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

+ + + + +

ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

+ + + + +

SEC ISSUES WORK GROUP

+ + + + +

MONDAY
JULY 28, 2014

+ + + + +

The Work Group convened at the Hotel on the Falls, 475 River Parkway, Idaho Falls, Idaho, at 1:00 p.m. Mountain Daylight Time, James M. Melius, Chairman, presiding.

PRESENT:

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

ALSO PRESENT:

TED KATZ, Designated Federal Official
BOB BARTON, SC&A
NANCY CHALMERS, DCAS*
HARRY CHMELYNSKI, SC&A*
DeKEELY HARTSFIELD, HHS
STU HINNEFELD, DCAS
TOM LABONE, ORAU Team*
JOYCE LIPSZTEIN, SC&A*
ARJUN MAKHIJANI, SC&A
JOHN MAURO, SC&A*
JIM NETON, DCAS
DANIEL STANCESCU, DCAS*
JOHN STIVER, SC&A
TIM TAULBEE, DCAS*
BOB WARREN*

*participating via teleconference

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

(1:11 p.m.)

MR. KATZ: Good afternoon, everybody. The Advisory Board on Radiation and Worker Health. It's the SEC Issues Work Group meeting.

Sorry for the slightly late start, but we were trying to get our Live Meeting situation straightened out, and it should be now. So people who are on Live Meeting should be able to see the draft criteria document from Dr. Neton.

We are not dealing with any sites in particular, really, in this meeting. So we don't have any conflict of interest matters to cover before we get going.

Let's just do roll call so folks on the phone know who's in the room and vice versa. So let's start with the room with our Board Members.

(Roll call.)

MR. KATZ: Okay, then. The agenda for the meeting, I'm not sure if it's posted yet or not on the NIOSH --

DR. NETON: I think it is.

MR. KATZ: It is? Okay. So that's posted on the NIOSH website -- it's very simple anyway -- under the Board section of the website, under today's meetings.

And there are a couple of papers posted there that we're going to be discussing today. A third paper has too much Privacy Act protected information to post. So the third paper will be talked about, but it's not available to be viewed by the public.

And if members of the public want that in redacted form, they can certainly request it from me. And we'll provide it in that case. But it really is -- the reason it's not redacted and posted is because it's really

not very useful here, given the extent of the privacy information.

And Dr. Melius, it's your meeting.

CHAIRMAN MELIUS: Yes, okay. Thank you. And I would just remind the people in the room and on the phone, when we are discussing that particular paper, please be careful. We don't usually have those situations, but with this one it's necessary.

So we're going to start today with -- essentially we're reviewing the three NIOSH reports. And we're going to start today with the first report, which is entitled Draft Criteria for the Evaluation and Use of Internal Exposure Coworker Datasets. And Jim, if you want to start off with your opening monologue and --

DR. NETON: Okay. I'll be happy to summarize briefly the thinking behind this. Actually, I noticed, I changed this document.

And I apparently didn't change the title. Because it really is for use of Internal and External Exposure Coworker. It's supposed to be a little more generic than that. But as we all understand, the internal coworker datasets are the most difficult to untangle.

But anyway, this was one of the assignments that I've had from the Working Group meeting -- I think it was a couple of meetings ago -- was to put out some draft criteria as to what we would need to consider to develop coworker models.

There's a lot of technical documents in DCAS that talk about coworker modeling. But there really was never any overarching document that sort of put the requirements, so to speak, on the table.

And so this is our attempt at putting together a -- it's a little more than an outline. It's certainly fleshed out. But

it's also far from complete. And so opening maybe discussions today can help flesh out some of the concepts that have been put forth.

The introduction to this document's pretty straightforward. It just attempts to set the regulatory basis of why it's okay to use coworker models. And that's right out of 42 CFR Part 82, the dose reconstruction regulation that says if individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment.

That's a nifty saying, a nice expression. But, you know, the proof is where the rubber meets the road. How do you do that? How do you develop comparable models?

In general, we've taken comparable activities and relationships -- when we discuss that, we speak in terms of coworker models,

which we all know what that means after discussing this for quite some time.

But they need to be, in our opinion, either representative of the workers' exposures or, and this is important, plausibly bounding of the dose received by those workers.

They don't have to be exact matches. But they at least have to be able to bound the exposure experience of the workers. And we can talk about the sufficient accuracy maybe a little later.

When we're developing these models, they need to be adequate for the task at hand. And when it talks about sufficient accuracy, there's a couple of things that need to be talked about. Data adequacy is the first one listed. I'm just going right through the document.

CHAIRMAN MELIUS: And if I can interrupt, I think what might be useful to do

is to sort of take this one paragraph at a time.

DR. NETON: Okay.

CHAIRMAN MELIUS: And get comments and discussion in that way, rather than going --

DR. NETON: Do you want me to go back to the --

CHAIRMAN MELIUS: No. I think that's essentially the introduction. But I think these other sections all have sort of, for the most part, are individual topics. And I think that would be helpful, rather than jumping around.

Because I think we're trying to decide what needs to be filled in, so to speak, in these. And I think that would be the most useful way of doing that. And John, Bob and Arjun, is that --

DR. MAKHIJANI: That's fine. We can do it that way.

CHAIRMAN MELIUS: Okay.

DR. NETON: Okay. So, Section 2 talks about criteria for the evaluation, the adequacy of the dataset. I mean, clearly, if the data aren't adequate, they can't be used.

So we've tried to flesh out here a few of the major concepts of what would be an adequate dataset that had comparable activities and relationships.

And so the first section on data adequacy talks about the measurement techniques. It sort of goes without saying, but we've always stated that the measurements that are available have to be able to quantitatively measure or evaluate the exposure of the workers.

And a good example of this was early on. It was very recognized that neutron monitoring, for instance, at many of the sites, these nuclear track films, couldn't see

neutrons below a certain energy threshold, whether it was 500 or 400 keV.

So, you know, you couldn't base a coworker model on that. Or, if radiochemical analyses were done, were the recoveries quantitatively sufficient so that you could use the data? Or was there so much uncertainty in the chemical recovery of the method that it couldn't be used?

And that's really what this was talking about here. I'm not sure we're going to get a lot of discussion on this, but we can stop there and talk about that.

CHAIRMAN MELIUS: The only thing I would add there is I also think that I would just add another bullet in there about sort of the method of collection needs to be appropriate.

DR. NETON: Okay.

CHAIRMAN MELIUS: And again, particularly for incident-based, you know, if

you don't have a reasonably complete set of collection, that can be -- or inappropriate timing or whatever. So it's more than just the method itself or sort of the measurement method, but also the collection method has to be, I think, appropriate for --

DR. NETON: Okay. I think that is covered in -- this was really meant to be just sort of the method, the chemical or analytical methodology. The program methodology or the program implementation, I think, is covered later when I talk about the routine versus the incident sampling. I get into that later on when we're talking about the adequacy of the program itself. I was really just intending this to be the analytical methodology.

DR. MAKHIJANI: Jim, are you covering quality of data here? By that I mean, Joyce had raised the question earlier, six or eight months back, in a discussion about

Savannah River data where the same urine sample had been, not two voidings, but the same had been analyzed twice and yielded quite different results.

DR. NETON: Yeah.

DR. MAKHIJANI: Is there a separate item for that? Or does it belong in --

DR. NETON: No. That would belong, that's an analytical methodology issue, how robust, I guess, is the methodology itself. By the way, we've gone through that at Savannah River, and there's good basis behind that method.

DR. MAKHIJANI: Okay, yeah.

DR. NETON: But, yeah. I think you're right. If you have multiple samples, and you get widely different results on the same sample, then you've got an analytical problem.

And, you know, there may be ways to treat that or deal with it. But it would have

to be addressed. I totally agree with that.

DR. MAKHIJANI: Is there kind of a screen that you've developed for evaluating the quality of the data under this?

DR. NETON: Well, again, this is an outline. It's not fully implemented. But I don't know if screen would be the right word. There certainly are topical concepts --

DR. MAKHIJANI: Or a checklist.

DR. NETON: Yeah, checklists or something like that, sure. I mean, that could be developed as a follow-on to this, for sure, which would be the more detailed -- I'm trying to keep the implementation guides a more higher level document that says here's the major concepts that need to be addressed.

How they're addressed in practice, I think, tend to be put in more, you know, procedural type documents or, you know, TIBs or whatever, something like that.

DR. MAKHIJANI: Yes. But you want the big pieces in your --

DR. NETON: Yeah, I think they're here. I mean, the quality of the data. You know, how you go about it though and how you actually screen or evaluate, I think, would be the subject of a different --

MR. BARTON: This is Bob. I'd like to make a comment here.

DR. NETON: Sure.

MR. BARTON: We often talk about data completeness and data adequacy anytime we're evaluating a coworker model. And adequacy, I think, really refers to the science behind it and how are you making the measurements and how is that reflected in actual worker exposures, whereas subjects such as Awas your monitoring program incident-based, were you actually capturing the right people with your monitoring program@

usually falls under completeness.

And when you talk about adequacy, it's somewhat difficult to really kind of get down into the bones of it. Because every site's going to have different issues that you might have to deal with as far as the data quality and the adequacy of it versus completeness, which is really looking at the coverage.

Aside from whether we can trust these measurements, are the measurements for the right people that we want to be able to build --

DR. NETON: Yeah, I agree. I think this first paragraph would fall under what you would call data adequacy issues.

MR. BARTON: I agree.

DR. NETON: I think the next paragraph starts to get into the completeness issue, which is do you have enough data? You know, are there sufficient measurements to

ensure that the data are bounding and representative?

You know, we oftentimes get into this percentage of workers that were monitored. And I would like to steer clear of a percentage. Because, as I try to point out in here, there are programs, like at Savannah River, where only 15 people were working on some operation with some exotic radionuclide.

And, yeah, there's 10,000 people at Savannah River, but that doesn't -- it's not a really good indication of the completeness of the monitoring. Because it's the completeness of the exposed population that needs to be addressed.

And, you know, a good example here is the National Laboratory. They have a lot of different experiments with a wide variety of nuclides. But not everybody was exposed to those nuclides.

That brings into play a whole different issue, which is how do you apply those coworker models to those little pockets of individuals.

MEMBER BEACH: How do you identify who fits in the --

DR. NETON: Yeah, and that's something I would actually like to discuss in some more detail. You know, in the past, I think we've been able to say, well, we'll apply it to everybody. But I'm not 100 percent certain that that is appropriate either.

If you have 15 people that were exposed, and you've got 1,000 potentially exposed workers, it doesn't seem to me to be appropriate to say, okay, I'm going to give all 1,000 workers the exposure that probably only 15 people received. So I'm not sure how that plays out.

CHAIRMAN MELIUS: Well, that's a

section I think needs to be developed more.

DR. NETON: Yes, I agree.

CHAIRMAN MELIUS: And it's sort of just taking a look at what is available. In two ways: what is available and then what holes are we trying to fill? So again, you know, what data's available? How does it break down by, you know, building, and task, and type of work, and process involved and so forth, so you have a good idea of how wide that coworker model might be or how many parts there are to it or who might be included and who's not.

But I also think a second part of that is what gaps are you trying to fill? And are those, you know, gaps -- because, essentially, the bigger the gap you're trying to fill, if you have 15 people, or 100 people, whatever, and you have only monitoring from one year and you have monitoring, you know, 20 years later, well, what happened in those intervening

18 years is a bigger gap to predict with a coworker model than if, well, occasionally somebody's missing or there's a year where you have some problems with the laboratory or something, you know, where you can't use the data and so forth.

And, well, you've got good data on both sides of it and so forth. But that's, I think, a different question. And I think it's also a different statistical question of what you're trying to predict.

DR. NETON: I agree, I agree.

CHAIRMAN MELIUS: And I don't think there's hard and fast rules for doing that. But I think you have to take and examine the data, and array it and look at it with some process to how you would -- and documentation of what you're doing.

And I think that's some of what we've been missing in terms of what we see. It may

very well be done or, you know, it may be done appropriately. But I'm not sure. But then when it comes down to it, there's got to be sort of a strategic decision of where does the coworker model work and, you know, be feasible or not feasible in terms of what we're trying to do.

DR. NETON: I think we've kind of done that as we go through these deliberations on like Savannah River, you know. But it would be better to have done it up-front. I totally agree.

CHAIRMAN MELIUS: Yeah, yeah. I just don't know if we've always done it consistently.

DR. NETON: Exactly.

CHAIRMAN MELIUS: We may have, may not have. And part of the reason we might not have done it consistently is because we're still wrestling with how to do it.

MEMBER BEACH: Well, some of the sites that come to mind, and I don't know if this pertains, but the Oak Ridge, the hospital, I mean, we gave it -- we did the full, you know, the full grouping. Because we didn't know the handful --

DR. NETON: Right.

MEMBER BEACH: So it's important that we get this right.

DR. NETON: Exactly. That's a good example, Josie, yes.

MEMBER BEACH: There's been a couple of good examples that we've given --

DR. NETON: I tried to do that when I was putting this together, is going through it and looking at how we've behaved in the past. And I think we've been somewhat consistent.

But we've never started from a common point, like here, where we said, okay, let's go here, here, here and here, almost like

Arjun was just talking about, that sort of checklist almost where, you know, we start from there.

MEMBER BEACH: But there's another site that comes to mind that was one building and we gave it to the whole facility. And it was just a couple of years ago. I can't think of -- no, it wasn't Mound.

CHAIRMAN MELIUS: There was Linde, where we had --

MEMBER BEACH: No. It wasn't Linde either, because --

CHAIRMAN MELIUS: We had Fernald where there were --

MEMBER BEACH: It wasn't any of those main sites. It was just -- it was a different --

DR. MAKHIJANI: Yes. There was a place where --

(Simultaneous speaking.)

DR. NETON: Blockson? Blockson became an SEC, because the radon model wasn't sufficient. But I think AWEs are good examples though. Bethlehem Steel, even though it's an SEC, it still has dose reconstructions done for uranium that is the same dose for every single person, every single claimant.

MEMBER BEACH: I guess my point is if this is important it's going to be challenging, obviously. We've been struggling with it for a couple of years.

DR. NETON: Yes.

DR. MAKHIJANI: Yes. But Bethlehem Steel and Mound, I guess, were a couple of different examples. Bethlehem Steel, there was no way to identify who was in that rolling mill, right? Wasn't that --

DR. NETON: Well, correct. But you can make the same argument for, again, to go back to Savannah River. I've got 15 people that

worked on a neptunium encapsulation project. If I can't identify it, then can I reasonably identify who was in that area? Now, I don't want to get into specifics on issues with badges and access and entry. But that's what we're trying to do here.

And my opinion is if you can demonstrate with some confidence that you can bound the work, you know which workers were in those areas, then, yeah, you could say I want to apply to these workers that had access to this building during this year. And I think that's okay.

DR. MAKHIJANI: Well, then you deal with a lot of other issues that go away too in terms of comparison.

DR. NETON: Yeah.

DR. MAKHIJANI: Because if your universe of worker is fairly uniform, then a lot of issues go away.

CHAIRMAN MELIUS: But we've also talked about sort of a nightmare issue of what happens if -- do we get to the point where we do an SEC for an individual worker? Because that individual worker, he just doesn't fit whatever models we have and is somewhat, you know -- and we don't have adequate data. And you're not going to identify that worker until you get to the point of doing the individual dose reconstruction.

And that's a tough issue. Because, again, that was one site where I had mentioned, and I think Stu and Jim ran out of the room --

(Simultaneous speaking.)

DR. NETON: Let's think about how we actually behaved in situations like this. Thorium has been sort of the poster child for adding SECs, right because it's almost impossible to monitor, at least on a personnel monitoring basis, with sufficient accuracy.

It's hard, but not impossible.

But very often, we've found instances where thorium was used on a fairly limited basis and made the entire site an SEC because we don't know who was in that area. And it's likely that a small fraction of the workforce was exposed to thorium. So that precedent has sort of been set.

DR. MAKHIJANI: Yeah. I think between thorium and Bethlehem Steel you have a fairly clear precedent that if you really can't identify you've got to do the whole site.

Now, between that and, say, in Mound you actually had, you know, the tritides. Didn't you initially start out with the idea that there was a specific group of people, and then it turned out that it was very fuzzy at the edges?

MEMBER BEACH: Yes.

DR. MAKHIJANI: And it became more

difficult. I wasn't too involved but that's sort of my vague memory.

DR. NETON: Actually, in Mound we ended up reconstructing, because we had the --

MEMBER BEACH: They got it for radon.

DR. NETON: Right. The Mound was tritides were reconstructable because we had a lot of smear data and surface contamination measurements that allowed us to bound it.

CHAIRMAN MELIUS: But I think why this document is important, why I wanted it first, is that I think what we learned from thorium was that it wasn't as easy as saying, well, just every thorium site should be an SEC.

DR. NETON: That's true.

CHAIRMAN MELIUS: We found ones where we can do dose reconstruction. And there's also issues of, well, how much exposure was there even, you know, at the extreme of given

what's happening at that site.

So I think it's more been determined by the facility, you know, all the individual factors. And I think if we can achieve, through this kind of a document, eventually get to the point where we have sort of a process that's consistent and at least will identify where coworker models make sense to do, when shouldn't we even try, or how do we then set up those coworker models, or for what group.

MEMBER ZIEMER: Dr. Melius?

CHAIRMAN MELIUS: Yes, Paul, go ahead.

MEMBER ZIEMER: Yeah. I just wanted to raise sort of a general question at this point, because we're getting into a lot of specifics here that are site-oriented.

But it seems to me that, and let me ask the question, isn't this document intended not to be very prescriptive, but more almost

philosophical on what issues have to be considered? And then for each site you would have to answer the question, have you met sort of the broad-brush criteria? I mean, how much specificity?

I'll ask Jim Neton first. Because in terms of reading this document, it seems to me it's currently fairly broad, and maybe that's the way it should be. There are a lot of details built into each given site, into each of the sentences. But it doesn't seem to me you'd want the specificity in this document that would cover all cases.

DR. NETON: Well, you're right, Dr. Ziemer. I intended this to be fairly general, you know.

MEMBER ZIEMER: Yeah, that was my point. And a lot of the questions we raise very specific to certain situations and sites, which you would have to answer on an individual basis,

but you certainly can't cover it in that kind of detail in this sort of document.

DR. NETON: But at the same time, I guess, I kind of feel that, given what we've learned from the past, we might be able to incorporate some guidance in here that is helpful.

