

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

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SEC ISSUES WORK GROUP

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FRIDAY
FEBRUARY 5, 2010

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The Work Group convened, via
teleconference, at 10:00 a.m. Eastern Standard
Time, James M. Melius, Chairman, presiding.

PRESENT:

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

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ALSO PRESENT:

TED KATZ, Designated Federal Official
LYNN ANSPAUGH, SC&A
HANS BEHLING, SC&A
NICOLE BRIGGS, SC&A
PETE DARNELL, OCAS
SAM GLOVER, OCAS
STU HINNEFELD, OCAS
EMILY HOWELL, HHS
LARA HUGHES, OCAS
JENNY LIN, HHS
JOHN MAURO, SC&A
ROBERT MCGOLERICK, HHS
DAN MCKEEL, Dow SEC Petitioner
JAMES NETON, OCAS
LaVon RUTHERFORD, OCAS
BILL THURBER, SC&A

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

(10:01 a.m.)

MR. KATZ: This is Ted Katz. I am the Designated Federal Official for the Advisory Board on Radiation and Worker Health and this is the SEC Working Group.

Beginning roll call with Board Members, note, please, if you have any conflict with either the Dow Madison site or Ames or Met Lab when you identify yourself for everyone related to the agencies, including the Board Members.

CHAIRMAN MELIUS: This is Jim Melius. I don't have any conflicts.

MEMBER ZIEMER: Paul Ziemer. No conflicts.

MEMBER BEACH: Josie Beach. No conflicts with either Dow, Ames, or Met Lab.

MR. KATZ: Okay. And then is Gen with us, Roessler?

(No audible response.)

MR. KATZ: Okay. Well, we'll call

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1 for Gen and Mark again later because Mark is
2 going to be a little late, too. I think Gen
3 had some business away and was connecting from
4 afar.

5 MEMBER ROESSLER: Hi, Ted. This
6 is Gen.

7 MR. KATZ: Oh, hi. Great.

8 MEMBER ROESSLER: I am not away,
9 actually, this week.

10 MR. KATZ: And no conflicts, Gen?

11 MEMBER ROESSLER: Pardon?

12 MR. KATZ: No conflicts?

13 MEMBER ROESSLER: No conflicts.

14 MR. KATZ: Great. Okay. And then
15 let's go on to the OCAS-ORAU team.

16 MR. HINNEFELD: Stu Hinnefeld, the
17 Interim Director of OCAS. I don't have
18 conflicts with those three sites.

19 DR. GLOVER: This is Sam Glover.
20 No conflicts.

21 MR. RUTHERFORD: LaVon Rutherford.
22 No conflicts.

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1 DR. NETON: Jim Neton. No
2 conflicts with those sites.

3 MR. DARNELL: Pete Darnell. No
4 conflicts.

5 DR. HUGHES: Lara Hughes. No
6 conflicts.

7 MR. KATZ: Okay. And then SC&A?

8 DR. MAURO: John Mauro, SC&A. No
9 conflicts.

10 MR. THURBER: Bill Thurber, SC&A.
11 No conflicts.

12 MR. ANSPAUGH: Lynn Anspaugh. No
13 conflicts at these three sites.

14 DR. BEHLING: Hans Behling. No
15 conflicts.

16 MS. BRIGGS: Nicole Briggs, SC&A.
17 No conflicts.

18 MR. KATZ: All right. Then HHS or
19 other government officials or contractors to
20 the federal government?

21 MS. HOWELL: Emily Howell, HHS.

22 MS. LIN: Jenny Lin, HHS.

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1 MR. MCGOLERICK: Robert
2 McGolerick, HHS.

3 MR. KATZ: Okay. And then members
4 of the public or staff of congressional
5 offices who want to identify themselves?

6 DR. McKEEL: This is Dan McKeel.
7 I am the Dow SEC petitioner.

8 MR. KATZ: Welcome, Dan.

9 DR. McKEEL: Hi.

10 MR. KATZ: Okay, then. Let me
11 just remind everyone who is not speaking to
12 put your phone on mute, *6 if you don't have a
13 mute button, *6 to take it off of mute. And
14 please don't put the call on hold. Hang up
15 and dial back in if you have to leave. Thank
16 you.

17 And, Jim, it's all yours.

18 CHAIRMAN MELIUS: Okay. Thank
19 you, Ted. This is Jim Melius, Chair of the
20 Working Group. As I said, Mark Griffon will
21 be a little late. He should be joining us
22 shortly. He was on his way to the office when

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1 he called me a few minutes ago.

2 The agenda today, two major items,
3 one, we will spend some time on Dow, the
4 Madison site, to get an update on that; and
5 then, secondly, we will start talking about
6 the 250-day issue. I think, as you all know,
7 John Mauro at my request has pulled together a
8 lot of the information on the 250-day issue
9 and has inundated us with documents, most of
10 which, I think all of which, we have seen
11 before, at least most of them, but I think it
12 was helpful to see sort of the paper trail
13 because this has been -- we have talked about
14 a lot of different sites in regards to this
15 issue in the 250-day issue. And it is, I
16 think, helpful.

17 And then my understanding is that
18 Sam Glover is now our main OCAS contact on
19 this, the person who will be working through
20 this Work Group. Some of that compilation was
21 also to help Sam get caught up with all the
22 past discussions that we have had on this Work

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1 Group.

2 So I would like to start with Dow.

3 And I have asked John to sort of update us on
4 what has transpired and sort of what issues
5 are outstanding with Dow Madison that we had
6 discussed Dow at our last meeting of this Work
7 Group, which was in July, so, really, what has
8 gone on since that point in time.

9 John?

10 DR. MAURO: Yes. I'll pick it up
11 from July unless -- well, let me give you a
12 really brief story. There were several
13 stages. The original stage was the 1957-1960
14 time frame, in which there was an SEC granted
15 and there was the whole -- we went through the
16 entire process related to that time period.

17 Then there was the -- and,
18 basically, as you recall, Dow was doing
19 thorium alloy work, where there was
20 thorium-232 being handled and uranium at the
21 same time during that time period. And there
22 is a lot of literature. We put some reports

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1 out on that. We had meetings on that.

2 Following that, there was another
3 time period of interest, the residual period,
4 where the concern was reconstructing exposures
5 from the residual period. And for that
6 period, it was a NIOSH position that they
7 could reconstruct the doses to both uranium
8 and thorium using a variety of methods. And
9 that was the subject of considerable
10 discussion.

11 Along the line, there was also a
12 special report dealing with some 700 documents
13 that were -- 700 pages of documents that arose
14 during the process which were put into the
15 record. SC&A was asked to review them and to
16 see what relevance it might have.

17 And it turns out that, by and
18 large, there was nothing of great substance
19 there that really changed any of the dialogue
20 we had, which brings us quickly to the meeting
21 we had on July 24th, where, in effect, SC&A
22 was requested to review the Dow Madison work

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1 done by NIOSH, their reports, dealing with the
2 post-1960 residual period and the methods in
3 general that were being used, in light of
4 TBD-6000.

5 And then SC&A put a report out
6 dated August 2009. It was sent to everyone.
7 It has been redacted and went through PA
8 clearance. That document is available for
9 public release and that is really the last
10 report that I believe that SC&A put out on the
11 subject.

12 By the way, Bill Thurber is the
13 person that did 90 percent of the work on
14 this. He is on the line and I am just going
15 to very briefly go over. We had a number of
16 findings related to the residual period and
17 the methods that were being employed by NIOSH.

18 I would like to say that none of
19 this has any -- doesn't really have any
20 bearing on the 250-day issue, but it does have
21 bearing on the surrogate data issue, something
22 that maybe we should just draw your attention

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1 to, even though today's discussion is zeroing
2 in on 250-day.

3 There are certain surrogate data
4 issues that have come up and the issues really
5 have to do with, NIOSH in reconstructing doses
6 for this facility is taking advantage of the
7 great deal of data that is in TBD-6000 and is
8 relying on that, the information that stands
9 behind a lot of data that has been compiled
10 related to airborne uranium at metal-handling
11 facilities.

12 One of the more important comments
13 we had, which I don't believe is an SEC issue,
14 is that the method they have adopted was to
15 use the geometric mean of the generic data for
16 the particular categories of workers, as
17 opposed to -- and that was based on a
18 relatively limited amount of data for that
19 category of worker, as opposed to using the
20 95th percentile value.

21 So we have what I would call one
22 of the more conventional commentaries that go

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1 toward whether or not NIOSH was selecting from
2 a data set at the right place in the
3 distribution as their default approach for
4 reconstructing internal exposures. And, by
5 the way, that would apply to the operations
6 period, 57 to 60.

7 It was also a question of, during
8 the residual period, reconstructing inhalation
9 exposures. And, again, this is one of the
10 more conventional comments that we have had on
11 many occasions.

12 We felt that the resuspension
13 factor that was selected was too low and they
14 basically based the results on some estimate
15 of residual radioactivity. And in order to
16 get airborne activity, they apply a
17 resuspension factor.

18 Their standard value of ten to the
19 minus six, I believe this is a generic issue
20 that is being looked at by NIOSH. So this is
21 not a concern that goes specifically to this
22 site but is really a universal concern we have

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1 regarding the use of a resuspension factor.

2 Another finding we had is that in
3 doing the residual period and looking at the
4 methods employed, one of our comments was that
5 they -- again, this is a recurring theme.

6 There is a very good OTIB out
7 called OTIB-0070, which lays out a methodology
8 for reconstructing external exposures and
9 internal exposures during a residual period,
10 when you have limited data for the residual
11 period. And OTIB-0070 has one particular
12 protocol that we find extremely useful.

13 I think one of our comments was
14 that that methodology should be applied. I
15 think it wasn't entirely applied in this
16 particular situation. I guess that really
17 goes to the heart of the issues.

18 As I understand -- and, Bill,
19 please fill in where I may have missed
20 anything important -- the essence of our
21 concerns with the methods used for
22 reconstructing exposures during both the

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1 operations period and the post-operations
2 period go more toward how the data were
3 applied from OTIB-0060 and the protocol they
4 are using.

5 There is certainly some discussion
6 that might be warranted regarding surrogate
7 data issues. That is, they did draw upon
8 TBD-6000 and to do some of the dose
9 reconstructions. NIOSH did draw upon data
10 from other facilities, the Bay City facility,
11 to help with the thorium exposure.

12 So there was a considerable amount
13 of drawing from other resources from other
14 facilities to construct an overall approach to
15 dose reconstruction during both the operations
16 period and the residual period for thorium and
17 uranium.

18 And when we reviewed this, I guess
19 we felt that, as an overarching perspective,
20 that the idea of using surrogate data -- and I
21 know this is a subject that is before the
22 Board -- in this particular application, when

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1 you are dealing with a metal-handling
2 facility, there is so much experience and data
3 out there at a great level of resolution and
4 granularity that you should be in a position
5 to select from that vast amount of material
6 and, if used appropriately, make assignments
7 to a facility, such as Dow, to place a
8 plausible upper bound. That has been SC&A's
9 position related to that particular aspect of
10 surrogate data.

11 So we do see it as scientifically
12 plausible to reconstruct external/internal
13 exposures for metal-handling facilities -- I
14 want to make sure it's clear -- because of the
15 amount of information that's out there.

16 However, we do have concerns on a
17 case-by-case basis when this is done, whether
18 or not the most claimant-favorable and
19 appropriate approach was used in applying that
20 data.

21 That, I guess, gets up-to-date my
22 reading of our material. And, Bill, is there

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1 anything you would like to add regarding the
2 work we have done?

