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CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL
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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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SPECIAL EXPOSURE COHORT ISSUES WORKING GROUP

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FRIDAY
FEBRUARY 22, 2013

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The Work Group convened via teleconference at 11:00 a.m., James Melius, Chairman, presiding.

PRESENT:

JAMES MELIUS, Chairman
JOSIE BEACH, Member
PAUL ZIEMER, Member

ALSO PRESENT:

TED KATZ, Designated Federal Official
JOE FITZGERALD, SC&A
STUART HINNEFELD, DCAS
JENNY LIN, HHS
JAMES LOCKEY, SC&A
ARJUN MAKHIJANI, SC&A
JAMES NETON, DCAS
LAVON RUTHERFORD, DCAS
JOHN STIVER, SC&A

T-A-B-L-E O-F C-O-N-T-E-N-T-S

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

(11:00 a.m.)

MR. KATZ: Why don't we get started here?

This is the Advisory Board on Radiation and Worker Health, the Special Exposure Cohorts Issues Work Group. And let's do roll call.

We have a lot of sites potentially to be talked about today which makes it impractical to address conflict of interest specifically to Board Members and others. But everybody keep in mind what the conflicts are, and please don't speak to an issue on a site for which you have a conflict and I think that'll take care of things.

So let's go to roll call, beginning with the Chair.

(ROLL CALL.)

MR. KATZ: Okay. So just a couple of things in the agenda for this meeting

that's posted on the NIOSH website under the Board's section under schedules, today's date, and with it there should be two papers from NIOSH DCAS related to today's call, one on sufficient accuracy generically and one on thorium dose reconstruction.

Anyone's on the line who's not speaking press *6 to mute your phone if you don't have a mute button. Press *6 again to come off of mute. Thank you.

CHAIRMAN MELIUS: Okay. Thank you. And welcome, everybody. I think it's still good morning for everybody on the phone.

The issue we're going to discuss today is really in follow-up to NIOSH's ten-year review. And one of the issues in the ten-year review was to try to sort of develop a definition or parameters for what was meant by sufficient accuracy because that is something that has continually come up particularly in our reviews of Special

Exposure Cohorts at various sites, but there is also pretty central about how dose reconstruction is done, and essentially the entire DCAS program.

So NIOSH is working, I believe with ORAU, who has produced White Papers that we'll talk about in a second. It got to the Board -- what -- sometime in the last several weeks. And so Board Members had time to review them. We've not had any sort of formal technical review from SC&A, although we did ask them to sort of familiarize themselves with the two White Papers.

I think what we want to accomplish today is sort of hear a little bit more about where NIOSH thought they were -- or why they thought these papers might be helpful in looking at this issue and try to have some discussion of what do we think would be the best approach to address the issue of sufficient accuracy, and then finally, how do

we want to work with the other members of the Board on doing that.

So I think it would be helpful first if -- and I don't know who, Stu, from your group wants to talk -- at least a brief introduction on these two papers or what you saw them accomplishing and how you thought they might be helpful.

MR. HINNEFELD: Well, okay. I'll speak very briefly about the general one -- the view of parameters associated with defining sufficient accuracy, and say that in response to the ten-year review item which talked about coming up with some sort of clarity about what does it mean to be sufficiently accurate, we've worked on that or thought about that for a while and kind of concluded that we didn't have really a better definition than we had back when we wrote the regulations a number of years ago -- the regulations for SEC. It's just very difficult

given the variety of situations that you run into in terms of exposure potentials and records availability. It's really difficult to come up with a nice definition.

But we thought what we could do would be to assemble, for lack of a better term, a sort of case law situation that sort of documents the decisions that have been made in the program so far and to try to be able to assemble from that, maybe, some sort of guidance for consistent application -- consistent decision-making -- as we proceed so that we have sort of at least a standard to shoot for.

The idea here was to have what is the standard you're shooting for in terms of sufficiently accurate. And lacking the ability to really provide a good definition for that, we thought sort of a careful look at decisions that have been made up to date and then so we have a guideline to continue to

operate in accordance with those decisions. So that was the idea behind doing this.

