

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

convenes the

WORKING GROUP MEETING

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

The verbatim transcript of the Meeting of the
Advisory Board on Radiation and Worker Health
Working Group held at NIOSH, Cincinnati, Ohio, on
Nov. 17, 2005.

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

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

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P R O C E E D I N G S

(9:20 a.m.)

WELCOME AND OPENING COMMENTS
DR. LEW WADE, EXECUTIVE SECRETARY

1
2
3 **DR. WADE:** The work group met yesterday chaired by
4 Mark. It's a work group that works in
5 individual dose reconstructions, site profiles
6 and procedures review, and they focused on
7 Bethlehem and Y-12. Three things happened of
8 note. The work group determined that it will
9 not have need for a Board call on the 28th of
10 November. They need more time for various
11 pieces of deliberation. So their need for that
12 call no longer exists. Whether or not we have
13 that call will depend upon the need expressed
14 by this work group.

15 Just so you know what's going to happen on
16 Bethlehem is that NIOSH and SC&A will be having
17 a discussion of the topic on the 22nd of
18 November, and the work group will schedule a
19 brief call on the 28th of November to try and
20 complete its deliberations in anticipation of
21 making a report to the full Board on Bethlehem.
22 On Y-12 it's going to take a little bit more
23 time. There's information to be exchanged and
24 work to be done. NIOSH and SC&A will have a

1 call on the 19th of December leading up to a
2 work group face-to-face meeting in Cincinnati
3 on the 5th of January.

4 As you recall, we've reserved the possibility
5 of a Board call on the 9th of January, and that
6 work group is anticipating, wanted to have that
7 call take place so that they could report out
8 on Bethlehem and Y-12 to the full Board.

9 Again, this work group has all of its options
10 open to it. That is, a Board call on the 28th
11 of November and/or a Board call on the 9th of
12 January leading up to the full Board meeting in
13 Oak Ridge on the 24th, 25th and 26th.

14 Just as background, the Board is going to face
15 a Y-12 SEC petition at the end of January. The
16 ideal thing from my point of view would be the
17 Board having reached sort of scientific closure
18 on the site profile, and then the Board having
19 a sense of what its responsibilities are when
20 it recommends out on SEC petitions. And that's
21 the purpose of this most important work group.
22 So with that we have also, we've invited an
23 incoming Board member to join us, Brad Clawson
24 is with us, was with us yesterday, and showed
25 himself to be capable of dealing with marathon

1 work group meetings. He did not sleep once
2 during the deliberations so Brad is welcome.
3 As I've reported to you, new Board members will
4 join us in January, but they will not be voting
5 in January. After the January meeting then
6 they'll be fully seated and voting.

7 So Jim, it's all yours.

8 **DR. MELIUS:** Just one question on, when will we
9 see the Y-12 SEC evaluation report? Is the
10 working group going to see that or is that
11 going to more likely be after the site profile?

12 **MR. ELLIOTT:** The site profile review is
13 settled.

14 **DR. ZIEMER:** Could you repeat, the Bethlehem
15 Steel, NIOSH and SC&A will meet face-to-face or
16 --

17 **DR. WADE:** On the phone on the 22nd. That's
18 next Tuesday, I think.

19 **DR. ZIEMER:** And then --

20 **DR. WADE:** The working group is going to hold a
21 call on the 28th. It will schedule it
22 depending upon whether or not the Board has a
23 call, the timing of it. I think we said
24 tentatively 2:00 p.m.

25 **DR. ZIEMER:** Is that one dependent on the

1 outcome of the 22nd or is that --

2 **DR. WADE:** Technically, it is although we feel
3 pretty good about --

4 **MR. GRIFFON:** We feel pretty good they're going
5 to close it out, yeah.

6 **DR. NETON:** I think so, I think so. We're very
7 close.

8 **DR. WADE:** Liz has one comment to make.

9 **MS. HOMOKI-TITUS:** I just want to let you know
10 that OCAS has provided you with the page out of
11 the law that discusses the standards that have
12 been assigned by Congress and also the page out
13 of the regulation that discusses SEC sufficient
14 accuracy as well as the discussion from the
15 preamble of the rule. And although the Board
16 is obviously free to make its decisions how it
17 will, these are the legal requirements that the
18 Secretary will follow, and we wanted to be sure
19 that you had them for your reference at this
20 meeting.

21 That was all, thanks.

22 **DR. WADE:** Okay, Jim, it's all yours.

23 **WORKING GROUP DISCUSSION:**

24 **COMMENT ON SEC RULE**

25 **DR. MELIUS:** When preparing for this meeting, I

1 guess the Board knows this, but we were talking
2 in the cab on the way over. I came across
3 something that actually the Advisory Board had
4 recommended about two and a half or three years
5 ago which I hope is actually should have been
6 the charge for what we're doing today which is
7 some comments on the idea of sufficient
8 accuracy or comments on the SEC rule, I think
9 the second round if I remember right.
10 Therefore, the Advisory Board recommends, it
11 would be helpful if NIOSH would provide
12 additional clarification of this concept of
13 sufficient accuracy. Therefore, the Board
14 recommends that guidelines addressing
15 feasibility and sufficient accuracy be
16 developed, and then it goes on with some more
17 specific things about that being done.
18 But it struck me and others that in dealing
19 with the SEC petitions and dealing with some of
20 the site profile reviews that we've been sort
21 of struggling to come up with how do we, how
22 does the Board evaluate those? And I think my
23 sense is that NIOSH has been, Jim and Larry,
24 your staff has been sort of struggling to
25 figure out what's the best way of evaluating

1 the petitions and then presenting it to the
2 Board so that we make a decision.

3 And for the way that system is set up it
4 probably has to be the way the law's written,
5 we sort of have to make one decision. It's not
6 like, it's not an incremental set of decisions
7 on that. And I actually thought that if we, I
8 mean, originally, I hope I'm describing this
9 right, you sort of did a general evaluation,
10 said yeah, you thought you could do it. You
11 thought if it met the criteria, it could be
12 done.

13 And then as questions came up with Mallinckrodt
14 and some of the others, you sort of did a more
15 detailed, you know, evaluation sort of breaking
16 it down into so I would call it different
17 subclasses. Yeah, you know, we can cover all
18 of these in terms of being able to do
19 reasonable dose reconstructions.

20 But we still, even with that, we were still
21 struggling, and it also struck me that we were,
22 we were struggling both with situations where
23 there wasn't much data, such as Bethlehem. I
24 mean, and that's even though it's a relatively,
25 I won't call it simple is not the right word.

1 But it's not a very complicated multiple
2 exposure situation.
3 But we're also struggling like with
4 Mallinckrodt where we had lots of information,
5 maybe too much in some ways to try to come up
6 with this assessment. And so I thought it was
7 worth trying to go back and now that we've all
8 had experience with a number of cases,
9 experience reviewing individual cases,
10 experience reviewing SEC petitions and
11 evaluations, to try to come back and develop
12 some guidelines for how that would be done
13 because we're not in sync on that completely.
14 And I think if we continue to do it on a, not
15 that we want review individual cases, but we
16 can try to do it sort of a case law approach.
17 You know, let's sort of develop this over time
18 based on our experience with individual
19 petitions that should not take us a long time.
20 It's going to be some long, long meetings, and
21 I'm not sure it's going to be a very productive
22 approach. I don't think it's, in some sense,
23 fair to the claimants because we're there
24 spending hours trying to figure out what to do
25 with these, and so, with these petitions,

1 evaluations and groups of that.
2 So some time put in now to try to develop a set
3 of guidelines that would provide some overall
4 guidance for the process of evaluating
5 sufficient accuracy, evaluating potential SEC
6 situations would be helpful. Jim's going back
7 and looking at the regulations because we just,
8 the problem is I think though is that the, you
9 left yourself a lot of flexibility in doing the
10 regulations which is, may have been appropriate
11 at the time. Who knows? This isn't easy to
12 come up with a simple set of guidelines or
13 numbers or criteria that can be, certainly can
14 be put into a regulation very easily.
15 I think what we need to do given those
16 regulations, given what's in the law, go back
17 and see what can we, how can we sort of flesh
18 that out? Can we come up with better guidance
19 that would help us all, you, in sort of
20 evaluating these, presenting them to the Board,
21 the Board in making a decision on how to go do
22 that.
23 And I don't know if these are a combination of,
24 I think if they're criteria, they have to be
25 criteria that would deal with different aspects

1 of the, of what we, you know, of such different
2 types of situations. It's not going to be a
3 simple one test for everything. And some of
4 them may just be process. What's the best way
5 of you -- you, being NIOSH -- going through and
6 evaluating these situations and determining
7 what is sufficient to present to the Board so
8 the Board can make an evaluation.
9 Because some of the problem I think we have is
10 that we'd have you pursuing so many different
11 avenues, so many different aspects of
12 individual dose reconstruction that it in, what
13 data might or might not be available or how
14 complete or comprehensive or accurate is that
15 data. There's a lot of time spent that is not,
16 just takes a lot of resources to do that. And
17 we need to, I think, be aware of that. I mean,
18 at some point it becomes, we're spending more
19 doing these evaluations in time than given the
20 number of cases that are really in play. To me
21 it doesn't seem to be very worked out
22 especially given all the other things that are
23 out there to do. It's not like there isn't
24 other stuff to do. I'm sure after every
25 meeting Larry must, you must go back and say,

1 well, here was your to-do list, and now the
2 Board's just given you 20 more things to do and
3 a whole bunch of deadlines that aren't any, I'm
4 sure, going to make life easier.

5 **DR. WADE:** Let me just add some observations to
6 frame the issue. I think one of the lessons we
7 learned through the Mallinckrodt process is
8 that while this is a continually evolving
9 process, there comes a moment in time when the
10 Board has to make a decision, and we need to
11 manage that process. There needs to be, I
12 think, some understanding that at a moment in
13 time we will freeze that reality and that will
14 be the reality that the Board will operate
15 against. We can't keep chasing the ever-
16 changing background, and that's difficult. But
17 we need to talk a little bit about that.
18 The other thing, speaking for the NIOSH
19 Director, the reality that he faced after
20 Mallinckrodt which was a program recommendation
21 from OCAS. A close Board vote in opposition to
22 that is not the ideal situation for him to find
23 himself in. Now, if he has to be in that
24 situation, so be it, but I think we need to
25 understand that we do this within sort of a

1 political world. And if our processes and
2 procedures and guidelines could be crisper,
3 that could lead us to a clearer statement of
4 decision. That would be a good thing. It's
5 not a required thing. It would be a good thing
6 though from the NIOSH Director's perspective.

7 **MR. ELLIOTT:** I think that we, a lot of what
8 you had to say, Jim, is, I have a high
9 resonance to, we certainly feel stressed here.
10 Our role is to provide a sound scientific basis
11 in dose reconstruction and compensation and
12 decision. I think it goes to interpretation of
13 sufficient accuracy. I think we need to arrive
14 at a joint interpretation of sufficient
15 accuracy.

16 And I think there's also some advantage to, as
17 you put it, process. And in that regard I
18 think it's important for us to deliver the best
19 scientific products, that they be peer
20 reviewed, that they be examined. And we need
21 to do that in a sequence such that site
22 profiles, we understand where the holes are.
23 You understand where the holes are.

24 We take a position on how we can address those
25 holes, and if that meets your satisfaction,

1 fine. If it doesn't, we understand. But I
2 think that we have to have these site profiles
3 essentially put in the can and on the shelf.
4 And from there we devise a, and develop our
5 understanding of the petition that comes
6 forward relative to a specific site. We can't
7 have them both going forward at the same time.
8 That's not going to be successful for anyone.
9 At the same time we've got to do this in a
10 timely manner. And such a lot of work to be
11 done.

12 **DR. WADE:** See, Y-12 is a perfect example that
13 in spite of the best efforts of the work group
14 and everyone involved, when we look at that
15 petition in January, there will still be open
16 issues on the site profile, so we have to be
17 prepared to deal with it.

18 **MR. ELLIOTT:** I think we also need to be very
19 careful with our interpretations. We need to
20 examine very closely what representativeness of
21 data means. We need to understand perceptions
22 and perspectives about quality of data and the
23 purpose of collecting the data, and program
24 integrity or lack thereof in the performance of
25 that collection of data. And I think there's a

1 lot of things that we haven't talked about in
2 those, in that context, that maybe we should
3 have a discussion. I think it would benefit
4 not only the claimants and the workers at these
5 sites, but it would benefit us as well at NIOSH
6 in understanding how people perceive the DOE
7 practices.

8 **DR. WADE:** Jim.

9 **DR. NETON:** I'd like to maybe take a little
10 step back even further from where Larry was and
11 the issue of the site profiles and their
12 relationship to SEC petitions. It was my
13 thought early on that we would not necessarily
14 require even a profile to do an SEC, I mean, it
15 would certainly be helpful, but it hinges on
16 this definition of sufficient accuracy and
17 maximum dosimetry.

18 I think it hinges on this definition of
19 plausible circumstances is really where we have
20 a disconnect. And to hold the site profile as
21 the judgment point of doing supposed
22 reconstruction with sufficient accuracy, I
23 think it's going to hinder us if we go down
24 that path because we're not going to have site
25 profiles at many of these sites.

1 And then I think the discussion needs to hinge
2 upon the level of data that are required for us
3 to say that we can do something. And Dr.
4 Melius points out a good example of Bethlehem
5 Steel. You know, you don't necessarily have to
6 have the individual monitoring data. You have
7 to be able to describe the process. And then
8 you can get down to a Mallinckrodt that has a
9 lot of data, a lot of profile development, but
10 the process was so complex that we might not
11 have been able to flesh out, at least to the
12 Board's satisfaction, we knew what was going on
13 there exposure-wise.

14 **MR. ELLIOTT:** That's a point well made, and I
15 didn't intend to mean that we had to have a
16 site profile in every case for every position.
17 That's not what we're going to see, but we will
18 have, well, we'll have to articulate how we
19 will treat cases from a site where we don't
20 have a site profile. I mean, utilize the
21 exposure model approach or it's a, you know,
22 what's our understanding of the process and the
23 data and monitoring that were collected for
24 that process, and how we'll use that. And we
25 have to be able to provide that to you in order

1 for you to make a rational decision.

2 **DR. MELIUS:** But it's always going to be hard
3 for the Board to deal with a SEC petition for a
4 site that we've had no discussion on. I mean,
5 NBS and things, those are, but I mean for any
6 sizeable site, it's just very hard to come in,
7 but I mean, can it be done? Yes, but we're
8 going to have to then, I think, have another
9 process for that which is going to be a lot
10 more familiarity with the site and maybe that's
11 the new task for SC&A as sort of what they need
12 to do in terms of evaluation ahead of time for
13 those particular types of sites or something.
14 Just is very hard because all these questions
15 are always out there then, and they haven't
16 been even discussed at all. And you really
17 haven't had time to sort of present and explain
18 the site.

19 And we can't present these sites. And then one
20 of the other just process things I think we
21 have is that it's very hard for the situation
22 in a Board meeting to adequately present all
23 the information that you really need to
24 evaluate, you know, a petition or even a site
25 profile.

1 I mean, I'm hoping with the working groups and
2 subcommittee that we'll develop a set of
3 procedures that will allow the Board to be able
4 to, I mean, so that not all of us have to go
5 through all that time and effort and can rely
6 on different groups of people at times. But
7 we're going to have to have some background on
8 doing that.

9 **DR. ZIEMER:** The reality is in a number of
10 these cases there is or will be a site profile,
11 and you know, one thing we learned from
12 Mallinckrodt was if you take this incremental
13 approach, you have this constant battle between
14 when is enough enough? And have we really
15 finished the site profile? And I think the
16 timeliness issue does impact on the sufficient
17 accuracy at some point. As Lew suggested, we
18 have to freeze it in time. I think in the case
19 of Mallinckrodt that site profile continued to
20 emerge and in a sense, rightly so. You were in
21 a discovery process and yet we were dealing
22 with the petition at the same time.