3 MR. THURBER: No, I don't think
4 so, John. As you say, some of the issues that
5 we raised in our review of Appendix C of
6 TBD-6000 are, in a sense, generic issues: the
7 choice of the 95th percentile versus the
8 geometric mean, that sort of thing, but I
9 think you have covered it very nicely.

10 DR. MAURO: Okay. There's one
11 last issue that I forgot to mention that I
12 believe has been resolved. And that has to do
13 with, during the residual period, one of --
14 the reconstruction of the internal dose of the
15 inhalation of thorium-232 is based on
16 measurements of thorium-232 collected during
17 the operations period -- this is the pre-1960
18 period -- of airborne thorium-232 levels. And
19 then that was used as the starting point for
20 inhalation exposures during the residual
21 period.

22 Now, we find that fundamental

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1 approach is, in fact, the approach recommended
2 in OTIB-0070. We think it is a very good
3 approach. The only commentary we had, which I
4 think has been resolved, is that, in all
5 likelihood, based on the operation that took
6 place at the facility, the vast majority of
7 the thorium alloy that was processed and used
8 was for commercial purposes. And I think less
9 than one percent of the material processed of
10 thorium at Dow was for AWE purposes.

11 And then this also goes for the
12 residual period, not only during operations,
13 during -- when I say operations, during the
14 period 1957 to 60, but also post-1960, the --
15 you know, right now I don't believe there's
16 any information that says that there were any
17 AWE activities going on, but there was
18 certainly plenty of commercial activity going
19 on.

20 So what happens is, if you use the
21 airborne thorium data during the operations,
22 1957 to 60 period, as our starting point for

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1 the residual period and then from there
2 project what the exposures are throughout the
3 residual period, you are certainly going to be
4 placing a very high estimate of the thorium
5 exposures to the workers during the residual
6 period by, I would say, more than one or two
7 orders of magnitude.

8 However, we did have an extensive
9 discussion of this matter. And I believe Jim
10 Neton pointed out that the language in the
11 rule was such that when you cannot make a
12 distinction between the sources of exposure to
13 a particular radionuclide, it is appropriate
14 to simply apply the numbers, even though you
15 realize that, in this case, the thorium is due
16 to perhaps mostly by far either commercial
17 operations -- it is appropriate within the
18 framework of the regulations to just assume
19 that all of that exposure to thorium was from
20 AWE activities. And that certainly places an
21 upper bound on what the exposures could be.

22 And so I think we did resolve that

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1 issue during our last meeting and that that
2 really, I think, closes the loop on our
3 understanding of where things are right now on
4 this site.

5 CHAIRMAN MELIUS: Okay. Thank
6 you, John.

7 Any Board Members, Work Group
8 members, have any questions of John or Bill on
9 this?

10 MEMBER ZIEMER: This is Paul
11 Ziemer. Are you going to mention the status
12 of the investigation into the possible change
13 in the time of the residual period and the
14 outcome on that?

15 CHAIRMAN MELIUS: Yes. I was
16 going to get next.

17 MEMBER ZIEMER: Okay. Thanks.

18 CHAIRMAN MELIUS: Yes. Thanks,
19 Paul.

20 Others? Mark, are you on the
21 phone yet?

22 (No audible response.)

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1 CHAIRMAN MELIUS: Okay. NIOSH, do
2 you have any --

3 MEMBER GRIFFON: Jim, I am on, by
4 the way. Sorry.

5 CHAIRMAN MELIUS: Oh, good.
6 Welcome.

7 MEMBER GRIFFON: I had to find the
8 mute button there.

9 CHAIRMAN MELIUS: Okay. Thanks.
10 For our court reporter, that is Mark Griffon,
11 our other Work Group Board Member.

12 NIOSH, do you have any comments
13 you want to make in regard to --

14 MR. RUTHERFORD: Yes. Dr. Melius,
15 this is LaVon Rutherford. You know, it kind
16 of goes through each of the findings and talks
17 about a response to them.

18 The first one concerning the use
19 of the geometric mean during the operational
20 period. First, I want to point out that that
21 is during an SEC period so it is not an SEC
22 issue, obviously, because it is already an

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1 SEC.

2 What we did was actually arrange a
3 value, TBD-6000. I also want to point out
4 that that is the only spot I believe we use
5 surrogate data. The actual residual period,
6 as John mentioned; we used the actual thorium
7 concentration from the Silverstein report,
8 which was taken from Dow and we used that as
9 our starting point.

10 The geometric mean we used
11 actually had two points, the minimum value and
12 the maximum value, to develop a geometric mean
13 with a GSD of five.

14 So I think we do have a very
15 claimant-favorable position, recognizing that
16 there were only two periods of operations that
17 are actually covered during the operational
18 period for uranium.

19 If we assume the maximum value, I
20 believe your actual PoCs are going to go down,
21 which was the actual value of, I think, 4,300
22 dpm per cubic meter. So I really don't think

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1 that it would actually be claimant-favorable
2 by using the maximum value.

3 And if you actually took the
4 distribution along with the GSD and took the
5 95th percentile, that really drives you to
6 almost- implausible measures or intakes during
7 that operational period.

8 So I think we are actually at a
9 pretty good value with the current approach
10 during the operational period for uranium. I
11 will go through each of our responses for each
12 one of these findings. And then we can go
13 back to whichever ones we want to discuss.

14 The resuspension factor -- again,
15 I think John mentioned that is like an
16 overarching issue that I think the resolution
17 to that is going to affect a number of
18 different appendices and approaches. So I
19 don't know that we really need to address it
20 specifically on Dow.

21 The third finding that they had
22 was NIOSH consider developing an exponential

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1 decay function for uranium removal during the
2 residual period. For some reason, we didn't
3 do that. We did it for thorium. We used a
4 constant exposure for uranium.

5 We agree to be consistent, that we
6 should use an exponential decay function.
7 However, I will say that that will lower the
8 dose. And almost -- all but five of the
9 existing claims that we have for Dow are
10 complete right now. So those claims that are
11 already complete would not be affected. But
12 we will look into actually revising our
13 uranium approach to be consistent with the
14 thorium approach with an exponential decay.

15 The fourth finding, actually,
16 which was not mentioned by John, I don't know
17 that it -- there appears to be a data-entry
18 error in Table C-2 for the residual period.

19 Again, we agree with Bill on that
20 one, with SC&A, that we did enter some data
21 incorrectly. It is actually just -- we
22 transposed the data incorrectly. But, again,

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1 that will actually lower the dose when we fix
2 that. So we don't intend to go back to redo
3 any dose constructions and actually lower dose
4 on those.

5 I discussed the surrogate data
6 issue. Again, I believe the only use of
7 surrogate data is during an SEC period and
8 those would be for the non-presumptive
9 cancers.

10 During the residual period, I
11 guess you could argue that the residual period
12 used it because the uranium starting point is
13 actually based on surrogate data. So that
14 would be the only argument I guess you could
15 use to say that it is surrogate data during
16 that period, during the residual period.

17 That is pretty much our responses.

18 DR. MAURO: This is John. Just a
19 couple of quick ones, you know, just reacting
20 and listening. When you had mentioned the
21 uranium, using the geometric means for the two
22 values and that if you used a max value, it

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1 would be even lower than using the geometric
2 mean, I guess I am not following that.

3 That is, if you have got two
4 values, data points, let's say, for air
5 concentration of uranium for the purpose of --
6 now, if you took the -- my understanding is,
7 if you've got two values, the geometric mean
8 is the product of those two values and the
9 square root, square root of the product, two
10 values, that would be your geometric mean.
11 And then on that you used a GSD of a factor of
12 five.

13 And our comment was, in a
14 situation like that, when you have limited
15 data and you are trying to place a plausible
16 upper bound on all of those -- now, this is
17 during the operations period for uranium and I
18 recognize it only applied to people who are
19 not covered under the type of cancer.

20 How would using the maximum value
21 be less conservative than using a fixed 95th
22 percentile value that you might get out of

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1 that distribution? I am not following that.
2 You lost me.

3 MR. RUTHERFORD: Well, I'm saying
4 we could use that. We could go ahead and use
5 that maximum value. I think there is concern
6 from our internal dosimetrist, Dave Allen,
7 that it made lower PoCs.

8 And Jim Neton, maybe, will pipe in
9 on that. I'm not sure.

10 DR. NETON: This is similar to a
11 discussion we had, I think, on another site,
12 where if you put a GSD of five about the
13 geometric mean, you end up with a distribution
14 that we are applying. And that is going to
15 generate a distribution of values of which
16 you're going to have some very high values up
17 at the upper tail --

18 DR. MAURO: I got it. I got it.
19 I see. So by getting the geometric mean by
20 issuing those two values, okay, you've got a
21 number and then, independent of that, you
22 apply this geometric standard deviation of

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1 five --

2 DR. NETON: Exactly.

3 DR. MAURO: -- where that five
4 puts you way over the upper end of the value
5 you got when you got your geometric mean.

6 DR. NETON: Exactly.

7 DR. MAURO: I see. Yes. We
8 haven't checked that, but intuitively, I --

9 MR. THURBER: John?

10 DR. MAURO: Yes?

11 MR. THURBER: This is Bill.

12 DR. MAURO: Yes?

13 MR. THURBER: We had this
14 discussion here a few weeks ago and we did
15 some calculations and in some cases, it
16 showed, as you will recall, that using the
17 geometric mean and a GSD of five resulted in a
18 higher Probability of Causation. And in some
19 cases, using the deterministic 95th percentile
20 resulted in a higher Probability of Causation.
21 So I don't think one can say --

22 DR. NETON: Bill, we're not

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1 talking about using the 95th percentile as a
2 distribution.

3 MR. THURBER: Yes.

4 DR. NETON: We're talking about
5 using the maximum value of the range that was
6 observed. That is very different.

7 MR. THURBER: Yes. Yes.

8 DR. NETON: See, we're saying
9 you've got a range of values. You can either
10 use the highest value you found of all the
11 values or you can use the geometric mean of
12 the values, of the two values that were
13 observed, the ranges that were observed with a
14 GSD of five.

15 MR. THURBER: I understand what
16 you're saying, but I think our comment, our
17 finding at the time, back in last August or
18 whenever, was that we felt the 95th
19 percentile, which you can determine from those
20 statistics, was a more appropriate measure.
21 We didn't say, use the maximum value.

22 DR. NETON: And that is what LaVon

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1 had talked about. If you used the 95th
2 percentile, you end up with some, I think,
3 values that come out extremely high, you know,
4 something around 25,000 dpm per cubic meter
5 for, I think it was at that time, a
6 rod-straightening operation or something.

7 I think the arguments are on the
8 table. Maybe we don't need to belabor it on
9 this call because, again, as LaVon indicated,
10 this is already an SEC.

11 These values are being applied to
12 non-presumptive cancers. And we are certainly
13 willing to discuss that as an issue, maybe
14 aside from the SEC evaluations.

15 DR. MAURO: I think the issue is
16 very clear. What is good about this is that
17 there are different strategies that one could
18 apply when dealing with this particular
19 circumstance.

20 Now, if you've got two
21 measurements, you are confronted with the
22 situation, you know, what do you do with two

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1 measurements? You know --

2 MR. RUTHERFORD: John, I want to
3 point out there are more than two
4 measurements. Yes. There are two
5 measurements that were used to define the
6 boundaries of the max and the min. There were
7 a lot more measurements in between those.

8 DR. MAURO: Okay. Okay. Well,
9 you know how I am thinking about this -- and I
10 see the mechanics of it now, then. It all
11 rings true in terms of understanding why it
12 comes out the way it comes out.

13 It's this geometric standard
14 deviation of five. That creates the
15 circumstance by applying it to the geometric
16 mean you got from these two values.