And other than that, I don't expect I'll be saying much today. So other, more specific questions and information I think can be probably best answered by LaVon or maybe Jim.

CHAIRMAN MELIUS: So you're putting LaVon on the spot?

MR. HINNEFELD: Yes. You bet. He knew coming in that he was.

MR. RUTHERFORD: Yes, that's right.

And specifically on that, we did look at the past year's worth of Secretary's determinations and designations for the parameters that drove either the feasibility or the denial of a class. And we tried to lay all of those out and see if we could come up with some items that were routinely seen and then feasibility determinations or some

parameters that we could pull together.

And I think ultimately if you review the paper and looking at the paper, you find that really what we see is in an evaluation, you follow the hierarchy of dose reconstruction looking for information to determine whether dose reconstruction is feasible and not. And you work through those parameters. And what we found out is you just could not, because there's so many different factors in making that determination and so many different data points that come in, you can't define specific items that really drive the infeasibility. It's just a case-by-case basis. And that's why it makes it difficult to define, any further, sufficient accuracy.

CHAIRMAN MELIUS: What do you think was added by the thorium?

MR. FITZGERALD: Well, our thought was, geesh, we have designated so many classes because of our infeasibility to do thorium,

and thorium has driven so many of these determinations and designations, we thought well, we've looked at this so much. Maybe we can just pull together specific criteria for thorium that can be used that could make our decision process quicker or more timely in future evaluations if we pull together and summarize these factors.

But I think ultimately in the end when the paper was finished, you'd come back to the issue. It's really case-dependent. There's a number of situations that are laid out in the thorium paper -- either infeasibility or denials of classes where we've determined it is feasible. And it's case by case. But you still follow the same hierarchy for dose reconstruction.

CHAIRMAN MELIUS: Yes. I'm glad you agree with me because I was a little frustrated by the papers because I'm not sure that -- you're right. You end up looking at

just what are the facts at a particular site. And, you know, that doesn't necessarily help -- that doesn't at least appear to help the actual issue of how to evaluate the sufficient accuracy because if you compare the different sites, it really is dependent on what information is available at those sites and what the circumstances were for the use of thorium, what other materials were used and what was the nature of the monitoring at that site that make it difficult.

Any other Board Members have some general views of whatever or reflections?

MEMBER ZIEMER: I have some comments that I'd like to insert at some point if this is an appropriate point.

CHAIRMAN MELIUS: I think it is.

MEMBER ZIEMER: Well, first of all, I do like the concept of the case-law approach to this thing. I hadn't thought of that term but I think it describes an approach

pretty well.

And when I read in the two papers and then thought about it, I said to myself, what question are we really trying to answer or what is the end point going to look like. And it seemed to me that we're trying to say what are the characteristics of sufficient accuracy or what are the criteria that must be met to achieve it. And it seems to me that in the two papers we've gotten so far, although very simply descriptive, they have been able to identify some factors that might lead us to a -- maybe a more concise conceptual framework, and it might even parallel what we did for surrogate data where we said, you know, it had some criteria to see if we've met those criteria.

And so what I'm thinking about is, if you ask the question what are the characteristics of sufficient accuracy and could ask that in the general sense -- and I

think LaVon's paper has identified some of those characteristics, like you've shown that you've monitored most of the exposed workforce, or you have eliminated methods that resulted in implausibly high values -- things like that. You might be able to identify the characteristics of it.

And then you might also ask the same question for special cases. And insofar as thorium may have additional sort of characteristics, those could be identified as well.

So I'm thinking in terms of a kind of a framework that these two papers might represent a first step toward defining what that framework might look like and sort of ask ourselves moving forward are they tests for sufficient accuracy that we can apply -- for sort of data analysis, as we go back and say have we met these tests? And I'm asking myself, can we do that for sufficient

accuracy. Are there methods that we can say, have we met them and how well have we met them? Or if we haven't, is there a way to meet them?