For example, we just talked about the thorium and why haven't all sites gone SEC just because thorium was there. And the thought occurred to me is it has to do with the extent of the spread of contamination, or the possible extent of the spread.

So, you know, one could put in here a little bit of verbiage about, you know, how widespread -- these are not going to nail it down specifically, but --

CHAIRMAN MELIUS: I just want to make -- Paul, I'm just trying to make sure we have all -- I won't say all -- most of the factors

that need to be considered included in here. They don't need to cover the specifics for every site, but that all these factors that need to be considered in deciding to do and then developing a coworker model get included. And so we --

MEMBER ZIEMER: Well, I understand that, Jim. For example, let's just take a sentence that says you have to have adequate calibration methods. Well, add to that a paragraph of the kinds of things that have to be considered. I mean, there all kinds of issues around each of these. So how much specificity are we talking about?

CHAIRMAN MELIUS: Well, I think we need to, you know, as we go through this, point out where we think more specificity would be helpful. And I would agree with you on calibration. We don't want to have this have, you know, a 200-page textbook on all the

calibration methods that are out there.

MEMBER ZIEMER: Yeah, or a checklist or something like that.

CHAIRMAN MELIUS: And I'm probably underestimating the number of pages.

(Laughter.)

CHAIRMAN MELIUS: So I agree with that. I think there are other areas where we've -- part of the problem we have when we're wrestling with these coworker issues is that we haven't had assurances that we're seeing all the same information that's important, that we're not missing something.

MEMBER ZIEMER: Right. If we can identify what the issues that have to be grappled with and maybe whatever level they have to go on it. But, yeah, I was just concerned that we're starting to discuss specific sites and getting way down into the weeds here.

CHAIRMAN MELIUS: Yeah. Well, I

don't think we're trying to settle any specific sites. I think it's only --

MEMBER ZIEMER: Yeah, I know we're not trying to settle them. I got the idea you were trying to get that much detail into the document. It's got to be somewhere above that.

If we can identify, for example, the thorium issue, as Jim suggested, probably needs to be addressed in some way, in a broad way, to make sure that it's handled always and consistently. And same with other issues of that type.

DR. NETON: I was just wondering if maybe this is the spot that an appendix to the Implementation Guide that had sort of some checklist points in it. You know, not fleshed out in detail but, you know, each sentence -- not each sentence -- but any sentence where it seemed warranted, one would sort of say such as, you know, items to be considered, et cetera, you

know, just four or five things, just to give it a little more guidance there but not getting into the specifics of it.

But say, you know, you should also -- some of these sentences do beg for some expansion maybe just to give some examples of what the sentence is referring to. I've done that a little bit in here, but I haven't gone, certainly, extensively into it.

CHAIRMAN MELIUS: And I would just, you know, do something simple like adding paragraph numbers or something. So, you know, you have 2.1, but it would be 2.11 and 2.12. And label each of these paragraphs so that --

MEMBER ZIEMER: Yeah, I think that would be a good way to do it. Either that or have an appendix where you expand it appropriately for each item. For example, if you had some calibration specifics that need to be considered across the board, you embed that

in an addendum or something like that.

CHAIRMAN MELIUS: Or refer to other existing documents, there may be existing documents.

MEMBER ZIEMER: Or existing documents, right.

CHAIRMAN MELIUS: Okay.

MR. BARTON: Yeah. This is Bob. I think it's going to be very difficult to be prescriptive when it comes to all these different sites. I mean, that's why they have these meetings. That's why we have Site Profiles, because you're going to encounter different issues depending on what's happening where.

But also, I guess in the general sense, I'd like to reply, Jim, to your comment about you sort of gave the example of where you have a site with thousands of workers. But, you know, maybe you only have 15 workers who are

working with a specific exotic radionuclide.

So, really, your exposure potential's pretty much restricted to that small group. But I think in the context of this program, I think that a really high bar has to be set to actually exclude them and say you couldn't have been exposed.

Now, at certain sites that's, you know, evident, if you have access registers where they simply couldn't have entered the facility. That would be a very powerful piece of evidence. And it's going to vary from site to site. But I just wanted to make that comment that I think a very high bar has to be set if you're going to unequivocally state that they weren't exposed and that's why we're not going to be applying a given coworker intake.

DR. NETON: I agree. And we oftentimes run into a situation where we know exactly who worked with the material. These 12

people were on this list. But then you always run into a situation where, well, what about the maintenance folks who were in there, and the janitorial type staff or, you know, cleanup people? You know, clearly you had to decommission that at some point, so how do you deal with those people?

And that's when we -- well, I won't say it falls apart, but it's harder to justify then that only these 12 people trying to get assigned to that.

MEMBER BEACH: It definitely falters at that point.

DR. NETON: On the other side of the coin, though, to get back into the coworker model arena, you know, you have only 15 workers who were potentially exposed, and they were the ones working with the material full time. You know, is that model applicable then to these few other workers who came in on sort of a

miscellaneous basis? I mean, that's another question.

CHAIRMAN MELIUS: And is there another model for them? That's, I think -- you know, in some ways, for efficiency purposes, we've tended to try to keep this, you know, simple. And I understand that. But, you know, if we know there's these 12 workers, you know, and they have a certain range of exposures or whatever --

MEMBER BEACH: But doesn't that triangle effect that we were dealing with, I think, with GSI, where a certain percentage got this, and the next level got a certain point and then the lower -- we've done that. Would something like that apply here or in a coworker model situation?

DR. NETON: Well, yeah, but you have to define who falls into each of those three groups.

MEMBER BEACH: Right, I realize that.

DR. NETON: That's the difficult part.

MEMBER BEACH: It's complicated.

MR. STIVER: And these tiered models are always difficult to use, to classify people by exposure potential of a job type.

DR. NETON: My only answer to that is that I feel we've been extremely claimant-favorable in those regards. But that's also subject to interpretation.

MEMBER ROESSLER: I think the danger in all of this, or the downside, is that we could be severely overestimating doses for a lot of people. And that's not a realistic or representative thing. I think that we have to keep that in mind as well as not accounting for exposures that people get.

DR. NETON: We always have to keep

in mind, it's easy to think about who was exposed and what their exposures were, but you also have to keep -- I think it's in here somewhere, I hope it is -- that you're reconstructing doses of people who weren't monitored.

And to the extent that you can define why they weren't monitored and show their exposure potentials were either limited or non-existent, then it's a different ballgame.

You know, the way it's sort of a priori right now is we're assuming that anybody that's unmonitored, unless it can be proven otherwise, had a pretty high potential for exposure. I mean, that's the way we've been working it. And I'm not sure that's the right way to go. I mean, that's the way we've been doing it. Because there are many cases where people weren't monitored for very good reasons. And it's a hard thing to demonstrate though.

I think that'll come up later.

We're getting maybe a little bit off the subject of this one paragraph. I think that the next paragraph, I think, is going to be the subject of a little bit of discussion.

This talks about -- I tried to put in something about the minimum number of samples required to be available for a model -- actually, one interval of the model. Like if you have one year, one quarter. And this was in RPRT-55. So it's nothing new. But it seemed to me that you need to specify some minimum. And here we put 30 in here. And that, in the context of 30, would mean 30 individuals with monitoring data, not 30 samples. Because that's another issue we need to talk about it: is this individuals or individual samples?

But in the way we're thinking to run this, it will be 30 individuals. But that's flexible too, because if you have the universe of all monitored people is 15, then it is what

it is. But if you had a large cadre of workers that was much more than 30, and you had a minimum of 30 that were somewhat representative, I think that seemed to be a fairly decent number.

Although the dose reconstructor or person developing the model would certainly have some leeway, you know, to deal with special situations. That's what I had in mind here.

MR. BARTON: And just to add on to that, because you actually do say it later in your paper, I'm not sure what exact page it is, but you mention the fact that, you know, when we're looking at a time interval, you can't just consider the number of samples you have in the time interval. You have to consider what campaigns were going on, you have to consider the air sampling to make sure that, when you choose an exposure regime -- I guess, you know, that's term we could sort of use for it -- that those people who are included that period,

normally we say it's a year, but in fact it may not be a year.

DR. NETON: Yeah, yeah.

MR. BARTON: You might want to get the campaigns and whether there was a change in exposure potential. Say they started a campaign in July, it ran through June of the next year, it really might not be appropriate to average each of those individual years but rather look at the campaign interval. So while I see what you're saying there --

DR. NETON: That's why we like the OPOS. But that's a different story.

(Laughter.)

DR. NETON: Sorry.

MR. BARTON: But I was just saying, when you choose a time interval, I think it's important not just to look at the number of samples you have in a given interval but --

DR. NETON: Yeah, and I was just

saying that certainly a coworker model with five samples doesn't seem to me to be a very valid coworker model, unless there were only five people that worked with that material and that was all there was.

But 30 seems to be a good number. I know there's been some discussion on this in the past, about where it comes from and, you know, the central theory and all that.

But, you know, anyway, I feel it's appropriate at least to have some minimum number in there. But it's not a hard and fast rule. That may be not one of our major points of contention after all.

CHAIRMAN MELIUS: I would just sort of expand a little bit on what Bob was saying a little bit, I think what is important, probably more important, is it's not the number but sort of the circumstances at the site and, you know, looking at both what happened at the

site, what were the nature of the exposures, what's the range within that group of workers? You know, was there something else going on? Or can you differentiate in some way among those that might make a difference in terms of your coworker model?

And then the other side of it is what gaps are you trying to -- how big are the gaps you're trying to fill?

DR. NETON: Right.

CHAIRMAN MELIUS: And there may be times when, you know, having ten people and you know the process was very stable, didn't change over time, and you have ten people monitored for a number of years, that may be adequate for a large group.

And you look at the history of that particular area or whatever, that that's been relatively stable throughout the time that it was monitored and the monitoring was

appropriate.

So I think getting people to look at that and sort of getting that into the decision process is as important as the 30. Yeah, you're not going to do it with three samples or five or whatever if it's a huge number and, you know, a fair amount of variability.

DR. NETON: This really comes into play usually when we have what we would call exotic radionuclides, and, you know, small amounts of workers dealing with curium, californium, something like that.

But I agree. And the final sense of this one I think is -- I don't know if it needs to be expanded on -- but, in my mind, it's extremely important. It speaks to like the validation effort.

If you've got an electronic database on the site or some summary records, and you're using that to develop your model, it should be

reviewed against some representative sampling of the original data to demonstrate that the pedigree is okay, that you've got -- that's sometimes harder to do than others. But to the extent one can do that, you know, we've gone to the point where at some point you have summary data and you get the original log sheets that say, well, there's 1,500 samples that the lab said they processed in this month in >53. And lo and behold, you've got about that number in your bioassay records. And it gives you a good, comfortable feeling that you're not dealing with something that's just totally, you know, out of joint.

So I don't think there's going to be too much argument. To the extent, I guess, that we do this, is subject --

CHAIRMAN MELIUS: Is subject to a great deal of argument. Unfortunately, because it can be very cost --

DR. NETON: It can be very cost prohibitive. I mean, because we've been there. I could think of various sites where, at Rocky Flats, we were just comparing the data sheets and some values. The representative sampling seemed to be okay. I certainly don't think we have to go and do them all. I mean, that's not --

MEMBER BEACH: No, a sampling set or something.

DR. NETON: Yeah, a subset and just look at, just to give yourself a comfortable feeling that the dataset you have is complete, that it represents something.

And even if it's not 100 percent complete, it's not missing data that would bias your model, you know, one direction or the other. Or all the incident samples are in a drawer somewhere, you know, that kind of thing.

CHAIRMAN MELIUS: Yeah. I would

say either in this document, or in maybe another document, you may want to sort of do a procedure for that or something that would -- anything that would, you know, capture a lot of the same things that we've talked about in this section already.

But I think one of the problems we have is that we tend to do an inadequate job. And then we argue as to whether that inadequate, that limited -- say we do a very limited job, a quick look. It looks okay. Then we argue about, well, is that representative? And we didn't put a lot of thought into the original one, because it's a sample of convenience.

DR. NETON: Right.

CHAIRMAN MELIUS: And then we try to figure it out. And meanwhile, we often have complaints from the workers that, you know, their data's missing, or whatever, something was missed or whatever.

And I think having some better, agreed upon process for that would be very helpful and would avoid a lot of problems for the rest of us, except for Stu who has to come up with a budget to --

MR. HINNEFELD: Well, I don't have any trouble coming up with a budget. They tell me what it is.

(Laughter.)

MR. HINNEFELD: Then we just work until we're out of money.

MR. STIVER: I'd say that historically it’s kind of been driven by, you know, by the economics, really, but also the criteria for an SEC determination was a little bit, at least historically, has been a little more stringent.

And so we haven't done, at least from SC&A's perspective, we haven't done the really in-depth data adequacy and completeness

analyses for each Site Profile review that we've done. And so this can come back at a later date when an SEC Petition is filed. And then we have to go back and say why didn't you do this, and that and so forth.

DR. NETON: My recollection is they're all very thorough.

(Laughter.)

DR. NETON: You know, we're talking about a lot of things. I'm hoping other folks can help me take down some minutes. Because it's not possible for me to think, and write and talk at the same time.

(Simultaneous speaking.)

CHAIRMAN MELIUS: Well, we'll have the transcript.

DR. NETON: I agree, the transcript is the gold standard. But I have a feeling that time is of the essence with this stuff.

MR. BARTON: If I could comment,

this last sort of concept we were talking about, that might be one place where we could get a bit more prescriptive. Because what we would be talking about, essentially, is you have an electronic database of some sort. And then you have records, a sample of records where you can compare it against what would be an acceptable, I guess you'd call it an error rate, or what is an acceptable percentage of missing records that would obviate or would not obviate a certain coworker model?

And then you also mentioned, and I think it's very important, missing records that we do uncover, what effect would they actually have on a coworker model? As was mentioned, you know, if you're missing all the incident samples that could be a major problem, whereas the actual percentage of missing records might not even matter anymore because you could be just missing the sort of upper percentiles.

So I think, you know, maybe a literature review of some sort, we could actually sort of get a more prescriptive approach that would apply across all these different sites.

Because, again, we're just comparing sort of an electronic database forming the basis of the coworker model versus whatever available hard copy records we have.

DR. NETON: Well, that's the problem, though. The hard copy records that are available are not uniform. I mean, you can't predict. So in some cases, we have numbers of samples taken by months, some places we have actual laboratory notebooks.

So it depends. And I guess, you know, can you not build a the coworker model, then, if you don't have the gold standard to compare your dataset against?

CHAIRMAN MELIUS: Yeah. But I

think there'd be a way of looking at that that's not so intensive or extensive that it would -- I think the hardest one is the incident issue.

Because, again, that's one where you usually have, you know, people claiming there were incidents, and not being able to find the monitoring records and lots of reasons for that, both good and bad. And so we need to -- but for sort of routine sampling, you're right, they're not uniform.

And it's not just, you know, taking a random sample of 30 out of, you know, 20,000 or whatever. It's something, you know, more by year and making sure certain areas are covered and so forth. But that's all, you know, pretty straightforward statistics to do. And I think it could be done. Famous last words.

DR. NETON: I guess we all agree that some more guidance is required here. Whether it goes into this document or into a separate one,

you know, I don't know if it should fall under a checklist or -- probably not a checklist. This would be more of a philosophical, we do you really need to prove completeness.

DR. MAKHIJANI: Well, the incident thing is very difficult. Because, you know, as Jim was saying, workers claim they were in incident, especially like construction workers who weren't there all the time and may not have had the same level of health physics coverage because they might have been feeling they're in clean areas, but they were not.

That, I think -- I mean, we have dealt with situations where we were able to show that there were adequate incident records. I can't remember where we did that, a site where we did a detailed investigation. But at Savannah River, it's been a little bit more difficult because --

DR. NETON: I think you're talking

about something slightly different. I'm talking about if there are incident samples in your original log books, they better show up there in the summary data.

DR. MAKHIJANI: Oh, I see.

DR. NETON: Whether they had properly quantified or evaluated incidents, I think is another issue we're going to talk about, probably in this next item.

DR. MAKHIJANI: Okay, fine.

CHAIRMAN MELIUS: Can I just interrupt a second, just thinking procedurally. And it actually goes back to Jim's comment.

In terms of going forward, maybe one way of thinking about this is that we set -- I'll let you to think about this and maybe we'll come back and talk about it more later.

But we sort of set a time limit and say, within the next two or three weeks or something like that, is that we give comments to Jim.

(Laughter.)

DR. NETON: I was going to say, there goes my vacation.

CHAIRMAN MELIUS: You've got a reprieve, you can relax on the beach and be fine. And if SC&A has something more they want to elaborate on that wasn't in your report, they have more time. And then we get that to Jim.

And then we do a revision after that. Because that I think deals with some of the capture, it also gives, you know, thoughts you have on the plane on the way back, I wish I had said whatever, brought up this or that and re-look at it. And, again, not that this won't be reviewed again or whatever. But I think that may be helpful.

And I also want to have everybody sort of scribbling notes, if there are things that they think of now, to write them down now and so we can get back to Jim. Maybe it's a

simple email, maybe it's something in an edited the document, but whatever works best for you.

DR. NETON: That'd be great.

CHAIRMAN MELIUS: And now that we know when Jim's vacation is, shall we say three weeks? Or what was your --

DR. NETON: Well, I think, you know, the next few weeks are going to be difficult for me because I've got some vacation scheduled.

Three weeks is fine. If you get me these things in three weeks, I can digest them and try to incorporate them, you know, give you some time to do that. And that's what I'm looking for, some valuable feedback.

CHAIRMAN MELIUS: John, Bob, Arjun?

DR. MAKHIJANI: Bob, does that mean -- we've sent you something.

(Simultaneous speaking.)

CHAIRMAN MELIUS: I'm just saying, something beyond --

MR. BARTON: As a result of this meeting.

CHAIRMAN MELIUS: Yes. As a result of this meeting, you have additional --

DR. MAKHIJANI: So basically elaborating on, you know --

DR. NETON: Anything that's either changed or is added based on you feedback. Because you did provide some feedback.

MEMBER BEACH: For me, not to move that part too far, the minimum 30 samples, I'd be interested to hear a little bit more about that maybe. Because we didn't really -- I think you expected more comments on it.

DR. NETON: Well, only because we got comments the last time we talked about this.

