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

WORKING GROUP MEETING

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

SURROGATE DATA

The verbatim transcript of the Working Group Meeting of the Advisory Board on Radiation and Worker Health held telephonically on Nov. 16, 2007.

STEVEN RAY GREEN AND ASSOCIATES
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C O N T E N T S

Nov. 16, 2007

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P R O C E E D I N G S

(2:00 p.m.)

WELCOME AND OPENING COMMENTS

DR. CHRISTINE BRANCHE, DFO

DR. BRANCHE: Welcome to the conference call for the working group on surrogate data. Thank you for joining the call. I want to make sure, do a short roll call to make sure that we have members of the committee. Jim Melius.

DR. MELIUS: Yes, I'm here.

DR. BRANCHE: Josie Beach.

MS. BEACH: I'm here.

DR. BRANCHE: Mark Griffon.

MR. GRIFFON: Here.

DR. BRANCHE: Jim Lockey.

DR. LOCKEY: Here.

DR. BRANCHE: Wanda Munn.

MS. MUNN: Here.

DR. BRANCHE: And then, Stu, you're sitting in for Jim Neton?

MR. HINNEFELD: That's correct.

DR. BRANCHE: John Mauro.

DR. MAURO: Yes, I'm here.

DR. BRANCHE: Are there other people who'd like to introduce themselves? Let's start with other people within NIOSH, please.

MR. ELLIOTT: Larry Elliott is here.

DR. WADE: Lew Wade is here.

MS. BURGOS: Zaida Burgos.

DR. BRANCHE: Other people from HHS.

MR. STAUDT: This is David Staudt from PGO of CDC.

MS. HOMOKI-TITUS: Liz Homoki-Titus with HHS.

MS. HOWELL: Emily Howell with HHS.

MR. BROEHM: Jason Broehm in the CDC Washington office.

DR. BRANCHE: Are there others from other federal agencies?

MR. KOTSCH: Jeff Kotsch with Department of Labor is here.

DR. BRANCHE: Any other members? Anybody else who would like to offer their names? Any members of the public?

DR. MAKHIJANI: This is Arjun Makhijani from SC&A.

DR. BEHLING: Hans Behling, SC&A.

DR. BRANCHE: Okay -- I'm sorry. Did I cut someone off?

MS. BERMINGHAM: This is Sarah Bermingham in Senator Schumer's office.

DR. BRANCHE: Thank you.

All right, we have a quorum of the group, and but yet not of the Board. Isn't that right, Lew?

DR. WADE: Correct.

DR. BRANCHE: Thank you for participating in the call. We do ask that if you're not speaking, if you could please mute your phone so that others can hear what's going on in the call. The background noise can often make it difficult for every word of the speaker to be heard. And if you don't have a mute button, if there's some way for you to cover the receiver of the phone that would be helpful.

We're going to start with some information from Liz Homoki-Titus, and then we'll go on to the Chair, Dr. Jim Melius.

Liz.

MS. HOMOKI-TITUS: Thank you, Dr. Branche.

Based on a document that was recently produced by SC&A that the Office of General

Counsel received yesterday, I need to remind the Advisory Board that SC&A is not a legal advisor to the Advisory Board or to Health and Human Services. It's not appropriate for SC&A to provide legal analysis or opinions on the statute or regulations to the Advisory Board in this format, i.e., the document that they provided to you, or any other format. We're asking that you do not rely on any of the opinions that SC&A provided you in this document since they're inappropriately provided and a number of them are incorrect.

I'd also like to remind you that any legal or interpretive questions regarding the statute or the regulations are to be made by HHS. And if you ever have any questions regarding the proper interpretation of EEOICPA or the statutes, you need to provide them to Lew Wade or whoever your designated federal official is and then the program will be in touch with the Office of General Counsel to reply to the Advisory Board as appropriate.

If I may, I would like to remind you what your statutory duty is as an Advisory Board, and I'll be repeating this information

to the full Advisory Board at the meeting on Tuesday. According to the Energy Employees Occupational Illness Compensation Program Act, which can be found at 42, USC, Section 73840 which describes the Advisory Board's duties. It reads, quote, "Advisory Board on Radiation and Worker Health, Section B, Duties, The Board shall advise the President on, number two, the scientific validity and quality of dose estimations and reconstruction efforts being performed for purposes of the compensation program."

There is nothing in EEOICPA or in the charter that gives the Advisory Board authority to advise the Secretary on legal issues or to seek illegal advice from your contractor.

Thank you.

DR. BRANCHE: Thank you, Ms. Homoki-Titus.

Dr. Melius, I'll turn it over to you.

DR. MELIUS: I'd like to make one correction to what Liz said. I think it's fair to say it's her opinion that some of these may be incorrect, but it's only the opinion of the General Counsel of HHS. It may not be

necessarily true. Opinions can --

MS. HOMOKI-TITUS: The opinion of the Office of General Counsel is the one that provides you with the legal interpretation of EEOICPA.

DR. MELIUS: As I said, it's an interpretation.

MS. HOMOKI-TITUS: Right, and that's HHS' interpretation, and that's the interpretation for the Advisory Board. The Advisory Board was provided with the interpretation of EEOICPA on this question, and you charged your contractor with a specific duty which our contractor went outside of. So therefore, we're advising you that SC&A is not your legal advisor. The opinions provided are not the proper opinions or interpretation of EEOICPA.

INTRODUCTION BY CHAIR

DR. MELIUS: What I've asked John to do today is to walk through the reports because we had not had an opportunity to meet and discuss this before. And so if John could walk through the two reports to brief everybody on what the content is, does not take long. And then I'd like to talk mainly about how we move forward from here.

DR. MAURO: I'd be happy to do that. Can everyone hear me okay? I'm on my cell phone.

MS. MUNN: Yes, John, but before you start this is Wanda. I'm sorry, Jim, you said two documents. I was only looking at the Surrogate Data Report from SC&A of 11/06. Is there another document that we should be looking at simultaneously?

DR. MELIUS: Yeah, there's a September 12th, 2007, document.

MS. HOMOKI-TITUS: Dr. Branche, I don't think anybody in OGC has received that. Could you please e-mail it to us?

DR. BRANCHE: I'll make sure that it gets to you.

MS. HOMOKI-TITUS: I have the November 6th document. I don't know if Emily has the other one.

DR. BRANCHE: Emily, do you have the other one?

MS. HOWELL: I'll have to double check. I don't believe I do.

