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CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH

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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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SEC ISSUES WORK GROUP

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THURSDAY
SEPTEMBER 26, 2013

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The Work Group convened in Conference Room A-11, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, Cincinnati, Ohio, at 9:00 a.m., James M. Melius, Chairman, presiding.

PRESENT:

JAMES M. MELIUS, Chairman
JOSIE BEACH, Member
R. WILLIAM FIELD, Member*
GENEVIEVE S. ROESSLER, Member

ALSO PRESENT:

TED KATZ, Designated Federal Official
NANCY CHALMERS, ORAU Team
HARRY CHMELYNSKI, SC&A*
DeKEELY HARTSFIELD, HHS
STU HINNEFELD, DCAS
JOSH KINMAN, DCAS
JENNY LIN, HHS
ARJUN MAKHIJANI, SC&A
TOM LaBONE, ORAU Team
JOHN MAURO, SC&A*
JAMES NETON, DCAS
DANIEL STANCESCU, DCAS
JOHN STIVER, SC&A*
TIM TAULBEE, DCAS

*Participating via telephone

C-O-N-T-E-N-T-S

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

9:17 a.m.

MR. KATZ: Good morning, everyone in the room and on the lines.

This is the Advisory Board on Radiation and Worker Health, SEC Issues Work Group.

I apologize for the late start but we had security matters for getting into a federal facility, and we're done with all of that.

So, for everyone's information, there is an agenda and several presentations, two presentations and two papers, all posted on the NIOSH website, on the Board site under meetings, under today's date. So, you can follow along with the presentations as they are given and you can see the background materials that are being discussed. We are not focusing on a specific site, so we don't have any conflict-of-interest matters to cover here.

So, let's just run through attendance, beginning with the Board.

(Roll call.)

MR. KATZ: Welcome. No members of the public right now. Okay. So, that's it for matters.

Folks on the phone, please mute your phone except when you're addressing the group, just so we don't have any audio problems: *6, if you don't have a mute, to mute your phone, and *6 again to take yourself off mute.

And, Jim, it's your meeting.

CHAIRMAN MELIUS: Okay. Welcome, everybody, now that we can get started.

I just want to introduce a little bit. This meeting, while in some sense it is responding to an ORAU Technical Report and the review of that, which is a little bit somewhat narrow in terms of its focus.

We are also at the same time dealing with sort of bigger issues related to

how do we deal with -- what's sufficient accuracy. And, also, there are lots of other coworker issues other than some of the ones we have focused on in these reports.

So, I would like to spend a fair amount of time today talking about that and putting those other two issues and sort of the general coworker issue as well as the general sufficient accuracy issue, because I don't think we can address the more narrow focus without dealing with those other two issues. I think they provide both context and in some ways really the way to resolve some of the differences we may have or differences in interpretation we may have over this more narrow issue.

So, I just want to say that upfront. And so, some of what we may say, it is not really a criticism of, for example, what Tom's done and other people at ORAU have worked on. It is more of let's sort of step back and sort of how do we use this and what

are some of the limitations, and what are some of the strengths of it, and where can these kinds of approaches be appropriately applied?

I think we all have somewhat different perspectives on it. I am an epidemiologist by background. So, I tend to think of exposure modeling and so forth from an epidemiological perspective, where that is different, I think, for health physics or sampling sort of perspective, or how a toxicologist or a laboratory scientist might think of some of these statistical approaches.

So, we need to sort of then take all of our backgrounds and sort of what information we have, and then put it in the context of a compensation program, which is really very different, and really very different from in some ways what this environmental sampling or another sampling that has been done at these facilities has

been intended for. It was intended to protect people, and now we are trying to use it for something else. And I think not a use that is very common necessarily, not a use that there are a lot of publications or rules on, or whatever, as we have discovered.

And I think we are sort of making this up as we go along, so to speak. I think we just have to recognize that and do the best we can.

But I just wanted to put that out. We will talk more later I think more specifically about this. But one reason I asked for an in-person meeting was so we could do this in a less formal way and maybe a little less rushed than we are with conference calls and other things. And so I do appreciate people that took the time to come here today. We beat the government shutdown or whatever may happen next week.

(Laughter.)

MEMBER BEACH: Barely.

CHAIRMAN MELIUS: Barely, yes. Yes, if your plane is delayed, you may be in trouble.

(Laughter.)

We'll see if government employees and contractors are stranded at airports for weeks. And I'm a former federal government worker, and I have lived through that also.

Anyway, I think we will start with Jim and his presentation, and then let's sort of go from there. But I don't know if anybody else has any comments at this point. If not, then go ahead, Jim.

DR. NETON: Thank you, Dr. Melius.

I would like to say I do appreciate the Working Group convening. I think this is one of the last major issues that we need to come to grips with. We have dealt with a lot of other issues, such as surrogate data and all those other things. And I think this is a key issue. Believe it

or not, I have been looking forward to this meeting because I think there are a lot of open issues that we can collectively maybe get our heads together and come to some resolution on.

I would just like to take the beginning of the meeting and present a truncated version, a shortened version, of what I put forth at the Board meeting, which is what we are doing with coworker models and what sort of drove that thinking. And then maybe like a 10,000-foot level, nothing really deep, into the statistics.

This, to me, is the biggest vexing issue in coworker modeling, is bioassay samples, how you take a bioassay sample and convert it into something that is meaningful for someone who doesn't bioassay sample. Obviously, we have a lot of measurements on people. And you have to figure out, well, if the person wasn't monitored, what potential do they have for

internal exposure, if any?

MR. KATZ: Before Jim goes on --

DR. NETON: Yes.

MR. KATZ: -- let me just check. Harry and Bill, can you hear well?

MEMBER FIELD: I don't have any problem hearing.

MR. KATZ: Okay.

DR. CHMELYNSKI: Yes, it's okay.

MR. KATZ: Okay. Very good. Thanks.

DR. NETON: So, the second slide is the summary of how we go about doing internal dosimetry coworker calculations, a little box model here. Obviously, we start with the urine data. And the second box is, we'll call them the OPOS Urine Data box.

And that is probably one of the areas where we have some significant disagreement at this point with SC&A, is what do you do with the urine data that you have? We have a lot of monitoring data. Not

everybody was monitored at the same rate. People who had a higher potential of exposure have more samples in a given time period than those that weren't. People that had incidents were sampled at a higher rate.

So, the concept was developed by the ORAU team, that NIOSH subscribes to, which is this OPOS statistic: one person, one sample. If you have, for instance, 100 bioassay samples and 30 of them are from one person, it makes no sense to include those 30 samples individually in the distribution. We are recommending that we take the average of those samples and use them as sort of -- it's sort of a bad word -- but a surrogate for their intake, because that is more representative of what their intake was, not the individual samples.

So, you have the OPOS urine data, and then we convert that to a distribution of some type. It has been our experience, and it's well-known by the Board, that worker

monitoring data typically fits a log-normal distribution. And if you do a cumulative probability plot, you get a nice function that one can fit the 50th and 84th percentile of the data. And I have got an example of a plot here that we use.

This would represent the intake for a specific year or a specific time period. Most often it's a year. If you have enough bioassay data on a year-by-year basis, we will generate a log-normal distribution for each particular year and, as indicated, calculate the geometric mean in the 84th percentile, which is one geometric standard deviation.

And most of the time they fit a fairly nice straight line, as you can see here. And that is used in the intake calculation.

This is where we have a fairly -- well, there's a disagreement on whether or not this particular function in a

given year, since it's all workers, represents all workers or are there stratifications in there of workers? And that is probably one of the key issues we want to talk about today: how do we determine if that data set is representative of all workers? Are they or are they not?

And that is almost a step backwards from a lot of discussion in the RPRT-0053, which is the sort of nuts-and-bolts statistics of how you go about determining if there is stratification. In my opinion, one first needs to decide whether that needs to be stratified in the first place. That's my opinion.

Okay. So, you take an individual year's worth of plot, for example, bioassay data, and then you have to convert that to some sort of an inhalation intake. You can't just say, well, the 50th percentile excretion is .5 picocuries per liter and do anything with it. One has to figure out what that

means in terms of how much radioactive material the person breathed in.

And so the next step in the process is to use the ICRP models and fit intake curves through the data points. So, for example, each one of these blue data points is one of those graphs. So, the 50th percentile in this graph, the geometric mean in this graph, would be here. And then you take the next year, plot it here or here or here, and then one fits a chronic intake function through the data points. And it's just a piece. We do this on a piece-by-piece basis because the data tend to be variable. And so there is some judgment involved here.

This fits a fairly nice curve. But you notice that there's a lot of distribution about these points. So, for example, here's one point and another point. This point is way down here. One fits a weighted least squares regression analysis essentially through these points.

So, remember, if the data were stratified, like on the previous slide, and there was some difference, one could calculate, say, a 10-percent difference in the geometric mean of the distribution. One would wonder how big an effect that would have on the fitting of this curve, which is where the rubber really meets the road.

So, we take, here I think it's like 14 data points. You have a few of those data points. One could show that, for instance, construction trade workers are slightly different. I'm not convinced that it makes a big difference in the overall fit here.

Another thing to remember is that the data are fit. This is just the 50th percentile. We also fit another curve, which is the 84th percentile of the bioassay data, which would generate another graph way up here. That would be the geometric standard deviation of the distribution. That

typically is a minimum in our program of a geometric standard deviation of 3. We use that as a default minimum, no matter what the data say. But, typically, it can be a GSD of 4 or 5.

So, the input in the IREP, you convert this intake to dose. The intake is not the geometric mean of the distribution. It's the geometric mean with the entire GSD around it, and that's what is sampled in the IREP program. The intake is converted to dose, of course, through that particular order.

So, we are saying our best estimate of the intake for this particular person is this fitted line, but we don't know it with a large degree of certainty. So, we're going to allow for it to be up to, you know, with a certain geometric standard deviation, that would be sampled. So, it's not an individual point that's put into the IREP. It's the distribution of all those

points. I think that is a very important thing to remember.

And, again, a 5- or 10-percent difference in one of these points, where you throw a GSD of 5 on top of it, it gets into what we have been calling, is there really a practical difference here in the calculation?

DR. MAKHIJANI: And the red dots at the left?

DR. NETON: That would be a different fitting regime. For instance, you have years and years. You would fit this to a different function than this because it obviously has some different exposure potential. So, you would fit a chronic exposure for these years and say that's my intake during these years. Then you fit a chronic exposure to the next regime that seems to fit a reasonable function.

So, there is subjectivity involved here. We'll have, for over a 30-year plant operating period sometimes -- Tom,

help me out -- three, four different regimes, maybe five or six chronic models.

MEMBER ROESSLER: It's just orange or red points are very distracting because they weren't labeled.

DR. NETON: Yes.

MEMBER ROESSLER: But I thought maybe that was back-calculating for this individual.

DR. NETON: No.

MEMBER ROESSLER: But that's just a different --

DR. NETON: That is a different exposure regime, I'll call it.

MEMBER ROESSLER: Okay.

DR. NETON: See, so, when we fit these chronic models, you pick the place on the curve that looks like it could reasonably be represented by this chronic model here, but you would go here and fit another chronic model here. It would be way up here.

So, if a person worked during

this period, he would get this intake. If a person worked during this period, he would get a different intake.

An interesting outcome of this is, if a person worked during both of these periods, you would give him this intake. At this intake, his predicted urinary excretion would be way up here. It's a way overestimate of what the person really inhaled because it's an artifact of the way we fit these little chronic intake pieces.

Tim?

DR. TAULBEE: In the earlier years, those red dots tend to be higher because you're looking at the 1950s and 1960s data.

DR. NETON: Right.

DR. TAULBEE: And then, as radiation protection programs progressed, they all decreased. This is why we do some of this piecemeal fitting, is because of changes within the program.

DR. NETON: Yes. If you look at any of our coworker models in the back, you'll see there's always at the end a series of curves, using Type S, Type M, fitting them to show what the intake patterns are during those years. And that's what we assign.

And so we are assuming that the person is chronically exposed during this entire time period.

DR. MAKHIJANI: If I remember -- and I don't have all the curves from RPRT-0053 in my head -- but this seemed to be fairly typical of what the curves look like.

DR. NETON: Yes.

DR. MAKHIJANI: And so this really sharp discontinuity, that's kind of strange.

DR. NETON: It is. It is.

DR. MAKHIJANI: So, one can understand that programs improved, but then to have a kind of a cliff where suddenly the

bioassay measurements become much lower than they were the year before or six months before is a little mysterious as a characteristic.

DR. NETON: Well, yes.

DR. TAULBEE: In some cases, the process or the program ended. And so they stopped producing, say, thorium or americium, curium, californium. And so you do see a sharp decrease of the exposure potential.

