THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

CENTERS FOR DISEASE CONTROL AND PREVENTION

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

MEETING BETWEEN REPRESENTATIVES OF NIOSH AND SC&A

DAY TWO

JANUARY 12 AND 13, 2005

The verbatim transcript of the above-mentioned meeting held at SC&A, McLean, VA, on January 12, 13, 2005.

DAY TWO

(8:30 a.m.)

OPEN DISCUSSION

DR. H. BEHLING: Good morning, everybody. We're going to try to rush this a little faster than even we thought yesterday because yesterday we thought we would probably finish up by 12:00, but if we possibly can because Mark has a departure date here. In other words he may have to leave this meeting as early as what, 11:00 o'clock, Mark?

MR. GRIFFON: Yeah, but I can miss the last few minutes.

DR. H. BEHLING: Okay, we'll try to be as quick as we can and keep Mark involved in all of them, but if not, if for some reason we are not in the position to finish with the last of these cases, we'll just have to do without Mark. How about you, Mike?

MR. GIBSON: I'm fine.

DR. H. BEHLING: Are you going to be able to stay here at least until lunch time, and so does everybody else?

MR. HINNEFELD: Oh, he's here till lunch.

DR. H. BEHLING: Okay, but we'll try to

finish up by lunch time.
Okay, yesterday we finished all the cases inclusive of the last one which was Case 13, and then we skipped 14 and 15 because there were no comments.

MR. GRIFFON: Mark Griffon. On those I was just going to ask, we mentioned the question of the format of the report and stuff. Can we have that discussion maybe now in case I have to leave before we get through the cases?

DR. H. BEHLING: Okay, the issue here is what do we do with regard to the comments and the discussions that have taken place yesterday and continuing today with regard to how these will be integrated into the revised report, realize that the original report was just a draft report. The Advisory Board has recommended that we make some changes, and I think the discussion that's going to take place in the next few minutes here is what do we do with this information.

MR. HINNEFELD: I just wonder, Ray -- Is Ray recording yet?

COURT REPORTER: Yes.

MR. HINNEFELD: You are recording. Okay, great.

DR. H. BEHLING: I guess it's going to be a discussion here between Mark, Mike and Wanda because they are the representative of the Advisory Board and we'll listen to what they may have to say on that issue.

MR. GRIFFON: Yeah, Mark Griffon. I guess part of what I thought we were going to do at this meeting was to sort of roll up a report that could then be presented to -- in a public format, and that's -- as I understand it, a Board product. And I think we want to try to summarize, you know, not case by case, but say out of these first group of 20 cases, we saw these kinds of findings. And I've even been thinking of sort of a graded approach to show the significance or lesser significance of some of them. You know, there's different ways, you know, observation versus findings, whatever kind of language we decide on. And I think some things just come up in these 20 cases, lend themselves well to grouping.

Other things, you know, we may just have a miscellaneous category, but you know some are technical issues, some are procedural issues --

MR. HINNEFELD: This is Stu Hinnefeld. I'd like to offer as well -- Some are absolutely case specific, and some have a broader applica --

MR. GRIFFON: Right, right --

MR. HINNEFELD: So there's a lot of opportunity for categorization, and I think from a NIOSH standpoint we recognize we don't play a role in this. And this is the Board's report and their contractor's report, so I don't have an opinion about categorization except to the extent that the categorization comment may influence whether we feel compelled to have another opinion, you know, in front of the Board. If categorized in a certain fashion we may -- you know, for instance just like an observation or something, we may not feel compelled to say anything, but if it were categorized in some other fashion we may feel compelled to make a comment or a

counterpoint of some sort to put in front of the Board.

So from our standpoint I have no role in it, other than at some point we'd kind of like to know how things were categorized and to know whether we would have a view -- or maybe that, maybe that product occurs after the Board's product -- I mean that's our -- our situation there may occur after the Board has a product. That may be actually more workable.

MR. GRIFFON: Yeah, I think -- You know my feeling is, at least with this first one and maybe in the future ones, we can sort of, the Board can establish our categorization system and then SCA can adapt it, but I was thinking if out of this meeting if we can get comment resolution process completed for the most part, then SCA can revise as needed their report -- as issued last time, just where revisions were appropriate, get it to the Board, and then through some process the Board has to generate the summary report and come up with the categories and how we want to categorize it, and that will be the

report presented to the public.

MR. HINNEFELD: Right, and I think our reaction to the categorization should probably occur after the Board's product, I would think.

MR. GRIFFON: Right, right.