DR. MELIUS: It's actually the one that we discussed in that brief working group meeting at the last Board meeting.

MS. HOMOKI-TITUS: I definitely don't have that document. If I could get someone to send me that right now so that we can follow along with this discussion.

MR. HINNEFELD: This is Stu Hinnefeld. I can do that.

MS. HOMOKI-TITUS: Thank you.

DR. MELIUS: Okay, Stu, because if not I can.

DR. LOCKEY: This is John Lockey. Would you send that to me because I had to leave early before that ad hoc meeting in September.

MS. CHANG: This is Chia-Chia. Will you send that to me please, also?

MR. ELLIOTT: This is Larry Elliott. I would just like to note for the audience on the line that's outside of this government circle here that these two documents from SC&A are working draft documents, and they have not been made public at this point in time. So there is no copy on the website for review for the public.

DR. MELIUS: Can I ask the status of the September 12th document then?

MR. ELLIOTT: You're asking that of me, Jim?

DR. MELIUS: Well, I'm asking, well, I never know who to ask that of, Larry.

MR. ELLIOTT: I can understand. Well, since Liz or Emily doesn't have it, I suppose they have not had a chance to review it for redaction although I'm not sure, that I may be misspeaking there because perhaps John Mauro should speak to this. I'm not sure if John Mauro and SC&A felt that that document was at a state of completion they wanted it reviewed for public distribution. So I don't know.

DR. BRANCHE: I don't have a copy of it either.

DR. WADE: John, maybe you could talk to us about the status of that document.

DR. MAURO: Certainly --

MS. MUNN: It's a problem because if I filed it, I did not file it under the heading Surrogate Data, which would have made it easier for me to find. So this is Wanda, and I'm struggling trying to find it, too.

MR. HINNEFELD: I'm adding names to my address list here.

DR. WADE: Well, let John though speak to what the document is.

SURROGATE DATA DRAFT REPORT OF SEPT. 12, 2007

DR. MAURO: Yes. We delivered a draft report dated September 12, 2007, to the working group which I referred to as more of a survey or a compendium which describes the degree to which surrogate data of various types were used in various site profiles, primarily site profiles.

As you know SC&A has reviewed 21 site profiles, and the question that was posed to SC&A is for us to go back to our review of those documents and identify places where the site profile -- in other words, the primary mission -- made use of surrogate data from other sites. In other words are there any site profiles that took advantage of data and information from sites other than the site for which the site profile was prepared in order to supplement, complement, help fill in the blanks, the site profile for a given site.

That report was delivered on September 12th, and it's primarily a compendium of information, a large table. And that was delivered. And subsequent to that once the compendium was there a question arose, okay,

now that we have a set of how and to what degree other site data is being used in various site profiles, in various procedures and also in various dose reconstructions at least based on the slice that we view, and in terms of the site profiles we reviewed; the SEC petitions we reviewed, the evaluation reports and the dose reconstructions that we reviewed. We provided that information.

Then subsequent to that the working group convened --

DR. WADE: Can I stop you for just a moment, John, just to -- so the September 12th document has not been submitted as a contract deliverable?

DR. MAURO: No, it was delivered as a draft report solely to the working group.

DR. WADE: So you haven't submitted it for a Privacy Act review at this point?

DR. MAURO: No, it has not.

DR. WADE: So I just want to get that on the record. If it's the desire of the work group to do that, then we can talk about that. But, okay, fine, you can go ahead, John.

DR. MELIUS: And I would say that it is the

desire of the work group.

DR. WADE: Okay, John.

DR. MELIUS: I mean, I think we need to get this out so that we can --

DR. WADE: So then the action, John, would be for you to submit it through the channels that have been developed.

DR. MAURO: Certainly, and we do have a follow-up procedure for doing that. It goes to our point of (inaudible), and certainly I will advise Nancy to get in touch with Liz. Okay, let's put this one in the queue for putting it through Privacy Act review, no problem.

DR. WADE: So then you can continue, John. I'm sorry.

MR. HINNEFELD: Real quick, this is Stu Hinnefeld. I'm preparing to forward this to Liz, Emily, Chia-Chia, Dr. Wade, Dr. Branche, Dr. Lockey, Ms. Munn and Ms. Beach, I think, was the one that said she didn't have it. Anybody else?

MS. BEACH: I actually have it. Mine was dated November 6th. This is Josie. Is this that correct --

MR. HINNEFELD: I think this is a different one. I believe this is an earlier report from --

DR. MELIUS: It's an earlier one, Josie.

MR. HINNEFELD: Then I will send.

DR. WADE: You're a good man, Stu.

MR. HINNEFELD: I trust that will be the sum total of my contribution.

MS. MUNN: Probably not.

DR. BRANCHE: Thank you for sending it.

So, John, please continue.

(no response)

DR. BRANCHE: John Mauro?

(no response)

DR. BRANCHE: John, did you have the floor?

DR. WADE: I wonder if we have John or not. That's more the issue. We might have lost contact. I assume if we did, he would call right back in.

MS. MUNN: Well, he said he was on a cell phone so that may create a problem.

DR. BRANCHE: Dr. Melius, could you please (inaudible)?

DR. MELIUS: Yeah, I'm here. I just, sort of waiting. I'd asked John to do the summary.

DR. WADE: Let's give John a minute to call back in. He's a resourceful fellow. He'll solve the problem.

DR. MAURO: Hello, this is John Mauro.

DR. WADE: Told you.

DR. MAURO: I was on the cell phone and for some reason we lost connection so I called from a land line, so I'm back online. Should I continue?

DR. BRANCHE: Please do.

DR. MAURO: I'm sorry for that. That's one of the problems with cell phones.

During the Naperville meeting on October, I believe it was on October 4, 2007, there was a brief meeting of the working group whereby we very briefly discussed that September 12th report. And the working group then asked if SC&A would prepare a supplement to that report which, in effect, the direction was to come up with suggested technical review criteria for the appropriate use of data from other sites which is the document that you have before you that's dated November 6th, and it's titled "Supplementary Report Concerning the Use of Data from Other Sites".

And our direction was to, when we explore this issue, to make it as regulatory driven as we could. In other words given the regulations, and how they're framed to come up with suggested technical criteria for the conditions under which according to the governing regulations would appear to be the drivers for when and under what conditions it would be appropriate to use surrogate data for other sites. And that was my understanding of our mission, and that's described in the introductory language to this relatively brief report which is about six or seven pages.