23 **MR. ELLIOTT:** You were asking us to do best
24 estimate dose reconstructions, and we would
25 have got there had we worked through the cases

1 under that site profile, shown you best
2 estimate. You could have examined dose
3 reconstruction, but we were tasked to try to
4 prove that we could reconstruct dose on every
5 case.

6 **MR. GRIFFON:** That's where it came from.
7 That's where the whole thing came from.

8 **DR. NETON:** That's the whole key issue.

9 **MR. GRIFFON:** What are we asking, how much
10 proof are we asking for? And we have to come
11 to a common understanding on that in the
12 evaluation report. I think what happened is we
13 did it, we did evolve down to asking for
14 example DRs and maybe that's incorrect, maybe
15 that's correct, but let's get it on the table.
16 I mean, when we started there, I think there
17 was a revelation on NIOSH's side too that when
18 you started to examine the initial evaluation
19 report and how you presented the data, I think
20 the dose reconstruct -- you know, and we asked
21 for examples. They said, well, jeez, this is
22 going to be difficult to use this air sampling
23 data in this fashion. We might use a different
24 approach.

25 And so I think the, and when I look at this

1 definition, all these pieces are important to
2 me. Sufficient information, that begs the
3 question that Larry was raising which is the
4 credibility and representativeness of the data.
5 And we've got to come to some matrix and common
6 understanding of that. Maximum radiation dose,
7 it's obvious under, for plausible
8 circumstances.

9 And the last part, in my mind anyway, this is
10 the SEC Rule 83.13(c)(1)(i). It's highlighted
11 in, but the last part says maximum radiation
12 dose incurred in plausible circumstances by any
13 member of the class. And I guess that's where
14 in Mallinckrodt we started to pursue that.
15 Well, you say you can do this for the whole
16 class. Who's in this class? Give us some
17 examples of how you're going to do it for this
18 type of worker or this type of worker. And
19 that's where we ended up going down these, you
20 know the cases, so I guess we have to
21 understand how does NIOSH present and defend
22 that in an evaluation, and if we're working
23 from the same matrix then your initial report
24 will be more of what, we'll both be kind of
25 coming out of the same place.

1 **DR. NETON:** Let me go way back to where I
2 thought where this process started, and
3 Mallinckrodt's a good example because it's
4 already done. But, and we've had some
5 discussion to this extent at the Board
6 meetings. Let's say that we have a lot of air
7 sampling data in Mallinckrodt. And we did. We
8 had, I forget how many, anyway, thousands of
9 air samples. And it was our thinking at least
10 that to bound the exposures, one could take the
11 air sample data at a worst case and use that to
12 estimate the maximum plausible dose to the
13 workers.
14 Now would that at the end of the day be used
15 once? Like Larry suggested we refine these
16 gross reconstructions and got them to be more
17 accurate? Probably not, but at least we could
18 demonstrate up front that that would be a
19 maximum plausible dose to the class of workers
20 whether or not we assumed it was thorium or
21 radium or we'll just pick the worst case
22 nuclide. We have, we believe, a technique or a
23 data set if we could validate the air data that
24 could be bounded.
25 Now, we took some criticism there because those

1 were not called individual dose reconstructions
2 which is something I'd like to explore as well.
3 I'm a little confused about the use of that
4 term in the SEC petition. But that's where we
5 started anyway, and then we started having to
6 ratchet down to where we ended up, well, can
7 you reconstruct the dose for this class of
8 workers, and to show that we could do all the
9 classes.

10 And I felt we were trying to say up front we
11 have a lot of air data, and we know what the
12 maximum dose to anybody was in that facility.
13 I think we did, but was it plausible? I guess
14 that's what it comes down to.

15 **MR. KATZ:** Can I just get some, a little more
16 historical perspective too because, and it sort
17 of relates to what Jim raised. You know, when
18 the Board made its comments, and we responded
19 to those comments with the final rule and also
20 with internal guidelines.

21 And the internal guidelines for NIOSH for
22 dealing with SEC, when the emphasis of that was
23 to, we were to do two things really in
24 addressing the petitions. We would address,
25 there was explicit concerns that were raised by

1 the petition in terms of feasibility, and then
2 beyond that, of course, since given what the
3 rule says about how you determine feasibility,
4 we would do the basics of showing sort of, as
5 Jim just explained, that you can at least do
6 maximum dose or show more.

7 But that really you were just doing a very
8 basic job of showing feasibility, not going
9 down every path that wasn't necessarily raised
10 in the petition. Because, of course, when you
11 get to a big site like Y-12, who knows how many
12 garden paths there are. I mean, there's
13 millions of possibilities and to explore all of
14 those in an SEC petition, you would spend a
15 year just doing the SEC evaluation, or more.
16 So just in terms of historical contents, I
17 don't know how much it will help you for this
18 discussion forward. Really, the emphasis was
19 to address those issues that were explicitly
20 raised by the petition and then otherwise just
21 do a very summary job of showing that in
22 general it appears that we have the data needed
23 to do dose reconstructions here.
24 And that wouldn't foreclose then down the road
25 someone raising, you know, as SC&A digs down

1 and so on as they do their work in reviewing
2 dose reconstructions and finds aha, here's a
3 class at this site. We said we can do dose
4 reconstruction for this site, but here's a
5 class for which we have real issues, and the
6 Board agrees, and it doesn't, and so, you know,
7 you can have a petition that follows -- that
8 finds that there is a class, subclasses of the
9 site that should be added.

10 **DR. MELIUS:** Yeah, but the problem with that,
11 Ted, is that one is, I mean, some of what we
12 need to decide is what is, how much feasibility
13 do you have to show? How wide does that have
14 to be? And I think it'll never be, there will
15 be some maybe some small groups that are,
16 because of individual data or whatever or work
17 area, are not possible. At the same time I
18 think it would be very problematic for this
19 program to have turned down a petition and then
20 end up that a quarter of the people covered in
21 that petition later you couldn't do dose
22 reconstructions on because you just picked the
23 wrong feasibility to evaluate. And you just
24 did such a broad sense of feasibility. I mean,
25 if it's such a sizeable number of that group

1 that is sort of denied, you know, you've done
2 three-quarters of them. You've done whatever.
3 It just would be, it doesn't make sense in
4 terms of efficiency of the process. It seems
5 to me that there's, that we don't want to have
6 to wait until, for everyone until you can't do
7 a dose reconstruction before they become an
8 SEC. And there would have to be some way up
9 front of evaluating that.

10 **DR. WADE:** To go back to your example, Jim, in
11 Mallinckrodt you said we've got all this air
12 data. It's plausible. We can do dose
13 reconstructions for members of the class
14 through the digging of the process so that the
15 raffinate workers emerged. And we basically
16 said, well, we wouldn't use air data to do the
17 dose reconstructions for this class of workers.

18 **DR. NETON:** At the end of the day we did say
19 that.

20 **DR. WADE:** So in retrospect --

21 **DR. NETON:** We went back to it. Yeah, we went
22 back to air data. That was our sort of our
23 safety net saying the air data is the worst-
24 case scenario here, but we were doing more
25 refined dose reconstructions. As Larry

1 suggested, we said, well, show us how you're
2 going to do a dose reconstruction for a person
3 working with radium. Well, we'll pick radon,
4 and we'll do that. If you didn't have that
5 radon data, we would have always gone back to
6 the air data and said the air data are the
7 bounding values for this class of workers.
8 That's what we were thinking. I'm not saying
9 right or wrong. I'm just saying that was our
10 thinking.

11 **DR. MELIUS:** Another thing I'd like to throw
12 out because I think it's relevant to how we're
13 approaching both the individual dose
14 reconstructions as well as these, and that's
15 the whole issue of where we don't have adequate
16 data or complete monitoring data or whatever,
17 we sort of keep increasing the amount of error
18 we -- in our estimates and so forth. We do
19 that in claimant friendly.

20 And claimant friendly becomes sort of the
21 default way of dealing with a lot of the
22 imperfections of the data and so forth. And at
23 some point it just seems to me in this process,
24 both from the site profile as well as the SEC,
25 we just keep adding a lot of error to the

1 estimates and the bounds keep getting bigger
2 and bigger. And at what point does that, I
3 mean, and then --

4 **MR. ELLIOTT:** Where's the line of plausibility?

5 **DR. MELIUS:** -- yeah, where's the line of
6 plausibility? And also the fact that you add
7 it to one term and then you add it some place
8 else. Well, and this came up with where we
9 started to do the individual dose
10 reconstruction reviews. I mean, SC&A was
11 criticizing you for, well, you weren't claimant
12 friendly here. And you said, well, we can't be
13 claimant friendly every place. Well, then
14 where's the line?

15 I mean, how claimant friendly should you be,
16 and if we keep, if the answer to all our about,
17 you know, criticism of a particular how you're
18 dealing with progression or SC&As or whatever
19 is to just becoming more claimant friendly. At
20 some point that becomes, I don't want to say
21 absurd, but it seems to be defeating the
22 purpose of, you know, that's not an individual
23 dose reconstruction either if it's, you know --

24 **MR. ELLIOTT:** I guess we'd have to have a
25 discussion about just that, claimant friendly

1 or benefit of the doubt and what each of those
2 claimant favorable assumptions add or impact on
3 a dose reconstruction and a decision on
4 compensation.

5 By and large our opinion here is by and large
6 the probability of causation at the 99
7 percentile is the most claimant favorable piece
8 in this whole process. It weighs the most. It
9 has the most impact. And what we're doing when
10 we talk about ingestion models and these other
11 things, we're only tweaking that. And I think
12 we need to do a better job in our conversations
13 and talk about the degree of impact these
14 claimant favorable assumptions really have or
15 don't have.

16 **DR. NETON:** I think there's a slightly
17 different issue that I think Dr. Melius is
18 bringing up, but it's the use of the 95th
19 percentile that is consistently recommended by
20 SC&A versus the use of our best estimate of
21 what that really was, and then assignment of
22 some uncertain distribution. And you're
23 absolutely right. If we don't know, we're
24 going to open that distribution, but the nice
25 thing with Monte Carlo model is that you don't

1 end up compounding 95th percentile, 95th
2 percentile, which is where we're heading with
3 some of these suggestions by SC&A which is
4 relevant to sufficient accuracy. And we would
5 prefer to use the full distribution and then
6 let the uncertainty take care of itself in the
7 analysis. And as Larry suggested, the 95th,
8 99th percentile is where the metric is for
9 condensation.

10 But the problem with that is if you look at it
11 on surface is the uncertainty in the dose
12 estimates are relatively small compared to the
13 overall uncertainty of all of the risk models.
14 So by increasing the uncertainty, and SC&A
15 knows this very well, does not necessarily do
16 much at the end of the day for moving that 99th
17 percentile. But I would suggest that that's
18 part of the issue. It is what it is.

19 **DR. ZIEMER:** I have a question. As I look at
20 what the rule itself says, in essence, it seems
21 to be saying that this is what NIOSH believes
22 sufficient accuracy means, and it describes
23 that. I guess the question I have is, in fact,
24 from NIOSH's point of view, is this really an
25 adequate description or in your mind are the

1 things we're talking about holes in the system
2 as you still see it?

3 I mean, at the front end of this, going into
4 this when the rule was established, I think you
5 felt you had a pretty good feel for what the
6 term meant, at least philosophically. And
7 that's what the attempt was to describe that
8 here. It says, "radiation doses can be
9 estimated with sufficient accuracy if," and
10 then it describes the conditions. So I think
11 going in the front end you felt that this was,
12 in essence, the description or the definition
13 of sufficient accuracy. Is that not correct?

14 **DR. NETON:** That's correct, and in the context
15 of a hierarchical approach that we outlined.

16 **DR. ZIEMER:** Right, my question really is, is
17 this, and it's a kind of a philosophical
18 statement, but is it in your mind sufficiently
19 specific to actually apply it in cases, or is
20 it just a fuzzy framework?

21 **DR. NETON:** I think it's hard to define, but in
22 application I think it works. It's my opinion
23 that if you look at the hierarchical approach
24 of data that we've allowed for in dose
25 reconstruction which starts with the best

1 quality data, the individual monitoring data,
2 working its way all the way through down to
3 source term.

4 So if one is looking at a population for SEC
5 and we're saying, well, do we have individual
6 data? No. Do we have air data? No. Our own
7 dose reconstruction regulation will allow us to
8 eventually end up at the source term and say,
9 well, do we have any knowledge of the source
10 term and can that be used to bound and create a
11 maximum exposure for this situation. So you
12 sort of end up applying it in that manner, and
13 if you have any of those, it could allow you to
14 do them.

15 Now in some cases I agree. The source term is
16 not a really good metric for a very large,
17 messy facility, but let's take a more limited
18 example. A person working with a couple grams
19 of uranium and they're grinding it. The source
20 term alone might be sufficient to put a
21 bounding estimate on it. So you almost have to
22 do it individually, but I think we need to
23 think about it in terms of the four data sets
24 that we have access to to do these
25 calculations.

1 And every step of the way not saying, do we
2 know this accurately? Can we bound it? Is
3 there enough information available to bound the
4 exposure of those workers? I think Bethlehem
5 Steel is a good example of that. Is there
6 enough information to legitimately bound if the
7 exposures are less than X? Now it might not be
8 satisfying to say that everybody's going to get
9 that X, and that's maybe what we're talking
10 about here because we end up saying a one-size-
11 fits-all model might not be very satisfying,
12 but that's where we would end up under this
13 structure.

14 **MR. ELLIOTT:** Working this closely, I think
15 this is a good framework and we are applying it
16 as best we can. We're learning about its
17 ability and utility and how we do use it here.
18 Where it says plausible circumstances, I take
19 you back to Bethlehem Steel, and we just don't
20 think it's plausible that they could be burning
21 the cobbles out. We took a stand on that. I
22 think we have to look at these things.
23 Mallinckrodt, reliability of data, we didn't
24 examine as closely as we should have in the
25 early years. And I think we learned from that

1 experience, and we will examine more closely
2 issues of reliability.

3 **MR. GRIFFON:** And that's where I think if we as
4 a group can come up with, I broke that whole
5 definition out into two sort of points that I
6 think we need to better come to grips with as
7 a, on all parties involved. And that is the
8 sufficient information in the first part of the
9 definition. What's sufficient information?
10 That talks about reliability, credible data, et
11 cetera.

12 Everybody has their own sort of subjective view
13 of that. If we can start to try to better
14 define that and get closer, I think that would
15 come a long way to what you come to the Board
16 with in the first evaluation report, and then
17 we don't have to keep, you know, picking at it.

18 **MR. ELLIOTT:** But what is sufficient?

19 **MR. GRIFFON:** And then the second part -- I'm
20 not ready to define that necessarily, but the
21 second part is that maximum plausible or
22 maximum radiation dose under plausible
23 circumstances for any member of the class and
24 that, again, I'll emphasize that because that's
25 part of the reason we started, I think, going

1 after the individual DRs because, you know,
2 Jim, you had a lot of data at the beginning
3 with a couple ratios, but we said are you sure
4 you bounded that for, you know, you're saying
5 you're going to bound it. But without looking
6 at all those different workers, how can we, how
7 are we assured of that? How are we certain
8 that we got the maximum plausible?

9 **DR. WADE:** Just to emphasize what you're
10 saying, I think history has taught us one thing
11 relative to Paul's question. This is an
12 interesting framework, and reasonable people
13 can disagree about decisions within this
14 framework. And I think that demands more
15 specificity about this framework. I think it's
16 a good starting place, but it hasn't worked the
17 way it was intended to work. And therefore, we
18 need to bring more clarity to it, and Mark is
19 sort of pointing a way to do that, and I think
20 that's the way we should --

21 **MR. GRIFFON:** Probably we all need a real, real
22 world example, too.

23 **DR. NETON:** I think Mark's hit the nail on the
24 head here with this first bullet on sufficient
25 information because there's a pattern emerging.

1 I mean, we started with the data validity issue
2 at Mallinckrodt which was raised by the
3 petitioner and correctly so. You know, we had
4 to go back and with some pain, go back and try
5 to show that the data were not tainted or
6 biased or whatnot.