Those are kind of some thoughts that came to me to try to focus beyond the descriptive stuff. And that could frame out in terms of what they described as the case law. You use the cases as a background.

We have in essence made the decision based on whether we believe we have met similar laws of these criteria even though they may not be fully spelled out.

So, those are my initial comments.

CHAIRMAN MELIUS: No, I think I'm on the same track.

But Josie, do you have any?

MEMBER BEACH: No. This is Josie.

I agree with what you said, Jim, and also those ideas from Paul. Those sound like reasonable ideas. I don't have anything

else to add, though.

CHAIRMAN MELIUS: Okay. Let me try. Maybe it's an example. But one is a comment.

I think this is sort of a key concept because sufficient accuracy also goes to I think two other efforts that DCAS is involved in from your ten-year review. One is what is claimant-friendly and how do you make that operational in this program. And secondly, another issue you're working on is the co-worker models.

And so to do that, develop parameters for co-worker models really comes back to very weak or sufficiently accurate dose estimates of that. So I think to some extent, even to address those issues, we have to sort of come to grips with sufficient accuracy.

But where I thought you were originally going to go with these papers, and

maybe it's just because I was thinking of some recent examples where the Board had reached various determinations on SEC evaluations was right now, yes, we do have -- so what's a plausible -- is it a plausible upper bound. And I think clearly if we're able to quantitate sufficient accuracy a way, or some parameters on it that bounding or the variance or whatever would be sort of part of that. Say something is accurate if it meets some certain parameters in terms of variance or bounding around what you believe to be the actual value. So I think that's sort of fundamental to the concept.

But if you look at how we've approached this, when there are circumstances where, so the absolute value of the exposure is relatively low. And let's say just in general for residual exposure periods at these sites. We tend to be able to accept a much more general upper bound. We're not trying to

individualize exposures as much because we don't think that those exposures will make -- or is likely to make a significant contribution to the person's overall dose, and therefore their risk or Probability of Causation.

And in other circumstances where the absolute value of the exposure may be much higher, then I think we're much more concerned on how accurate these dose estimates may be whether it be from a co-worker model or from some other approach that they're using or how that is being applied to the population that's being evaluated. I guess the example that comes to my mind offhand is one of the Linde SECs where we had a fairly good set of monitoring data on some of the cleanup and renovation activities, but that only covered one part of the population. We had another large part of the population at that same facility at the same time that we had no

information on. And we couldn't tell who was who. In fact, the larger population -- the production population -- most likely had relatively low exposures unless they went into the contaminated buildings, particularly if they went in there during the renovation periods and active cleanup that was going on.

And in that case, the potential for exposure absolute value was fairly high, at least for the cleanup and renovation. And then we had another population where it was probably very low. I think the other population -- I saw in the production population, we consider as part of a residual period or relatively exposure and would have accepted a very general approach to reconstructing their exposure, where, for the people doing the cleanup and the renovation in the one building, we saw that they would have much higher exposure, we'd want much more accurate information or robust data on their

exposures in order to be able to say their doses could be reconstructed with sufficient accuracy.

And you mix the two together and you really had sort of two different populations mixed together -- one with a low exposure, one with a probably higher exposure, and an inability to separate the two.

But it seems to me that if you look back at all of our decisions for a period of time -- and I think it also goes to our evaluation of dose reconstruction. If the absolute value of the exposure is relatively low, then we're willing to accept more variability in the dose if it's being calculated for an individual. And if the exposure's absolute values are higher, then we're looking for a more accurate dose reconstruction method. And then I think we're also wanting to take into account the variability of exposures within the population

that we're evaluating. So that's sort of a second parameter.

So it seems to me that going back to what Paul was saying that we could develop a set of guidelines, one of the things you'd look at is what's the absolute value of the exposures that you're looking at for this population trying to do dose reconstruction. That would be one thing to take into account. The second thing might be the variability of that exposure within the population that you're assigning those doses to.

