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.

C O N T E N T S

Nov. 17, 2005

TRANSCRIPT LEGEND

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P A R T I C I P A N T S
(In Alphabetical Order)

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OTHERS PRESENT:
ELLIOTT, LARRY, NIOSH
HINNEFELD, STU, NIOSH
HOMOKI-TITUS, LIZ, HHS/OGC
HOWELL, EMILY, HHS/OGC
KATZ, TED, NIOSH
KOTSCH, JEFF, DOL
NETON, JIM, NIOSH
RUTHERFORD, LAVON, NIOSH
SHIELDS, LASHAWN, NIOSH
SUNDIN, DAVE, NIOSH

P R O C E E D I N G S

(9:20 a.m.)

WELCOME AND OPENING COMMENTS
DR. LEW WADE, EXECUTIVE SECRETARY

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

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

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

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

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

Just as background, the Board is going to face a Y-12 SEC petition at the end of January. The ideal thing from my point of view would be the Board having reached sort of scientific closure on the site profile, and then the Board having a sense of what its responsibilities are when it recommends out on SEC petitions. And that's the purpose of this most important work group.

So with that we have also, we've invited an incoming Board member to join us, Brad Clawson is with us, was with us yesterday, and showed himself to be capable of dealing with marathon

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

So Jim, it's all yours.

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

MR. ELLIOTT: The site profile review is settled.

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

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

DR. ZIEMER: And then --

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

DR. ZIEMER: Is that one dependent on the

outcome of the 22nd or is that --

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

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

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

DR. WADE: Liz has one comment to make.

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

That was all, thanks.

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

WORKING GROUP DISCUSSION:

COMMENT ON SEC RULE

DR. MELIUS: When preparing for this meeting, I

guess the Board knows this, but we were talking in the cab on the way over. I came across something that actually the Advisory Board had recommended about two and a half or three years ago which I hope is actually should have been the charge for what we're doing today which is some comments on the idea of sufficient accuracy or comments on the SEC rule, I think the second round if I remember right.

Therefore, the Advisory Board recommends, it would be helpful if NIOSH would provide additional clarification of this concept of sufficient accuracy. Therefore, the Board recommends that guidelines addressing feasibility and sufficient accuracy be developed, and then it goes on with some more specific things about that being done.

But it struck me and others that in dealing with the SEC petitions and dealing with some of the site profile reviews that we've been sort of struggling to come up with how do we, how does the Board evaluate those? And I think my sense is that NIOSH has been, Jim and Larry, your staff has been sort of struggling to figure out what's the best way of evaluating

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

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

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

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

But it’s not a very complicated multiple exposure situation.

But we’re also struggling like with Mallinckrodt where we had lots of information, maybe too much in some ways to try to come up with this assessment. And so I thought it was worth trying to go back and now that we’ve all had experience with a number of cases, experience reviewing individual cases, experience reviewing SEC petitions and evaluations, to try to come back and develop some guidelines for how that would be done because we’re not in sync on that completely. And I think if we continue to do it on a, not that we want review individual cases, but we can try to do it sort of a case law approach. You know, let’s sort of develop this over time based on our experience with individual petitions that should not take us a long time. It’s going to be some long, long meetings, and I’m not sure it’s going to be a very productive approach. I don’t think it’s, in some sense, fair to the claimants because we’re there spending hours trying to figure out what to do with these, and so, with these petitions,

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

of the, of what we, you know, of such different types of situations. It's not going to be a simple one test for everything. And some of them may just be process. What's the best way of you -- you, being NIOSH -- going through and evaluating these situations and determining what is sufficient to present to the Board so the Board can make an evaluation.

Because some of the problem I think we have is that we'd have you pursuing so many different avenues, so many different aspects of individual dose reconstruction that it in, what data might or might not be available or how complete or comprehensive or accurate is that data. There's a lot of time spent that is not, just takes a lot of resources to do that. And we need to, I think, be aware of that. I mean, at some point it becomes, we're spending more doing these evaluations in time than given the number of cases that are really in play. To me it doesn't seem to be very worked out especially given all the other things that are out there to do. It's not like there isn't other stuff to do. I'm sure after every meeting Larry must, you must go back and say,

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

DR. WADE: Let me just add some observations to frame the issue. I think one of the lessons we learned through the Mallinckrodt process is that while this is a continually evolving process, there comes a moment in time when the Board has to make a decision, and we need to manage that process. There needs to be, I think, some understanding that at a moment in time we will freeze that reality and that will be the reality that the Board will operate against. We can't keep chasing the ever-changing background, and that's difficult. But we need to talk a little bit about that.