7 And we need to do that, I think, before we can
8 do what I suggested is this hierarchical
9 approach is say what we have air data, I think
10 you're absolutely right. We need to present
11 the Board with an analysis that says not only
12 do we have air data, but we've looked at it in
13 sufficient detail to feel comfortable about it.
14 I don't think, and I think there's been an
15 approach early on (unintelligible) examples so
16 how can that not be sufficient?

17 And I hear loud and clear now. I've learned
18 that lesson. Those numbers of samples need to
19 be quantified. So I think I like the first
20 step you've mentioned here which is sufficient
21 information. Then we can talk about whether,
22 if we have that information, and we have
23 determined that it's quality data --

24 **MR. GRIFFON:** As I was just thinking on this
25 when I think of it, I think of credible, valid

1 and representative in sufficient information.
2 Now I think each one of those needs more
3 discussion, but those are kind of the things
4 that come to mind when I think about that. And
5 the representativeness I think ducktails with
6 the second part of that definition. It's just
7 representative for the class at hand.

8 **DR. WADE:** There's credible, valid, what was
9 the third?

10 **MR. GRIFFON:** Representative.

11 **DR. ZIEMER:** If I could follow up. I, the
12 point -- I want to get to is that if we can get
13 agreement that the framework is still okay and
14 simply needs some fleshing out or some
15 specificity, it seems to me at this point it's
16 important at least to go back to the starting
17 point and say is that still the right starting
18 point for this. Is this still okay? If it's
19 not then there's no point in getting into a lot
20 of detail if we're operating off the wrong
21 framework. So that's really the nature of the
22 question I'm asking.

23 **DR. MELIUS:** Well, I would approach it
24 different because --

25 **DR. ZIEMER:** I know, we can't change the

1 framework but we can ask that question. It
2 wouldn't have to be a --

3 **DR. MELIUS:** I don't think the framework is the
4 proper framework, but I still think we should
5 work that way because I think we've got to
6 figure out where, how far we can take this
7 framework. Does it get us into a reasonable
8 place, and by putting guidelines out there and
9 coming up with some process and procedures I
10 think we can, you know, let's see what we can
11 go with that --

12 **DR. ZIEMER:** If we can do it within the current
13 framework that's more desirable.

14 **DR. MELIUS:** Right, and then if we find it's
15 not something, just isn't going to work because
16 of the framework or whatever, then you start
17 talking about whether you change the framework.

18 **DR. WADE:** I think that's the pragmatic
19 approach to take.

20 **DR. MELIUS:** Yeah, and do that.

21 **MR. GRIFFON:** I guess the, I mean, the other --
22 and I sort of agree with what Jim said. I'm
23 not thrilled with the framework, but I was
24 trying to how can we work policies out within
25 this framework was what more what I was

1 thinking of. But one thing I've been troubled
2 with is this -- and this goes back to the DR
3 estimate idea, is that in the current framework
4 -- and I'm not suggesting that this is what's
5 happening, but maximum plausible you could just
6 say well, let's throw out this huge number, and
7 we think this is plausible. This will cover
8 everyone at this site, not necessarily going,
9 but there's no -- the petitioners are saying
10 can you reconstruct all our claims within, all
11 the people in this class, can you reconstruct
12 dose for all the people in this class? That's
13 the gist of this. That SEC rule requires this
14 sort of evaluation as to whether you can
15 calculate a maximum plausible for any member of
16 the class, but there's no connection back to
17 the DR. So there -- I guess here's what I'm
18 looking for more information in that evaluation
19 report is because I don't want to, you know,
20 you could say well, we know we've got all this
21 data. We know, okay, Mark's got a concern
22 about this. We'll bump that number up a little
23 higher. Is that maximum enough, Mark? Okay,
24 now it's maximum enough to answer an SEC
25 petition, and then when all the DR plans are

1 done, now we sharpen the pencil, and we go down
2 and --

3 **DR. NETON:** Well, that's exactly the issue.

4 **MR. GRIFFON:** But that's -- right, that is an
5 issue, and these two, the regs are not
6 connected in any fashion.

7 **DR. NETON:** But the SEC --

8 **MR. GRIFFON:** And they're not intended to be, I
9 know.

10 **DR. NETON:** Exactly, see, I think that, you
11 know, I've complained -- I don't think complain
12 is to use the right word at the Board meeting.
13 Well, if you want us to do all the dose
14 reconstructions to prove we can do them for the
15 SEC, then why are we here? Why are we doing
16 them? But let's take Bethlehem Steel as
17 another good example again, maximum plausible.
18 We've adopted a position where the 95th
19 percentile of the highest exposed workers is
20 going to be used as the maximum plausible dose,
21 and we've applied that to all 400 or 500 cases.
22 I sense that people are okay with that. I
23 haven't heard that this is not reasonable, and
24 that's what we've done, and we would do that --

25 **MR. GRIFFON:** That's Bethlehem Steel, right?

1 **DR. NETON:** Yeah.

2 **MR. GRIFFON:** So with a site profile --

3 **DR. NETON:** It's a site profile, but what I'm
4 saying though is let's --

5 **MR. GRIFFON:** -- which is driving individual
6 DRs.

7 **DR. NETON:** -- but let's say that we were doing
8 this, let's say that it was an SEC evaluation
9 for another uranium facility. And we said,
10 well, we have access to air sample data. We're
11 going to use that. We could at least do it
12 this way. We haven't done all of our homework
13 and found out whether we have all these urine
14 samples where everybody's at least as high as
15 this. Is that acceptable to answer the SEC
16 question?

17 See, we would say that we don't feel that we
18 need to go back and pull the thread all the
19 way. We'd just have to need to show that we
20 know enough about the site to put that upper
21 bound. It's easier with a uranium facility
22 because you don't have the unique mix of the
23 raffinate.

24 **MR. GRIFFON:** Much easier.

25 **DR. NETON:** But I like to think in simple

1 terms, and that's what we've done. I mean,
2 we've done that for one facility, and I think
3 it works. So I'm not sure, you just have to
4 show that it's a maximum plausible; I guess is
5 what we're saying. I mean, I agree, we can't
6 pick a number out of the air and say,
7 (unintelligible), but we can surely say the
8 dose was less than 500 rem because people would
9 be dead, you know, or something like that.

10 **MR. GRIFFON:** But for all members of the class,
11 and I think at the end of the day at
12 Mallinckrodt, did some doses get higher? I
13 mean, was the maximum plausible higher than
14 your initial evaluation report by the end of
15 the day? That's a question actually I'm not
16 even sure of the answer. But I know that we
17 had this additional thorium issue at the end.

18 **DR. NETON:** Right, that would hinge on whether
19 or not we assume the thorium was the
20 controlling radionuclide using the air sample
21 data. See now if we would have said the
22 maximum plausible dose is thorium 230 exposure,
23 we're going to assume all the air samples with
24 thorium 230 at 95th percentile, I would suggest
25 that that's a maximum plausible dose for that

1 workforce, internal dose anyway.

2 **MR. GRIFFON:** I guess my question is without
3 going down that path and examining those
4 smaller subsets for every member of the class,
5 any member of the class, and you know, we can
6 define that by buildings, by job category, you
7 know, it's not every individual claim.

8 **DR. NETON:** I think I know where that comes
9 from.

10 **MR. GRIFFON:** I think your evaluation
11 conclusions, I think it changed.

12 **DR. NETON:** Well, I don't think it did.

13 **MR. GRIFFON:** Your maximum plausible was the
14 same in the first report as it was in the final
15 report?

16 **DR. NETON:** We didn't, the first report didn't
17 have any dose calculations. That's the point.
18 I mean we suggested that we would use air
19 concentration data or urine data whichever were
20 the higher for any worker. And so if we used
21 the air concentration data, we would have been
22 the highest dose. I mean, the dose
23 reconstruction were refined for a different
24 scenario. I mean, you were asking for refined
25 doses.

1 **MR. GRIFFON:** But at the end of the day, Jim, I
2 thought when we examined and we decided we
3 couldn't determine who had which job so you
4 ended up always using that thorium model, and
5 it was going to be a worse case and the doses
6 were higher. You know, if you had said we were
7 going to use urine, and we had job titles, I
8 think the doses would have been lower, the
9 maximum plausible doses that you --

10 **DR. ZIEMER:** Had you done the --

11 **MR. GRIFFON:** -- had you done, and that's all
12 I'm saying is without examining a little
13 further, and I'm not sure where that line is
14 either. I know you're right, we can't, you
15 know, if you're going to do every case in the
16 class, you might as well as well just do dose
17 reconstruction, right?

18 **DR. NETON:** But let's say that we did identify
19 up front at the beginning thorium 230 as the
20 limiting nuclide, and we said we have 10,000
21 air samples, just theoretically. And we know
22 pretty well that all the messy operations were
23 covered by these air samples. Is that maximum
24 plausible in your mind to answer an SEC
25 question?

1 **MR. GRIFFON:** See, that's with the benefit of
2 hindsight, I guess because I don't know that
3 thorium 230 was --

4 **DR. NETON:** Well, let's say it was. Let's say
5 we identified the most controlling nuclide.

6 **DR. ZIEMER:** But you're asking a priori do they
7 know if that really is the controlling nuclide.

8 **DR. NETON:** Well, we need to demonstrate that.
9 I guess, that's what Mark is saying, I think,
10 is how do we demonstrate maximum plausible
11 without going through individual --

12 **MR. GRIFFON:** Well, without going through every
13 individual dose reconstruction --

14 **DR. NETON:** That's the question because --

15 **MR. GRIFFON:** -- just try to define it better.

16 **DR. WADE:** The Board process in reaction to
17 your original proposal brought some
18 understanding to you that had you make some
19 modification. There again, does it need to go
20 all the way to doing individual dose
21 reconstructions for everyone? No, but there's
22 a certain amount of probing that was useful in
23 the process, and it would have been better if
24 we had brought that to the Board originally.

25 **DR. NETON:** Well, the original SEC -- I didn't

1 pull it out, but it said we had a lot of air
2 sample data that we can use to reconstruct
3 doses. That's what we said basically. And the
4 Board said, well, show us how you're going to
5 do that. So we did some examples.

6 **MR. GRIFFON:** Well, first, I think we have to
7 examine this with sufficient information, the
8 data, and then we ask for examples.

9 **DR. NETON:** And see, into our, what we did with
10 that though is we actually tried it, you know,
11 because the regulation says not only do you,
12 for a maximum or better I think is some
13 language they used, put a maximum cap on it or
14 do better than that. And so we had some
15 examples in there that showed how we thought we
16 could do better that may have had some flaws in
17 them because they didn't identify this thorium
18 230, but the maximum air concentration still
19 was bounding. I think if we stuck with that
20 approach --

21 **DR. WADE:** But we didn't say in the beginning -
22 - This is just to try to make it better the
23 next time. We didn't come to them in the
24 beginning and identify the thorium issue as a
25 key issue in the basis of our statement of

1 maximum plausible.

2 **DR. NETON:** Right, but I think as Larry
3 suggested, we would have been there when we
4 started doing dose reconstructions.

5 **DR. WADE:** See that's the issue that's --

6 **MR. GRIFFON:** -- We need to make our decision
7 on this --

8 **DR. WADE:** -- You say and trust us, we would
9 have got there. I say this was the value we --

10 **DR. NETON:** I understand. I understand.
11 You've got a point, a very good point.

12 **MR. GRIFFON:** I'm not trying to relive
13 Mallinckrodt.

14 **DR. WADE:** But Mallinckrodt has a lot of good
15 information.

16 **DR. MELIUS:** I'm sure we spent enough time on
17 it.

18 **DR. WADE:** But if these guidelines would put
19 you in a position to bringing that full story
20 to the Board originally in your SEC evaluation
21 report, that would be a good thing.

22 **MR. GRIFFON:** And I guess we've got to come to
23 an agreement of how full a story do we need.

24 **DR. NETON:** I keep harping on the air data, but
25 usually we're going to have air data over

1 bioassay for a lot of these earlier facilities.
2 **DR. WADE:** And just to finish, and when they're
3 probing and poking causes us just to say, oh,
4 well, take a look at it from this perspective,
5 then we have a credibility problem. Then all
6 of a sudden in playing this out in front of the
7 public, you know, exacerbates that problem so
8 the question is how do we get it right the
9 first time.

10 **DR. DeHART:** I was not attending that meeting,
11 but I had the opportunity and took it to read
12 the total transcript of the discussions that
13 went on. I read them twice. You've touched on
14 this issue, but in reading it what came across
15 to me that was the most important thing toward
16 the end was the mention of time.
17 Commonly it came up, these people have waited
18 long enough. They're -- and here we're going
19 to have to go over it again, and that came to
20 an end. And I think we can't lose sight of
21 that. But there were technical issues
22 certainly, but people felt pressured to make a
23 decision, at least some did. And when you read
24 through it that became the overriding factor.
25 **MR. GRIFFON:** I think we all felt that pressure

1 to leave that meeting with a decision one way
2 or the other. And there is part of the statute
3 says feasible.

4 **DR. ZIEMER:** Do you know where that is, Liz?

5 **MS. HOMOKI-TITUS:** No, I'll find it for you.

6 **DR. WADE:** But the way to deal with that
7 timeliness issue is when we cover -- when NIOSH
8 comes the first time, we need to make as
9 complete and definitive a presentation within
10 the framework of this Board's expectation as
11 possible and then let the process start there.
12 We started two or three steps earlier than
13 that, and we paid for it. And now Mark wants
14 to lead us to an understanding of what that
15 full presentation means, and that's really what
16 we need, as much guidance as possible.

17 **MR. GRIFFON:** You call on me to lead this. I'm
18 not ready to lead.

19 **MR. SUNDIN:** I realize we didn't give you a
20 full copy of the rule, but 83-13 --

21 **MS. HOMOKI-TITUS:** Dr. Ziemer, Emily went
22 upstairs to search electronically for it.
23 She'll bring it --

24 **DR. ZIEMER:** There's a section of a preamble on
25 feasibility of dose reconstructions timeliness,

1 cost and availability of records.

2 **MR. SUNDIN:** If you look at 83-13 B.

3 **DR. ZIEMER:** What page is that on?

4 **MR. SUNDIN:** Three 0783.

5 **DR. ZIEMER:** Determine that records and
6 information requests will be (unintelligible)
7 timely basis.

8 **MR. GRIFFON:** I think the question of feasible
9 in the statute though is feasible to estimate
10 with sufficient accuracy, we've come back to
11 that phrase about a million times. But that's
12 the other sort of, that's something that I have
13 to admit is stuck into my mind while I'm
14 looking at your evaluation reports is, okay, we
15 have to consider that feasibility so I think --
16 maybe I'm wrong, Jim, but I think we learned
17 something, too, on Mallinckrodt on the
18 feasibility side from your program standpoint.
19 And that was that using that year-end data, or
20 using the air data, I think it was the issue of
21 using the air data it was going to become --
22 not that it was not doable, but it was going to
23 become very complicated, people moving from job
24 to job or area. You had very specific job
25 information, very specific air information, but

1 from the practical standpoint of reconstructing
2 an internal dose to take all of those metrics
3 and carry them through was going to be a lot
4 more cumbersome than using a distribution of,
5 you know --

6 **DR. NETON:** Right.

7 **MR. GRIFFON:** -- I think --

8 **DR. NETON:** We would have ended up with a 95th
9 percentile --

10 **MR. GRIFFON:** -- yeah, so if we were to
11 evaluate that first report, again in hindsight
12 here, but I mean, there's a question of
13 feasibility there because that, to do it job
14 title at a time, you know, I remember earlier
15 comments. We don't want this to become a
16 research project, and that could have really
17 been a, you know, research effort.

18 **DR. NETON:** And we did learn because we made
19 statements many times that we have a lot of job
20 title information, we can position these
21 people. At the end of the day we found out
22 that it was a lot harder to do than you really
23 would think a priori.

24 But that, and we would have ended up eventually
25 probably at the 95th percentile of the air

1 sample distribution and said we don't know
2 where these people were, but we will pick this
3 as representative.