17 If you were to take all of the
18 values that you do have, which it sounds like
19 you do have more than two then, and you were
20 to make a ranking from high to low and using
21 -- forget about deriving the 95th percentile
22 based on the geometric standard deviation of

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1 five that you get the way -- you know, sort of
2 like an artificial spread, but use the real
3 spread.

4 In other words, let's get the real
5 data. Let's say you have 20, 30 numbers. I'm
6 not sure how many numbers you actually have
7 for that category of worker. And you rank
8 order them. Don't even try to -- well, you
9 can come up with an upper-bound value.

10 Let's say you simply just rank
11 ordered them and, from that, you pull off the
12 non-parametric 95th percentile. I would be
13 very interested in knowing where that fits in
14 because if you do have the real data, then you
15 are looking at a situation where the geometric
16 standard deviation that really exists may not
17 bear any resemblance to five. It may be
18 something much less.

19 And then, all of a sudden, I guess
20 where I am headed with this is, the scientific
21 basis upon which you are making your
22 conclusion is actually drawn from the full

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1 distribution of data that you do have.

2 And if you are pulling off the
3 high end of that number and applying that as
4 your way of reconstructing in this case
5 uranium exposures for the time period of
6 interest, that would be much more in keeping
7 with the philosophies that we have been
8 talking about.

9 Taking the min and the max and
10 then you may end up -- I mean, I don't know
11 where you will come out, but taking the min
12 and the max and multiplying two, taking the
13 square root, and getting your geometric mean,
14 and then applying this factor-of-five GSD and
15 then using the full distribution, that brings
16 you to a place where, when you use that as
17 input into IREP, okay, you will come out with
18 a Probability of Causation.

19 I would be very interested in
20 knowing if you did it a different way, one
21 that I feel is more scientifically grounded,
22 take all your data that you have for that

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1 category, pick off the upper 95th percentile,
2 wherever that happens to fall. And I like the
3 rank order approach, as opposed to the
4 curve-fitting approach, for a variety of
5 reasons. And take it off the 95th percentile
6 and then running with it and seeing where that
7 brings you in terms of the Probability of
8 Causation.

9 It may end up bringing you lower,
10 you know, than the approach you are using or
11 higher. I just don't know. But it seems to
12 be a scientifically more well-grounded
13 approach than this application of the GSD of
14 five, as adopted. I think it is at least
15 worth looking into.

16 MR. RUTHERFORD: I will let Dan
17 respond to that.

18 DR. MAURO: But, I mean, there are
19 going to be lots of -- I am not going to say
20 lots. There are a number of cancers that you
21 do have to reconstruct doses for.

22 MR. RUTHERFORD: Well, I agree. I

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1 understand the approach you suggested, and we
2 are certainly willing to look into that.

3 DR. MAURO: Thanks.

4 CHAIRMAN MELIUS: Why don't we
5 leave it at that? We are trying to focus on
6 the SEC review here.

7 Anybody else have questions or
8 comments, Board Members?

9 (No audible response.)

10 CHAIRMAN MELIUS: Okay. As Dr.
11 Ziemer mentioned earlier --

12 MEMBER ZIEMER: I'm sorry. What
13 did you say, Jim?

14 CHAIRMAN MELIUS: I was actually
15 saying as you mentioned. I was actually
16 picking up on your point.

17 MEMBER ZIEMER: Oh, right. Okay.

18 CHAIRMAN MELIUS: I was giving you
19 credit for raising it.

20 One of the reasons that there has
21 been delay in addressing the SEC issues here
22 -- I think they are to some extent

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1 interrelated -- is there have been concerns
2 about some information provided regarding what
3 should be the covered period for this
4 particular facility.

5 And then, I guess related to that,
6 the petitioner, Dr. McKeel, has had long
7 delays in getting access to some of the
8 information that the petitioners believe and
9 so I would agree with him are relevant to them
10 having adequate information to represent the
11 favor of their petition.

12 Maybe a way to start on that would
13 be, Dr. McKeel, you are still on the line?

14 DR. McKEEL: Yes.

15 CHAIRMAN MELIUS: If you would
16 like to sort of update us on where you are?
17 And then I believe that you had also asked Ted
18 Katz to share some of the more recent
19 correspondence with the Department of Labor
20 with the Work Group members, which Ted did, I
21 believe, earlier this week.

22 Dr. McKeel?

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1 DR. McKEEL: Yes. So where that
2 stands is I first asked Ted Katz, could I
3 retrieve [identifying information redacted]
4 information that she presented to the Board
5 and then as information packets? I wasn't
6 exactly sure she had given to the Board, but
7 my question was, could I obtain that
8 information directly from the Board under
9 FACA?

10 And there was a seven-month gap
11 where NIOSH was formulating policies for
12 sharing information that was given directly to
13 the Board.

14 And the bottom line was the answer
15 came back that no, the Board couldn't share
16 that information. So I've submitted a FOIA
17 request for all of [identifying information
18 redacted] information to Department of Labor.

19 And they indicate that, actually,
20 they should have a response soon, maybe
21 including today or within a few days, to not
22 necessarily deliver that information but just,

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1 could they provide it and would they provide
2 it.

3 And, actually, the Department of
4 Labor was very cooperative. And Rachel Leiton
5 sent me copies of both her responses to
6 [identifying information redacted] in which
7 Department of Labor gave their reasoning why
8 they do not think that the information she
9 presented was sufficient documentation to
10 enable them to change the covered period.

11 I have a response to the last
12 letter, which I have not yet had a chance to
13 deliver to the Department of Labor, but the
14 absence of [identifying information redacted]
15 last presentation to the Board on this subject
16 and the thrust, as I understand it, of the
17 material she sent to the Department of Labor
18 were that there was a particular temper of
19 HK-31 magnesium-thorium alloy that was only
20 made at Dow Madison and that that was the
21 specific temper that was used in the nuclear
22 weapons that led to the classification of Dow

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1 as an AWE site based on thorium work.

2 So I don't know. That particular
3 point was not well addressed, in my opinion,
4 in the final letter. And that was the essence
5 of what new information [identifying
6 information redacted] claimed she had.

7 My request at this point is that
8 -- so the Department of Labor has gotten that
9 material. I believe [identifying information
10 redacted] sent similar packets to NIOSH and to
11 the Department of Energy. And I don't know
12 whether she sent it or not to SC&A and/or the
13 Board.

14 But, in any case, it should be
15 available from NIOSH. And I certainly think
16 that that information -- I do not have a copy
17 of it yet.

18 So I would like to propose, ask,
19 and request that the Board task SC&A to review
20 all of the material that [identifying
21 information redacted] has presented because it
22 doesn't go just to changing the covered

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1 period.

2 It goes to what some of the
3 production processes were. It goes to the
4 specific issue, which was new to me, that
5 there was a particular -- I think she cited
6 five or six different tempers of the way that
7 the HK-31 alloys were cured.

8 And, you know, one of them turned
9 out to be ideal for nuclear weapons. And she
10 says that that was made at Dow Madison's
11 plant.

12 So I think there needs to be an
13 independent assessment of that apart from
14 Department of Labor, which, you know, is one
15 voice and certainly is the primary decider. I
16 think all of that information is highly
17 relevant to the SEC. So I would ask that that
18 be done.

19 I think from everything I
20 understand, the Department of Labor will
21 probably send me the [identifying information
22 redacted] information rather quickly. I don't

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1 know what the time frame would be. So that is
2 where that issue stands.

3 I do have a few comments, just a
4 couple, on the discussion we had about the
5 findings on Appendix C. I don't know if it's
6 appropriate to comment on those.

7 CHAIRMAN MELIUS: Why don't you
8 wait a second?

9 DR. McKEEL: Okay.

10 CHAIRMAN MELIUS: Let's pick up on
11 what you just said --

12 DR. McKEEL: Yes.

13 CHAIRMAN MELIUS: -- so we don't
14 lose the train of thought. But I will come
15 back and give you an opportunity for the other
16 comments.

17 DR. McKEEL: Yes.

18 CHAIRMAN MELIUS: This is a hard
19 question to grasp because we don't know what
20 was submitted and where it went and so forth.

21 Does NIOSH have any response?

22 Does NIOSH believe that the

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1 information that [identifying information
2 redacted] sent to Department of Labor that
3 NIOSH also -- does NIOSH also have that
4 information or believe they have that
5 information?

6 MR. RUTHERFORD: This is LaVon
7 Rutherford. I do believe we have that
8 information that [identifying information
9 redacted] sent to the Department of Labor.

10 CHAIRMAN MELIUS: And is that
11 information available to SC&A or has it been
12 made available to the --

13 MR. RUTHERFORD: All the
14 information [identifying information redacted]
15 supplied to us is on the Site Research
16 Database and available to SC&A. Now, from a
17 dose-reconstruction perspective, the
18 information is not really affecting anything
19 associated with dose reconstruction.

20 CHAIRMAN MELIUS: I guess that is
21 NIOSH's conclusion about it based on their
22 review. That is not something that the Board

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1 has dealt with nor SC&A, if I understand it.

2 MEMBER ZIEMER: Dr. Melius?

3 CHAIRMAN MELIUS: Yes?

4 MEMBER ZIEMER: Paul Ziemer here.

5 I understand Dr. McKeel's request. I would
6 simply make a point, which I make frequently
7 in many such situations, not SEC situations
8 per se but in general, and that is it seems to
9 me that the ball is in NIOSH's court to make
10 an initial evaluation.

11 I always have to point out I don't
12 like SC&A doing federal work. I want them to
13 do Board work and I think it is premature for
14 us to look at [identifying information
15 redacted] data, which she submitted to DOL.

16 I don't believe the Board per se
17 -- she has not submitted this to us, as far
18 as I am aware. It seems to me that in the
19 evaluation, it is NIOSH's job to evaluate this
20 kind of thing and make recommendations to DOE
21 or DOL if they believe the period should be
22 changed.

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1 I agree, at some point if it
2 becomes obvious that there is an issue on how
3 that evaluation was done or whether the
4 correct evaluation was done, but until we see,
5 for example, a product, it seems to me at this
6 point, it is inappropriate to task.

7 We haven't even seen it. So I
8 think we would be tasking sort of in the dark
9 at this point.

10 MR. HINNEFELD: This is Stu
11 Hinnefeld from NIOSH. I just wanted to offer
12 one thing. I wasn't quite sure what Paul felt
13 like our action would be there. Did you want
14 us to look at this and make some kind of
15 recommendation?

16 MEMBER ZIEMER: Well, I believe I
17 heard Dr. McKeel say that he felt we should
18 task SC&A to review the [identifying
19 information redacted] data and evaluate, and
20 Dr. McKeel can clarify. I think he was
21 interested both in the processes which might
22 certainly be of interest from a

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1 dose-reconstruction point of view, but the
2 heart of the matter is the issue of changing
3 the covered period, which, in essence, is a
4 DOL/DOE task and to some extent is outside of
5 our purview to start with. So I get a little
6 antsy about getting into that ballpark with
7 the tasking of reviewing material that we have
8 not even seen.

9 MR. HINNEFELD: Yes. Our role in
10 things like extension of classes or the length
11 of classes or things like that has always been
12 that we would provide any information we found
13 that we thought was relevant to the Department
14 of Energy or Labor, whichever was applicable
15 or both. But we don't particularly give them
16 advice on their interpretation of that
17 information and how to set the Class.

18 So that responsibility is assigned
19 to them. And we have not really put ourselves
20 in a position of sort of evaluating that
21 information for them and advising them.