MEMBER BEACH: So I'd want to make sure we --

DR. NETON: You know, what's the statistical basis for it, why is it valid. And

there really is no real --

MR. STIVER: To me, it'd be kind of retreading a little bit of this. I know in RPRT-53 we talked quite a bit about the minimum numbers of samples required from the statistical standpoint.

MEMBER BEACH: I know we had but --

MR. STIVER: And there's always going to be some objectivity or subjectivity involved in looking at what whatever group you have, whether it's truly adequate for this particular group.

DR. NETON: The bottom line is there's no really good, hard and fast statistical analysis that one can do to say that 30 is appropriate.

DR. MAKHIJANI: That's true.

DR. NETON: Because there's a lot of things pointing to that that maybe it's okay, but that you really can't justify it based on a

purely statistical -- especially when you're doing something like this where you have, you know, the 50 year old data and, you know, what are the exposure potentials to begin with, and who was monitored and how many people were exposed? I mean, it's a lot of different things come into it.

MR. STIVER: It's not like a traditional approach where you can go out there and decide how much more data you need to collect. And you only have so much to begin with --

MEMBER BEACH: Yes, sure. I understand that. I just --

CHAIRMAN MELIUS: I think we had a good discussion on that at that in-person meeting in Cincinnati.

DR. MAKHIJANI: What you're saying is that 30 may not be enough. But certainly you need at least 30. It could be more than that.

DR. NETON: Oh, yeah. Thirty is minimum.

DR. MAKHIJANI: Harry, am I remembering right, in a few of the examples that we did, that we showed that 30 was not enough in some cases and 30 was enough in other cases?

DR. CHMELYNSKI: Yeah, that's right, Arjun. When the GSDs sort of came up around four or five or higher even 30 may not be worth looking at.

DR. NETON: Right. Yeah, we agree, it's on a case-by-case basis. I just wanted to put something down here to say, you know, I don't want someone going through doing a coworker model and they have 15 samples per year and say, oh, here's your coworker model. No, let's talk about is that reasonable?

CHAIRMAN MELIUS: And what we eventually put in, let's also be aware that there are other situations where 30 is not adequate

either.

DR. NETON: There are a lot of caveats.

CHAIRMAN MELIUS: Yeah.

DR. MAKHIJANI: It would be helpful, Jim, if there were a couple of examples in this document that didn't kind of say, okay, here's a number or here's a bright line but --

DR. NETON: Examples of this --

DR. MAKHIJANI: Like this particular issue, or maybe in other cases also. But in this particular case, we actually have some work that was done that showed the kind of consideration that went into figuring out --

DR. NETON: I hadn't thought about putting examples in, but it's worth considering.

CHAIRMAN MELIUS: Well, we have a -- speaking of examples, I think there's -- and I haven't seen any of this, so I don't know, but there's an SRS review that is underway right now

that we were hoping to be ready for this meeting. It wasn't, and, you know, the SRS Group has referred to us to review. Very nice of them.

(Laughter.)

CHAIRMAN MELIUS: They didn't tell us, but that's okay. So maybe that will be one we can think about as going through and think about how this would apply there and so forth.

Now, I don't think we're expecting all the documentation to be in the original report and so forth. But it would address all of what we might have talked about here or will talk about.

But it will be a way of going through and sort of seeing are we missing something or are we not being appropriate or whatever.

DR. MAKHIJANI: Jim, are you thinking of the RPRT-55 review, the trivalent actinides?

DR. NETON: No. That was done, I

thought.

DR. MAKHIJANI: No, the thorium one was --

MR. BARTON: There was some overlap because they use the same data.

DR. NETON: Yeah, that's what I was thinking.

MR. BARTON: As far as examples go, I think we can actually sort of generalize it a little bit. Your example of where, you know, maybe it's okay to have less than 30, the example of where you only have a handful of workers who are actually handling material.

In that case, you're not going to get more than 30, because there just simply weren't that many workers there. That's an instance where 30, you'll actually have to get to that, I guess, what we call a threshold.

And then, as Harry just mentioned, there are situations where just analyzing the

data, the geometric standard deviation or variance are such that 30 really becomes no longer sufficient as that sort of baseline number.

But I understand why 30's in here, because you have to start somewhere. But I think those are the two generic examples where having less than 30 is okay. And there might be situations where having 30 is just not sufficient.

DR. NETON: Yeah, I agree with that.

MEMBER ZIEMER: This is Ziemer. Can I add a comment?

CHAIRMAN MELIUS: Yes, certainly. Anytime, Paul.

MEMBER ZIEMER: Thanks. And I agree with Bob. I think what happens, and 30 is a good example of this, it’s where the burden of proof changes. If you’re below 30, someone has got to make a case for why that's okay.

Once you pass that point, someone has to make a case for why that isn't okay. It depend on who's crossed that line, in a sense. But I think that that's what the previous speaker was -- I didn't know who was saying that, but that's basically it. It changes the burden of proof, is what happens when you cross the bright line.

CHAIRMAN MELIUS: Now that I've got my dig in at SC&A about their report wasn't done, I'll give another example we might be looking at is INL, where the internal exposure coworker model seems to be in limbo as of your updated report for this meeting.

DR. NETON: Yes. Well, that --

CHAIRMAN MELIUS: And, again, I'm just saying it's something we can -- it might be something we want to look at as an example of these kinds of issues and so forth that would be -- if the timing is appropriate.

DR. NETON: No, I agree.

CHAIRMAN MELIUS: Yeah.

DR. NETON: Part of the issue with the INL, of course, is that we're sort of waiting on a resolution --

(Simultaneous speaking.)

DR. NETON: I get routinely asked, well, how should I do the analysis? And I say, well, maybe after Monday I'll let you know. Maybe that's not going to happen.

CHAIRMAN MELIUS: Since everyone's to blame, we can bring it all back and everyone can share with -- or if there's parts of that that are in process that may be good to talk about, that would be helpful.

Again, I don't know the details. Again, it's as much to assure us that we're not missing something that you or your, you know, staff or ORAU staff are finding problematic or whatever.

DR. NETON: That's a good point.

MR. BARTON: Well, with regards to the SC&A report that is currently late, really there were some findings that were related to that and also the thorium, since they pretty much use the same database. And one of the findings we had in both reports, essentially, was there were periods where years were grouped together.

And it appeared that maybe one of these in there, and I think there was text to that effect, was that, you know, we wanted to reach a certain threshold so that we could do some comparative studies.

And, you know, so we came back and said, well, there's that and, you know, that sounds okay, but you really have to do that analysis of when you start pushing these different periods together. Are we actually comparing a period of different exposure potential, but we're building together an

averaging them and that information's being lost?

And, Jim, I don't want to steal your thunder, because you do describe how you should be able to go in and look at the operational data and production data, air sampling, even some, you know, claimant interviews and such, where they say, you know, this really sort of nasty campaign started at such and such time.

And then that's maybe when you want to go back and look specifically at some periods of time to see if it's, one, appropriate to combine multiple time intervals.

So I guess that's what I'd say as far as the trivalent, and thorium issue and this notion of is 30 workers going to be enough.

And I think that the case has to be made when it's not, and that perhaps you have to combine certain years. The case has to be made that conditions were sufficiently similar to

allow that combination.

DR. NETON: I have no disagreement with that. I mean --

CHAIRMAN MELIUS: And again, I think that is a good example and would be, I could see, put into this document as for example.

DR. NETON: Yes.

CHAIRMAN MELIUS: That and just a sentence or two that would be helpful and I think would not be an uncommon situation.

DR. NETON: Agreed. Okay, I think we've covered data adequacy 2.1. Now we can get into some more -- less controversial issues, just kidding.

(Laughter.)

DR. NETON: The second, 2.2, deals with the application --

(Simultaneous speaking.)

DR. NETON: But, yes, the first one was thought, okay, can you build a model. And,

you know, what do you need to have to move forward. And now that you have a model, how do you do it?

And, you know, in here is some very familiar language that you've heard probably more than you care to about how we feel about who was monitored.

We've outlined the three types, we believe, of monitoring programs, that they were either routine which was a representative sampling of the workers, or there were routine measurements of workers with the highest exposure potential or there were collections of samples after identification of the incident.

Of course, the incident samples could permeate both one and two. Because you're always going to have incidents in the midst of a routine sampling program. We recognize that.

The one that's not on here that oftentimes, you know, I sort of get the feeling

that people are implying is that the workers with the least potential, or the lowest potential for exposure, were monitored.

And I've never really believed that to be true. You know, I know the argument about the NTS workers is raised as sort of representative of that. But that was added as an SEC because it was primarily an incident-driven sampling program.

So, you know, that's the case where it would fall into Category Number 3. And we can talk a little bit more about what our thoughts are on incident sampling programs. But I think that was, correct me, was misidentified as a Category Number 2.

DR. MAKHIJANI: I think that was --

(Simultaneous speaking.)

DR. NETON: I think that was the issue that I, as I recall, but anyway, it wasn't considered.

DR. MAKHIJANI: I just want to set the record straight a little bit. I don't believe we ever said that workers with the lowest exposure potential were monitored. And I don't believe, it's a long time ago, but I don't believe we ever said that at Nevada Test Site.

I think what happened there, and maybe it would be exemplary for what we're trying to untangle here, is there was a claim that the most exposed workers were monitored. And here's 100 of them, and we know what the external and internal were. So there's a kind of procedure that was developed.

And leaving aside that internal/external turned out to be not very well correlated, or at least a correlation couldn't be established went to the question, well, you know, were the most exposed people monitored or were the monitored people representative of the most exposed, even if some sub would do that.

And I think what happened is that we were able to show that some of the people who were, some groups of workers had potential for higher exposure based on some of their monitoring data, which was pretty sparse. Then the groups were mostly monitored.

So we weren't saying, I don't think, and I don't think we've ever said that at any site, although I have not been involved in many of the sites that the lowest exposed workers were monitored, I think what we've often challenged is the assertion that the most exposed workers were monitored or that the monitored workers were representative of the highest exposure.

DR. NETON: Well, so here --

DR. MAKHIJANI: That's a very difficult thing to prove. And it's been sort of a point of debate.

DR. NETON: Well, here you have, and Dr. Melius just pointed it out, then you get in

a situation is it a Category 2 monitored workforce or Category 3?

Category 2 is workers with the highest potential. Category 3 is an incident-based sampling program. It turns out Savannah River, I mean, NTS was a combination.

You know, the rad techs seemed to be on a routine monitoring program, because they were all over the place. They wanted to know what they were exposed to so they monitored them fairly frequently.

The workers, and I have to say, NTS is a somewhat different beast because of the way things were run there, but the workers were incident-based, based on the shots and, you know, did they feel?

So there you have two groups of workers that I think were under two different monitoring programs. And I think I've seen that correctly, you know, identified that issue. We

eventually agreed that, you know, we had it miscategorized.

That doesn't invalidate anything we're saying here though. What I'm saying here is true, that they're going to fall into one of these three categories. And sometimes you're going to have a mixed bag which, I guess, is what I would agree happened in that Nevada Test Site.

CHAIRMAN MELIUS: And I think the issue of is there a fourth one, only lowest exposure, I think, you've got covered on one. If it's representative sampling, it should be representative of high and low. I mean, that's --

MEMBER BEACH: Well, doesn't this kind of go back to the way they set their programs up too, I mean, individual sites?

CHAIRMAN MELIUS: Yes. And it changes over time.

MEMBER BEACH: It does change.

CHAIRMAN MELIUS: And it changes with new processes being brought in and it's new directives from above, et cetera, or hiring more health physicists and that kind of thing --

DR. NETON: It's fairly easy for sites that handle uranium, one radionuclide, a lot of monitoring, easy to measure. Sites that, as we know, handle multiple radionuclides that, the national laboratories are great examples of that, are very hard to convince yourself that they had any routine type monitoring program.

The question then is did they really need it? Then we have to get into that analysis. Because, just because they didn't have it doesn't mean it wasn't needed.

And, you know, we're going to talk a little about that. You know, what kind of other health physics indicators are there that can demonstrate and make one feel comfortable that the workers really weren't exposed.

Because I've always maintained, and I think it's not just me, but you don't use people as human air samplers. You set up your program so that they aren't exposed.

The routine program is really just there to convince yourselves that yeah, we did a good job making sure they weren't exposed or the exposures were kept as low as we thought they were, based on our administrative and engineering controls.

So, you know, these are not about using people as air samplers. We've got to keep that in mind. Because there are other things in place, other barriers.

CHAIRMAN MELIUS: But a control program is not, by itself, adequate for doing dose reconstruction. And I think, you know, and this sort of permeates the whole dose, all EEOICPA, is the sense that, you know, record keeping wasn't done in a way, and monitoring

wasn't done in a way necessarily that will allow you to go back and do dose reconstruction.

And to me that's how I've interpreted the national labs, because we just have so little data there that it's just not feasible to turn that data into a plausible model. Because diversity of exposures combined with the lack of monitoring data.

It does not mean they weren't necessarily protected. I agree that I think that applies to a lot the sites where we've done SECs, not just the national labs, but, you know.

I mean, look how many sites we've done because the personnel wasn't categorized and kept track of in a way that would lend itself to dose reconstruction.

And that's people who -- now, that's not necessarily a problem, I mean, we don't know, you know, we talked about the example earlier. So I think that's something that's sort of

separate from this.

I didn't think, to me the key thing on the type of sampling program, where we're having a problem with coworker models, is can you do a coworker model where you have one group that's under one kind of regimen and another under another type of sampling program.

And to me that's very, very difficult to do in a statistically adequate way. And I think that's what we're, you know, what we need to wrestle with.

DR. NETON: I think that's worth pursuing. The first, I'd just like to talk about one of your first comments about control programs not being sufficient for dose reconstruction.

I think that may be true in the older eras, you know, 60s, 50s, those where, you know, we really don't have a good program.

But in my opinion, in the modern era

where you have 10 CFR 835 where, you know, there's a requirement that people with less than 100, people who have more than 100 millirem potential for internal exposure need to be on a monitoring program.

That's pretty well evaluated, and the documentation is there and the controls, I think, are there and the demonstrations. I think, in those situations, you can.

But I would agree in the earlier days, and obviously NIOSH has agreed with that, many of the national laboratories just can't make the case.

CHAIRMAN MELIUS: Yes. And it's diversity of operations --

DR. NETON: Yes, right.

CHAIRMAN MELIUS: -- et cetera. But production facilities and situations are different.

DR. NETON: So, you know, in this

Section 2.2, we're talking about the routine monitoring program and how one should go about determining if it was actually a good routine monitoring program that could be used for a coworker model.

And I've highlighted here what must be evaluated to demonstrate that it was a good program with a representative of the exposed population, the workers with the highest exposure potential -- oh, sorry, I got ahead of myself here a little bit.

MR. BARTON: I think that was really SC&A's main comment about this section was that we agree, for a coworker model to be valid, we sort of have to fit it into one these two --

DR. NETON: Right.

MR. BARTON: -- categories. And we just want to make sure, maybe just a little word tweaking would take care of it, that it was never assumed, a priori, that that's the case. But

you have to sort of demonstrate it somehow.

DR. NETON: Yes, yes. I agree. And, you know, we've gone, lately it's been more of a standard mode of operation to go back and look at the procedures, and at Savannah River in particular, and say here're the sheets, the checklists that say who has to be on a monitoring program.

And then not only is that sufficient in itself, but you've got to go back and say did they really take those samples.

MR. BARTON: Yes, did they do it?

DR. NETON: And once you can make that case, then you're pretty far along saying I think we've got a fairly good situation.

All right. This is one of these paragraphs though I think that maybe some checklist-type items for filling out, it would benefit that.

Again, I like to keep the

implementation guide simple, mostly because I don't like to write 60-page documents. That's fine. No, I think you need to have an upper tier that is more general.

CHAIRMAN MELIUS: That's why you have staff and ORAU.

DR. NETON: You can proclaim what's important and then have the details fleshed out.

CHAIRMAN MELIUS: Yes, that's right.

(Laughter.)

DR. NETON: Okay. Now, this last one's going to be, I'm sure, subject to some discussion which is incident-based sampling. Can you use an incident-sampling program to do anything as far as coworkers?

MEMBER ROESSLER: Could we go back to Paragraph 2 there?

DR. NETON: Sure.

MEMBER ROESSLER: I think you have a

correction to make in the last sentence. Don't you have that backwards?

MR. BARTON: Yes, it does look like it is in backwards, but --

(Simultaneous speaking.)

DR. NETON: Representative samples or worker -- in these cases the assignment of coworker dose --

(Simultaneous speaking.)

DR. NETON: -- for distribution measured values --

(Simultaneous speaking.)

DR. NETON: Oh, yes.

MR. BARTON: Or representative, see that?

DR. NETON: Or representative, yes.

MEMBER ROESSLER: Okay. Just wanted to --

DR. NETON: It is backwards.

MEMBER ROESSLER: -- point it out to

you, okay.

DR. NETON: It must have been right around lunch time when I wrote this.

(Laughter.)

DR. NETON: Okay. Thank you for that comment. Now, this last paragraph, I'm not willing to agree that incident sampling programs in themselves are not useful to develop an inference as to what the unmonitored coworkers' exposure was.

And this may, and I know Dr. Melius' opinion on this, because he just said it, but if you have a program in place that has put controls in there, I mean, I'm talking about situations where there's glove boxes, there's alpha CAMs, there're smears taken daily and there's no evidence of upset conditions.

And then all of a sudden, so the workers aren't monitored for good reason, all of a sudden there's a clear indication of an

incident out there. Someone came out of an area where they got contaminated, the alpha CAM went, you know, that sort of thing. Then you have an incident sample.

So if you have a couple of incident samples on a worker, and you assume that those incident samples -- now this is where it is a bit of a stretch -- are representative of a chronic model, which is what our coworker models are, then you've bounded the exposure of those workers.

It can't be any higher than that for that worker. His chronic exposure could not be higher than the chronic exposure that put through the value of that first incident sample that may have happened three or four months into the monitoring period. So I think you can get some useful bounding information out of that.

DR. MAKHIJANI: Is that a way to bound something though?

DR. NETON: I mean, it is.

DR. MAKHIJANI: Because that incident, because the way you described your routine monitoring was a worker protection program, right?

DR. NETON: It was --

(Simultaneous speaking.)

DR. MAKHIJANI: -- equipment to make sure workers are not exposed.

DR. NETON: Right.

DR. MAKHIJANI: And then you do your monitoring to verify that your systems are working.

DR. NETON: Right.

DR. MAKHIJANI: So that's a situation in which you're not expecting to find anything.

(Simultaneous speaking.)