And then there's probably some more. The hierarchy of monitoring, also an exposure assessment probably also fits into that.

MEMBER ZIEMER: Jim, this is Ziemer. You're suggesting perhaps that even the concept itself may be somewhat different in terms of the exposure level. That is we consider sufficient at very low doses may look

different than what we think was sufficient at high doses.

Am I understanding that clearly?

CHAIRMAN MELIUS: Correct. Yes. We think about it in terms of we --

MEMBER ZIEMER: We certainly actively assess those levels when we make decisions. Yes.

CHAIRMAN MELIUS: Yes. I don't know if we can quantify it precisely. But I certainly --

MEMBER ZIEMER: No. But it could be characterized, I think.

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: I would think in terms of what the characteristics are. I'm not sure you put numbers with these things.

CHAIRMAN MELIUS: Well, no, I don't think you would. But you certainly do that because if the absolute exposure is relatively low, what percentile you apply to

it -- is it 95th or 90th or whatever doesn't really make that much difference in terms of the actual effect on the exposure you're assigned or affect the Probability of Causation. Whereas a much higher exposure -- how you characterize that exposure in terms of 95th percentile of whatever parameter you're using is going to make a very significant difference in terms of their estimated exposure, the Probability of Causation -- however you want to determine it.

And I think we've been operating that way for a while in terms of making our evaluation. I don't think we're always so consistent about it, but I think we've tended to be able to reach agreements on it.

Is that making sense to Stu or Jim or LaVon?

MR. RUTHERFORD: Yes, it is. It does make sense to us. And I do agree with you that I think that we have been behaving

that way.

And I think the paper hasn't specifically called that situation out. But I think that is good characteristics that could be added. I don't know if Stu or Jim will answer that.

DR. NETON: I agree with what you're saying. We've been behaving that way. I guess I need to think about how that tracks back to the rule and the definition of health endangerment.

CHAIRMAN MELIUS: I think that part of the reason that we're at this difficulty is that we are at a level or quantification for health endangerment. So health endangerment doesn't help us get out of this or address the situation to any --

DR. NETON: I understand that. Without the definition --

CHAIRMAN MELIUS: But it's implicit in it.

DR. NETON: Yes.

CHAIRMAN MELIUS: It's implicit in it. But we've never had a way of operationalizing or whatever you want to call it or using health endangerment as a parameter. And when we have tried to do it with short-term exposures, we get tied up among ourselves pretty well on that and haven't been able to do that. And some of that is the nature of the regulation.

I think what I was saying was very compatible with the current regulation.

DR. NETON: I don't necessarily disagree. I just need to think about it. But --

CHAIRMAN MELIUS: Yes. I'm not trying to get you to agree or disagree. But I think it is -- what is a plausible upper bound. We all know we can upper-bound anything. So this always come out with sort of what's the plausibility of that. And then

there's some other verbiage in the Act that puts a little different twist on that.

And I think bounding sort of makes sense because we know that we can't do an absolute accurate estimate of dose. And we're always estimating dose.

DR. NETON: I agree.

CHAIRMAN MELIUS: And you calculate all the factors. When you do dose, you essentially look at all those factors.

DR. NETON: Agreed.

CHAIRMAN MELIUS: Provide variabilities of the measurements that you're using. So I think that's fine.

I think the question is, does it improve our ability to make sort of consistent and fair decisions.

DR. NETON: Right. I think what we're really saying is it's easier to define a plausible upper bound as the exposures get lower and lower.

CHAIRMAN MELIUS: Yes.

DR. NETON: You're not getting into the realm of ridiculous levels of exposure. You're just saying well, it's low and it's certainly no lower -- it could be this low and maybe this high. When you get in the very high-end exposures, that's when it doesn't pass the laugh test, so to speak.

CHAIRMAN MELIUS: Yes.

DR. NETON: So I think we can work with this.

CHAIRMAN MELIUS: Yes. And in the two White Papers, I think it's captured in some of the examples in there.