22 So if the desire is that we

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1 provide some sort of analysis to explain
2 either our conclusion that there is no effect
3 on dose reconstruction or that here is the
4 information and this is our position with
5 respect to dose reconstruction, we can do
6 that.

7 But with respect to the duration
8 of the covered period, I would not think that
9 we -- I mean, I can speak with others in the
10 Institute after we get off the meeting, but I
11 would not think we would start to take on the
12 role of giving advice to the other agencies on
13 fulfilling what are their responsibilities.

14 CHAIRMAN MELIUS: Yes. Jim
15 Melius. A couple of comments on that. I
16 agree that the covered period and processes;
17 that is not our purview. I guess what was
18 said was about the submission of information
19 as you find it during your research would be
20 -- you know, it's appropriate if you find
21 something that brings into question the
22 covered period or something else important

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1 about the site that DOL should know, then you
2 would bring it to attention.

3 I guess the only situation where I
4 think that something else arises, you know, do
5 you have information that, in combination with
6 what [identifying information redacted]
7 provided, would be of pertinence to the DOL's
8 review? But even that I think is not
9 something that certainly the Board is directly
10 involved in.

11 I guess my question was more from
12 the point of view, was there something in that
13 information that would be relevant to what we
14 were reviewing now, which we have already
15 granted the SEC for the current cover. There
16 may be information in there that would be
17 relevant that NIOSH would use in the dose
18 reconstruction for the non-covered cancers.

19 It may or may not be. I don't
20 know. You know, I have not looked at that
21 information so I can't say. I mean, but that,
22 again, is not something currently -- our Work

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1 Group is currently looking at.

2 And I guess the issue that we are
3 looking at right now is the question of,
4 should the SEC be extended to include parts or
5 all of the residual period?

6 I guess the question would be, it
7 would be any of the information there in that
8 -- that has been submitted by [identifying
9 information redacted] and NIOSH has. Is that
10 relevant to the residual time period?

11 DR. McKEEL: Dan McKeel.

12 CHAIRMAN MELIUS: Yes?

13 DR. McKEEL: Can I make a comment
14 about that specifically? I mean, my
15 understanding is that the information involves
16 new information about the AEC contract that
17 governs the thorium work and that that, what
18 she is saying is that she has presented
19 information that indicates the production
20 period for thorium extended beyond 1960. So
21 that would be into the residual period and I
22 think that makes it directly relevant.

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1 And also I would point out that
2 [identifying information redacted] did make
3 her presentation directly to the Board and had
4 handouts which had summaries of that
5 information. And it is in the Board
6 transcript.

7 So this is not something that was
8 only given to NIOSH or only given to DOL or
9 DOE. It was also presented directly to the
10 Board.

11 Now, whether she transmitted her
12 information packet to the Board I don't know,
13 but, for practical purposes, her information
14 packet, as Stuart just said, is on the SRDB.
15 So it is readily available to you all and it
16 will soon be to me.

17 As a practical matter, as soon as
18 I get it, I will forward it to the Board. So
19 that is just something to consider.

20 COURT REPORTER: This is the court
21 reporter. May I ask who you are?

22 DR. McKEEL: I'm Dan McKeel.

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1 COURT REPORTER: Dan McKeel?

2 Okay. I just wanted to make sure.

3 DR. McKEEL: Yes. Sorry.

4 COURT REPORTER: Okay. Thank you.

5 CHAIRMAN MELIUS: Anybody else
6 have comments from the Board Members?

7 (No audible response.)

8 CHAIRMAN MELIUS: Dr. McKeel, you
9 had some other comments also?

10 DR. McKEEL: Yes, I did. I will
11 make them very briefly. I believe that the
12 surrogate- data issue is a big issue and would
13 take exception to the discussion this morning.

14 There are several places where surrogate data
15 was used. And the SC&A review of Appendix C
16 cites these as well.

17 For example, film badge data from
18 the Bay City, Michigan Dow plant was used.
19 And the comment was made as far as justifying
20 this as appropriate use of surrogate data was
21 that the Bay City, Michigan facility was
22 similar -- that's a quote -- to Dow Madison

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1 without any other justification at all. So I
2 don't think that has been proven how similar
3 it was. So that is just a statement.

4 The other surrogate data that was
5 used was data from Conalco, which eventually
6 wound up owning the Dow, former Dow facility
7 but air sampling data from the 1980s was
8 applied back to characterize air
9 concentrations during the operational period
10 in the 1950s. And I would question that as
11 being entirely appropriate.

12 The other thing is that I have
13 raised repeatedly, and it really has not been
14 settled, and that is that the Silverstein
15 report from 1956 and 7 -- although Dr.
16 Silverstein on paper was the radiation safety
17 officer for Dow Madison plant, it is clear
18 that he was based in Michigan. He did not
19 live or stay, certainly, at the Dow Madison
20 plant.

21 In fact, none of the workers that
22 are now alive and have given testimony are

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1 aware of Silverstein's work. That doesn't
2 mean that it doesn't exist, but they do point
3 out that Dr. Silverstein in one of his reports
4 provides a diagram of what is supposed to be
5 the Dow Madison pot room, where they did the
6 castings for thorium alloys.

7 And it simply is not a picture of
8 any configuration of that pot room that any of
9 the workers alive now are aware ever existed.

10 There were seven pots shown in the schematic;
11 whereas, there were ten actually at Dow.

12 So they believe that that is a
13 sketch of another facility, maybe the pot room
14 at Bay City, for example. But it is not the
15 pot room at Dow Madison.

16 So I have contested, and I don't
17 believe it has really been settled. There is
18 a very loose use of the word Dow, which
19 encompasses many of the sites. Dow had a
20 single thorium license to cover their
21 facilities in Michigan, in California, the Dow
22 Madison plant. And I think the only relevant

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1 data that is not surrogate data is data
2 directly from Dow itself.

3 So, for example, when you talk
4 about Bay City being similar to Dow Madison,
5 one thing that wasn't similar was that they
6 had film badge data from the Bay City,
7 Michigan facility. If it is so similar to Dow
8 Madison, why wouldn't they have any film badge
9 data for Dow Madison? And there is zero film
10 badge data or bioassay data for Dow Madison.

11 So if Dr. Silverstein were the
12 radiation safety officer at both facilities,
13 it seems inconceivable that he would institute
14 a film badge program at one and then at
15 another place, where it is stated there were
16 identical production facilities, he wouldn't
17 institute a film badge program at Dow Madison.

18 We don't have any indication that
19 there was a film badge program at Dow Madison.

20 So I just think that whole issue is a huge
21 issue.

22 The Surrogate Data Work Group has

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1 not been involved in that decision. And
2 clearly in my mind, the justification for
3 using that surrogate data at Dow Madison
4 certainly doesn't comply with the criteria,
5 either the draft Board criteria or the OCAS
6 IG-004 surrogate data criteria. So I just
7 make a plea that that be examined.

8 The final comment that I wanted to
9 make was about using exponential decay for the
10 residual period for both uranium and thorium.

11 Now, I can understand it for uranium, where,
12 as far as we know, once the extrusion work
13 that was done and the straightening operations
14 were done during 57 and 60, that there was no
15 more introduction of new uranium at the Dow
16 facility.

17 And so you could say that there
18 was a level present at the end of the
19 production period and then it decayed
20 exponentially throughout the residual period.

21 That's okay, although uranium-238 has a very
22 long half-life.

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1 But, anyway, let's say that that
2 were true. For thorium, I don't think that is
3 the case at all. As was acknowledged by John
4 Mauro, the language of the Act says that if
5 you can't distinguish between AEC and
6 commercial radioactive materials, then all of
7 it has to be considered as AEC material. And
8 I think that is very clear.

9 So in the case of Dow Madison,
10 there was active production of
11 magnesium-thorium alloys HK-31, HM-21 that
12 extended from 1961 through the 60s, the 70s.
13 Conalco made it. And, actually, it extended
14 up until the time that Spectrolite bought the
15 facility and the workers have testified that
16 there were thorium production runs into the
17 early 1990s at least.

18 So what I believe should be a more
19 appropriate model is that you had multiple
20 introductions of thorium source term material.
21 And so a single exponential decay curve
22 wouldn't describe that situation at all.

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1 Rather, what you have is multiple
2 introductions of thorium.

3 We know that there was thorium all
4 over the facility in the 2006-2007 period,
5 when Pangea was cleaning it up, actually
6 starting in 2004 but completing it late in
7 2007, there was thorium in every building in
8 the Dow building complex.

9 So, you know, if you thought of
10 multiple exponential decay curves, then there
11 was always a peak and a beginning of the down
12 slope. And then another curve would be
13 superimposed on that so that what you would
14 actually have is an average value during the
15 residual period that would more approximate
16 close to the peak values, rather than a decay
17 curve where at the end of that decay curve,
18 you know, it was sharply curtailed. So I just
19 question that model as being the appropriate
20 one.

21 The final, other comment I will
22 say is that, although everybody seems to

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1 accept that TBD-6000 is an excellent model for
2 what happened at Dow Madison. I will comment
3 that TBD-6000 has zero information about
4 thorium in it. That's one.

5 And, number two, when you talk
6 about metal, heavy metal operations on uranium
7 and thorium, there is a very highly pertinent
8 issue that basically has been glossed through.

9 And that is that at many DOE sites
10 -- and I have seen pictures of them. I can
11 produce pictures of them. Many of the
12 extrusion presses for uranium were covered by
13 vacuum hoods. And they were constantly
14 operating and sucking the dust away from those
15 machines as that uranium, which was often --
16 you know, it was a very dusty operation. It
17 would often crumble. Pieces would fall out.
18 Men would have to dig those up.

19 But, anyway, those vacuum hoods
20 were expressly designed to carry that dust
21 away. And it is clear at the Dow Madison
22 facility, there were absolutely no hoods at

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1 all on any of the extrusion presses, of which
2 there were I think nine at one period.

3 In my reading of TBD-6000, the
4 distinction between an extrusion press with a
5 hood and without a hood and showing the
6 comparative doses of uranium or thorium dust
7 inhalation just aren't present in that
8 document. So I don't think that is an
9 entirely adequate document for the uranium
10 intakes that were experienced at Dow Madison.

11 Okay. So thank you very much.

12 CHAIRMAN MELIUS: Thank you, Dr.
13 McKeel.

14 Any comments from Board Members or
15 NIOSH?

16 (No audible response.)

17 CHAIRMAN MELIUS: No? My only
18 comment -- and maybe Stu or someone can
19 clarify -- is your comment on the multiple
20 exponential decay. My understanding, I
21 thought, was that during the residual period
22 only, the sort of the covered processes were

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1 what were taken into account.

2 It's different during the covered
3 period, as opposed to the residual period. Is
4 that correct?

5 MR. HINNEFELD: Yes, that's
6 correct, that during the residual period, that
7 we were required to reconstruct the material
8 that is residual from the covered operation.

9 CHAIRMAN MELIUS: Yes.

10 MR. HINNEFELD: And so those ended
11 in -- I forget the date now -- 1960 or
12 whatever the determination was at the end of
13 the covered period that the Department of
14 Labor has made. Then we would be
15 reconstructing, during the residual period,
16 contamination that was left over from those
17 operations that ended in whatever it is. I
18 forget the date.

19 COURT REPORTER: This is the Court
20 Reporter. Please identify yourself.

21 MR. HINNEFELD: I'm sorry. I'm
22 sorry. Stu Hinnefeld.

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1 COURT REPORTER: Okay. Thank you.

2 CHAIRMAN MELIUS: Even though that
3 may not be logical in terms of the exposure
4 people experienced, it is the way the
5 legislation is set up.