DR. MAKHIJANI: You actually have, well, most of the time you have to have results

--

DR. NETON: In the early years, we were allowed, it was not so --

DR. MAKHIJANI: That's true. In the early years they were allowed to be exposed quite a lot.

DR. NETON: Yes.

DR. MAKHIJANI: But I don't see how you can, because incidents, by their very nature, are not representative of anything normal and you have very high results.

And then you're necessarily going to get into situations where there, well, basically you're saying this kind of incident is occurring all the time which --

DR. NETON: No, no. I would say as a, a routine monitoring program, in my mind, would be in place when there was, there was a reasonable potential to generate airborne radioactive materials, for somewhere that has

processes going on that are either, you know, pushing things through an extrusion press and, you know, you could have a pop, or something like that or grinding on uranium surfaces.

That's when you have routine monitoring. But even though you've got engineering controls in the early days, people were, it was acceptable to have routine airborne in the area. We were just trying to make sure that it didn't exceed what you were expecting based on your controls.

But there are situations in Savannah River, I keep harping on that or hate to keep harping on that, is there are situations where their people are, a very confined process, extremely confined, you have no expectation that there's going to be anything.

But you have enough workplace indicators there to let you know when something does go off the B- not a normal situation.

And then, in that situation, you have a bioassay sample that can be used to bound the workers' exposure through the first six, eight months of the monitoring period. And he's no higher than that.

Because that incident sample is not only representative of his exposure during the incident, it's representative of his exposure during the first few months of the year, or whatever time period elapsed.

DR. MAKHIJANI: That second part, the representative --

DR. NETON: I mean it's bounding. It's plausibly bounding.

(Simultaneous speaking.)

DR. NETON: I'm open for discussion. That's the way I view it right now.

DR. MAKHIJANI: Yes, yes.

CHAIRMAN MELIUS: I think the threshold's going to be pretty high on that.

I'm not saying those situations don't exist, but I think it would be a situation where they come up with a plausible upper bound.

I can agree on the bounding would be an easier threshold to meet. But I think a plausible upper bound, I think, is going to be much harder, because it --

DR. NETON: Well, I think you'd be hard pressed to convince me that the unmonitored workers that were working in those same situations had a higher exposure than those guys who were incident samples.

CHAIRMAN MELIUS: But that's bounding. What I'm saying is plausible is a representative of, you know, is that sufficiently accurate to represent those workers?

And what it's going to do is it'll come down to what is the nature, the number of incidents, the documentation of the incidents,

the number of, you know, what levels were found and so forth.

And I think, I don't want to say it can't be done. But at the same time, I would be very skeptical of accepting it.

DR. NETON: I don't disagree that it's a high bar to prove. I mean, I think I've sort of said that in the last seconds here. You can demonstrate the effectiveness in the engineering controls, adequate to prevent exposure except during upset conditions. It may be possible to use incident-based.

CHAIRMAN MELIUS: I hate to close the door on it just because --

DR. MAKHIJANI: Actually, I am going to keep the door partially open, give you two examples that are completely different. They're different.

So if you have a situation like Ames where you know that you are having a lot of these

blow outs and that they happen fairly frequently, and we, of course, discuss this at some length around the 250 day issue.

You can make a case there that there were so many of these incidents that, if you could characterize the number, then you could say that this was some, almost a kind of a routine exposure, although you weren't looking for blow outs, they happen very often.

On the other hand, there was that incident with the pig at Savannah River, where there was a cobalt something, I can't remember exactly. It was, you know, it was clearly a very unique thing that happened once.

You can't take something like that and say I'm going to take this incident, I think it might even be an external, but I'm not quite sure.

But if you have something that's clearly unique, a red oil explosion, you know,

very rare, and say that that's going to give you some plausible upper bound. It'll give you a big number, but it won't be plausible. So I think you have some burden of proof about the plausibility of the condition.

DR. NETON: Yes.

DR. MAKHIJANI: Without saying that, you know, you can never do this. I don't think you can do it often.

DR. NETON: I don't disagree. It's a high bar to demonstrate. But --

CHAIRMAN MELIUS: I mean, if you want to try it, and you can get Stu to take it on --

DR. NETON: Well --

(Laughter.)

DR. NETON: See, in my opinion the reason that people weren't on a routine monitoring program is because they were pretty darn confident that there was a very, very low

potential for exposure. And if you can show that, you know, that it wasn't just negligence on their part, well I'm only going to --

CHAIRMAN MELIUS: Yes.

DR. NETON: The guys could have been exposed to quite a bit of material, but I'm only going to sample when I know that there was a problem.

I think, and most often, if you have a routine program in place, then you have an incident program in the same facility, there's a reason for that. And the reason is that it has been evaluated to be a very low potential situation. I mean, so you have to give some credit for that.

DR. MAKHIJANI: Why can't we find those Evaluation Reports? If we could find those, the job would --

DR. NETON: I think we have some at Savannah River. I think we do. I think there

are some. Yes.

MR. BARTON: Yes. I think that really feeds into the high bar of being able to establish a concept like this. Do the records we have actually cover the incidents that were at the site?

And was the monitoring that took place after those incidents adequate so that we are reasonably certain you captured all of these sort of acute intake scenarios?

And that would have to be part of sort of establishing also that the administrative controls would have detected any sort of off normal occurrence, and it was properly documented, and we have access to those documents.

CHAIRMAN MELIUS: In that case, why wouldn't we have some sort of a, you know, process-based whatever, coworker model-based ignoring the incidents and then adding the

incidents as individual exposures for those where it was documented? Because we're saying they'd be completely or close to completely documented and evaluated.

DR. NETON: Well, if the process-based analysis says there is no potential for exposure then I would agree.

CHAIRMAN MELIUS: Yes, yes, yes. There would be very little.

DR. NETON: I mean, that's what I'm saying. That's what I tried to say here. I said if you could demonstrate this thing is a locked tight situation, and I don't expect that there's any exposure here unless something really awry happened, and it would be easily noticeable, you know, and it wouldn't escape notice, because you're talking about plutonium, alpha CAM, you know, that kind of situation.

CHAIRMAN MELIUS: And I also think that we, you know, I think there's always going

to be individual situation and a variety of different approaches --

DR. NETON: Exactly.

CHAIRMAN MELIUS: -- that are going to be very specific to the site and the incident.

DR. NETON: Yes, exactly. And again, this is going to be more and more common as we approach the modern era, as we get past 10 CFR 835 implementation. Hopefully, our documents out there, they can say here's what we've done to demonstrate that the potentials are very small, and we don't need to monitor these workers.

CHAIRMAN MELIUS: Well, can I suggest break now, since it's been two and a half hours. And 2:30 I should say, an hour and half.

MEMBER ROESSLER: It has been a one and a half, but that's okay.

CHAIRMAN MELIUS: Huh?

(Simultaneous speaking.)

DR. NETON: It seems like two and a half hours.

(Laughter.)

CHAIRMAN MELIUS: According to my watch it's been, yes, 46 seconds over an hour and a half.

MR. KATZ: Ten minutes, what do you want?

CHAIRMAN MELIUS: Ten minutes.

MR. KATZ: Ten minute break. Is everyone on the line? And I'm just going to put the phone on mute so you don't have to hear jibber jabber.

(Whereupon, the above-entitled matter went off the record at 2:33 p.m. and resumed at 2:51 p.m.)

MR. KATZ: Okay, we're back. Let me just check and see. Paul, do we have you on the line?

(No audible response.)

MR. KATZ: Dr. Ziemer?

(No audible response.)

MR. KATZ: Maybe you're on mute?

MEMBER ZIEMER: Yes, I'm on the line.

MR. KATZ: Oh, great. All right. I don't know if we need to check on anyone else? John, do you need to check on anyone, your people?

MR. STIVER: No, we don't need to check.

MR. KATZ: Okay.

MR. STIVER: They're expected to be ready.

DR. NETON: They're expected to be. If they're not, when we look for them --

DR. MAURO: Well, I'm here, of course. You think I'm going to leave you alone --

(Laughter.)

CHAIRMAN MELIUS: Call the operator, cut off that line.

MR. KATZ: Okay. Let me just remind everyone that's on the line, Mr. Warren, if you could mute your phone, because we can all hear you. If you don't have a mute button, then you press *6. That'll mute your phone. Thank you.

CHAIRMAN MELIUS: Okay. Jim, go ahead.

DR. NETON: Okay. We're up to Section 2.3 which is titled Appropriateness of the Model Data for the Unmonitored Population.

In here we were just trying to get the point across that you need to look at the people that weren't monitored and make sure that it fits, you know, were the monitored workers and the unmonitored people really part and parcel of the same exposure group?

The idea here, of course, is you could have maintenance workers and such that are

doing very different tasks than the person who is running a lathe, you know, doing something else. So we need to be careful about that.

The converse of that is also true though if the unmonitored population had no potential for exposure then we don't really need to apply a coworker model at all. So I think it's important to look at both sides of the -- both sides of the fence.

Okay. And I think that's not too controversial. I'll move on to one section that is, Analysis of the Monitoring Data.

So, you know, this gets into the heart of the matter as to how we're going to construct the coworker model. You know, we've already, based on the first couple of sections, decided that the data reasonably represents the workers. And we want to figure out how to analyze the data.

And traditionally I have put down

what we've done. We can represent the data by a log normal distribution with a corresponding geometric mean and standard deviation to represent the distribution.

We talked about this last time, that workers who are considered to have been heavily exposed or potentially exposed, those who are working with materials where airborne radioactivity was possible, would receive the 95th percentile of the exposure distribution.

Those that were not would receive the full distribution which would be the geometric mean and standard deviation.

I put a note in here, because I know we've been asked multiple times, or several times at least, well, how do you know? And actually it came up in SC&A's review.

It was like, well, it would be nice if you could define who those heavily exposed workers are. And it's been my feeling that you

really can't. You'd have to do it on, as I say here, also on a case-by-case basis.

Because there are some workers who could be classified as clerks, who you might think would not be heavily exposed, but they were involved in, you know, inventorying of materials and stuff in radiation areas that had a lot of high potential for airborne.

So I don't know if one can really say with any confidence, develop a list that is, of these workers. I mean, in my mind, people such as the trades workers, pipe fitters, those type folks, electricians, welders who worked in radiological areas would fall into that category.

The other side of the spectrum, I would say someone who had a job title as a secretary, possibly not, administrative folks who didn't really frequent the controlled areas, this came up in the GSI discussion.

We'd have to be pretty certain, you know. I think the bar is pretty high to determine, you know, when it would be a 50th percentile versus a 95th percentile.

MR. STIVER: But, Jim, apparently it's kind of an ad hoc procedure that's left to the dose reconstructor to decide.

DR. NETON: Yes, yes. Pretty much so. I don't know if, you know, maybe we can develop some more general guidelines. But it's really difficult to say, you know, that these job categories are always going to be highly exposed and these aren't.

But, you know, you could have pipefitters that never worked in a radiological area, electricians the same way. I mean, if you can clearly see that in the record, and it came out in the CATI and such, then, you know, it'd be silly. It'd be inappropriate to assign them the 95th percentile.

MEMBER ROESSLER: If it's left to the dose reconstructor, and there're a lot of them, is there somebody then who overviews, well, they --

DR. NETON: Well, these are reviewed at several levels. I mean, you have the dose reconstructor, then there's the internal ORAU review, and then a NIOSH DCAS person, health physicist, that reviews every dose reconstruction before it goes out as well.

CHAIRMAN MELIUS: Yes. But this is at the Site Profile level we're talking about, not at the dose reconstruction level.

DR. NETON: No, no, this would be at the dose reconstruction level.

CHAIRMAN MELIUS: No, no, no, no. What I'm saying, we don't care about the dose reconstruction level here.

MEMBER BEACH: This is the overarching.

CHAIRMAN MELIUS: We want the overarching. And I think that's one of the problems we're having, when we talk about this, is we tend to convolute the individual dose reconstruction which has a separate set of considerations. They overlap and they're, in some ways, sometimes very similar.

This sort of Site Profile coworker issue, which has frankly a lot more statistical issues to deal with, now the Site Profile issues essentially guide the, well, parts of it guide both.

DR. NETON: Right, yes.

CHAIRMAN MELIUS: And then the Site Profile issues and coworkers would obviously guide the individual dose reconstruction.

And one of the things that I just think about in terms of organizationally is that we sort of, in this section analysis, that we sort of back up and then include, you know, but

you're going to examine, evaluate the monitoring data that's available.

You're going to look for, you know, are coworker models going to be needed, are they necessary? But also, are there stratification issues that need to be dealt with?

Because I think those are, you know, would come about, and we've talked about this already, from other considerations other than, you know, trying to come up with a unifying model. Are there multiple models that need to be looked at?

DR. NETON: Right.

CHAIRMAN MELIUS: Which you already do, based on exposure. Again, Savannah River being an example.

DR. NETON: Well, that's covered in Section 4, I mean, I think.

CHAIRMAN MELIUS: Well, yes. But I'm just saying does some consideration need to

come back or you're repeatedly going to be looking at the data. Then that's, well, shouldn't it be part of sort of initial decision making and consideration?

DR. NETON: Oh, I see. You're suggesting that we don't develop an all monitored workers model first, we actually start with pieces?

CHAIRMAN MELIUS: Well, no. You start with considering is an all monitored worker appropriate, going to be appropriate. Are there strata that are going to need to be considered? And then evaluate both, essentially. Because you really can't evaluate one without the other.

DR. NETON: No. Oh, I agree.

CHAIRMAN MELIUS: Because the reason you're not going to do a general model because there are strata that aren't appropriately captured through that.

And I also think it addresses this, you know, 50th, 95th, that's going to be secondary to, you know, some of your decision making on what's the appropriate model for which groups and so forth. I'm just thinking more procedurally. If I were the --

DR. NETON: Yes.

CHAIRMAN MELIUS: -- the Site Profile author, I would start, I would array all this data, I would look at what monitoring data is available, obviously try to break it down into some meaty chunks and then parts of the facility or areas of exposure and then look at this.

Because I think we're coming to stratification sort of late. And I think if it was done earlier, I think it would sort of capture some of the other considerations better. I don't know how other's feel on that --

DR. NETON: Yes.

CHAIRMAN MELIUS: -- this feeling

that, yes, because I think it, because it's not just a technical, statistical issue. It's an issue of sort of what's appropriate for that site and --

DR. NETON: Well, whether the data's stratified or not, this first paragraph is still valid. I mean --

CHAIRMAN MELIUS: No, no, I --

DR. NETON: -- distribution.

DR. MAKHIJANI: Well, I think what Jim is raising is, at that stage, you need to consider whether you're developing a distribution in a singular or whether you're developing in the plural.

So it seems if you decide, to develop a distribution you already made a lot of decisions underneath that.

DR. NETON: Well I tend to disagree. I think the development of the all coworker, all monitored worker distribution and the conscious

decisions we made to say you're going to get to 95th percentile or four distributions depending on your job type.

Then one can go and see are there any distributions out there that would make that not appropriate, for reasons that we could talk about later but, you know, is it more claimant-favorable to assign the 95th percentile, recognize that we really can't put many people in these job categories very well. You know, we don't know.

Or is it okay? Just to say all B - heavily exposed people get the 95th percentile. And, by default, the other ones get the 50th, I can't find any strata in there that give those people more dose than 95th percentile, because there's so much uncertainty.

And the other part of this issue is we could pretty much only do this kind of analysis at Savannah River. Let's be honest

about it.

What other facilities do we have the granularity of data to go and pull out all of these job categories and do these detailed analyses. In many cases, the coworker models are based on CEDR data. We don't know what these people did.

CHAIRMAN MELIUS: Then why are we doing them? That's --

DR. NETON: I'll bring in a table. Because I think that, as I showed, the 95th percentile is a fairly good claimant-favorable number to use when you look at it in terms of Probability of Causation analysis outcomes. There has to be a factor of two or greater almost increase in the median value for it to be more claimant-favorable to stratify.

CHAIRMAN MELIUS: But is it plausible?

DR. NETON: What do you mean, is it

plausible?

CHAIRMAN MELIUS: Sufficiently accurate, is it sufficiently accurate individual dose reconstruction being done?

DR. NETON: Well, again, these are the monitored workers. Now let's talk about is that bounding for the unmonitored workforce?

You're suggesting that if we don't know the job categories of all the workers that comprise the coworker model, then you can't do dose reconstructions for unmonitored workers. And essentially it becomes an SEC. In that situation then, the unmonitored workers are in the SEC, the monitored workers aren't.

CHAIRMAN MELIUS: Yes.

DR. NETON: And I find that to be, I don't know, disturbing's not the right word, but not appropriate, that people who have very low potential for exposure, or lower potential for exposure in general based on these models, based

on these monitored programs we talked about, most heavily exposed workers, representative workers, not incident-based, I find it hard to wrap my head around the fact that those people would be SEC. And the heavily exposed people that were monitored are not. That's the end conclusion of that.

DR. MAKHIJANI: I think that's a little too schematic about what we're talking about. So there may be like an administration building where people did not have, or almost never had contact with a radiological area.

And you could say that they were not monitored. They had lower exposure potential. And if you do any of these things, they're going to be covered. And I don't think you get any disagreement from me if you can show all those things.

What we are talking about though is workers who we know had presence and work in

controlled areas, many of whom were very infrequently monitored and where there was a lot of job diversity.

So that's really what we're talking about. I mean, in the interviews with the construction workers at Savannah River Site, Brad unfortunately isn't here.

But a number of construction workers described in considerable detail the variety of jobs that they did. And while they did their construction jobs, they also were kind of, you know, they were there and they were low on the totem pole and they did what they were told. And mostly, a lot of that involved doing all different kinds of work.

So yet we find that their monitoring was incident-driven when, I think, if you look at it more objectively you can't conclude that they didn't have routine exposure potential or they weren't completely unlike production

workers in that respect.

We're not talking about a very schematic situation of low exposed workers and high exposed workers. We're talking about workers with exposure potential who had reasonably good monitoring and others who didn't have reasonably good monitoring. That's a tough situation.

DR. NETON: But there you're talking about a situation where you've got incident-driven people, bioassay, and it was 100 percent incident-driven. And there is not, we don't have an ability to demonstrate the controls were in place to prevent exposures. I agree with you. That's NTS. That's exactly how that works.

CHAIRMAN MELIUS: Right.

DR. NETON: So I'm not disagreeing with you on that aspect.

CHAIRMAN MELIUS: Yes.

