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

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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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SPECIAL EXPOSURE COHORT ISSUES
WORK GROUP

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MONDAY
JUNE 24, 2013

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The Work Group met telephonically at 1:00 p.m. Eastern Daylight Time, Jim Melius, Chairman, presiding.

PRESENT:

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

ALSO PRESENT:

TED KATZ, Designated Federal Official
TERRIE BARRIE, ANWAG
STU HINNEFELD, NIOSH ORAU
JOSH KINMAN, NIOSH ORAU
ARJUN MAKHIJANI, SC&A
JOHN MAURO, SC&A
MARTHA McNEELY
JIM NETON, NIOSH ORAU
MICHAEL RAFKY, HHS
JOHN STIVER, SC&A

A G E N D A

P R O C E E D I N G S

(1:02 p.m.)

MR. KATZ: So, let's get started with roll call. We're not speaking about a specific site so there's no conflict of interest admissions needed here. Let's just begin with -- well, I just heard the Board Chair, Dr. Melius. Let's go through the Board Members and then we'll go from there.

(Roll Call.)

MR. KATZ: Okay, very good. We have an agenda for the meeting. It's posted on the NIOSH Board page on the web under today's date for meetings. And there should also be a paper from DCAS posted there, I believe. LaVon can let me know if that's not the case. And, Jim, it's your agenda.

CHAIR MELIUS: Okay. Thanks, Ted. I'm glad you could make it today. And hello to Josie, Gen and Paul.

And our agenda is, I think, pretty

straightforward today and I want to talk about, essentially, two things. One is to talk about the draft outline that's been prepared by NIOSH on sufficient accuracy in follow-up to our last conference call. And then, secondly, talk a little bit about -- we'll follow-up on this, and also discussions at our July Board meeting.

So, I thought we would start. If, I don't know, Stu or Jim, who wants to talk? But if you want to present a little bit on your -- on the outline, sort of what you --

MR. HINNEFELD: I think Jim will probably lead the discussion for us.

CHAIR MELIUS: Okay, great.

DR. NETON: I can get the ball rolling, I guess. This is Jim.

Just as a follow-up to the February 22nd meeting that Special Exposure Cohort Work Group had where NIOSH had originally prepared a couple of papers that

you remember in January for the February meeting, and they were a review of the parameters associated with sufficient accuracy.

The approach that we took actually ended up reviewing, if you remember, sort of the case law that had been developed over the last year's worth of decisions on SECs to see if we could glean any particular criteria, or develop any guidance from those decisions. And, as it turned out, we really couldn't. There wasn't anything specific that popped out. Even when we looked at the thorium data that we thought might be more informative, there was nothing there, either.

And what came out of it was that the hierarchy of data for dose reconstructions seemed to have been used in the development of the decisions all along the way, and that's where we ended up.

At the February 22nd meeting, the

Working Group, and NIOSH agreed, thought that it would be good that we might sort of summarize those salient points in a brief outline, a several-page outline to put down our thoughts on paper as to what we were thinking on this. And that's what was issued in May by LaVon.

And, essentially, what it has is a summary of the requirements, and then goes to the hierarchy; although, we did add some preliminary steps in evaluating the criteria, and one is this issue that was discussed at the last meeting, which was to determine the potential for exposure variability. One-size-fits-all models I think we have come to agree are not necessarily appropriate, and we need to take care to determine if there's any underlying variability or stratification in the models.

And the other piece that was added as a result of the Working Group discussion

was the concept that variability in itself, a larger amount of variability or variance in the model could be tolerated given that the -- if the exposures were very low. In other words, the lower the exposure maybe the greater the variability that could be tolerated. When you have very high exposures, a large amount of variability wouldn't be appropriate.

So, those two pieces were added into the discussion to the general concept of reviewing the -- using the hierarchical approach to evaluating the data.

That's about what I can say. If there's any questions, I guess I can answer them.

CHAIR MELIUS: Jim, it might be helpful if you use just one part of the hierarchy to sort of illustrate where you're going. I think it would be useful.

DR. NETON: Okay. The way that we

sort of envision the hierarchy, and this seemed to come out when we looked at the cases that we evaluated, is that the hierarchy that's included in the regulations included, you know, sort of a stratified approach. One is, you look at personal monitoring data and determine if the maximum-exposed workers were monitored. And, actually, either maximum or representative, I think, workers were monitored. And those methods, even if they were monitored, we had to determine if the monitoring methods allowed for the exposure of interest to be correctly identified. In other words, they had -- the uranium bioassay had to be appropriate; it could detect uranium if that was the exposure potential.

And we couldn't -- and we determined in that analysis that we also couldn't use data that would result in what we call implausibly high, and I think we might want to discuss that a little bit today; come

up with implausibly high determinations. That would be, for example, substituting thorium -- assuming that a gross alpha analysis for uranium could bound a thorium exposure, and result in very high intake values.

And then in the personal monitoring data you end up, finally, if you don't -- you know, you have to develop a coworker model. And, again, in the coworker modeling situation one needs to account for potential stratification we put into this document. And the example that was talked about at the last Working Group meeting was the case at Linde where we had construction monitoring data, decontamination data for workers that we felt bounded the overall exposures. Yet, there was another offset of the population that worked in offices where, certainly, it should have bounded their exposures, but really wasn't sufficiently accurate because it was a different set of --

a different population of workers that were being exposed.

That kind of covers what we do for personnel monitoring. I don't know if you want me to go through the remainder or --

CHAIR MELIUS: No, no. Jim, that's fine. I just wanted to sort of tie it into the stratification issues, and sort of accuracy issues, and so forth.

Do any Board Members have comments or questions?

MEMBER ZIEMER: This is Ziemer. I have several questions. Is this the appropriate time to raise them?

CHAIR MELIUS: Yes, it is.

MEMBER ZIEMER: Okay. First of all, under the third item, Preliminary Steps, under B.2 where we had the statement, determine if there's any potential for exposure variability within the exposed populations, that -- obviously, there's always potential for

variability. In fact, not just potential, there's virtually always variability.