So given that what I did, and I think this is where the offending language came in, that is, I went through and I read, I started with the statute, and I read the statute very carefully to judge is there any language in there that would speak to the question of the use or non-use of other site data in performing dose reconstructions. And as you may have noticed, I try to quote those portions of the statute, starting with the statute, that might, might directly or indirectly be relevant or related to that.

And basically what I concluded was, well, the statute really is silent, but I did make one conclusionary statement. That's on page two of my report toward the bottom which I suspect is probably part of the problem that we're discussing today whereby -- I'll actually read the words that I wrote that says, "the law itself is somewhat ambiguous but may imply that data used for dose reconstruction should be from the same facility where the employee worked."

As I pointed out in the introduction, this is purely my reading or our reading, SC&A's reading, and I was trying my best to communicate my sense of the degree to which there's any direction given in the statute. And we came away with that conclusion. And I suspect that that's probably one of the places where there's some concern.

The report then goes on --

MS. HOMOKI-TITUS: John, there's a number of places that are as much, probably even more concern than that, and I'm not comfortable with you going through this document and providing your legal opinions that you

provided in it.

DR. MAURO: Yeah, I was hoping they wouldn't be legal. What I was doing, the way I think about this is I was doing what I used to do which is called a licensing engineer. For many, many years my role at engineering companies was to read the regulations that were in place and try to help identify what the technical implications are of those regulations so that the engineers and scientists would be preparing their work products, like environmental impact statements or safety analysis reports that met the letter and intent of the governing regulations.

So the way I look at this is sort of as a bridge, a technical bridge, that says, okay, as best I can tell this is the regulatory drivers. So it's something that I'm very familiar with and have done quite a bit of on behalf of the design of nuclear power plants, for example. But in any event that's what I did, and I take full responsibility.

And then I moved on to do the same kind of thing, you'll see on the bottom of

page two, Section B, you'll see a brief review of CFR-81. And then I go on to CFR-82 and then CFR-83 where I effectively, to the best I could, summarize those portions of the implementing regulations that say something either directly or indirectly that might be pertinent regulatory drivers pertaining to the use of other site data.

And then I conclude the report on page seven with three -- and this is my creation, three what I call technical review criteria that says, gee, as best I can tell from reading the regs, these would be what you would use as your, in other words if someone were to be, was about to use other site data to let's say support a site profile or a dose reconstruction, it seems to me the regulations would establish, at least give you some ground rules that you could interpret as best I can tell, and these would be the criteria, these three that I wrote here.

And I don't know if it's necessary to go through them, but it's my construct of what I believe to be technical review criteria that would be almost like a test. You could use,

based on reading the regs, it seems that you could use other site data, especially under part 83, but it also seems that there are certain tests that you have to meet, you know, criteria, technical criteria, that need to be met before you could leap to other site data as the basis for, let's say, doing your review of compliance with part 83 and also part 82.

And that's what this report was. And so in summary without going into the details of those criteria, this is my contribution to, my response to the directives that we received from the working group.

DR. MELIUS: What I'd like you to do, John, is to just briefly describe the three technical criteria.

DR. MAURO: Sure.

DR. MELIUS: Because I think aside, I mean, aside from the regulatory issues, I mean, the regulations reflect the, essentially were to enable what would be a procedure for doing dose reconstruction. And I don't think that the criteria are as much regulatory driven as they are sort of what are the procedures we're going to put in place for doing dose

reconstruction.

And I think that's what we want to focus on in the working group is the technical side of these issues and not the regulatory or legal side. And frankly, as far as I'm concerned, and others may feel differently, if Liz or General Counsel's Office finds the first six pages so offensive or difficult, they can be taken out. Because I think what the key to this and for our working group going forward is page seven on.

MS. HOMOKI-TITUS: The only part we want taken out is where legal conclusions are drawn. Where he lists what part of the statutes are appropriate is fine.

DR. MELIUS: Yeah, I mean, you can work that out. I'm not trying to, but it does, really, you approached it in the way you're used to, John, and that's fine. But if you think about it, it also reflects what procedures Larry and his group and his contractors do in doing dose reconstructions that we're all familiar with and in part of now.

And the idea is how do we put the use of surrogate data in the framework of the

current program in sort of a technical procedural way, not in a legalistic approach to that. So if you could just go through those because I think that's what I'd sort of like to focus our attention on in this brief call.

DR. MAURO: I'd be glad to, and they're really relatively brief. They start on page seven, and the first one that I call "Technical Review Criterion One" -- and I call that hierarchy of data, and I do cross-reference the part 82 section that I felt was applicable here.

And it really boils down to that what I'm offering is the second paragraph in that section that says, "under this technical review criterion" -- which I'm suggesting -- "NIOSH would need to demonstrate that good faith effort was made to use worker-specific workplace-specific and site-specific data before resorting to data from other sites to replace, complement, supplement or confirm data of greater stature in the hierarchy of data."

So the way I read it is this. There

is a hierarchy of data that needs to be used and preference is given to site-specific data and before you resort to other site data, you would want to make sure you worked your way starting with the onsite data and demonstrate that an attempt was made to do that.

MR. ELLIOTT: John, this is Larry Elliott. Just if I could jump in --

DR. MAURO: Sure.

MR. ELLIOTT: I offer a point of clarification. The hierarchy of data that is presented in our regulation specifies the preferences being on individual monitoring data.

DR. MAURO: Yes, but you do go to, for example, eventually you can go to criteria related to the operation of the facility in your different hierarchies. Well, for better or worse, I mean, I'm not saying --

MR. ELLIOTT: Not in the hierarchy, but the preference, the data that we prefer to use is individual monitoring data for individuals, an individual working at that given site.

DR. MAURO: Right, right. Yes, and well, what I'm saying is that eventually if you do

use, move to data from another site, the philosophy being -- and this is my interpretation, and it was my offering so that it would actually initiate a discussion that we're having right now.

Before you move to, let's say, using data from another site whether it's air sampling data or bioassay data or whatever, data from another site, you would want to exhaust the availability of data from the site of interest. And that's criteria number one, pretty simple and pretty straightforward.

Then the second criterion, documentation, and it's really related to the first one, is that at least some data was used from the site of interest. This goes, of course, to part 83 that actually explicitly requires that. But then I go on to explain that one of the areas that may need some further development related to that, what I call exclusivity constraints, is how much and to what extent would you define, that is, the rule in part 83 does require that at least some data be used from the site of interest.