DR. NETON: But I think, well, I don't know. I think, in general, we probably know the construction worker better, by job title. Because we know they are contractors, right. I mean, so that might be true. But I was speaking the other models --

PARTICIPANT: Could I say something?

(Off the record discussion.)

DR. NETON: Anyway, I don't know. If you really don't have definitive job categories for everybody in the coworker model, I don't know. I find it, I don't know.

I still feel the 95th percentile is the reason that we've adopted that and because there are multiple strata in there.

So if you go up to the 95th percentile, then you say, okay, we don't know. But we've bounded it and it's less than that. I guess your argument is it's not sufficiently accurate. But I don't know.

CHAIRMAN MELIUS: Well, but I think the onus is on you to show that it's sufficiently accurate. And that's what we're trying to get at and trying to make sure that there's enough information presented to us the Advisory Board that we can evaluate that assessment.

And I think what's been happening is we're not getting that information. And so what we're trying to get at is a procedure to get that information.

So we're not trying to, we are being critical in the sense of trying to say let's get the information, and let's make sure that all approaches have been considered that are appropriate for a given site in a given circumstance.

DR. NETON: Yes. And I, okay, I agree. At Savannah River, I think, we can do this type of analysis. We're doing this type of analysis. But I guess this discussion started

when, you know, we said, well, you should stratify up front, not wait.

CHAIRMAN MELIUS: No, no, no. And it's not what I said. I said you need to consider stratification up front, that evaluating and analyzing data, you need to make that consideration earlier.

You know, but what I feel you're doing is jumping immediately to one model. And that becomes the null hypothesis. I'm not even sure it's, and then what you're telling us, well, that's a null hypothesis, it can't even be tested, that at every site other than Savannah River which is even more --

DR. MAKHIJANI: I mean, I think you alluded to this before but it did not kind of hit me over the head as it did today.

Okay, here's something that's very stark and big, I think you have to deal with. Because you cannot stratify in principle even to

-- then how do you demonstrate whether the 95th, you have to figure, I guess, we have ways in which we could demonstrate that if you had some job titles.

DR. NETON: Yes. There are some job titles, it's not zero. But I guess Savannah River is really robust with job titles. But it's sort of the best one that I've seen. There are job titles at other facilities, but in some cases --

DR. MAURO: This is John. I'd like to, a thought struck me really early on. Could you give me a minute or so to try to communicate something that just hit me real hard about maybe you don't need OPOS, and maybe you don't need pooled data either.

And maybe if you go back to doing it the right way, right, I'm sorry to use the word right way, but actually reconstruct the doses to real people the real way, the way, you know, you would like to do it all the time when you have

real, and you want to build a coworker model with that data.

Let me just try something out. What I just heard, Jim, is you can have a very large group of people working over some time frame. Let's say it's one year, and it's at a facility.

And you know that they were under a fairly robust health physics program, and that if there were any outliers, something unusual occurred that was being picked up and data would have been gathered unique for that person and you may have gotten a whole series of measurements, bioassay measurements.

So in theory, what you're really saying, you may have several hundred workers, maybe a thousand workers, working in a plant over a given year.

In a perfect world, you would reconstruct, you would say okay, we really have, within this population, we have the routine guys

that were monitored more or less routinely, maybe monthly, quarterly.

And then you have these smaller groups that were really monitored a lot, because they were involved in incidents. So you're watching everything, okay.

And then you have this other group of people that you don't really know, you don't know exactly what they did. And you want to reconstruct their doses using a coworker model. And you're suggesting OPOS.

Now, I heard you say that, well, you grab all these people. And rather than pooling the data for all these people, and I'll set aside these people that have data with high exposures because you caught those people. You have them. So let's put them over there on the side for a minute, in the parking lot.

And then you have all of these other people. But you don’t want to reconstruct

entirely the doses for 1,000 workers in that year to build this coworker model, this distribution. Because it's just implausible, it's just that the resources would be off the chart.

But you also said at the same time that that population of workers are not experiencing wild shifts in intakes. Because those would be unusual circumstances.

So if that's the case, and you're saying you have more or less a homogeneous group with individual variabilities from month to month that fall within the normal range of variability for this kind of operation or sets of operations, and there's nothing about it that could drive the special group of high exposures, why not sample randomly from that group, 30, 40, 50, not all 2,000, and reconstruct their doses the right way.

And make that your coworker model for people you believe appropriately fall within

routine range of operations that occurred at that time period.

And that would be your coworker model for them, and you didn't have to go to OPOS. You know, why would you have to go to OPOS if you believe that your statistical sample, which would be select large enough as Harry discussed, maybe 30 is a good number, would represent the distribution for that group of people.

Then, I'm almost done, guys, bear with me. But then you have this other group of people who did experience something unusual. And there may be some group, by the way, I'm putting this nested, what's the word we're using for different like construction workers?

DR. NETON: Strata.

DR. MAURO: I'm putting that aside for a minute. Now we have, within that same group of people, there are some workers for some reason had higher exposures. That's got to be

a relatively limited number of people.

And the argument you're making is, well, you really don't need a coworker model for that, because they've been captured. You're not going to have any people like that.

But then you say to yourself but, you know, maybe we're wrong. Maybe there could have been a guy or some people that were involved in this unusual circumstance.

And I would say, again, if there's reason to believe that that might occur, why not reconstruct the exposures for the people involved in the unusual circumstance and have a coworker model for that set of circumstances using the right way of reconstructing the doses.

Then you really have two coworker models for this group of people. And it's not anybody involved in the strata. Notice I didn't say the word strata yet. I'm putting that off to the side.

I'm just trying to think about the starting point which is a coworker model and trying to avoid having to go to OPOS if we can. That's a thought I wanted to leave on the table, it's a lot of this discussion.

DR. NETON: Okay. John, I'm not sure I quite followed exactly all of that.

CHAIRMAN MELIUS: And, John, since we're not talking about OPOS yet --

DR. MAURO: Okay.

CHAIRMAN MELIUS: -- I'm failing to see the relevance of this.

DR. MAURO: Okay. I thought that's where we were all heading.

CHAIRMAN MELIUS: No. At this point, we were really more talking about, we're still on the first paper.

DR. MAURO: Okay. My apologies.

DR. NETON: I guess to finish up what we were talking about, and when I talk about we

didn't have necessarily the job titles for all the people, at least as well at other sites that we had at Savannah River, I think it still goes back to Section 2.1 on data adequacy where it's incumbent upon us to evaluate the representativeness of the bioassay collection method and show that it's one of those two categories of workers.

Now, where is that, Section 2.2, I guess. Right. It must be established who was monitored and why they were monitored and whether they either representative of a sample or were they workers with the highest exposures.

And if we can do that. I think that's done. I mean, if you don't have, if the monitoring program captured all those workers then, you're okay with that coworker model, the thing that sticks out is the scenario that Arjun kind of likes to go back to, which is the incident stuff.

You know, if you don't have a routine program, and it captured the full distribution of the workers then, yes, you have a set of workers that were just purely incident sampled. Then, yes, that's a different issue.

And we have added sites for programs that had incident-based sampling, only NTS, I think, Fernald recently had a Class added because the construction workers were incident-based.

CHAIRMAN MELIUS: But, I mean, I stratification is also appropriate for routine monitoring. It's the same, you know, in some ways a lot less complicated to evaluate. Certainly sample size, other issues that come up, which is why I'm just trying to --

DR. NETON: Right.

CHAIRMAN MELIUS: -- sort of move it up, just so that, again, we're thinking about doing this rather than making it as the final

step. That's all.

And you know, you can argue either way I am just trying to think, procedurally, as you're going through, it's sort of the checklist thing.

Are you considering it now? It may not be the first thing to evaluate, but in some cases it may be. Because it's distinct populations and --

DR. NETON: I completely understand what you're saying. I guess I'm worried about putting limits on these type of what ifs. Some are obvious. You could say, okay, chemical operators.

But how far down in the weeds do we have to get to demonstrate that, you know, there could be 30 different strata that have to be evaluated. And then you get into to diminishing sample sizes.

CHAIRMAN MELIUS: Yes. But -- we

were sort of maybe overextending ourselves in terms of, you know, the datasets are small at a lot of the sites.

But, you know, you can tell a lot by just sort of a line listing of, you know, breakdown by job title and what exposure data you have.

I mean, if it's going to tell you -- and even by your process information. I mean, the example you used, you have those 15 workers that were doing the special operation or whatever that are going to tell you what's appropriate for that.

And again, I'm not saying that this 95th, 50th percentile approach is inappropriate, because it may be, it may, you know, be different ways to categorize that.

But I think it's going to, you know, how you prove it, I don't know. Because I think you're going to be basing it on looking at the

data and what makes sense in terms of that particular site, the operations, et cetera.

MR. BARTON: If I might, I think one place we were kind of, maybe got a little tripped up back there is the kind of example that we're talking about where you have real problems would be if you didn't have that job title information.

Because you may have a distribution, and you may believe that the relevant job types are captured there. But you also really can't tell the monitored workers in the upper tail of that distribution if there's a singular job title that would not be covered by an all worker model at the 95th percentile.

DR. NETON: Oh, yes. I mean, you have to have very good job worker information in order to do this. I mean, if you don't have it --

MR. BARTON: Right. And if you can establish job titles, I mean, there's a number

of things you can do. One example of what we did at Fernald for subcontractors where we said, okay, let's actually evaluate intakes for a very limited number of subcontractors that we had data for.

And we had information for when they were actually operating at the site. We did best estimates for that group of workers.

And we said, all right, how is this all worker coworker model, say we didn't have this information on them and then wanted to apply a coworker model would it actually cover their best estimate intakes? And that's one, I guess, litmus test you can always put out there. And it's sort of limited to claimants in most cases. Because you need information about employment periods and what type of intakes they actually experienced.

But there are ways to try to get a handle on if, you know, maybe it's not, maybe the

hypothesis testing won't give you enough granularity to tell, but sort of a second tier way to get around the problem, or to get a handle on the problem rather, is to perform intake analysis for a group of workers who you feel may have the potential to be way up there.

And then compare that back to what your all worker distribution would have assigned them, then it's either going to cover what they actually experience or it won't.

DR. NETON: Well, I mean, all that proves is that you demonstrated that there's workers in the tails of distribution. I mean --

MR. BARTON: But if there's a consistent job title that was up there above the 95th.

DR. NETON: And remember, these were the monitored workers, not the unmonitored workers. Just because there's a monitored worker up there with a certain job title that's

in the upper tail doesn't mean all the unmonitored workers --

MR. HINNEFELD: With that job title.

DR. NETON: -- with that job title were in that upper tail as well. I mean, you've got to --

MR. STIVER: It might provide a proof of principle, if you saw that you have some monitored workers who would be far above and beyond the 95th percentile.

CHAIRMAN MELIUS: Yes. I actually, I think that's --

MR. STIVER: I mean, that's how --

(Simultaneous speaking.)

CHAIRMAN MELIUS: If everybody in that upper tail you have from their CATI interviews or whatever, that did certain jobs or whatever, I mean --

MR. HINNEFELD: In the Fernald example, what that exercise showed was that this

group of monitored contractors, it would not have been suitable to do their dose reconstruction with a coworker, which you would not have done anyway, because you had their monitoring results.

The question at Fernald was, in this instance, Fernald saw these exposed contractors, and sufficiently it applied a monitoring program.

But there wasn't a lot of confidence that that was a routine occurrence, that it was, quite likely, since there were so few pockets of contractors being monitored up until the 80s, it's likely that that consideration didn't occur consistently for contractors.

And so there was no confidence that the contractors -- I think, you know, it was cool, it was a nice exercise. All it proved was that these monitored people shouldn't get the coworker model, but they wouldn't get it anyway.

MR. BARTON: I guess the assumption would be that people who were doing the same types of jobs that weren't monitored would have the coworker model applied to them.

MR. HINNEFELD: Yes. But, you know, we -- let's don't divert into the Fernald discussion. Because we can go a ways on that.

CHAIRMAN MELIUS: But you use your coworker models to fill in, you know, gaps in your monitored, mostly monitored workforce.

MR. HINNEFELD: I'm trying to, I think, Jim, your discussion here is that that's what we're interested in, what are the gaps in my monitored workforce?

And there might be multiple, there might be different gaps. And each different gap deserves a different treatment. Is that kind of where you're at?

CHAIRMAN MELIUS: Yes, yes.

MR. HINNEFELD: It may deserve its

own treatment.

CHAIRMAN MELIUS: You need to consider it or you, and how big those gaps are is, I think, has a large impact on --

MR. HINNEFELD: Okay.

CHAIRMAN MELIUS: -- the validity of your model that you're going to be using. A coworker model that fills in a small gap is not as potentially problematic as a coworker model that fills in big gaps or covers, and again, it's all site specific.

MR. HINNEFELD: But, well, as a practical matter, I'm trying to decide what are the characteristics you used to define the gap. And I think that's where Jim was going earlier on.

Because depending upon what characteristics and how many you decide to use to define the gap, you could have a very large number of small gaps.

And so there has to be some thought, I think, at some point, probably not at the meeting today, but at some point some thought put into what are the criteria that would be used if you're starting to evaluate what is the gap. So that's one thing. And then the second thing that concerns me, I'm trying to envision how this would work, is if you, you know, how will you know exactly the existence of the gap?

DR. NETON: Exactly.

MR. HINNEFELD: Because you will have, if you have the bioassay records for, you know, the entire database from places we have that for some places, you'll have the monitored population.

But you don't have the unmonitored population in its entirety. You have, if you have claims that don't have monitoring data, then you have a sampling of the unmonitored population from your claimants who don't have

monitoring data.

So you may be able to conclude some things from that. Now, that is a sampling. I didn't say it was a random sampling.

I don't know that you're going to believe it's not a random sampling, but you have a sampling. So it's not entirely clear to me how you identify your unmonitored population which is a precursor to identifying your gaps.

So there're some practical complications that, I think, would have to be worked through with some thought and certainly by people smarter than me. But there are some things that have to be thought about in terms of doing.

CHAIRMAN MELIUS: But I think you want to classify your gaps. You have gaps that, among the monitored workforce you have gaps by year, or within a year, you know. Then not everybody gets monitored every year. They miss

it for some reason, or there's a year where it doesn't get done.

MR. HINNEFELD: Oh, yes, I haven't gotten to that.

CHAIRMAN MELIUS: Yes. So you've got that. And that's where you're using your coworker model there, right, to fill those gaps? Or do you --

DR. NETON: No.

CHAIRMAN MELIUS: What do you do, you ignore the year?

DR. NETON: No. We have a coworker model that will have multiple data points in that year. But a person, well, you bring up an interesting point. Because if the person is only monitored -- he has monitoring data, we are going to reconstruct his dose using just that monitoring data.

CHAIRMAN MELIUS: But what if he's missing three years of monitoring data?

DR. NETON: With three years, he'd probably end up with some coworker.

CHAIRMAN MELIUS: Okay. So, what I'm saying, that's one consideration. And then Stu brought up another one. Then you have the unmonitored populations.

And then the question is can you, you know, how do you apply your coworker model criteria? And that's probably mostly what we're trying to talk about.

But there can be big gaps that are the same. If it's a ten year gap or whatever, or a year where there's very little monitoring data, and it seems to be, you know, much higher than the previous year, but it's all situational.

And so you say why don't you take a look at that. If they're totally unmonitored, then you're going to have to go back to your interviews and try to characterize who those people are and so forth.

DR. NETON: But the general sense is there are not huge yearly, multiple year gaps for people who I would consider heavily exposed workers, the ones that were chemical operators, you know, the ones that were working in the process area apparently routinely.

And I don't think that's an issue. I do think that we've done similar analyses where you can go and take the job categories of the unmonitored workers in the claimant population and do an analysis and say where would they fall in the coworker model.

I'm trying to think this through. I don't know. I lost my thread on that.

But Stu is right, you don't know who the monitored population is, really.

CHAIRMAN MELIUS: Yes.

DR. NETON: Except for the gaps. I mean, maybe there're gaps in some of the worker -- but it's really all based on claimant data,

not based on, you don't know who was unmonitored, I guess. That's the problem.

CHAIRMAN MELIUS: Yes. Which makes it even more problematic to use a coworker model there. And I think we, that's why I'm saying, you want to separate out your application of coworker models.

What's the number of unmonitored workers, which is always an unknown.

DR. NETON: Yeah. We have time to think about this a little more.

DR. MAKHIJANI: I still think it's, at Savannah River we had, when we dealt with external dose always a less difficult or easier issue on the stratification question.

I remember there was a NIOSH exposure ratio to be used for construction workers compared to non-construction workers.

DR. NETON: For external monitoring.

DR. MAKHIJANI: External monitoring and unmonitored workers. And when we, when Steve Marschke actually devised this procedure.

And we came up, we agreed that in the vast majority of cases where you find for pipefitters it wasn't. And it was a useful, it doesn't tell you that the unmonitored workers, you know, it doesn't tell you about the universe of unmonitored workers. But it does tell, it gives you some confidence that if the unmonitored workers were like the monitored workers or less exposed than that, then you have some confidence in what you're doing. If you don't know that, of course, then it's very difficult.

DR. NETON: That was for external dosimetry. And the coworker models are treated somewhat differently there.

I think in the external, the unmonitored, people who are unmonitored for

external exposures are given the full distribution whether they were the, you know, were highly exposed workers or not. There's reasons for that. And we've discussed that.

DR. MAKHIJANI: I don't remember that.

DR. NETON: Yes. So they don't get the 95th percentile. And to me that's, the 95th percentile the reason we do that for internal is because it's much more complicated and hard to factor out.

DR. MAKHIJANI: I didn't remember that. Thank you.

DR. NETON: But I'm still having a little trouble working through this. Because once you do, if you do show there are differences, then we need to talk about the next issue, is what's the significant difference?

How does that, you know, how does that affect -- because as, you know, we're not

talking about that paper yet, but there's clearly examples in multiple, multiple instances that it has to be a factor of two to produce a PC that's greater than just using the 95th percentile.

So I'm struggling with that. I don't know, you know, you can stratify and give a person 25 percent more dose with the full distribution, but they're going to get a lower PC at the end of the day.

And is that really where we want to go with it? I don't know. I mean, it doesn't make sense to me, especially if you can't statistically show that they're good. You know, that's probably for further discussion.

CHAIRMAN MELIUS: But I think just back to the sort of monitored/unmonitored issue, I think it's also, maybe we have to think of it in terms of types of coworker models.