DR. NETON: Yes, it is.

CHAIRMAN MELIUS: Yes. I think it actually comes up all the time. And we may have verbalized it more recently but it's always been part of how we've approached things. It tends to get lost though because a lot of them are the same. A lot of it comes

to what are the circumstances at a particular site for all the various exposures we're looking at.

MEMBER BEACH: Well, Jim, this is Josie.

I might be totally off here. But one thing that comes to mind is we make a lot of judgments on professional judgment. And I just wonder how that fits in, or if it doesn't at all.

CHAIRMAN MELIUS: Well, I think it's sort of the same thing. If your professional judgment is about -- let's call it low dose -- issue, then you've got more leeway in making that. It's less concern. If it's about a very high-dose situation, then I think you'd want to be more careful in your professional judgment.

Now again, professional judgment -- if the dose reconstructors are doing it, it also takes in a lot of other factual

information -- what they know, where the practice is, how things are done -- things that may not be necessarily captured in all the PoCs and so forth. I mean, you can't get guidance on every absolute detail.

MEMBER BEACH: No, I guess I look at it as more of a consistency.

CHAIRMAN MELIUS: Yes. And how do we make it consistent? And you make it consistent I think if you focus on where it's most important to have consistency.

MEMBER ZIEMER: Well, I think Josie's right. Professional judgment will always be part of it in any regard. This kind of a concept -- sufficient accuracy -- is never going to be a very sort of a precise, like a number, that if you achieve this number or something like that.

But this is going to always require some professional judgment. I think that you're right that what we're looking for,

Josie, is consistency in how we go about making that decision. And I think doing this, not only having -- there is a pretty good definition in the regs. I have looked at it several times again in the last couple weeks. And I think the regulation is fine. It's how we apply it and do we apply it consistently.

And in fact, can we depict something that is in place to -- personally, I like the idea of having sort of a set of criteria that we can say this is how we go about it. It's still going to be a judgment. But this is how we go about reaching our judgments on this and these are the parameters that we look at.

And I think we're making a good first step here with these papers to build on, and maybe NIOSH can go back and develop this further. SC&A can help us with some of these ideas as well. But -- anyway.

CHAIRMAN MELIUS: SC&A, you've

been quiet, so we'll give you an opportunity to weigh in, if you'd like.

MR. STIVER: This is John Stiver.

I think you guys are right on the money.

The kinds of decisions that are made have a larger impact, getting the compensation decision right. That will the biggest impact on the PoC action is what are the more refined types of the determination's going to be made.

From our standpoint, when we do SEC Evaluation Reports, the two things that always come up, the decisions seem to turn on the issues of the completeness and adequacy of the data set for the particular site -- the particular exposures that are there. In terms of adequacy, it's really not so much the amount of data that's available but does it really provide a meaningful interpretation of what the actual exposures were.

And an example that comes to mind for that is this recent determination for Fernald for the thorium. At first blush, it looks like you've got a lot of data -- thousands of data points for the material of interest -- which I'm looking into the basis for that. We found that it really didn't tell us anything about the actual exposures.

And so there's that aspect, and there's also the completeness. There's kind of a three-dimensional array of whether all the job types and time periods and locations can be adequately covered, given the fact that you have adequate data.

So in my mind, that's how we approach it. Now, it's more of the I guess the yeoman's aspect as opposed to looking at the big philosophical picture. What exactly does it mean? That's kind of how we come to our determination.

And maybe Arjun or Joe might want

to weigh in on that.

DR. MAKHIJANI: A couple of thoughts. I agreed with the low/high dose when you get the doses are stratespherically high then it's kind of a subjective you-know-it-when-you-see-it, implausible definition without putting a number on it.