It seems to me that we need to develop that statement a little more to delineate or explain what the concept of potential for exposure variability really means in this case. I mean, I think I know the answer to it, but I think for someone just reading it, it needs to be developed a little more.

DR. NETON: I agree with you, Dr. Ziemer. I mean, it definitely needs to be fleshed out a little better. I think it demonstrates that we're still a little cloudy in our thinking on this.

MEMBER ZIEMER: Yes. Well, that was really just a comment. Then I have another question.

I was trying to remember -- you have the statement under 4.A under personnel monitoring data, you have the statements about

the coworker data and the stratification of exposures.

There's a lot of beeps on the line. Is this my line, or is some -- are we hearing beeps?

CHAIR MELIUS: I'm also hearing beeps, Paul.

MEMBER ZIEMER: Okay.

CHAIR MELIUS: I think it's the --

MEMBER ZIEMER: Okay, I'll just proceed.

In any event, my question --

Do we have -- I can still hear it.

MR. KATZ: Right. Paul, I guess hold on a second. This is really getting to be difficult to listen to. Somebody is probably inadvertently mashing a button on their phone, so just everyone be aware of that. Maybe it's a cell phone and it's harder to know when you're doing that or not.

MEMBER ZIEMER: Okay?

MR. KATZ: Okay, Paul, why don't we try again.

MEMBER ZIEMER: Okay. So, I was trying to remember -- Jim, if you can -- Jim or Stu, do we have any coworker models that have been based not on personnel monitoring but on either air monitoring or source term data? You know, air monitoring of the highly exposed group, and then a coworker model developed for others who may have had other -

DR. NETON: I think we do have in the source term -- in the source term data, the only one that comes to mind is we developed some source term models for radon exposure. In the air monitoring data, I've not been familiar with what's been going on at Fernald, but I do understand that some daily weighted averages were being used for exposures to thorium.

MEMBER ZIEMER: Yes. Well, what I was looking for here was a sort of parallel

statement about coworker models similar to -- or along the lines of what you have for personnel monitoring data. Are there some statements about coworker models for air monitoring data or for source term data that would require sort of a parallel statement to 4.A.3?

DR. NETON: I understand what you're saying, and I agree with you. This is kind of -- the way this reads, it's definitely limited to bioassay, but there have been instances where we've used other models. Good point.

MEMBER ZIEMER: Just wondering if there would be a parallel statement or maybe any special conditions for both models under those other circumstances. That's really the question I had on those. And based on -- and maybe you need to just go back and look at what we have, and if there's anything special about what we did in those cases. I just

couldn't remember.

CHAIR MELIUS: Yes, that's a good point, Paul. And I was sort of thinking along the same lines, but maybe somewhat in the other direction, is that in most instances when we're relying on air monitoring or source term, we don't really have enough monitoring data, and it's not sort of dense enough to be able to even detect whether there's stratification, or differences among different people doing different tasks and so forth. It's certainly hard. It tends to be something we're falling back on that data. I think the Fernald case is an exception to that. But as we're getting into that part of the hierarchy, it -- we don't have the information, usually.

I don't know if that's a strength or a weakness. It means we avoid sort of having to deal with some of these issues with coworker models, but at the same time, it may be that we're ignoring a significant amount of

stratification or differences among the people doing different tasks, or with different job titles within a building, or within a -- even within the whole plant.

But I think they are -- I think you're right, we need to sort of think about it from -- as an overall issue, and not just something confined to personal monitoring.

MEMBER ZIEMER: Yes. Well, whichever way it goes -- I mean, what you just said may be exactly the answer to it. I think we just need to know.

CHAIR MELIUS: Yes.

DR. NETON: Yes. I have -- we have a concern internally, at least I do, regarding the stratification issue; and that is, at what point -- at some point you have to have almost a basis for why the data would be stratified before you start analyzing, because otherwise you can do a tremendous variety of different tests and come up with stratification that may

or may not be meaningful. But you have to almost have some underlying rationale as to why we believe this particular data set could have some stratification in it.

MEMBER ZIEMER: We sort of have that case, you know, at GSI where we're relying on source term data, and we're stratifying to some degree between radiographers and layout people and administrative people.

DR. NETON: That is true.

CHAIR MELIUS: Yes.

MEMBER ZIEMER: Those are sort of the main questions I had on the document.

CHAIR MELIUS: Gen or Josie?

MEMBER ROESSLER: Am I off mute?

CHAIR MELIUS: Yes, you are.

MEMBER ROESSLER: This is Gen. I don't have any real question, but I think when we get to the final document the thing I'm looking for the most backup on is the

discussion. And it comes up quite a bit in the outline about what happens when we have unrealistically high estimates, or implausibly high. That's something that's always just sort of been hanging there, is just where do we go from that? So, I think that really needs to be identified in the document.

CHAIR MELIUS: And how do we, you know, sort of evaluate that they are implausibly high? And then who are we referring to? Are we referring -- you know, is it -- are they implausibly high for the highest exposed worker or for all workers?

MEMBER ROESSLER: Yes, defining the population.

CHAIR MELIUS: Who are we comparing it -- yes, who are we saying it's implausible for, because there may be -- it may be plausible for the highest exposed worker, and totally implausible for the lower exposed worker.

DR. NETON: Yes, I hear what we're saying there. It sort of puts us in an interesting situation, though, where if you say you can plausibly bound the highest exposed workers but not a subset of that, then you're sort of saying, well, I will make an SEC for a lower exposed worker class, but then it's always been difficult for us to put people in positions and places in the factory or plant. So, then you end up making a class for all workers, even though there is a subset that one might agree that you could plausibly bound their exposures. It's kind of --

CHAIR MELIUS: Yes, you can err on either side that way. I mean, I agree, it's a conundrum in terms of how we -- partly because we're limited by what data we have. And often, the lower exposed workers, or what we think are the potentially lower exposed workers aren't monitored, or certainly not as -- monitored as often and as completely as the

higher exposed -- at least potentially higher exposed workers.