DR. NETON: Yes, and it's even more complicated than that because, remember, these people didn't necessarily quit at this time period, and they were exposed. So, they're still excreting some residual amounts into here, which is contributing to this as well. So, I don't know exactly how high this was. All we know is this is what we have experienced.

The alternate way would be to fit -- there's a number of different ways to do it, but this is the way we decided on

doing it, which is an extremely claimant-favorable approach. Again, if I worked during this entire time period, I would receive an intake up here for this period; I would receive an intake based on this fit for this period.

And you know that if I had this intake, I would still be excreting over in here, but it's not even considered. It is just like a separate intake, like step functions almost.

DR. MAKHIJANI: It seems like that.

DR. NETON: Yes, and that's the way we have been doing this from the very beginning. This is nothing unique to 0053 or anything else. This is the way coworker models work.

But I just want to point out how claimant-favorable they are and how -- and this is what I was trying to get at at the Board meeting; I did a lousy job -- how a

minor perturbation in this, because of some 10-percent, 15-percent difference in the geometric mean, is kind of lost in the way the models are built. These models are very -- there is a professional judgment involved here, and there is also uncertainty in the fits themselves.

I mean, we put a GSD of 5, or whatever, on these points, each of these points. So, you know, you will give a person an intake and, say, it's the midpoint with a whole geometric standard deviation of 5 as his dose. But the fit itself also has its uncertainties, about a 10-percent uncertainty in just fit to those data points.

So, it makes me wonder about these stratification adjustments that we could talk about later, how really meaningful they are or how practically significant they are, given what we are really doing to implement these internal coworker models.

DR. MAKHIJANI: Could I ask a

question about your box chart?

DR. NETON: Sure.

DR. MAKHIJANI: All the prior coworker models were not based on OPOS, right?

DR. NETON: That's correct.

DR. MAKHIJANI: So, this is new.

DR. NETON: OPOS is new.

DR. MAKHIJANI: So, you're essentially saying that the prior coworker models will be revised according to this?

DR. NETON: Yes, we would have to do that. Yes, the OPOS, it would actually tend to reduce the exposures, in my opinion.

MEMBER BEACH: That was one of the answers that was given in the report, that they would have revise.

DR. NETON: Yes, we would have to revise. The OPOS, it makes sense in light of our current thinking. I mean, you know, you don't think about this five or ten years ago.

DR. MAKHIJANI: Oh, yes.

DR. NETON: But, in my opinion, it makes the most technical sense of anything. And I know SC&A has their opinions on the statistical issues with that. But if you think about, again, 100 workers monitored, 100 bioassay points, and one worker has 30 of them in one year, those 30 samples, the average of those 30 samples more accurately represents his intake than putting all 30 into a cumulative probability distribution. And that's all we have been saying, and it makes perfect sense to me. And we can talk about that more.

DR. MAKHIJANI: Sure.

DR. NETON: I don't want to get too far --

DR. MAKHIJANI: Right, right.

MEMBER ROESSLER: Has this sort of an approach been used in any other fields?

DR. NETON: What, the one person, the one sample?

MEMBER ROESSLER: Yes, I think I

read in the report it hasn't really.

DR. NETON: Well, ideally, though, if you think about it, we would take and just calculate intakes for each person, right? And do a cumulative probability plot of the intake in a given year.

So, I have 100 workers who were monitored in a year. I would calculate the intake for every single worker and generate a cumulative probability plot of their intakes. But we can't do that. We don't have enough granularity to do that.

So, what we are saying is an average of an individual worker's bioassay sample is sort of a surrogate for intake. It is directly proportional to their intake. The amount, the average mount of uranium you excreted during that year, is more representative of your intake than putting 20 data points on a cumulative probability plot and saying that's the population distribution. It's not. You have to think

about worker distributions.

And so what we're saying is we're plotting a cumulative probability distribution of the workers' exposures, where one worker happens to have 20 bioassay samples. Well, our surrogate -- I hate to use the word surrogate -- our approach to defining that worker's exposure is to use the average value, not the 20 data points, which would make up 20 percent of 100 bioassay points.

DR. MAURO: Jim, this is John Mauro.

DR. NETON: Yes.

DR. MAURO: I'm sorry I didn't introduce myself in the beginning.

I have a quick question. You said something very important just now that was always at the heart when I was thinking about it. I always thought, in a perfect world. you would try to build a coworker model, and you had data for, let's say, the

100 workers, let's say, in a given year. And you would look at each worker by himself and say, okay, let's try to estimate the intake for Worker No. 1 for that year, and we would come up with his intake. And then, we would do Worker No. 2, Worker No. 3.

In my mind, in a perfect world, that would be your best data set upon which to build a coworker model. But you're saying that is not the case?

DR. NETON: I'm saying that would be the perfect --

DR. MAURO: I didn't quite follow that.

DR. NETON: I'm saying that would be the perfect world, but we can't necessarily do that.

DR. MAKHIJANI: Why not? I don't understand that.

DR. NETON: Tom, maybe you can --

MR. LaBONE: Consider the time it would take, if you had 100 people, how long

would it take to reconstruct their doses for each year for 50 years, for example? It's just the time it would take to do that is prohibitive if you consider how many dose reconstructions have we done, as far as best estimates, and how long has it taken to do them. So, we are talking about every one of these would have to be a best estimate.

DR. MAURO: I think that's why I asked the question. So, I do hear agreement that that would be an ideal circumstance, but it is an enormous burden to try to do that.

DR. NETON: Right.

DR. MAURO: Okay. Because I misunderstood --

DR. NETON: Right. I'm sorry. Maybe I wasn't clear. But, if you think about it, John, the average value of a guy's urine data ends up being sort of an indication of picocurie per liter days during that monitoring period of excretion. And, in my opinion, picocurie per liter days of

excretion is a very good indicator of intake. It is directly proportional to your intake, right?

DR. MAKHIJANI: But, you know, it is very radionuclide- and solubility-dependent. I know you're excluding --

DR. NETON: Well, that's not relevant. I mean, no, it doesn't make any difference. What you say is true, but the models are for each independent solubility class and nuclide. We have a model for every single solubility class and every single nuclide that we're trying to reconstruct. They're all different. That's why we have so many.

But you're right, I mean, the uranium, we'll do solubility Type M and Type S. You will see at the back of every one of our coworker models curves that fit both. And so we covered the waterfront of the possible exposures. And then, on top of that, we'll take the highest one, the highest

exposure potential, for the organ that is being reconstructed.

DR. TAULBEE: And one of the things to keep in mind with these models, this is for a coworker. So, we are taking these data from monitored workers and applying it to an unmonitored worker in this particular scenario.

So, if you go back to Jim's example of if you have 100 data points and 30 are from one individual worker, by using OPOS, now each worker is counted individually into this general model that we are applying to unmonitored workers, instead of one worker dominating the entire scenario. So, that's where the power of the OPOS statistic comes in.

And, as he is pointing out, the average of that is a pretty good surrogate for what their intake was, without going through the onerous calculations that Tom was talking about.

DR. NETON: And there's conservatism built in it because, remember, you have the complication of the censored data sets as well, and there is a slide that kind of talks about that a little bit, how we have been conservative in that respect as well. We don't take censored data as zero. We'll assume that it is equal to the detection limit. So, that's even another level of conservatism that is built into the calculation.

MEMBER FIELD: Jim, this is Bill. I had a quick question.

Is the assumption that the monitored workers are the ones with the highest potential for exposure?

DR. NETON: Well, we would maintain that it's either the monitored workers had the highest potential for exposure or at least were representative of the exposure potential of the workers.

And I think the key, then,

becomes in defining what we mean by representative.

MEMBER FIELD: Right.

DR. NETON: Because people can have different opinions on what that means. But if it is representative, I mean, if all strata were monitored representatively, and then you get this 95th percentile, and we have a pipefitter who wasn't monitored, I believe that the 95th percentile is an adequate bounding value for his exposure.

It could be higher. I mean, you have to pick some number. We sort of define the 95th percentile as a reasonable bound, but there is always a 5 percent chance it could be more than that.

MEMBER FIELD: Right.

DR. NETON: But, you know, you can't build a program around that. You have to pick some --

MEMBER FIELD: Right. I understand. Thanks.

DR. NETON: Yes.

CHAIRMAN MELIUS: But you are also saying that you would use the same coworker model even if everybody was monitored for each individual --

DR. NETON: If everybody was monitored, we wouldn't have any coworker model.

CHAIRMAN MELIUS: Yes.

DR. NETON: The coworker model is only for people --

CHAIRMAN MELIUS: Yes. Okay. That is sort of what you said before. I'm sorry.

DR. NETON: Yes, maybe I'm talking in circles.

CHAIRMAN MELIUS: No, no, no. It was John's fault.

(Laughter.)

DR. NETON: Yes, and the real trick is to look at the workers that weren't monitored and figure out what their potential

exposure was. And that has a lot to do with looking at the radiological protection program that was in place in that time period, and not only looking at the program, but then looking to see did they really follow up on what they said they were going to do.

And that is what I think we mean by representative, is they had a program in place to do that. In my opinion, most of the time the highest-exposed workers were monitored just because that makes sense to me. Why would you not monitor the highest exposed?

Bioassay samples are expensive. If you are trying to set your program up so that you make sure that your workers don't exceed this regulatory limit, the way they did that -- and Dr. Melius pointed out earlier -- is these programs were not designed to really estimate dose. They were designed to protect workers. The best way to

protect your workers is to monitor the highest-exposed workers to make sure that they are not exceeding the regulatory threshold. It just makes sense to me.

They weren't trying to reconstruct the dose of all the workers. They were trying to say, are my highest-exposed workers close to being over the threshold? That's what they were doing.

DR. MAKHIJANI: Well, I think, you know, we have gone over this in various contexts.

DR. NETON: Sure. Yes.

DR. MAKHIJANI: And I think it's not always true, it's not always the correct assumption You know, the neutron exposures in Rocky Flats, for example, come to mind. They didn't know -- they made a certain assumption about who was the highest exposed, but it turned out that some other group was at some potential for higher exposure.

DR. NETON: No argument.

DR. MAKHIJANI: So, there is a judgment about that.

In the case of construction workers versus non-construction workers, which is a lot of what we have been talking about, there seemed to be some kind of decision that construction workers were not as much exposed. So, they weren't as much monitored.

But the evidence we have from construction workers is that that wasn't necessarily the case. At least at Savannah River, for instance, they have said very clearly, with many examples -- and there is other documentary evidence to that effect, too -- that they were doing work that had as much exposure potential, at least very often, not always, as production workers.

But the monitoring data is very thin. And when you consolidate it into a one person, one sample per year, then you wind up with this problem very often. With certain

radionuclides, you have very few data points. But, leaving that aside, I think the idea that a certain -- so, it's not intentional, but there was an assumption around who was monitored.

At Nevada Test Site, it turned out the health physics people were more monitored than anybody else, and not necessarily because they had the highest exposure potential. It was because they were the closest to the program, and there was a certain assumption behind it.

DR. NETON: Here we have to differentiate between an incident-driven bioassay program and a routine monitoring program.

DR. MAKHIJANI: Sure.

DR. NETON: At the Nevada Test Site, the exposure potential is considered to be almost -- not non-existent -- but it's so low that the monitoring was not required. They didn't expect people to get anywhere

near the regulatory limit.

And so, the only time often that they sampled was when there was an upset condition. There was a known air sample was high. That is a different issue, I think, than when you have a routine bioassay program for uranium or plutonium where workers are routinely selected to be monitored on a periodic basis, which is what you have at Savannah River.

My question to you with the construction workers, is were or were not the highest-exposed construction workers monitored? See, that is the issue that one has to deal with. It is not that weren't they monitored. Were the highest-exposed ones monitored or not? And it is quite likely that a lot of construction workers weren't monitored. Either they were more lower exposures or they worked in different areas that weren't required, didn't require monitoring.

DR. MAKHIJANI: Actually, the monitoring data are so thin, for some radionuclides at least -- I haven't looked at uranium and plutonium. So, it may be different for the major radionuclides, and usually is.

DR. NETON: Yes.

DR. MAKHIJANI: But, for many radionuclides, there just is insufficient information to know, because there was some kind of policy assumption that you are not monitoring these people, because they are incident-driven and you only monitor them when they are incident-driven, even at Savannah River Site, it seems. And this has been NIOSH's opinion also.

So, they had routine exposure potential. Then you have a problem that, because they are not monitored for routine exposure, you don't know what the exposure potential was.

DR. TAULBEE: You know, you

indicate this at Savannah River. You are saying that you don't feel the construction trades workers were -- that they were undermonitored. But if you look at some of the data that we are looking at, take americium, curium, californium, for example, 1973. We've got 115 construction trade workers monitored in that year. The following year there's 86. The year before that there's 109.