But there's also the accuracy problem. It's not only when it's unrealistically high. It is the attribution of a particular material or surrogate radionuclide or is the placement of the worker reasonable. So you could in the example that is given at the bottom of page one -- gross alpha measurements that were primarily caused by uranium resulted in unrealistically high thorium exposure. Well, if it was not reasonable to apply uranium intakes to thorium, then in my mind, it doesn't matter whether it's unrealistically high or not. It's just scientifically not plausible to

apply that because it doesn't apply to the situation.

And so the problem of accuracy where sufficient accuracy is being defined as one phrase. But there is the accuracy part of it, and it seems in some situations it's inaccurate to do something regardless of whether you get high or low results. In the case that you were discussing earlier, it seems reasonable to do it that way.

And so, a couple of other -- NIOSH often says that we know the highest exposed workers were monitored. And in one of the examples actually, NIOSH said that highest exposed workers were not monitored. Now correct me if I'm wrong. I'm doing this from memory of reading the paper. But the demonstration of that has turned out to be quite difficult in our reviews, and we've had extended discussions of that. It might be useful to try to narrow that down as to what

kind of objective evidence from the site do we need regarding their monitoring practices before we can make that assertion.

And then placing workers in the situation, you may have a lot of monitoring data but can you place workers in the situation where they had exposure potential, especially for surrogate radionuclides? I think pretty important.

And the last sort of minor comment, I thought it would be important to have the Board's surrogate criteria explicitly referred to in these papers.

MR. FITZGERALD: Yes. This is Joe. And I agree with what my colleagues have brought up as well.

But you know, in my experience it's a two-step process. And I think this has been outlined by Arjun and John as well.

The first step is really a deliberation on weight of evidence which gets

down to the actual completeness of the documents, whether the information itself -- the data -- would support a concern.

And once we pass a threshold where one way or the other there's agreement that there's a sufficient weight of evidence that there is an issue, that's when we get into this question of sufficient accuracy. Then it becomes a question as to whether the analytic approach to dose reconstruction that's being proposed would give you an estimate that's sufficiently accurate.

Having spent years in the first phase in terms of weight of evidence, looking at some of the cases that are outlined in LaVon's paper, I think from experience some of those actually were more a question of weight of evidence versus technical accuracy. And the reason I raise that is because I guess a case-study approach was mentioned earlier sort of similar to the surrogate analysis policy

that was laid out before.

And I think the challenge on this one, going back to an earlier comment by Paul Ziemer, is if you come up with some approach, you have to be sure that that approach is based on apples and apples, and a case-study approach is one that's going to have to be based on apples and apples. I think in this case there's some that really were leaning more toward is there sufficient evidence. For example, at Mound, that you had chronic exposures or exposure potential from those internal nuclides. That's number one -- the first example that's provided.

The Work Group could not prove that there was in fact any chronic exposure or exposure potential. There wasn't any bioassay data. There really wasn't sufficient evidence one way or the other. So at a certain point, there was no need to go further because there just was no way to ascertain that question.

So that's the only cautionary note I would make that in terms of weight of evidence, that's a different question than the technical accuracy question that we're getting into here. And I think we've got to be careful if we're basing a policy to make sure it's based on that second phase of the technical accuracy of the analytic approach that's taken for dose estimation.

But beyond that, I think the question of consistency and tying that to the potential dose itself makes a lot of sense. I think that has a lot of merit.

CHAIRMAN MELIUS: Yes. Going back to Arjun's comment, I think it's sort of a Linde example that I was giving and it really maybe convoluted different concepts.

But we saw two issues. One is -- and I think it's gotten better recently but a lot of it's been initially it was, well, as long we can do it in upper bound and that's a

plausible upper bound for the highest exposed individuals, then that method was okay, and we didn't really look at how that upper bound was -- the population it was being used for. And so it may be a plausible upper bound for a certain group, but it really may not be a sufficiently accurate plausible upper bound for the others in that same population.

And we started to look more I think at the population being evaluated. I think that is the critical issue with the co-worker models is sort of what's the right sort of -- what level of detail, how far do you have to go down in terms of the characteristics of the people -- the workers that you put into that model in order to have that model be sufficiently accurate upper bound.