So, then it's -- yes, I think sometimes we've dealt with it by saying well, there aren't that many of those people. I mean, sort of the discussion we were having with the -- on the Fernald Work Group call last week, talked about the coworker model there.

Well, if you're going to do subcontractors, who are they? Are they the construction workers, are they the plant physicians or, you know, other -- you know, delivery people, whatever. I mean, there's a range there, and how do we -- you know, how do we find the right way of describing who we're trying to, you know, do dose reconstruction for, evaluate, or put in a Class; and, yet, make it practical in terms of implementation.

I'll raise sort of a similar issue, but this is more in relation to the

coworker models, because I've been reading some of the reports on that. And I'm not sure if everybody else has. I know, Paul, you have, because it's come up before the Procedures, and Josie, perhaps. I don't remember when this came up.

But it's -- in looking at sort of ORAU and SC&A, going sort of back and forth on coworker models and doing some of the -- suggesting some of the kinds of statistical testing that might be done on that, it sort of struck me that we're -- there are a lot of difficulties in reaching a conclusion on that, because we really don't have a criteria for sufficient accuracy that's quantitative at all.

You know, we look at sort of an upper limit, an upper bound, but we don't go -- really go beyond that, specifically. And, therefore, the statistical testing, I think, has limitations, and you can argue -- you can

have examples that would go both ways because if you're testing on the variance of something, a lot of that depends on the sample size more than it does on the actual numbers involved, so you can have a very high variance for a low -- relatively low exposure quantitatively, you can have the opposite of that for what's a very high exposure; yet, I think the higher exposures are the ones where they're more likely to affect dose reconstruction.

And I think until we think about how we're going to deal with, you know, realistically what's a -- what levels of exposure or what doses, you know, are we really interested in. And we've already dealt with that in some ways, for example, with what we refer to as environmental dose, or for, you know, residual contamination on a site where we, basically, take a fairly simple approach to that because we believe that those

exposures are quite low; and, therefore, how much variability we have in them, you know, doesn't matter. And we don't usually have a great deal of data, anyway, and we don't take those into account and so NIOSH has this in this outline. We talked about it at our last meeting. But I think what when we're trying to judge coworker models, and if we're going to assess coworker, or evaluate coworker models based on some sort of statistical testing of those, I think it's going to be very hard unless we come up with some more specific criteria in the area of what -- sort of what level of exposure are we going to worry about, and try to take into account.

It's hard, we've never defined a number for endangerment, health endangerment. We've always looked at it from sort of the sufficient accuracy. And there we don't really have a quantitative approach defined on sufficient accuracy, so I think we're -- I

think dealing with the application of this is going to get hard unless we come up with, I think, some sort of guidelines or guidance on what levels of exposure are we going to be concerned about taking into account in coworker models, or any other approach to dealing with sufficient accuracy.

MEMBER ROESSLER: Jim, you just brought up a whole new ball game, it seems like, and I'm wondering if when we talk about defining the level of endangerment, and I'm not sure if you're really suggesting that that be done, it almost seems like that's a scientific issues committee assignment.

CHAIR MELIUS: It could be. I mean, if you remember way back when, we as a Board talked about trying to define endangerment and decided not to, basically. Partly because it was, you know, controversial and difficult, and partly because we thought it -- we weren't necessarily sure that it needed to be done.

And I'm not saying it needs to still be done. I'm not sure we want to take that on through the Board. I'm not sure that NIOSH wants to take on that assignment either.

But I think we -- at the same time, there -- I think -- and we may find ourselves that we have to have some practical ways of approaching that in terms of how we deal with this issue, because we're -- the issue of sufficient accuracy, because I think, you know, that -- sufficient accuracy sort of begs for some sort of numerical criteria.

MEMBER ZIEMER: This is Ziemer again. Let me throw out some comments or ideas on that.

I think we also in a way would feel comfortable if we had a number that we could peg things on, and then say okay, we met this number criteria. I have a feeling that in a sense this could differ in every case, or at every site in the following ways.

First of all, let's take the low-dose end of the thing where you have a particular component of the dose reconstruction that is a very small fraction of the total. We know sort of intuitively that you can tolerate a lot of variance there, and it has very little effect on the Probability of Causation.

You could be within a factor of 10 and still have very little effect. And we recognized that before, and we talked in the outline about, at the low dose end of things, that you can tolerate a lot of variance without having a big effect on the final outcome.

But what that number would be, it seems to me, could be different in every case. And it seems to me what we might want to think about was just having some criteria where for a particular situation we ask that the sufficient accuracy be demonstrated according

to some sort of rules, rather than according to a particular number.

It's sort of like what we do with the situation where we're looking for the -- one particular site to represent another in the surrogate data case. You have to look at each one specifically following some guidelines, and then make your judgment.

Maybe we could have guidelines on what sufficient accuracy looks like, both at the lower and at the high end without coming up with a particular number. At the high end, obviously, you don't want to have a factor of 10, let's say, on your estimate and say well, it's between this and that, and one end of that is below the PoC, and the other end is above it. So, you're looking at a much tighter sort of variability in the final outcome.

But I'm just wondering if we can think in terms of having a guideline, and then in each case it would -- the burden would be

to say here's what we've got, and here's why we think it is of sufficient accuracy.

CHAIR MELIUS: No, I don't disagree with that, Paul, but I think it's -- the high end and the low end are probably easier than the middle.

MEMBER ZIEMER: That's always the case, isn't it?

CHAIR MELIUS: Yes, where's the cut-off. And, certainly, it's going to be individual, because it's going to depend on the site, and what the exposures are, and are there -- what materials are involved, what are the sources, what are the -- how are people exposed, and so forth. So, you know, it's not going to be by, you know, radionuclide or something like that. It's going to be, you know, really depend on the exposure situation.

