

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

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ADVISORY BOARD ON RADIATION AND  
WORKER HEALTH

+ + + + +

WORK GROUP ON SEC ISSUES

+ + + + +

WEDNESDAY  
APRIL 18, 2012

+ + + + +

The Work Group convened telephonically, at 1:30 p.m., James M. Melius, Chairman, presiding.

PRESENT:

JAMES M. MELIUS, Chairman  
JOSIE BEACH, Member  
GENEVIEVE S. ROESSLER, Member  
PAUL L. ZIEMER, Member

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ALSO PRESENT:

TED KATZ, Designated Federal Official

TERRIE BARRIE

STU HINNEFELD, DCAS

JENNY LIN, HHS

JOHN MAURO, SC&A

DAN MCKEEL

JIM NETON, DCAS

LAVON RUTHERFORD, DCAS

JOHN STIVER, SC&A

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

2 1:35 p.m.

3 MR. KATZ: Okay, it's about time,  
4 so let's get started with roll call. It's the  
5 Advisory Board on Radiation and Worker Health,  
6 it's the SEC Issues Work Group.

7 (Roll call.)

8 MR. KATZ: Okay then, as I said,  
9 the agenda's posted on the website. It's very  
10 simple, one issue. And Jim, it's your agenda.

11 CHAIRMAN MELIUS: Welcome,  
12 everybody. And what we had talked about at our  
13 last Board meeting when we were discussing the  
14 implementation of NIOSH's ten year review  
15 recommendations, one of those recommendations  
16 had to do with developing a definition, at  
17 least an operational definition, for  
18 sufficient accuracy, which has been an issue  
19 that's come up repeatedly in the Board's  
20 review of the SEC evaluations.

21 And we were a little unclear what  
22 was the best place within the Board, how the

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1 Board should approach this. And so, really  
2 what I want to do, and I don't expect this to  
3 be a very long conference call today, but is  
4 for us to see where NIOSH is in terms of  
5 working on this issue.

6 And secondly then, talking to some  
7 of the Work Group about how we might approach  
8 it and who should be involved from the Board  
9 or if there's anything we want our contractor  
10 to start working on at this point in that.  
11 So, Jim Neton, do you want to let us know  
12 where you are with this issue?

13 DR. NETON: I could. I was hoping  
14 Stu might take the lead on that. Stu, are you  
15 on the phone yet? Okay.

16 CHAIRMAN MELIUS: Stu's decided  
17 you are.

18 DR. NETON: I guess so. We have  
19 started, as part of our matrix of these action  
20 items that we've developed out of the ten year  
21 review, and it was a two part approach to  
22 this.

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1           One is to establish a review  
2 matrix looking at previous SEC decisions for  
3 examples of how past decisions were made. And  
4 that might inform us as to where we currently  
5 stand with sufficient accuracy, at least from  
6 a case history perspective.

7           And then from that we were going  
8 to develop a series of paragraphs to define  
9 some aspects of a definition, based on what we  
10 gleaned from where we think the case history  
11 informed us.

12           That's being worked on. But,  
13 honestly, I have not been doing that  
14 personally. I'm not familiar with where we  
15 are status-wise. But that's the approach that  
16 we've adopted.

17           CHAIRMAN MELIUS: Who's handling  
18 that for NIOSH, it's LaVon or Stu?

19           DR. NETON: Stu had the action  
20 item on the matrix. I'm not sure who would  
21 have been doing that.

22           MR. RUTHERFORD: I can up-date it.

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1 This is LaVon, I can up-date it a little bit.  
2 We have pretty much pulled together most of  
3 the decisions from previous SECs. And we  
4 actually had already had that in place. So  
5 we've got a pretty good start on that portion  
6 of it.

7 The other portion of it, the  
8 paragraphs, I know nothing about that at this  
9 point. And I can tell you the matrix itself,  
10 with past decisions, is well on its way.

11 CHAIRMAN MELIUS: Well, LaVon, I  
12 should tell you that when I talked to Stu the  
13 other day about something else we talked very  
14 briefly about this meeting. And he threw you  
15 in also. So I didn't hear you in the  
16 background or I would have put you on the spot  
17 first.

18 MR. HINNEFELD: Dr. Melius, this  
19 is Stu Hinnefeld.

20 CHAIRMAN MELIUS: Oh, yes, okay.

21 MR. HINNEFELD: Time got away from  
22 me for a little bit there. I didn't realize

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1 it was 1:30, I'm sorry.

2 CHAIRMAN MELIUS: That's okay. We  
3 started more quickly than we usually do.  
4 LaVon or Stu, whoever, Jim, do you have a time  
5 table for when this matrix might be available?

6 MR. RUTHERFORD: I'll jump in on  
7 this, Stu. I think the matrix itself, that  
8 with the past decisions, that will be  
9 available, I would say, probably by the Board  
10 meeting, close to the Board meeting anyway.