If you look at the actual non-construction trades workers, yes, we're looking at about a factor of 10 higher where we are looking at a thousand workers. But this is for americium, curium, and californium. It is confined to two areas.

And so if you look at the procedures as to who was monitored onsite and their reasoning, they go through and they identify maintenance workers and building services. They were monitored at the same frequency as the chemical operators and so

forth, by procedure. And we see that in the data when we look at relative proportions of population.

So, there is a disconnect here as to, at least with that particular site, as to what we are hearing from some of the interviews and what we are seeing in some of the data.

DR. MAKHIJANI: Insofar as I remember the analysis of the data that we have looked at, there hasn't been a demonstration of what you have just said: that here were the construction workers -- I mean, apart from the question of whether we have a representative sample of construction workers or not, which remains to be settled. But we haven't seen, at least I haven't seen, an analysis that the construction workers who were monitored worked in these locations.

And for thorium, for example, we actually don't have a notation in the records as to who was working with thorium. And they

weren't the same places where americium, californium, curium, or the same times necessarily.

So, you've got this disconnect. You are trying to dose reconstruct for one thing, and you've got another set of data. But the processing was happening at different times and places. So, how do you know whether the most exposed people with thorium were monitored or whether that data set is representative for this other radionuclide? So, it is a pretty big puzzle.

DR. TAULBEE: Let's get into a site-specific-type issue.

DR. MAKHIJANI: Yes.

DR. TAULBEE: What I am trying to bring it back to is from a construction trades in general across all sites --

DR. MAKHIJANI: Right.

DR. TAULBEE: -- and I was using this as an example here.

But, I mean, jumping back to that

initial point of representativeness, there is lots of weight-of-evidence type of information that should play into that particular role. And maybe we haven't done a good job of explaining all of that details in the report, and perhaps that is something that we should do in future coworker-type models, in explaining that, why we feel this is representative.

DR. NETON: Yes, I think we have this little section we call pedigree of the data, and the pedigree of the data usually talks about number of bioassay samples and quality of the data. Does it have a sufficient detection limit, censoring, that sort of stuff. But we never really get into the next level, which is are the data representative? If we are going to build a coworker model, are those data sufficiently representative that we can use it to do that?

In some cases, I don't know how you would even define that, though. Savannah

River happens to be a site where we have a lot of data to look at.

CHAIRMAN MELIUS: But I think if we are going to -- I mean, I think everyone agrees that all this is very site-specific when it goes to application. There's lot of different scenarios we can come up with and we have already experienced.

But I think you're correct, Jim. I think if we are going to be using these coworker models, we need to sort of have a checklist of what kind of pedigree issues do we look at, and probably more level of detail on the administrative aspects of the monitoring program, for example.

I think there are also issues, just, you know how many people do we have that were monitored? How are we, then, applying their monitoring data to how many people? What's the proportion between the two?

I mean, I think one of the things

that Arjun was sort of referring to was that if we only have five people monitored and there's 6,000 people that were exposed, then, you know, that is a different scenario, and that is also an exaggerated scenario, because I don't think you would be doing a coworker model in that case. But it's that thing. It's a lot different than if you have 90 percent of the people monitored.

And then you have to go year-by-year, what do you have in terms of production data, source-term data that would tell you should exposures be going up or down? What was happening with the radiation protection program, and so forth?

DR. NETON: I think the percentage of workers that were monitored is kind of fraught with some air of uncertainty because you have to look at were the workers exposed? My classic example is, you know, in a hospital, maybe 2 percent of the workers in a hospital are monitored because only 2

percent of the people work with radioactive sources in hospitals. So, if you have a very small percentage of workers that are monitored, it may be because those would be only ones that had high potential for exposure.

That would have to be demonstrated or discussed, but I think that is true in many cases, especially for these exotics. Maybe two dozen people work with these exotic radionuclides. And so it's not surprising that you will have 20 samples or 30 samples, even though the site population is 6,000.

CHAIRMAN MELIUS: But if we are applying the results from the 20 to the 6,000 --

DR. NETON: Yes, that's a problem.

CHAIRMAN MELIUS: -- that's a problem on that.

DR. NETON: Yes.

DR. NETON: Often, the difficulty has been to show that the population of workers who had the exposure potential, that that was the universe of workers who had the exposure potential.

DR. NETON: Well, but, again --

DR. MAKHIJANI: I think it's tough.

DR. NETON: Yes, it is. But, again, I think if you look at what they are doing, these are compliance-driven programs. If I had a compliance-driven program, I would make sure that the workers I thought had the highest potential to be exposed were monitored to demonstrate that they didn't exceed the regulatory limits. I wouldn't start monitoring the lowest exposed workers. In fact, I wouldn't even do representative workers because that is a lot of money spent without much -- unless maybe to demonstrate that your controls were adequate.

But, in general, though, I think

it can be -- well, you have to demonstrate it. But I think the way the regulations were in place at the time, the highest-exposed workers were monitored, by and large.

And one can't, then, pull out a subset of workers, for example, and say, "Oh, this set of workers has a higher mean value, geometric mean, than the coworker model," and say that's proof that the model is inadequate, because they were the highest-exposed workers. And you have got to look at why these other workers weren't monitored. It's as important, I think, to talk about why the other workers weren't monitored, as to why the other ones were.

I mean, because if you look at the job categories of workers that were monitored, and then oftentimes these 50th percentile values are applied to almost administrative-type or people that had job assignments that appeared to not involve very high exposures. The 50th percentile with a

GSD of 5 is applied to people such as clerks that may have rotated around the plant, security folks, firefighters, inventory control people. Those are the type of people that get the 50th percentile.

And then the 95th percentile is reserved for the Class where maybe the guy was monitored, but we can't find his bioassay data. And he was a chemical operator. Well, then they would receive the 95th percentile, or the pipefitters. And I think the 95th percentile is bounding.

To start making these strata up at the 95th percentile, I don't know. Given what we are doing with all this, to me, it seems to be giving credibility to a level of precision and the available data that isn't there. That's my opinion.

CHAIRMAN MELIUS: Yes, but I think that -- without beating this example to death, I think there needs to be sort of a demonstration of that at some point. You are

already claimant-friendly. Any change in procedure is going to have a minimal effect.

DR. NETON: Yes.

CHAIRMAN MELIUS: As much as we want to avoid, you know -- and we have talked about it in terms of sufficient accuracy dealing with the residual period, a period when we know exposures were low. We're not going to spend a lot of time worrying about that or developing complicated coworker models, or whatever, for those time periods because it just doesn't make sense in terms of any outcomes that we might have.

DR. NETON: We could do that -- and we have thought about this quite a bit. It is hard, though, to come up with a good example. I mean, any example you come up with is just that. It is an example of one case. And one can always speculate some other scenario that would end up with a much higher --

DR. MAKHIJANI: Really, Jim, what

you have raised is a very important thing in the whole sufficient accuracy argument.

DR. NETON: Yes. Right.

DR. MAKHIJANI: It's that you have, within construction workers, you know, when we did the analysis for the tritium, most of the construction workers did jobs that appeared to have lower exposure potential in most periods than the all workers, at least if I am remembering our charts correctly.

But that wasn't always the case. Sometimes there were big differences, and pipefitters and laborers I think were the two that stood out. And you can imagine, physically, from the nature of their work, that you expect they're working with the valves and pipes that carry high-level waste, and so on and so on and so on, or in the reactors. So, you expect that result from the nature of their work.

And so I think for those kinds of

workers, based on the nature of the work they did, some kind of demonstration is needed that, well, if you are doing an all worker model in which that particular group of workers is a small minority, that what you are doing is adequate.

DR. NETON: But what you are saying is these were the monitored workers that are contributing to the upper tail of the distribution to begin with.

DR. MAKHIJANI: But there are very small number of construction monitors who were monitored. One of the points that we made is that, especially when you do all this aggregation, the construction worker data is lost.

And maybe, Harry, you can pitch in because this is a point that you made. It's lost in the all worker data.

DR. NETON: But they are in this distribution, Arjun. And if they are up here, they are covered. If they are down

here, they are covered. Because we would take a pipefitter and give them the 95th percentile, this entire distribution.

DR. MAKHIJANI: You are giving them the 95th percentile of the production work. So, you're giving them the 95th percentile basically of the production worker distribution. Because there are very, very few construction workers in there.

DR. NETON: Right, but they're in there, and if they are in the upper tails -- unless they are above the 95th percentile, unless all tritium-exposed workers are above the 95th percentile, which I doubt, then I think the 95th percentile is bounding.

We tend to confuse high monitoring results with a certain worker population and saying they were highly exposed, but then now we have to look at the unmonitored worker. What does it mean for them? And those high-exposed workers are built into the distribution.

And, yes, if they are in here, unless you can demonstrate that they are well above the 95th percentile somehow, I don't know --

CHAIRMAN MELIUS: I mean, I can think of scenarios where they wouldn't be above the 95th -- or they would be above the 95th, and well above it, if all your production workers were quite low. It depends on the situation. I think that needs to be -- at least it has to be evaluated in some way.

DR. NETON: Right.

CHAIRMAN MELIUS: And the problem with that, I mean, I think we all know, is that often we don't have very many of a particular group of workers monitored. So, it may be difficult.

But what data we have, I think we have to look at it and take account of it. Is that a fair assessment? It may very well be in this particular example, but it may not

be in other situations.

DR. NETON: But, again, if you go back to the premise that the highest-exposed workers were monitored, the unmonitored workers were not exposed as highly as the monitored workers. I mean, if you can demonstrate that, that the highest-exposed workers were monitored, then you're trying to reconstruct a dose for someone that has no monitoring data. And there may be valid reasons why they weren't monitored, because their exposure potential is low or much lower; they were down in here. You can't assume because a few data points show a high exposure that all coworkers should receive that exposure.

CHAIRMAN MELIUS: Yes, but I don't think you can assume the other way, either. I think you have to base it on some level of information and facts.

DR. NETON: Right. You have to look at the radiation protection program that

is in place at the time.

CHAIRMAN MELIUS: Yes. And, again, if it is one worker and there was an incident or something, that is very different than if it were 30 people that were monitored out of 100, or whatever, that would fit into that group.

And a lot depends on how could their exposures have differed from those of the average production worker or the distribution of production workers, as an example.

MEMBER FIELD: Jim, this is Bill. I had a question.

DR. NETON: Sure.

MEMBER FIELD: That question about the assumption that the highest-exposed workers were monitored, and I think the 95 percent percentile would probably be bounding. But, just for the record -- I am not advocating this -- but why wouldn't the 99 percent percentile be used?

DR. NETON: Why wouldn't it be? It's convention. That is what we've adopted in this program in the very beginning. There is no real reason why it couldn't be used, but this is what we have chosen as sort of a default value. And that was actually early on in dealing with SC&A and these models. That's what we both sort of agreed upon.

DR. MAURO: Bill, this is John Mauro.

MEMBER FIELD: Yes, John.

DR. MAURO: One of the reasons I became comfortable with the concept of the 99 percentile value, whether we are dealing with external or internal, is the way in which it's being implemented is by year. So, if you have a worker that is there for many years --

MEMBER FIELD: Right.

DR. MAURO: And I would agree with you. If you were looking at a worker that was there just for one year, and you

wanted to assign some number to him, one could say, using the 95th percentile, well, there is a 5-percent chance that his exposure might have been higher.

But that is not the case, though, if a worker is there for many years. To say that this same worker happened to fall above the 95th percentile year after year after year, now you are getting into the realm of infinitely-small probabilities.

So, I have become comfortable with the concept of the upper 95th percentile as being the basis for constructing your coworker model because it's almost intuitive that, do you really believe it is likely that the same worker is going to be in the upper 5 percentile year after year after year? So, that's how I became comfortable with that position.

MEMBER FIELD: Yes, I understand that. But if you have workers with a short duration of exposure, it sounds like, if you

want something to be surely bounding, the 99 percent percentile might be worthwhile considering.

DR. MAURO: I understand that, and I am inclined to agree. Most of the time, when we were doing our work, we noticed that the workers were there for many years. But you're right, if it is a single year, that is a reasonable question.

But while I still have the time, we jumped over this OPOS -- bear with me. I know we're into the stratification part of the conversation, and that is by far the single most important question. But I do want to put the OPOS question to bed because I think it's something clearly separable from the stratification question, unless I am wrong.

I think it is important that we say, listen, if we have a population of workers and we all know that they come from the same distribution -- okay, we know that

there is no strata, okay, there is only one strata, okay? But we also know that only 10 percent of the people, whatever the percent, of those workers have bioassay data, and some workers have maybe two samples, one sample, some have 20 samples. But only a percentage of this single strata. I'm sort of stipulating that.