And, somehow, I think it comes back to what extent that exposure -- that type of exposure in that particular site and, you

know, what we are assuming about the variability or non-variability of that exposure. To what extent will that affect the -- you know, a person's dose reconstruction?

It's going to affect it, you know, say 10 or 20 percent in terms of Probability of Causation. And then, obviously, that's, you know, a significant difference. If it's going to be a very, very small amount, you know, .01 percent or less, or whatever, then I think we'd have, you know, less concern about that, and do that.

So, I think that's the -- and it's sort of finding that the middle ground -- where do we get in the middle? And I think it is on a case-by-case basis, so I think it will be on guidelines, because I actually don't think we often have the numbers, or want to put NIOSH or whoever through all the work it might take to do these estimates. It could get quite complicated, I think, and beyond what is

necessary. So, it would be a general set of guidelines just to identify certain instances, but I don't think we can ignore it, because I don't think we'll -- I think if we found it, at least in some instances we're having difficulty dealing with sufficient accuracy. And I also think that the approach that NIOSH is taking -- and we would consider coworker models and stratification within, in coworker models, is if we're going to have any way of evaluating that using statistics, I think we're going to have to come up with some guidance to direct that.

As I said, when I was reviewing the OTIB -- it's not OTIB, it's ORAU, whatever report, 53 on coworker models and stratification. And then the SC&A review of that, I mean, I could agree with both -- I could think of examples where I'd agree with both what ORAU was approaching, and I could disagree with it. In SC&A's critique, I had

the same, you know, sense of, that it was -- that it would depend on the situation, and I wasn't sure that those were going to provide the kind of general guidance that we needed for dealing with coworker models without, you know, some more guidelines or guidance attached to it.

So, SC&A, you've been quiet. Do you want to add anything?

DR. MAKHIJANI: Dr. Melius, this is Arjun.

CHAIR MELIUS: Yes.

DR. MAKHIJANI: I've been dealing a lot with this question of stratification and its application to Savannah River Site, as you know. We haven't seen the reports yet, but one of them has gone to DOE and you'll see it soon, I hope.

But the problem is actually much more complicated. When we got into the neptunium database we found that even though

you have the minimum number of samples, which are 30, and you cross that threshold -- sorry, that came up in the thorium, sorry about that.

The minimum number of samples necessary to assure that you're not saying that they're the same distribution when they're not, so you're controlling that type of mistake. It will depend also on how many samples there are below the minimum detectable limit that you have to fit in with a statistical distribution, and how many are actually detectable, and the relative geometric mean compared to the geometric standard deviation. If you imagine the distribution if you have the means that are far apart, you will see the two bell curves, or two log-normal bell curves separately. And in that case, it'll be easy to tell that there's different distributions.

If they're close together, the means, but the deviations are large, they'll

be all smeared out and you won't be able to tell whether they're different with high confidence.

So, it turns out that the problem of the number of samples is somewhat more complicated even than presented in Report 53. And you might have to do it on a case-by-case basis. We examined four years in the thorium report, and in two years it came out fine with the number of samples, and two years it did not.

CHAIR MELIUS: Yes, that was sort of what I observed. And I agree, I think it is very much dependent on what kinds of -- what types of information you have from the site. And you're right, with below detection raises problems, as well as the nature of the way some of the sampling was done, or who was selected for sampling.

DR. MAKHIJANI: Right. And the other -- one of the other issues is, was the

protocol for the sampling for the two groups the same? So, was one group monitored only after incidents mainly or largely, and the other group routinely? So, in that case they become non-comparable data sets, at least as we -- and you've seen that in the report that's already gone out from Harry.

CHAIR MELIUS: Right.

DR. MAKHIJANI: So, sort of, the stratification is necessary in some circumstances, as at Savannah River Site we've shown, but it's very complicated and difficult.

CHAIR MELIUS: Yes. And one of my concerns is that if we -- that we're never going to be able to reach a resolution on those issues unless we have some idea of what, you know, level of difference are we looking for? Some guidance on how to evaluate sort of the sufficient accuracy part of these coworker models.

Anybody else from SC&A want to say anything?

MR. STIVER: This is John Stiver. I think Arjun summed it up pretty well, you know, what we're dealing with. We're finding a lot more complexities once we start really trying to implement the Report 53 approach. You know, you get to a point where there's just not enough data available to really discern whether -- and the variances are overlapping to the extent that you can't really separate out any substrata. How then do you deal with these low-exposed strata? You know there are people there for which the high exposures probably don't apply. And we're still grappling with how would we go about naturally trying to implement something like that, given the limitations we have on the data sets.

This is something we're dealing with at Fernald quite a bit. It's just almost

impossible to -- in earlier years to place people in particular buildings. And, oftentimes, the job descriptions are lacking or missing, so you may have somebody who was an office worker, but --

DR. NETON: This is Jim --

MR. STIVER: -- we are forced to give them the type of exposure you'd expect for a laborer. So, yes, I guess I'm talking around in circles here, but I -- how to go about quantifying sufficient accuracy. You're almost coming out of a situation where you think you recognize it when you see it in a particular circumstance, but as far as setting up rules, that's -- I don't know. We're going to have to think about this quite a bit more.

DR. MAURO: This is John, to weigh in a little bit.

What we haven't talked about, and that's maybe because the first attempt at trying to go back historically and see what

was done, but when we did decide to deny an SEC because there was a sense that there was sufficient accuracy and completeness, so that you can reconstruct the dose, whether it be external, or thorium, or uranium, it was interesting that when we looked at the data, we were able to say -- and there was like very little discussion of well, why do we believe that's sufficiently accurate? What kind of test did we put it to with respect to completeness?

And, you know, I think back to all of those times when we converged eventually, and concluded yes, I think that group and that tier or strata can be reconstructed with sufficient accuracy, and what brought us to that point? What is it about the data that led us to a place where we all achieved concurrence?