6 DR. McKEEL: I understand that.

7 CHAIRMAN MELIUS: Yes. Thank you.
8 Yes. No. Thanks. Thank you.

9 What I would propose we do is -- I
10 think we all need, at least I need, to re-look
11 at the letter from the Department of Labor, I
12 think in the context of what Dr. McKeel, some
13 of the issues he raised and some of the other
14 questions.

15 But I think we would, I think, try
16 to at our next meeting of this Work Group pull
17 everything together and try to -- I think we
18 need to reach a conclusion on this particular
19 SEC petition as applied to the residual period
20 as best we can based on where things stand at
21 that point in time, and recognizing that there
22 are unresolved issues that may be continued

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1 concerns about the covered period.

2 So maybe at the end of the call,
3 after we have talked about the 250-day issues,
4 we will sort of figure out a schedule and put
5 it together. And I would plan on doing that
6 between now and obviously not the next Board
7 meeting but the following Board meeting.

8 Is that satisfactory with other
9 members of the Work Group?

10 MEMBER ZIEMER: This is Ziemer.
11 Could you clarify -- I think I have a general
12 sense of what you're saying, but specifically
13 what will happen now? Are you talking about
14 another Work Group meeting to come to
15 resolution on this issue?

16 CHAIRMAN MELIUS: Right. Yes.
17 That is a quick sum.

18 MEMBER ZIEMER: But the
19 extended-period issue is not one that we as a
20 Work Group or Board can sort of come to
21 closure on, I don't think. I mean, suppose we
22 say yes, we think that that is -- well, I

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1 guess, what exactly are you proposing to do
2 with that? It wasn't quite clear.

3 CHAIRMAN MELIUS: I don't believe
4 we can do anything or should do anything on
5 the covered- period issue. That is the
6 Department of Labor.

7 All we do is, again, one, if we
8 have information that is relevant to that that
9 we find that through other documents or
10 interviews or something that perhaps NIOSH or
11 ORAU missed or didn't appreciate, that we
12 bring it to whoever's attention to be
13 communicated to Department of Labor, but, you
14 know, we are not charged with reviewing that
15 particular issue. And I'm not proposing that
16 we should.

17 I think at least that is my
18 understanding of our role.

19 MEMBER ZIEMER: Right. This is
20 Ziemer again. And then, although it is not
21 the purview of this particular Work Group, I
22 think Dr. McKeel's issues on the surrogate

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1 data will need to be dealt with. And, of
2 course, the Surrogate Data Work Group is
3 working to come to closure on the criteria
4 issue and perhaps that will speak to those
5 issues as well.

6 I think that is more in our
7 purview, anyway. We need to put to rest the
8 issue of use of the surrogate data for this
9 facility in the covered period, although we
10 already have an SEC there.

11 CHAIRMAN MELIUS: Right. So it's
12 not the --

13 MEMBER ZIEMER: So it has to do
14 with -- well, it would have to do with dose
15 reconstructions for the non-covered cancers, I
16 guess.

17 CHAIRMAN MELIUS: But it is also
18 the residual period.

19 MEMBER ZIEMER: Right. Right.

20 CHAIRMAN MELIUS: Yes. I believe
21 in --

22 MEMBER ZIEMER: And so far as that

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1 starting point may be affected by the
2 surrogate issue.

3 CHAIRMAN MELIUS: Correct. We can
4 do that. So presumably, if we reach some
5 better closure on the surrogate data issue at
6 our meeting next week, I think then we'll
7 probably have a better idea of sort of
8 scheduling and how to sort of pull those, sort
9 of that surrogate data issue matters as well
10 as the other issues we have been talking about
11 and can bring some closure to the site, at
12 least based on the information we have to
13 date.

14 MEMBER BEACH: Hey, Jim, this is
15 Josie.

16 CHAIRMAN MELIUS: Yes?

17 MEMBER BEACH: It would be helpful
18 for me if you could -- I know we are going to
19 set a date for the next Work Group meeting,
20 but if you could send out an e-mail kind of
21 outlining the issues?

22 CHAIRMAN MELIUS: Yes.

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1 MEMBER BEACH: Because it is very
2 complicated between the surrogate and the
3 250-day.

4 CHAIRMAN MELIUS: Yes. And maybe
5 one of the things we want to charge SC&A to do
6 is to provide that outline as a task to make
7 sure that we have covered all of the points
8 that have come up through that. Maybe we can
9 talk about that at the Board meeting.

10 DR. MAURO: Jim, this is John
11 Mauro. I would just like to point out with
12 regard to the surrogate data issue, there have
13 been specific Site Profile and SEC petition
14 reviews where we were deliberately tasked to
15 say, even though the criteria that were
16 developed, the draft criteria developed by the
17 Surrogate Data Work Group, were very much
18 draft, I know we are in the process -- you are
19 in the process of trying to finalize that as
20 part of the process to help feed that
21 decision, those judgments. We did review a
22 number of documents where we explicitly

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1 evaluated the degree to which the particular
2 approach adopted at that facility met or did
3 not meet the four criteria.

4 That was not done here. I do not
5 believe it was done here. Bill, who does a
6 lot of this work, I do not believe we have
7 ever explicitly compared, okay, here is how
8 the approach used --

9 CHAIRMAN MELIUS: That is correct,
10 John.

11 DR. MAURO: -- stacks up here.
12 Our position in terms of, say, the 1960 time
13 frame and the use of the uranium information
14 and the Bay City data for external, I believe
15 was used, that we did not do a one-on-one
16 comparison on how it stacks up.

17 Our response, if you recall,
18 regarding surrogate data was that it was our
19 general feeling that, given the amount of
20 material that is historically covering all
21 time periods, all types of facilities, related
22 to the machining and handling and rowing and

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1 extrusion of uranium that is out there, that
2 there probably exists a pathway where we feel
3 confident there is a pathway of finding the
4 right data.

5 Dr. McKeel makes some very
6 important points. That is, if you are going
7 to do that, you had sure better make sure you
8 pick an extrusion facility that didn't have a
9 hood if you are going to use surrogate data.

10 And I agree with that completely.
11 That is, you know, checking to see the
12 applicability and -- which I have to say right
13 now, I can't say when we looked at this
14 whether or not we went to that level of detail
15 to see did the particular surrogate data
16 adopted take into consideration some of these
17 factors.

18 So I would like to leave you with
19 that.

20 CHAIRMAN MELIUS: I appreciate it,
21 John. Let's see where we are on the surrogate
22 data issue after our meeting next week. And

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1 hopefully we'll have some -- I just hesitate
2 to say we would assign something for when
3 perhaps the way you would review it would
4 change or something.

5 DR. MAURO: Correct. That's for
6 sure.

7 CHAIRMAN MELIUS: Also I think we
8 need to think about -- there is already an SEC
9 for the current covered period. And so we are
10 really talking about the residual period.

11 And so there may be surrogate data
12 issues related to that. There also may be
13 surrogate data issues related to the earlier
14 period. I'm not sure. There's some different
15 information on that but those who I think
16 would be probably more -- could be more in the
17 area of the dose, you know, dose
18 reconstruction for non-presumptive cancers.

19 MEMBER ZIEMER: Dr. Melius?

20 CHAIRMAN MELIUS: Yes?

21 MEMBER ZIEMER: Ziemer here again.

22 In terms of evaluating that, I would like to

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1 insert one other thing. Again, we're sort of
2 getting off into the surrogate data issue, but
3 I think one of the points Dr. McKeel mentioned
4 was what I would classify as a work practice
5 issue. This is aside from the hardware and
6 the facility and the hoods and all of that.

7 It is very curious if Dr.
8 Silverstein indeed was the RSO. I think I
9 would characterize him as a corporate RSO,
10 which means he has overall policy calls, even
11 though he may not have physically been there.

12 It would be very curious as to why
13 one facility had external monitoring and the
14 other didn't. One of the surrogate data
15 issues when we talked about equivalence is not
16 just the same process, but the work practices
17 also come into play.

18 I think certainly if SC&A gets
19 into this, we want to look at that work
20 practices issue. Was there a conscious
21 decision not to have external monitoring at
22 Dow Madison? Because such a decision itself

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1 says something about maybe an evaluation of
2 what kind of levels were expected there.

3 I think that has to be part of the
4 surrogate data evaluation as well. Why were
5 there different work practices?

6 CHAIRMAN MELIUS: That's a good
7 point, yes. Thanks. Okay.

8 CHAIRMAN MELIUS: We're now going
9 to change gears and/or topics and focus on the
10 250-day issue. I believe that John was going
11 to sort of give us an overview of where we
12 have been on this issue.

13 DR. MAURO: Yes. This is John
14 Mauro. I would be glad to try to do it
15 briefly. It has quite a history, as you know.

16 And I have sent out a package of SC&A reports
17 and also recently what I would call a road map
18 on all of the minutes, transcripts of the
19 various Work Group meetings and Board
20 meetings, where the 250-workday issue was
21 discussed. In some cases, it was a relatively
22 brief discussion. In some, it was a very

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1 elaborate discussion. And I believe everyone
2 should have gotten that.

3 And hopefully, you know, as
4 necessary, the page numbers and the dates of
5 the minutes are all laid out there so that if
6 we actually start to delve into any one of
7 these complex discussions, we could quickly,
8 as necessary, go dive into that particular
9 section of the transcripts and get
10 clarification of what transpired.

11 But I will try my best to give you
12 the broad brush story of the 250-workday issue
13 and where we are right now. The process first
14 began by struggling with the very difficult
15 question of what criteria should be used. We
16 first thought in terms of we had meetings
17 where, well, what is equivalent to a
18 criticality exposure for those who had the
19 language in the regulation, uncontrolled
20 exposures, where the types of exposure were
21 comparable to what one might experience with
22 criticality.

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1 And that took us down a road that
2 lasted a while. And we filled out a number of
3 work products to try to explore that a bit.
4 We had quite a bit of animated discussion
5 early on regarding that matter.

6 I think we walked away, this is
7 really what I walked away with anyway, and I
8 think it is also in the transcripts, walks
9 away with, that the exposures that were
10 experienced in the past on the criticality
11 situations varied from the millirem range to
12 the thousands of rem range. You know, we have
13 a nice report that sort of summarizes all of
14 the criticality experience.

15 So that really didn't help us very
16 much except to say that, oh, my goodness, you
17 know, going down that road, it wasn't too
18 helpful in terms of zeroing in on can we pick
19 a dose or a range of doses.

20 But at the same time, I think that
21 the complex discussions we had went toward
22 that, well, we all agree that when the doses

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1 start to exceed around ten rem and start to
2 approach 100 rem, now we're talking general
3 acute exposures, whole body, certainly within
4 the realm of what we believe was the intent
5 of, might have been the intent of, putting in
6 that language. And I think we sort of walked
7 away with that as being one of the places that
8 would help guide our thinking.

9 We also had lots of discussion on
10 what about biological endpoints like, did
11 anyone experience a drop in white blood cell
12 count. That would be another circumstance
13 that under uncontrolled circumstances that
14 might be indicative of a condition that may
15 warrant a 250-workday consideration.

16 And there is lots of discussion
17 and nuance on matters like that. I guess we
18 walked away from that conversation that we are
19 really not quite sure if we can come up with
20 something: nice, clean criteria, either
21 dose-based or based on not dose but maybe
22 biological endpoints, medical aspects, that

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1 would really help to make it a clean
2 decision-making process.

3 So that was really more of what I
4 would say the high-level discussion, to see if
5 we could come at this in some general way with
6 general criteria, sort of what we are doing
7 right now with surrogate data, come up with
8 some fundamental principles that will help
9 guide us, make these decisions.

10 I think, quite frankly, we tried
11 that, and we found it very difficult. That is
12 the story that emerges I think in my
13 recollection of reading of the transcripts.