The other thing, speaking for the NIOSH Director, the reality that he faced after Mallinckrodt which was a program recommendation from OCAS. A close Board vote in opposition to that is not the ideal situation for him to find himself in. Now, if he has to be in that situation, so be it, but I think we need to understand that we do this within sort of a

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

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

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

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

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

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

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

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

DR. WADE: Jim.

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

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

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

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

for you to make a rational decision.

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

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

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

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

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

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

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

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

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

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

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

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

DR. NETON: Let me go way back to where I thought where this process started, and Mallinckrodt's a good example because it's already done. But, and we've had some discussion to this extent at the Board meetings. Let's say that we have a lot of air sampling data in Mallinckrodt. And we did. We had, I forget how many, anyway, thousands of air samples. And it was our thinking at least that to bound the exposures, one could take the air sample data at a worst case and use that to estimate the maximum plausible dose to the workers.

Now would that at the end of the day be used once? Like Larry suggested we refine these gross reconstructions and got them to be more accurate? Probably not, but at least we could demonstrate up front that that would be a maximum plausible dose to the class of workers whether or not we assumed it was thorium or radium or we'll just pick the worst case nuclide. We have, we believe, a technique or a data set if we could validate the air data that could be bounded.

Now, we took some criticism there because those

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

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

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

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

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

But that really you were just doing a very basic job of showing feasibility, not going down every path that wasn't necessarily raised in the petition. Because, of course, when you get to a big site like Y-12, who knows how many garden paths there are. I mean, there's millions of possibilities and to explore all of those in an SEC petition, you would spend a year just doing the SEC evaluation, or more.

So just in terms of historical contents, I don't know how much it will help you for this discussion forward. Really, the emphasis was to address those issues that were explicitly raised by the petition and then otherwise just do a very summary job of showing that in general it appears that we have the data needed to do dose reconstructions here.

And that wouldn't foreclose then down the road someone raising, you know, as SC&A digs down

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

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

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

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

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

DR. WADE: So in retrospect --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. ELLIOTT: But what is sufficient?

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

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

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

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

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

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

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

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

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

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

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

MR. GRIFFON: Representative.

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

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

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

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

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

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

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

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

DR. MELIUS: Yeah, and do that.

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

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

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

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

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

DR. NETON: But the SEC --

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

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

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

DR. NETON: Yeah.

MR. GRIFFON: So with a site profile --

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

MR. GRIFFON: -- which is driving individual DRs.

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

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

MR. GRIFFON: Much easier.

DR. NETON: But I like to think in simple

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

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

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

workforce, internal dose anyway.

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

DR. NETON: I think I know where that comes from.

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

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

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

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

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

DR. ZIEMER: Had you done the --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

maximum plausible.

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

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

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

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

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

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

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

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

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

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

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

bioassay for a lot of these earlier facilities.

DR. WADE: And just to finish, and when they're probing and poking causes us just to say, oh, well, take a look at it from this perspective, then we have a credibility problem. Then all of a sudden in playing this out in front of the public, you know, exacerbates that problem so the question is how do we get it right the first time.

DR. DeHART: I was not attending that meeting, but I had the opportunity and took it to read the total transcript of the discussions that went on. I read them twice. You've touched on this issue, but in reading it what came across to me that was the most important thing toward the end was the mention of time.

Commonly it came up, these people have waited long enough. They're -- and here we're going to have to go over it again, and that came to an end. And I think we can't lose sight of that. But there were technical issues certainly, but people felt pressured to make a decision, at least some did. And when you read through it that became the overriding factor.

MR. GRIFFON: I think we all felt that pressure

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

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

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

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

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

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

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

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

cost and availability of records.

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

DR. ZIEMER: What page is that on?

MR. SUNDIN: Three 0783.

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

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

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

DR. NETON: Right.

MR. GRIFFON: -- I think --

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

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

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

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

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

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

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

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

DR. NETON: For the unmonitored worker.

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

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

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

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

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

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

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

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

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

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

credible, valid and representative.

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

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

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

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

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

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

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

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

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

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

representative, any member of the class. What's the gold standard on credible?

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

MR. ELLIOTT: I see no trends of that.