I just want to make sure that everyone is comfortable and agrees that the OPOS approach to simplifying the construction of a coworker model is valid. Namely, not doing -- remember, the question I originally asked was, why wouldn't you do the complete workup of each of those individuals? Let's say it is 100 individuals for that year. And that would be a burdensome effort. That is, you would have to model the intakes using all of the bioassay data for each person, as opposed to the averaging approach, the OPOS approach.

So, that question, that issue of

OPOS as a strategy, in my mind is a separate issue from the stratification problem. Is everyone comfortable that, if we know we are dealing with a single strata, and we want to build a coworker model for that single strata, the OPOS approach is okay? And that is, we are comfortable reducing each person to a single average concentration in the urine as being a metric for the purpose of building a coworker model.

I think it's important that we get that behind us, so that then we could say that, okay, we're okay with OPOS as a method for building a coworker model for a single strata. Now the question becomes, you know, how do you deal with the possibility that there may be multiple strata that we have to deal with? Or are the two confounded in some way? Right now, in my mind, they are separable, but maybe I'm wrong.

DR. MAKHIJANI: Well, you know, John, I don't know, there have been a number

of reports in which we have dealt with this question. You know, we haven't said we accept or reject it. As you noted in your report, we haven't kind of given you a finding on that because we see that there is some basis for your argument that when you have 20 samples from a single worker, that at the same time we have had other problems with it.

You know, when we get into the OPOS, we can discuss them. But we haven't been comfortable with the OPOS approach. And so we've raised concerns about it both in our review of RPRT-0053, and then, as we got deeper into it, when the model was actually applied in neptunium and thorium and americium, we actually developed more concerns with how it was being applied.

So, we have a significant number of concerns with OPOS as it stands today in the reports that we have sent to the Board.

DR. NETON: Well, I guess my

question is, if it's not OPOS, then what is it? You know, if you are advocating for using the individual data, then we just can't accept that. And I don't know any other better way than to use the OPOS method. So, that's kind of where we are.

DR. MAKHIJANI: One reason we haven't -- and, Harry, you know, please say something. And I'm sorry, actually, I should have asked Joyce to be in on this discussion. I didn't think of it.

But many of our concerns are expressed in the most recent report we've sent you. So, one concern is the way the OPOS data are compiled, you've gone into the logbooks and used the raw data rather than when the logbooks say report less than .3 or some censored level, and you use all the negative numbers and the numbers that are zero or very close to zero, much less than the detection limit, and then average them all. Very often, you come out not only with

a number that is much less than the MDA, but with a negative result for the OPOS value.

And that's clearly physically unacceptable to have a negative number for an average exposure of a worker for a year, because, if you apply that in a dose reconstruction, you get a negative radiation dose.

DR. TAULBEE: I don't recall that.

DR. MAKHIJANI: Sorry?

DR. TAULBEE: I don't recall that happening a lot.

DR. MAKHIJANI: It does happen a lot, in some cases. If you look at the late `80s, if you look at the late `80s for americium, californium and curium data, you will find that it happens a lot.

DR. NETON: I would suggest that is an implementation issue.

DR. MAKHIJANI: Well --

DR. NETON: Now, are you saying

that OPOS is okay except for how we implement it?

DR. MAKHIJANI: No. I'm just raising that as an example of a problem.

Then, there is the issue of losing some of the variability.

A third issue that I have, for instance, is if, as appears to be the case at the Savannah River Site, one group of workers has an incident-driven monitoring and the other group has both incident and routine monitoring, dominated by routine monitoring. If you are compressing -- so, there is a use of OPOS for comparing. And when you compress the data into a single sample, and you already have very few samples to start with, now you have got far fewer samples which are non-comparable. And you can say you're going to compare incidents with incidents, as you said in your report, but that's not what actually happens in practice.

You are comparing an incident-

driven monitoring set, which assumes that certain exposures are only incident-driven, which assumption may not be correct, and I would argue for some construction workers, at least what they have said, it isn't correct. And you are comparing it with a much larger data set that was collected based on a different idea of exposure potential. So, I think --

DR. NETON: Well, that would only tend to drive the data high. I mean, it would bias the models high.

DR. MAKHIJANI: Not necessarily. We recognize, of course, that it would, but if you missed all the routine exposures of one group of workers, then you have missed a lot of exposures for many workers because you are not monitoring them.

DR. NETON: Oh, well, I'm confused then. Because we would have a routine program intermixed with some incident results. I mean, there is no doubt in my

mind that routine programs are going to show up positives and they are going to do more follow-ups because there was an incident that the routine program detected. That is what we are talking about here.

I don't think that you are going to mix a routine monitoring program for uranium with an incident-driven program for uranium. They are sort of part and parcel of the same monitoring program. It's just you do more follow-ups when you have a positive routine. Or there was evidence of an upset condition where you had a high airborne and you said, "my goodness, these people are in trouble, let me take some urine samples." Well, those are going to drive the distribution to the high end. It's conservative.

DR. MAKHIJANI: What we've said in the specific instances in which we studied -- because these are all new, so we have to take the examples as we have looked at the

actual data and its application.

In the particular applications, what we've said is that there are many workers who may have had routine exposure potential and who may have had incidents. In fact, construction workers have said, you know, incidents weren't followed up for them.

And so if there wasn't the routine monitoring program for this one group of workers, we have an insufficient data set where all the --

DR. NETON: That is different than OPOS, though. OPOS is used when we have routine monitoring data, a routine monitoring program in place.

DR. MAKHIJANI: Well, you have said for construction workers at Savannah River you didn't have a routine monitoring, and you are still using OPOS for it. That's part of our problem.

DR. TAULBEE: That's not true. We have not said that it was not routine.

There were some that were monitored routinely. The maintenance folks that were inside the facility were monitored routinely, and those were construction trades. There were pipefitters within that group, and they are included as part of that routine. And then there were others who are incident-driven. So, you've got both.

Now, the relative population of operators to building maintenance is different, yes, but there was both routine and incident for both populations.

DR. MAKHIJANI: Unfortunately, I don't have a searchable report.

MEMBER ROESSLER: Arjun, what I am trying to get as I weigh this is, if you don't use OPOS, then what is your alternative? And why would that be better? That is, I think, what we are really talking about. We can't just toss something out unless we have another route to follow.

DR. MAKHIJANI: Well, normally,

we haven't -- you know, we weren't tasked to come up with an alternative. We were tasked to review what was on the table. And I would agree that we haven't, so far as I know, we haven't put an alternative on the table.

But, if the objections to the OPOS are valid, then it's a very important question as to what you would use. I'm not saying it is not a legitimate question. It is important and it needs to be considered.

We haven't put an alternative on the table. We haven't said that OPOS doesn't have merit. We have said that it has certain problems that need to be addressed. And maybe we should look at the question of what the alternative would be, quite apart from how the OPOS data was in practice compiled, which is a big problem.

CHAIRMAN MELIUS: I have read some of the SC&A reports, recent reports on SRS. I think the answer to John's question is that we need to look at OPOS, we need to

see -- it has benefits, potential benefits. It has potential limitations. And those are probably going to be site- and situation-specific. I think we can look at those in that context.

Certainly, the issues that SC&A has raised about OPOS and stratification, the evaluation of stratification, I think are significant. Can they be overcome? Do they mean we don't use this technique? I don't know. You know, Gen's right, what are the alternatives?

I actually was thinking, as we were talking, this may be the first time -- if we decide that you can't use OPOS and that your whole coworker approach is negative, it will be the first time we have written a report to the Secretary saying NIOSH has sufficient data, but doesn't want to use it, the dose reconstruction.

(Laughter.)

Or refuses to make the time and

effort. We might get a letter back in that case, I think.

DR. NETON: One other on this point on the OPOS that we hadn't mentioned, is that there is a correlation of data, which to me is a statistical issue that can't be ignored. I mean, if you have 20 samples on one person and incorporate them individually in the distribution, recognizing that they are fully correlated because it is the same guy being sampled repeatedly, it just doesn't make any statistical sense.

MEMBER ROESSLER: So, what we should be weighing is what you just pointed out, the really big issues that are of benefit, against maybe some of the small concerns.

CHAIRMAN MELIUS: Exactly. I agree, Gen. And I'm sorry to interrupt. But I think we need to evaluate how big, how much difference does it make or doesn't make? My statistical training, you know, if you had

multiple samples from a person, that was a no-no to combine those. You would never do that. But, you know, that was theoretical statistics, not necessarily practical statistics.

And I think we have to see what level of difference it makes and what the situations, and try to understand what variability there is and what accounts for that variability within an individual with multiple samples.

DR. NETON: I think I would appreciate it if SC&A would review this from the implementation perspective, which is the intake calculation perspective. I get the sense from looking at the SC&A report that it was a purely statistical review. It didn't incorporate the practical significance of what a coworker model really is, which is an intake model.

And if you are trying to generate an intake model, you need to start with

intakes, as John Mauro talked about, recognize we can't do that. This is the most reasonable alternative, in our opinion. And if anybody can come up with a better approach, we are all for listening for it.

But we can't just isolate your review in a statistical vacuum and say, you know, there's heteroscedasticity and all this kind of stuff. I mean, this is the practical significance of the correlation of data with people, and you're trying to get an intake for everybody. If you have one sample, there is no question. Picocuries per liter days for the whole year, that's his intake. But if you have five samples, you have to estimate their intake, and it's not each of those samples in the distribution. So, that's the nuts and bolts of our opinion.

DR. MAKHIJANI: Yes, I agree that our review of RPRT-0053 was essentially statistical, but our subsequent reports in which a review of the method is automatically

a part of it -- and Joyce was a big part of both reviews -- we actually have some health physics implementation, dose calculation, intake calculations type of concerns that were laid out both generally as with regard to the sufficiency of the data, and also in regard to the use of OPOS.

I mean, new concerns came out when we actually tried to take this set of concerns and look at how the method was actually applied in the two cases that we have reviewed. And so, actually, in a way, it might be useful to look at all those findings together. I know NIOSH hasn't had time, perhaps, to look at especially the most recent report that just went out a couple of weeks ago. And it's a pretty long, complicated report. But that might be a useful thing to do.

CHAIRMAN MELIUS: Before we drink the OPOS Kool-Aid --

(Laughter.)

DR. NETON: Well, I certainly haven't looked at those reports in any detail.

DR. CHMELYNSKI: If I could interject here. This is Harry Chmelynski.

MR. KATZ: Yes, go ahead, Harry.

DR. CHMELYNSKI: Okay. I would like to go back to the two plots that were shown in the PowerPoint presentation and just make a couple of comments.

First, on the slide that says the regression -- using the regression on order statistics procedure. One of the things I think that is hidden in this plot is a big assumption that up there on the far right there is the worker who is 20 times the geometric mean. And what ROS does is assume that, out of those 140, or whatever it is, 140 non-detects, there must be one of them that is down there 20 times lower than the GM.

In other words, the ROS method

assumes a symmetry around a geometric mean. So that for every worker who has high exposure, we are assuming there is somewhere in those non-detects another worker that has just as low of an exposure compared to the geometric mean.

In this graph, we are talking about almost half of the data points that we are making an assumption for, that they are all symmetric to what we see here. Now, nobody can decide whether that is true or not. But sometimes, when you start getting down to a factor of 20 or 50 or 100 below the GM, it stretches the imagination that, indeed, there are workers down there.

DR. NETON: I would disagree, Harry. There are many people that have zero exposures or very close to zero exposures. I mean, that's the --

DR. CHMELYNSKI: But you can't measure this, though. Twenty times below the GM, are you sure you can say that?

DR. NETON: No, you can't measure it, but I am saying all we're saying is it's below that. I mean, there have been studies --

DR. CHMELYNSKI: Whether or not you're not just saying it's below that, by assuming a log-normal distribution, you actually are assuming they are on the line all the way down there.

DR. NETON: Actually, we have another TIB on this that deals with the distribution of detectability. If a person had zero samples, you have a normal distribution of detectability around the detection limit. But I don't see your point, really, because all --

DR. CHMELYNSKI: I'm just saying that we are making an awful big assumption here that, out of the 100-and-some non-detects here, that we know how they are arranged on that line.

DR. NETON: Yes.

DR. CHMELYNSKI: And that is a big assumption, is all I'm pointing out. I am not saying that it's necessarily wrong.

DR. NETON: What significance does that have, though, in terms of reconstructing doses?

DR. CHMELYNSKI: Well, there is the whole question of sufficient accuracy. Exactly what does this log-normal plot mean? How well did we estimate the log-normal distribution that we say we are going to be using on the next page?

Okay. Now, we get to the second page. Several times an issue was raised saying, well, if these points were 5 or 10 percent higher or lower, what difference would it make? Well, we're not talking 5 or 10 percent here; we are talking factors of 5 and 10. That is a big difference between 5 and 10 percent.