And all I'm really raising here is

there's probably a little work that needs to be done to define what the threshold is for that. As I point out in this write up, I've seen it range from, for example, where the data from, when you take a position that, yes, we did use data from the site of interest.

Perfect example as I point out in the write up is Bethlehem Steel where there's quite a bit of site-specific data that was available, was used, and then you resorted to Simonds Saw data to sort of supplement that where some data was lacking. That would be a place where there was considerable amount of site-specific data used. To the other extreme would be, for example, TBD-6000 where just the knowledge that a site was a metalworking facility would be sufficient site-specific information. What I would call that would be very low threshold.

And as long as you know that a site was a metalworking facility, uranium metalworking facility, that constitutes site-specific information. And then you can move on and use TBD-6000 which is a compendium of information for many sites to supplement the

data for a given site.

So I use that as two examples of the range of interpretation, and I guess the point being made here is that I guess it would be helpful to establish some type of reasonable threshold of when have you made use of onsite data, met the letter intent of part 83 and met some threshold. I think right now there's a lot of judgment left on that.

Finally, what I talk about in Criterion Three is really something that needs to be developed also. And when I prepared the compendium, you may, those of you who had an opportunity to look at it, you may have noticed that I described the type of surrogate data into different categories. I actually broke them into two types, one and two, and where you could see that there's a vast array of other site data or surrogate data in general that is made use of, the conditions under which you would use other site data differs depending on what the data's being used for.

So what I describe here is that there probably is a need to provide some guidance as

to, this gets really into what you would call the implementation of this philosophy. You know, when would you use lower limits of detection from another site? When would you use bioassay data from another site, air sampling data from another site, under what conditions?

For example, if you are going to take, a great example would be the Bethlehem Steel-Simonds Saw example. Under what conditions is it appropriate to use air sampling data from one site to supplement data from another site? And there may be a lot of, I guess, guidelines that could theoretically be developed for each category of other site data that, and you may hold some data to a higher threshold because they're more fundamental, for example, bioassay data or air sampling data which really go directly toward the dose reconstruction process.

But other data such as what are you going to assume to be a default lower limit of detection. There may be a different threshold or criteria as applied to the use of neutron-to-photon ratios, medical x-ray exposures. In

other words each one is, theoretically, you could draw upon experience at other sites or throughout the complex, and if you're going to apply it to a particular site, there needs to be, what I see, some direction or guidance on under what conditions is it appropriate to do that.

And that is really what I discuss under Technical Review Criterion Three. And that really boils down to my offering for the consideration by the working group in response to the questions that, well, I guess the mission that was given to SC&A.

DR. MELIUS: Are there any questions for John?

MS. MUNN: No, but this is Wanda. I have a comment with respect to his observation about the need for judgment as opposed to establishing some clear criteria. So far as I believe we have observed to-date, this hierarchy that we discuss is pretty well agreed to and understood by most everybody involved. It seems strange to me that we could consider the possibility of establishing guidelines for these circumstances where we

get down in the third, fourth levels of the hierarchy because each of the sites that we would be comparing would in most cases have such different histories even though they were doing the same kind of work.

I don't think we have assurance with respect to the time elements involved. It's hard for me to see at this juncture how we can establish criteria and eliminate the need for judgment on the part of the individual dose reconstructor or the individuals who are reviewing the sites for an SEC. Maybe I'm missing some of the finer points, but I don't see how we can eliminate the need for reliance on judgment at some juncture.

DR. MELIUS: Yeah, I understand. I agree with you. I think John would. I think the issue is sort of maybe not what we call strict criteria, but it would be more there are maybe guidelines or factors that need to be considered as part of that judgment because you also want that judgment to be consistent from case to case so that, or situation to situation, so that you're not ending up with vastly different types of judgment or you'd

have the situation where two people looking at the same situation would come up with very different interpretations or very different judgments.

So there's sort of, I think, a happy medium there where you provide the framework. And I actually think that many of the procedures that OCAS has developed are really providing guidance to the dose reconstructors recognizing that judgment is required but providing some framework for that judgment so that it's done in a consistent and fair manner and reflects the overall approach of the program.

Is that a fair way of putting it, Larry?

MR. ELLIOTT: I appreciate what you said there, Dr. Melius, and I do agree. I think that's been what we strive to do is provide instruction and guidance to make sure that we have consistent dose reconstructions. So anything that we can do to improve upon that, we certainly would be interested in doing.

DR. MAURO: Larry, this is John. What drove me in the direction of the, especially the

third item, is I was thinking about the way in which other site data has been used. And the two places that come to mind immediately, something I became intimately familiar with, was Bethlehem Steel and TBD-6000.

MR. ELLIOTT: Yes.

DR. MAURO: And I thought they were very good examples of, okay, what happened with Bethlehem Steel where data from Simonds Saw, air sampling data, was used to supplement. And I said, hmmm, and I thought about it. A lot of thought went into that, that is, in terms of the design of the facility, the mode of operation, the type of ventilation system, the kind of equipment, the salt baths.

In other words before that air sampling data were used a great deal of thought went into whether or not it's prudent to do that. So of course, those judgments were made but not within a framework that had any guidelines that said, it almost was like good science.

In other words let's make sure we do our homework before we use the Simonds Saw data. And it's very well documented in the

work that was done. So I said to myself, okay, what does this tell us. What does this precedent tell us? It tells us that, yeah, there probably are some guidelines that could be assembled of when you're going to use air sampling data from one site.

And then I went on and said, okay, what's the other place where I have some pretty good experience. And I said, well, when I looked at TBD-6000, I said what do we have here. I said, well, you have a one-size-fits-all. If you're a uranium metalworking facility, and you have very limited site-specific information, you could resort to TBD-6000 as a bounding default approach for doing dose reconstruction.

I said, okay, what cautions should someone use, and basically what I pointed out was that -- and this is actually in the write up that you have before you -- is that, well, there is a certain degree of care that must be taken to make sure that the array of data upon which TBD-6000 is based, the measurements that were taken, the historical records, are, in fact, bounding and appropriately applied to

the particular case at hand where you're using TBD-6000 as your other site data surrogate for exposures at a given site.

And I think that one of the things, the cautions, I put in here is that having TBD-6000 is an extremely convenient tool, and in my opinion, and again, I'm talking from a technical perspective, there's a place for such a tool. But, of course, it's also easy to use, and there should be some criteria of when you resort to that and certain tests you may actually want to impose upon yourself as a dose reconstructor.