So I think that's sort of another parameter is how is this being applied to the population. What's the nature of that

population, and does that really cover the entire population, and then how much leeway do you give on that, basically? Because there's always going to be some variability in whatever methodology you use. So it's not fair to say that you have to always separate out the lowest from the highest exposure and have different parameters. Often, you can't identify who that is, so that's why you're doing some sort of an estimate method. But I think you have to take that into account in some way.

MEMBER ZIEMER: Yes, I would agree. This is Ziemer. I think whenever you can do, it makes sense. The problem is you can't always do it.

But again, that's another issue that could be part of the characteristics. We're already going in the direction of sort of identifying what it would look like.

CHAIRMAN MELIUS: Yes.

Any other comments or thoughts?

(No response.)

CHAIRMAN MELIUS: Then how do you want to proceed?

MR. HINNEFELD: This is Stu.

I think from our standpoint, what we hear is there's a follow-on document that we need to prepare. And it will be an attempt, because we certainly value the advice we get.

First of all, I want to thank everybody for weighing in on this. This ten-year program review item ostensibly is our item, but we do value the advice we're getting here, and we want this to be the most useful that we can do.

We have a follow-on document to prepare which is to describe the characteristics of sufficient accuracy as Paul said. And then that would follow from what we have done so far and provide a follow-on

document for people to review to see if we've caught that.

And if anyone feels like there are things that they really feel should be addressed in this, we'd appreciate you sending those to us. You can send them to LaVon, Jim and me or to any one of us, and we'll share among ourselves in order to assist us in doing that.

Now we can do it if left to our own devices, and you guys can review what we do. It would work that way as well.

CHAIRMAN MELIUS: Can I suggest something -- sort of a modification of that -- that I think might be helpful?

It would be if NIOSH developed an outline of what would be in that document: what are going to try to cover in that, what needs to be part of that? The idea we come up with is something similar to what was done for SEC evaluations and then what both NIOSH and

the Board have done for surrogate data evaluations.

But developing an outline or a shorter document that maybe didn't have as much detail in it but we definitely would do another Work Group meeting to discuss that document.

MEMBER ZIEMER: Jim, as sort of a framework to flush it out, I think that makes sense.

CHAIRMAN MELIUS: Yes. I hate to have you spend a lot of time and effort developing something and then we're all saying well, no, you missed this or it's not quite right or whatever and do that. And it may also be helpful to at least after one iteration bring it back to the Board for comment to see if other people have ideas.

I think one, it's a very important key concept. And we're wrestling with it all the time. So even having some discussion of

it by the Board itself I think would be helpful. I don't think we're quite ready for that yet. But we'll talk about some at the next, upcoming meeting. It may be more procedural.

But I think if we had sort of an intermediate step where you produce a two- or three-page -- whatever it will -- it will be sort of an annotated list outline that would hit some of how you think it would be organized and what would be the key concepts. And then we have a meeting to discuss that.

And then the next step would be to flesh that out. I think we'll want more detail.

MR. HINNEFELD: Okay. That sounds like a good idea to us.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: Dr. Melius, may I make a comment?

CHAIRMAN MELIUS: Go ahead, Arjun.

DR. MAKHIJANI: I want to pick up on something that John and Joe alluded to earlier and kind of try to cast it in a little bit different words.

A lot of the difficulties that we've had and a lot of the time in SEC reviews is spent on disagreeing and then agreeing as to whether something is an issue or not before you get to the sufficient accuracy question. I mean, the thorium issue at Savannah River Site is a very good example.

For a couple of years, we argued about whether it was an SEC issue or not and whether and how much thorium handling had happened. And I think a lot of sort of that threshold that Joe was talking about where something is bumped up to an SEC issue, where a lot of the difficulties occur before we get to the -- is it sufficiently accurate or is upper bound so high that it's not credible and so on. I don't know how you want to address

that, but it might be useful. It's not strictly in the sufficient accuracy definition. So maybe you don't want to include it right now.