DR. NETON: Where is the 5 --

DR. CHMELYNSKI: I just don't see

this -- that these are plus or minus 10 percent, what difference would it make? That presumes that there are no differences in the --

DR. NETON: Wait, wait. Factors of 5 and 10 --

DR. CHMELYNSKI: That, again, is by assumption because there is not enough power to determine if there are.

DR. NETON: Wait, wait, Harry. Five and 10 on what, on each of the points?

DR. CHMELYNSKI: A factor of 5 and 10.

DR. NETON: On what?

DR. CHMELYNSKI: On the individual points for an exposure. I mean, you don't know that the two groups that are the same. So, you are assuming that the guy -- that they all fit on this curve. Now, in fact, if there was a difference of 5 in the two populations, you are going to use the same curve for both of them. That's my

problem with it.

DR. NETON: I'm missing it. I think what you are saying is there is so much variability, it's very hard to detect small differences in values. Yes, I'll agree with that.

DR. CHMELYNSKI: Well, your term of small, which, again, goes back to 5 and 10 percent, and my idea of small when you're talking factors of 5 and 10 --

DR. NETON: Are you saying that there are individual coworker models that are stratified that have a factor of 5 or 10 difference in the geometric mean?

DR. CHMELYNSKI: I'm saying that you couldn't see that when you did your test if the sample sizes are too small.

DR. NETON: Right.

DR. CHMELYNSKI: That's all I'm trying to say here. You know, we are making a lot of things here by assumption, basically. There is not enough data to

support either the first plot or the second plot.

DR. NETON: Right, but my point was that, you know, one can stratify and pull out some construction workers and show that, "oh, my goodness, there's a 10-15 percent difference in this particular year," and use that as an argument that the data need to be stratified. And I'm saying that's not going to make a difference in the overall practical -- it is not going to make a practical difference in the dose reconstruction. That is what I was trying to argue. Just because you could come up --

DR. CHMELYNSKI: I agree, if you are talking 5-10 percent, then I agree there is not a difference. But I just don't see that we are only talking those small differences.

DR. NETON: Well, have we seen those kinds of differences in the stratified data? That's what I'm trying to say. Have

we seen a factor of 5 or 10 difference? I would agree, if there is a factor of 5 or 10 difference in a data set that we had compared to the coworker model, there's an issue there. I would agree that's true.

DR. TAULBEE: If you look at the americium, curium, californium, the exotics at SRS, there is one year where there is a factor of 4, and the other ones it's less than a factor of 1. There is one year, 1985, where construction trades are a factor of 4 higher. One year.

DR. CHMELYNSKI: And that is if we just rely on arithmetic calculations on the actual data, which is a small data set.

But, in terms of the hypothesis-testing, again, this is going to get back to the power question, which hasn't been brought up yet, but maybe we should defer until later, as to whether the sample sizes here are sufficient to make these kinds of statements.

DR. MAKHIJANI: Could you go back to the previous chart?

When you were explaining the below MDA measurements -- and that slide when Harry made his point -- you said that the usual assumption is that below MDA measurements are assumed to be normally distributed.

DR. NETON: Well, they can be, yes. There is a component of that --

DR. MAKHIJANI: That is what you often assume in your dose reconstructions, right? Individual dose reconstructions are often done, maybe not always, but generally done that way. The below MDA measurements are assumed to have a certain distribution around --

DR. NETON: No, they're not normally distributed. What is it? For an internal dose reconstruction, when you have below the MDA, we assign the MDA as the midpoint of the distribution. The 95th

percentile is the -- I've forgotten this. It's not a normal distribution.

DR. MAKHIJANI: Unfortunately, I don't have that thorium report in front of me, because we listed all the ways in which you do that. You sometimes use MDA over 2 for every point.

DR. NETON: Right.

DR. MAKHIJANI: And sometimes there is a distribution around the MDA with zero as the minimum and MDA as the cut-off.

DR. NETON: Right.

DR. MAKHIJANI: And one of the problems we had -- and this relates to how the OPOS data were actually compiled -- is that you didn't do that when you compiled the OPOS data. Although you say that censored data are going to be treated in a certain -- yes, you say that in the report, but if you look at what is considered as censored data, in the actual data compilation, we were surprised that this

procedure wasn't actually followed, because not all of the points that are treated that are noted in the logbooks as report less than a certain value, whatever the MDA is, were not treated.

That is part of the objection we have been raising. The actual compilation is -- very often you get numbers that are zero, less than zero, for the OPOS values because you didn't adopt the same procedure as you do in your dose reconstructions for compiling less than MDA data.

DR. NETON: Wait, wait. Dose reconstructions where we have data are different than assembling coworker models.

DR. MAKHIJANI: I understand that, but --

DR. NETON: When you have real people data, we are not going to use a coworker model, remember.

DR. MAKHIJANI: But you are compiling real people data here. You are not

compiling -- to prepare a coworker model, you are compiling real people data into some kind of a distribution.

DR. NETON: That's what we're --

DR. MAKHIJANI: And when you come out with data points that are below zero, below actual arithmetic zero, sometimes with great frequency, because you are not actually using the censored value that is written in the logbooks.

DR. NETON: Those are going to appear down in -- they are not even going to be reported on this curve. They are censored data at that point. If it was below zero --

DR. MAKHIJANI: But they are not being treated as censored data.

DR. NETON: But it doesn't matter because it is part of the cumulative distribution. I mean, they are down here, Arjun. I mean, when you do a cumulative probability plot, they all fall down in here, not up in here, which is what we are trying

to estimate.

DR. MAKHIJANI: If you take a look at the thorium report that we just sent you and look at the years in the `80s that are called out in there, and look at how many negative numbers you actually have, arithmetically-negative numbers, as numbers to be used in a coworker model, I think you would be surprised.

DR. NETON: I think we are confusing two different things here.

DR. TAULBEE: We will look at it.

DR. NETON: There's the thorium report --

(Simultaneous speaking.)

DR. TAULBEE: The maximum mean methodology, we will look at as to how that occurred, because I don't think that --

DR. NETON: Yes, I can't speak to that. It sounds odd to me, what you are saying. And if we did, maybe we didn't follow our own method.

DR. MAKHIJANI: Yes, it certainly surprised us.

CHAIRMAN MELIUS: Can I suggest that, since Jim has already made it through the first four slides in about an hour and a half, that why don't we take a short break? We will see if we can speed him up. He needs a little more coffee.

(Laughter.)

Okay. Why don't we reconvene in 15 minutes, at quarter of?

MR. KATZ: Okay. I'm just putting the phone on mute.

(Whereupon, the foregoing matter went off the record at 10:34 a.m. and went back on the record at 10:49 a.m.)

MR. KATZ: Okay. We're back.

I'll just check. Bill, do we have you on the line still?

MEMBER FIELD: Yes.

MR. KATZ: Great.

CHAIRMAN MELIUS: Jim, do you

want to try another slide?

DR. NETON: I might try to move on. All I have to say is that it has been a very interesting, I think somewhat -- maybe not productive, but evolving conversation.

(Laughter.)

Okay. So, here's how we do the coworker model. And I just wanted to talk about the application, you know, how these coworker models are really used.

I alluded to this when I talked about the intake slide. Based on the potential for exposure, you take the unmonitored workers, and they are not all the same flavor. You have workers could have frequented the area, been exposed to airborne particulate, weren't working directly with materials. Then there's the workers who had their nose to the grindstone, so to speak, chemical operators, that sort of thing.

And so I like to say that we essentially have a two-component job exposure

matrix: the 50th percentile with the full distribution and the 95th percentile. That is our job exposure matrix, and it's very simple.

So, the full distribution would be applied to these sort of -- how would you want to call it? -- intermittently-exposed or not-heavily-exposed workers, with the full GSD. So, again, the 50th percentile with a GSD, a minimum of 3. Sometimes the distributions are tighter than that, but we have recognized the biological variability of the urinary excretion. It's a limiting factor of 3, just because of the way the models are and differences, various differences, in the way excretion patterns work. I won't go into the details of that, but we have adopted a GSD of 3.

So, again, that intake is converted into a dose. You know, if you so many picocurie-per-day intake over this time period, chronically, what's your dose to the

liver, if that is the cancer of interest?

And so the liver would be assigned a dose that would be proportional to the GSD with the full distribution. The dose is directly proportional to the intake.

DR. MAKHIJANI: Proportional to the GM.

DR. NETON: Yes, the central estimate of the dose is proportional to the GM, and then the GSD is added on top of that.

DR. MAKHIJANI: I see.

DR. NETON: And that is sampled repeatedly in IREP. So, it'll sample the GM, it'll sample the 95th, the 99th. It will go through just like Monte Carlo is supposed to work, recognizing that the program pays at the 99 percentile. And so you can't exactly figure out how that skews the sampling of that distribution, but, clearly, adding that uncertainty does skew the PC value in the positive direction because you are allowing for this uncertainty.

I thought at one point we could actually figure this out, but you can't because the cancer models themselves have uncertainties. And if you have a very uncertain cancer model, even with a GSD of 3, it might not contribute much to the 99th percentile.

So, it's not obvious, but it does at least -- it has to skew. The larger the uncertainty, the more it skews and biases the result and keeps the value high.

DR. MAKHIJANI: Is that true based on what you said when Harry was talking about, you know, for each point, let's say, a factor of 20 above the GM, you have a factor of 20 below the GM. So, you are sampling the whole space that is below the GM. And in many cases you've got these artificially reconstructed points that are below the MDA that may be a factor of 100, a factor of 50 below the MDA. So, you are also sampling them as frequently because they are half the

points that are below.

DR. NETON: You are, but the program selects the upper 99th percentile of the PC value.

DR. MAKHIJANI: Oh, that's a different --

DR. NETON: You generate a distribution of PC values that are proportionate to that envelope.

DR. MAKHIJANI: But the question is whether you're generating a distribution, a dose value that is necessarily claimant-favorable when you sample the whole distribution based on a GSD.

DR. NETON: You do. You do. Trust me.

DR. MAKHIJANI: You do?

DR. NETON: Yes. Definitely. We went through this before. In fact, for the most part, it is almost as if you would pick the 84th or 80-something percentile as central. We have done this before.

If you take out the GSD and make it a constant, and you keep moving your value higher and higher as a constant, you will get about the same PC as if you put in a constant around the 80-something percentile of the distribution. That is not a hard-and-fast rule because, again, it varies a lot, but we have done this. In fact, that is going to be a discussion, a topic of conversation tomorrow on the DuPont Deepwater Works, where we have demonstrated that, that putting the GSD about it is as claimant-favorable as having a higher centralized --

DR. MAKHIJANI: Okay.

DR. NETON: It's true.

DR. MAKHIJANI: I just haven't seen that.

DR. NETON: Yes. It's true.

Okay. So, there's that, but, then, you know, if the person appears to have been a pretty-heavily-exposed worker, based on job category and such, we give the 95th

percentile. Again, our two-part job exposure matrix. So, it is possible that either the worker wasn't monitored or they lost his monitoring data, or whatever. We would default and we would tend to be somewhat claimant-favorable in this respect, like we do in most things. So, that is the way we apply the coworker model.

And it says here each situation is evaluated on a site- and case-specific basis. I think some of the dose reconstruction, remember, we went through this process.

However, you know, this is all assuming that the one-size-fits model and the stratification has become -- it has been talked about for years, actually, but it is sort of coming to the head now, in particular, I think in relation to the Savannah River, which is where we happen to have data that allows us to evaluate stratification. I think most other sites

wouldn't have the data to allow you to do this.

And so, to handle stratification, the ORAU team was tasked with looking at how we are going to do this. And that ended up resulting in the RPRT-0053, which is subject of an SC&A review. It introduced the concept of the one person, one sample. And that was a direct result of trying to compare distributions of populations, and you really can't do that very easily unless, you know, OPOS works.

Well, the reason we did that -- we talked about it -- minimizes the issues with the correlation of data. You've got 20 samples from one person. They are all correlated.

In doing so, we tried to be conservative and use a maximum possible mean approach. I have examples of what that means. If you have all positive values, you are just going to take the average positives.

If you have one positive and, say, three -- or two positives and two less-than values, you are going to assume that they were all positive and take the mean just like you did in the first example, reported as 6. If they are all below the detection level, you are going to take the mean of the values and calculate it and report it as less than that mean.

Arjun has raised some issues about negative values. We need to look into that. I am not familiar with that problem right now.

DR. TAULBEE: I can see how it happened, but I can see where we have potentially misapplied this in that, when you have a raw result of, say, two counts in 24 hours and the background was four counts. And so, you could end up with a negative result, but I believe we should have been truncating it at detection level at all times.