MS. K. BEHLING: This is Kathy Behling. I'm just wondering if the first -- the first go-around with this that after this meeting if we can sit down with our draft report and maybe at the end of each case put in an additional paragraph that states what came from this meeting, possibly, if there were issues resolved, if we agreed to disagree, maybe add that as a final paragraph to the cases, and then we submit that report to the Board.

MR. GRIFFON: Yeah, I think that would be helpful. I've been kind of making -- that's why when I wasn't clear about this meeting I was asking what's the what's the action here, are we in agreement or is there a disagreement, or pending further research on NIOSH's part or SCA's part, so if you can put that kind of summary I think that would

be helpful.

MS. K. BEHLING: And one other thing, that we require, in looking back to our notes, that we contact Stuart just to verify is this what we agreed on.

MR. HINNEFELD: I hope I will remember.

MS. K. BEHLING: Okay.

DR. H. BEHLING: Yeah, I think to sum it up, one of the things SC&A will have to do and may in fact then penetrate the Board in whatever decision they may make, how to process this, this transcript, and make it available to the public, for us to rewrite the report, amend the report with all of the changes we agreed upon at this meeting, and then perhaps add to each of the cases maybe a final table that says we agreed -- certain things, we resolved these issues, and we may even have some kind of a scorecard at the end that's basically defines all of the issues that a basic review was to look at and then provide a score -- For instance, one of the categories, we have a slide -- in fact Kathy, go back to slide number two. That may prove to be a roadmap for us to

follow. The very first opening slide. This is -- again for those -- and I'm sure Wanda and Ray don't have their handout yet --

MS. MUNN: Wanda now has hers.

DR. H. BEHLING: But in our handouts there is a slide number two entitled, "Criteria for Conducting Basic Review as Defined by NIOSH." And there are various categories. The first one, the big heading is "Review of Data Collection," and it says, "In behalf of a basic review we would evaluate whether NIOSH receives all measured data for the DOE or AWE site from any relevant data source or repository."

But in the case of the 15 cases that involve non-AWE, that may simply involve a check-off that says NIOSH requested such-and-such data from the DOE, and that includes dosimeter records, bioassay data, radiological incidents -- And that's just nothing more than a check-off and we can have a consultation that says yes, we know what that data is, we received it, and the data was in fact supplied by the Board, in the case of missing data they may even have

something there. It's just a check-off review in that case.

But the critical ones are in B -- in section B in this basic review has the title, "Review, Interview and Documentation Provided by Claimant." That's another check-off that says is the CATI report complete? And for instance are there issues in the CATI report that were not addressed by the -- in the dose reconstruction report -- with perhaps a statement that says well the claimant says he was monitored but further checks seem to suggest that maybe the claimant was in error or something like that. It will be a subjective review that says the CATI report is in place, it's either completely consistent with the dose reconstruction report, or in some instances as we so talked about yesterday in behalf of a couple of the claims there were differences of opinion that may require some resolution in terms of did the NIOSH people follow up to see if in fact the claims made by the interviewee was supported by the facts.

And so that again is a fairly simple check-off list that says yes, there's consistency or no, there's a discrepancy, but I think we can resolve discrepancy based on circumstantial evidence.

And the big ticket item is C, which is "Review of Internal and External Dose Estimates." There are a whole series of checklists here that again lend themselves to some kind of re-evaluation as to whether or not we agree, and we don't have to necessarily deal with for instance a four millirem would substitute with an eight millirem, because they're inconsequential. We'll try to exclude the nonsensical.

And I'll have to say our review of the first 20 cases was really a test case, and admittedly when I took this one on I basically gave instructions to all of the people who were part of the SC&A team and said verify each number and don't worry about if it's eight millirem or ten millirem. If you think it's ten millirem, they said eight, check it off. And it was strictly -- and I think I put it in each of

the cases that says we don't care if it has any significance. What we really did was to go through and somehow other try to understand what the dose reconstructor did and try to match his number and then secondly determine whether that number is correct.

Now I think under a more -- I guess under more mature review -- we're going to stop doing this. We're going to say if it's close enough in the ball park, if it's inconsequential, we're not going to continue this for the remainder of our review. This nit-picking, it's like we were H&R Block auditors of a Internal Revenue document, and every single nickel and dime had to be accounted for. We're probably going to stop doing this in the future, knowing that it has no consequence, and we're going to be considerably more tolerant of issues. I think the first go-around was fair to demonstrate that SC&A has people who know what they are doing and if in each of these cases there was a minor discrepancy that had no consequence, we were willing to make that

statement only to demonstrate that we understand the procedures, we know what's in them, and for whatever minute reasons there was a discrepancy, we would identify. I believe we're going to stop doing that. If we realize that these differences are minor with no consequence we will probably in the future stop doing this kind of thing. We may even make a note but not make an issue out of it.

