the raw data that we are talking about, this file contains the raw data that we are talking about.

MEMBER GRIFFON: Where is this data?

CHAIR MUNN: In the Excel file.

MR. MARSCHKE: The Excel file that I attached to the email, 4-megabyte file that I attached to it, there are three worksheets in that file, the Y-12 external database worksheet. And the columns N, O, P, Q are readings one, two, three and four, even though Q is labeled comments, it's really the

reading four. And the question about how many go through there, and I have not done this, Mark, but we could do that right now.

MEMBER GRIFFON: I didn't see the spreadsheet before.

MR. MARSCHKE: We could do a -- you could do a -- you could count up the number of NRs in there. I don't know that we have done that, let's put it that way. I don't know that we have done that, but we can certainly go through there and count up -- do a sum if, or count, I guess, how many NRs there are in each one of those columns, and that would tell us how many -- what the percentage of NRs are. It won't tell us why it's an NR.

MEMBER ZIEMER: Well, for example, the first name on the list has all -- basically all NRs through the early part of '48. Maybe he didn't wear a film badge. Then it starts to be recorded.

MEMBER GRIFFON: And there is a

lot of -- we don't have to do it now obviously, but I have the data, so I can look at this myself. I'm not asking for any action. But just from the interviews I've seen on there at sites, I was told that the pocket dosimeters were usually not recorded, they were just used for field controls. And I was just curious, the number of NRs for the pocket dosimeters versus the films and stuff like that. But I don't think I'm asking for any action. I was just curious. And thank you for pointing that out, the spreadsheet; I didn't see that.

CHAIR MUNN: Okay, so you can satisfy yourself from the data you have?

MEMBER GRIFFON: Absolutely.

CHAIR MUNN: Okay, good. Now I'm still not crystal clear on where we are with what we are going to do on the status of these two leftovers on OTIB-0047. But Steve knows what we are doing, right?

MR. MARSCHKE: What I would

recommend to the Subcommittee that we do is that OTIB-0047-1 be tabbed in progress, until NIOSH gets back to us with their response to the email that I sent out yesterday. And then OTIB-0047-2, we change the status of that from in progress to in abeyance, with a note added to the Work Group directive portion saying that on this date, November 17th, part three was -- the status of part three of this issue was changed to addressed in issue OTIB-0047-1, and no longer needs to be addressed under this issue.

CHAIR MUNN: Yes.

MR. MARSCHKE: And then basically -- and that is that.

CHAIR MUNN: Good, that should work, perfect.

So for all intents and purposes, we have our arms around OTIB-0047 where we are.

MEMBER ZIEMER: And 49 -- oh, that's both 47.

CHAIR MUNN: All right? Now our next item was OTIB-0051.

MR. HINNEFELD: Wanda, have you given any thought to time for a break this afternoon.

CHAIR MUNN: Yes, I have. I thought there wasn't going to be much going on with 51 and so I thought I'd look at it before I declared a little break.

MR. HINNEFELD: It's always self-serving.

CHAIR MUNN: Yes, it is. The action item was to link OTIB-0051-01 to the white paper and close the item on the database. Were we able to get that done or not?

MR. HINNEFELD: As far as I know, we haven't got the links working.

CHAIR MUNN: All right, so we'll call that a carry-over to next time.

It is 12 minutes after three o'clock. We need a break. Let's call it a

10-minute break and make sure you are back by 15. You will return about 3:20?

(Whereupon, the above-entitled matter went off the record at 3:12 p.m. and resumed at 3:23 p.m.)

CHAIR MUNN: Let's take up where we left off. The next item on our list was the one that we had pursued briefly before, the Tech Call on 49-01, which I understand never occurred. And I guess the question for our action item list is whether or not it is going to occur.

Is that going to happen? This is estimating doses for plutonium, strongly retained in the lung. It's that issue.

MR. HINNEFELD: I think we would like to write a response first, and see if the conversation then would be helpful after that.

CHAIR MUNN: Okay, we are going to change -- response due, and that's a NIOSH action, correct?

MR. HINNEFELD: Yes.

CHAIR MUNN: That's what the action item will say next time. The next action item, OTIB-0057. Send the current material to the Subcommittee and update the database of the SC&A action.

MR. MARSCHKE: We did not update the database. We started to update the database. I did the status changes, but I did not include the NIOSH responses nor the SC&A response to the NIOSH responses.