4 **MR. GRIFFON:** No, right, I'm just pointing that
5 out as part of a feasibility question is we
6 don't want these to become --

7 **DR. NETON:** In the feasible sufficient accuracy
8 as we said before really is are we going to
9 deny, is anybody really going to be denied
10 because we don't have enough information here
11 to make a valid decision as to what their
12 maximum dose was. And we always feel
13 comfortable when we make these claimant
14 favorable decisions in the 95th percentile that
15 no one is going to end up being denied in our
16 estimation because we lacked enough information
17 for labor to make that decision.

18 **MR. ELLIOTT:** I think feasibility in that sense
19 though speaks to application and economy. I
20 mean we would only be doing that, I believe, on
21 a small, small number of cases as we've seen in
22 our experience.

23 **DR. NETON:** For the unmonitored worker.

24 **MR. ELLIOTT:** Certain types of cancers and
25 certain monitoring or lack of monitoring

1 experience that's where you find yourself. It
2 wouldn't be -- maybe I'm wrong in thinking
3 you're working with feasibility --

4 **DR. NETON:** Well, what happened with
5 Mallinckrodt is we had a lot of uranium data
6 where we could assign those doses and radon,
7 but the unmonitored thorium source term, we had
8 no monitored data for the thorium so we would
9 have had to rely on the 95th percentile of the
10 air sample data. And that really increased the
11 uncertainty a lot.

12 **MR. GRIFFON:** But I guess that when we as a
13 Board, you know, deliberate on your evaluation
14 report, we have to consider whether dose
15 reconstruction, whether it's feasible to do
16 with sufficient accuracy. So then when you,
17 you know, if -- and I'm not saying this was the
18 case in anything you presented. But if you
19 came in and said we've got 100,000 air samples.
20 They're real high. We're going to assume 95th
21 for everybody, and we, you know, oh, yes, but
22 it's got these other isotopes, and we're going
23 to adjust for that. We've got factors, but
24 trust us. We can do it. How do we evaluate
25 feasibility at that point? We really can't

1 because there might be that you have a lot more
2 research to do and we don't even know. That's
3 what I'm --

4 **DR. NETON:** I understand. With the raffinate
5 source term, and you know, there are some SECs
6 coming down the pike that are going to have
7 similar issues.

8 **DR. WADE:** We're going to see that in Y-12, I
9 think.

10 **DR. NETON:** And we're more sensitive to that
11 now that we need to have nailed down the
12 exposure for all the radionuclides, not just
13 the ones where we have a lot of monitoring data
14 for. There was sort of this prejudgment made
15 at times, and we need to be careful we don't do
16 that, that they monitor the nuclides that were
17 the most likely to have potential impact on
18 dose.

19 **MR. GRIFFON:** And I'm not criticizing at all.
20 I'm just, I think we're all learning. Through
21 Mallinckrodt we learned a great deal so...

22 **MR. ELLIOTT:** Typically, you kind of lead us to
23 earlier, Mark, on trying to come up with
24 criteria around sufficient information and
25 appreciate your thoughts on what would be

1 credible, valid and representative.

2 **DR. WADE:** Let's look at where we are. Mark
3 has brought us to the point that in this
4 universe of sufficient accuracy maximum dose
5 plausible, when he expects NIOSH now to stand
6 up when it makes that argument and have three
7 prongs to its argument. And that is, is the
8 data that you make that judgment on credible;
9 is it valid; is it representative? That's the
10 most we have at this point. And then he wants
11 us to deal with the fact that it will be
12 applied for any member of the class. That's
13 what we've got. Is that, is that what we go
14 from?

15 **MR. GRIFFON:** How do you defend the position
16 that it's maximum plausible?

17 **DR. MELIUS:** Again to be practical, I think,
18 you know, if we went from there, if we go from
19 there, let's see then what it doesn't get us.
20 I mean, I actually think the representativeness
21 is actually the hardest one because in
22 Bethlehem representative is somewhat simple. I
23 mean, but we get into these other situations,
24 we have different occupations, people moving
25 onto sites, much more complicated exposures,

1 and so forth. Then what's representative for
2 different people can vary. I mean, it just
3 gets --

4 **MR. GRIFFON:** I guess in my mind I started with
5 the, just that simple, you know, we've got
6 100,000 samples. Well, what if your class
7 isn't even represented by those samples?
8 That's the simplest --

9 **DR. NETON:** You can pick a facility that's more
10 complicated, that has different degrees of
11 enrichment of uranium, and different isotopes,
12 and different processes, and a more diverse
13 workforce.

14 **MR. GRIFFON:** And this gets to the question of,
15 and I think we've tried. I was actually, I
16 think I was looking at this issue strongly with
17 Mallinckrodt is can we split the, and you know,
18 we found that it wasn't very easy to split out
19 a class of --

20 **DR. NETON:** Well, I think we better define the
21 class definition, but could we identify those
22 workers unique to that class?

23 **MR. GRIFFON:** Yeah, that's in there.

24 **DR. WADE:** So let's start with Mark's
25 construct. So we've got credible, valid,

1 representative, any member of the class.

2 What's the gold standard on credible?

3 **DR. NETON:** I think we did a pretty good
4 discussion on that yesterday with the
5 evaluation as far as we've heard a couple times
6 now that NIOSH needs to validate the data, the
7 database that we're using. We'll start with a
8 large database, and we'll say we have 10,000 of
9 X. And the comment's been made several times,
10 how do you know it's valid? And I think to
11 some extent I have a better handle on that
12 about the pedigree of the data, where it came
13 from, who touched it, how far removed is it
14 from the raw data, and have you followed that
15 trail to some degree to give yourself comfort
16 that any adjustments that were made are, can be
17 defended.

18 **MR. ELLIOTT:** I see no trends of that.

19 **DR. NETON:** We don't want to make a research
20 project out of this either, but I do agree that
21 we need to have some comfort that we've
22 independently looked at the dataset and didn't
23 take it at the face value because we're not in
24 the business of reconstructing large datasets.
25 We'll take the Center for Epidemiologic

1 Research data or the Health (unintelligible)
2 Energy and Research Branch data and say these
3 are the data we're going to use. But I've
4 heard a couple times now, you can't just do
5 that. You need to critically look at it to
6 some degree.

7 **DR. WADE:** I guess so at this point for
8 credible we want to seek pedigree. We want to
9 deal with issues of chain of custody: who's
10 held the data; what they might have done. And
11 then we want some demonstration of internal
12 consistency?

13 **MR. HINNEFELD:** Most of yesterday's discussion
14 was about a database that's been compiled in
15 existence in terms of those things.

16 **DR. NETON:** Well, that's what I'm talking
17 about.

18 **MR. HINNEFELD:** What about the individual
19 record the Department of Energy sends us? The
20 individuals, I mean, the large fraction of dose
21 reconstructions depend upon the individual's
22 exposure record that the Department of Energy
23 sent to us. Is there a presumption of
24 credibility in that data? And if there's not a
25 presumption of credibility in a personal

1 monitoring record, what are the options for
2 establishing its credibility and its validity?

3 **DR. NETON:** We've had comments to that extent
4 before like how do you know that the technique
5 is accurate that they used. We're going
6 through that with Rocky Flats right now. What
7 is the detection limit of a measurement of
8 Rocky Flats? We all know that they used
9 (unintelligible) and certainly a chemical.

10 **MR. HINNEFELD:** Well, I mean there are certain
11 things you can define like that. I mean you
12 can understand how well they did bioassay. You
13 can understand how well they did dosimetry
14 largely by knowing what technology they used.
15 But the other matter is the numbers we get have
16 been recorded and placed in this person's
17 exposure record by the Department of Energy,
18 and they provide that information to us. And
19 while we can determine how well do they do
20 bioassay or how well do they do dosimetry and
21 make judgments and adjustments appropriately,
22 is there a presumption other than those
23 adjustments that the exposure record is
24 sufficient and has a sort of a de facto, maybe
25 not perfect. There may be -- and I don't want

1 to say for all science or in all cases, but
2 absent information to the contrary, is there a
3 sort of presumption that there is some
4 credibility there or at least sufficient
5 credibility so that the adjustments that are
6 made for misdose and other adjustments that are
7 made during the dose reconstruction process
8 will count for a credibility or a validity
9 problem there, absent evidence to the contrary.

10 **MR. GRIFFON:** So I have an answer.

11 **DR. ZIEMER:** So you don't have at this point an
12 established methodology for answering that
13 question I guess.

14 **MR. HINNEFELD:** I think as a general rule it's
15 pretty common that absent evidence to the
16 contrary there is a presumption of validity.

17 **DR. ZIEMER:** Let me ask a couple questions.
18 Does the claimant see the original dose record
19 that DOE sends?

20 **MR. HINNEFELD:** Not unless they specifically
21 ask for their record.

22 **DR. ZIEMER:** Therefore, many claimants will
23 have been privy to their dose records along the
24 way. They supposedly get an annual cumulative
25 report and so if something's amiss the claimant

1 might be able to spot that himself, or herself.
2 So it seems to me that that's one possibility.
3 If a claimant says, yes, to the best of my
4 recollection, or they may even have copies,
5 many claimants have copies of the record except
6 maybe in the very early days when they weren't
7 really required.

8 **MR. HINNEFELD:** So if we provided the claimant
9 information in the dose reconstruction that
10 said the records we received indicate this in
11 general terms, that you were monitored during
12 these years and that your total was, your
13 external -- they usually get an external total.

14 **DR. NETON:** We do give them that as
15 reconstructive --

16 **MR. HINNEFELD:** Well, not in every one.

17 **DR. ZIEMER:** I think using the original, the
18 dataset from the DOE is one that, is one that
19 many workers themselves will have seen along
20 the way.

21 **MR. HINNEFELD:** Right.

22 **DR. ZIEMER:** And if there's something greatly
23 amiss, they would, I think, notice it. That's
24 one possibility.

25 **MR. ELLIOTT:** If we ask for something different

1 than what they've seen then we'd have to roll
2 up what we have to --

3 **DR. ZIEMER:** I'm not suggesting that we do
4 that. I'm just asking some questions about how
5 we can get at this issue, and you wouldn't want
6 to do it for every person necessarily. You may
7 want to get a sample.

8 **DR. NETON:** We do look at the data captured at
9 the site relevant to interpretation of those
10 records and in some cases we found where the
11 Department of Energy as a self-identify, oh, we
12 made a mistake in 1954. We've gone back and
13 recalculated all the doses or whatever. So we
14 are aware of that and try to accommodate those
15 changes, but I don't know how you could move
16 forward if every single piece of data that DOE
17 provided us was held in question.

18 **DR. MELIUS:** At the same time you need a
19 general way of evaluating the credibility of
20 that information. I mean, it, certainly in
21 terms of the credibility of your program I
22 think it's important. And certainly I think
23 one of the common comments that come up at some
24 of the meetings you have about the site
25 profiles and so forth it would be helpful, and

1 again, not that it's easy, but we've got a lot
2 of survivors and so forth, and you don't know
3 what was recorded. And I mean there's time
4 periods involved and different parts of a
5 facility and so forth.

6 **MR. GRIFFON:** I guess under this construct it's
7 hard to say what, when you say, unless it was
8 challenged. My general answer to your question
9 was I think it depends, from my perspective it
10 depends. And part of what it would depend on
11 is, I mean, if it's challenged, I can look at
12 that a couple ways.

13 If it's challenged in the petition, that's one
14 very succinct, you know. Then I think you'd
15 have another level that you'd want to go to.
16 If it was challenged like Jim was saying in
17 these worker meetings that you've gone to for
18 all the sites, if comments would come out
19 several times about people dropping badges in
20 their locker and not wearing them in certain
21 jobs then that challenges the credibility of
22 the external monitoring records from DOE for
23 that site. So would that then be picked up in
24 a petition review for that, affecting that
25 site? I think it probably should.

1 And then the next level which might not be --
2 If you have less than the -- Well for the
3 record, like if you get summary data, I would
4 say that needs a level taken back, at least on
5 a sampling basis, not every record. But if
6 you're only getting annual and they were
7 measured weekly that needs some level of, to
8 verify.

9 **DR. NETON:** We take summary when the numbers
10 are pretty small.

11 **MR. ELLIOTT:** But I think that's something we
12 need to say. People don't understand in all
13 cases that we don't accept cumulative reporting
14 from DOE on this program. We want individual
15 resultant data. We go back to the badge
16 readings or the bioassay results themselves.

17 **DR. NETON:** And where we hear these type of
18 issues we do try to address them. Hanford's a
19 good example where we've heard from several
20 people that as they approached the exposure
21 limit they didn't wear their badge any more.
22 And you could see this when you watch the
23 cumulative doses start turning over like this,
24 and you can -- I don't know if we finished it.
25 We started a procedure to extrapolate what the

1 additional exposure may have been.

2 But I don't know how we would, I agree with you. It
3 depends on a case-by-case basis almost. We try
4 to get back as close to the raw record as
5 possible, but we almost never, to my knowledge,
6 get raw laboratory results. We have to believe
7 that the DPM per liter that's recorded was
8 faithfully recorded at some point.

9 **MR. GRIFFON:** Right, unless you have a
10 challenge on that one I guess that would be as
11 far as you can realistically chase it.

12 **DR. ZIEMER:** But the likelihood of data being
13 manipulated is probably not nearly as great as
14 the likelihood of badges being manipulated.
15 I've seen people do this even at our place
16 where you're trying to hide the fact they got
17 up close to a limit, and they, not that a
18 foreman told them to do it, they did it
19 themselves to keep working. And I think that's
20 probably more likely.

21 **DR. WADE:** Well, let's take stock of where we
22 are now. So to the issue of credibility we're
23 developing sort of a list of things we would
24 expect NIOSH to bring to the Board when it
25 presented an SEC petition evaluation report.

1 We would want them to deal with the pedigree of
2 the data. We would want them to deal with any
3 methodological issues that might result, the
4 technology used, those kinds of issues.

5 We're interested in chain of custody. If the
6 data was outside of a valid chain of custody at
7 any point in time, it might raise concerns, and
8 we need to talk about that. We would be
9 interested in evidence to the contrary, and
10 that evidence to the contrary might be raised
11 in the petition itself. It might be raised by
12 worker interviews, or it might be raised by the
13 first level of information we have isn't the
14 raw data. And that would be of concern to us.
15 And then the last issue is this issue of
16 internal consistency checks that could be
17 worked on the data. And we need to talk a
18 little bit about that as to what the
19 expectation of the Board would be in terms of
20 NIOSH demonstrating the internal consistency of
21 the data, and there's been some discussion of
22 that recently. And is there a way we can be
23 prescriptive about that at this point?

24 **MR. GRIFFON:** I mean, you've, not to go back to
25 your report, but you've done this on a few, in

1 a few cases, on a few sets of data anyway. So
2 I don't know that we're going to review the
3 methodology or anything, but I think --

4 **DR. WADE:** It's reasonable for the Board to
5 expect though that NIOSH would bring evidence
6 of the internal consistency of the data as --

7 **MR. GRIFFON:** I think this notion of
8 independence is crucial in this whole program,
9 that, and that would, you know, again, I think
10 that's part of the reason the program's at
11 NIOSH and not at DOE, and you know, it's this
12 concern from the public and a lot of the
13 claimants probably that DOE, you know, was not
14 trustworthy so therefore, we don't want to just
15 take their data verbatim. NIOSH is going to
16 independently validate that in some fashion,
17 and that's the question, I guess, is what
18 fashion? And I think it varies, but like we
19 discussed.

20 **DR. NETON:** I think I got a much better feel
21 for this, and I think we have been lax as to
22 looking at these pedigree issues.

23 **DR. ZIEMER:** You may have looked at these in
24 many cases and were just not aware of what was
25 done.

1 **DR. NETON:** Yeah, we have them documented.
2 Let's put it that way.

3 **DR. WADE:** So we'll write credibility up and
4 get it to everyone so we can consider it in a
5 moment. Now let's go to number two which is
6 validity.

7 **MR. GRIFFON:** In my mind those two are kind of
8 together. I'm not sure how to --

9 **DR. NETON:** Yeah, I think they are. The
10 validation of the data which tends to support
11 its credibility. I mean it would be kind of
12 hard --

13 **DR. WADE:** Are we comfortable saying that we'll
14 let this model deal with the first two points,
15 and then we'll talk about representativeness?

