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 June 9, 2008.

STEVEN RAY GREEN AND ASSOCIATES
NATIONALLY CERTIFIED COURT REPORTING
404/733-6070

C O N T E N T S

June 9, 2008

TRANSCRIPT LEGEND

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

-- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

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

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

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

-- ^ denotes telephonic interruption.

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

(By Group, in Alphabetical Order)

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P R O C E E D I N G S

(11:30 a.m.)

WELCOME AND OPENING COMMENTS

DR. CHRISTINE BRANCHE, DFO

DR. BRANCHE: This is the Surrogate Data working group meeting of the Advisory Board on Radiation and Worker Health. I'm Dr. Christine Branche, the Designated Federal Official for the Advisory Board.

Will the Board members participating on the call please state your name?

DR. MELIUS: Jim Melius.

MS. MUNN: Wanda Munn.

DR. LOCKEY: Jim Lockey.

MS. BEACH: Josie Beach.

DR. BRANCHE: Mark Griffon, are you on the line?

(no response)

DR. BRANCHE: Are there any other Board members?

(no response)

DR. BRANCHE: We do not have a quorum so we can continue.

NIOSH staff who are participating would you please state your name?

MR. ELLIOTT: Larry Elliott, NIOSH/OCAS.

DR. NETON: Jim Neton, NIOSH/OCAS.

MS. ADAMS: Nancy Adams, NIOSH.

MS. CHANG: Chia-Chia Chang, NIOSH.

DR. BRANCHE: Any ORAU staff participating?

(no response)

DR. BRANCHE: SC&A staff?

DR. MAURO: John Mauro.

DR. MAKHIJANI: Arjun Makhijani.

DR. BRANCHE: Are there any other federal agency staff on the line?

MS. HOWELL: This is Emily Howell with HHS.

MR. McGOLERICK: Robert McGolerick, HHS.

MR. KOTSCH: Jeff Kotsch with Labor.

MR. BROEHM: Jason Broehm, CDC Washington office.

DR. BRANCHE: Are there petitioners or their reps on the line?

(no response)

DR. BRANCHE: Are there any workers or their representatives on the line?

MS. BARRIE: This is Terrie Barrie with ANWAG.

DR. BRANCHE: Thank you, Ms. Barrie.

Are there any members of Congress or persons representing their offices on the line?

(no response)

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

MR. GRIFFON: Hi, Christine, it's Mark Griffon. I just joined. I don't know if you called Board members already.

DR. BRANCHE: I did. And thank you for letting me know that you're on the line.

Are there any others who would like to mention their names?

(no response)

DR. BRANCHE: Before we get started I do ask for the purpose of telephone etiquette but also because everyone is participating by phone and we need to make certain that everyone can hear all of the discussion. So only when you're speaking please un-mute your phone.

If everyone will please mute their phones, it will help us all to hear the dialogue. And when you are ready to un-mute

your phone, rather when you're ready to speak, please un-mute your phone. If you do not have a mute button, then please use star six. Thank you very much.

Dr. Melius.

INTRODUCTION BY CHAIR

DR. MELIUS: The purpose of this call is, I think actually the sole focus of this call is the draft document on the criteria for the use of surrogate data which was circulated some time ago. And we had comments, actually some written comments from Jim Lockey and from Wanda, Mark Griffon in an earlier draft. And so I think the purpose of this call is to try to resolve those comments. And I think it is, should be relatively straightforward to do. We'll see.

DR. BRANCHE: Jim, before you get started, are you the person who's in a public place?

DR. MELIUS: I hope not.

DR. BRANCHE: Okay, well, there's someone who is and if that person could please mute your phone, we'd appreciate it. Thank you very much.

Sorry, Jim.

DRAFT DOCUMENT: CRITERIA FOR USE OF SURROGATE DATA

DR. MELIUS: What I propose doing, there are a large number of comments. I think just sort of work paragraph by paragraph in terms of dealing with these.

MR. ELLIOTT: Dr. Melius, this is Larry Elliott. I wonder if before you get started working through the comments if you could just give a sense, your sense, of how this document would be utilized. Who it would be used by and just state for the record what your intent and purpose is in this document.

DR. MELIUS: The purposes of this document, intent for the use of the document would be, it would be a document adopted by the Board that the Board would use for the review of NIOSH site profiles, SEC evaluations and procedures that would provide a set of guidance for the Board's review, similar to the document that we have developed for the review of SEC evaluation reports. So it would set out as a series of general guidance.

(Interruption occurs.)