14 And then we moved into a mode
15 where we say, okay. Listen. Let's also, in
16 parallel, while we're entertaining these ideas
17 also look at some real world examples of where
18 we might have experienced, where situations
19 might have occurred that one would say we had
20 better consider the 250-workday issue here.

21 And it emerged for us -- and we
22 have reports on this that was part of the

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1 compilation -- at the Nevada Test Site with
2 some examples of circumstances that one might
3 consider to fall within the category.

4 DR. MAURO: We also had the Met
5 Lab report, Metallurgical Laboratory report,
6 that more recently came out and prior to that
7 was the Ames report. In the Ames report, that
8 raised a lot of very interesting discussion.

9 The Ames report in a nutshell
10 demonstrated pretty convincingly that there
11 were multiple blowouts that occurred where
12 workers likely experienced very high exposures
13 to airborne concentrations of uranium.

14 And even if they were only exposed
15 for a relatively short period of time, five
16 minutes, on that order, a matter of minutes,
17 the dose commitment, internal dose commitment,
18 to the lung and perhaps some other organs,
19 like bone, could have been very high, in
20 excess of 100 rem. And a lot of discussion
21 was held during the Work Group meetings.

22 But that is not really an acute

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1 exposure. So now we get into this dilemma of
2 is this comparable to something one would
3 consider like a criticality.

4 SC&A's position was, well, yes.
5 We are talking about acute, short-term
6 exposure. You run into this definition of
7 acute. Is acute the duration of exposure or
8 is acute the dose rate the dose is delivered?

9 You know, if you are exposed to
10 external exposure from a criticality, that is
11 acute in the most narrowly defined terms. You
12 know, it occurs over a very short time, and
13 the energy is delivered to every tissue in
14 your body, almost instantaneously.

15 Ames is different. Ames, yes, the
16 exposures occurred in a relatively short
17 period of time, but the inhaled material
18 that's in your body now is being delivered
19 over a protracted period of time.

20 And we had a lot of animated
21 discussion on that that type of exposure
22 scenario constitutes something that should be

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1 considered to a 250-workday issue. And we
2 certainly have not resolved that.

3 I think that goes to the heart of
4 the matter because I believe we will find that
5 in many circumstances, when we do encounter
6 situations where people might have been
7 exposed to fairly high levels of internal
8 matters for short periods of time, where the
9 doses might be on the order of tens or even
10 hundreds of rem to some organs but they are
11 dose commitments, not acute, short-term
12 exposures, and we are all struggling with does
13 that mean that we have a 250-workday issue?

14 That is what emerged from our Ames
15 work. What emerged from the Met Lab work --
16 and, by the way, the author of both the Ames
17 report and the Met Lab report was Hans
18 Behling, and he's on the line.

19 To distinguish, something
20 different occurred at the Met Lab, which was
21 very early on, where one could argue that the
22 radiological setting in terms of health

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1 physics practices, the kinds of things that
2 were going on, resulted in some workers who
3 were there clearly -- and you know this for
4 certain -- clearly for relatively short
5 periods of time, much less in 250 days, where
6 the potential for relatively high external and
7 internal exposures existed, to the extent that
8 I believe there are even some workers who
9 experience a drop in red blood cell count.

10 So here we have a situation where
11 we're talking about, a little different than
12 Ames -- Ames was mainly a concern because of
13 this external exposure from the blowouts. Now
14 we have a situation where on a day-to-day
15 basis while people are working at the pile at
16 the Met Lab. It was so early in the -- and
17 this, of course, is an SEC-covered period.
18 Both of these are.

19 But the question is, should there
20 be consideration of the 250-day issue to the
21 people at the Met Lab, who, many of them, were
22 there for relatively short periods of time and

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1 the nature of the exposures, neutron, external
2 gamma and internal, one could say, were they
3 under control? Well, you have to question the
4 degree to which they were under control
5 because there was very little knowledge at the
6 time of good radiological protection
7 practices.

8 And so I guess I will stop at that
9 point in terms of characterizing that we have
10 a circumstance where it is almost as if we
11 have to -- I'll tell you where I walk away
12 from this. I say, you know, it is very hard
13 to make general rules. We would love to be
14 able to make general rules and guidelines to
15 help steer us through the application of this
16 concern on a case-by-case basis, I mean, on an
17 over-arching guideline the way we are doing
18 with surrogate.

19 The more I think about this
20 problem is understanding the circumstances the
21 way they existed and making judgments. In
22 this particular case, it is clear and

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1 unambiguous that large exposures that occur
2 over a relatively short period of time,
3 whether they were external or internal, we
4 really can't put a handle on how high those
5 exposures are.

6 They were clearly high enough that
7 they were delivering doses that, whether
8 they're external or committed, are doses on
9 the order of levels that everyone agrees are
10 dangerously high, such as the number that I
11 have in my head, by the way, is 100 rem.

12 To me if there is any guideline
13 that I go by that I walk away from after
14 reading all of this stuff is that if I've got
15 a circumstance where the potential existed for
16 organ doses that are on that order, I'm
17 starting to think, yes, we've got ourselves a
18 250-workday.

19 I just gave you not only my best
20 shot at capturing the history of the story
21 that started, I believe, in 2006 and -- I
22 apologize. I also gave you a little of what

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1 my perspective is on how to deal with this
2 problem.

3 And, with that, Hans, certainly if
4 there are other aspects to it that you think
5 that I missed, please help out.

6 DR. BEHLING: Yes. John, I think
7 you summarized extremely well. And I just
8 want to say the distance between, really,
9 criticality events and a short-term exposure
10 that, however, may require you to manifest
11 itself in terms of organ dose is really a
12 difference between perhaps inducing -- both of
13 them will result in high doses. That's for
14 sure. But obviously the criticality-type
15 exposure has a potential of inducing the acute
16 radiation syndrome.

17 However, as John pointed out,
18 EEOICPA is not really there to compensate
19 people for acute radiation syndrome. We are
20 here to compensate people for
21 radiation-induced cancers and so that being a
22 difference that I consider is really

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1 immaterial to the issue that involves the
2 250-day criteria.

3 COURT REPORTER: This is the Court
4 Reporter.

5 CHAIRMAN MELIUS: Thank you.

6 COURT REPORTER: Would the person
7 who spoke please identify himself?

8 CHAIRMAN MELIUS: That's Hans
9 Behling --

10 COURT REPORTER: Hans Behling?

11 CHAIRMAN MELIUS: -- from SC&A.

12 COURT REPORTER: Okay. Thank you.

13 CHAIRMAN MELIUS: To extend John's
14 metaphor, we have tried the high road and the
15 low road. And neither one gets us there yet.

16 DR. MAURO: Well said.

17 CHAIRMAN MELIUS: I would add one
18 other complication to this that I think came
19 up in both Ames and the Met Lab situations was
20 that, even in those situations where I think
21 everyone sort of understood that some people
22 -- that the 250-day rule wasn't appropriate

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1 for people working there in terms of fairly
2 compensating them or whatever we want to call
3 that.

4 The other issue that we have to
5 wrestle with is, well, then, how would you
6 define the Class? Was it somebody that was
7 there for one day, one incident, you know, ten
8 days, a month, or whatsoever?

9 And when you have a series of
10 discrete incidents that are exposures that
11 occurred or operations that occurred that led
12 to the exposure, how do we appropriately
13 capture that in terms of a Class Definition
14 for someone there that just captures those? I
15 think that is a further complication to trying
16 to come up with a scheme or an approach that
17 addresses this.

18 Any Board Members have comments or
19 questions?

20 MEMBER ZIEMER: Well, this is
21 Ziemer. I will throw in my comments. I have
22 been giving a lot of thought to this past

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1 week. I don't have a solution to it. I think
2 it is a dilemma. Part of the dilemma, of
3 course, is the fact that we use the 250-day
4 criteria in a sense to define a break point
5 between the biological consequences and no
6 biological consequences, as it were, that is
7 very arbitrary.

8 What I was trying to think about,
9 for example, was let's take a place like Ames
10 where we had the blowouts. I don't recall
11 whether NIOSH felt like they could bound
12 those.

13 One of the things -- criticality
14 incidents are usually fairly straightforward
15 for bounding anyway, but let's suppose that
16 you have incidents like the blowouts, where --
17 well, let me ask it this way. Do we have
18 incidents where we're pretty sure what the
19 lower end of a bound might be? Let me put it
20 in as potential.

21 The potential is that you would
22 get at least some value. Maybe you can't put

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1 an upper bound on it, but you know it's at
2 least this amount. Say it's 10 or 20 rem or
3 something like that.

4 It seemed to me if you could do
5 that and if we were in a position to pick a
6 number, like John Mauro talked about. Is
7 there a dose number where, yes, we agree that
8 aside from 250, if you've got at least this
9 much dose, there's health endangerment by
10 definition and, therefore, if you were at an
11 incident where that occurred, we would throw
12 you into the SEC, for example?

13 I am trying to think in terms of
14 that kind of thing so that if you said, "Okay.

15 We know that at such and such a site there
16 were blowouts and if a person could establish
17 that they were present during the period where
18 those were known to occur," even if you
19 couldn't bound them, could you include that?
20 That is in your identified time periods during
21 which discrete incidents occurred that were
22 likely to produce doses above some value or

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1 that would be one thing.

2 Another thing would be if a person
3 could establish by medical records that they
4 got a dose, even if we didn't know what it
5 was, that resulted in non-stochastic effects,
6 which are not covered specifically; that is,
7 the non-cancers, but they are evidence of high
8 dose, could you include that person as part of
9 an SEC? Because we know that in many of those
10 cases where there are non-stochastic effects
11 years later, there are indeed stochastic
12 effects.

13 So I have been trying to think
14 about it in those kinds of terms.

15 CHAIRMAN MELIUS: Again with the
16 metaphor, I think you are trying to get us
17 back on the high road, but that actually -- I
18 mean, my own thinking is maybe not that we --
19 you know, we started out I think with
20 something similar. I don't think we were
21 thinking of it as a lower bound, but I think
22 we were talking about what exposure

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1 constitutes health endangerment.

2 MEMBER ZIEMER: Well, that is kind
3 of the issue. And, of course, it is different
4 for every organ and every age, but on this
5 thing, to some extent, just like the 250 days
6 is sort of arbitrary. One might have an
7 arbitrary guideline that you use to make a
8 decision.

9 Obviously, you know, what is the
10 difference if a person is there 249 days,
11 there is no health endangerment, and 250 there
12 is? Well, you know, that is just arbitrary.
13 But it is a decision tool.

14 CHAIRMAN MELIUS: And I actually
15 like that in that maybe use that as the
16 decision tool. Then based on the particular
17 facility that we're dealing with or
18 circumstances we're dealing with, you can then
19 sort of develop a Class Definition that would
20 encompass those at that facility who met that,
21 qualified in that way.

22 And so it might be different among

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1 different facilities. And there may be
2 multiple ways of sort of qualifying to do
3 that, I mean, the same with the stochastic
4 effects.

5 And so, I mean, I think there are
6 other ways of thinking about this. But that
7 may be a way of approaching this to sort of
8 combine the high and low roads.

9 MEMBER ZIEMER: This is Ziemer
10 again. I guess I would like to ask NIOSH,
11 maybe Jim Neton. Jim, is it conceivable that
12 one could characterize events in terms of a
13 lower dose potential, even in cases where you
14 know you can't get an upper bound but you are
15 pretty clear that you would have at least a
16 certain dose or am I thinking about this
17 wrong?