11 CHAIRMAN MELIUS: Okay.

12 MR. RUTHERFORD: Because, to be  
13 honest with you, we ran with this. The  
14 decisions that we made on previous SEC  
15 petitions, we pulled them together into a SEC  
16 petition matrix a long time ago.

17 It's just now we're going through  
18 trying to determine, we need to determine  
19 whether the details there, to really see our  
20 decisions that were made, as well as we need  
21 to for this.

22 So I'm going to work with Stu and

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1 Jim on that, to take a look at that, and to  
2 see if we need to pull in more detail or not.

3 CHAIRMAN MELIUS: Personally, I  
4 think that's a good way of starting on this.  
5 Because I think that it would allow you to  
6 classify the decisions and see, in what  
7 circumstances, how the issue of sufficient  
8 accuracy comes up in terms of making SEC  
9 decisions, both from the NIOSH perspective as  
10 well as the Board.

11 And again, I don't know where you  
12 are with it. But it might be interesting to  
13 identify where the basis for the SEC decision  
14 recommendation by NIOSH, and then if the Board  
15 didn't agree with that decision, where were  
16 the issues for the Board. And from what cases  
17 was sufficient accuracy a factor in the  
18 Board's disagreement with NIOSH?

19 And otherwise it's usually very  
20 straight forward because there's usually a  
21 history. And there's more information that  
22 comes up and it's complicated. But it would

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1 seem to me that would help to identify where  
2 we're having the most difficulty.

3 MR. HINNEFELD: This is Stu. If I  
4 could just offer, the volume of the material  
5 is a difficult thing here and the  
6 understanding in a particular case,  
7 particularly where we've had one opinion and  
8 the Board had a different opinion about  
9 feasibility of dose reconstruction.

10 That sometimes takes a lot of  
11 careful study to really remember and pull back  
12 up and summarize the heart of the issues  
13 there.

14 And so it's a little time  
15 intensive to, once we've got these things  
16 entered, it's a little time intensive to  
17 really understand and put some sort of  
18 interpretation on each of these. So that's  
19 the difficult part about this.

20 CHAIRMAN MELIUS: I can see that.  
21 And I'll even think that, even before you've  
22 reached the interpretation section, because

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1 even where you've identified the broad  
2 outlines of where there was a difference, it  
3 would be helpful to just discuss those.

4 Because your recollection may  
5 differ from ours and other factors. I mean,  
6 these are complicated decisions. But I think  
7 having the matrix also allows you to go back  
8 and say, well, this is where we agreed and  
9 this is a similar situation. What's the  
10 difference between the two?

11 MR. HINNEFELD: Right.

12 CHAIRMAN MELIUS: And I think it  
13 would be helpful. Of course, other Work Group  
14 Members have any comments on that?

15 MEMBER BEACH: Jim, this is Josie.  
16 The one thought that really comes to mind is  
17 having a really usable report. Because I  
18 think, like Stu said, this is going to be a  
19 lot of volume. So just having it in a way  
20 that we can go through it is going to be  
21 important.

22 MEMBER ROESSLER: This is Gen. I

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1 think this matrix that they're putting  
2 together is extremely important because I  
3 think one of the things that we have to look  
4 at is the uniformity or consistency of  
5 decisions.

6 And in order to do that, we  
7 certainly have to go back in time and look to  
8 see, first of all, if they were consistent  
9 from one place to another and then whether we  
10 can derive something to apply that consistency  
11 to the future.

12 CHAIRMAN MELIUS: Yes, and what  
13 factors went into how the decision was made  
14 from one incidence to another. Paul, do you  
15 have any comments?

16 MEMBER ZIEMER: Yes. One thing  
17 that I'm wondering is once we've done that,  
18 and that certainly will help us understand  
19 those issues, but at some point it might turn  
20 up, then, to be helpful if there's a  
21 formalization of what we actually mean.

22 It turns out to be very difficult

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1 because the accuracy that we're talking about  
2 here is quite different from the usual  
3 definition of accuracy in mathematics,  
4 particularly since we had the one side of the  
5 number is based on bounding.

6 And the other side of the number  
7 you can't go below what you think the true  
8 value is. So it's an interesting concept from  
9 that point of view.

10 But it would be good if we can go  
11 from seeing what we've done to formalizing, in  
12 some way, what we really mean so that we can  
13 compare future decisions against something  
14 that's a little more like a gold standard  
15 versus an intuitive.

16 CHAIRMAN MELIUS: Yes. I think  
17 you have not only a little different approach  
18 or use of accuracy and then you have the  
19 qualifier in there of sufficient, which  
20 loosens it up.

21 MEMBER ZIEMER: What is it that  
22 makes it sufficient in this application.

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1 CHAIRMAN MELIUS: Yes.