DR. BRANCHE: Excuse me. Someone is in an airport? If you could please mute your phone

it would be very helpful I think. No, I know it would be very helpful to us, but it's very clear that the person who's challenging our ability to hear is at an airport.

Dr. Melius, can you still hear me?

DR. MELIUS: I can hear you fine. I don't know if people could hear me.

DR. BRANCHE: Anything before my interruption, and while that interference was going on from the airport, I didn't hear you.

DR. MELIUS: I think I had finished up, but briefly summarized, this would be a guidance document similar to the Board's guidance document on the review of SEC evaluation reports. So it will provide a set of guidelines for our review.

MR. ELLIOTT: Thank you.

DR. MELIUS: Any other sort of general questions before we start?

(no response)

DR. MELIUS: And I just would add clearly at this point it's a draft document. It's not even been adopted by the work group and at some point needs to go to the Board for their review and adoption.

I'm going to start with the first paragraph, and I'm working off actually Jim Lockey's draft document he sent with comments which I re-circulated to the work group and some of the other staff involved in this program. And Jim had a comment about, the last sentence of that first paragraph, which I actually agree to, that's not very artfully worded.

And I would propose some sort of rewording to the effect of it's more often used during the early years -- this is referring to the use of surrogate data -- early years of some DOE facilities because of the lack of reliable monitoring methods, et cetera, and just try to make it more specific than that.

And again, I'm not asking people to adopt specific wording because I think you should see it in front of you, but it'd be something like that. I think it does need to be clarified. It's not an overly broad version there.

DR. MAKHIJANI: Dr. Melius, I have a question about this. This is Arjun. Did you

intend to add AWE sites to that or restrict it to DOE facilities?

DR. MELIUS: To be both AOE (sic) and DOE facilities.

DR. MAKHIJANI: Okay.

DR. MELIUS: The next comment we have under criteria number one, which is the hierarchy of data, and this comment comes from Wanda. And it is regarding the, I think it's sort of a critical point though. I think there are ways of dealing with it. And I think it refers to the third sentence there, "In general, surrogate data should not be used to replace available data from site inspections as a higher level of hierarchy."

And I think what Wanda's comment would remove that, change that a level so to speak that in really taking the last sentence there, if I understand Wanda's comments right, is she would sort of move it down a level and say that it would be used to replace data in the next level if certain criteria were met.

Is that capturing your comment, Wanda?

MS. MUNN: I am now un-muted. That was my general thinking. I'm at a slight

disadvantage because I don't have the documents in front of me, and I'm not at a place where I can pull them up on my computer. But if memory serves, that's roughly my intent with that slight change in wording. I don't think I changed it very much.

DR. MELIUS: No, it was simply changing that level. And I guess I would have two responses to that. One is that I think the criteria to use it at a next level would be stricter than if one were, more stringent than if one were using it at the same level. Because I can't imagine circumstances, I believe we've encountered some of these where we may have a small amount of sampling, personal sampling data, from a site for some particular exposure. And, however, that by itself is not adequate for doing dose reconstruction.

However, we may have some data from another site, what we refer to as surrogate data, that may be at the next level of the hierarchy, but it's particularly robust -- and I hate to use a word you don't like, Wanda -- but it would be, we might want to utilize that data. I think that we would then make the

justification for using this, the lower level of hierarchable data for dose reconstruction. We would probably be more stringent about that than we would if we were using data from the same level.

And so what I would propose doing in that paragraph is adding a sentence to that effect. Right now it states, in general, surrogate data should not be used to replace available data that are a higher level. Only we should replace data at the same level and blah-blah-blah.

Then I would say add a sentence that, however, there may be specific instances where data from a, surrogate data may be used to replace data that's at a higher level. However, that needs to meet more stringent criteria, et cetera.

MS. MUNN: Why don't we try having you (telephonic interference) truly want to say.

DR. MELIUS: No, that's fine. I'm not asking you to approve anything over the phone.

Anybody else have comments on that?

(no response)

DR. MELIUS: And I think it just reflects, I

mean, this has lots of different factors that go into judging what data is useful, not useful and so forth. And I think we need to, and we're struggling to come up with a simple way of stating that, what's often a complicated situation.

MS. MUNN: Usually a complicated situation lately.

DR. MELIUS: Anyone else have comments on that?