There's sort of a, you know, the

individual gap one. The other one, which at least comes to mind in a lot of sites, is that where you have early years where there's very sparse data, and then we wrestle with whether the coworker, how far back can the coworker model apply?

Because we have a handful of workers that were monitored earlier, you know, relatively small proportion. And then it gets more robust.

I hope Wanda is not listening. But as time goes by and we get, and then the question is how far do you go back? And that's sort of, usually you're assuming that, I mean, they're unmonitored for a different, you know, for one reason.

Then you have this whole other population that's just unmonitored. And the question is what's appropriate and applicable for them?

And I would think that, you know, at least my criteria, or tolerance or whatever you want to call it for, you know, how robust the coworker model has to be to be different in those situations.

I think if you're filling in a one or two year gap for certain individuals, that doesn't, you know, it's probably very reasonable to do.

But if you're filling back in a year or two, early on or, you know, that's more problematic. And then you go to apply to the totally unmonitored population, and then I think the bar gets pretty high.

And again, it may depend on what that unmonitored, what possibilities or what potential that unmonitored population had for being exposed.

So again, you're do the clerical -- the people who worked out front that, you know,

that's going to be, that's the level of exposure involved is also important.

DR. NETON: I have to think about this.

CHAIRMAN MELIUS: Yes.

DR. NETON: I'm just having trouble coming up with a predetermined set of criteria. I mean, you can never predetermine, but you have to have some basis for saying I think that I should stratify here somehow.

You can't just say let me do 50 tests. You know, it just doesn't make any sense. I mean, statistically you'll find some chance, happenstance. But it's --

MR. KATZ: Excuse me, there's someone having a family conversation perhaps in the background. Anyone on this line who's not addressing the group should be muted.

If you don't have a mute button on your phone, please press *6 to mute your phone.

But I'm just worried about other people on the phone in particular, we can hear ourselves, but whether they can hear us. Thank you.

DR. NETON: And I have to think about that some more. I've always agreed it needs to be done. I just don't know --

CHAIRMAN MELIUS: No, that's fine.

DR. NETON: -- I don't know how to do the -- you know -- in advance.

CHAIRMAN MELIUS: So we've spent 45 minutes on 3.0.

DR. NETON: Yes. 3.0 is going to be tough. 3.1, gets into the time interval. And I think we've already talked about that to some degree. You can't assume that all conditions stay the same over periods of time.

The evaluation stratification, which is probably the section that needs the most work, because I wasn't quite sure where to go with this. You know, we acknowledge that the coworker model,

the all monitored workers contains, more than likely, multiple distributions.

It's just because the GSDs tend to be large, and it's a spread. So you can try to stratify at some point. And then this is where we get into using the 95th percentile versus the full distribution.

And we spent a fair amount of time looking at this. And it's not just dose dependent. It really is PC dependent to the point where, if you can look at every single cancer model, the lowest difference is a factor of two.

So you can stratify and say, okay, I'm going to give this guy a 25 percent more dose at the geometric mean with the same GSD or slightly different.

The end PC result will be 50 percent less. Not 50 percent, but a lot less because of the way the 95th percentile plays against the

full distribution.

We've done a very detailed analysis of that which we really may not get to today. So then that brings in the question when should one, even if you can stratify and you can develop multiple distributions that have different geometric means and standard deviations, is it advisable, is it claimant-favorable or not? When should one do that?

And I am of the opinion right now that a statistical test, pure statistical tests based on the numbers is probably not the place we need to end up.

CHAIRMAN MELIUS: Where do you think we should end up?

DR. NETON: Well, I proposed in my write-up that, unless there's a factor of two difference in the geometric means, that we shouldn't stratify. Because otherwise, with a fair amount of certainty, the Probability of

Causation would be less for that person.

MR. BARTON: You indicated the GSD would obviously play into that too right? It wouldn't just be the geometric means you compared with --

DR. NETON: I compared geometric means with the same GSD. And they tend to be similar to GSDs when you stratify. In fact, when you stratify and the geometric mean goes a little higher, it seemed to me the GSD goes down a little bit. Because you shrunk, you know, that population.

And the converse is true. When the geometric mean becomes a little lower the GSD could become lower. But in general, the GSD stayed fairly stable.

And so for similar GSDs, I've run the calculations, Dan Stancescu's actually run the calculations many different ways. It's a factor of two difference.

So my position, at this point, would be that we can do our statistical analysis. If they're not statistically different, then don't stratify. If they are, go ahead. But if it's less than this factor of two, you probably shouldn't.

DR. MAKHIJANI: If what is less than a factor of two?

DR. NETON: The geometric means, the difference in geometric means. An example I provided, it was two distributions. I think they were real distributions. One has geometric means 24 percent higher.

If you run the PC calculation for the most favorable cancer, it's a factor of 1.6 lower. It's purely a matter of the fact that you are using the 95th percentile versus the full distribution. And that's just a fact.

It's not exactly that, because it’s hard to control all the parameters, we try to do

the analysis such that we maximize our chance to show that, you know, little difference. So that's to me food for thought.

CHAIRMAN MELIUS: Yes. I think the more problematic area is when you're doing stratification, or it's comparing the dose monitoring approaches used with the -- how different do those have to be to undermine the validity of your comparisons?

So, you know, the routine versus, particularly with the incident basis, or you have some mixed approach that's used for part of the population. And that's been the construction worker --

DR. NETON: Yes.

CHAIRMAN MELIUS: -- issue. And I think that's more of an issue.

DR. NETON: See, in my mind that construction issue falls more in the realm of is it going to be incident-based or not. Can you

do it all? That's like can I stratify or not?

When we start comparing similar programs, like both routine programs, and one's a chemical operator and one is, you know, and you compare the chemical operator distribution to all monitored workers, you say, wow, it's a --

CHAIRMAN MELIUS: Yes, yes.

DR. NETON: -- 30 percent higher for routines, okay. What is that going to get you in terms of PC values, it’s going to lower the PC values, even if it's 30 percent higher.

So I don't know. That's why I keep, sort of broken record, I keep harping on it. The 95th percentile sort of mitigates that by saying, well, you're trying to be, you know, favorable here.

We don't know exactly what it is. It's plausible the guy is up this high. It's plausible he's a little higher, but even if he is a little higher it's not going to be favorable

for him to use a little higher values. That's where I'm at. It's a very complicated situation.

MEMBER ROESSLER: It's very complicated. And it's so complicated that I have to ask a question, if I can even ask it.

When you talk about it, you're saying that if it can be shown that the use of the full distribution in the stratified subset is more favorable than using the 95th percentile, the general distribution, then you should use the full distribution. Can you actually when you are doing a dose reconstruction determine that and then go one way or the other?

DR. NETON: I think theoretically you could. But it'd be so unbearably complicated it would -- I think you could set guidelines, like I say a factor of two --

CHAIRMAN MELIUS: Yes.

DR. NETON: -- in my analysis. You

know, it can be a factor, as high as a factor of four for some cancers. The lowest cancer, the lowest difference was a factor of two, I think, for urinary cancers other than the bladder or something like that.

And so what I'm saying is, unless you can demonstrate that there's this huge difference in the geometric means, then it's not worth stratifying at all.

MEMBER ROESSLER: Yes, okay.

DR. NETON: So you can pick some number. Well, there's two situations. One is, the issue is that the statistics are not good enough.

You can't see small differences, statistically. You can't demonstrate that there're statistically different for small differences. It has to be a fairly large difference.

What I'm saying is, well, you don't

have to see small differences because, from a Probability of Causation point of view, a factor of two is not going to help the claimant at all by increasing his -- increasing his dose by a factor of two will not help him in his Probability of Causation outcome.

Now that's not hard and fast, that's not perfect. But that's a very good approximation, in my mind.

MR. BARTON: Jim, you lost me a little bit there. Because when I read this final sentence in Section 4, it sounds like what you were proposing was you have your all worker distribution. You want to know whether you need to stratify or not.

I thought what you were trying to say is, okay, we suspect some group of workers need to be tested for whatever reason, interviews or whatever.

And so we pulled them out and then we

create a separate distribution. And I thought what you were saying was, from a PC standpoint, you compare the 95th percentile of all worker to the PC generated from the full distribution of this new stratified set.

DR. NETON: Right.

MR. BARTON: And based on that comparison, you can say that the stratification is even warranted, if it would benefit claimant.

But then I thought I just heard you say, well, the results on this is we're just going to compare the GMs at the factor of two. But you would actually build the two strata first to sort of test it?

DR. NETON: You have to build a two strata.

MR. BARTON: Okay.

DR. NETON: But what I'm saying is do you do a statistical test or do a practical test based on the PC.

MR. BARTON: Okay.

DR. NETON: I mean, what I'm saying is, you can do it. And that kind of example I provided is a 24 percent difference in geometric mean. If you run the PC calculation using that value as a full distribution, as opposed to the 95th, the PC is lower, much less.

MR. BARTON: Okay, I understand.

DR. NETON: Eleven percent versus 20 percent for that particular case. So, you know, trying to be claimant-favorable on one side, you end up hurting the person's chances on the other side.

So, I don't know. I don't have a real answer for that right now. I clearly wanted to point that out. I brought this up at the last meeting, that this is how we behave, and we did the analysis.

And my intuition was correct, that it does produce lower PC values. So, you know, we

went ahead and stratified just blindly. Because the number was higher, you ended up not favoring the claimant very much.

CHAIRMAN MELIUS: Well, that's why we started down that road to begin with, what level of difference makes a difference.

DR. NETON: Right. And finally I came up with this thing --

(Simultaneous speaking.)

CHAIRMAN MELIUS: So, yes. And again, that's why I'm sort of trying to sort of front-load our meeting today.

I think that the key is going to be, where we're going to need to do the work is, you know, is up front in how we approach developing these models and so forth.

And then, you know, how we look at the monitoring things and how it's going be simple, too routine, one routine versus another, it's going, I think, be a much more mixture of that.

And how much of a mixture is going to -- and I don't know if statically we can deal with that. But I think there's probably some, you know, at least guidance we can give in terms of making sure that's looked at, and evaluated and, you know, addressed in the context of that site.

Because, you know, we're going to be different, we've got different sites, and different monitoring programs, and different exposures and so forth.

DR. NETON: I think we're, and I'm not sure. A lot of disagreement among us on most of these points, and I agree we need to stratify or at least evaluate. How much we do that is still a little bit cloudy in my mind.

But to close this all out, we're going eventually have to come to a decision on whether, how we do the final comparison to see what stratification is warranted. And prior to that, we need to make a decision on how the coworker

models themselves are constructed.

CHAIRMAN MELIUS: Yes. No, no, no. And I don't think we can do the, make the final decision, so to speak, until we address the other.

DR. NETON: Okay, that's fine.

CHAIRMAN MELIUS: I think --

DR. NETON: I feel --

CHAIRMAN MELIUS: You know, I don't think we're, I don't think we're far apart on that --

DR. NETON: Okay.

CHAIRMAN MELIUS: -- this situation. Arjun, you --

DR. MAKHIJANI: Well --

CHAIRMAN MELIUS: Good, conquered.

DR. MAKHIJANI: Yes, I'm okay with it.

CHAIRMAN MELIUS: We'll wait until next meeting.

DR. NETON: That finishes out my thoughts.

CHAIRMAN MELIUS: Three weeks, three weeks, comments.

DR. NETON: That'd be great. And again, all comments are helpful, please. I don't like doing this in a vacuum.

DR. MAKHIJANI: I do have one question. This factor of two, not making much of a difference in the Probability of Causation. How, we had a limited number of cancers, as I remember you didn't have very many cases to look at.

DR. NETON: I mean, I look at a lot of cancers. We looked at all 33 cancer models.

DR. MAKHIJANI: Oh, you took that certain dose information, then looked at all the cancers?

MR. HINNEFELD: Yes, it was one

particular stratified subset of a broader population.

DR. NETON: Well, that was the example. But on a generic basis, what we did is I said, okay, let's have a coworker model that has a GM of one and a GSD of three, okay.

How much higher would that model have to be to exceed the PC used in the 95th percentile of that distribution? And that's a factor of two at the least.

It's up to a factor of four for some cancers, assuming the GSDs are the same. Now, if the GSD is higher in the stratified model, then that's going to be a little lower, as you saw in the example, 1.6.

DR. MAKHIJANI: Right.

DR. NETON: But it's in that ball park. I'm not saying it is a factor of two, I'm saying my analysis is a factor of two. It's certainly in that ball park, in my opinion.

Although, again, I think I pretty clearly pointed out this wasn't exhaustive among all --

DR. MAKHIJANI: No, no, no. I think that analysis you did is very useful.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: So I'm not raising an issue about that.

DR. NETON: Yes.

DR. MAKHIJANI: I just was trying to, I didn't remember that you had actually looked at all the cancers.

DR. NETON: I did. We did analysis of GM of one, GSD of three for all 33 or whatever you call them, breast cancer too. And we did all of them. And I said, and we ranked them. It's in that paper.

MEMBER BEACH: Jim, that's the --

DR. NETON: Yes, that's table.

MEMBER BEACH: Oh, okay, that's what I thought.

DR. NETON: And the smallest difference was about two. I think it was urinary tract cancers.

DR. MAKHIJANI: Presumably there would be some way of using that analysis to give you a little bit more elbow room.

DR. NETON: That was my whole thinking, exactly what I was trying to do. You know, again, you can't see, statistically you can't see 20, 30, 40, or 50 percent differences. And you've already kind of decided on that.

I think Harry made his point very clear at the last meeting, you are comparing two geometric means with large GSDs, you need big differences in GMs to see that. And I'm saying you probably don't have to because of this, this issue. Or you could, you could do --

DR. MAKHIJANI: You need a very large increment dose to make up. When you get close to 50 percent.

DR. NETON: Yes. It puts the hundred millirem analysis to shame.

And so it gets even more favorable when you do -- remember, this is for one year. When you start doing multiple years, it becomes more spread apart because of correlation issues, in some respect. You're sampling the 95th percentile as a constant every single time.

Yes. And again, don't get me wrong. I'm not saying it is a factor of two. I'm saying it's a fairly large --

DR. MAKHIJANI: No, no, no. I heard you. I am actually saying thank you, you know, I didn't remember how thorough you had actually addressed it.

DR. NETON: And we used chronic alpha exposure, which I think tends to also increase the distribution. But, you know, that aside all the stuff we just talked about before still is valid. Because you still need to, you need

pieces or parts here before you get to that final analysis.

DR. MAKHIJANI: Right. This just gives you elbow room at the end.

DR. NETON: That's my thinking at this point. You get a little bit of, I guess, elbow room or, a little bit of variability in there that --

DR. MAKHIJANI: I mean, it's not some other negligible issue. So if you get to that last step, it makes your co-worker model results look more robust in light of the ultimate decision.

DR. NETON: Well, unfortunately, it has to take it about three steps further, but we won't get into that today. But this is not just based on one single year. You know, this would be based on a coworker model that fits a chronic exposure oftentimes over a ten year period.

I could show you this, but the distribution that's applied in the dose reconstruction is not the distribution of the bioassay samples for one year. It's the distribution of the chronic exposure intake over a ten year period oftentimes in that GSD. Because the analysis is still valid.

But that would only affect one year. If you had a difference even in one year, you still need to look at all ten years in the chronic exposure model to see if that actually changes the chronic intake which is what goes --

DR. MAKHIJANI: Right.

DR. NETON: The dose from that goes into the model.

DR. MAKHIJANI: Yes.

DR. NETON: I have some slides on this. But I think the analysis is pretty informative about at least decision making for stratification once we've done all these. Okay?

DR. MAKHIJANI: Yes.

DR. NETON: Okay.

CHAIRMAN MELIUS: Since Ted didn't put an end time on the agenda --

MR. KATZ: There's no end --

CHAIRMAN MELIUS: There's no end time.

DR. NETON: We have to stay here until midnight.

(Laughter.)

CHAIRMAN MELIUS: And they've locked the doors. Do you want a short break? And then we can move on to the next two. Or do you want to just go ahead? Seriously I had planned on going to 5:00.

DR. NETON: Yeah, I could keep going.

MEMBER ROESSLER: Let's plug ahead, yeah.

CHAIRMAN MELIUS: Okay. Coworker model?

MEMBER ZIEMER: How long are we breaking for?

CHAIRMAN MELIUS: No. We're not breaking.

MEMBER ZIEMER: Oh, you're not breaking. Okay.

CHAIRMAN MELIUS: Yeah. We got voted down. No one would believe me that we're going to stay here until 10:00. So, no, we're going to break at 5:00. But we'll finish up in about an hour.

DR. NETON: Okay, coworker. So --

CHAIRMAN MELIUS: We just talked about a good portion of this.

DR. NETON: Yeah. Which one do you want to talk about, the time-weighted average or the strata comparison?

MEMBER BEACH: Let's do the time-weighted. If we get to go --

DR. NETON: Okay.

CHAIRMAN MELIUS: I was going to say do the strata because we've been talking about it --

MEMBER BEACH: Okay, that works too.

CHAIRMAN MELIUS: -- to some extent, because I think it'll be --

MEMBER BEACH: Short?

CHAIRMAN MELIUS: I don't know.

DR. NETON: It should be pretty short.

MR. HINNEFELD: Jim didn't think we spent much time on the first one.

DR. NETON: I thought the first one we breezed through real quickly.

CHAIRMAN MELIUS: I had other ideas. I'm sorry.

DR. NETON: No, that's fine. All right. All right, this is Daniel Stancescu, who's on the phone, I hope, still. It’s going on 6 o’clock where he is. I think he's going to stick around. Anyway, he did much of the

analytical work behind this, but I'll take full blame for conceiving of the concept.

Anyway, RPRT-53, which we talked about a couple meetings ago, talks about a statistical approach for evaluation stratification. It's a two-tiered evaluation where the stratified distributions are first compared on a year-by-year basis and look for a difference in those strata.

And if any individual year or increment that's evaluated, whether it's something other than a year, are different, you still need to apply what we call a practical significance test, which is what I just sort of talked about.

I'm applying this to a chronic exposure model over a, most of the time, multiple-year period. Does that make a statistical difference to the chronic exposure model?

The test that's used to look at differences between strata are the Monte Carlo permutation test and the Peto-Prentice test, and we've talked about those. But the issue is, you can't really see very small differences between distributions.

And I got to thinking about this, and I broached this subject at the last Working Group meeting, that in reality, though, we don't compare a full distribution to full distribution. In practice, we'll apply the 95th percentile. If it's stratified, then you go and use the full distribution.