And so we will have a checklist that at this point will moderate our criticism to the point where these differences that we did in fact identify in the original first 20 reports -- and as I've said it was done for the simple reason to give the Board the warm and fuzzy feeling that SC&A knows what the procedures call for and if there are minor discrepancies in it, we're not going to sit there and make an issue out of it because they have no significant impact on the final statement, whether or not a claim is compensable or not. So I think having said that, we can at this point be a little more relaxed about our critique, and go on from

there.

MS. K. BEHLING: This is Kathy Behling. I just wanted also to point out that last week, early last week, I started to work on a checklist that's very similar to the checklist that the Advisory Board approved for Task Three, which was our review of procedures. And I used that similar type of format although I may modify it now based on what (unintelligible) just said.

I thought I would make this checklist. I'm utilizing this slide two, the basic review, and going through these categories that Hans just mentioned, the data collection, the interview process, and the internal and external dose estimates. And I was actually generating questions for the reviewer that would be a yes/no type of answer and then have a comment column, so that if it's no, they would say why the answer is no.

However, if you would prefer us to change that to a rating system like we did in Task Three, which is a one through five where one being the yes they were correct and everything they did -- Five is all correct,

I'm sorry, five is correct, it means yes that everything went fine and one means no, there were a lot of errors. And there is a range between one and five. But we were going to develop that and present that to the Board to see what their suggestions, for the remainder of the audit.

MR. GRIFFON: Mark Griffon. I think that would be -- I think that's a great idea. I'm not sure that my first reaction is the yes/no might be fine and then maybe if we decide how we're going to define in our summary report, as the Board, a level -- the level of significance question. Is it going to be high, medium, low? Is it going to be -- you know -- but some sort of -- and then maybe you can just include that column "Yes, but the level of significance is low." "Yes, but the level of significance is high." You know, something like that. I think that's a good thing for your future reviews. Also because it will be kind of a summary front end to your case reviews, and it will also, I think, your reveiwers with consistency of reviews 'cause there's been a

variety obviously of different approaches. So, yeah, I think that's useful, but I think, I think, I think the Board -- I think we need to discuss on the Board how we want to present that level of significance question. I don't know that I can ask you to do that in a draft, you know, in a working group or not, you know --

MS. K. BEHLING: Yeah, I will continue to develop this checklist and then Hans can bring it along and present it at the next meeting hopefully.

MS. MUNN: This is Wanda Munn. I certainly approve the concept of a checklist as Hans and Kathy has suggested and that's been established. I really don't see any other legitimate way where more than one or two people could view their results of the overview and get anything out of it. The notes that I made yesterday, Mark, indicated several things that I thought NIOSH and SCA were going to try to resolve a little more concretely between them. Those included, or perhaps the checklist could include some statement with respect to the

differences in which revision of ICRP was used and whether that use was justified or not.

We talked yesterday about issues over the High Five and whether those were going to be refined a little better so that everyone knew how to use them, and there were the issues about organically-balanced tritium. I personally am not convinced that issues over organically-balanced tritium are going to be significant enough in the overall case load that we have to spend too much time on them, but if our reviewers feel that those, that there are issues of magnitude there, that we should probably say something about it.

I'm just not at all sure that the possible maximum consequences from resolving that down to the gnat's eyebrow is going to affect very many cases. But the issue of clarifying whether the dose calculation methods -- For example, we had the one case where the method, the TLD of review methods were inaccurate. If there is additional instruction or guidance that we need to give

to the original dose reconstructors with regard to the accurate utilization of uncertainty issues in TLD readings, then perhaps that's something that we, the Board members, need to think about. I'm not sure that they -- I haven't gone back to look at the process to see whether those instructions are in fact adequate or whether we might have a small glitch there.

And I guess one of the statements that was made yesterday, I would hope, Mark, that any draft that the working group would bring to the Board would include the statements that were made yesterday with respect to the fact that established science not be sacrificed in the name of attempting to provide the best possible benefit for the claimant.

MR. GRIFFON: Yeah, I agree. I think we made those statements on the record that if the science is there that I don't think that NIOSH or ORAU has the intent to just be claimant favorable for the sake of claimant favorability if they've got this overwhelming data and science exists, then they've got to use that.

MS. MUNN: Agreed, I just think those words need to be in any report we make to the larger Board.