(no response)

DR. MELIUS: The next paragraph called Exclusivity Constraint, I agree, very stringently is an overkill and not necessary. So we can take out the very stringently justified and make it just stringently justified. And then Wanda had a comment about in the last sentence I think, again, some of these grammatical -- it currently reads the judgment needs to take into account not only the amount of surrogate data being relied on relative to data from the site, but also the quality of the surrogate data relative to data available to the site in question. And I think the second one is relative, relative to

data available at the site is somewhat redundant (inaudible).

DR. BRANCHE: Jim, the last few words that you said were lost.

DR. MELIUS: What I said was that the second relative to data available for the site in question is a bit redundant. But I'll correct that and include that when I re-circulate the document.

Any questions on that paragraph?

(no response)

DR. MELIUS: Paragraph number three, which is titled site or process similarities, Jim Lockey had one small change in that which is fine. Wanda had a number of changes, most of which were, I think all of which would be clarifications of that paragraph. And again, I'll just rewrite that and circulate it. I don't think it makes any significant differences to that.

Anybody else have questions or comments on that?

DR. LOCKEY: Hey, Jim, Jim Lockey. When I read this over the weekend, there was one sentence that maybe can be redone. That's

under number three, and it's the second, actually, it's the last sentence in that paragraph. And it starts, surrogate data should not be used if the equivalency, equivalent air claimant favorability.

And I understand what you're trying to do with claimant favorability, but maybe it should be at the beginning. It took me a long time to figure out why that sentence was, why the claimant favorability was in that position. It's just a wording issue I think.

DR. MELIUS: I agree, thanks.

MS. MUNN: You're going to rewrite it anyway, right, Jim?

DR. MELIUS: Yes, correct.

MS. MUNN: Sounds good.

DR. MELIUS: Paragraph number four is temporal considerations, and I had no, received no comments on that. I don't know if anybody has any at this point.

(no response)

DR. MELIUS: If not, then the other comment I had from Wanda actually concerns the SC&A report, and her comment was about the items described as type two in that report. And I

guess I'm at a little bit of a loss of what to say about that.

What I tried to do was, basically, I think Wanda's comment basically goes to the concept that surrogate data has been widely used in the development of standards, exposure limits and so forth. Somehow that SC&A document by calling it type two as a classification was calling into question those standards.

And what I tried to do in the, in our criteria was make sure that we've got that, the first sentence of this draft document says, for the purpose of this report the term surrogate data will refer to the use of exposure data from one site for individual dose reconstruction for workers at another site. And basically say this is not referring to the use of data from one site being used in the development of radiation standards or limits or whatever work practice criteria, whatever, that may be taken from one site, nor the experience learned at one site being used at another site. That the focus is purely on dose reconstruction.

Now if somebody could come up with a better word for surrogate data that would clarify that difference, I think it may be helpful. But short of that I think we're trying to keep our focus on that, and not a focus or questions on the use of data from one site being used in the development of standards and so forth. That's a different operation. It has a different set of scientific considerations and weighting of those scientific considerations and how that's done. Our focus is on dose reconstruction which has a whole set of other technical and other issues in the context of this program.

DR. MAKHIJANI: Dr. Melius, this is Arjun. The way, I have the SC&A report before me, and John might want to comment, too. The way, at least in some of the entries -- I haven't recently reviewed all of them, but the type two was used was whether generic assumptions were used for dose reconstruction and development of parameters for dose reconstruction at a particular site.

So, for instance, the first one is about recycled uranium, and we said some

generic assumptions are used for medical dose prior to 1977, and recycled uranium data prior to mid-1980s are based on DOE complex collective process knowledge. So this is actually data from collective process knowledge that has been proposed for use in individual dose reconstruction for Fernald in this case. And I just, I'm a little confused based on what you said as to how that, conversation you've just been having, would apply to individual dose reconstruction and the RU data at Fernald.

MS. MUNN: Arjun, these kinds of concerns were what I was thinking of, I believe, at the time that I tried to make additional comment about ^. Even though we tried earlier to specify what we're talking about here ^ limited specifically to the uses that we have identified.

It still is very easy to have this type of a policy document used in other venues and other kinds of reviews once it's been established. So I'm very concerned that we are more than just casually specific about how we're going to ^ surrogate data and that we

not find ourselves in the position like the one you just described which was, I think, detrimental to all of the people involved.

DR. MAURO: Wanda, Dr. Melius, from this conversation, I think what I'm hearing is the definition or the criteria that's under consideration right now seems to be oriented more toward the use of air sampling, bioassay and external dosimetry data.