Most of the conversation we're having is to show right now what are all the

reasons which make it extremely difficult to come to -- draw some conclusions regarding sufficient accuracy? And, I guess, I -- when we did agree, it would be -- I would like to get a better sense of what was about it that allowed us to come to that conclusion? And I think about it, and it's almost like sometimes it's self-evident, but it was never really articulated.

CHAIR MELIUS: No, and I think you're right, John. And I think part of that is that we were -- there are so many SEC evaluations to do that we reached a conclusion on them one way or the other, and then the -- sort of the Site Profile part of it sort of got, you know, procrastinated or delayed somewhat. And, therefore, we never have spent as much time on that, and as much discussion. So, I think -- I don't think we have as much of a record of discussing that. Yes, we evaluate an SEC, we do that, and then we --

before -- and I think the only place where we've done it has been on the potentially Dose Reconstruction Subcommittee, but in that case, for the most part, we sort of ignore the bigger Site Profile issues, so to speak. We don't take those on again, so I'm not sure that there's been as much discussion there.

So, I'm not saying we've done anything wrong or incorrectly, but I just think it is something we haven't spent as much time as a Board or within work groups discussing. We've been doing more of it recently, I think.

DR. MAURO: When SC&A writes a report and has its list of findings, and we all pay attention to the findings, but where we say, well, this looks okay, I guess we usually give reasons for it. I'm almost like thinking out loud now. You know, we would look at the data, how complete it is, how many years, how different, and there's a texture to

it. But somehow we've all --

MR. STIVER: John, are you still on?

DR. MAURO: Yes, I'm sorry. Go ahead. Someone just was speaking there. All I'm saying is that to what extent would it be helpful to look at the places where we agreed that there was sufficient accuracy. Is that what we've done previously when we -- when the first attempt was made at this? And what was it about the data set that led to general consensus that this did represent sufficient accuracy?

CHAIR MELIUS: Yes, I just don't think the record is there enough to be helpful, as much as the -- as when NIOSH did the opposite approach, which is basically sort of looking at where situations like the thorium situations and so forth, they -- a lot of those decisions were so site-specific, and it has to do with what data was available, and

different time periods, and so forth, I think it was hard to -- it's hard to generalize from those.

John, one thing I question. Do you really think we pay attention to SC&A reports?

DR. MAURO: Absolutely.

(Laughter.)

MR. STIVER: This is Stiver. I just came back on. For some reason, I got disconnected.

CHAIR MELIUS: Okay. I hope you didn't hear that then, John.

(Laughter.)

DR. MAURO: It was okay for my ears, though. Right?

CHAIR MELIUS: I wanted to see who was awake. Does NIOSH have any comments on what we're talking about?

DR. NETON: This is Jim. I guess I've got a few thoughts on a few things that were mentioned here.

CHAIR MELIUS: Yes.

DR. NETON: One thing I think that we haven't focused on is, you know, why were workers monitored and why weren't they monitored? In some cases, you know, it's totally appropriate, because they weren't monitored because they weren't exposed, or very lowly exposed, and a general coworker model would be appropriate. So, I think that's part of the analysis, is to say, okay, who was monitored and why. And what do we know about these unmonitored workers, to what extent? And if we can flush that out to some great extent, I think that's when we converge and agree that we can reconstruct the doses for the unmonitored workers.

The other point that was brought up that I guess I have some concern with is maybe tying the sufficient accuracy to Probability of Causation difference. We thought about that a lot in the past, and

there's so many combinations possible to calculate, that it probably wouldn't be very fruitful to do something like that, at least in my opinion.

CHAIR MELIUS: Oh, I was not suggesting that we try to do it for all these situations. I agree, I think it would be very complicated, but at some sort of -- I mean, that is sort of the test. I mean, we want to know, you know, for particular situations, to what extent does it contribute to -- you know, potentially contribute to a person's dose. And, certainly, at the low end we're making, you know -- we're already sort of implementing that.

DR. NETON: Right.

CHAIR MELIUS: I just worry that without some more thought to that and so forth, I really worry whether we'll be able to get very far with dealing with the coworker issues, at least using statistical

comparisons.

DR. NETON: I've got a little bit more thought on this: who was monitored and why. I mean, in my simplistic mind when we first started this coworker approach, we envisioned that you have the distribution of monitored workers. And let's say that we know with some certainty that either the highest exposed workers were monitored, or a representative sampling of the workers were monitored. In that situation, then, we ended up developing what I would essentially call a two-part job exposure matrix where one would assign the 95th percentile of that distribution to the workers that were potentially highly exposed, and the 50th percentile to all other workers that weren't monitored and more in categories that were not likely heavily exposed. I thought that seemed to make a lot of sense.

Now, I do agree that there are

some situations where maybe there were some categories of workers that -- and this typically comes up in the area of construction workers that had some very high exposures that are -- were not monitored that were in that upper tail of the distribution. Then you've got an issue, but for most other instances, I think it seems, in my opinion, fairly clear-cut that you have this sort of two-compartment job exposure matrix, it works fairly well. The trick, of course, is to define which job categories fit into which bin.

CHAIR MELIUS: Yes. And then do you have enough information on the -- to place people in those job categories. I think that is --

DR. NETON: I think for the most part we have a pretty good idea of what the person was doing. I mean, whether they were administrative. And, you know, we always tend to err on the claimant-favorable side.

CHAIR MELIUS: Yes, but I think that -- and I'm thinking more in terms of the SEC evaluations. There are a lot of -- well, there are a lot of workers that move around the facility, not just construction workers, security and so forth, and there are a lot of people, I think, that are hard to know where -- what category to put them in.

DR. NETON: Well, I don't know. I would say the 95th percentile covers the most highly exposed workers working on distinct processes, operations with their -- essentially their faces near the operations, and the glove boxes, and welding operations and such. And the ones who frequented the work areas on a regular basis, even, I think the 50th percentile would certainly capture that. But, again, that's just -- that's the way we set it up in the beginning, and that's why we're talking -- I guess it's not --

DR. MAURO: This is John. In

thinking about it in its simplest sense, are we asking ourselves the question that says okay, we have a group that may or may not be homogeneous. Okay? But we do have a lot of data. And we could pluck off the upper 95th percentile, and say it's very unlikely that any worker could have experienced the upper 95th percentile day in and day out, or year in and year out. And, as a result, as you just described previously, that becomes your coworker number for the high end individuals.