16 **MR. GRIFFON:** Most people see those things as
17 distinguishable. I guess I can put there's
18 credibility and validity, you know, or
19 something to that.

20 **DR. NETON:** Slash, they're fairly synonymous.
21 Well, they're not synonymous. They follow from
22 each other.

23 **DR. MELIUS:** We'll have some professor probably
24 give us a hard time about that.

25 **DR. ZIEMER:** It's incredible how they --

1 **DR. NETON:** Any time you say validated, they
2 decide it was --

3 **DR. ZIEMER:** They're incredible.

4 **MR. ELLIOTT:** At the last was ways to validate
5 the credibility. It's a process.

6 **DR. WADE:** So let's talk about
7 representativeness, a proper issue I think.

8 **MR. GRIFFON:** Can we take a little break?

9 **DR. MELIUS:** I'm sorry. Let's take 15 minutes.
10 (Whereupon, the Working Group took a break at
11 10:40 a.m. until 10:55 a.m.)

12 **DR. WADE:** The issue in front of us is the
13 almost trivial issue of representativeness.

14 **MR. GRIFFON:** Silence.

15 **DR. WADE:** I think if we came out with sort of
16 a similar list for representativeness that
17 would be good so anybody got any thoughts?

18 **MR. HINNEFELD:** Does it occur to anyone that
19 representativeness might be an issue when you
20 talk about all members, all members of a class?
21 Because when you kind of move into the all
22 members of a class part of the definition,
23 that's more representative.

24 **MR. GRIFFON:** That's where I came up with the
25 notion.

1 **MR. HINNEFELD:** So --

2 **DR. MELIUS:** It's sort of how do you define the
3 class? I mean, it's that whole --

4 **MR. GRIFFON:** Yeah, that's what I said, it kind
5 of overlaps with the second part of that
6 definition, the all members of the class thing.

7 **DR. MELIUS:** So is one of the evaluations is
8 the data representative for all members of the
9 class?

10 **DR. ZIEMER:** In the rule where it says any
11 member, we're thinking that means, I guess, the
12 highest exposed individual, in some subgroup or
13 whatever that class is.

14 **DR. DeHART:** That's the way I interpret it.
15 But does it necessarily just the petition,
16 because we've broken them out from petitions
17 before into separate groups.

18 **COURT REPORTER:** I'm getting total static.

19 (Whereupon, a short break was taken to
20 correct technical problems.)

21 **DR. WADE:** Okay, we're back on. Jim, you were
22 saying?

23 **DR. NETON:** I was just saying we're talking
24 about any member of the class. I don't think
25 it means all members of a class. It means a

1 maximum dose for any individual member in that.
2 So if you can find a maximum dose for any, the
3 highest exposed individual in that class then
4 you've got it. Does that, I mean, do we agree
5 to that?

6 **DR. MELIUS:** Yeah, but that's what I'm saying.
7 It goes back to class best definition. I mean
8 is that what you're evaluating representative,
9 is you have defined that class.

10 **MR. GRIFFON:** So it's not exceeded by
11 individuals no greater than --

12 **DR. NETON:** Let's take Mallinckrodt again. All
13 workers at Mallinckrodt were defined as a
14 class. And we're saying we believe that we can
15 pinpoint the highest exposure received by an
16 individual at Mallinckrodt is in that class.
17 So it would be the highest dose that could
18 conceivably been received at that facility.

19 **DR. WADE:** But when we then said we've got a
20 lot of urine then the problem came about when
21 people said well, what about these raffinate
22 workers? And that's to your point as well.

23 **MR. ELLIOTT:** Well, if you would have defined
24 the class at Mallinckrodt as all workers except
25 raffinate-exposed workers, the reaction might

1 be different.

2 **DR. NETON:** Right, but see, I think that we
3 would have backed up though and said, well, the
4 urine data is not representative but the air
5 sampling data might be. We're talking about
6 the maximum dose.

7 **DR. MELIUS:** Yeah, but what you're presenting
8 to us needs to be representative. I mean, what
9 we're evaluating, it has to for that class as
10 you're presenting it to us.

11 **DR. ZIEMER:** Do you have to do it by cancer
12 type?

13 **DR. NETON:** We can't do it by cancer type. It
14 has to be, any cancer has, we have to be able
15 to calculate the maximum dose for any cancer.

16 **DR. ZIEMER:** For any cancer, but I mean --

17 **DR. NETON:** Cancer-specific issues are not
18 allowed.

19 **MR. HINNEFELD:** It would be helpful to think of
20 the class in terms of subcategories of the
21 class in terms of the data available for a
22 class. For instance, if a prospective, a
23 particular site you may have cases where you
24 have an individual who is monitored throughout
25 their employment for external dosimetry and for

1 internal dose for all the radionuclides of
2 dosimetrics.

3 That is a category that you feel like you could
4 do a dose reconstruction if you had a complete
5 monitoring record of both internal and
6 external, and the external for all categories
7 of significance. Then you can step back from
8 that. You would have, just thinking on the
9 external side of monitoring, you would have
10 someone who was monitored for some portion of
11 their employment but not all. And then,
12 subcategories of that, those people would
13 either, you would either have job category
14 information which would inform you as to why
15 they were missing, maybe they switched to a job
16 and didn't require monitoring.

17 You would have cases where you don't have job
18 information so it's harder to judge the reason
19 for the break or the discontinuity in the
20 monitoring record. Okay? And then just go
21 right down the list, and on the internal
22 monitoring side you would have people who were
23 monitored for their entire employment for all
24 categories or all dosimetrically significant
25 radionuclides. People who were monitored in

1 all categories but for not all dosimetric
2 radionuclides.

3 And in discussion of can we provide a dose
4 reconstruction of sufficient accuracy for these
5 categories, we would have to address the
6 various categories of cases that we may
7 encounter. What could we say about those
8 categories of cases? And would that be a
9 helpful construct for arriving at some
10 confidence that we can do dose reconstructions
11 for any member of a class?

12 **DR. NETON:** See, I think that gets into the
13 more specific individual dose reconstruction
14 approach that I would prefer to avoid in an SEC
15 evaluation. If you can do a maximum one way,
16 then you can certainly always do better or you
17 should, you might be able to better than the
18 maximum with this technique, but we're only
19 required at this point to say that we know the
20 maximum, or we've established the maximum.

21 **DR. MELIUS:** But I think does the data that you
22 use for that maximum, is that applicable to all
23 members of your class? I think that's one of
24 the representative --

25 **DR. NETON:** And that gets into the source term

1 issue which is what nuclides do you have which
2 is maybe where you're going. So at
3 Mallinckrodt we have uranium. We have
4 raffinate. We've got raffinate and radium, so
5 like three or four different types of mixtures
6 of radionuclides, and we need to be able to
7 demonstrate that we can bracket exposures to
8 each of those different groups.

9 **DR. WADE:** Your two points are the same. You
10 need to tell a cogent story. That's what
11 you're saying. But that goes to what you were
12 saying. That's one way of telling that story.

13 **DR. NETON:** But the more detail you put in
14 there, well, it takes a lot longer to, you have
15 180 days to do this whole process.

16 **DR. WADE:** That's the tension, but again, you
17 need to make a convincing argument. The level
18 to which you go to make that argument, you
19 know, remains to be seen.

20 **DR. ZIEMER:** But let's say that you're using
21 say the air sampling data, and you're making
22 worst case assumptions for maximized lung dose.
23 What do you do about individuals for whom the
24 cancer is let's say the spleen or something.
25 Maybe those maximizing assumptions would

1 actually result, maybe there would be different
2 maximizing assumptions if the cancer of
3 interest was not the lung because of solubility
4 of --

5 **DR. NETON:** We would assume in that analysis
6 that we picked the solubility that gave the
7 highest organ dose.

8 **DR. ZIEMER:** When you actually did the dose
9 reconstruction a priori you don't have that
10 information.

11 **DR. NETON:** Right, but we would say whatever
12 that air sample result was, we would pick the
13 most --

14 **DR. ZIEMER:** And then for the individual you
15 would customize --

16 **DR. NETON:** Customize it for their particular
17 exposure. I thought you were going down the
18 ingestion pathway.

19 **DR. ZIEMER:** Well, my question really would
20 have been for people with other types of
21 cancer. Would you actually, would the maximum
22 lung intake have to be different. I guess you
23 would use a different solubility class or
24 something, then the lung dose would have
25 actually come out differently.

1 **DR. NETON:** I think a priori we'd have to make
2 the case that inhalation exposure was the
3 limiting dose, the limiting mode of exposure.

4 **DR. ZIEMER:** Right, at some concentration and
5 that's what you would use.

6 **DR. NETON:** Right.

7 **DR. MELIUS:** I think the more common problem's
8 going to be that there are different groups of
9 workers so the source term you used or
10 whatever, or set of data, whatever you're
11 using, may just not really apply to that group
12 of workers or you may not have sufficient
13 information to be able to fully characterize
14 that group in the way that you're doing it.

15 **DR. NETON:** Right. That gets into this
16 representativeness issue because let's say at
17 Mallinckrodt -- and I hate to keep using it,
18 but it's a good example -- we had thousands and
19 thousands of air samples that were taken in the
20 uranium production areas which were already
21 purified uranium and not nearly as many samples
22 in the raffinate areas because they were wet
23 processes and probably not that much high air
24 dust. But then so what happens though is now
25 if we don't know where a worker was, whether he

1 was a uranium operator or a raffinate worker,
2 the pool of available air samples for raffinate
3 workers was smaller. So we would have to
4 demonstrate in this case that the smaller pool
5 of air samples would be our limiting population
6 of the data that was still representative of
7 the workers.

8 **DR. WADE:** Let's get it all on the table
9 because we're skirting the second and most
10 difficult issue I think. Representativeness
11 can take at least two forms. In terms that
12 representativeness as judged against the
13 workforce and the different types of workers.
14 The other question of representativeness is
15 just the amount of data that you have. If I
16 have a workforce of 10,000 workers, and I have
17 six monitoring pools, is that representative?
18 We have to start to get to the issue of how
19 much data is enough data? How much data is
20 representative? And I think that's a tougher
21 issue.

22 **DR. ZIEMER:** Well, I think it's both spatial
23 and it's numbers of samples as well as
24 location.

25 **DR. NETON:** But its even another layer on top

1 of that is were the areas that were the highest
2 potential concentrations were the ones that
3 were monitored.

4 **DR. ZIEMER:** Well, that's a spatial --

5 **DR. NETON:** Well, we've never not been able to
6 seem to get past that issue. If we have 100
7 air samples or 100 urine samples and there were
8 1,000 workers, what level of proof is required
9 on our part that we believe, that we can
10 demonstrate that those 100 workers were the
11 ones that were the most maximally exposed
12 workers? Because that's probably our biggest
13 hurdle in this, especially in the early years,
14 Y-12, I think, in 1959, '51, there's only like
15 five percent of the workers were monitored, and
16 you've got almost 100 percent in 1961.

17 **DR. WADE:** Let's sort of frame it, Jim. If you
18 have good data, if you have representative
19 data, a large sample of the workforce
20 monitored, that issue doesn't appear. It's
21 when you don't have it we default to the
22 argument to say we don't have everyone
23 monitored, but we assume we have the maximum
24 exposed monitored. So we come to it through
25 that path. And we need to decide how the Board

1 wants to see that presented starting with
2 whether we have enough. And if we don't have
3 enough, then we make logic to say, we don't
4 have enough, but what we have is special.

5 **MR. KATZ:** With internal data it's always a
6 smaller population.

7 **DR. MELIUS:** Yeah, it's not the size of it.
8 It's the assumption as to whether it really
9 captured those with the highest exposures or
10 not, but by the very design of the monitoring
11 program. And I tend to be skeptical of that
12 all the time. Every time you say it, I -- one
13 level I understand it is a method, and again,
14 it's this whole issue we're trying to take the
15 data that's collected for other reasons and use
16 it for dose reconstruction. And so the
17 question is what is it representative of.

18 **DR. NETON:** The question is we have proposed to
19 take, if we have the monitoring data, if ten
20 percent of the workers were monitored, and we
21 have those ten percent happened to be
22 claimants, we're going to use their data.
23 That's not an issue, assuming it's valid.
24 We're going to use these samples to predict or
25 project what these 90 percent were exposed to.

1 We have had a tendency to say that the 50th
2 percentile of that distribution is certainly
3 claimant favorable because these are lesser-
4 exposed workers than the ones who were in
5 harm's way. One could argue if we don't know,
6 we put the 95th percentile because, I think
7 that's --

8 **DR. MELIUS:** And you may come down to having a
9 procedure like that. I mean, it may, you know,
10 because it's not, what do you do, flip coins?
11 I mean, how else do you sort of decide. But
12 also I think the other issue also comes back to
13 what kind of group of workers were monitored.
14 But then it's the type of worker that's getting
15 included in the bigger class. So the data is
16 collected on the production workers, and it may
17 be very, I mean, I can accept that you, that
18 their dosimetry is going to be directed in a
19 way that it's going to try to capture the
20 higher exposures.

21 But then how do you then apply that to, is that
22 assumption valid for maintenance workers or
23 people that might have had a different type of
24 non-production? What's relevant?

25 **DR. NETON:** The extremes are pretty easy,

1 clerical types and the administrative areas.
2 Now you have maintenance workers, security
3 guards, those type of folks who were in those
4 areas.

5 **DR. MELIUS:** Yeah.

6 **MR. ELLIOTT:** And maybe they weren't monitored
7 at all because they weren't -- unless they went
8 into a rad-controlled area and they had to be
9 monitored, but that doesn't necessarily mean
10 they didn't have any exposure.

11 **DR. MELIUS:** Right, right, and the nature of
12 their task may have been, exposed them in
13 different ways than the people in production,
14 less than more.

15 **DR. NETON:** I mean there's really three classes
16 that I can think of. The workers who were
17 monitored because they're the highest exposed,
18 and then there's the approach that there was
19 cohort badging, they're just sampled, you know,
20 one security guard, one maintenance guy, one
21 this, and that would be reflective of the
22 entire population. And then the third class is
23 the people who, and the third one, there's
24 cohort, oh, and then at Iowa it was suggested
25 that they monitor the people who were at the

1 lowest exposure. And then that was the
2 argument that was made is there may have been a
3 conscious effort to not, you couldn't prove
4 that they didn't --

5 **MR. GRIFFON:** The cohort of the lowest doses.

6 **DR. NETON:** Otherwise we would have picked the
7 distribution and said it was a cohort
8 distribution, picked the 95th percentile, and I
9 think we would have had a case. But I think
10 the arguments were made that we couldn't even
11 prove there was cohort badging. They may have
12 just randomly issued a few badges to make
13 people feel good. I'm not saying they did
14 that, but we couldn't make a case. So you've
15 sort of got three classes, and I don't know
16 what level of proof or comfort how we can get
17 there with these different categories easily.
18 It's more of a subjective issue.

19 **DR. WADE:** I think there's pretty good evidence
20 to the contrary. There's always that
21 methodology. Do you have evidence to suggest
22 either through worker interviews or the
23 petition itself that there was something else
24 at play. That's a test I think we need to be
25 prepared to take.

1 **DR. NETON:** I think my sense is the bar is
2 higher than I, at least, perceived it to be.
3 And I understand better now, I think, that just
4 because there are written procedures in place
5 that say that's what one should do, doesn't
6 mean that we come to that conclusion.

7 **DR. WADE:** You know, one thing I think one
8 lesson I've learned is we need to, we need to
9 listen to the workers more, and we need to show
10 them that we listen to them more so the
11 strength of the worker, input of the worker, I
12 think needs to be played up.

13 **DR. NETON:** But all those issues aside, I think
14 for an SEC petition evaluation processes, if
15 you don't have all of your homework done, and
16 you haven't had a chance in this 180 window to
17 interview dozens of workers, one could default
18 to the, well, I guess the worst case would be
19 to default where they didn't monitor anybody in
20 any fashion, and that would mean we couldn't do
21 anything. But the cohort badging would end up
22 being sort of the default in most cases.