DR. MAKHIJANI: And that's what we thought. So, it is something that crept in in the process, and I don't know that it applies to everything. We only came across it when we tried to -- I don't know what we were investigating, and we thought let's look at the raw data. And when we went to the logbooks, we found these problems.

And so, I think definitely, I don't know if it applies to all the compilations or only to that americium one. I think it applies to all of them, but I'm not sure.

DR. NETON: That's a valid point.

DR. TAULBEE: Because this is how it should have been.

DR. NETON: Yes.

DR. MAKHIJANI: But wasn't.

DR. NETON: And that, to me, is an implementation issue --

DR. MAKHIJANI: Right.

DR. NETON: -- not an OPOS issue.

DR. MAKHIJANI: Right. I agree.

DR. NETON: Okay. So, if OPOS does work, then how could one use the OPOS-derived cumulative probability distributions to look at stratification? You know, it's possible that there were subgroups in there, but it is our opinion that you have to have some basis for stratification to have occurred or to be valid. It doesn't seem reasonable to go and start parsing the data in the various different permutations looking for differences unless you have some valid reason for doing so. There has to be some underlying rationale as to why people that worked in a certain area who had a lot of activity going on are going to be different than someone else who didn't, that sort of thing to stratify the data.

And so, we came up with two types of tests, depending upon sort of the quality of the data that you have. There is the Monte Carlo Permutation Test, which is used

if the data are not heavily censored. If you have the majority of the data, the overwhelming majority of the data are censored, so you have a lot of data where you can generate things like a log-normal distribution and start doing comparisons of the different log-normal distributions.

In some cases the data are so heavily censored that you can't do that. You can't presume any distribution function, and that is where the Peto-Prentice Test was implemented.

I do say -- and this is sort of not a minor point, but it is a point -- you have to evaluate the effect of multiple comparisons. Once you start doing dozens of comparisons and you have a 5-percent chance of detecting something, you're going to, by sort of random chance, have positives because you did so many comparisons.

DR. MAKHIJANI: Before you go on, I just want to put something on the record.

Because in the report that you issued, you kind of raised this question of data dredging, as if we had gone looking for some collection of data points that would be bigger than some others. We didn't do that.

This whole process started with your RPRT-0052 in which you look at construction workers and non-construction workers. And you had actually stratified construction workers according to the jobs that they actually do. So, it wasn't your stratification or our stratification. It was the stratification that was present at the sites and how they classified workers according to their jobs that they did.

And in that evaluation, you will remember that the pipefitters kind of stood out.

DR. NETON: Right.

DR. MAKHIJANI: And so, when we did the internal, we used the same process. So, it wasn't a data-dredging thing, and that

is very important to put it on the table because the way it was presented in your report is as if we were sort of arbitrary looking for problems, and we weren't. We did the same stratification as you did in RPRT-0052, and that stratification was made by the sites, not by you or us.

So, that is what these comparisons have come out of. And I just want to be clear on the record that we did not engage in any data-dredging operation.

DR. NETON: Okay. Fair enough.

So, the Monte Carlo Permutation Test -- and these are outlined in 53. I got the sense that the SC&A comments on these tests were not necessarily that they're invalid tests; it is really more of the implementation of the test, you know, what confidence levels might be used and that sort of thing, and how valid they might be in teasing out these distributions.

But, like I said, you have to

have the data that are log-normally distributed to some degree and not heavily censored. And then, you take your stratification, based on some a priori characterization, like construction workers versus non-construction workers, and you take these two populations. You have already identified, you are able to identify them within your single function as independent. And you calculate a geometric mean and a geometric standard deviation for each of those two strata.

Okay. So, now you have got two geometric means and two geometric standard deviations. You calculate the difference between those two and you plot this on a graph, the Y coordinate being the geometric mean and the X coordinate being the geometric standard deviation.

So, you have one data point there. What is the plot of the geometric mean and the geometric standard deviation?

And then, you do a Monte Carlo simulation and you pull out -- let's say I had 150 construction workers and 250 non-construction workers. And then, you randomly sample 150 times, 250 times, 150 times, 250 times, and you calculate all the possible combinations of geometric means and standard deviations that come out of that analysis and you get something that is kind of pretty to look at, but you get this sort of envelope of possible differences in geometric standard deviation and geometric means, and you plot them.

This would be, typically, 10,000 iterations. And then you compare the difference in the data points of the strata that you are evaluating, this black dot here, and determine whether it falls in, this would be like the 95th percentile envelope of those differences.

If the data point falls within that envelope, you can say that I can't conclusively say they are different,

statistically different. Or, if the data point falls outside, like in that graph, then you have concluded they are. So, it is kind of an interesting way of comparing permutations within the data set to see if you can tease out that difference that you have identified, you know, that isolated strata that you identified. Can you find that somewhere within this data set? And on the left example, clearly, it is not statistically different and on the right it is.

So, that is what we have proposed in 53 to be able to review strata. And I am sure there's a lot of SC&A comment on power of this and statistically appropriateness and that sort of thing. But just to remind people of what that is.

The second test, the Peto-Prentice Test, is a much simpler test, and when it is very heavily censored, you really can't generate or assume any distribution.

You end up with essentially a rank, a Wilcoxon ranked-order test. You have ranked the data from A to B, a modification of that, a fancy version. I don't know, maybe I am simplifying it too much.

But you end up ranking the data and identifying which data points belong to Strata A and which data points belong to Strata B. And you essentially compare the differences between where those data points fall on the strata. And if you had, for example, the data points for one strata fall pretty high up, you're going to end up with a much larger test statistic than if they fall lower on the curve. Or, alternatively, if they are randomly distributed throughout this curve, the differences will come out to be insignificant, and that is the value test.

I will let the statisticians deal more with how this is exactly implemented. It is a pretty simple test. And they have done a lot of reviews of this test and feel

that it is a pretty robust test for looking at the differences in the strata when you have all this censored data.

MEMBER ROESSLER: So, how do you make the decision between the one that says not significant and not significantly different?

DR. NETON: Okay. There's a test statistic.

MR. STANCESCU: The Peto-Prentice Test is a P-value that is computed, and you compare that with the significance level 0.05.

MEMBER ROESSLER: Okay.

MS. CHALMERS: The P-value is actually on the plot? It is real tiny on the plot --

MR. STANCESCU: Yes.

MS. CHALMERS: -- but it is on there?

MR. STANCESCU: Yes. It is the P-value. For the first one, the P-value is

0.17, where there is no significance. For the second one, where there is a significant difference, the P-value is 2.51 to the minus 11.

MEMBER ROESSLER: Oh, okay. My glasses aren't quite strong enough.

MR. STANCESCU: Yes.

MEMBER ROESSLER: Okay.

DR. NETON: Yes, I don't want to get into the details of the test statistics, but --

MEMBER ROESSLER: Yes, that's better. Okay. Oh, okay, I see it. Okay. Thanks.

DR. NETON: Anyway, those are the two tests that we would use to look at stratification, if we had some a priori reason to suspect that the data could be stratified.

And my summary really just sort of rehashes what we have been talking about for the last hour and a half or so. You

know, we believe that a single coworker model is appropriate unless there is some reason to suspect. If there is a reason to suspect, we are proposing the one person, one sample be used. Actually, we are proposing the one person, one sample be used for all coworker models.

Given that, then, if there is reason to suspect stratification, we propose that we use this Monte Carlo Permutation Test and the Peto-Prentice Test to evaluate the significance of that difference.

DR. MAURO: Jim, this is John.

DR. NETON: Yes?

DR. MAURO: On those examples, are those real cases, where you found the one place you did have the stratification and the one you didn't? Did I miss that?

DR. NETON: Tom or Daniel would have to answer that. I don't know.

MR. LaBONE: Those are real cases.

DR. NETON: Those are real cases.

DR. MAURO: They are or are not?

MR. LaBONE: They are.

DR. NETON: Yes.

DR. MAURO: They are? Oh, okay. Good. Thank you.

DR. NETON: So, that's my 15-minute slide presentation.

(Laughter.)

It took a little over two hours, but that's okay.

CHAIRMAN MELIUS: Should we take another break? No.

(Laughter.)

You did the second half, actually, the second two-thirds or three-quarters quite quickly, and so forth.

Arjun?

DR. MAKHIJANI: Can we go to the previous slide? Yes, the Monte Carlo slide.

Harry?

DR. CHMELYNSKI: Yes, I did want

to make some comments about the Monte Carlo Permutation Test.

And I agree, I think it is a neat concept to do it this way. I just have some problems. I have some problems that I am concerned about.

First off, it only is based on an assumed distribution. The geometric mean and the geometric standard deviation are the parameters of the log-normal distribution. So, willy-nilly, we assume that is the right distribution regardless of how well it fits.

Now, when we then apply the test, we look for differences on this two-dimensional plot between the sigmas and the GSDs and the GMs, however you want to phrase them or parameterize them.

And yet, it is very difficult to see on these plots how far apart two distributions actually might be. Even on this graph that I am looking at here in the upper lefthand corner for the Monte Carlo

Permutation Test I see a black dot and a red dot at zero, but, for the life of me, I can't figure out how far apart those two points are. And I'm not even sure you can put a metric on this graph, given that one is a standard deviation, a GSD, and the other is a geometric mean that has units and the other one doesn't. It sounds great, but I just have problems of trying to interpret what this means.

The second test, however, the Peto-Prentice Test, I, too, like. It is a non-parametric test. Therefore, we don't have to assume what kind of distribution.

However, there are two things to keep in mind with any hypothesis test, and Bayesian statisticians commonly point out these problems. The classical statisticians refuse to recognize them.

(Laughter.)

The first one is that, if you have enough data points, you will always

reject the null hypothesis for any finite difference that you can think you are trying to look for. If you don't have enough data points, the test will have a very difficult time trying to reject the null hypothesis, and especially if you make a stringent alpha or a stringent probability requirement for the test.

So, when you are done here, this hypothesis-testing scheme seems to work pretty well when you are in the middle range of data, somewhere around 30 to a couple of hundred maybe. And that tends to where we like to use it.

Unfortunately, it is being applied here in places where it probably shouldn't be. And again, this gets back to the power calculation questions.

Those are my general comments on these two slides. We have a whole set of 25 slides. I'm not sure we are going to go through them, but each of these, a lot of

them deal with this issue of what is the power of these tests.

MR. LaBONE: I had a couple of responses. This is Tom.

First of all, we wanted to have two tests because in the one chart that Jim Neton had, the little flowchart -- can we put that back up? -- we considered the further along that flowchart you were towards Probability of Causation, the more relevant your decision would be.

So, for example, a decision made at step two with the OPOS data would be less compelling than a decision made at step four with GM and GSD. So, we wanted a way to check simultaneously the GM and GSD. You had two parameters you were looking at.

I can send you references for this test. I think it is a fairly standard representation of looking at the slope and intercept of a line, if it concerns you. But we also needed to go backwards again to step

three because we had this issue with the censored data.

So, again, if you would like additional references on that type of presentation, I think it is fairly obvious for the non-statistician looking at that plot to say, hey, what we observed is not within the 95th percentile ellipse of this data that you would expect to be generated randomly if there was no difference. And so, it is fairly obvious, looking at the plot, that there is a difference; there is not a difference. So, it was just for ease of interpretation. That was pretty much the comment.

Again, there was a reason behind having two tests. And again, we could choose from them. And I think, in general, they tend to come up with very similar results when they are both applicable.

Daniel, do you agree with that?

MR. STANCESCU: Yes.

MR. LaBONE: Yes? Okay. So, that was the comment I had.

DR. CHMELYNSKI: Just one more question. Can you tell me how far apart those two points are?

MR. LaBONE: Does it matter?

CHAIRMAN MELIUS: Yes, I think it does. Actually, something Jim brought up earlier, if they are not very far apart, do we really care?

MR. LaBONE: You're asking what is the practical significance?

CHAIRMAN MELIUS: Yes, yes.

MR. LaBONE: Okay. This is statistical significance.

CHAIRMAN MELIUS: Yes.

MR. LaBONE: Okay. RPRT-0053 is based on statistical significance.

CHAIRMAN MELIUS: I know, but we need to look beyond that.

MR. LaBONE: Okay. But, in order for me to tell how far apart that is, you

have to tell me what is important to you.

CHAIRMAN MELIUS: Right.

MR. LaBONE: And without that, there is no used talking about how far apart they are.

CHAIRMAN MELIUS: No, it is the conundrum we have with what is sufficient accuracy.

MR. LaBONE: In statistical tests --

CHAIRMAN MELIUS: Yes.

MR. LaBONE: -- versus practical significance?

CHAIRMAN MELIUS: Right.

MR. LaBONE: Yes.

CHAIRMAN MELIUS: Yes.