Then doesn't the next question that goes now towards sufficient accuracy, is that you have to ask yourself the very difficult question, are there lower tier groups -- and this is what happened, of course, with the construction workers at Fernald. Are there lower tier groups that in theory, their upper 95th percentile might be higher than the aggregate upper 95th percentile?

I'm sort of drawing upon the experience we just went through on Fernald. So, what it becomes is a combination of quantitative and a qualitative approach. The qualitative side is doing some introspection that within the overall group, is there reason to believe that there are subgroups that might for some reason, such as the construction workers and subcontractors, could -- it's almost a sense from experience, could have experienced something different; and, therefore, they're a different population.

But then the second part becomes quantitative. Then the second part becomes yes, we do believe that there are these groups that might have been problematic.

Then you see if you could find data for that group. And I don't have an answer to this, but the real question you have to ask yourself is, given the data, can we assign to that sub-tier an upper 95th

percentile, and is that upper 95th percentile greater than the aggregate group?

And these are a couple of -- a process that in thinking through what we've done before, it really came down to that. And if we weren't able to do that, we found ourselves in the realm of, I think we've got ourselves an SEC issue.

DR. NETON: Well, see, John, in my opinion you have to establish that not only were they more highly exposed, that group, but they were also not monitored.

DR. MAURO: Yes.

DR. NETON: Because by definition, you have some data from that population that is higher than the rest of the population. Grant you that.

DR. MAURO: Yes.

DR. NETON: But then I think it's C- you need to look at it and say okay, well, were there a large number of these people in

that group that weren't monitored at all?

DR. MAURO: And could have had these high end exposures.

DR. NETON: Could have had these high exposures. See, that's the key. One has to --

DR. MAURO: I agree with that.

DR. NETON: You've got to look at the whole data set.

DR. MAURO: Yes, but you see, those first couple of questions are very subjective. You know, are there these groups, did they have the potential for exposure? And, if so, do we have any data? You know, so --

DR. NETON: We've got that. I mean, we see that. And Arjun has pointed out a couple of examples where, yes, there are construction workers that have -- at least on paper the mean value is higher.

DR. MAURO: Yes.

DR. NETON: The median value, but

there's a large amount of variability on top of that. But then were there a large number of these other workers, or any workers that were in that high category that weren't monitored at all? You know, I'm not saying they weren't. I just say that that needs to be somehow established.

DR. MAURO: Yes.

DR. MAKHIJANI: This is Arjun. Am I off mute?

CHAIR MELIUS: Yes, you are, Arjun.

DR. MAKHIJANI: The -- you know, if we look at Savannah River external and internal, we didn't have much problem with the construction worker or non-construction worker on the external dose. And NIOSH had put forward a comparison, and then we reviewed it, and we found there was one job category, or two, if I'm remembering correctly, where construction workers had higher exposure potential. And we were able to agree on a

multiplying factor for a coworker model, but that's because the amount of monitoring data available was so large that we were able to go through these comparisons with some great amount of confidence.

The problem with internal doses is you've got so many radionuclides, and for some of them, typically, uranium/plutonium, you often have a large amount of monitoring data, but the amount of monitoring data for many radionuclides is quite small, your neptuniums, your thoriums, and so on. And then it becomes very, very difficult to settle these questions in terms of stratification, who was higher than whom, what was the monitoring protocol, or was there a monitoring protocol?

And that's, I think, where many of these practical difficulties -- I actually like the paper overall that NIOSH put together. I think it needs a little bit more scientific graininess, and there's some gaps

in terms of scientific reasonableness that needs to be put in, and some statistical constraints that need to be there, but overall I think these kinds of constraints, we actually follow them in an SEC. You tend to come up against difficulties with particular radionuclides because there just isn't enough data.

CHAIR MELIUS: No. I think that is usually the difficulty. And I think that's often why in the past we have given -- made certain sites into SECs based on that.

DR. MAKHIJANI: Right. Exactly.

CHAIR MELIUS: And now we're coming to some situations where maybe there's, you know, some more monitoring data. But the question is, is it enough? And then how do we -- is it appropriate to apply it maybe with a less stratified model than we might use if there were -- because it wouldn't support any evaluation of stratification.

And, again, as you said, Arjun, often we have much more limited information on the sort of the sampling strategy and so forth for those. So, those are the ones that, you know, again, for these sites, they're the ones we're mostly interested in because, certainly, they're the crux of what we do in terms of making an SEC evaluation at these sites.

Any other comments on the report or these issues right now?

MEMBER ROESSLER: Jim, this is Gen.

CHAIR MELIUS: Yes.

MEMBER ROESSLER: I was trying to get off mute. I would like to not just simply dismiss the thought that John Mauro brought up about looking at the cases where we thought there was sufficient accuracy. You know, I don't think it deserves a great detailed evaluation, but I would think that someone would be able to kind of look at them and see

if there's a general trend, or if there's anything sort of on the surface there that could be looked at deeper.

CHAIR MELIUS: NIOSH, do you have any response to that?

DR. NETON: Not right at the moment. I'd have to think about that.

MEMBER ROESSLER: I think, at least think about this.

DR. NETON: It might be worth doing. I don't know. I just don't have a feel in my brain right now, as to which sites that would be, and what data might be available.

MEMBER ROESSLER: I just don't want to completely dismiss it because it seemed like a pretty interesting concept.

CHAIR MELIUS: Yes, I think the -- at least, personally, I think one of the problems in thinking about that is that -- at least I was disappointed in the other reports, because I actually thought we would get more

out of those, and they'd be more helpful than they were. And I'm not faulting NIOSH or ORAU, whoever prepared those reports. I just think it's -- our SEC decisions are very much driven by the specifics about a particular site. And often, work monitoring wasn't done, and the nature of operations of these sites. And these sites are quite diverse, so in terms of sort of general conclusions, we didn't get as much out of that as we thought we might. But let's think about doing that.