2 MEMBER ROESSLER: Jim, this is Gen.  
3 I have an additional couple other thoughts.  
4 As I think about sufficient accuracy, and  
5 doing it properly, I think back to when this  
6 whole program was put into place.

7 And whoever wrote this must have  
8 had some idea as to what that meant. And I  
9 don't even know who that was. But can we  
10 elicit some of that background information to  
11 see whether, in fact, we're following through  
12 on what the intent of the program was.

13 MR. HINNEFELD: We do know the  
14 author and I think we could get her to provide  
15 us that kind of information. If you like that  
16 in an oral discussion at some meeting at some  
17 point or --

18 MEMBER ROESSLER: I'm not talking  
19 about the ten year review, I'm talking about--

20 MR. HINNEFELD: The ten year review  
21 author?

22 MEMBER ROESSLER: Pardon?

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1 MR. HINNEFELD: Is that who you're  
2 talking about?

3 MEMBER ROESSLER: No, I'm talking  
4 back at the beginning --

5 MEMBER ZIEMER: The original.

6 MEMBER ROESSLER: -- when the  
7 program was put into place. Somebody sat down  
8 and said here's how we're going to do it. And  
9 then there's probably a case where you cannot  
10 calculate dose and then came up with this  
11 sufficient accuracy terminology.

12 I'm just wondering what the writer  
13 or the writers of that original document  
14 that's in the rule, what their thought was as  
15 to how that should be done or what that means.

16 MR. HINNEFELD: You're talking  
17 about the language that's in the rule then,  
18 the --

19 MEMBER ROESSLER: Yes.

20 MR. HINNEFELD: -- regulation?

21 CHAIRMAN MELIUS: This is Jim  
22 Melius. And Jim Neton, Paul and others, jump

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1 in on this. But there's a sufficient accuracy  
2 was in the law. And I don't believe that  
3 there's any background, at least helpful  
4 background, on that in terms of Congressional  
5 intent or other language that helps to  
6 interpret that.

7 And way back when the Board was  
8 first meeting and NIOSH was developing the  
9 regulations on SECs and dose reconstruction,  
10 we had fairly extensive discussions on this  
11 issue and, I guess, how to implement it would  
12 be a fair way of putting it.

13 And I know that NIOSH struggled  
14 with that also, coming up with what was a way  
15 of making that operational for the purposes of  
16 making SEC evaluations, and really came up  
17 with the bounding, that became at least part  
18 of what was making that definition  
19 operational.

20 But then we ended up with how to  
21 then interpret what a plausible bound was.  
22 And so we've, I think, gone back and forth

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1 interchangeably between is it a plausible  
2 upper bound or it's a surrogate for, in our  
3 discussions, although it's in the regulation,  
4 for sufficient accuracy.

5 So I hesitate to claim that our  
6 initial discussions would be helpful now but  
7 they might be. It's been obviously a long  
8 while. It's ten years. And I certainly  
9 haven't gone back and looked at those  
10 discussions.

11 MEMBER ROESSLER: It might be good  
12 to revisit them if we could find them.

13 CHAIRMAN MELIUS: They're there on  
14 our website.

15 MEMBER ROESSLER: But to locate the  
16 right spot.

17 MS. LIN: Dr. Melius, this is Jenny  
18 Lin with HHS.

19 CHAIRMAN MELIUS: Yes?

20 MS. LIN: I think what you're  
21 asking in terms of the regulatory history, I  
22 think the very first place that we should look

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1 at is the regs themselves and then going back  
2 to look at the reg's preamble, the intent  
3 language of what the Agency has intent, the  
4 sufficient accuracy to mean.

5 And it actually does have a  
6 definition in there. I think the question the  
7 Work Group has tried to answer is a practical  
8 application of that term.

9 So I'll be happy to provide an  
10 excerpt from the preamble because it's a more  
11 definitive history of the regulation on the  
12 record as opposed to seeing individual authors  
13 opinions of what that sufficient accuracy  
14 actually means. So I'll be happy to provide  
15 that to the Work Group and to the Agency as  
16 well.

17 CHAIRMAN MELIUS: But, Gen, you  
18 weren't involved then. But you should know  
19 that, if I recall correctly, the Board's  
20 comments on those regulations were quite  
21 critical, particularly in the fact that you  
22 didn't have a adequate definition of

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1 sufficient accuracy.

2 MEMBER ROESSLER: I think,  
3 actually, I've been involved since the  
4 beginning. But that's been ten years and I  
5 don't remember that.

6 But I think if Jenny can provide  
7 what she's just suggested, of course then the  
8 practical application of the term is what we  
9 can get some hints from by looking back at the  
10 Board's discussions of it.