23 If we couldn't prove that the highest exposed
24 workers were badged, then this cohort concept
25 would come into play. And then we would have

1 to, essentially, then you would assign the 95th
2 percentile of distribution to all unmonitored
3 workers which is not real appealing in some
4 sense because you're giving more dose to the
5 workers who weren't monitored than the, 95
6 percent of the workers who weren't monitored
7 than the ones who were.

8 **MR. GRIFFON:** Well, maybe then, I think, it's
9 site by site, but we'd have to figure out
10 cohort sampling as you said, it could be cohort
11 sampling of the population and the class. And
12 the SEC could be a smaller set of that so you
13 could even use the cohort sample in that. And
14 that's on the petition.

15 **DR. NETON:** And I guess I would ask is
16 assigning the 95th percentile with distribution
17 with sufficient accuracy for all workers? I
18 mean, I don't know. That's a question. It's a
19 good question.

20 **DR. MELIUS:** And is that individual dose
21 reconstruction?

22 **DR. NETON:** I think maybe if we could prove
23 cohort badging at a minimum, we could say well,
24 we certainly believe that --

25 **DR. MELIUS:** I don't know if I ever, I may have

1 asked this during one of our meetings, but I
2 don't remember the answer. Is part of doing
3 the SEC evaluation, do you actually look at the
4 interviews? Is there a way, I mean, does
5 someone --

6 **DR. NETON:** The CATI interviews that we've
7 done?

8 **DR. MELIUS:** Yeah, the CATI interviews and --

9 **MR. ELLIOTT:** Yeah, the other cases that have
10 been completed, dose reconstructed, we look at
11 the interviews and look at the data that was
12 used in those dose reconstructions, and how it
13 was used.

14 **MR. GRIFFON:** But a lot of times the DRs that
15 have been completed to date are maximizing,
16 right? So...

17 **DR. MELIUS:** But then do you look at the
18 interviews, I guess, for the ones that haven't
19 been I guess is my question.

20 **MR. RUTHERFORD:** Yes, actually what we do is we
21 go back, and we look at the total number of
22 cases that we have on file. And then we try
23 to, even with Y-12 where we had hundreds, we
24 try to go back and look through, if not all of
25 them at least a large majority of them, and

1 focus on that. You look at production workers.
2 You look at maintenance workers. You look at
3 each one of those.

4 **DR. MELIUS:** Because what are we talking about,
5 availability of evidence to the contrary. We
6 even think just saying, look, we've interviewed
7 x numbers of people and nobody raised this
8 issue or you know, whatever. This is the
9 information we've got on, from those would be
10 helpful to know.

11 **DR. NETON:** And so you end up with these
12 special populations that end up being
13 problematic. External dosimetry's a good case
14 where you have maybe 60 percent of workers were
15 monitored. On face value (unintelligible) had
16 mentioned that you may have these certain
17 maintenance staff operators that were not
18 monitored, that when you interviewed them you
19 end up hearing some stories. Now of course, I
20 was right there with the people, and they just
21 never badged me, for whatever reason. And then
22 you end up with this potentially special class.

23 **DR. WADE:** You have to consider. If the
24 evidence takes you to the direction that you
25 need to make arguments for a subset of the data

1 based upon things you heard, you need to be
2 prepared to do that.

3 **DR. MELIUS:** Yeah, I mean, I think we're better
4 off doing that than, because if not, what we
5 end up doing is we pick the example and argue
6 from the sort of a counter-subset, a special
7 class, we argue from that, and then we apply it
8 to everybody and either we're really doing it
9 inaccurate, we end up pushing at that, or we're
10 not really doing justice to that group either.
11 If we know that they can be divided out in some
12 way; we identify them some way. I know that's
13 the harder part of it maybe, but --

14 **DR. NETON:** It's appealing to keep this little
15 subclass, but then the Department of Labor
16 would have to make a determination as to that
17 subclass can be identified. And if one can't,
18 you end up at the same position which is
19 everybody is in because you're not going to
20 make a determination.

21 **DR. WADE:** But the presentation of that path to
22 this Board will go a long way towards helping
23 them to make a decision.

24 **DR. DeHART:** We've got a Y-12 petition with
25 three trades in it as I recall. And it could

1 be that each of those trades separates out
2 because of the kind of exposures they might
3 have had.

4 **DR. WADE:** So let me tell you where we are now
5 in terms of some of this intellectual
6 construct. On the representativeness we have
7 three major breakouts. The first looks at over
8 the range of types of workers. We have to show
9 that what we have is representative for all of
10 the different types of workers. We need to
11 show representativeness spatially for the
12 facility that we're dealing with, and this is
13 if we're dealing with air samples for example.
14 And then the most difficult is that we have to
15 show representativeness of data subsets that
16 we're going to use. They might be datasets.
17 They might be data subsets. And the way we're
18 going to deal with this issue of
19 representativeness of data subsets is to say
20 that we will assume that this data subset is
21 either broad enough statistically to answer all
22 questions. We have enough of the workers
23 monitored that statistically we have power.
24 Or if we don't have that, then we have to make
25 a certain assumption as to what we do have.

1 And the three possible assumptions are: we
2 assume this data subset is a subset of the
3 highest exposed workers, or we assume this data
4 subset is a cohort badging subset, or more
5 nefariously we assume that this data subset is
6 the lowest exposed worker.

7 We have to be able to make an argument,
8 convincing argument, for the first, and absent
9 data for the third, we would default to the
10 second. So that doesn't mean that we're
11 finished now, but that's sort of what you have
12 allowed.

13 **MR. GRIFFON:** I guess all of the pieces of this
14 all falls under sufficient information, and
15 another note I had in my scribblings last night
16 was that I think we should think about when is
17 the information not sufficient. It's sort of
18 that last thing when you think about it was if
19 you have a sampling and there's evidence that
20 shows that it's, they badged all the low-end
21 exposed people, at some point is there, where
22 is our line when we say, how does NIOSH, how do
23 we all determine that? Why is this information
24 not sufficient?

25 **DR. NETON:** Well, the integrity of the data and

1 at Mallinckrodt early years we have a fair
2 amount of data in the second period, yet we
3 said integrity questions had arisen related to
4 potential manipulation and whatever, and that
5 would be --

6 **MR. GRIFFON:** I think there's a bunch of
7 reasons, that I think maybe outline some of the
8 ones we found so far. It might be useful.

9 **DR. WADE:** Because NIOSH could be using this
10 template to bring to you proposals for
11 recommending the approval of the petition so
12 you can't do it.

13 **DR. ZIEMER:** Because elaborate and I think,
14 Lew, your summary is very good, and I think,
15 your dataset points more toward the individual
16 monitoring. I'd like to suggest, particularly
17 on air room monitoring, that both the numbers
18 of samples and the frequency also be
19 highlighted in there.

20 You should have a large number of samples that
21 are just done in a very compressed time period
22 versus periodic samples or continuous samples.
23 It seems to me the frequency as well as the
24 numbers of samples becomes important also.
25 However, just to elaborate --

1 **DR. NETON:** Dr. Ziemer, are you talking about
2 spatially?

3 **DR. ZIEMER:** That's temporal really, the
4 distribution in time. I think we have cases
5 where we have concentrated sampling, I mean,
6 the extreme of that is not the NIOSH program is
7 in the reconstruction of miner data for the
8 radon work. You know they have the one sample
9 a year, and they apply that to every miner who
10 ever worked there.

11 **MR. ELLIOTT:** We certainly have sites where we
12 have, like Bethlehem Steel where we have data
13 when they did it, then they tailed off on their
14 effort to monitor that. They were after, the
15 purpose of monitoring --

16 **DR. ZIEMER:** Right, that becomes important.

17 **MR. ELLIOTT:** A pilot effort. And we have
18 other sites where monitoring was done under a
19 whole different purpose.

20 **DR. ZIEMER:** Yeah, regulatory or --

21 **MR. GRIFFON:** Certainly there's temporal
22 distribution in the data. It comes up in the
23 Y-12. I don't know how much we can --

24 **DR. NETON:** Well, I know, when you start with
25 200 samples in '51 and work up to 30,000 in

1 '62, and --

2 **DR. ZIEMER:** Well, but it's better than issue -

3 -

4 **MR. GRIFFON:** Where's the cutoff?

5 **DR. ZIEMER:** Yeah, I don't think we know the
6 answer to that, but somebody's -- At some point
7 you say this is sufficient or it isn't.

8 **DR. NETON:** But at Iowa we went down that path.

9 **DR. ZIEMER:** We can say we don't believe this
10 is sufficient.

11 **DR. NETON:** We made an argument for a cut point
12 and again, it just wasn't, you couldn't
13 convince anyone that it was a reasonable cut.

14 **DR. MELIUS:** I mean I would hope that what we
15 talked about sort of a kind of criteria would
16 make it easier to justify a cut point to some
17 extent.

18 **DR. ZIEMER:** Well, at least there'd be a
19 rationale --

20 **DR. MELIUS:** A rationale for --

21 **DR. ZIEMER:** -- this is the basis for it.

22 **DR. MELIUS:** That's where I am because I think
23 that we're just going to have to because --

24 **DR. NETON:** They're somewhat connected. The
25 frequency of the number is of course related to

1 the populations who were monitored, but they're
2 issues that need to be addressed.

3 **MR. SUNDIN:** This is probably just for my own
4 clarification, but I assume this analysis only
5 applies when NIOSH is positioned in its
6 evaluation of analysis which might be based on
7 source term data or other just -- so this
8 analysis wouldn't necessarily apply to every
9 site. I mean, I can foresee a site where there
10 are absolutely no monitoring data whatsoever or
11 approach to doing dose reconstruction.

12 **DR. ZIEMER:** But I think you have to ask the
13 same question. Is the source term data
14 credible? How do you validate it, and how
15 representative is it.

16 **DR. MELIUS:** Because actually with the
17 representativeness, I mean, it's really, that's
18 probably going to be the key thing I think
19 because what's going to be the questions are
20 your assumptions you're making based on that
21 for exposure based on that are they
22 representative or do they, you know, they
23 capture different sorts of people and so forth
24 and, yeah.

25 **MR. SUNDIN:** Numbers of samples.

1 **MR. ELLIOTT:** And with source term you have to
2 deal with the client, so in all years was the
3 client the same. Maybe that client has changed
4 over time.

5 **DR. MELIUS:** How good is that? What was the
6 source term.

7 **DR. NETON:** I can think of an example of a
8 situation where you might have a radium source
9 shield so there's no potential for an internal
10 exposure, but maybe some radon. If you know
11 there's one gram of radium there, one can do a
12 source term calculation and bracket the radon
13 potential intake. You'd have to be assured,
14 certain ventilation, but it could be done.

15 **DR. WADE:** So again just to review before we
16 get it typed for review, under
17 representativeness we have now four main
18 categories: representativeness considering all
19 types of workers, representativeness on a
20 spatial perspective, on a temporal perspective,
21 and then four, the representativeness of data
22 subsets and the fundamental question do we have
23 a statistically robust sample.
24 If the answer is yes, we present the
25 justification for that. If the answer is no,

1 then we make an assumption of the type of non-
2 robust sample we have. Either that it
3 represents the highest exposed worker. It is
4 simply a cohort sample, or it is the lowest
5 exposed worker, and the burden of proof is on
6 us to show that it is the highest exposed
7 worker, for example. Absent that we default to
8 two. And we'll have a chance to go over this
9 again. This is where our discussion has been
10 at this point.

11 **DR. MELIUS:** Now what about procedurally in
12 terms of how this is presented because this is,
13 I think there's actually two thoughts here.
14 One may make more work and the other makes
15 less, but first in terms of presenting to the
16 Board, is it helpful to do it, for example, as
17 representative, but the idea of evaluating like
18 we did in Mallinckrodt, evaluating a number of
19 typical cases that would be from the cohort,
20 again, some reasonable number. Is that -- and
21 I personally found it helpful to understand
22 what we were doing. The caveat on that I think
23 is that it has to -- and I think it applies
24 also to some of this other stuff. Do we need
25 to focus on variables that are critical in

1 terms of determining exposure. Probably I
2 think what happened, I thought with
3 Mallinckrodt and stuff, we tend to get
4 sidelined with long discussions on some
5 variables that weren't really very important.
6 You know, I mean, you could argue about them
7 and they may have been important elsewhere or
8 they may not be. I can't think of an example,
9 but it seemed to me there was an awful lot of
10 wheel spinning going on over stuff that wasn't
11 --

12 **DR. ZIEMER:** Might not affect the final
13 decision.

14 **DR. MELIUS:** It wouldn't affect the final
15 decision in any meaningful way at all. At the
16 same time I thought sort of looking at, both in
17 terms of how it was convincing to the
18 petitioners and the people affected by this
19 program that that was helpful to see that.

20 **DR. NETON:** The place I think it would be most
21 informative is in this issue of plausibility.
22 Are you coming up with doses given your
23 approach, your maximizing approach that, you
24 know, let's take the hypothetical pit in Iowa.
25 It became pretty clear in some people's minds

1 that we might have bracketed it, but it was not
2 really a plausible exposure scenario. That's
3 kind of extreme, and maybe at Mallinckrodt I
4 was thinking at one point that we were coming
5 up with such high intakes that everybody was
6 going to get paid no matter what. And that
7 didn't seem plausible at some point, too, one
8 of the paths we were going down.

9 **MR. ELLIOTT:** Well, in my mind it would help
10 not only to speak to what's plausible, for what
11 we think is plausible, but to say also what we
12 think is implausible. If you provided both of
13 those on the table at the same time for
14 comparison. And from that I think one method
15 that might, we might show a convincing
16 argument, but we'll at least learn the other
17 perspectives about that. If we don't show
18 that, if we only show what's plausible in our
19 minds, then I think we're cheating ourselves as
20 well as cheating our audience.

21 **MR. GRIFFON:** And I think you said some of that
22 in some of your, I mean, some of the things
23 that you've said that if we increase this to
24 this point, it would be impossible to ingest,
25 you know, it couldn't be an error that way.

1 **DR. NETON:** Yeah, with the bracketing.

2 **MR. GRIFFON:** So that's an important, we're
3 getting up near implausibility.

4 **DR. NETON:** The other area where I think it
5 might be culpable is in this disparity issue.
6 It's not necessarily written in the regulation,
7 but I understand that the concept of are you
8 being so claimant favorable to one class
9 because you don't know this information that
10 your doses are 100 times higher for these folks
11 than people who you have some monitoring data
12 really low, and is that really -- Is that, I
13 guess almost speaks to plausibility.

14 **DR. MELIUS:** Yeah, and another way it would be
15 helpful to relate that is it would identify
16 subclasses, whatever we want to call them, that
17 there may be feasible to do it. It may not.
18 You'd be able to separate out the different
19 groups better and decide how to label and maybe
20 make the whole process somewhat more efficient.
21 The downside is that we get hung up on every
22 individual detail. And I think we need to be
23 explicit that the details we're, what we're
24 going to focus on aren't going to be things
25 that are critical in the dose calculations.

1 It's not going to be something that --

2 **DR. NETON:** One thing I'm a little worried
3 about with this is that if these are SEC
4 evaluations, they're not necessarily the
5 refined dose reconstruction we may end up with
6 after we have time to complete more research.
7 And there's this sort of tendency on people's
8 part to look at these and say, well, how many
9 people are going to get paid overall on using
10 this approach? And I'm saying, well, this is
11 not a refined dose reconstruction. This is
12 just what would happen if we did apply what we
13 proposed here. And we need to be careful of
14 that.

15 **MR. ELLIOTT:** We have to be careful with
16 leading individuals to a perception that's a
17 misunderstanding, a misperception, that some
18 people are going to get paid, how many people
19 are going to get paid under this approach
20 versus how many -- these cases are so
21 individual specific the circumstances around
22 them drive these things different ways.