And my sense is that right now the guidance in 6000 does say use site-specific information when you have it, but it doesn't say too much about under what conditions should you use, if you don't have site-specific data, and you're about to resort to TBD-6000, are there any questions you should ask yourself about what you're about to do.

And it seems to me right now I don't believe that kind of guidance exists. And that was my intent in the third category. So I drew upon that experience to try to

generalize and create these criteria, and that was my intent. And so --

MR. ELLIOTT: The other point of guidance in TBD-6000 that I would point out, John, is that it specifies use for specific facilities down to the name of the facility.

DR. MAURO: Yes, the appendices are there. There's no doubt about it.

MR. ELLIOTT: So that may, in some people's mind I hope it may need to be explicit, but it would imply that before you pick this document up and use it for a facility not on that list, you better make sure you understand why it's okay to use it, or you can't use it. So maybe we need to look at it that way.

DR. MAURO: I agree and keep in mind that the appendices are there, and they're growing. So data is being compiled, and you certainly go to the appendices --

MR. ELLIOTT: Appendices really are developed, for TBD-6000 the appendices are developed for unique exposures that are not addressed in the cover document, the Technical Basis Document 6000 itself. So I just want to be clear on that point because I don't want

people to become confused that the appendices speak to something more on uranium metal refining or manufacturing than is already in the TBD-6000.

I don't believe those appendices do that. I believe they only speak to unique exposures outside of the, like the Appendices BB for GSI and the Betatron. That only deals with that Betatron exposure, that appendix. See what I'm saying?

DR. MAURO: Absolutely. I guess I'm going in the other direction, when you're going to use the TBD-6000, and you don't have an Appendix BB or CC, and you want to reconstruct the doses at a particular site. You don't have the data. You have all the look-up tables which are well researched, but they are based on certain datasets.

And all I was saying was that when you're going to use that as your surrogate, perhaps it would be a good idea to have certain, I guess, a checklist to make sure that you have a full appreciation of how that dataset was compiled and why it is appropriate to use for the particular case at hand as a

bounding method or at least a claimant favorable method. I guess it's as simple as that and not just go directly and resort to it.

MR. ELLIOTT: I think we understand your point.

DR. MAURO: Yeah, and that's all I was offering up. So there's nothing really very profound about my three criteria. They sort of fall right out of the regulations, and that's the reason I put the regulatory review in the front. Because as I said, I do think in terms of regulatory-driven technical criteria. And that's all I was trying to do.

DR. MELIUS: Other comments?

(no response)

DR. MELIUS: From anyone?

MS. MUNN: Well, that certainly stirred up a storm, didn't it?

MR. ELLIOTT: Well, this is Larry Elliott. I would take us back to the other document that was presented to the working group on, dated September 12th. I believe it was before the last Advisory Board meeting. We, of course, at NIOSH haven't responded to anything

I don’t believe yet that’s couched in that document. And we certainly, I think, may have some thoughts and ideas in reaction to how John has categorized or perhaps identified certain uses of surrogate data. So just want to put that marker out there that we haven’t had a, haven’t come back with any response, reaction or thinking about that yet, and we would like to do that.

DR. MELIUS: Let me talk about what I see as a way forward. And part of it was, not that I necessarily disagreed with the September 12th document, but as much as I didn’t think it provided enough of a framework for us to do what we need to do in terms of this particular working group. And I thought we ended up, we end up really getting into sort of the weeds of what Wanda’s Procedures work group is focusing on it.

It didn’t make sense to have two groups doing some of the same thing. So it was in reaction to that document that I asked John to do the second document as a way of sort of stepping back a little bit and thinking about how would we judge, how would

we develop a set of guidelines that would sort of provide a framework for the use of surrogate data in this program. And what I would have in mind going forward is that we produce a document that is similar to the SEC review document that we put together a couple years ago now at least, doing that that would try to lay out the framework and guidelines within that framework for the review of, for the use of surrogate data in this program.

And it would not necessarily try to address particular instances, though I think it should be informed by particular uses that are already in place, but wouldn't, because I think you want it to be useful. You don't want to be having a set of guidelines that don't apply to anything that's being used but reflect the variety of uses as well as some of the complexities of this program and the issues of judgment and so forth that Wanda raised into that.

And I guess I'd like people's reaction to that as a way forward because I think this particular issue obviously is a source of heartburn for all of us in many ways. It

gives the Legal people heartburn because of what's in the regulations and law and so forth. And it obviously, Larry, and I think all of us, have to be concerned that we're already doing a lot and already using surrogate data a lot in this program. And we have to be mindful of that and the fact that we are comfortable in its use in many instances.

And so I think what may be more useful both in a sense of going forward is having a document that looks at it from a sort of overall guidelines criteria perspective like the SEC document. So I guess I would be interested in people's reaction to that.

MS. MUNN: This is Wanda. I'm not at all sure I understand the format that you are suggesting, Jim. Are we discussing the insertion of some criteria in, for example, a workbook? Or are we considering something else?

DR. MELIUS: It would be a document. It would be entitled as a straw document so to speak, you know, "Guidelines for the Use of Surrogate Data in the Dose Reconstruction

Program". And it would list the various criteria, I think, using, say starting with something equivalent to the three criteria that John has starting on page seven of the second SC&A report, and an explanation of how those would be applied. And then it may have some procedural recommendations also.

MS. BEACH: This is Josie. Do you mean procedural recommendations or would we actually make this a procedure?

DR. MELIUS: It wouldn't be a procedure. This would be sort of an overall guidance document like the original SEC review document. Again, what we did there was produce a set of guidelines and general criteria that would be used in the review of SEC evaluation reports. And these would be things, was basically was designed to be the type of information that would be a guide for OCAS in preparing the evaluation reports, and I don't want to say a checklist, but sort of a general type of areas that the Advisory Board felt should be focused on in the review of those evaluations.

MR. ELLIOTT: I thought you were starting

off with this being a Board-related tool, but now it sounds like it's, you're leading it more to a guidance tool that we would use.

DR. MELIUS: Well, I think it's both. I think the SEC ended up in some ways being both because you used it as a -- correct me if I'm wrong, Larry -- but as a way of, sort of an outline for your reports, SEC evaluation reports, the things that would be covered in them. And then the Board used it as a way of how we would evaluate.

MR. ELLIOTT: Yeah, essentially how I recall that going down was the Board through your working group provided some recommendation on how to develop an evaluation report that addressed some things, some elements, some concerns, some problems that you were seeing in our evaluation reports. And you wanted to make sure that we attended to those, and we accepted that recommendation, and we started living by that. So that could happen here, I guess.