Well, we got to thinking about, well, what difference would that make, practical difference, in terms of a Probability of Causation outcome? So we went and explored the relationship between the PC generated for a stratified model using a full distribution and the 95th percentile.

The paper describes the sort of input parameters that were selected and why. I won't bore you with those details. You can look at them. But there are caveats. We had to make certain assumptions and we've outlined or described, I think pretty well, why we picked what we did.

To get to the bottom line, though, if you look at the table that I think Josie was just showing, this is a table of all the IREP cancer models. And we put into the IREP cancer model either a full distribution, and got a PC outcome -- and the distribution was a geometric mean of one and a GSD of three. These could be any units, but for comparison purposes we just stuck with one and three.

And then we calculated what the 95th percentile that distribution would be. And that is 6.09.

So in one analysis, for example

female genitalia, the first cancer here, we put 6.09 into the IREP input model and got a PC result. And then we reran the analysis and put in the stratified model, which would be a geometric mean of one and a GSD of three, and the stratified model would have to have a geometric mean four times that of the geometric mean of one in order to get the same PC value.

So that's the worst-case analysis. And there is a distribution of PCs because all the PC models have different uncertainties associated with them. The bottom line is, if you get down to the last cancer, the lowest one was urinary organs excluding the bladder, and to get the same PC as the 95th percentile, the full distribution would have to have a geometric mean of 2.07 and a GSD of three to get the same PC as putting in 6.09, which is what we would use.

DR. MAKHIJANI: GSD of what?

DR. NETON: Three. Now, we've done

this for other GSDs: four, five, six. Not gotten as high as six, but four. I'm not sure we did five. It seems to track with GSD. It doesn't really matter what the GSD is on the distribution as long as they're equal.

Once you start getting into discrepancies in the GSDs, these values will, of course, change. If the GSD is larger for the stratified model, then the multiplier would be somewhat lower.

And the example I provided is these two cases here. There's a full and a stratified model. You could see that the GM is 0.75 with a GSD of 4.05, and stratified had a GM of 0.9 with a GSD of 3.7.

We compared those and I believe the analysis showed that the PC would be 1.6 lower. I got the numbers here.

DR. MAKHIJANI: 1.6 percent?

DR. NETON: No. Hang on, let me get

to the values. Where's my example? Yeah. So when you run that -- do I have the PCs listed in here? Daniel, are you on the phone? Oh, here it is.

At the 99th percentile, the PC was at the -- hang on -- yes, the first run used 7.51 as the input term. The second one used the full distribution at the 99th percentile, which is where we select the values. The NIOSH output results were 12.2 percent for the stratified subset and 20 percent for the 95th percentile.

So if you use the 95th percentile, even though that geometric mean is 24 percent higher, you get a 20 percent PC. For using the 95th percentile, you only get a 12 percent PC for the stratified model even though it's got a much larger GM and a slightly higher GSD.

So I think this kind of analysis can be done somewhat repeatedly for many different examples and you come up fairly close.

So I'm not saying it's a factor of two. It's a large difference. If the GSDs are the same, it's a factor of two or more. So that's the end result of that analysis.

DR. MAKHIJANI: But is it realistic to assume that the GSDs are saying -- I mean, when you have stratum like the construction workers at Savannah River where you have few data points for that stratum, you're going to have a pretty big GSD, right? And that's why we had this --

DR. NETON: Well, I don't know.

DR. MAKHIJANI: -- difficulty arriving at a conclusion. I don't know. Maybe Harry or Bob might want to say something about that, because I don't think I remember enough about the details this far in time now.

MR. STIVER: Yeah, you're talking about the RPRT-53 analysis that Harry did?

DR. MAKHIJANI: Yes.

MR. STIVER: Harry, are you on the

line? Could you say a few words?

DR. CHMELYNSKI: Yes, I am, Bob. I'm trying to remember what kind of GSDs we saw there, but they often are up in the fours and fives for these subgroups. I don't know exactly how that compares, though, with the overall all-worker models.

DR. NETON: Right. I think they can be higher, but they're in the same ballpark. I mean, they're not typically, you know, widely different because it's -- especially if the geometric mean is higher, you start -- you're pushing yourself up towards the end of the distribution and it seems to me that that would almost tend to lower the GSD.

I've seen that in a number of cases, where if you're pulling out a distribution that has a higher GM then you've got a more shrunken down subset to deal with.

DR. MAKHIJANI: That seems like a --

it seems difficult to generalize from something where you're assuming the same GSDs where one stratum doesn't have many data points.

DR. NETON: Yeah, it may be where one evaluates it on a case-by-case basis from the general term, in a general sense.

This analysis I did is very simple to do. You stratify and you run the two values at the 95th percentile versus the models and you just look. You say how big a difference am I going to need in order to be more claimant-favorable? I mean, that could be done. That could be a test, not maybe the only test but at least a test.

DR. MAKHIJANI: So can you develop, like, an algorithm that could be very easily applied?

DR. NETON: Oh, I mean, the calculations are simple. They're very simple calculations.

MR. BARTON: Jim, if I could ask you a question. I mean, these examples are essentially just on a year basis, right?

DR. NETON: Right.

MR. BARTON: And as you say, when you generally create a coworker model you combine multiple years based on patterns you see in the bioassay data.

DR. NETON: Right.

MR. BARTON: So I'm wondering how this might get complicated in picking your intake regimes because wouldn't you have to -- I mean, it seems like you would have to pick the same intake regime for the all-worker and the stratified. But when you actually examine the stratified dataset and the all-worker, you might not find that that makes a lot of sense to have the exact same intake intervals.

DR. NETON: I'm not following.

MR. BARTON: Well, let's say, in

practice, if you were to use this type of comparison would you make that comparison for each year?

DR. NETON: No, no. We're doing it for one year. I think what would happen is, if you did it for multiple years, the difference would tend to get larger. Because you're putting the 95th percentile in as a constant every time, and if you put the full distribution, its sampling, I'm pretty sure that it would be more disparate.

MR. BARTON: Okay. What I'm saying is --

DR. NETON: We could test that.

MR. BARTON: There could be the possibility of a disconnect, because when you look at the excreted values for a given year the years that it makes sense to group together for the all-worker might not be the same as the years it makes sense to group together for any

potential stratified. Just wondering. I mean, that could complicate this. I don't know how much it would complicate this.

DR. NETON: Well, I think you'd have to do it on a case-by-case basis, like if you had multiple regimes.

CHAIRMAN MELIUS: I mean, I think it would be worth looking into.

DR. NETON: It's worth looking at. If you make that comment --

CHAIRMAN MELIUS: Yeah. Yeah, just to --

MR. STIVER: Would it necessarily be a requirement they track together? I mean, if you've already established they can a different coworker model for the subgroup, it may have some slightly different --

CHAIRMAN MELIUS: I think the question, it's harder to grasp sort of from a distance, is how much of a difference does it

really make, though? And I think that's sort of Jim's point, is that it doesn't really -- some of these, you know, quantitatively don't.

But it's not to say that we're not thinking of the right example, the wrong example, you know, however you want to look at it. There may be some circumstances where it could occur where it could, so if people are thinking of those, let's suggest them.

DR. NETON: And, again, this doesn't really apply to the individual distributions of bioassay. It applies to the -- I'm going to get into this in the next paper -- it applies to the chronic intake model itself. That's where that difference needs to be demonstrated. Is it going to change your chronic intake model?

DR. MAKHIJANI: Yes, you showed that on one of your previous --

DR. NETON: I have some slides I think that I'll show that will make that much

clearer.

CHAIRMAN MELIUS: One question I have, this goes back to some of the earlier papers and so forth, I think, but why do we have this array of differences by organ system, this particular hierarchy? And is this similar to what we found earlier?

DR. NETON: The array?

CHAIRMAN MELIUS: Yeah, the hierarchy of Table 1. You have differences.

DR. NETON: Oh, that's just the way the results came out, I mean.

CHAIRMAN MELIUS: So there's no --

DR. NETON: There was no rhyme or reason to that. It was just we ran all cancer models and we ranked them by their --

CHAIRMAN MELIUS: So is that going to be consistent across different exposure scenarios, I think, was my question. And are there something about some of these IREP models

that might make them more sensitive, so to speak?

DR. NETON: Well, yes and no, to be perfectly honest. These IREP models, of course, are very complicated mixes of multiple distributions. And you can't predict, to the extent they generate a distribution themselves of PC outcomes, and how broad that is is really what drive these numbers.

Now, I also used alpha exposure in here because that has a very broad distribution in itself. It tended to broaden the model because alpha exposures have a raised effectiveness factor that go all the way up to 100 on one end and two on the bottom end. So anything that tends to increase the full distribution would minimize this difference.

It's hard to say. You know, we picked certain parameters we thought would tend to show a fair analysis, but I can guarantee you that we could run this different ways and come

up with different numbers. It just struck me that there were these huge differences with sort of a routine analysis.

This is sort of a run of the mill alpha exposure and this is where people tend to be compensated more often, as well, with alpha exposures to the lung. In fact, I guess I could argue that alpha exposures to many of these organs would not almost be realistic.

CHAIRMAN MELIUS: That's what I would say, yeah.

DR. NETON: And if you substituted something like photon exposures to get there, it would probably make these comparisons even broader. That would be my guess, because they don't have that alpha distribution on them.

But again, you know, as I point out several times, this was preliminary. We did this. It's food for thought.

MEMBER ROESSLER: Jim, were you just

asking what are the reasons that the ranking came up the way it did with the different types of cancers?

CHAIRMAN MELIUS: Yes.

MEMBER ROESSLER: Is there some rationale behind that, some reason that certain ones would come up really quite a bit higher than others?

CHAIRMAN MELIUS: And I think Jim's explanation is correct, that it has to do with sort of the nature of the distributions, differences between alpha and other exposures, and then also the distributions found within the models and so forth. So it's not, you know --

DR. NETON: The 84th percentile of a cancer model, or the 95th percentile of the cancer model versus the full distribution is different for each cancer model.

If you could say, and I think I pointed out, the 84th percentile is kind of a good

surrogate for the full distribution. The difference between a PC of the 84th to the 95th percentile is dependent on how broad that cancer model is. And some are known with more certainly than others.

I mean, but there's many, many, many factors in these models. You really can't characterize them actually as a distribution. They're more -- I call them histograms.

MR. BARTON: I have a question. I mean, this sort of assumes that we've identified which strata we want to take a look at and compare against the all-worker.

I mean, do you have any ideas or thoughts on how you would go about initially identifying that strata? I mean, you said, you know, construction workers or --

DR. NETON: Well, that gets back to the last discussion.

(Laughter.)

DR. NETON: I don't know. I mean, you know, how you do that? You have to pick something, and to be fair I think you got to be consistent.

But I don't know, I just don't know. I mean, some are easy. Some are obvious. You know, chemical operators, the guys that got their nose in the material and there's airborne. Some maybe are less obvious.

CHAIRMAN MELIUS: At one o'clock he was sure but we wore him out.

(Laughter.)

DR. NETON: Now I have no idea. Okay, so that's this paper. Again, this is preliminary work. You know, it's very interesting how it came out. It was a lot bigger difference than the 100 millirem, you know, where we said that there was no difference.

I think this is good food for thought and I'm not married to this analysis so any valid

criticisms are totally acceptable to me.

DR. MAKHIJANI: Definitely more interesting.

CHAIRMAN MELIUS: And you have three weeks. Jim's allowed to have vacation again on this paper and --

DR. NETON: Okay, yes. Thank you.

DR. MAKHIJANI: Can we take vacation after that?

(Laughter.)

CHAIRMAN MELIUS: Oh, yeah. I think SC&A should give you a big bonus.

DR. NETON: All right, now I'm looking for the last paper.

CHAIRMAN MELIUS: This was Jim's birthday present to me.

DR. NETON: Was it? I didn't know that. Happy birthday.

CHAIRMAN MELIUS: I got OPOS too.

(Laughter.)

MEMBER BEACH: So let the record note that your birthday's on June 16th, is that what you're saying?

CHAIRMAN MELIUS: You didn't have to let the record --

(Laughter.)

CHAIRMAN MELIUS: Though I have been told it's someplace on the internet.

DR. NETON: First, I want to show something that I think might help. Somewhere on here I have a presentation. Coworker slides Idaho, okay.

All right, I put some background information here because I feel it's important that we all talk about the same thing. And you've seen these slides before but I think it's important to emphasize -- not these things, although I could think about those forever too.

Okay, this is just a summary of how you do coworker model calculations. And these

little shaded boxes show possible areas where we can take data and we do something with them.

You can take the urine data and that will be, what, all the urine data and then develop 50th and 84th percentile urine data and you could use what SC&A is now calling the pooled analysis, which is all the urine data, and just rank it up.

There's actually at least five ways I can think of that you could use the data. You could just rank up all the pooled data. You could take a simple mean of the data per worker, individual worker, what would be the maximum possible mean. Or you can do some sort of time-weighted average, whether you do a reverse or a forward analysis, make some differences depending on what the data look like. Or you could do some sort of a connect-the-dots analysis, which gives you a little better resolution. Or you could do a full-blown dose reconstruction like John was just talking about.

There's many different ways to do it.

In my mind, the simple pooled data analysis is the least scientifically valid because it's not modeling people, it's modeling samples. And this is a coworker model, it models individual workers' exposures.

And if you can agree that the full-blown dose reconstruction for everybody is the gold standard, then going backwards you end up with the first choice being, in my opinion, the least desirable.

And then we'll fit 50th to 84th percentile intake rates. This is where it gets tricky. Okay, so here is the distribution it will generate for one year, right? This is a one-year distribution, whether this is OPOS, stratified, I mean, OPOS, some stratify, doesn't matter, time-weighted average, full dose reconstruction, just you get this distribution for one year.

Now you're going to take that distribution, and if the slides cooperate, you're going to come up with -- you're going to do an intake calculation.

So each of these data points is one of those distributions, in this case by year. So you got about nine or ten years here of data. And you assume that on this 3,700th day this person started to breathe some chronic amount of material, and what is the best fit intake through these points to give you a coworker model for this little piece of the model?

Okay, so now I want to give you an example, a real example, from Savannah River. It was the coworker model, I think, for uranium from Savannah River, and this little blue highlight area is the model from 1991 to 2000. So this is that chronic intake piece where each of these blue dots represents one of those distributions, okay?

So we fit that to come up with -- this is the 50th percentile coworker model. So you take the 50th percentile of all those individual distributions and fit it across and get this curve and you come up with an intake. That particular intake down here is 58 dpm per day.

DR. MAKHIJANI: 50th percentile of all the individual --

DR. NETON: Right.

DR. MAKHIJANI: Which?

DR. NETON: So each of these distributions, okay, you take the 50th percentile, which is geometric mean, and that's the excretion for that year.

DR. MAKHIJANI: Okay, all right.

DR. NETON: Then you take all these excretions for each year and plot. We don't plot them here. You plot them here and then you fit an intake curve through here.

So what would a person have to breathe

in every day in order to have this pattern for ten years? That's a chronic intake. And we're saying for this entire ten-year period this person is breathing in almost 59 dpm per day, every day for ten years. That's the 50th percentile of the coworker model. That's different than the 50th percentile of the individual.

Now we go further than that. We say what is the 84th percentile excretion? So you take the 84th percentile from that curve and you do the same analysis and you generate this curve.

Now you see the 84th percentile is 141.1 dpm per day. From that calculation you can calculate the GSD of the intake itself, which in this case is 2.4.

Now, we've adopted in practice never to assign a GSD of less than three. So anything less than three is automatically made three if the GSD is less than two.

So in this particular case then the 95th percentile is this number times -- the 95th percentile of a GM of 58, a GSD of three, is 358 dpm per day and that is what we will assign.

So this worker will receive, every day, 358 picocuries per day over a ten-year period when the 50th percentile was really 58.7. So this is, in my opinion, a generosity built into this coworker model, for entire ten years, based on that bioassay data.

So when we talk about inputting into IREP values, we're not talking about inputting this curve. This curve has nothing to do what goes in IREP. It's this analysis here that goes into IREP. Well, it’s actually the dose that is calculated from this analysis.

So I think that's important to keep in mind because just because you can have a difference in one of these dots of 20 percent, doesn't mean it invalidates this entire ten-year

period.

You'd have to have multiple years to make a significant difference in this ten-year regime. And, in practice, many of these regimes are multiple years. I mean, they're obviously more than one year. So I think that's important to understand. It's how they're built.

Okay, enough on that. I just want to make sure we're all talking about the same thing. Okay, now let me get to the other paper. Bear with me. Time-weighted, okay.

So, the last time we talked, we had proposed this maximum possible mean analysis which was -- here we go. We had proposed this maximum possible mean. We just essentially used the maximum possible mean, which was a mean value of all the values.

Well, since that time, we got to rethinking about whether that is really the approach we want to use, because in reality you

have to account for differences in excretion patterns. And the easiest way is just to show you one of these curves.

Daniel took the americium data for a certain time period. And you can see here, this is the average daily excretion for 1971 for some particular person. And all these red and blue dots are samples, whether they're censored or uncensored values.

But you can see, what you're really trying to do is get the area under the curve. How much did this person excrete in this particular year?

So, you know, you could integrate going forward, as we've done in our analysis, weighting each amount by the -- think I got -- yeah, each of these are little triangles. So you integrate these triangles where a guy is not excreting much and then he pops up. This is clearly an incident sample because he got a lot

of samples down, following down. You integrate all these little rectangles and you divide by the total days in the year and you get at the time-weighted OPOS.

Did he not list the -- yeah. The OPOS value for the maximum -- using the mean value was 3.6. And in using this new time-weighted analysis you end up with 0.95, because clearly this is not contributing much to the overall excretion. It's a blip in time and goes down pretty quickly.

Now, that's if you integrate forward. SC&A has suggested, and there's some basis for this, that you should integrate going backwards because the bioassay point is actually a measure of what happened before it, not after it.

What that tends to do, though, is it weights these incident samples. And that's why I like going forward, but I'm not married to either one.

If you go backwards, then this 12 would essentially generate a rectangle like this. It would go up from 0.3 to 12, so it would much more heavily weight the incident. The main difference is going backwards weights the incident samples a lot more.

MR. HINNEFELD: The assumption being that the incident sample would be taken shortly after the incident?

DR. NETON: Right. Which is, it's an incident, is typically what happens.