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

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

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

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

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

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

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

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

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

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

MR. GRIFFON: So I have an answer.

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

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

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

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

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

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

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

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

MR. HINNEFELD: Well, not in every one.

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

MR. HINNEFELD: Right.

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

MR. ELLIOTT: If we ask for something different

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

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

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

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

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

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

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

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

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

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

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

additional exposure may have been.
But I don't how we would, I agree with you. It depends on a case-by-case basis almost. We try to get back as close to the raw record as possible, but we almost never, to my knowledge, get raw laboratory results. We have to believe that the DPM per liter that's recorded was faithfully recorded at some point.
MR. GRIFFON: Right, unless you have a challenge on that one I guess that would be as far as you can realistically chase it.
DR. ZIEMER: But the likelihood of data being manipulated is probably not nearly as great as the likelihood of badges being manipulated. I've seen people do this even at our place where you're trying to hide the fact they got up close to a limit, and they, not that a foreman told them to do it, they did it themselves to keep working. And I think that's probably more likely.
DR. WADE: Well, let's take stock of where we are now. So to the issue of credibility we're developing sort of a list of things we would expect NIOSH to bring to the Board when it presented an SEC petition evaluation report.

We would want them to deal with the pedigree of the data. We would want them to deal with any methodological issues that might result, the technology used, those kinds of issues. We're interested in chain of custody. If the data was outside of a valid chain of custody at any point in time, it might raise concerns, and we need to talk about that. We would be interested in evidence to the contrary, and that evidence to the contrary might be raised in the petition itself. It might be raised by worker interviews, or it might be raised by the first level of information we have isn't the raw data. And that would be of concern to us. And then the last issue is this issue of internal consistency checks that could be worked on the data. And we need to talk a little bit about that as to what the expectation of the Board would be in terms of NIOSH demonstrating the internal consistency of the data, and there's been some discussion of that recently. And is there a way we can be prescriptive about that at this point?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. ZIEMER: They're incredible.

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

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

MR. GRIFFON: Can we take a little break?

DR. MELIUS: I'm sorry. Let's take 15 minutes.

(Whereupon, the Working Group took a break at 10:40 a.m. until 10:55 a.m.)

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

MR. GRIFFON: Silence.

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

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

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

MR. HINNEFELD: So --
DR. MELIUS: It's sort of how do you define the class? I mean, it's that whole --
MR. GRIFFON: Yeah, that's what I said, it kind of overlaps with the second part of that definition, the all members of the class thing.
DR. MELIUS: So is one of the evaluations is the data representative for all members of the class?
DR. ZIEMER: In the rule where it says any member, we're thinking that means, I guess, the highest exposed individual, in some subgroup or whatever that class is.
DR. DeHART: That's the way I interpret it. But does it necessarily just the petition, because we've broken them out from petitions before into separate groups.
COURT REPORTER: I'm getting total static.
(Whereupon, a short break was taken to correct technical problems.)
DR. WADE: Okay, we're back on. Jim, you were saying?
DR. NETON: I was just saying we're talking about any member of the class. I don't think it means all members of a class. It means a

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

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

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

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

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

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

be different.

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

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

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

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

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

DR. NETON: Cancer-specific issues are not allowed.

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

internal dose for all the radionuclides of dosimetrics.

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

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

all categories but for not all dosimetric radionuclides.

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

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

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

DR. NETON: And that gets into the source term

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. NETON: Right.

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

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

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

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

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

DR. NETON: But its even another layer on top

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

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

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

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

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

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

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

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

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

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

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

DR. NETON: The extremes are pretty easy,

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

DR. MELIUS: Yeah.

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

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

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

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

MR. GRIFFON: The cohort of the lowest doses.

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

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

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

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

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

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

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

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

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

DR. MELIUS: And is that individual dose reconstruction?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. ZIEMER: Right, that becomes important.

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

DR. ZIEMER: Yeah, regulatory or --

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

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

’62, and --

DR. ZIEMER: Well, but it’s better than issue --

MR. GRIFFON: Where’s the cutoff?

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

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

DR. ZIEMER: We can say we don’t believe this is sufficient.

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

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

DR. ZIEMER: Well, at least there’d be a rationale --

DR. MELIUS: A rationale for --

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

DR. MELIUS: That’s where I am because I think that we’re just going to have to because –-

DR. NETON: They’re somewhat connected. The frequency of the number is of course related to

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

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

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

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

MR. SUNDIN: Numbers of samples.