CHAIRMAN MELIUS: My immediate reaction is I agree it's an issue and it's probably the most frustrating issue we have, particularly at these larger sites.

DR. MAKHIJANI: Right.

CHAIRMAN MELIUS: Because we want to try to focus on what important issues for an SEC petition which covers a large site.

And even with all the work that's been done on a site up until now, we have trouble doing that. We have trouble sorting through and sort of figuring out what those are, short of the usual way which is to go through issue by issue and develop it.

Maybe this will help, but I'm not sure if this would very much. But I think maybe we can think about that when we look at

the outline and we've all thought about this a while. And maybe they'll be things that'll come up then.

But I agree with you, Arjun, it's important. But I have trouble thinking how this -- because some of it's factual, some of it's the circumstances. Some of it's sort of peeling back what may appear to be a reasonable dose reconstruction method, but when you look at it in more detail -- so the SEC at Fernald, I think took some peeling back and evaluation to sort of focus at least on the one we've done so far.

DR. MAKHIJANI: Yes. No, I agree with you. I think maybe it's not an issue that's amenable to any general rules especially for the large sites that we've been dealing with like Hanford and Savannah River and Rocky Flats.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: Okay.

CHAIRMAN MELIUS: I mean, there's a lot of times when we see a petition come in or take a first look at the slides that are being presented, well, we really should focus on this and that's the key issue for the SEC. And the batting average is pretty low.

(Laughter.)

And I think NIOSH -- and I think everybody has the same -- I'm hoping it's not just me.

DR. MAKHIJANI: No, I agree. It's very difficult.

MR. STIVER: This is John Stiver. I agree with you 100 percent.

I'd like to add one thing. We've just recently completed the review of ORAU Clarksville report, the SEC, Special Exposure Cohort, which was put out in 2005. And we have two appendices in there that might be useful --

CHAIRMAN MELIUS: Okay.

MR. STIVER: -- particularly for NIOSH in developing their framework.

The first appendix is an example of the strategies that we've used in reviewing completeness and adequacy of the records. And the other would be examples of the strategies in analyzing allegations of corrupt data or data falsification.

And it kind of lays out the framework that we go through. So it may be useful to look at this in developing the framework.

CHAIRMAN MELIUS: Yes.

MR. HINNEFELD: John, this is Stu.

What was the specific document that you reviewed that had the two appendices?

MR. STIVER: Okay. I can actually send it out to you.

It was prepared in October 2012. It's called, Review of ORAU Clarksville Report Special Exposure Cohort, Revision 00, October

17, 2005.

MR. HINNEFELD: Okay.

MR. STIVER: Actually, Special Exposure Cohort, Revision 00, October 7, 2005.

MR. HINNEFELD: Okay. Thanks.

MR. STIVER: Okay. And I can go ahead and send it out to the group here.

CHAIRMAN MELIUS: Yes, that would be good.

MR. STIVER: Okay. Thanks.

CHAIRMAN MELIUS: Great.

Anything else? Thoughts?

(No response.)

CHAIRMAN MELIUS: If not, I will talk to Stu and Jim and put together a presentation for the Board meeting in Augusta just sort of outlining what we've been talking about and then what we see the next steps are.

MR. STIVER: Okay. That sounds good.

CHAIRMAN MELIUS: I think this is

helpful, but I think if we sort of go step-wise, I think we can get there put together which I think is important on this one also.

MR. HINNEFELD: I agree.

CHAIRMAN MELIUS: We should be able to after how many years it's been, wrestling with these issues.

Agreed?

MR. STIVER: Agreed.

CHAIRMAN MELIUS: Okay. Thanks, everybody. And have a good weekend. And we'll see you all in Augusta.

Ted, any last words?

MR. KATZ: No, I thought that was a great discussion.

CHAIRMAN MELIUS: I wanted to give you a chance to say something, you know.

Okay. Thanks, everybody.

(Whereupon, the above-entitled matter went off the record at 11:54 a.m.)