23 **MR. GRIFFON:** And, Jim, you -- one of my notes
24 on here, this question of the Board's
25 credibility and NIOSH's credibility. I mean,

1 if we're not clear in the way that's
2 communicated then that could be a problem down
3 the line. People could say, oh, they said
4 maximum 100 rem or whatever, you know, for one
5 dose, and they get their report and it says two
6 rem or something. What happens? I can see
7 that, so I think we have to be really careful
8 in the way it's communicated.

9 The other reason I speak to Jim's idea of
10 sample DRs, the only reason I think that's
11 really critical in this is that the question of
12 feasibility. It is not my concern that if we
13 come to agreement on this notion of maximum
14 plausible or if you put out a guide that's a
15 maximum plausible dose, and yet we're not sure
16 how that's going to be carried through and you
17 are missing some pieces, and we've got some
18 more homework to do, I don't think we have any
19 way sort of as a Board to sort of evaluate.

20 And I don't know we even have a clear
21 understanding of what does that mean, the
22 feasibility. But I guess we've heard this over
23 and over. We don't want this to be some long-
24 term -- So this is the notion of well, we've
25 got a lot of unknowns here, but I know it's not

1 greater than 5,000 rem. And then it takes you
2 five years to reconstruct their doses because
3 there was so much homework left undone. I
4 think that's why I think it's useful to get
5 some examples, best estimate DRs so we can say,
6 yeah, we've got all our research.

7 **DR. NETON:** Best estimates would be found.

8 **MR. GRIFFON:** Not best estimates, but like Jim
9 was saying --

10 **DR. NETON:** The application of our approach.

11 **MR. GRIFFON:** With the high dose consequence
12 kind of factors considered.

13 **DR. NETON:** With all kinds of caveats built in
14 there, and I guess the question is are they
15 real cases or can you just come up with some
16 hypothetical claimants, you know, 14 years of
17 exposure and --

18 **MR. ELLIOTT:** Can you get examples of how you
19 apply the approach -- a resistant, I guess,
20 using real cases.

21 **DR. MELIUS:** But I think they have to be
22 realistic and based on the distribution of the
23 cases you have applied in terms of where people
24 worked, the type of jobs, the --

25 **DR. NETON:** We can put together what I call a

1 composite case. We'll mix and match.

2 **DR. MELIUS:** And there may be, you know, four
3 composite cases in this class --

4 **MR. ELLIOTT:** Or whatever approach. Here's an
5 example of a dose reconstruction and be done.

6 **MR. GRIFFON:** I don't think we -- well make
7 known that there was real examples. And we
8 don't need real examples, but that became an
9 issue. But anyway, those categories might come
10 up when you're putting your evaluation
11 together. For instance, you see a bunch of
12 people in your class have urinalysis but don't
13 have this, you know, and a bunch of people
14 don't. So how would you treat this case
15 versus, you might have three hypotheticals.

16 **DR. NETON:** Well, that gets a little tougher,
17 and that's sort of along the line where Stu was
18 heading which is if you can do refined ones but
19 show some refined ones, but really, that's not
20 what we're speaking to in this analysis. We're
21 speaking to the SEC process.

22 **MR. GRIFFON:** Why is that a requirement?

23 **DR. NETON:** Well, I mean, we're trying to say
24 we can assign the maximal plausible dose to a
25 claimant in this class. That's all we're

1 saying. Then why would we start doing refined
2 dose reconstructions using all the full
3 complement of urine and external data if at the
4 end of the day we're saying we have sufficient
5 air data that brackets all these workers'
6 exposures, and we do define these classes down
7 to the most exposed --

8 **MR. ELLIOTT:** Well, this is the subset.

9 **MR. GRIFFON:** This is the feasibility again in
10 my mind is that we can say that, but then if it
11 takes three more years to get all of those
12 pieces together for your whole class --

13 **MR. ELLIOTT:** And speaking to the data subsets
14 though you're going to do that. You're going
15 to have to say on an individual subset basis
16 how you're going to handle it. But I think if
17 you restrict it to the subset level, you don't
18 get into rolling all of that up, and go here's
19 the best estimate dose reconstruction. It
20 would in eventuality.

21 **DR. NETON:** I'm just thinking bounding here,
22 and I understand where Mark's issue is it's one
23 thing for us to say on paper we can bound this
24 and convince folks, but if it takes us, if we
25 don't believe that that bounding is

1 representative, we can do a better job, and
2 it'll take us three years more to do that, then
3 that's not a very --

4 **MR. GRIFFON:** -- Yeah, to go back to that
5 statute of feasible, feasible to reconstruct
6 doses so.

7 **DR. NETON:** First of all there's no timeliness
8 requirement on a dose reconstruction. I'm not,
9 not saying we don't need to hurry, but --

10 **DR. MELIUS:** But yeah, in terms of the program
11 you just can't, once you've said you can do it,
12 you can't take four years to do it or --

13 **DR. NETON:** My concern is though once you start
14 doing these more refined things, that's when
15 people start really nitpicking on certain
16 issues when that's not central to the SEC
17 process.

18 **MR. GRIFFON:** Well, I'm not sure how my
19 examples, how did that make it, I misspoke with
20 best estimate, but for case, you know, I'm just
21 saying that you have cases --

22 **DR. NETON:** If you have urine samples and
23 external data that's the best estimate. We
24 would just take that and analyze it.

25 **MR. GRIFFON:** I guess I'm saying, and here I

1 should have framed all of that. I said as in
2 Mallinckrodt so when you had urine data, you
3 were saying we were going to use that intake
4 and use your (unintelligible) so just to
5 describe this is how we would do it if we had
6 this. If we didn't have this piece, we might
7 try and get it with air sampling. And these
8 three cases are sort of the all the cases that
9 we can expect in an entire class. They all
10 kind of fit into this. And as you can see, our
11 maximum plausible bounds all of this. I guess
12 that's, you have to demonstrate that all the
13 cases or all the members of your class sort of
14 are bounded by the maximum plausible by taking
15 a couple hypotheticals of the different types
16 of cases you feel fall into your -- types of
17 claims you feel fall into your class. You
18 demonstrate that.

19 **MR. HINNEFELD:** It's a more careful
20 consideration of the population is what you're
21 asking for, a more careful consideration of the
22 population of claims rather than just say a
23 general, we can do a match. That's kind of
24 what we're talking about.

25 **DR. MELIUS:** Doing that focuses on --

1 **MR. GRIFFON:** Because it answers the both sides
2 of this. We can maximize it, and it's also
3 feasible.

4 **DR. ZIEMER:** But the subsets are the same
5 thing. There's not a subset in here that
6 really is so different that you would get a
7 different max than you're thinking about.

8 **DR. NETON:** I think I see this.

9 **DR. ZIEMER:** Because ultimately if you truly
10 have the maximum value then you don't really
11 need to do all this. It's just how do you know
12 you're there?

13 **DR. NETON:** That's what I'm thinking, yeah. I
14 mean, how do you --

15 **MR. GRIFFON:** And this is a test of it, I
16 think, and when you're putting this together
17 it's a test of it.

18 **DR. ZIEMER:** And we simply say, well, we tried
19 this out on some subsets --

20 **MR. GRIFFON:** Everybody in the class, I mean, I
21 guess it's easy to say, you know, in my mind
22 it's easier to say on this first film, well,
23 all these people got the same, we don't have to
24 look at all these cases. We know that we've
25 got this air data and this, and we know that

1 there was this much percentage was plutonium.
2 So we'll factor that in. We know how to do
3 this, and the maximum dose is this.

4 **DR. NETON:** I think I follow what you're
5 saying.

6 **MR. GRIFFON:** This small group had a higher
7 percentage of plutonium, and they have urine
8 data, and when I recalculate, wait a second,
9 that skewed my math.

10 **DR. NETON:** That may help redefine your class
11 and ultimately until you get to the point where
12 that subset is covered by this upper bound.

13 **MR. GRIFFON:** We're sort of validating the
14 maximum plausible.

15 **DR. WADE:** Okay, so we've got two sort of main
16 items we're going to talk about. NIOSH is
17 going to stand up and make a presentation when
18 it does an SEC petition evaluation report that
19 deals with issues of the credibility and
20 validity of the data, the representativeness of
21 the data.

22 And then this last section which I call sort of
23 a show me section. This is where NIOSH is
24 going to stand up and show the Board some
25 things. And I think there are three issues

1 that have come up here. One is we're going to
2 speak to what is plausible and what is
3 implausible based upon what we've said to this
4 point.

5 We're going to deal with this issue of this
6 does not result in disparate treatment. I
7 think we all know what that means. It's what
8 happened to us in Iowa where we do all of this
9 and all of a sudden we wind up with a
10 discontinuity between workers. And we have to
11 demonstrate that that's not the case.
12 And then lastly, NIOSH is going to present
13 sample DRs that will be realistic examples
14 designed to demonstrate the range of approaches
15 that we have basically alluded to in the
16 previous materials. Realistic examples
17 designed to demonstrate the range of
18 approaches.

19 I'll get this all typed up, and then we can
20 chew on it, but I hear those three things
21 being, if the Board says, show me this, show me
22 this. And that's quite reasonable.

23 **DR. MELIUS:** And I also think that by doing
24 that it also does force you to sort of look at
25 the feasibility in the sense of is there a cost

1 effectiveness of doing this. Is it really
2 worth to get to that point or is it going to
3 take so much work that it just doesn't make
4 sense for this program to be doing that. It
5 may be possible in five years or whatever, but
6 --

7 **DR. ZIEMER:** Well, and that's kind of this
8 issue.

9 **MR. GRIFFON:** Let's look at the idea on where
10 you might change this approach, why are you
11 doing, if you're considering these things, you
12 might have a change just because of that.

13 **DR. NETON:** But it may be there are no subsets
14 of the bounding approach.

15 **DR. ZIEMER:** And then you point that out.

16 **DR. NETON:** There are no subsets. We can't
17 refine this any better. We have no more
18 additional data.

19 **MR. GRIFFON:** Well, I leave you with that last
20 quote there, Lew, I would tie in the fact that
21 that is sort of an attempt to address it
22 because it was a feasibility issue.

23 **DR. WADE:** I changed it to, the heading is
24 going to be to explore feasibility, to present
25 sample DRs and... Anything we want to add to

1 this sort of show me list?

2 **DR. ZIEMER:** Can we make sure that there is
3 some level of addressing the timeliness issue?
4 In other words, if you say we can do all these,
5 but it's going to take whatever it is. I mean,
6 when you get a petition, the clock starts to
7 move. Then when we get it, the clock kind of
8 stops. And I think we also have to address
9 that, can we position for ourselves.

10 It's kind of a, I think it's a Board issue,
11 Jim, in part, where we have to say how much
12 more will we demand. Do we want to set a
13 timetable? I'm not sure we should answer this
14 now. I think it's a Board decision. But we
15 need to have some parameters to guide us as,
16 and maybe this freezing the clock issue.
17 See, at this point regardless of what else is
18 found, the decision is going to be based on
19 what we have now, or it's going to be based on
20 what we have in three weeks, or whatever it is.
21 But it seems to me we need to couple that with
22 this whole picture somehow.

23 **DR. MELIUS:** And I think, even just on this, we
24 need to have the evaluation report we're
25 expecting from you to be something that can be

1 done within your mandated timeframe. And I
2 think this because I don't think we could --

3 **MR. ELLIOTT:** Well, that's one problem we're
4 going to decide here because I have to manage
5 the process to the point where we meet our
6 deadlines.

7 I think we're certainly willing to do that. I
8 also agree that the Board has to have some
9 decision on timeliness as well in what you do.
10 We need to bring something forward that will
11 enable you to be timely.

12 **DR. MELIUS:** And then there's a third
13 timeliness which is what you're proposing that
14 it be actually, you say it's feasible to do it,
15 do the dose reconstructions, is it going to be
16 feasible to do within something that's
17 reasonable. It's not going to take five years.

18 **DR. NETON:** Well, we're talking about putting
19 this in the evaluation report itself?

20 **MR. ELLIOTT:** Well, I don't know at this point.
21 The last one I don't think is going to be, it's
22 going to matter much. We're moving through
23 these claims. We're going to be at a point
24 very soon where we know what we can reconstruct
25 and what we can't. We're working through

1 those.

2 **DR. WADE:** On the show me page I can put that
3 one of the things the Board wants NIOSH to show
4 it at this point is that these dose
5 reconstructions as proposed here will be done
6 in a timely manner. That's okay to have NIOSH
7 --

8 **DR. ZIEMER:** Well, think about this though,
9 you'll come to us with an evaluation report,
10 and presumably, we will have a critique of that
11 also, possibly from SC&A. Now you can imagine
12 they will raise some issues, and we know from
13 the past that some of the issues are
14 interesting scientific points that have very
15 little impact on the bottom line, others may be
16 significant. At the front end it's sometimes
17 hard to filter those out, but at some point we
18 have to be able to assess those and say, you
19 know, it will take us six months to address
20 this, and it's not going to impact the bottom
21 line, or I don't know --

22 **MR. ELLIOTT:** But I think we're saying that,
23 Paul. We're saying that.

24 **DR. ZIEMER:** I don't know if we're saying that
25 or you. I mean, you could be saying that, too,

1 it seems to me, but somehow we have to be able
2 to deal with this, yeah, both of us.

3 **MR. ELLIOTT:** If we could get an SC&A comment,
4 we could say, NIOSH could say, well, you know,
5 it'll take six to eight months to evaluate
6 this, do the research on it, put it together
7 and present it to you. We don't think that's
8 an appropriate expenditure of resources.

9 **DR. ZIEMER:** And then they'd say, fine, stop,
10 we'll make that decision without that.

11 **DR. MELIUS:** If the process. If these
12 guidelines we come up with keep enough focus on
13 sort of what is important in terms of dose
14 reconstruction. Then we are going to be
15 instructing SC&A to focus on those same things,
16 not to focus on the smaller details. Now they
17 may find something or, I mean, I think we want
18 them to say if NIOSH missed some important
19 issue that was going to affect dose
20 reconstruction.

21 **DR. ZIEMER:** Or there's some nuclide you
22 haven't considered or something about the dose
23 reconstruction --

24 **DR. MELIUS:** But not that you haven't refined
25 some trivial point from -- and maybe we can

1 keep that task focused. Then I think it will
2 avoid some of these issues so your evaluation
3 can be sort of more targeted than that of, then
4 I think we can handle the review process.
5 It'll be much more efficient and fair and
6 timely. It just doesn't make sense for them to
7 go off in some other different pathway.

8 **MR. ELLIOTT:** Does that help?

9 **DR. WADE:** So now we've got a completed body of
10 work to consider. What I'll pass around is
11 sort of a summary of our discussions on
12 credibility/validity and then our assumptions
13 on representativeness. So we go all the way
14 around with each. And process will be the
15 third piece that will be typed up as we're
16 discussing this which is the show me piece
17 which is the special burden that NIOSH will
18 take on to show things to the Board.

19 **DR. ZIEMER:** Now everybody write a date on this
20 right now so a year from now you will know.

21 **DR. WADE:** And we can sort of go through this.
22 Two principle elements of Mark's construct
23 which is credibility/validity and
24 representativeness. In the credibility we
25 expect NIOSH to stand up and present on the

1 pedigree of the data, sort of any methodology
2 issues. This relates to the types of badges
3 used, and there are a range of things. I don't
4 need to summarize them I don't think.

5 Then we had this issue of chain of custody,
6 some question raised as to what that meant. I
7 think we need to talk a little bit about that.
8 But then NIOSH needs to present evidence to the
9 contrary that might have been collected on
10 credibility or validity. This could be
11 pointing out things in the petition itself, a
12 complete scanning of worker interviews.

13 And then we need to be concerned if we didn't
14 start with the raw data, if we started with
15 some man-made representation of the raw data,
16 then we have some things to prove. And then it
17 would be incumbent upon NIOSH to, looking at
18 the data, to present some tests of internal
19 consistency. It's difficult to define what
20 they would be, but there would be a burden on
21 NIOSH to explore the data. And we've all lived
22 with datasets long enough to know how one can
23 go about doing that.