CHAIR MUNN: Did we get -- I'm not clear what sending current material to us would involve. Did that happen?

MR. MARSCHKE: No, that did not happen. It should have happened, but it did not happen. I don't have any good reason why it did not happen.

CHAIR MUNN: So our current action item is to send the current material to the Subcommittee.

MR. MARSCHKE: Yes.

CHAIR MUNN: And provide the hot

link for the supporting data, right? The hot links stuff needs to stay in there.

MR. MARSCHKE: What we have is the response to issue number three is quite -- particularly on the SC&A portion -- quite long. I guess that is what they were talking about.

CHAIR MUNN: Yes, that's what we were talking about. We were talking about having a hot link to get to that exclusive material we had.

MR. MARSCHKE: All the portions about updating the database, until the database gets stable --

CHAIR MUNN: Changed, changed, changed, that's happened.

MR. MARSCHKE: It's happened, but it may become unhappened, when they update it.

CHAIR MUNN: I understand. I assume that you will double-check that, and our remaining action item that is clearly open is sending current material to the

Subcommittee and providing a hot link to the supporting data.

MR. MARSCHKE: That is right.

CHAIR MUNN: Okay. Next item is a carryover from last time, a NIOSH item to provide a response for PROC-95.

MR. MARSCHKE: We still owe you those.

` CHAIR MUNN: Next item, check the documents on PROC-97 and assure all nine findings are covered by a PR-12. And that's the SC&A item.

MR. MARSCHKE: We still owe you that.

CHAIR MUNN: Next item is load responses into database and ensure paragraphs are numbered properly for TIB-0013. NIOSH?

MR. MARSCHKE: Not done yet.

CHAIR MUNN: The other carryover for responses to 54 and 14 to NIOSH. Did you not send us 54? I'm trying to remember whether we saw the responses for 54.

MR. MARSCHKE: We still owe those.

CHAIR MUNN: I was imagining things? Okay.

No, I don't see 54.

MEMBER ZIEMER: PROC 97, was that an SC&A action?

MR. HINNEFELD: It was an SC&A action.

CHAIR MUNN: Yes, it was.

MR. HINNEFELD: Worker outreach. That was the ORAU. ORAU doesn't do worker outreach any more. We have a different contractor who rewrote the procedure. We attempted to address some of the findings from PROC-97. I'm not saying we did that for all of them, but some of them we did.

CHAIR MUNN: Your job was to check the two and see, and make sure that everything was carried over properly.

MR. MARSCHKE: Clarification, we don't have -- this is basically just to check the nine findings, the nine PROC-97 findings

and not to do a separate review of TIB or PR-0012.

CHAIR MUNN: No, it was to make sure that the carryover was correct.

MR. MARSCHKE: Just to make sure we're on the same page.

CHAIR MUNN: Absolutely. Status of TIB-0010, item eight for possible closure?

MEMBER GRIFFON: Can we go back to the last one just for a second?

CHAIR MUNN: Back to where?

MEMBER GRIFFON: Back to your last action item, or your last agenda item?

CHAIR MUNN: Right, 54 and TIB-0014?

MEMBER GRIFFON: Yes, TIB-0014, are they ORAU TIB-0014 or OCAS TIB-0014. Because I'm still on TIB-0014 is transferred -- oh well, TIB-0014 has transferred, maybe I'm looking at the wrong one.

CHAIR MUNN: Hold on, let me see if I can get to the right spot. OTIB-0014.

MR. HINNEFELD: OCAS TIB-0014 is the extension of Rocky Flats.

MEMBER GRIFFON: But if it's TIB -- if it's OCAS TIB-0014, didn't that go to the Rocky Flats?

MR. HINNEFELD: Yes, that's one that should be transferred to Rocky Flats.

MEMBER GRIFFON: Oh, okay, got it, thank you.

CHAIR MUNN: Okay. TIB-0010-8 for possible closure?

MR. HINNEFELD: I don't have anything today. OTIB-0010 is the glove box. This is about benchmarking the ATTILA with MCNP, and basically we just, we take a look at the NIOSH MCNP for any calculation package that NIOSH had put together for that comparison and verification.

CHAIR MUNN: That whole software issue.

MEMBER GRIFFON: Excuse me, I think I have to go back to that last one

again. I think you are showing the wrong one transferred in the database. The Rocky Flats is OCAS TIB-0014, and that should be transferred, but that's showing it open. And then the ORAU TIB is showing it transferred. Am I wrong in that? Someone should check that.