MR. LaBONE: Again, there is no used talking about that unless you can tell me what's important to you. And I don't know that.

DR. CHMELYNSKI: I firmly -- oh, I'm sorry.

MR. KATZ: Go ahead, Harry.

DR. CHMELYNSKI: Okay. I firmly agree that this is a question of how big of a delta are we willing to accept.

MR. LaBONE: Yes, I agree.

DR. CHMELYNSKI: I think the whole idea of power is all based on that one statement: how large of a delta are we willing to accept?

And here, you don't even know what it is that we are trying to accept. But, at least when you do the Peto-Prentice, you are actually looking at the delta. And even then, it is hard to make a decision how big of a delta you are willing to accept.

So, this is where the real problem with power of these tests comes in, I think, is that no one is willing to make the decision. What we are saying is, hey, look, I don't see any significant difference, but nobody is willing to say what a significant difference is.

MR. LaBONE: It is statistically significant.

DR. CHMELYNSKI: I understand that, but I am just saying, if it is more than 20 apart, is that going to bother you? If it is more than 200 apart, 500 apart? I don't see anybody willing to put their heels on the ground and say, "Ah, this is what I'm trying to test for." I would like to know what we are trying to test for before we say, "Ah, we didn't see it."

MR. LaBONE: What you have to do is define for me, in order to do that, what is the difference that is of practical significance to you in a Probability of Causation decision if you have two neptunium results.

DR. CHMELYNSKI: I agree, that's the question.

MR. LaBONE: Okay. I don't know how to do that. I have asked, and it is not clear to me for every type of cancer, for

every sort of intake regime, how you come up with a single estimate of practical significance. If you have some suggestions on that --

DR. NETON: Yes, where you end up is, is there such a thing as de minimis dose differences in this program?

MR. LaBONE: Yes, yes.

DR. NETON: Because dose drives PC. And de minimis dose, I don't know that anybody is willing to sign up and say that a 100-millirem dose is insignificant or 1 millirem, well, maybe 1 millirem. But where do you draw that line? And then, that dose difference, again, it is built into this intake model, but, then, it is converted to an individual organ dose on a case-by-case basis.

So, you know, you can take this model and calculate a liver dose, a lung dose, a kidney dose. So, it is a very complicated scenario.

We have talked about this a lot. Can we identify that significant difference? And it always comes back to a de minimis dose difference. And I'm not sure that it can be defined.

CHAIRMAN MELIUS: Or we're not willing.

DR. NETON: Or we're not willing to.

MR. LaBONE: Make it even easier. What external dose is basically of no interest to you? Is it 100 millirem, 500? I don't know.

DR. NETON: Because that is what it comes down to.

MR. LaBONE: Yes.

DR. NETON: We would be stratifying models and fitting these curves and coming up with very different scenarios for no real benefit possibly. But, again, we would have to figure out what the dose difference is, and I'm not sure --

CHAIRMAN MELIUS: And it may be different for different workers. And how long you worked there or what kind of work you did and what your exposures were, and so forth.

And I think when we were first talking about this, we said, well, you know, any exposure could be critical because it might get you from 49.9, you know, whatever, get you over the top, so to speak, in terms of doing dose reconstruction.

MR. LaBONE: You are talking significance testing.

CHAIRMAN MELIUS: Yes.

MR. LaBONE: You're talking what we're doing here.

CHAIRMAN MELIUS: Yes. Yes. And I think, on the one hand, we need to wrestle with that issue.

I think when we were looking at using statistical testing, I think we have to sort of think of how are we going to utilize those; what assumptions do we make going in,

and so forth. And I think some of the differences between what Tom and ORAU wrote up and what SC&A is this sort of, well, which assumption applies in which situation? Do we assume that, should we come in and assume that there is stratification? Or do we assume that there is no stratification and say that only if it is statistically significantly different do we then apply stratification. And that is going to vary by sample size and depend on a whole bunch of other things. And as we said, we can have a huge amount of data and find something statistically significant that's of maybe very little practical significance.

DR. NETON: Part of the problem of being very generous in assuming stratification, in other words, very claimant-favorable to stratify for one set, is you are robbing from Peter to pay Paul.

If you assume a priori that I am going to say this data set is stratified and

you have a very lax statistical acceptance criteria, you are taking dose away from the other strata by definition.

DR. CHMELYNSKI: I agree with that, but it glosses over the reality. Let's say you have 1,000 and a couple from the construction workers. And now, what you are selling is that, if I leave those construction workers out, I am robbing the non-construction workers of that little contribution.

However, if you turn it around and say I have a handful of my construction workers, and now I am going to, instead, mix in 3,000 data points from the non-construction workers, you are actually hurting them more in the terms of trade and trade facility.

And so, I think the general statement is, yes, that you will always be -- you can't be claimant-favorable to both sides. But I think what we are interested

here is being claimant-favorable to the highly-exposed workers. And what we are doing is not --

DR. NETON: Well, we don't know if they are the highly-exposed workers. That is what we are trying to find out.

But the other issue is, if you do stratify on a year-by-year basis, one has to accept the fact that in some cases it is going to be the dose is less. You can't always just cherry pick the high ones and say, well, it's higher in 1956. And if it is lower in '55, that's the way the chips fall. So, I don't know.

DR. MAKHIJANI: Obviously, a stratification decision has to be made on some objective criteria, not whether somebody is going to get a higher and lower dose in any particular year.

DR. TAULBEE: If I could use an example of tritium, let's say, at Savannah River, and if you look at the people in the

tritium facility versus the 100 areas, the reactors, the reactors, believe it or not, have a significantly higher exposure to tritium than the people in the tritium facility. It is was working in a disassembly basin. They got larger intakes doing maintenance activities out there.

But what we are doing is we are applying this to unmonitored workers. And so, if you look at the population of the reactor workers that had this higher exposure and compared to the tritium facilities, you will see statistical differences. But both sets, I mean, if you talk to the workers, they talk about leaving urine samples out there, whether they are construction trades or not. And so, we end up with about 80 percent of the people working in those areas have tritium-monitoring data.

So, now we are applying this model to the 20 percent that were not monitored in this particular case. So,

stratification, you are making kind of a decision of this person should be in the reactors versus this other area, and we can do that. But the whole coworker model, especially if you apply like the 95th percentile, as Jim was talking about, I think is appropriate. It is easier for us. We don't have to go through and try to evaluate more of where this person worked, at which time period, which year he was here at the tritium facilities. This year he was over at the reactor facilities. The general coworker model seems to work.

So, there is a case where we see a statistically-significant difference, and it is a big one. Well, I shouldn't say "big one" because it is actually more like 10 millirem to 30 millirem. So, it is not huge from a dose standpoint, but it is statistically significant.

So, this is a case where one general coworker model I think is

appropriate.

DR. MAKHIJANI: I think this goes back to a question that came up earlier. When you can actually demonstrate, rather than assume, that people with the highest exposure potentials were systematically among those who were monitored, and most of them were monitored, then you have a very good taste.

But in many of the cases that we are talking about, the monitoring data for these neptuniums, the thoriums, and so on, are pretty thin in some cases. And americium data are plentiful in some years and not so plentiful in other years. And in some cases for neptunium the data on construction workers are pretty thin in almost years, if I remember correctly.

So, in those cases you actually have a much bigger problem because you have to go and demonstrate that the construction workers who were monitored, were actually

monitored, were in the areas where they had exposure potential relative to other construction workers. And that needs to be demonstrated. And I think, so far, it has just been assumed.

DR. TAULBEE: I would agree and disagree.

(Laughter.)

Where I agree is that we certainly need to do the evaluation, and we have, where I disagree with you saying we assumed it. We didn't assume it. We did evaluate it, but we have not documented it well.

DR. MAKHIJANI: Okay.

DR. TAULBEE: And that is something that we can do.

DR. MAKHIJANI: I think your report said you assumed it. So, that is according to your report.

(Laughter.)

CHAIRMAN MELIUS: The footnote

got left out.

(Laughter.)

DR. TAULBEE: There were other things that we evaluated. The words "Technical Report," identifying incidents, the bioassay control procedures, who was monitored and when and why, and then, the followup of the number of samples that we have relative to the general population working in those buildings. So, those are all things that we qualitatively analyzed before that assumption.

DR. MAKHIJANI: If I could circle back to the prior discussion that Jim raised and Tom was saying about what delta is significant, what dose level is significant, you know, we had this discussion in a very different context of the 250-day discussion. And I remember Jim Neton saying that, you know, 1-rem dose could make a difference in some cancers, leukemias I think, if I remember correctly.

And so, I think we have some notion of a level of dose that does make a difference for at least one cancer, 500 millirem or 1 rem in some circumstances. So, the kind of differences that are factors of 2 and 3 in that chart that is up being displayed, your slide No. -- for people on the phone -- I don't --

DR. NETON: Four.

DR. MAKHIJANI: -- slide No. 4, we could potentially evaluate what's important and whether it meets the practical significance criteria, which hasn't been done so far, as you said. So, potentially, it can be done with some objective practical criteria.

DR. NETON: Yes. Yes. It would be somewhat cumbersome, though, because, remember, these models, these fits go in piecemeal order through the 30 years. So, the new fits to these individual data points that make up the 50th percentile would have

to be rerun and come up with a new intake regime, so to speak, you know, Intake Regime 1, 2, 3, 4, and then, compare that to some dose of consequence based on a presumed hypothetical case. I mean, I don't know how else you would do it. You would say, okay, if I had liver cancer, I was exposed during these years, what dose difference will that make?

DR. MAKHIJANI: Well, you could come up with a general number of dose of consequence that is conservative, which is what you were doing when we discussed the 250-day question.

DR. NETON: Yes, yes.

DR. MAKHIJANI: The 500 millirem or 1 rem; I can't remember the exact number.

DR. NETON: I like the line of thought here because it kind of ties in with the residual period and small doses versus -- you know, how meaningful are these small doses in the residual period, which is

kind of a similar issue, not similar issue, but similar problem.

MR. LaBONE: Think about it for how would you do this for external dose. Take the easy case.

DR. NETON: Yes.

MR. LaBONE: Okay? Are we going to stratify on external dose?

DR. NETON: Yes.

MR. LaBONE: Okay. And so, how would you --

DR. NETON: But that's another issue, though.

MR. LaBONE: How would you come up with the de minimis for external for all cancers? I mean, so do the easy one first, and then, move on to the tougher one.

DR. NETON: Yes, that is a very good point.

MR. LaBONE: Yes.

DR. NETON: So, you take internal, and we haven't talked about it,

but, I mean, clearly, if you are stratifying for internal, you are going to stratify for external, right?

CHAIRMAN MELIUS: Which may have been a mistake.

(Laughter.)

There's too many complications, but, conceptually, I think you've got to remember, if we go back when we were initially struggling with SEC decisions, and so forth, it was, well, show us how you would do the dose reconstruction. It is a little different issue. And then, as a result of that, I think people then could come to an agreement, well, you know, we haven't worked this out yet, but it is not going to make that much difference or it is straightforward or this would be a good procedure, and so forth.

And I think the same approach might be useful here without getting tied to trying to come up with what the value should

be. Let's just do the calculation or do the calculation around some arbitrary --

DR. NETON: Well, you can come up with the intake difference. It is pretty readily -- I mean, that's not hard. It would be cumbersome, but it is doable, right? I mean, you fit your new -- you stratify the data and you come up with your different geometric means, for example, for construction workers and you fit them into the model, as if you are going to have a separate model. And then, you compare the intakes that come out of that analysis.

In my opinion, see, that's where the difference is. If the intakes fall within the uncertainty here, you are not really changing --

MR. LaBONE: But you can't work off the intakes because it is the time period. It is the dose up to the date of diagnosis. And so, even for a particular intake rate --

DR. NETON: Well, no, you would have to compare it for the intake regimes that we have.

MR. LaBONE: Yes. Okay.

DR. NETON: I mean, because, in reality -- and I talked about this earlier -- what we do when a person straddles the intake regimes is you give them both.

MR. LaBONE: Yes.

DR. NETON: And then, what happens is you end up with an overestimate of the intake by a factor of 3, 4, 5; I don't know. Clearly, this intake contributed a lot more dose than this one, and this continued on, you know, this person still continues to get dose from this way out into here, you reset --

(Laughter.)

CHAIRMAN MELIUS: I am very impressed with that one.

(Laughter.)

DR. NETON: Anyway, I think I

made my point with this.

CHAIRMAN MELIUS: Very well, very dramatically.

(Laughter.)

DR. MAKHIJANI: You know, we actually, for external dose at Savannah River Site, we actually did stratify for the specific construction worker category of pipefitters. If you remember the TIB-52 discussion where the construction worker dose reconstruction method is laid out, mainly for external dose, we called out pipefitters from among the construction workers.