24 On representativeness, representativeness
25 relative to the fact that this is

1 representative of all workers, that it is
2 representative of the spatial extent of the
3 petition we're looking at, that there is
4 temporal representativeness, not two samples
5 one year and 2,000 every other year. And then
6 we get to the real knotty issue of the
7 representativeness of data subsets. And you
8 know, we'll either say that we have a
9 statistically robust sample and stand up and
10 show you that by the rules of statistics.
11 Or if we do not, then it'll be incumbent upon
12 us to assume that we have a subset that
13 represents the highest exposed worker. If you
14 can't present evidence of that fact, then we
15 would default to the assumption that it was a
16 cohort sample and treat it as such. Again, if
17 there's evidence to show that it's the lowest
18 exposed, then we would need to present that and
19 deal with that accordingly.

20 So that's what I hear you guys talking about.
21 And it seems as far as it's gone reasonable.
22 The question is always, and Jim raised this
23 earlier, what have we left out. I'll bet you
24 there's something terribly important we haven't
25 captured here, and I think we need to think

1 about it.

2 **DR. MELIUS:** Or the next petition, something --

3 **DR. DeHART:** There's an outcome issue, too, I
4 think that we haven't addressed that should be
5 kept in our minds and that's fairness and
6 precedent as perceived by others. We see that
7 all the time, at least in Oak Ridge. It's a
8 special cohort.

9 **DR. ZIEMER:** I sort of agree with that, but I'm
10 not sure that we can address the fairness issue
11 that well. I mean, a priori the law seems a
12 little unfair to start with to most people. I
13 mean there are some groups that were singled
14 out for special treatment, and every group we
15 hear from that's the starting point. It's not
16 fair that they got this treatment and we
17 didn't. But can we, I mean, I think we can
18 make it important that we are fair and within
19 the limitations of what the law allows us to
20 do, but that unfairness issue is going to be
21 there all the time anyway in people's minds I
22 think.

23 **DR. DeHART:** I don't know that we can offset it
24 totally, but if it's understandable and easily
25 explained then that makes it easier to defend

1 what we've done.

2 **DR. WADE:** I don't think it's bad for us to
3 capture on another piece of paper sort of Board
4 -- I won't say Board rules, but Board
5 behaviors. We've already talked about the
6 timeliness one. The Board needs to be timely
7 in its action. I think the Board needs to be
8 internally convinced that it is fair. It needs
9 to be, it needs to focus on the fact that its
10 work can be understood. And I think so we'll
11 capture that. I think it's okay for us to
12 capture it.

13 **DR. MELIUS:** And we have to be consistent, and
14 this definitely helps that part of it. It
15 would keep us evaluating the same parameters
16 and so forth.

17 **DR. ZIEMER:** It would treat the groups in a
18 similar way. That's a --

19 **MR. ELLIOTT:** We talked earlier about
20 disparity. We don't want to contribute to that
21 unless we're bound by the construction of the
22 law and the regs.

23 **DR. MELIUS:** I mean, the fact that we use IREP,
24 there's some disparities built into that
25 somewhat.

1 **DR. WADE:** So we will generate a fourth sheet.

2 **MR. GRIFFON:** Can I say one thing on the
3 representativeness page, that bottom construct
4 category comment. I would say present evidence
5 for the assumptions, period. I don't think
6 you'd default to number double I necessarily,
7 do you?

8 **DR. ZIEMER:** You're not sure why you would
9 necessarily default?

10 **MR. GRIFFON:** -- default to the assumption that
11 is the cohort sample.

12 **DR. NETON:** Well, it'd be pretty hard, you'd
13 have to have some evidence that it was the
14 lowest exposed. I think that my issue would be
15 I would make number three not lowest exposed
16 but unable to discern. What would you, see
17 that?

18 That sort of has a presumption of guilt or
19 something when you say lowest exposed,
20 intentionally. I think if you're unable to
21 discern then I'm not sure what we do, but that
22 would end up being the default. And then I'm
23 not sure how we would deal with it at this
24 point.

25 **MR. ELLIOTT:** We agree on Mark's suggestion

1 that we just say present evidence for
2 assumption, in the parenthetical?

3 **DR. WADE:** So we change three to unable to
4 discern and the parenthetical will end at the
5 word assumption.

6 **MR. GRIFFON:** And you may make an argument that
7 we can't discern then what we're going to
8 assume because we have a number of reasons for
9 us to believe.

10 **DR. NETON:** And I think that's what we --

11 **MR. GRIFFON:** We might defer to two, but not --

12 **MR. ELLIOTT:** If we make an argument on the
13 highest exposed, the argument based upon we
14 have no evidence to the contrary --

15 **DR. NETON:** We don't want to do that. We tried
16 that. It didn't work.

17 **MR. GRIFFON:** You can say that all the time.

18 **DR. NETON:** No, I think we just have to pick
19 one of these categories and defend this. And
20 if we're unable to discern that would be the --

21 **MR. GRIFFON:** That may be a piece of your, that
22 we have no, you know, we've looked through all
23 the interviews. Nobody said any differently,
24 but the procedure, it seems to support this is
25 what it was.

1 **DR. WADE:** All that stuff you were doing
2 yesterday, where you introduce a whole many
3 more samples but the maximum doesn't change.

4 **DR. NETON:** Yeah, those kind of constructs that
5 you can come up with.

6 **MR. ELLIOTT:** When you were saying, I just
7 wanted, where I was going with that, I want to
8 make sure that my understanding here is that
9 we're to present things but these are evidence
10 based.

11 **DR. WADE:** Yes.

12 **MR. ELLIOTT:** It took me a while to spit it
13 out, but we're saying these are evidence based.
14 We're not saying this is based on no evidence
15 or evidence to the contrary. We do not have
16 any evidence to the contrary. We're taking
17 this position. I want to make a point. This
18 is evidence based.

19 **DR. ZIEMER:** Lew, you left us hanging on chain
20 of custody a little bit. Were we going to try
21 to define today what that means? I'm not sure
22 I know what it means in this case. But not a
23 chain of custody like the legal people. Here's
24 the sample, I've sealed it. I'm going to hand
25 it to you. I've initialed.

1 **DR. NETON:** In some ways that kind of rolls up
2 under pedigree, I think is where we're at.

3 **DR. WADE:** What I meant was that if a critical
4 dataset was out of adult control for some
5 amount of time, I would worry about it. Now I
6 don't know what, if that can happen in your
7 world. I mean, if you were to find a derived
8 dataset somewhere last Thursday and not know
9 where it came from.

10 **MR. ELLIOTT:** Well, I took it to mean, that's a
11 good valid point you're making.

12 But I took it to mean in my thinking we have
13 datasets that have been developed by other
14 entities, and we just pick those up off the
15 table and use them. We need to scope the
16 pedigree, but we need to question how they were
17 constructed, were they validated, were there so
18 many keystroke mis-entries here, and what does
19 that mean?

20 **DR. WADE:** It could be pedigree is enough for
21 all this.

22 **DR. NETON:** I think we're trying to speak maybe
23 to were these databases altered at some point
24 from the original. When an EPI study took it
25 over and ORAU, the documentation says they

1 threw out these high values because they appear
2 to be anomalies. That's not necessarily a
3 chain of custody though is sort of a pedigree
4 but it's a little different. Pedigree to me is
5 --

6 **DR. WADE:** Give me a better word. If it's
7 different than pedigree, we should capture it.

8 **DR. NETON:** I'm trying to think of what it is.

9 **MR. KATZ:** Pedigree, I just think of pedigree
10 though as sort of the natural history of the
11 dataset.

12 **DR. NETON:** Yeah, what happened? Where did it
13 come from? What's the genesis of the data?
14 Who had it? Where did it go? Has it been
15 modified?

16 **DR. ZIEMER:** I think that pedigree gets to that
17 though.

18 **DR. WADE:** Pedigree-slash-history. Will that
19 do it? Just to show some sort of not only
20 where was it born, but where was it.

21 **MR. ELLIOTT:** Does it make sense to move chain
22 of custody under the subheading of pedigree?

23 **DR. WADE:** No, just I think take chain of
24 custody out and put pedigree-slash-history.

25 **DR. NETON:** I think that kind of captures the

1 whole -- I've got a number of things written
2 down here.

3 **DR. ZIEMER:** Basically, you want to be able to
4 get back as close as you can to the prime
5 dataset, not secondary or tertiary summaries of
6 it.

7 **DR. MELIUS:** In terms of a guidance document,
8 we know you did a good job, Lew, but if we
9 think we need more than this, would something
10 that would flesh this out proscriptively, or
11 more importantly, have key questions attached
12 to it. There wouldn't, we're never going to
13 have every question or every judgment that
14 would go into these, but if we had some of what
15 were some of the key questions that would need
16 to be answered as part of the SEC evaluation.
17 I mean, you started to get that like in the
18 show me that a little bit and you certainly
19 discussed enough. But that to me would be a
20 document that would not be overly long, that
21 would not be exhaustive, but would have, would
22 communicate what's being done, and would sort
23 of foster the communication between the Board
24 and NIOSH and sort of the general public and
25 the petitioners that are involved in this. Is

1 that sort of a goal to try to get to with this?

2 **DR. WADE:** Yes.

3 **MS. HOMOKI-TITUS:** That just has to go to the
4 Board before you can --

5 **DR. MELIUS:** We know that. We're working for
6 the Board with whatever --

7 **DR. WADE:** And we have Board opportunities in
8 front of us before the end of January meeting,
9 so it actually would be wonderful to take with
10 us.

11 **DR. MELIUS:** The other question though, I mean,
12 maybe should that be a Board document or should
13 that be a NIOSH document?

14 **MS. HOMOKI-TITUS:** That's up to you guys.

15 **DR. MELIUS:** Is it the guidance document for --
16 or are there two documents, the guidance
17 document on how you develop your SEC
18 evaluations. You already have a procedure on
19 that, but this, I think, would make, would
20 modify that.

21 **MR. ELLIOTT:** Our procedure would be modified
22 based upon where we come out on these.

23 **DR. MELIUS:** And then this Board document, how
24 the Board's going to evaluate.

25 **DR. WADE:** I think it would be well to imagine

1 that this would result in a communicating from
2 the Board, agreed to by the Board, owned by the
3 Board, and then sent to NIOSH. And then NIOSH
4 could modify its procedures accordingly. Then
5 the Board would be attached to it consistent
6 with its own communication, and NIOSH would
7 know what to do. But this needs to be fleshed
8 out.

9 **DR. ZIEMER:** This is basically the outline of
10 what's on paper which is basically the Board's
11 position on -- sufficient accuracy is the
12 overriding theme.

13 **DR. WADE:** There is a fourth piece, but I don't
14 have it. It'll say overriding Board
15 considerations: timely, fair, understandable,
16 consistent and mindful of precedents. Just so
17 you know there'll be a fourth piece of paper
18 you'll have. And then I think that needs to be
19 explored as well.

20 Now what we could do is talk about how you guys
21 are going to go about doing that. We could
22 start to do it. We could, all kinds of
23 options. But I'm still more worried about the
24 fact that what are we missing; I'll bet you
25 we're missing something terribly important.

1 I'll bet you. I mean my challenge to you would
2 be what's more?

3 **DR. MELIUS:** At one point we'll recognize those
4 just when we start. And particularly I would
5 like on the show me page part of this to really
6 have some, it would have to be fairly specific
7 criteria that we can be consistent with and
8 sort of try to capture really what that final
9 judgment will be that will drive the
10 recommendation because that's what will keep it
11 focused.

12 **DR. DeHART:** There's another party that's
13 missing from the table and that's the
14 petitioner themselves. Is there something
15 there that needs to be coming in here? I don't
16 know, but --

17 **DR. WADE:** I bet you. That's a good point. I
18 think it would be wise for the Board to sort of
19 vet with some of the people we serve.

20 **DR. ZIEMER:** In essence when we meet in full
21 meeting, the public has the opportunity to hear
22 what the approach would be and then give us
23 input on that. I mean, that really is the
24 process, is it not?

25 **DR. DeHART:** Or intentionally making every

1 effort to meet where --

2 **DR. ZIEMER:** I mean, we can't (unintelligible)
3 to a particular petition.

4 **MR. ELLIOTT:** I think we're all somewhat
5 obliged to making sure that we communicate to
6 the audience with possible potential
7 petitioners what it is we're, what these
8 guidelines are, what this criteria is that's
9 going to be used because then that will enable
10 them to develop their petition, and make sure
11 they develop it on the basis of the rules and
12 also more importantly on them.

13 **DR. MELIUS:** I can see one area that, I mean,
14 I'm trying to remember what's in your part in
15 your petition, but it's the issue of pedigree.
16 Did they have evidence or knowledge of
17 something that would question the pedigree or
18 the -- datasets.

19 **DR. NETON:** It's one of those.

20 **DR. MELIUS:** Is it on there already? I can't
21 remember whether it's in there. That's the
22 question.

23 **MR. ELLIOTT:** We don't ask it. I mean, is it
24 spelled out in the basis or qualification?

25 **DR. NETON:** It's not uncommon.

1 **DR. WADE:** We would be doing the world a
2 service if someone who's about to file a
3 petition could read through this, knowing what
4 the test would be. And I think that would
5 happen. Just again thinking of timing and this
6 working group would prepare something for the
7 Board to consider on January 9th, and then news
8 on January 24th.

9 **DR. MELIUS:** I would, I guess I would be, I
10 don't think it's best to have the Board
11 consider some of this type of document by
12 phone. I think it just doesn't work. I think
13 to have some discussion of it on January 9th,
14 at least awareness and even give them something
15 before January 23rd.

16 **DR. WADE:** Something before the 23rd, have the
17 Board audit one of its first actions at its
18 face to face meetings, consider this and adopt
19 this and then make use of it in its decision
20 the next day or the day after.

21 **DR. MELIUS:** Could very well, I mean, I think
22 if we captured what the Board, what we as a
23 Board thinks we should be doing. We do
24 represent the other members of the Board, and
25 they agree with us, then I think it should be

1 helpful. And I think we have at least in my
2 private discussions with the other Board
3 members.

4 **MR. GRIFFON:** You have to understand that NIOSH
5 has to get a petition for Y-12 before then, so
6 we have --

7 **DR. WADE:** The work group could be guided by
8 this.

9 And so the plan is some work by the working
10 group, a discussion by the Board on the ninth,
11 the Board will take formal action early in this
12 next meeting.

13 **MR. ELLIOTT:** And we will use this discussion
14 and then transfer from today's proceedings to
15 guide us in the development of Y-12 and the
16 future evaluation reports.

17 **DR. WADE:** Not to put you on the spot, Brad,
18 but what do you think? You're a reasonable
19 person coming in now.

20 **MR. CLAWSON:** I, reading through this and stuff
21 like that, you know, I think that we've got a
22 good approach to it. Actually, I feel like
23 we're leaving something out, and I can't put my
24 finger on it. I really can't. You know, but
25 this is, in my world this is a good blueprint

1 for where we're going. But with the Board
2 we're going to, as this evolves, I'm sure
3 there'll be changes to it. But I think it's a
4 good start. Some of your terminology though,
5 your chain of custody and so forth like that,
6 we should be very careful of because there are
7 other individuals that it means something
8 different than what is actually there.

9 **DR. MELIUS:** On procedure, I think we're
10 getting that shortly?

11 **DR. DeHART:** It's out there.

12 **DR. MELIUS:** Oh, it's out there. Why didn't
13 you say so? Some of us need to look at the
14 feasibility of getting out of here earlier.
15 And what we'll do is we'll talk and then we can
16 eat lunch. And as we're eating lunch we can
17 look at that feasibility and then we can sort
18 of regroup and decide what we want to do given
19 what the, how much time we have.

20 **DR. WADE:** Yeah, whatever the working group's
21 desire is.

22 (Whereupon, the Working Group concluded at
23 12:15 p.m.)
24
25

C E R T I F I C A T E O F C O U R T R E P O R T E R**STATE OF GEORGIA****COUNTY OF FULTON**

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported and transcribed the above and foregoing from the day of Nov. 17, 2005; and it is a true and accurate transcript of the testimony captioned herein.

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

WITNESS my hand and official seal this the 5th day of December, 2005.

STEVEN RAY GREEN, CCR

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