In other words really, when you want to use surrogate data for those types of dosimetric problems, Arjun and I agree that recycled uranium, minimum detectable levels, medical X-ray exposures, there's a lot of generic weapons complex-wide information that's used across the board collectively. And I think that what I'm hearing is in this particular instance there's an intent to embrace, define surrogate data in a narrower sense at least for the purposes of bioassay, air sampling and film badge data. Would that be a correct statement?

DR. MELIUS: No.

DR. MAURO: Okay.

DR. MELIUS: I don't think so to the extent

that other types of information are being used as a basis for dose reconstruction.

DR. MAURO: Under those circumstances then, the issues that Arjun just mentioned, there are a large number of -- I wouldn't call them NCRP, ICRP or standard dosimetric guidelines that come out from national committees, but there is a lot of generic work. And I'll mention three of them.

I think the three that come to mind immediately are recycled uranium; I think the high-fired plutonium is another example, and X-ray, minimum detectable levels both for bioassay and for film badges. These are all assumptions that are part of the process of doing dose reconstruction that goes toward those reconstructions that are being applied site specifically but do come from collective knowledge done by resource ^ done by NIOSH's contractor. So if we are ^ to that, then you know that we're engaging in a more challenging set of criteria.

DR. MAKHIJANI: You've just mixed up a couple of different things. My question was a little bit narrower than using a Super-S model

that's specific to Super-S Plutonium. Super-S Plutonium isn't different at Fernald or Rocky Flats or Hanford or Savannah River Site. So I'm not talking about the model, and I share Wanda's concern about that. And I think that clearly, there's a model that generally is applicable at a time.

But what I was asking about and what I'm still confused about, maybe Jim has just clarified it, is that from recycled uranium data from Hanford as to radioisotopes ^ recycled uranium as being applied to Fernald, then that seems to meet Fernald dose reconstructions. And that seems to fall into process data from another site being applied to dose reconstruction.

And I just wanted to ask whether you can narrow the question, whether process information from some other site as opposed to, say, medical X-ray characteristics of some piece of equipment or something like that, can be used as surrogate data on what those criteria would be. The process information is part of FR-82^ in the hierarchy of data if I remember correctly.

Am I right, Jim? I'm not looking at the regulation. I'm saying that from memory. Jim Neton?

DR. NETON: Yeah, that's correct. I don't want to say anything much here, but I think we're getting into the area of the differentiation between what I call supporting surrogate data, actual data and then also in the development of what I would call analytical models ^ used quite extensively.

MS. MUNN: And you're correct. The reason I brought the issue up, Jim, is that if we are going to be using these criteria that we're establishing in one way now but broadening them as we go along, then we do get into a situation where we confuse those three items. And I wanted to make very sure that we were not saying or doing anything in our policy statement that would lead us to, for example, reject the minimum quantities that have been established and used widely as a profession as not being adequate because they were not developed at the site where we were at that moment. ^.

So I think it's a very real concern,

and I would hate to think that these criteria might later be used in some way other than what we intended at the time I believe Jim wrote these. How we clarify that more distinctly than just simply saying -- well, it's in the first sentence -- I'm not sure, but I feel the question is more than relevant. I think it bears on our ability of statements that we might make for the Board to approve.

DR. MAURO: Wanda, this is John. There was a reason I made the distinction in my original draft that not only in the criteria draft but also in the compendium. We ^ very large compendium ^ where surrogate data was used where I did make a distinction between type one and type two because I realized that this challenge would confront us. That is, we may want to make a distinction between type one and type two.

Type one refers to straightforward bioassay, film badge, air sampling data. Type two would go more toward the kind of things that Jim Neton just referred to as research information that has broad applicability. This is a tough question, and I think what

you're saying is correct. I think the nature of the definitions of the four criteria that we are embracing now are more oriented toward type one than type two.

MS. MUNN: I remember the size of those compendia. I do not remember the content. I'd have to go back and take a look again.

DR. MELIUS: This is Jim Melius, two comments. One is I think it's, one of the issues we have to deal with is are there different criteria for reviewing type one versus type two or can we capture them all in one set of criteria, and I don't know the answer to that. But one of the reasons I was advocating that before we finalize the criteria we try applying it to some limited number of examples would be so that we make sure that we're setting the boundaries on it right and that we've captured the appropriate factors that are going in and weighed in the criteria.

We'll never get everything just given how complicated this is, but we need to, may be able to refine these in a way that avoids some of the potential pitfalls that Wanda's

concerned about, and at the same time make this useful in terms of dealing with dose reconstruction issues. And I think that if you remember right, the SEC evaluation criteria were built from our experience, actually, some of our problems in evaluating SEC evaluation reports.