DR. H. BEHLING: This is Hans Behling. I think one of the things that we have to come to realization is that the three tasks that currently exist for SC&A to complete and continue working on, which is Task One, Three and Four, are really interrelated. And coming to the issue of why do we have some of these problems -- What was the basic root cause for some of the issues that we were addressing between NIOSH and SC&A? And I have to say -- this is my opinion and someone can disagree with that, but I think the primary problem for the differences that we discussed yesterday between NIOSH and SC&A are not the fault of the dose reconstructor, I believe. I think we have some very, very fine people out there who are doing this, but I believe there are problems associated with which procedures are to be used, under what conditions. And some of the procedures, quite honestly, as pointed out to me by Tom, yesterday, I

personally -- and I can't tell you how many times I've reviewed some of these procedures, and there's still some measure of doubt how to use them. So there is an issue of procedure, the clarity, some of the procedures are not consistent, and if I have to say what is root cause for some of these issues, it is possibly too many procedures, too many procedures that are not necessarily consistent among themselves, and at times are very ambiguously written where no matter how much time you spend reading, rereading, and trying to figure out what it is you were supposed to do, in the end you still don't really know. And I think that is basically root cause.

I do not fault the dose reconstructors --

MS. MUNN: Nor do I.

DR. H. BEHLING: I think there are too many instances where these people are probably stretched to the max in trying to establish what it is they should be doing, and I think case in point, and I don't think Stu or Tom would argue, is the issue of uncertainty associated with dose of record. It is a

very difficult thing for them to tackle. And we see this over and over, where they simply refuse to do it, or if they allow estimate for uncertainty, default to a doubling of dose which exempts them from establishing the uncertainty.

And I understand that, and I think everyone has to realize that we have imposed a burden on the dose reconstructors with technical sophistication and detail that is inefficient and is probably unwarranted because it really won't make a big difference. And so I think part of the problem is the issues that we discussed, the root cause of those issues are probably too many procedures, too many uncertainties how to apply these procedures consistently, et cetera.

For instance, in the case of occupational medicine -- occupational radiation exposure, every single site profile has its own version of the Ron Catherine report, which is a procedure. And Ron Catherine, being the health physicist that he is, went into great, great detail in categorizing organ

doses based on the time frame and even (unintelligible) the rest of the facilities and then when I look at the dose reconstruction, no one uses them.

MS. MUNN: Um-hmm.

DR. H. BEHLING: He will say, oh, for efficiency reasons we will, for instance, default to the highest dose which for some instance was a **breast lateral dose, which is in some instance, 84 millirem, when in fact the organ of concern was the colon and rectum. At that point it's a fraction of one millirem. And apparently according to a spreadsheet that we've never seen, people have used that as a default value, which seems to say, well, which procedures did they use? They didn't use any procedures. They didn't use the site profile, they didn't use the Ron Catherine, and they went to a spreadsheet that allows them to use an organ dose that is far removed from the organ of interest. And so for efficiency purpose, they opted to assign a very high dose, when in fact the procedures group -- which basically allow you to go down this

list on a table, say well, here's the code. Give them one E minus four millirem for each exposure, but instead they opt for a lateral **breast of the dose, which to me doesn't make scientific sense.

And again, this exemplifies the problem with too many procedures that are not consistent.

MS. MUNN: I agree, Hans. This is Wanda. Anyone I think who has read the procedures, or even attempted to read the procedures, would have great sympathy with the dose reconstructor. And I believe your assessment of the base cause is probably quite accurate.

MS. K. BEHLING: This is Kathy Behling. Just to add one more issue, and I know we've discussed this yesterday quite a bit, but just to also sum up. One of the difficulties that we had as reviewers -- and I know that NIOSH is fully aware of this, and at this point I'm sympathetic to the fact that they have a lot of pieces to do here and they didn't have a whole lot of time to write a very thorough dose reconstruction report, but that was also

such a frustration for us because we would get one paragraph that would say the photon missed dose -- We would get a paragraph explaining that we ended up using this, and these procedures, and this was the dose, and we had no other choice but to wade through all of the procedures, all of the documents that we had, and reproduce that number down to the last decimal point, just because we weren't given that road map, and I know NIOSH is aware of that.

So, but that was also something I think was beneficial that has come out of all of this for both NIOSH and SC&A.

MR. GRIFFON: Yeah, I think that -- I mean that gives us a path for -- and I agree with your comments, Wanda, and I think maybe the Board has to grapple with this. And I'm not sure, it might be possible for our work group, on a separate phone call, to maybe draft something from -- you know, but I don't know of the timing here 'cause we sort of have to wait for SCA to sort of finalize their report and by the time that happens we may be close to the date for the Board

meeting anyway, so --

MS. MUNN: We probably will be.

MR. GRIFFON: Yeah.