MEMBER BEACH: Jim, this is Josie, to add onto that. SC&A uses a set of criteria when they develop whether a certain site or a certain issue is sufficiently adequate. Have we talked about looking at their criteria, and maybe that will help in the thinking of how to look at that?

CHAIR MELIUS: I don't know what their criteria you're referring to are.

MEMBER BEACH: Well, SC&A would

probably have describe that. I'm sure --

CHAIR MELIUS: No, no. I was making an opening for SC&A of --

MEMBER BEACH: Oh, thank you.

MR. STIVER: This is Stiver. Are you talking about our data adequacy and completeness reviews?

MEMBER BEACH: Yes, I believe so. I mean, you go through a set of criteria when you're looking at whether a site has adequate --

MR. STIVER: Well, yes, we try to list to determine whether they're -- you know, all the years and buildings where operations took place have monitoring data. Basically, the same kind of thing that's laid out here in this hierarchical approach. So, we don't necessarily have a set of fixed criteria that we look at. That's sort of a kind of approach, you know. You look at the source terms, the exposure potential, you know, the different

aspects of that, and then look to see whether the proper type of monitoring was invoked based on the types of radionuclides and so forth.

As Arjun said, we've mentioned earlier, Savannah River is a pretty good example. You typically have pretty good external dosimetry data which allows you to make some kinds of adjustments for certain strata, but oftentimes you don't have that for the less well represented radionuclides, like thorium or neptunium and so forth. So, it becomes a matter of looking at those and seeing what operations are going on, what radionuclides were in place, and what the exposure potential is. And then given that, do you feel they're statistically significant data available of high quality that can then be used to reconstruct dose? A lot of it comes down to a matter of professional judgment.

(Simultaneous speaking.)

DR. MAKHIJANI: I would supplement that a little bit. This is Arjun. We have procedures by which we -- for reviewing SECs, and also for reviewing site profiles, and those were submitted to the Board early on. John Mauro, correct me if I'm wrong.

DR. MAURO: You are correct.

DR. MAKHIJANI: And we generally follow those procedures. We also, you know, bounce off of specific NIOSH reports when we're reviewing SECs with which I'm more familiar. We start with the -- we start, obviously, with the evaluation report typically when it says dose reconstruction is feasible. And then we go through a very, very similar set of criteria, but I think the scientific and statistical feasibility sides of it are a little bit more elevated than they are in the document that NIOSH sent out on the 20th of May. But the ideas about source term, the availability of monitoring data, the

various kinds of radionuclides, external and internal; external are usually not a problem, so mostly internal. And they're not very different than the ones you have before you.

We have -- and I think if NIOSH probably developed a document in more detail, you won't come up with something that's very different than what we do.

DR. MAURO: A good example; I mean, when we recently worked on PROC-44 where one of the things we added to the attachment was -- in a funny sort of way, it goes very much to this topic where we say, well, there are a number of sites that SC&A worked on with the Board and NIOSH, and where we did come to convergence, eventually, by pushing the data through a certain process. I'm thinking -- and there are four examples, I believe, in PROC-44. And we did it solely as a way to review the current protocol that NIOSH employs for doing SEC reviews.

And if you recall, one of our commentaries was to get more explicit, and perhaps with some examples of what does constitute -- how do you go about getting to the point where you achieve what we call completeness, accuracy, adequacy, that sort of thing?

Now, the best we did is give a few examples in Attachment A to PROC-44, but I think that goes toward the things we're talking about. When -- under what circumstances were we able to get to a place where there was consensus, yes, we think we agree that there is data adequacy and completeness? We don't usually use the term, meets the test of sufficient accuracy, but we usually do get to a place where we say we think they're scientifically accurate and claimant-favorable.

I would just maybe want to point everyone to that attachment in PROC-44 review

that we submitted six months ago or so, as being a place just to take a look at, because it goes a little bit toward what Gen had mentioned earlier, that, you know, under what circumstances did we achieve convergence? And I think a few examples are in there, but certainly there are more.

DR. MAKHIJANI: If I might add something for Josie. You know, it's not so much the specific criteria that are different, but maybe how sometimes we look at them. So, for instance, in this paper, NIOSH says it must be possible to demonstrate that the highest exposed workers were monitored. And we agree, and we -- but often the discussions and differences are, were the highest exposed workers actually monitored, and how do you demonstrate that? Because it says it might be possible to demonstrate, because once you've demonstrated that, then as Genevieve was saying earlier, then your road to a coworker

model is clear. But in terms of demonstrating that for some radionuclides, it's very, very difficult.

I'm recalling about a site where a certain population of workers was very frequently monitored, but we weren't able to establish the relationship, at least that's my interpretation, between that monitoring and many other groups of workers who didn't have very much monitoring, but who had exposure potential.

So, it's the -- and then the statistical depth to which you need to demonstrate something is a pretty important consideration, so I just ended one example. So, in Report 53, NIOSH had a hypothesis that the two distributions of construction workers, or two distributions being compared, say construction workers and non-construction workers, are the same. And the bar for rejecting that was very high, so when you look

at it the other way, the bar for -- you can often be wrong and say they're the same when they're actually not the same. But we believe that you need to look at that question with as much rigor as the first question. So, you need to control for both types of errors.

So, how you -- so, a lot of the differences, Josie, have arisen not in the things that we look at, because we all look at the same things. We look at the source terms, the work, and the monitoring data, and how much is available, and what the radionuclides were. It's in how we approach the demonstration of whether these data can do the job or not.

MEMBER BEACH: Absolutely. Thanks, Arjun.

CHAIR MELIUS: And I would just add, I think the -- often it's the -- that's just the numbers -- it does come down to what extent is there data available to demonstrate.