18 I recognize for chronic things,
19 you could make the same argument, but we sort
20 of assumed on a sort of regular facility where
21 you don't have "incidents," everything is
22 operating kind of normally, that the 250 days

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1 gives you a year of exposure. And sort of
2 intuitively you say, "Okay." That means in a
3 general sense if they are operating normally,
4 a person -- it sort of puts them over a five
5 rem dose if you use that as kind of an
6 operating -- you know, the limit for typical
7 operations without acute incidents.

8 The 250 days in my mind kind of
9 puts you at a five rem cutoff point, that if
10 you worked more than a year, then possibly you
11 got above five rem.

12 MR. HINNEFELD: This is Stu
13 Hinnefeld, Paul. Jim I'm sure has dropped off
14 the phone because his particular conflict is
15 affected by the 250 days.

16 MEMBER ZIEMER: Yes.

17 MR. HINNEFELD: So he has dropped
18 off.

19 MEMBER ZIEMER: Okay.

20 MR. HINNEFELD: With respect to
21 your question, you asked, are there incidents
22 where we could say, "Well, if someone were

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1 present for this incident, the dose would be
2 at least as high as some number."

3 MEMBER ZIEMER: Yes. That's sort
4 of what I am thinking about.

5 MR. HINNEFELD: I don't know that
6 we have ever tried to do that.

7 MEMBER ZIEMER: And then you'd
8 have to decide what that number was. But
9 conceptually can you do that?

10 MR. HINNEFELD: Well, you know --

11 MEMBER ZIEMER: And then if the
12 number is 100, like John Mauro is suggesting,
13 in my mind I would use a lower number. I
14 would use like 50, which is kind of the
15 threshold for non-stochastic effects. But, in
16 any event, whatever that might be.

17 MR. HINNEFELD: Well,
18 theoretically there might be some incidents
19 where we could say that someone could if they
20 were present for this incident could have been
21 exposed to at least 50 rem. I think
22 theoretically that seems to be possible now.

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1 I don't know, though, that when we
2 start to go down that path, that we will
3 really be confident that we will be able to
4 say that.

5 MEMBER ZIEMER: I am just trying
6 to think of a way to think about this. I may
7 be completely off on a wild track here, but
8 I'm trying to deal with an issue that says --
9 I mean, we all feel sort of intuitively that
10 there are cases where a person wouldn't have
11 to be around 250 days if they were present
12 when one of these events occurred.

13 MR. HINNEFELD: I think we would
14 disagree with that.

15 CHAIRMAN MELIUS: I don't recall
16 on the Met Lab discussions, but I do recall
17 with the Ames that I think we were pretty
18 close to making these types of calculations.

19 I remember at one point Jim Neton
20 was going to go back and sort of do dose
21 reconstructions for those people. In fact, I
22 think SC&A had done some hypothetical

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1 reconstructions on people just to try to see
2 where you would end up in terms of dose and so
3 forth. I don't remember the details of that,
4 but I think we thought that it was something
5 that we would be able to do.

6 You know, you are dealing with
7 issues of sort of bounding because these are
8 difficult to reconstruct accurately obviously.

9 MR. HINNEFELD: Right, but the
10 issue is we are talking about incidents we
11 can't reconstruct --

12 CHAIRMAN MELIUS: Right. So --

13 MR. HINNEFELD: -- because we're
14 going to be in SEC class. And so I don't know
15 if we can do a lower bound or not.

16 CHAIRMAN MELIUS: Yes, come close,
17 I guess. We may not be comfortable with dose
18 reconstruction. I mean, in fact, at one
19 point, Ames, we were trying to think, could we
20 do the dose reconstruction, you know,
21 essentially come up with a reasonable upper
22 bound and so forth?

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1 DR. GLOVER: This is Sam Glover.
2 I did want to mention I think Arjun summarized
3 it in the SC&A December report that it's a
4 catch-22 thing. If you can set an upper
5 bound, you can make it a non-SEC.

6 And so I was thinking, Paul, very
7 similar to what you were that there may be
8 circumstances where we can come up with some
9 number that it's not the upper bound, but it
10 gives you some feel for the level of hazard,
11 that it was a big number.

12 MEMBER ZIEMER: Well, yes. I'm
13 focusing on lower bound here, that if a person
14 was -- and you would have to place the person.

15 I mean, it's not like, all right, there was
16 this event and the person was ten buildings
17 over.

18 If you can't show that they
19 weren't -- if you have a situation where they
20 could have been close enough to the event,
21 whether it is a blowout or whatever it is,
22 then you would say, "Well, there is a high

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1 probably they got at least a certain amount."

2 We don't know what the upper bound
3 is, but if you had a lower bound, like you
4 could say, "Well, they certainly would have
5 gotten at least 50 rem from that event," then
6 I would say, "Okay. Well, maybe you put them
7 in."

8 But, again, it is a conceptual
9 thing. You don't really talk about numbers
10 unless conceptually you say, "Yes," you can do
11 it.

12 DR. MAURO: Paul, there is
13 something very attractive about the way you
14 are thinking. This is John Mauro speaking. I
15 didn't think of it this way.

16 In effect, when you think about
17 the 250-day again, you know, to go back to the
18 idea that, well, if there is a radiation
19 protection program, things are under control.

20 We are managing the work correctly.

21 We are going to be limiting people
22 to three rem per quarter, really, five rem per

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1 year, but three rem per quarter was the number
2 that historically was used, you know, in
3 trying to keep them under that.

4 So what I am hearing is one
5 concept could be if there was a circumstance
6 that arose where a person could have
7 experienced in a relatively short period of
8 time more than is the quarterly limit, I mean,
9 this almost becomes a regulatory driven
10 philosophy. It means that, first of all,
11 there was some degree of loss of control. And
12 that goes towards the language.

13 That may be a good way to get a
14 handle on this. That goes toward the language
15 that is currently in the rule; that is, loss
16 of control. There is a definition of loss of
17 control, clearly a loss of control where a
18 person experienced an exposure that was in
19 excess of radiation protection limit.

20 There are circumstances where
21 people are allowed to get more than three rem
22 and a quarter under action conditions where

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1 people are under controlled conditions go in
2 that deliberately -- and you know what their
3 exposures were. They were controlled.

4 If a person for some reason was in
5 a situation where there was a very real
6 possibility that he could have experienced
7 more than three rem in a quarter, that is a
8 nice place to start to think about this. I
9 like the way that goes.

10 And now that sort of triggers,
11 triggers the process in a way. And now, of
12 course, then if you buy in on that philosophy
13 that this is the place to trigger when you
14 start to think about this, the next step
15 becomes, does that include dose commitment
16 from internal emitters? I think that is going
17 to be a very difficult question to deal with.

18 But in theory it should apply if
19 you adopt that philosophy that there clearly
20 was obviously a loss of some control because
21 the person was not supposed to get more than
22 three rem in a quarter, we have got a

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1 situation.

2 Now, if it goes to the other side,
3 where the dilemma comes in, does that bring
4 you to the place that is comparable to a
5 criticality? Then, of course, things get very
6 difficult.

7 The idea of zeroing in on loss of
8 control and the circus there, I didn't think
9 about that before. And I, for one, find it an
10 attractive way to get at this thing.

11 DR. BEHLING: John and I guess
12 everybody else, this is Hans Behling. That
13 was the very issue that I was trying to bring
14 out in the Met Lab report in talking about
15 tolerance limits.

16 Just for an example, I went
17 through all series of air concentrations,
18 internal exposures, et cetera, but, for
19 instance, in exhibit 1, which is on page 16 of
20 my report, I cite as one of the examples a
21 tolerance limit that allowed a person at the
22 time of the Met Lab operations to be exposed

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1 for a single day up to 280 microcuries of
2 iodine-131, which based on the dose conversion
3 factors would lead you to have an exposure
4 well over 300 rads to the thyroid. That was
5 one of the limits.

6 And so when we talk about limits
7 in terms of contemporary limits, you have to
8 also realize that those limits have changed
9 over time and especially when you start out at
10 the time of the Manhattan Project, where we
11 talk about limits that, by today's standards,
12 are some -- one of the comparisons I made was
13 air concentration limits that were invoked
14 during the time of the Met Lab, as compared to
15 contemporary limits defined in units of facts.

16 And for some isotopes, the ratio
17 between what was allowed then and what is
18 allowed today was a 50,000-fold difference.
19 So we have to realize that one of the problems
20 we have to encounter when we talk about
21 limits, regulatory limits, as a defining
22 parameter for this 250-day issue is that it is

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1 a sliding scale in terms of time-wise.

2 MS. HOWELL: This is Emily Howell.

3 I just wanted to clarify for the record
4 something that I think everyone in the Working
5 Group understands, which is some of the ideas
6 that you guys are throwing around would
7 require a rule change. And there is nothing
8 wrong with that. I think the Agency is
9 beginning a review process and is open to
10 hearing those.

11 I just want to be clear with
12 members of the public who may be interested in
13 this topic that we are talking about the
14 scientific issues here. And some of them
15 would require regulatory changes.

16 I also wanted to clarify that,
17 again, I think, looking at these questions
18 scientifically is important, but in terms of
19 understanding the terms used in the regulation
20 currently, it is really up to the Department
21 to interpret the regulation and how they want
22 to interpret things like criticality.

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1 But that shouldn't limit your
2 discussion. I just want to be clear with
3 members of the public and on the transcript.

4 CHAIRMAN MELIUS: Any other
5 comments? Anybody think that this is not
6 something worth pursuing?

7 (No audible response.)

8 CHAIRMAN MELIUS: Okay.

9 DR. GLOVER: Hey, Jim, this is Sam
10 Glover.

11 CHAIRMAN MELIUS: Yes?

12 DR. GLOVER: Just since I wasn't
13 when you initiated the Work Group -- and I do
14 want to say that I was very appreciative of
15 John sending this week a very large package of
16 information. It was very, very helpful to I
17 think both Stu and myself.

18 When you set out to -- when you
19 established this Work Group, was it to define
20 your parameters of how you were going to look
21 at the 250 days or to provide guidance to us
22 or --

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1 CHAIRMAN MELIUS: It was --

2 DR. GLOVER: -- to pick up the
3 issue? I just want to know what your --

4 CHAIRMAN MELIUS: It's been a long
5 time, Sam, but it was to provide guidance to
6 you, I think.

7 DR. GLOVER: Yes.

8 CHAIRMAN MELIUS: But it was how
9 to deal with particular sites that got
10 referred to this Committee, where because of
11 the way the petitions were worded -- I can't
12 remember going back but also because of when
13 our review of these places where the SEC
14 classes were granted, that we had concerns
15 about the -- was 250 days appropriate?

16 In some cases, the petitioners
17 raised the issue. I'm thinking of Ames and
18 Nevada Test Site -- I can't remember -- and
19 Met Lab. So it came out of that that it was
20 sort of a continuation of trying to deal with
21 the SECs there based on the petitions but also
22 the idea of trying to come up with an overall

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1 approach, recognizing that there, as Emily
2 pointed out, are some regulatory
3 interpretation issues as well as some of the
4 scientific issues to deal with that.

5 Actually, my next question was
6 going to be, again, going back to something
7 Dr. Ziemer pointed out, though, we usually let
8 NIOSH take the first steps in addressing these
9 issues. I am not looking for a commitment
10 here on the phone, but I think it is something
11 to think about. I think to move this forward
12 on a scientific basis, I think that if NIOSH
13 could develop a sort of background paper or
14 something addressing this issue, are you
15 comfortable doing that and we have provided
16 enough guidance for that.