11 CHAIRMAN MELIUS: Yes, I guess what  
12 I was recommending was that there's their  
13 discussions. And I think there were two  
14 attempts at the regulations and that there  
15 were a set of Board comments, plus some  
16 individual comments on the regulations, that  
17 would be useful to review again. Obviously,  
18 after ten years I think it changes but it  
19 maybe helpful as background.

20 MEMBER ROESSLER: Plus, we've  
21 learned a lot in the ten years that we've been  
22 doing this. So it might be beneficial to look

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1 at that again.

2 CHAIRMAN MELIUS: At least we hoped  
3 we've learned something, right? Anybody else  
4 have comments or thoughts on that?

5 DR. MAURO: Dr. Melius, John Mauro.  
6 I just had another thought. Early on, when we  
7 were on the Board, we were asked to write a  
8 procedure for doing SEC Petition Evaluation  
9 Report reviews, which is quite detailed.

10 And it was reviewed extensively by  
11 the Board. And it has a lot of language in  
12 there regarding completeness of data, accuracy  
13 of data, that sort of thing.

14 Basically it's the test that we use  
15 when we do a scientific review of  
16 completeness, et cetera. There may be some  
17 language in there that will be helpful, also  
18 as a source of information to shed light on  
19 how we've been coming at this problem in the  
20 past.

21 CHAIRMAN MELIUS: It's a good  
22 point, John. And I think it comes to wrestle

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1 with the plausibility. I interpret a  
2 plausible upper boundless was one of the  
3 issues.

4 But it doesn't provide a direct  
5 definition, or a criteria, as much as a set of  
6 what needs to be evaluated and a procedure for  
7 that evaluation.

8 DR. MAURO: I could say that  
9 procedure, which goes back a ways, does not  
10 talk about plausibility. Plausibility  
11 actually emerged when we worked on the  
12 surrogate data question that became front and  
13 center, which was quite a bit later than when  
14 we wrote the procedure for the SEC reviews.

15 CHAIRMAN MELIUS: Any other  
16 comments, Paul or Josie?

17 MEMBER ZIEMER: No, I think it'll  
18 be helpful to gather this information  
19 together. And we can proceed to determine  
20 whether it's really feasible at some point to  
21 develop a more formalized definition or  
22 structure against which we measure future

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1 decisions.

2 CHAIRMAN MELIUS: Yes, I just want  
3 to make sure we were moving this along and not  
4 ignoring it. And I think waiting wasn't  
5 something we should be doing and --

6 MEMBER ZIEMER: No, I think we're  
7 waiting for NIOSH to complete their first step  
8 on this, right?

9 CHAIRMAN MELIUS: Yes, that's what  
10 it sounds like. And I don't want to give you  
11 an exact date, Stu, but I think if we could  
12 have that matrix sometime around the time of  
13 the June meeting, or say by the end of June or  
14 whatever, and then we could set up a Work  
15 Group meeting to focus on that and to provide  
16 further discussion.

17 Same time we could, Jen, you said  
18 you could help us and pull together the  
19 regulatory history and so forth, that would be  
20 useful also. I don't know if the old dockets  
21 are kept online, hidden away someplace or --

22 MS. LIN: Actually, I have them.

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1 That's how I felt that the Board's comments  
2 were all captured in this regulatory document.

3 CHAIRMAN MELIUS: And I believe  
4 that our comments were submitted to the  
5 Secretary at the time. I can't remember  
6 exactly what the capacity was then but I know  
7 we came to an agreement.

8 And I think there were some other  
9 maybe helpful comments that were submitted on  
10 those regulations also that would be useful.

11 MEMBER ROESSLER: Could Jenny send  
12 those to Work Group Members?

13 CHAIRMAN MELIUS: Yes, we could put  
14 together a package of information or make it  
15 available on the O: drive or something.

16 MS. LIN: Okay, I can work on that.

17 CHAIRMAN MELIUS: Yes, good.

18 MEMBER BEACH: Sounds like a good  
19 start.

20 CHAIRMAN MELIUS: Okay, any other  
21 comments or suggestions? If not I think that  
22 really accomplishes at least what I wanted to

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1 accomplish today.

2           And just long as I promised it  
3 would be short. But I think we needed to get  
4 organized and get coordinated with NIOSH in  
5 order to be able to do this.

6           And let's move forward with that  
7 plan and assume that we'll have a Work Group  
8 meeting sometime after the June meeting in  
9 Santa Fe. And then let's see where we go from  
10 there.

11           I think pull hard until we've sat  
12 down and met and had time to go through this.  
13 Good, thanks everybody for taking the time.  
14 Ted, do you have anything else you need to --

15           MR. KATZ: No, that's good. Thank  
16 you, Jim.

17           CHAIRMAN MELIUS: Thanks and guess  
18 I'll talk to everybody again next Thursday  
19 next week. Okay, thanks. Have a good day,  
20 everybody.

21           (Whereupon, the meeting was  
22 concluded at 1:58 p.m.)

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