

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  
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**TRANSCRIPT LEGEND**

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In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (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**

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6        Director

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MAURO, JOHN, SC&A  
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NETON, JIM, NIOSH

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

(11:30 a.m.)

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WELCOME AND OPENING COMMENTSDR. CHRISTINE BRANCHE, DFO

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**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.

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

3           **MR. ELLIOTT:** Larry Elliott, NIOSH/OCAS.

4           **DR. NETON:** Jim Neton, NIOSH/OCAS.

5           **MS. ADAMS:** Nancy Adams, NIOSH.

6           **MS. CHANG:** Chia-Chia Chang, NIOSH.

7           **DR. BRANCHE:** Any ORAU staff participating?  
8 (no response)

9           **DR. BRANCHE:** SC&A staff?

10          **DR. MAURO:** John Mauro.

11          **DR. MAKHIJANI:** Arjun Makhijani.

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

14          **MS. HOWELL:** This is Emily Howell with HHS.

15          **MR. MCGOLERICK:** Robert McGolerick, HHS.

16          **MR. KOTSCH:** Jeff Kotsch with Labor.

17          **MR. BROEHM:** Jason Broehm, CDC Washington  
18 office.

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

21 (no response)

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

24          **MS. BARRIE:** This is Terrie Barrie with  
25 ANWAG.

1                   **DR. BRANCHE:** Thank you, Ms. Barrie.

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

5                   (no response)

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

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

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

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

15                   (no response)

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

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

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

4 Thank you very much.

5 Dr. Melius.

6 **INTRODUCTION BY CHAIR**

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

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

20 **DR. MELIUS:** I hope not.

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

25 Sorry, Jim.

1           **DRAFT DOCUMENT: CRITERIA FOR USE OF SURROGATE DATA**

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

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

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

23                   (Interruption occurs.)

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

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

5 Dr. Melius, can you still hear me?

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

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

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

17 **MR. ELLIOTT:** Thank you.

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

20 (no response)

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

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

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

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

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

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

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

5 **DR. MAKHIJANI:** Okay.

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

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

23 Is that capturing your comment, Wanda?

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

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

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

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

1           justification for using this, the lower level  
2           of hierarchible data for dose reconstruction.  
3           We would probably be more stringent about that  
4           than we would if we were using data from the  
5           same level.

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

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

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

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

23                    Anybody else have comments on that?

24                    (no response)

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

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

7 **MS. MUNN:** Usually a complicated situation  
8 lately.

9 **DR. MELIUS:** Anyone else have comments on  
10 that?

11 (no response)

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

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

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

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

10 Any questions on that paragraph?

11 (no response)

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

21 Anybody else have questions or  
22 comments on that?

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

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

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

12 **DR. MELIUS:** I agree, thanks.

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

15 **DR. MELIUS:** Yes, correct.

16 **MS. MUNN:** Sounds good.

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

21 (no response)

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

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

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

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

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

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

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

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

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

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

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

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

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

23 **DR. MELIUS:** No.

24 **DR. MAURO:** Okay.

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

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

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

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

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

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

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

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

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

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

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

25                   So I think it's a very real concern,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 **DR. MAURO:** Jim, if I may make one

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

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

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

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

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

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

20 Any other comments or questions?

21 (no response)

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

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

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

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

18 **MR. GRIFFON:** Sounds good.

19 **DR. LOCKEY:** I'm fine with this.

20 **DR. MELIUS:** Josie.

21 **MS. BEACH:** Sounds great with me, too.

22 **DR. MELIUS:** Okay.

23 Christine?

24 **DR. BRANCHE:** Yes, sir.

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

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**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.)

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**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.

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**STEVEN RAY GREEN, CCR, CVR-CM, PNSC****CERTIFIED MERIT COURT REPORTER****CERTIFICATE NUMBER: A-2102**