17 I mean, I guess alternatively SC&A
18 could, but I guess I get a little concerned
19 that, I mean, we usually try to let NIOSH take
20 the first step into this area if we are all
21 agreeing that it is something that is worth
22 pursuing and we are really not reacting to any

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1 other reports or rulings or whatever from
2 NIOSH.

3 DR. GLOVER: This is Sam Glover.
4 That is kind of what I was wondering on the
5 surrogate issue if your guys' recommendations
6 sort of are "Here are some things we thought
7 you may want to consider" and then we
8 responded to that.

9 I apologize. I wasn't part of
10 that and wasn't sure how you went forward on
11 that issue.

12 CHAIRMAN MELIUS: Surrogate was a
13 little bit different in that the Board started
14 to, through a Work Group, develop criteria.
15 Then while we were developing criteria, NIOSH
16 published criteria. We were trying to then
17 get the two to mesh since that time.

18 MR. HINNEFELD: This is Stu
19 Hinnefeld --

20 CHAIRMAN MELIUS: This is why we
21 have been more dealing with specific sites,
22 trying to address this issue, but as part of

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1 that coming up with some sort of overall
2 scheme for addressing it or how it should be
3 addressed in a more general sense.

4 MR. HINNEFELD: This is Stu
5 Hinnefeld. We can tank that option. I think
6 based on the discussion and earlier
7 discussions and the communications that have
8 been shared, I think everybody who has
9 participated recognizes that this is kind of a
10 difficult question to frame or to put down an
11 approach that seems consistent that
12 accomplishes the objective here and still,
13 though, is somewhat consistent with the facts
14 and the intent of the regulation, which says
15 that this is sort of an extraordinary
16 circumstance.

17 So kind of where we are going here
18 is that they are quite likely -- and I don't
19 know that any of us are arguing with this, but
20 there are circumstances other than
21 criticalities, where you have this instants
22 external dose, where you could have sufficient

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1 possibility of harm, as described in this
2 program, as we treat it in this program, so
3 that you would get there in less than 250
4 days. And so there is a lot.

5 You have talked about taking the
6 high road and the low road and all roads lead
7 back to where we started from. So we can try,
8 and we can come up with something. And I
9 would think that we might even put some
10 alternatives in there, like, well, we can do
11 this or we can do this, those kinds of things.

12 I would hope that that would be
13 accessible for our effort, for our product, to
14 not come -- I don't know that we want to come
15 back with a definitive recommendation here.

16 CHAIRMAN MELIUS: An alternative
17 to that, Stu -- and maybe this makes it easier
18 in terms of the regulatory issue -- is maybe
19 we just schedule a Work Group meeting where we
20 would sit down and just go through this. I
21 mean, we all have a framework for it. And
22 maybe we need to put that framework out and

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1 some description of it.

2 But then we would just get
3 together for a day in Cincinnati and sort of
4 talk it through given we've got a lot of
5 background, a lot of facts we have developed
6 already. So I don't think there's a lot of
7 sort of technical stuff.

8 And maybe doing it in that
9 setting, rather than -- then producing a
10 document, appropriate documentation, may be a
11 better way of --

12 MR. HINNEFELD: Stu Hinnefeld
13 again. That would certainly be helpful from
14 our standpoint.

15 CHAIRMAN MELIUS: Yes.

16 DR. MAURO: Jim, this is John
17 Mauro. I just had a thought that goes toward
18 the regulatory-driven philosophy that, as a
19 dimension, as we think about this, I would
20 like to just put it on the table -- what we
21 have is if you were to adopt that approach,
22 the question almost then becomes here we have

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1 a worker who is there for less than 250 days
2 and, therefore, is not included within the
3 cohort that is being compensated who has come
4 down with a particular cancer.

5 And so, all of a sudden, if
6 internal is going to be on the table, dose
7 commitment, the question then becomes for him,
8 was this worker present at a site where a
9 situation existed where the potential for --
10 let's say the iodine story that was just
11 described to us by Hans at the Met Lab. The
12 issue, then, really is only applicable in that
13 circumstance to thyroid cancer.

14 Similarly, one can argue that for
15 a transient, such as the type we have with
16 blowouts at Ames, if we were going to go with
17 that, the situation becomes applicable to only
18 some set of cancers, certainly lung cancer,
19 perhaps others.

20 What I am getting at is one of the
21 dimensions of the discussions and the think
22 piece is, do we start to apply it if we move

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1 down that road and it becomes cancer-based?

2 That is, the person might have
3 been present during a given transient that is
4 documented where we really can't place an
5 upper bound but we certainly know the
6 exposures were high, but it would only be of
7 concern for particular classes of cancer.

8 That is something we have never
9 discussed before. And I think I would just
10 like to put that out as something to entertain
11 as we think through this problem.

12 CHAIRMAN MELIUS: We actually did
13 discuss it. If I recall correctly, the
14 original SEC proposal, regulation proposal,
15 from NIOSH was to do just that, that SECs
16 would be organ-specific.

17 DR. MAURO: That predates my date,
18 though. Okay. I understand.

19 CHAIRMAN MELIUS: I don't think it
20 predates your date, but, anyway, it was a long
21 time ago. Anyway, not in terms of the 250-day
22 issue but overall.

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1 DR. MAURO: Oh, the overall. Yes,
2 yes.

3 CHAIRMAN MELIUS: Overall rem
4 regulation.

5 DR. MAURO: Got you. Okay.

6 CHAIRMAN MELIUS: I think the
7 Board's recommendation was not to do it that
8 way. Again, it doesn't mean we would reject
9 it out of hand or whatever and consider it.

10 I mean, another way of thinking
11 about this is that we are already giving -- I
12 think Dr. Ziemer mentioned this already. You
13 know, we sort of have sort of the threshold is
14 the 250-day threshold or maybe it's you, John,
15 that talked about it a little bit.

16 So I think the other issue is sort
17 of equity. If we are compensating people
18 based on their exposure of 250 days, is it
19 fair to people that in these situations, SECs
20 that would not have worked 250 days but may
21 have had sort of similar exposures to not
22 compensate them and so forth?

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1 Now, I think we think of it that
2 way. Then it's sort of, how do we approach
3 it? The more I think about it, the more I
4 think it may be better just let's have another
5 Work Group meeting in person where we can all
6 get together and spend more time and sort of
7 look through the different possibilities,
8 rather than try to produce, either NIOSH or
9 SC&A produce, another document at this point
10 in time.

11 DR. GLOVER: This is Sam Glover.
12 I think, Stu, we would be happy to participate
13 in that. We would be happy to participate
14 with Stu.

15 CHAIRMAN MELIUS: Hello?

16 MR. HINNEFELD: This is Stu
17 Hinnefeld. I can hear you.

18 CHAIRMAN MELIUS: Okay. Work
19 Group members?

20 MEMBER ZIEMER: This is Ziemer
21 again. I think that is a good approach. We
22 still have some issues such as this specific

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1 new client issue that could be discussed, but
2 to the extent possible, you have to keep it
3 parallel with the existing SEC regs.

4 CHAIRMAN MELIUS: Yes. I say this
5 without getting in trouble with Emily, but I
6 think if we do it -- we are having
7 discussions. And I think we have a little
8 wider latitude in terms of what we are talking
9 about. And then if it requires a change in
10 the regulations, that is something that could
11 be considered.

12 But let's sort of focus on the
13 issue and how we may come up with something
14 that would be workable and fair in this area,
15 rather than trying to produce a report and
16 worry about, well, how does that fit into the
17 regulations or whatever at this --

18 MS. HOWELL: I think to sort of
19 respond a little bit to Dr. Ziemer's concern
20 and Dr. Melius -- this is Emily -- I think
21 that you guys are certainly, the Board is
22 certainly, within its rights, if it determines

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1 that a different framework would be helpful
2 that is not within the rule. You know, you
3 can always send a letter to the Secretary with
4 the results of your work and the basis for it.

5 I know you will be hearing a
6 little more next week about a program review
7 that NIOSH is undergoing. So these kinds of
8 discussions, I mean, I think it is up to the
9 Working Group and NIOSH to figure out if you
10 want to come up with options that are within
11 the rule versus that would require a rule
12 change, but, again, these are questions that
13 our office may have to see kind of what you
14 come up with and figure out.

15 We are not going to be able to for
16 everything necessarily give you an extant
17 answer of whether or not something is
18 envisioned by the rule and would be allowed
19 under the current rule framework.

20 DR. NETON: Yes. That's a good
21 point. What I would see us doing is
22 developing sort of the options or the

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1 approaches. And then they would have to be
2 looked at from a legal issue, regulatory
3 issue, as to whether they fit or not or could
4 be fitted or whatever.

5 MEMBER GRIFFON: Jim, this is Mark
6 Griffon. I agree it would be good to do this.

7 I think it might be useful, too, if we can
8 find the discussions that you reference
9 because I do remember there were discussions
10 early on and discussions around the time when
11 the Board was commenting on the SEC
12 regulation. I think if you find those
13 transcripts and maybe pull them together for
14 the Work Group members all in one spot, it
15 might be useful in terms of not --

16 CHAIRMAN MELIUS: Yes.

17 MEMBER GRIFFON: I feel a little
18 déjà vu in these conversations. So to the
19 extent that we have had some of these
20 discussions, it might help us when we're
21 trying to pull it all together into some
22 policy options.

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1 MEMBER ZIEMER: Jim, this is
2 Ziemer again. Am I online or am I --

3 CHAIRMAN MELIUS: You are online.

4 MEMBER ZIEMER: Okay. I always
5 forget which button I pushed.

6 CHAIRMAN MELIUS: Right. I have
7 the same problem.

8 MEMBER ZIEMER: I might point out
9 I just received this week a letter from
10 Senator Reid. I don't know. Ted, did that
11 get distributed to the Board yet?

12 But, in any event, he specifically
13 requested that the Board take another look at
14 the 250-day issue, in any event. And I think
15 we want to be responsive to that request to
16 the extent possible as well.

17 So I think what Dr. Melius has
18 suggested would certainly in fit in with that
19 request that we got from Senator Reid to
20 address the 250-day issue as well.

21 MR. KATZ: Paul? Paul, this is
22 Ted. I just went off with one of the Board

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1 Members.

2 I did receive that, I think
3 yesterday, late. I was already away out of
4 the office. And I forwarded it to the whole
5 Board by Blackberry, but a couple of times I
6 got failed messages. I don't know whether
7 it's failed to go to everyone or just failed
8 to go to perhaps one Board Member.

9 MEMBER ZIEMER: Well, in any
10 event, we will be distributing that. But I
11 just wanted to point out that we do have a
12 congressional request, actually, to study this
13 issue further. So I think it's appropriate.

14 MR. KATZ: Right.

15 CHAIRMAN MELIUS: It failed to get
16 to me, Ted.

17 MR. KATZ: Okay. Then it probably
18 failed generally.

19 MEMBER ROESSLER: This is Gen. I
20 didn't get it.

21 MR. KATZ: Okay. Then I know that
22 there is no way for me to remedy this without

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1 being out of the office right now.

2 CHAIRMAN MELIUS: We understand,
3 Ted. Thanks. Good.

4 Okay. I think we've reached the
5 end of our meeting. What I will do is when we
6 are in Los Angeles next week, I think we can
7 work on scheduling a meeting of this Work
8 Group. It will be an in-person meeting in
9 Cincinnati. And we will go on from there.

10 I would like to thank everybody,
11 NIOSH and SC&A, for their input and
12 involvement; Dr. McKeel, earlier when we were
13 talking about Dow; and, obviously, the Work
14 Group members. And we'll see everybody in Los
15 Angeles next week.

16 MEMBER ZIEMER: Great. Thank you.

17 (Whereupon, the above-entitled
18 matter went off the record at 12:05 p.m.)

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