And if we're -- that data is not available, what do we -- what assumptions do we make? Do we assume that it means that the exposures aren't stratified, or that between various groups, or that they are? I mean, that's -- I think right now we would assume they aren't. And is that a valid approach?

And then if we're going to make that -- if we don't have adequate data to make -- to evaluate that, then we're going back to how do we, you know, interpret, or how much do we know about, you know, what people did to make sure the sampling protocols for the site and so forth. So, there's a lot of different types of information that we would take into account. So, now we've learned that SC&A hasn't already figured this out. And the Board hasn't, and NIOSH hasn't.

So, what I would suggest doing, going forward, we're going to be discussing this at the Board meeting in Idaho. And I

think we, you know, should -- and we're going to also be discussing the ORAU-0053 and the SC&A review of that, so I think those two will tie together. And we have a fairly significant amount of time devoted to that. I think actually later in the meeting we'll also be discussing the Fernald site. There's an example where we'll be dealing with this coworker stratification issue, so I think there will be a lot of time to think about that and so forth.

I mean, what I would like to do is get some input from other Board Members, and get a sense of what should we be doing to approach this? What makes sense to do at this point in time? Is that reasonable with the other Board Members on the Work Group, and with NIOSH?

DR. NETON: Yes, it sounds good.

MR. HINNEFELD: Same here.

CHAIR MELIUS: Okay.

MR. HINNEFELD: Now, for the July Board meeting would you expect us to have taken a shot at some of the sites where SECs were not granted, to kind of look at what was special there, or what was --

CHAIR MELIUS: Well, let's wait until we get up to -- out to Idaho.

MR. HINNEFELD: Okay.

CHAIR MELIUS: That's not to not do it, that's -- I just don't think there's time to --

MR. HINNEFELD: I don't think we could do much of it.

CHAIR MELIUS: Given some of the resource constraints and so forth, I don't want to burden you until we may be able to pin it down a little bit more.

MR. HINNEFELD: All right.

CHAIR MELIUS: Do that. I mean, because there are some other things that come up. One of the things I was actually thinking

about when Arjun was talking about the Savannah River is, well, what is it about the external monitoring data that led us to sort of accept that in terms of coworker models? And then what -- you know, how far did we go with that in terms of stratification, or non-stratification and what was that based on?

And that would be examples where we have less constraint due to the amount of data available, and probably more information -- because the data is so dense that we have more information on understanding and confidence in the sampling strategy and so forth, so that we weren't concerned about some of those issues. Well, then what did we conclude based on that? You know, we conclude it was sufficiently accurate. It wasn't -- I mean the SEC is not based on that, so maybe that's an example of something that would be useful to think about from this perspective. But let's all think about it. There will be

other examples from other sites that -- different issues that we want to -- would like to get more information on.

DR. MAKHIJANI: Yes, Dr. Melius, that -- you know, if I might expand on that for a moment. We've been discussing this mostly in whether an SEC was granted, or whether all parties agreed there was enough data to deny an SEC. But it may be more useful to be a little bit more fine-grained, because there have been many areas where we agreed outside of, you know, whether an SEC was granted or not. But many areas where we agreed that there was enough data, even in the internal data. Of course, SRS external data is a very good example, and there the stratification was pretty fine-grained. But, you know, plutonium data at Rocky Flats, I think we didn't have very much argument about that, if I'm remembering correctly, for example, and uranium data at some sites. So,

it may be useful to look at that.

CHAIR MELIUS: Okay.

DR. NETON: I can speak for the Rocky Flats, and I was going to mention that earlier. That's a case where the data were not as robust as we liked, and we ended up using the 95th percentile for all workers. That's one where we sort of agreed.

DR. MAKHIJANI: Yes, and we did agree that there were enough data to do that.

DR. NETON: Right. But we agreed that we would use the 95th percentile for everyone, and not try to stratify it in the 50th or the 95th. That's sort of a different example, but it might be worth looking at here at this point.

CHAIR MELIUS: Anybody else on the Work Group with last words or suggestions? If not, we'll see everybody in Idaho. We're hoping someday Ted will find us a place to stay, other than camping behind Brad's house

or something. I'm not sure what we have in store for us, but --

MR. KATZ: I think Brad lives in a nice place.

CHAIR MELIUS: Does he? Does he have room, you know, in the garage for a bunch of us?

MR. KATZ: He's very handy. If he doesn't, he might be able to do something.

CHAIR MELIUS: Yes, that's why I say, we'll get the notice, bring sleeping bags.

MR. KATZ: So, everybody, the other thing -- I think it's pretty obvious to me what materials I should distribute related to this discussion. But please, to everyone on the line, give some thought as to what you might -- what might be additional reading materials that would be helpful to people, and I'll distribute those, as well. The obvious ones I'll cover.

CHAIR MELIUS: Yes. No, I think this outline would be one. And then, obviously, the -- some authority you already have on your list, but 53 and the --

MR. KATZ: Right, right.

CHAIR MELIUS: And so forth.

MR. KATZ: Right. No, I'm just saying, if it occurs to anyone that something else is particularly germane, just let me know.

CHAIR MELIUS: Yes.

MR. KATZ: And I'll add that to what I distribute to all the Board Members, and what we have out there at the meeting, too.

CHAIR MELIUS: I'll let you know. I also assigned -- tried to assign to our eminent epidemiologists on the committee the -- -I just remembered I left off one, but I sent them copies of the report, the 53, and the review of the 53 to read ahead of time.

MR. KATZ: Oh, good.

CHAIR MELIUS: Yes. See if I can get them interested before the plane ride out there.

MR. KATZ: That's good. That's good. Well, they both could bring something to the table.

CHAIR MELIUS: Well, I began with four of them, and I left out -- I forgot Jim Lockey.

MR. KATZ: Right.

CHAIR MELIUS: Just thought about it. Okay. Everybody, thank you, and as I said, we'll see you in July in Idaho, if not sooner. Thank you.

MR. KATZ: Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 2:17 p.m.)

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