The need to systematize that I think, maybe working through some of the examples and so forth would help to address these issues also and make sure that, one, we're not missing somehow an important set of things that should be reviewed. At the same time we're not including things that are inappropriate to being reviewed.

DR. MAURO: Jim, this is John Mauro. When we did apply the four criteria, and they served us very well, when we did Blockson, and we're in the middle of doing it also for Texas City; however, when we applied the criteria, the framework within which we were working, dealt mainly with external dosimetry and air sampling data.

We really never engaged issues that I would call type two surrogate data. So right

now I could say, at least in the two instances where we attempted to apply the fourth criteria, Blockson and Texas City, it served us very well when it came to type one criteria, type one surrogate data.

DR. MELIUS: ^ once we've agreed on the draft criteria, then I think applying them to some other examples including some type two I think would also be helpful. What my proposal, before we start down that road is that I will rewrite the document, circulate it to the work group, and given the timeframe and so forth, I think that I'll wait to hear, see what people's comments are. People can get back to me individually. If necessary, we'll schedule another meeting.

Hopefully, we can ^. I'll have captured people's comments well enough that we'll have a draft document and can move forward. And then my proposal would be that we then apply this to some examples and so forth. But I also would like to circulate it to the Board, at least for some informal comments before we do that.

DR. MAURO: Jim, if I may make one

observation, we did learn something important when we went through Texas City that I think does bear on the four criteria. Something that certainly the work group may want to ^ and that is the possibility of what I would call a fifth criteria that might serve us well, and I like to call that plausibility.

One of the things we found in Texas City is that surrogate data were used, both external exposures and inhalation exposures, that were drawn from datasets that resulted in implausible exposures. In a strange sort of way what happened was the scenarios and the exposure settings in the surrogate data that was used overestimated the potential for exposures at Texas City to such an extent that one could question whether or not such exposures are plausible and perhaps challenge the use of surrogate data from the perspective that it is unrealistically high. It's not plausible.

Because there is language in the rule that says that the dose reconstruction scenarios must be plausible. And one of our concerns, and you'll see when our report comes

out, is that in an effort to try to place an upper bound, sometimes the assumptions are so conservative that they're no longer plausible. That may be a fifth criteria (sic) that might serve us well. I just wanted to put that on the table for your consideration.

DR. MELIUS: This is Jim Melius. I actually haven't read the Texas City report yet, and my general comment is that I think we've always viewed criteria as sort of cutting both ways. That it's possible to be overestimating or underestimating within the context of this program.

So I guess I have some general questions about having that as a separate criteria (sic). I always thought of that as sort of a fundamental criteria or basis of our approach here. But let me look over the report and the situation before I generalize.

Any other comments or questions?

(no response)

DR. MELIUS: So everybody agreed that I'll be writing, taking account comments plus the verbal comments we received here, circulate it to the work group, and then hear back from the

work group. And before taking any other action, I will check with the work group.

MS. MUNN: That's certainly appropriate from my point of view. I guess the concern that's raised with respect to the use of data being so far away from any accuracy even when being used as a bounding limit or is one that I don't think we did address very well in the four items that we put there. Whether or not it's a thought that needs to be incorporated at some point whether as a fifth item or not I haven't had an opportunity ^ get my thinking, but certainly the next step obviously is the one you have outlined, Jim, I think. I think that's appropriate.

DR. MELIUS: Mark, or Jim Lockey or Josie, any comments?

MR. GRIFFON: Sounds good.

DR. LOCKEY: I'm fine with this.

DR. MELIUS: Josie.

MS. BEACH: Sounds great with me, too.

DR. MELIUS: Okay.

Christine?

DR. BRANCHE: Yes, sir.

DR. MELIUS: We're done, with the call.

DR. BRANCHE: I knew what you meant.

Well, I hope you all can stay cool today. If you're going to be in climates that are anything like what we're expecting here in the D.C. metro areas, stay indoors and drink plenty of fluid. Thank you very much for a productive call. It seemed to be from what I observed. And, Jim, we'll hear from the group soon.

DR. MELIUS: Correct.

DR. BRANCHE: Thanks so much. Have a great day.

(Whereupon, the working group meeting concluded at 12:15 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 June 9, 2008; 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 7th day of August, 2008.

_____

STEVEN RAY GREEN, CCR, CVR-CM, PNSC

CERTIFIED MERIT COURT REPORTER

CERTIFICATE NUMBER: A-2102