DR. MELIUS: Yes, I mean, I think that there's differences clearly. I mean, I think the use of surrogate data is in some ways more

diverse. There's different --

MR. ELLIOTT: Yeah, it is.

DR. MELIUS: -- yeah, and so I think, yeah, some guidelines may apply, some criteria may apply to one use, it may not apply to another. And I think we have to try to make sure we reflect that and so forth. What I'm thinking of like a procedural recommendation, I mean, there may be things like I would actually (sic) responding to something you had just said, Larry, which was for the 6000 procedure, the appendices deal with unique situations.

MR. ELLIOTT: Yes.

DR. MELIUS: Essentially the exceptions. Well, maybe one procedural recommendation is that there should be an explicit procedure for dealing with the exceptions.

MR. ELLIOTT: Or site profiles or technical basis documents that utilize surrogate data need to be explicit in how that came to be. Maybe that's where we --

DR. MELIUS: Yeah, exactly, exactly.

MR. ELLIOTT: -- because I think we do it a little bit of justice and service in some of our documents while in others perhaps we are

not as explicit as we should be about the use of surrogate data.

DR. MELIUS: And we all recognize some of that as the programs mature then as we all gain experience, and particularly your group gains experience doing literally thousands of dose reconstructions that situations become more evident. I guess others on the work group? Do I have you completely puzzled?

DR. LOCKEY: Yeah, Jim, Jim Lockey. I just maybe a further explanation for me (sic). What you're suggesting is that when surrogate data is felt to be appropriate, appropriate for use by NIOSH, this is the hierarchy as to how that data would be used. Is that what you're suggesting?

DR. MELIUS: No, these would be guidelines that would guide the consideration of the use and the utilization of surrogate data.

DR. LOCKEY: So what you're proposing is a step before that. In other words a step in regard to how NIOSH arrives at the decision that surrogate data is appropriate for use.

DR. MELIUS: But I actually think that's part and parcel of what goes on already. I

mean, I'm sure that, you know, some of it's sort of obvious. If you have adequate data for the site, you don't consider it, right? So that already goes on. That's part of the hierarchy.

MS. MUNN: Yeah, this hierarchy has essentially been in place from the outset.

DR. MELIUS: One mustn't rewrite the hierarchy. So it's guidelines on, if essentially those guidelines aren't met, you're not going to do it so to speak. But I mean --

DR. LOCKEY: That's what I'm asking. Since the hierarchy's in place and that, then what are you proposing? That's what I'm having trouble.

DR. MELIUS: I think there are criteria beyond just the hierarchy, and there are criteria as to what is the, let's call it the suitability of surrogate data. I mean, one, it's not always available. It doesn't always, there's many cases where it's not going to be used.

MR. ELLIOTT: Jim, if I might maybe I can help out here and explain as I see what you're

talking about for Dr. Lockey here.

If we take the Bethlehem Steel example that John Mauro spoke of earlier, and we identified that we had some data gaps. In that instance we didn't have enough exposure monitoring data, and it led us to use air monitoring data. And we still felt we needed a little bit better handle on that aspect. And we looked around, and we said, well, here, we've got another site that was a pilot operation similar to Bethlehem Steel. They were rolling uranium. In fact, they were trying the same process at Simonds as they were trying to do at Bethlehem. And they learned something at Simonds that they applied at Bethlehem. So maybe there's some data at Simonds that we can use to bound doses at Bethlehem. And so that's exactly what we did, but we didn't explain perhaps clearly and well enough and thoroughly enough why we felt we could use that data from Simonds. It could have been that we looked at that Simonds data and said, well, we can't use that, and we should explain why we couldn't use that. I think that's where Dr. Melius is going.

DR. LOCKEY: I understand. I assumed that that's what you were doing. What I didn't understand was that the justification of your decision was not recorded.

MR. ELLIOTT: Well, I would say it is recorded, but perhaps it could be more explicit than it is.

DR. MAURO: This is John. I was very close to the evolution. And one of the concerns throughout the process in the review of Bethlehem Steel was the use of Simonds Saw data. And during the deliberations a great deal of information was brought forth to describe why the data that was used from Simonds Saw was appropriate in this circumstance. So that emerged during the course of our deliberations.

So in a way that process represents a good example of the kinds of deliberations that were used in the past to get to the point where it was generally felt that we can do it under those circumstances. And in a way that very same deliberative process is appropriate for any time you're going to draw upon other site data to help supplement the data you have

for a given site. So that's why I went to Bethlehem Steel as a good example. And that deliberative process emerged. That wasn't something that was self evident from the very beginning. It emerged during the course of working through some of the issues that we raised related to Bethlehem Steel.

DR. MELIUS: I mean, even if you, another way of stating more generally, well, if data's not available from a site for a particular process or something or whatever. OCAS will say, well, we'll consider the use of data from another site, surrogate data. Well, under what criteria would you do that? I mean, and he'd say, we'll, we'd use our judgment. Well, what goes into that judgment, and how is the decision made to use it?

But once a review takes place of that information that would determine that it's appropriate and that it is applicable in that situation. Now clearly, these situations are diverse, so we're not going to try to produce a document that covers every specific situation, but I think there are some general criteria that -- I mean, again, the same with

the SEC.

All the sites are different and the criteria, the evaluation document does not cover every situation or every consideration, but I think it provides a framework, and I actually think the process helps to, you know, both the Board and the Board working with NIOSH to sort of have a consensus on how we will go forward on, you know, in one case the review of SEC evaluation reports and the other case with whatever Larry and the group propose the use of surrogate data for a particular situation or as part of a particular procedure or dose reconstruction.

DR. BEHLING: Dr. Melius, can I make a comment here? This is Hans Behling of SC&A.

DR. MAURO: This is John. If it's okay, I would like to break. I am in a position where it's very difficult for me to continue on the line. If you'll forgive me, but certainly, Dr. Melius, if I could give you a call at a convenient time, any actions you'd like us to take I certainly could discuss it, but I do have to break right now.

DR. MELIUS: Okay, John.

DR. MAURO: Okay, thank you very much.

DR. BEHLING: Dr. Melius, can I make a comment here?

DR. MELIUS: Yes, go ahead, Hans.

DR. BEHLING: And I guess we've discussed an awful lot about when is the use of surrogate data appropriate, and what are the potential criteria. And I think collectively we can talk about the degree to which surrogate data has parity with the facility for which we have no data. And parity is really based on the number of criteria that can be used.