MR. MARSCHKE: You're right, Mark. I think the reason for the ORAU TIB-0014 being transferred, it was transferred and addressed, it's the construction worker.

MEMBER GRIFFON: Okay, so they should both be transferred?

MR. MARSCHKE: Yes, it's transferred and reviewed under the review of OTIB-0052.

MEMBER GRIFFON: Okay.

CHAIR MUNN: That went out.

MR. MARSCHKE: So it could be addressed under OTIB-0052, but it was transferred.

MEMBER GRIFFON: Oh, okay. Okay.

CHAIR MUNN: And TIB-0014-02 is -- SC&A finds it to be incomplete because it does not address what? Because it does not address in vivo counting results. That's a Rocky Flats internal dosimetry issue.

MEMBER GRIFFON: Should that one show as transferred or not?

CHAIR MUNN: Well, it shows as open. Are we going to send it over to Rocky?

MEMBER GRIFFON: I don't know.

CHAIR MUNN: I don't think we had said before that we were likely to transfer that one because it's kind of this internal dosimetry coworker issue is one of the overlapping issues between sites.

MR. MARSCHKE: I think at the end of the last meeting, the October 15th meeting, we were going through the various procedures and trying to identify which ones could be next up for action on them. And I think TIB-0014 kind of fell into that box as being a TIB which we hadn't done anything on yet and which

we could do something on in the near future. And I think that may be why it got listed in the action item list because right now the database is showing that we haven't received anything back from NIOSH on that.

CHAIR MUNN: Right.

MR. MARSCHKE: And --

CHAIR MUNN: That's why it's, you know, shown as a NIOSH action item to provide a response.

(Simultaneous speakers.)

MEMBER GRIFFON: Yes, it doesn't have to be transferred. I was just asking.

CHAIR MUNN: Yes, no.

MR. MARSCHKE: It doesn't come out of the commonality analysis.

CHAIR MUNN: No, but it's the kind of thing that we encounter often.

Okay with that, Mark?

MEMBER GRIFFON: Yes, that's fine.

CHAIR MUNN: Okay, we were looking at 10 for possible closure, and that was a

carryover, too, 10-8. And we still just continue to wait for a NIOSH response, right?

MR. HINNEFELD: Are we still talking about OTIB-0014?

CHAIR MUNN: No, we've gone to 10-8.

MEMBER ZIEMER: 10-08

MR. HINNEFELD: TIB-0008? Yes.

MEMBER ZIEMER: That's the ATTILA.

CHAIR MUNN: Yes, the software thing. Note the transfer of us from Work Group TBD-6000 of OTIB-0070 finding 6, and set the priorities.

MEMBER ZIEMER: Well, you haven't gotten the formal letter from me on that.

CHAIR MUNN: No.

MEMBER ZIEMER: But we -- I guess the 6000 Work Group approved the transfer, so all we need is the letter. So you know it's coming. But -- and we can pull it up, I think, probably. Or, no, that wouldn't be on this thing, would it?

MR. MARSCHKE: Well, that is what I just was wondering. We have a whole bunch of issues on OTIB-0070 here. And I don't know, first of all, if they're identified here as being open and not being transferred to the TBD-6000 Work Group. So I'm confused.

MEMBER ZIEMER: Well, let me pull up the matrix for that item. It may refer to this OTIB.

CHAIR MUNN: Look specifically at 6, that is what we were concerned with. OTIB-0070, finding 6, says use of Horizons summary survey data as a default value for operational air concentration at a thorium refining facility is inappropriate and not claimant-favorable. No, that's not OTIB, sorry, I'm giving you the wrong information.

MR. HINNEFELD: What is the TBD-6000 -- you are talking about transferring to --

MEMBER ZIEMER: I was going to pull up the matrix for that.

CHAIR MUNN: OTIB-0070 --

MEMBER GRIFFON: I think that was the right one, wasn't it, Wanda, that you read out?

CHAIR MUNN: It's the right one on our list. But I'm remembering something that had -- that we had not established a priority for, and it was something that was necessary for us to move ahead. That's what I had.

MEMBER ZIEMER: Let's see, TBD, finding 6. Let me just pull it up. This is underestimate of resuspension factor. And it's -- in order to drive upper bound of default inhalation exposure due to resuspension of uranium particles on deposit surfaces, TBD uses default suspension factor. That's a common issue in a lot of sites. NIOSH response talks about the details appear in OTIB-0070. And then SC&A has a response why they recommend the use of 10 to the minus 6 and so on.