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

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

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

DR. WADE: So again just to review before we get it typed for review, under representativeness we have now four main categories: representativeness considering all types of workers, representativeness on a spatial perspective, on a temporal perspective, and then four, the representativeness of data subsets and the fundamental question do we have a statistically robust sample.

If the answer is yes, we present the justification for that. If the answer is no,

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

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

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

DR. ZIEMER: Might not affect the final decision.

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

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

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

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

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

DR. NETON: Yeah, with the bracketing.

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

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

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

It's not going to be something that --

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

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

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

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

The other reason I speak to Jim's idea of sample DRs, the only reason I think that's really critical in this is that the question of feasibility. It is not my concern that if we come to agreement on this notion of maximum plausible or if you put out a guide that's a maximum plausible dose, and yet we're not sure how that's going to be carried through and you are missing some pieces, and we've got some more homework to do, I don't think we have any way sort of as a Board to sort of evaluate. And I don't know we even have a clear understanding of what does that mean, the feasibility. But I guess we've heard this over and over. We don't want this to be some long-term -- So this is the notion of well, we've got a lot of unknowns here, but I know it's not

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

DR. NETON: Best estimates would be found.

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

DR. NETON: The application of our approach.

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

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

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

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

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

composite case. We'll mix and match.

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

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

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

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

MR. GRIFFON: Why is that a requirement?

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

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

MR. ELLIOTT: Well, this is the subset.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. MELIUS: Doing that focuses on --

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

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

DR. NETON: I think I see this.

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

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

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

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

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

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

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

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

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

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

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

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

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

We're going to deal with this issue of this does not result in disparate treatment. I think we all know what that means. It's what happened to us in Iowa where we do all of this and all of a sudden we wind up with a discontinuity between workers. And we have to demonstrate that that's not the case.

And then lastly, NIOSH is going to present sample DRs that will be realistic examples designed to demonstrate the range of approaches that we have basically alluded to in the previous materials. Realistic examples designed to demonstrate the range of approaches.

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

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

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

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

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

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

DR. ZIEMER: And then you point that out.

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

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

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

this sort of show me list?

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

It's kind of a, I think it's a Board issue, Jim, in part, where we have to say how much more will we demand. Do we want to set a timetable? I'm not sure we should answer this now. I think it's a Board decision. But we need to have some parameters to guide us as, and maybe this freezing the clock issue.

See, at this point regardless of what else is found, the decision is going to be based on what we have now, or it's going to be based on what we have in three weeks, or whatever it is. But it seems to me we need to couple that with this whole picture somehow.

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

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

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

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

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

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

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

those.

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

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

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

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

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

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

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

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

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

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

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

MR. ELLIOTT: Does that help?

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

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

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

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

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

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

On representativeness, representativeness relative to the fact that this is

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

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

about it.

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

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

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

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

what we've done.

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

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

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

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

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

DR. WADE: So we will generate a fourth sheet.
MR. GRIFFON: Can I say one thing on the representativeness page, that bottom construct category comment. I would say present evidence for the assumptions, period. I don't think you'd default to number double I necessarily, do you?
DR. ZIEMER: You're not sure why you would necessarily default?
MR. GRIFFON: -- default to the assumption that is the cohort sample.
DR. NETON: Well, it'd be pretty hard, you'd have to have some evidence that it was the lowest exposed. I think that my issue would be I would make number three not lowest exposed but unable to discern. What would you, see that?
That sort of has a presumption of guilt or something when you say lowest exposed, intentionally. I think if you're unable to discern then I'm not sure what we do, but that would end up being the default. And then I'm not sure how we would deal with it at this point.
MR. ELLIOTT: We agree on Mark's suggestion

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. WADE: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. ZIEMER: I think that pedigree gets to that though.

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

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

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

DR. NETON: I think that kind of captures the

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

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

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

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

DR. WADE: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. DeHART: Or intentionally making every

effort to meet where --

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

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

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

DR. NETON: It's one of those.

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

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

DR. NETON: It's not uncommon.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. DeHART: It's out there.

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

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

(Whereupon, the Working Group concluded at 12:15 p.m.)

C E R T I F I C A T E OF COURT REPORTER

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.

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STEVEN RAY GREEN, CCR

CERTIFIED MERIT COURT REPORTER

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