For instance, time is a critical aspect as was the case with Simonds Saw and Bethlehem Steel. The two facilities operated during the same time period so time is of critical importance of significance in the sense where you wouldn't want to compare a facility that's operating currently with one that operated in the '50s and '60s.

The other issue is one of the facility. The engineering controls, the design of the facility. Another one would be, for instance, the quantity of materials processed. You cannot compare a facility that

processed a very small quantity with a facility that processed megatons.

Another one would be the role of the processes, the type of processes. Are they identical or is there parity between the chemical processes or the mechanical processes. And lastly, there may be issues regarding a known or established radiological incident that would perhaps make one facility not appropriate for it to another facility.

So these are all the criteria. And collectively, I think the importance here in using surrogate data is to establish a degree of parity that says, yes, they are close enough or nearly identical to the point where there's no reason not to use it as opposed to recognizing their differences in design, in facility designs, the differences in the time periods during which they operated at differences in the processes that were used for the same endpoint.

All these things would either determine whether or not it's appropriate to use surrogate data or perhaps the use of surrogate data has certain limitations to it.

And I think there could be a reasonable, easy checklist that would essentially provide an overview in saying, yes, there is tremendous amount of overlap here between these two facilities that would make one set of data very appropriate for use at a facility that lacks that data.

DR. MELIUS: Thanks, Hans, I think that's helpful.

Anybody else have comments?

MS. MUNN: If we can all get on the same page with this it would be enormously helpful for all of us I think. And it's of extreme interest not only to the people that we have on the call here, but certainly this is a real hot button for most of the claimants who cannot understand why it would be beneficial for us to be using data from some other site. It's, I think, really important for us to be able to all agree what these guidelines are appropriately without obliterating the fact that we're always going to have judgment calls that are involved here. I see no way we can ever avoid that.

DR. MELIUS: Other comments?

MS. BEACH: I have a question. Will we use any of these recommendations to go back and look at previous dose reconstructions and how they were used, or will we just be going forward at this point?

DR. MELIUS: I think it's, in essence, it's going, in some ways it's going forward, but this -- I don't know how to state this, but essentially the program is sort of always in flux in the sense that procedures are always being updated and changed and so forth. And I'm not, I think we have a, for example, a Procedures work group that's underway and to the extent that we have a document for them relatively soon, they will use that. I think that as always whenever anything changes in this program, if it's felt that it would have an impact on a set of dose reconstructions that had been done in the past where it might need to be reviewed, then I think NIOSH's policy has been to go back and look at those and see if it does change it. But that's probably jumping ahead, and I'm not predicting that's what --

MR. ELLIOTT: This is Larry Elliott.

DR. MELIUS: Larry, I don't want to --

MR. ELLIOTT: If I could, I would speak to Josie's question with this answer. Josie, we here at NIOSH don't believe that we have made use of surrogate data inappropriately up to this point in time. We've been very careful, in fact, with when and where we use it, fully recognizing that it should be used appropriately and to the advantage of the claimant, not to a disadvantage.

And that somewhat is in the eye of the beholder I know, but we would, if it comes to pass that we have used surrogate data outside of any guidelines or checklist or criteria that gets established through this deliberative process that we're engaged in right now, we would then go, and if that, in fact, added dose, that changed added dose, then we would institute and implement our program evaluation review to look at all non-compensable claims that came from that misuse of that data. But it's only when we increase dose do we look back at claims. If we decrease dose, we don't go revisiting claims.

MS. BEACH: Thank you.

MS. MUNN: My guess would be that what we ultimately determine our suggestions to be will not vary in large degree from what has been done in the past. It's more a question in my mind of whether this needs to be formalized or not. As Larry said, the perception in my mind is that we've seen a very careful use of surrogate data. I'd be surprised if our guidelines strayed from what's been done in the past very much.

DR. LOCKEY: This is Jim Lockey. From what Hans was saying, the various criteria that he was listing to me seemed to be really quite self evident and I would expect that that, in fact, is what's going on. So if that's what we're sort of looking at and going back and making that a more formal written process or at least guidelines as such, I think that's a reasonable approach to take. It seems logical that the guidelines, if that's the approach that would have been taken rather than the same production year or same type of process, same type of manufacturing process, et cetera.

MS. MUNN: Or at least reasonably --

DR. MELIUS: Yeah, with some general

parameters on reasonable and so forth. And then I think it helps, but --

DR. LOCKEY: That's what you're talking about, Jim?

DR. MELIUS: Yes.

DR. LOCKEY: Okay, I think that's --

MR. ELLIOTT: If I might, this is Larry Elliott again, Dr. Melius. If I could offer another comment here. Ancillary to this discussion is this working group I feel really needs to come to grips with, is the use of surrogate data allowed or not allowed. We have the Bethlehem Steel SEC evaluation before the Board and one hold on that is the outcome of your discussion on use of surrogate data. And at some point we really need to move that along, but we also need to come out with a collective consensus about the use of surrogate data.

DR. MELIUS: I thought you were about to have Liz strike me with lightning again or something. You said allowed. No, I...

MR. ELLIOTT: At NIOSH and at OCAS, we certainly feel that the law allows us, the regulations allow us to use it appropriately.

But the perception on the outside is that that's not read that way, or they don't see it that way. And certainly in the Bethlehem Steel instance we're tolling time on that evaluation for that petition.

FUTURE PLANS

DR. MELIUS: No, I think we appreciate that issue. Let me talk about what I see as the way forward because I did try to promise everybody we would do this call within an hour. What I would like to do going forward propose is that I think everybody should take a look at the first, the September 12th report because I think it's just a useful compendium and albeit whether everything's completely characterized or whatever. I think aside from that it's useful just, to me, sort of the breadth and different uses. It was helpful to me in sort of thinking about this issue.

And then also again look at the second report and the three criteria. And if there are any sort of general suggestions or something that people would have about the other criteria, major criteria as opposed to sort of the checklist type of criteria. We'll

get to the more detailed criteria a little bit later.

But I would propose is that people get back to me say within a couple of weeks with any comments or sort of general suggestions. I will work with SC&A to produce a sort of a draft general report that sort of be an outline and codify what we've been talking about today in the form of a draft report that would then circulate to the work group.