So since this was basically a TBD

-- OTIB-0070 issue because this resuspension factor issue comes up at many sites. That's why it was being transferred.

CHAIR MUNN: Yes, and it seems that --

MEMBER ZIEMER: So it's --

CHAIR MUNN: I think the error is in saying finding 6.

MEMBER ZIEMER: No, it's our finding 6 on the TBD-6000 Work Group. It's finding 6 in their matrix, and it's the general issue of the resuspension factor which shows up in OTIB-0070.

CHAIR MUNN: In many of the findings under 0070, not just one.

MEMBER ZIEMER: So the TBD-6000 Work Group officially said we will transfer that to this Subcommittee since the Subcommittee's dealing with that as part of the TBD -- or the OTIB-0070 issue.

CHAIR MUNN: And I recall some concern about the conversation over no

priority having been set that would pull this up to the top of the heap, and we were ostensibly going to --

MEMBER ZIEMER: Well, this is what priority is it for you folks.

CHAIR MUNN: For us.

MEMBER GRIFFON: I think it falls under OTIB-0070-10, finding number 10.

CHAIR MUNN: Well, we have multiple findings that impinge upon this.

MEMBER GRIFFON: Yes, it sort of hit on it, but 10 is just specifically--

CHAIR MUNN: Quite clearly.

So the action item here isn't NIOSH's really.

MR. HINNEFELD: Well, we owe responses on OTIB-0070.

MEMBER ZIEMER: There were responses already on the TBD -- on the TBD-6000 Work Group.

CHAIR MUNN: But not here.

MEMBER ZIEMER: And those

responses would need to be transmitted to you.

CHAIR MUNN: They need to be transmitted to you as well.

MEMBER ZIEMER: Because SC&A then had another response to it. NIOSH's response is very brief. There is little specific information related to resuspension factors in the SC&A review of this TBD. They are talking about 0070. As such insufficient detail is provided to allow NIOSH to address the comment. It is suspected that the details appear in the SC&A review of OTIB-0070. And then SC&A has a fairly extensive reply which I won't read here. But I think nothing is showing up here.

MR. MARSCHKE: No, I have been out of the loop on this.

MEMBER ZIEMER: Okay, so I need to carry and submit this document to all the -- to the Work Group and to you, Steve, as well.

MR. MARSCHKE: I have to convey to John when he gives responses to OTIB-0070 or

other questions or other procedures that are in the database that he should put me on cc so I can update the database.

MEMBER ZIEMER: Yes. This reply goes back -- this is a November of '08 reply.

CHAIR MUNN: So I'm going to break this out into two different action items. One is the transfer of the Work Group TBD-6000 finding 6 to us for us to set priority. And the other is the remaining OTIB-0070 responses due from NIOSH. Is that acceptable? No grief with that?

Now that is the end of our list of action items that we brought forward. Does anyone else have anything that they feel needs to be on our database which will magically become current and updated before our next meeting?

If such things occur, do please let me know. Yes?

MR. MARSCHKE: I have one which I'm trying to find it now.

MEMBER GRIFFON: Do we have a date set for our next meeting?

CHAIR MUNN: No, that is the next thing for us to do.

MEMBER GRIFFON: I got an email from Ron Buchanan who was looking at PROC-0042, and PROC-0042 has to do with Y-12. And I think Ron is indicating that in our report we had identified -- this is a copy of the thing from the report, this is a copy of the report itself. And they had identified a number of issues, and then they had identified a couple of issues with the workbook. And if you look at the database, the workbook issue that was identified with PROC-0042 did not get incorporated into the database. And Ron is saying that the workbook includes an error, and it hasn't been corrected to this point. And I guess the error manifests itself when scaling factors, negative scaling factors are utilized. It works okay when the scaling factor is zero or positive, but it creates a

problem if the scaling factor is negative.

And I guess the question begs itself, this is really not in our issues database, and I don't think NIOSH has been actively addressing, probably because it's not in the issue database. But it is a concern that was identified in the report, and it's just to basically our oversight of when we transfer data issues from the report into the database. But this did not get incorporated.

And so I wanted to bring this up at the Subcommittee meeting here today, and I will forward this email from Ron to the Subcommittee when I get back to my office tomorrow. I just got this yesterday, and I don't know how we want to handle this type of thing.