So I don't want to get too much into the statistics. I mean, there are some formulas in here that give you how it's calculated. But in essence we're just saying we feel that a better approximation of a person's urinary excretion for the year is the time-weighted OPOS, which is based on this formula right here, whether it's M or M plus one. I'm not going to argue.

SC&A has corrections on that but, you

know, this value here, OPOS is the mean, the mean value, just linear mean, and this is the time-weighted value. We're now suggesting or recommending, hoping, that we will use this value in our calculations.

SC&A's analysis, as I read, still is suggesting that it okay -- you know, mean value is still appropriate, with some concessions, that if -- I'm not sure how you define this -- if there is significant data, what do you call it? Data --

MR. HINNEFELD: Data dominance.

DR. NETON: Dominance. Then it should be used. In my opinion, if it's okay to use when it's data dominant, why isn't it okay to use when you have three, four, five, six samples?

I think the argument where it says it's only one percent of the samples are affected by these type calculations. If you look at it,

though, it's the percentage of the samples, not the percentage of the people, you know, that are affected.

So you want to represent the people affected, that's very different than saying it's one percent of the samples. It's typically going to be much more than that.

So I feel, I strongly feel, that this is a more appropriate approach than using the pooled data. It may or may not be -- it's more accurate than just taking a linear value, I mean, a simple mean value, because it definitely accounts for the time-dependent distribution, which I think is more appropriate.

As far as I could tell, the only argument for staying with the pooled data is it produces higher means and standard deviations, but I'm not sure that's valid given the technical reasons for using, you know, a more time-weighted approach. So that's it in a nutshell. I'd be

happy to entertain any questions.

MR. BARTON: Well, if I may, I think that we all agreed over at SC&A, when we saw the time-weighting, that it represents kind of an improvement over unweighted OPOS because it has an element of time in it now.

But I think really our concern is just with the averaging in general. And it's not only, essentially, in the end product you end up with lower assigned doses than you would with the older pooled model.

It was our understanding in reviewing the literature that basically the scientific validity behind averaging was that the mean value of a worker's excretion rate over some time was proportional to their intake over that time.

But it is our understanding, and maybe you can react to this, this is one of our findings in RPRT-53, that when you take the mean of a worker's sample and it's okay to do that if

you're only following a single intake. And I guess that's where our major misgivings are with it. It's just that we don't have, over a given time period, you know, one acute intake.

It's a mixed bag. You're going to have periods of no exposure, periods of, you know, medium chronic exposure. Then you might have acute exposure thrown in there and we're averaging them all together, and I'm not sure if it maintains that scientific credibility in that.

If I might, specifically from NCRP Report 164, it says, and this was quoted in our report, "This appendix provides a summary of the least squares method formula that can be used to derive the intake starting from measurements of activity in bioassay.

"The formulas assume only one intake, no prior knowledge about the magnitude of the intake, biokinetic model parameters are known

perfectly, and all the measures are independent and properly normalized."

So I guess I'd like to hear, or we'd all like to hear, your reaction to that. Because it was our understanding that, yeah, when you take the mean value of a worker's excretion rate it is a very good measure if we're only talking about a single intake, which is really where we came out with our principle finding from RPRT-53, is that we think OPOS does have a place and it's after that -- if we go back to that chart you showed us -- after that spike acute intake and that, you know, averaging those values that are clearly a result of that intake, which would pose sort of the data dominance problem of that worker submitting more samples than your normally chronic exposed worker, that we felt that was really the place for OPOS, whether unweighted and, like we just said, we feel the time-weighting represents a significant

technical improvement. So, I mean, do you want to comment on that?

DR. NETON: Okay. Tom, are you still on the phone? Are you on mute? Tom LaBone?

MS. CHALMERS: Hey, Jim. This is Nancy. Tom had to leave.

DR. NETON: Oh, he had to leave? Oh, great, because this is a question that Tom -- we talked about this and I think that's a misinterpretation of the NCRP document where it's single intake.

DR. MAKHIJANI: Joyce is the one who -- Joyce, are you on the phone?

MR. KATZ: She may have had to leave.

DR. LIPSZTEIN: Hi.

DR. MAKHIJANI: Joyce, do you want to comment on that, since you did the original analysis, if I remember right.

DR. LIPSZTEIN: -- interpretation of

the NCRP document or the agency document. That's exactly what they wanted to say. Actually the agency document, I wrote that paragraph but I think that's why you came out with the time-weighted OPOS, right?

DR. NETON: Yeah.

DR. LIPSZTEIN: They thought that the OPOS, the mean was only proper for a single intake, that when you had other measurements that didn't relate to that intake that the OPOS couldn't be applied. I thought that that's why we came out with the new time-weighted OPOS approach.

We thought a lot about the time-weighted OPOS and we came out with the same thing that we had before, that if you had, if you want to compare two distributions and the distributions don't have the same monitoring protocol -- so it doesn't matter if you use time-weighted OPOS or not -- it's not appropriate

to compare them if they have different monitoring protocols.

But I think that's what you came out on the first discussion we had today on the first paper -- correct me if I'm wrong or if I misunderstood -- but on the first paper that we discussed today, when it was appropriate to do a coworker model, how to do coworker models and things like that.

I think one of the things that was agreed upon is that you have to look at the monitoring protocol to see if they are the same strata or not, right?

DR. NETON: Yeah, yeah, definitely. I agree with that. You know, there are going to be some incident samples embedded within a routine monitoring program. I mean, that's just going to happen.

And rather than just try to guess and strip out the incident samples, if we leave them

in there and we use time-weighted OPOS, it will accurately reflect the excretion pattern for the year. And, if anything, the incident sample is going to drive the value slightly higher, the time-weighted value, but not much.

As you can see, if you account for that little blip of an incident that happens over a week period, even though it's a fairly high value, it adds very little to the overall urinary excretion for the year.

DR. LIPSZTEIN: Yeah, I made some calculations and it makes -- using either a single incident and the continuous intake using the time-weighted OPOS, the way you put it, not the way that Harry has suggested. And you come out with an intake that is, if you use the continuous intake, if you come out with a total intake in the year which is about one half of the one if you use the acute intake.

DR. NETON: It depends, Joyce. It

depends on whether the adjacent sample, the previous sample, is lower or higher. And if you could do it both ways for a large number of cases I guarantee it's probably going to come out about the same on average.

I'm not against going backwards, you know, backwards integration. That doesn't bother me. I mean, I'm totally willing to accept that. That's a detail of implementation.

I just think that the time-weighted approach is a much more accurate depiction of the person's urinary excretion for the year, rather than treating them as individual samples, which makes no sense to me, to be honest. It just makes no technical sense.

I think an integration of the area under the curve, and even if you went to a connect-the-dots, a trapezoidal-type analysis, it's a little better even, and more accurate. But I think it gets closer and closer to the true

intake of the person than if you did a full-blown model on everybody, intake model.

So that's why we're recommending using time-weighted OPOS. And I'd be happy to implement a backwards integration. Wouldn't bother me.

MR. BARTON: Well, I think part of our concern was also that we thought that the science behind doing the averaging, which is going to get us closer to what the actual intake was, we had questioned whether it applies to situations when you have mixed intakes, essentially.

And it sounds like NIOSH feels that we may have misinterpreted that report. So, maybe it’s a good idea to hear, you know, officially from Tom and he can --

DR. NETON: Yeah. Yeah, we could ask Tom about it. That’s not a problem.

MR. BARTON: -- and that might

alleviate that concern.

MR. STIVER: This is John Stiver. I have a question for Joyce. Maybe for Harry too.

Now, in our February report on OPOS, we had gone through, I think it was in Section 7.2 or one of those subsections there, that we had shown that, you know, this least squares weighting through the origin with the weightings that were, I believe, inversely proportional with variance could be shown to be mathematically related to a single intake, as according to the NCRP report.

And then the jumping-off point after that was, well, let's see how well OPOS does at estimating the true mean value of the excretion rate. And so the time-weighting then gets you a better approximation of the mean excretion rate, but it's still, in my mind, and maybe I'm wrong here, only applies to the single intake.

It doesn't necessarily -- it doesn't

provide more credibility for any other type of intake. I'd like to hear Joyce's response on that.

DR. LIPSZTEIN: Well, I think that the time-weighted is better than the OPOS itself, like it was the maximum, I don't know how it's called, the MPM.

MR. STIVER: Oh, the maximum possible mean.

DR. LIPSZTEIN: The one that was before, because when you had the excretion rates and you had -- for example, let's say the ones exactly like NIOSH is doing.

Suppose you have someone that didn't have an excretion or was not monitored during that period of time and suddenly he had an incident and assume the NIOSH proposed method you would, and if he didn't have any other monitoring the year before, you would apply that first monitoring result, which is the incident, to the

whole year before it.

So it's not that it's scientifically claimant-favorable but -- I'm sorry, that it's not scientifically correct but claimant-favorable, of course, because you are applying to the whole -- you know, let's say for one semester a guy didn't have any samples taken and then suddenly he has an incident and had one sample taken.

So the result of this sample would be applied for the whole six months that he didn't have any sample so this is claimant-favorable even if it's not, you know, scientifically reliable but it's claimant-favorable.

The problem with the OPOS as it was before is that it was not scientifically correct and was not claimant-favorable also.

So now we are dealing with that the formula could be either, as NIOSH pointed out, the way NIOSH is doing the time-weighted, or the

way Harry is proposing, which might be claimant-favorable.

But I don't think, neither of them is completely scientifically completely correct. But I think we are looking at something that is claimant-favorable.

My main complaint with this is that when you use this to compare to strata you have to be sure that the full strata, the full distributions, have the same monitoring protocol, otherwise you cannot compare them. But I think that this is explained on the first paper.

DR. NETON: Yeah, I agree with you, Joyce.

MR. BARTON: I guess the way I see it is we're kind of trying to weigh two things. One, I mean, rightly or wrongly, OPOS is sort of a data reduction technique.

Like you said, the end result is going to be a

little bit lower, which is okay if it's truly more scientifically defensible than the old method.

And that's sort of where we have to I guess come to a conclusion and put our heads together, and Tom can give us his interpretation of what our original finding was, was that it is scientifically defensible absolutely after a single intake, but maybe not if we're trying to cover multiple types of intakes, chronic, no exposed and acute, over the same averaging period. And I think that's kind of what we have to weigh.

If that is more scientifically defensible than the old method, well, then we can weigh that against the fact that the doses might be lower but we're actually getting closer to accurate dose reconstruction.

DR. NETON: I agree.

CHAIRMAN MELIUS: And the question is when is it accurate enough?

MR. BARTON: Sure.

CHAIRMAN MELIUS: Because we're not going to have perfect accuracy with these circumstances.

And then, secondly, are there circumstances where it's not appropriate? I mean, we've already talked about the monitoring issue, but there may be other situations, in terms of the nature of the incidents or whatever, in the way the monitoring programs were done or whatever, that may, you know, may just not be appropriate to use it in those.

And I don't think we have to look for extreme examples but if there are some that are practical that we encounter, we, you know, ought to be aware of those.

DR. NETON: Yeah, I agree. The one we discussed earlier was if you have a purely incident-based sampling program, and you're going to use this technique, you can come up with

a maximum bounding value and then we're going to have to decide is that sufficiently accurate?

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: Joyce or Bob, have we ever kind of made a table that compares the pluses and minuses, you know, here is the pooled data, here is the simple OPOS, here is the time? I'm kind of thinking that might give us a perspective because --

DR. NETON: Compare how, though?

DR. MAKHIJANI: You know, you've laid out some of the problems with the pooled model and you've laid out the problems with OPOS and the time-weighted OPOS and, you know, whether it's single intake and what do you do if there are multiple intakes and how close is it? Because ultimately you're trying to get something that is close to the -- that represents something close to the intakes. And maybe it's too simple-minded but --

DR. NETON: Well, Arjun, like I say, the closer you come to a -- here's one of the cases where it used the connects-the-dots analysis. I'm just showing this on the screen. Rather than using rectangles, we're using trapezoids. And that's going to be a little closer. But the question is, how far do you go? Because the gold standard is to do a full-blown intake calculation for this to get the actual intake that the person experienced during that year. That's what we're really trying to get at.

The closer you approximate these dots under real conditions, the closer you're going to get, and I can guarantee you it's not just using all the data in a pooled analysis and fitting a distribution to it. This is closer. The next closer one is the gold standard, which is a full-blown dose reconstruction.

So, to me, if you buy into the fact that a full-blown dose reconstruction is the gold

standard then you work backwards, this example on the screen would be the second best, rectangles followed by mean values followed by -- I'm not even sure using all the values makes any sense at all. So, I don't know.

DR. LIPSZTEIN: My thought, it's like if you have a person that was working the whole year in the facility, suppose you have someone that only worked for three months or six months at the facility in that one year, let's say in 1970. Then he worked in '71 and '72.

But let's say in 1970 he only worked six months on a certain facility and when you do the pooled data or when you do the pooled dose, if you have during that six months special working that made the intake and excretion rate of all of the workers during that six months go higher because you had a special job done there, and the first six months of the year you didn't have anything.

But if there were some -- you want to calculate someone that was a construction worker, for example, and he came only on the last six months, you're not going to use the whole year for him. You are only going to use six months, right?

DR. NETON: Yeah. Well, that's --

DR. LIPSZTEIN: But if they are using only six months and giving him the intake of a whole year where people had periods of no intake with periods of intake, then his intake is not going to be claimant-favorable. It will be the opposite.

DR. NETON: Right, but I think under the time-weighted approach it would be divided by the days of exposure, days he worked, right?

DR. LIPSZTEIN: Yeah, right. But that would give the mean exposure, the average exposure for the year, which is okay, the time average.

But what you lose is, when you have this time-weighted or OPOS anyway, one of them, you lose, you know, the division like before when you had the pooled approach, you used to divide it by quarters, so you could see for any quarter of the year if you had more exposure than the others.

I agree with you that, in the mean, for a worker that's worked the whole year, if you use the time-weighted it's going to be more or less his intake.

But if you had someone that worked only on that period of time where you had the high exposure, then you are going to assign to him an exposure that is less than what he really got if you use the time-weighted for all the workers. I don't know how you are planning to deal with those cases. Do you understand me, Jim?

DR. NETON: I heard the first part. The first one you agreed with me and I kind of

went blank after that.

(Laughter.)

DR. LIPSZTEIN: Okay, okay. Let's say you had the pooled approach like before, okay? You divided excretion rates in quarters of the year, let's say 1970, okay, you had four quarters.

In one of the quarters you had a high exposure, and you could see that with the pooled data, and actually in some facilities you'll get a higher intake for that --

DR. NETON: Oh, okay. I think I understand what you're saying, Joyce. We're not obligated to use annual data. The OPOS examples we've provided are annual data because that's what we currently have.

But if we have quarterly data, we would use it. It would be the same kind of thing. It would be the quarterly OPOS, I mean, the quarterly time-weighted averages.

So I don't know. You know, to answer your question, we would use all the data we can, all the data that are available, to the extent we can. And if we have enough data to do quarterly time-weighted averages, we would.

DR. LIPSZTEIN: Okay, but this is not explicit, right, and there are --

DR. NETON: I think when I talk about other monitoring intervals --

(Simultaneous speaking.)

DR. NETON: Yeah. No, we're not obligated to use a yearly basis. Maybe that seems that way because that's all the examples we've had. But I think I tried to put in there yearly or other monitoring interval, implying that it could either be more than one year or less than one year.

I could make it more explicit, because if we have quarterly data -- and you're right, early on in the uranium measurements at

some of the uranium plants we have enough where we currently have quarterly data and we wouldn't convert that to an annual OPOS. It would be a quarterly OPOS, quarterly time-weighted OPOS.

DR. LIPSZTEIN: Okay. And another thing, before when OPOS was derived, you were using all sensory data as you go to the minimum detectable activity, but when you gave the example of the time-weighted OPOS, you didn't do that.

DR. NETON: Right.

DR. LIPSZTEIN: Are you going to do it or not?

DR. NETON: Well, you don't have to take averages unless you have multiple samples in one day, right? So averages aren't involved anymore. And I am struggling with the idea of what to do with individual values that are negative. The scientist in me says that those are valid numbers. On a practical basis, I don't think we

would use them in the OPOS calculations.

MR. HINNEFELD: In a time-weighted OPOS.

DR. NETON: Time-weighted OPOS. Because there's just a number of issues. Using negative values is appropriate, in my opinion, when you're averaging values that are taken from the same distribution.

And in this particular case, these are taken from multiple samples over time under different exposure conditions. And I think that to be claimant-favorable we would just use at least -- I'm not sure whether we use a zero or the censored data point. I'm not sure. But I don't think I would end up using -- we would end up using negative values in time-weighted OPOS.

CHAIRMAN MELIUS: Okay, good. Thank you. Okay, so why don't we wrap up. It's close to 5:00. Any last words?

DR. NETON: I have no last words.

CHAIRMAN MELIUS: Okay. So --

DR. NETON: Although everybody get me your material to work with.

CHAIRMAN MELIUS: Three weeks.

DR. NETON: And if it comes in two weeks and six days, it's going to take me a little longer to digest all the material but please feel free to comment early and often.

[Identifying Information Redacted]

MR. KATZ: All right, so we're talking about anyway September. Get your comments in by September.

CHAIRMAN MELIUS: Three weeks. Three weeks is simple. Three weeks from today.

MR. HINNEFELD: Three weeks from today is the 18th of August.

CHAIRMAN MELIUS: Do you want to do the time-weighted average? The mean date of August?

(Laughter.)

DR. NETON: I recall we have a Procedures Subcommittee coming up at the end of August.

CHAIRMAN MELIUS: August 18th.

MR. KATZ: Okay. Yes, I was thinking about SC&A when I was pitching for September, but okay.

CHAIRMAN MELIUS: If you need longer, you know --

DR. NETON: Yeah, these don't have to be formal --

MEMBER BEACH: Just send a comment to that effect.

MR. STIVER: It would probably be better to try to pull them together soon.

DR. NETON: Yeah, I mean, they don't have to be formally, you know, written up in fancy White Papers or anything. Just --

CHAIRMAN MELIUS: And everyone's been so good that I think you can all come back

here tomorrow for the meeting.

(Simultaneous speaking.)

CHAIRMAN MELIUS: And thank you, everybody. Thanks, Paul, everybody on the phone.

MR. KATZ: Yes, thanks for hanging in there. I know it's tough. So take care, everyone on the phone. Good night.

(Whereupon, the above-entitled matter went off the record at 4:55 p.m.)

1