And say that happens within say roughly three or four weeks from now. That then we would, I think either try to do a meeting or more likely a conference call given just the many work group meetings that are coming up and the holidays coming. I'm not sure that another meeting or something is going to be easy to do, but to have something for discussion and comments so that we can, maybe even by conference call spending a little bit longer, a few hours on this. And then see if we can have something ready to at least talk about with the full Board in the January meeting.

DR. LOCKEY: This is Jim Lockey. I think

that's fine.

DR. MELIUS: And I will take the responsibility for doing a lot of the, writing an initial draft. I will get some input and help from John and his group to some extent on this.

MS. MUNN: I have one suggestion with respect to our next steps. Is there any disagreement currently within the working group with respect to the reasonableness of using surrogate data for SECs? Aren't we talking about putting together a document that is secondary to that issue? Have we not been discussing here an applicability that would move across both individual and SEC petitions?

DR. MELIUS: At some level there I think we try to think of them as being related. That if something is, yeah.

MS. MUNN: Yes, I do, too.

DR. MELIUS: Yeah, okay.

MS. MUNN: I guess my question is do we have any issues within the work group with respect to surrogate data being used in SECs. Does anyone disagree with that?

DR. MELIUS: But they're not used in SECs,

by definition.

MR. ELLIOTT: This surrogate data goes to dose reconstruction.

DR. MELIUS: Dose reconstruction. If it's not feasible --

MR. ELLIOTT: If we can't use surrogate data and that leads us to say we can't do dose reconstruction, then we do an 8314 for a class.

DR. MELIUS: I think what you're asking, Wanda, is that if a dose constructions can only be done using surrogate data.

MS. MUNN: Yeah.

DR. MELIUS: I mean, I think it's sort of the corollary of what you're saying. And I think that, I think we have to sort of, I'd rather answer that question, at least I can't answer that in a general sense, but I think that we would let's produce an evaluation report and set a criteria and it's applied appropriately. And whatever we have pending in terms of you know to the extent it's helpful in your work group's procedure review to the extent that it's helpful in dealing with pending SECs and so forth, that's fine.

But I think we need to, I'd rather write a report that doesn't try to think, specifically address particular instances. But rather let's, what are the general criteria and then figure out how it applies.

MS. MUNN: Yeah, I think we have to do the general criteria.

DR. MELIUS: And do that in a timely fashion which Larry's request, and I think that's quite appropriate.

DR. LOCKEY: Jim Melius, Jim Lockey. What about Larry's question? That's a question that we're not going to be able to answer. What I hear is that that's a legal question and Liz and group or whoever has to answer that question. Is that correct?

DR. MELIUS: Yeah, but I think what Larry was really asking is can we get in a position where we would say that the use of surrogate data is technically appropriate in particular instances. And he obviously I think has, he said he had, he was thinking of the Bethlehem situation which is we do, I don't know whether we tabled it or what our exact action was, but --

DR. WADE: We tabled it.

DR. MELIUS: -- it's contingent on us making progress on this particular issue. And I think that's more what he was asking than the issue of --

DR. LOCKEY: Yes, it was.

DR. MELIUS: -- appropriateness and -- and I hope Liz is still on the line. We're not trying to address the legal issues.

MS. HOMOKI-TITUS: Yes, I'm still here. I understand.

DR. LOCKEY: So, Jim, at the end of this process when we put criteria down as to what Hans was saying, and then look at each one on a case-by-case basis and the process was followed, then the end result one would say, yes, in this case it is appropriate. The criteria are reasonable criteria. They follow general guidelines and using surrogate data under this situation is applicable.

DR. MELIUS: Yeah.

DR. LOCKEY: I was trying to figure where we're going --

DR. MELIUS: Yeah, and then that's exactly where we're going. I think that's what

Larry's saying, you know, keep in mind that this has some practical or procedural implications, and we need to get on with it. But that's in some extent what I'm trying to do.

MS. MUNN: So do you have a feel for when you might be calling us back together?

DR. MELIUS: Either the week before the Christmas holidays, or I'm suspecting more likely the week after New Year's.

MS. MUNN: Okay, the week after New Year's we're going to be in Las Vegas.

DR. MELIUS: But the immediate week after --

MS. MUNN: Not the day after New Year's.

DR. MELIUS: Well, not the day after.

MS. MUNN: Two days after New Year's.

DR. MELIUS: Well, someone was trying to convince me we'd do a conference call next Thursday on another issue. It also involves NIOSH by the way.

MS. MUNN: Okay, so it'll be a month.

DR. MELIUS: Yes.

MS. MUNN: We need not --

DR. MELIUS: Again, two weeks for people to get general comments to me on criteria and

then within a week or two after that I will, in working with SC&A, we will get the report, at least you'll have the main, the general outline structure of the report. And we'll undoubtedly need refinement and then input from everybody.

MS. MUNN: Very good. Since I have not been keeping decent notes of the conversations we've been having here, it would be helpful if you'd send us an e-mail --

DR. MELIUS: I will.

MS. MUNN: -- defining what you want from us and when you want it.

DR. MELIUS: Okay, I'd be glad to.

MS. MUNN: Thank you.

DR. MELIUS: Other comments? Jim?

DR. LOCKEY: No.

DR. MELIUS: Mark, are you --

MR. GRIFFON: Still here and nothing to add though. I'm still here and nothing to add.

DR. MELIUS: If we've done then I think we can close off.

MR. ELLIOTT: Dr. Melius, this is Larry Elliott. Given what you've just decided here, does it still make sense I would ask to go

ahead with revealing and redacting the September 12th working paper or not?

DR. MELIUS: Yes, I think it would simply, again, I'm just more comfortable having our documents publicly available.

MR. ELLIOTT: That's fine.

DR. MELIUS: The nature of the document isn't such that I don't --

MR. ELLIOTT: I guess then that John will need to get that to Emily.

DR. MELIUS: Yeah, right.

DR. WADE: Yeah, he said he would take that as an action.

DR. MELIUS: Okay, thanks everybody.

DR. WADE: Thank you, very well done.

MS. MUNN: Thank you.

(Whereupon, the meeting was adjourned at 3:23 p.m.)

CERTIFICATE OF COURT REPORTER

STATE OF GEORGIA

COUNTY OF FULTON

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of Nov. 16, 2007; I, Steven Ray Green, then transcribed the proceedings, and it is a true and accurate transcript of the testimony captioned herein.

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

WITNESS my hand and official seal this the 12th day of December, 2007.

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STEVEN RAY GREEN, CCR

CERTIFIED MERIT COURT REPORTER

CERTIFICATE NUMBER: A-2102