CHAIR MUNN: I think you are on the right track. From my perspective the logical thing to do is to send it to us. We originally had, what, five findings, or were there more than that originally?

MEMBER GRIFFON: The database is showing five findings.

CHAIR MUNN: Five findings? It appears to me that in cases like this the only legitimate thing to do is for you to notify us that although this was identified in a report it was -- it fails to be incorporated in the list of findings, and identify what the specific issue is. And we should incorporate it as finding number six.

MR. SMITH: This is Matt Smith with the ORAU team.

CHAIR MUNN: Sorry, we can't hear you. Speak up.

MR. SMITH: I've got some input on that item. On that particular workbook, we don't use a negative number. We only allow the dose to be scaled upward. So in other words if a person's dose after 1960 would indicate that you could potentially scale the previous years, in other words the coworker years, downward. We don't do that; we only

scale upward. But go ahead and put forth the finding and have it go through the channels and I'll respond to it. But that scaling method, it has the potential to actually scale the dose downward, but we don't do that.

CHAIR MUNN: Good. Probably a good idea however to record this interaction.

MR. SMITH: I agree. We want to get it in writing.

CHAIR MUNN: That's good. So the action will be for Steve to get the statement and the necessary references to me, and at our next meeting we will incorporate that as finding six. And then NIOSH can give us a direct response to close it.

Anything else? If not, it's calendar time.

You have all been privy to the previous discussions with respect to the probable need for a meeting prior to the February Board meeting, and as I had indicated earlier, about the only time that I would be

available would be the last week in January. What do other Board members' calendars look like that week?

MR. KATZ: What are the agenda items? Can we go over that first just to make sure we will have material ready for that meeting, given the Christmas holidays and all that?

MEMBER ZIEMER: One was the PERs review --

MR. KATZ: Right.

MEMBER ZIEMER: -- bring that to the Board.

MR. KATZ: PERs review methods and selection criteria.

CHAIR MUNN: Which is a fairly biggie. That's likely to occupy a considerable amount of time for all of us, including at this meeting.

MR. KATZ: I think you made a lot of headway today on this issue.

MEMBER ZIEMER: Are we going to

have a revised -- I guess it's going to be not a revised but an edited copy, or what will it be?

MR. MARSCHKE: There were a few typos that were identified and a few other issues that were identified. Kathy, are you still on the line, or Hans?

MS. ADAMS: Did you say Nancy or Kathy?

MR. KATZ: Kathy or Hans.

Well, if they're not on the line, I will commit them. So what we will do is we will look over our notes of the conference this morning and clean up the draft procedure and re-issue it as a draft B.

So there is that, the PERs review, and then the carryover --

MEMBER ZIEMER: It's not clear whether those things will be ready.

MR. HINNEFELD: It is hard to predict. We are, A, going into the holiday season. We have an aggressive reconstruction

production goal, and we have aggressive goals on site research to get research out of the way so that all the sites are available for dose reconstruction -- so it is very hard for me to predict that we will have much product.

MR. KATZ: We have some very substantial Work Group meetings, NTS and Fernald, both of which were turned in and put to bed.

CHAIR MUNN: Are you speaking against a meeting?

MR. KATZ: No, I'm just trying to figure out if this is -- if there is so much that either -- whether there will be enough to do before the February Board meeting, or if there is only a little bit -- would we want to get it done for the February Board meeting, whether we don't do that by teleconference. If all we have really is the PER thing, then that might be accomplished by telephone without having to meet face to face.

CHAIR MUNN: No, I don't think so.

We did also want to provide the full Board with SC&A's completed document with regard to the commonalities, but we were going to do that at the teleconference, and that will be done.

MR. KATZ: Yes, Fernald and NTS; 28th is NTS, 29th is Fernald.

MS. HOWELL: Did that just happen?

MR. KATZ: Recently. Yes, I think -- maybe yesterday. It may have been yesterday that I sent out a notice. I copied you.

MS. HOWELL: I'm sure you did.

MEMBER ZIEMER: We have Mound early.

MR. KATZ: We have Mound early in the month.

MEMBER ZIEMER: Early in the month.

MR. KATZ: And we have Surrogate to show up somewhere.

CHAIR MUNN: And Dose

Reconstruction is already on the 7th.

MR. KATZ: Right.

CHAIR MUNN: So if we were going to meet that week it would probably be the 27th, if we felt that was appropriate.