MS. MUNN: I would appreciate it, Mark, personally, if you would be willing to put together at least a base outline of what you feel might go into our report, and that way Mike and I would have an opportunity to have a ladder to stand on.

MR. GRIFFON: Yeah, and Tony and Rich, yeah. And I'll, since Tony is really chairing this work group, I'll draft from what we've said here and I've just got some, this is a good refresher here this morning, but I can draft some general thoughts and general ideas on ways to categorize and then we have something to maybe we can go through a couple of edits on e-mail and then bring a draft to the meeting --

MS. MUNN: That sounds appropriate to me.

MR. GRIFFON: Okay.

MR. HINNEFELD: This is Stu Hinnefeld. I did want to just mention -- Wanda mentioned a couple of issues that we agree probably deserve additional conversation for

resolution, the organically-balanced tritium and the Savannah River High Five. I believe we said that would be resolved in the Savannah River Site Profile Review Task, in the Task One, in the conversation there with NIOSH. So rather than have this group, so we wouldn't expect to resolve that as part of this group.

MS. MUNN: Good, thank you.

DR. H. BEHLING: Okay, I guess we have come to some conclusion about what we are going to do next in revising our draft report.

PRESENTATION/DISCUSSION OF ISSUES FOR CASE #16

DR. H. BEHLING: We can now go on to Case Number 16, and Case Number 16, let me see here, is a Rocky Flats claim. The employment period for this individual was through so he was there approximately He worked at multiple locations at the Rocky Flats site and was an . The assigned dose, that was largely a hypothetical dose, was 11 rem, whole body, and the cancer in question was the rectum. Based on the dose and the cancer the POC for

that individual was .45 percent, less than a half a percent. And so having said that I will initiate this conversation by turning over to Stu who will talk about Issue Number One in behalf of this case.

MR. HINNEFELD: This is Stu. Issue Number One for Case 16 is that NIOSH incorrectly interpreted the DOE, dosimetry data, by assuming that the energy employee was monitored on a monthly basis when in actuality there was a quarterly badge exchange requested.

In looking at the case it appears the dose reconstructor utilized an overestimating technique that's described in the Technical Information Bulletin Number Eight. And there are certain (unintelligible) overestimating approaches there, including sort of a standard limited detection, a presumption of 12 exchanges per year, and then I believe a overestimating adjustment factor of two to ensure that it's an overestimate. This particular technical information bulletin was developed for use at essentially (unintelligible) sites as an

overestimating technique and it was -- the approach was developed relatively early on in the dose reconstruction program before very many site profile documents had been completed, and it was intended to allow an approach to take some population of claims from these sites and go ahead and do dose reconstructions before the research necessary to the site profile, for all those sites, was done. So it was an overestimating technique that was used for that purpose. It was developed for that purpose.

Now in matter of practice it's not necessarily true that the use of this discontinued once the site profile was published. Once this technique was established, even after a site profile was published, it has been acceptable to continue to use its overestimating technique for a certain select number of cases, so it has continued on in that, in that, in that vane, but that's the basis for the technique that was used here and in this context.

DR. H. BEHLING: Let me just comment. I'm

fully aware of the document that was used to come up with this estimate of assumed doses, missed doses because it is in fact a document that allows the dose reconstructor to estimate on a blanket scale the total number of missed doses based on years of service and simply multiplying those years by the number of exchanges. Now, and again this is in concert with what was previously discussed. When in fact you have real dose -- and this is for I guess we have to come to some conclusion as to how we treat these kinds of issues. I looked at the DOE records in behalf of this individual and realized, based on DOE records, that he was monitored on a quarterly basis, which is now a matter of scientific fact or documentation fact. This is reasonable to assign 12 missed doses per year when in fact we know that he was only monitored quarterly. And again, one could say for efficiency purposes, it eliminates -- by invoking this particular procedure, it obviates the need to even look at the records, which is time consuming. And one could justify it in

saying well, in this case by looking at the cancer and the low doses why would we invest even 15 or 20 minutes in scanning through the DOE records to realize he was only monitored quarterly, when we can go on a blanket assumption that is claimant favorable and assign 12 missed doses per year. And I understand that efficiency, but it is again an issue in our case, in this first 20 cases of review, where we said can we really match the records against the actual assigned doses? And the records clearly show this person was only monitored quarterly.

So we identified, or we gave it as a citation, but again an argument can be made for efficiency reasons we simply went overboard and assigned 60 missed doses when in fact we only needed to assign 15. In fact, actually only 11 because a part of those quarterly doses were actually positive. So that the dose reconstructor opted for a maximum of 60, even though they were only quarterly and they were obviously some quarters where the dose was positive