MR. KATZ: And my question is really is this a teleconference, or is this a face to face. Because if there is not a lot of work to get done and we are just dealing with this PERs work which has largely been discussed, and you are really just sort of wrapping things up so that you can make a recommendation, it seems like that could be accomplished on a teleconference.

MEMBER ZIEMER: Because two of the members are going to be on the phone anyway.

CHAIR MUNN: You think so?

MEMBER ZIEMER: Well, I don't know. That's been the pattern.

CHAIR MUNN: With NTS, and Fernald is coming up, too.

(Simultaneous speakers.)

CHAIR MUNN: You'd come for two days, wouldn't you, Mark?

MR. KATZ: Mark is already coming for two days. He's got NTS and Fernald.

MEMBER GRIFFON: I'm not on NTS.

MR. KATZ: Oh, you are not on NTS?

MEMBER GRIFFON: No.

MR. KATZ: Okay, Fernald.

MEMBER GRIFFON: Yes, Fernald.

MEMBER ZIEMER: Maybe we should sort of block off the time and make sure we are available if we need to meet. But when does it have to be --

CHAIR MUNN: Let's for the time being say that we are going to do it on the 27th.

MEMBER ZIEMER: You have to register it anyway, even if it's by phone, don't you?

MR. KATZ: Yes, either way, no difference.

CHAIR MUNN: So let's go ahead and

do that, and I will put together an action item list so that we can perhaps get a little better handle then on what items we really should be addressing in addition to PERs by that time.

It's hard to get through.

MR. KATZ: Okay, the 27th, okay. The 27th if people are traveling -- so Mark wouldn't be coming the 28th. It wouldn't be a problem. All righty. Okay.

MEMBER ZIEMER: Mark, are you on Fernald?

CHAIR MUNN: He is on Fernald.

MEMBER GRIFFON: Yes.

MR. KATZ: He's on Fernald, but there is no issue, okay, with NTS. All those -- none of those individuals except for you -- none of those individuals are coming down on the 28th.

CHAIR MUNN: Okay. So we will tentatively leave it on the 27th, and hopefully by the time of the Board

teleconference in December we will be able to identify whether we will have a face to face or a teleconference event.

All right? Is that amenable with all? Mark?

MEMBER GRIFFON: Sounds good, yes.

CHAIR MUNN: Mike?

MEMBER GIBSON: Yes, that's fine.

CHAIR MUNN: Okay, very good, please leave it on your calendar, and I will try to get this action item list to you as soon as possible if I can figure out what I've written.

MR. KATZ: If you could just by December 8th give some consideration -- but if the answer is you guys aren't going to be able to get to this other work, then that will just push it toward the teleconference.

MR. HINNEFELD: What start time should we plan for the 27th?

MR. KATZ: For the 27th, if it's going to be a -- we still have the time

difference even if --

MEMBER ZIEMER: Well, 11:00 o'clock if it's teleconference because that's --

MR. KATZ: She'll be coming that day for NTS the next day, so how will that work in terms of a teleconference?

CHAIR MUNN: Badly.

MR. KATZ: So what would be a timing that would work?

MEMBER ZIEMER: Late in the day?

MR. KATZ: The 27th may not be a good day then for a teleconference, is what I'm saying.

MEMBER ZIEMER: If we're doing a teleconference, we could do it earlier in the week.

MR. KATZ: Yes.

MEMBER ZIEMER: Like Tuesday.

CHAIR MUNN: These are the kinds of decisions that try men's souls.

MEMBER ZIEMER: Are you on NTS?

CHAIR MUNN: Yes. 7:00 a.m. teleconference if it were at 10:00. A lot are traveling that day anyway, then it would be okay.

MEMBER ZIEMER: What time do you have to be at the plane typically?

CHAIR MUNN: Well, I have my choice of 9:00 o'clock or 11:00 o'clock. So I could make the 11:00 o'clock if we had a short teleconference. So, yes, let's say 10:00 Eastern.

MR. KATZ: Okay, then it's not a problem.

CHAIR MUNN: That's right.

MR. KATZ: I am going to hold off on sending out a notice for this.

CHAIR MUNN: Right. I have a brief note to myself here that no longer makes any sense, but it was a point that I felt needed to be made, so I will have to wait until the next time we meet in order to make the point.

Any other issues? Any other actions? If not, we are adjourned. Thank you.

(Whereupon at 4:05 p.m. the proceeding in the above-entitled matter was adjourned.)