And part of the thing that is underlying some of our thinking is we showed that pipefitters were more exposed, even among construction workers. So, there is a different adjustment factor for them that we all agreed would be appropriate. So, in that case we agreed there was kind of a coworker model --

DR. NETON: Well, but we have got

to go back and recognize that TIB-52 was a pretty rudimentary look at the data set. I mean, it was a long time ago.

And when we all did that, I recognized that that was probably not the most robust scientific analysis. It was the best we could do, given the data we had at the time. I am not saying it was wrong. It is just there are much better statistical approaches to be employed now, and that is where we are at.

DR. TAULBEE: I mean, we could go back and redo TIB-52 using the --

DR. NETON: Well, exactly.

DR. TAULBEE: -- Monte Carlo Permutation as well as the --

DR. NETON: Yes.

DR. TAULBEE: -- Peto-Prentice, and see, does that still hold? Is it greater? I don't know.

DR. MAKHIJANI: That would be interesting. I mean, would that adjustment

factor go away? Would we say pipefitters are no different using this test and sort of moosh away the differences?

DR. NETON: I don't know, but I wouldn't be surprised if it didn't.

DR. MAKHIJANI: You know, one of the things that, in my understanding -- and I am not into all the modern statistical, but I have some understanding of these things -- one of the things that stood out for me, when we were reviewing your RPRT-0053 was, and which you have made very explicit in your response, is that accepting the null hypothesis doesn't mean you're saying the null hypothesis is true. You are just saying that you are accepting it because you can't reject it.

DR. NETON: Right.

DR. MAKHIJANI: And what we were saying is that that is not good enough. And then, in some circumstances it could be very bad. And there was some discussion of how

bad it could be when you have very few data points, that it could be bad by a factor of 2, 4, 5, 6, 10. So, we are not talking about 5 and 10 percent.

And I know you have this whole argument among the statisticians about prospective and retrospective data, and I understand that to some extent. But the objective fact is that, if you don't know whether these distributions are the same -- and Harry said this in a different way just a few moments ago -- and you put a few construction workers who were highly exposed in a sea of large numbers of construction workers who have data, you are going to lose that. You're going to lose the claimant favorability for those workers, if, in fact, their distributions are actually different and your test isn't good enough to tell you.

DR. NETON: Well, wait a minute. We need to differentiate between the people

who were monitored and not monitored. You're saying you're going to put the highly-exposed construction workers into the data set because they were monitored. We need to figure out what was the exposure potential for those that weren't monitored. That's my point.

I mean, you get very confused with it. Because construction workers have high data points doesn't mean that the unmonitored workers were in that same category. Do you know what I'm saying?

DR. MAKHIJANI: Yes, I do get that point, and we have kind of done this a couple of times. Because most construction workers, at least for certain radionuclides that are important in the kind of decisions that we are talking about were not monitored -- well, you need to demonstrate that the construction workers who were monitored were --

DR. NETON: That's right. It

comes down to that --

DR. MAKHIJANI: You really need to do that.

CHAIRMAN MELIUS: Yes. Yes, we need to know what these populations are, how they were monitored, how they were exposed, and there's all sorts of different -- and, you know, we are also limited by the data information available to us. I mean, we see this all the time when we do these SECs. We have what appears to be a very narrow Class and end up with the whole site because of lack of information on where people actually worked. And that applies to whether they are monitored or not monitored often.

DR. NETON: I think that is an interesting precedent, and I wasn't part of that because I am conflicted at Fernald. But, recently, a Fernald Class was added for construction workers. I don't know what drove that decision, but somehow at some point in the deliberation process it was

decided that the construction workers were either completely not monitored or the data that they had were not representative of the overall -- I don't know what happened there.

MR. HINNEFELD: Well, I can go through that if you want.

DR. NETON: It might be interesting to understand the logic behind that.

MR. HINNEFELD: This is the first thing I know enough to say anything about in this whole meeting.

(Laughter.)

The question was, the construction contractors or subcontractors at Fernald, were they evaluated appropriately for monitoring in the way that the NLO -- that is the main contractor -- in the way the NLO workers were monitored? Because NLO monitored almost all of the NLO workers, and we have a really big data set from the NLO workers, and it is all computerized.

Now in that computer program, before 1986, there are essentially no contractor data, even though there were contractors working there. And so, the question became, well, why is that? Did they not monitor construction workers? Did they not really look at the work and determine whether they should have been monitored? Or did they monitor them and not save the data? Or did they save the data and we haven't found it in our capture?

And from my own experience, when I started even in the eighties, there was still an attitude that a construction worker isn't, you know, they're not really a rad worker because, theoretically, they are here for a short period of time for a particular job and, then, they are gone. And they are not going to be here the whole year. And so, they are not going to hit the annual limits, so to speak.

So, there was a little bit of

that attitude even when I started in the eighties. And so, it is hard to argue that the NLO was evaluating construction contractors thoroughly in terms of should they be bioassay monitored.

There were instances when contractors were monitored, and there have been some data sets captured, either on correspondence or, much later, on what we were called the urine sample request cards for construction workers. And you can pick them out because it will even have the construction contractor's name written on that card or it will have a badge number, the badge number series or sequence that was specific for subcontractors. So, you could find them in that data set later on.

And so, in the instances where we did have bioassay data, starting in about 1984 through -- '83, '84, '85, there was some bioassay data, and then, very sporadic before then. 1983 was the first year when I think

we had more than 30 contractors sampled in a given year.

So, for some of those early sampling episodes, the contractors were quite heavily exposed in the work they did. There was one circumstance, well, at least here is this one construction job or one job done by contractors where NLO did analyze, saying these people should be monitored, whether they were monitored from the start or whether once they started to observe what they were doing they started to be monitored.

So, there was a group of about a dozen or 14 contractors. You had several bioassay samples over several months' time in a single year, which seems like that would have been the duration of the work they did. They were taking the processing equipment out of Plant 7.

And those people's exposures, had you calculated their exposures based on their bioassay data, those were higher than what

the coworker model would have predicted for them. Even using 95th percentile values, they were still higher.

So, it appears, then, from that sampling of that group, which, of course, were bioassay sampled, there is potential for contractors to be exposed more heavily than the coworker model, which is built on the NLO workers, than that would indicate. So, you have that piece of data.

There are large absences. There is very few contractor bioassay data until you get to really 1984. There were a few in 1983.

And there wasn't really any evidence to make us conclude that NLO was carefully evaluating contractors and doing a consistent job of evaluating and collecting or recording in a fashion that was retrievable. So, we didn't really know, of the contractor bioassay data we have, we didn't know if we had just a smidgeon of a

whole lot of what was done or if we had everything that was done, and whether it was analyzed correctly in terms of how much should be done.

So, there's too many questions to say that we should be able translate this coworker data set from the NLO workers and say that really represents the work of the construction workers. And, in fact, there are construction workers who are claimants, or not claimants but advocates, who worked there in the eighties, the early eighties, and said, you know, there was nobody around. "We couldn't get them to frisk the equipment when we were remodeling the pilot plant" or the conversion facility and the pilot plant. "We didn't have a rad tag. You know, we didn't have anything."

One guy said, "Heck, I went and got a survey meter and surveyed this stuff that we were tearing out and found out it was contaminated, and almost got fired for

stealing the surveys."

(Laughter.)

So, those are the stories you hear about.

So, from that standpoint, then, starting in '83, there were than 30 people sampled, but they were all sampled late in the year. It didn't seem to be very representative of a year's worth of work. 1984 and 1985 have pretty nice populations of contractor data that were captured on these urine data cards. We seem to have captured essentially all of the urine data cards for those years because the majority of them are NLO people, and you can find those data in the database. But there were some contractors that you can clearly identify. And so, those were all compiled.

And so, we built models. What would the coworker model be for just contractors for '84 and '85? And we used the Peto-Prentice Test to show that '84 that is

different. You know, that will give you a different value than the NLO workers would have. In '85, I think it was still significantly different, but you could argue that there is no practical difference in '85 because it is statistically different, but the dose reconstruction doesn't come out very close.

And then, starting in '86, then, they were -- I think I have got these years right -- starting in '86, then, they are in the HIS-20 database. So, the construction workers are there and are a part of the total population then also.

And again, most people, at that time almost everybody was monitored, including construction workers, because that presented a contractor change from NLO to West. So, essentially everybody was monitored going forward from then.

So, based on our conclusion or the Advisory Board's conclusion, ORAU

maintained its position that the coworker approach was adequate. The Advisory Board concluded that the data to show that the NLO workers' exposures were representative of construction workers just wasn't there, that you couldn't really draw that conclusion. And so, that is why the Class was there.

I hope that was halfway clear. I didn't expect to have to speak today.

(Laughter.)

DR. MAKHIJANI: I have a question about '84. In '84, when you did have data and did this test, did the construction workers come out above the NLO workers or below them?

They came out above, even in '84?

MR. HINNEFELD: Yes. It was just higher. But the Board concluded that there is sufficient data in '84 --

DR. MAKHIJANI: Right, right.

MR. HINNEFELD: -- in a construction-worker-specific coworker model.

DR. MAKHIJANI: Right.

MR. HINNEFELD: And it is the same for '85. There is sufficient data. And then, like in '86, I think almost everybody is monitored.

DR. MAKHIJANI: Right.

MR. HINNEFELD: I don't know if they even need a coworker approach after 1986.

DR. MAKHIJANI: So, the Board kind of made a stratification decision for '84 and '85 that it was justified, but there were enough data to do it?

MR. HINNEFELD: Yes.

DR. NETON: I am not sure that was helpful, but it was a good thing to hear.

(Laughter.)

MR. HINNEFELD: No, I didn't suggest that it was helpful.

DR. NETON: Well, I didn't know. I didn't know, but I think what it points to is that each site is a little different. I

mean, you know, the Fernald site has its --

CHAIRMAN MELIUS: It is good to know what information there is --

DR. NETON: Right, exactly.

CHAIRMAN MELIUS: -- and knowing about the site.

MR. HINNEFELD: And I have personal experience at the site, and that did influence my behavior.

CHAIRMAN MELIUS: And even at Fernald, just going back to when they were first building the site, did you find --

MR. HINNEFELD: Well, yes, when they were first building the site --

CHAIRMAN MELIUS: Saying that construction contractors and workers were being exposed.

MR. HINNEFELD: We felt like the people who were building the plant wouldn't be exposed. But there are memos out there between a couple of HASL folks saying, you know, "Poor Joe Quigley," who was their

former colleague, who is now the Health and Safety Tracker at Fernald, "he's really got his hands full with this work starting up in these plants, and construction workers and everybody running all over the place, essentially."

So, there was essentially some evidence that parts of the plant would be built and they would start shakedowns or running radiological materials while the construction workers were in the same building, building other things. And so, there wasn't this exclusion. There wasn't this clean turnover from construction to operations. And so, that is why it goes all the way back.

DR. TAULBEE: I think that is typical at all sites.

MR. HINNEFELD: Well, at Fernald, it was fairly -- you know, we were able to do --

DR. TAULBEE: You see startup

dates at Savannah River, but the building hadn't been turned over by construction to operations yet.

MR. HINNEFELD: Yes.

DR. TAULBEE: But, yet, they had already started.

MR. HINNEFELD: Yes.

DR. TAULBEE: And so, both of them were there for a period of a year or so --

MR. HINNEFELD: Yes.

DR. TAULBEE: -- for each building.

CHAIRMAN MELIUS: I think that wasn't the assumption going into the meeting.

MR. HINNEFELD: No. We felt like where they are building a new facility they won't be exposed.

CHAIRMAN MELIUS: Yes, yes. Right.

MR. HINNEFELD: So, why worry about the early --

CHAIRMAN MELIUS: Yes, there is that overlap. And if we hadn't of found those memos, I don't think -- we would have left them out.

I don't know when lunch is coming.

MR. HINNEFELD: Lunch is coming anytime.

CHAIRMAN MELIUS: Okay.

MR. HINNEFELD: It was being picked up at about 11:35, as I understand, or we were leaving to pick it up at 11:35, and it's just a few minutes. So, it will be here pretty soon.

CHAIRMAN MELIUS: Well, let me tell you what I was thinking of, and these two issues are related. There may be other discussions we want to have also.

But one is to spend some time going through what are some of the factors we should be taking into account or looking at in terms of developing coworker data sets,

and sort of a checklist of things. I think we have talked about many of them. But sort of thinking what would be helpful to think about.

Some of them deal with the statistical testing. Some of them deal with more sort of general issues that come up.

The second, which may come out of that or may precede that, is what we have already started a little bit, but sort of what could we do that would help us understand what factors and to what extent we need to focus on certain factors. How do we evaluate? Maybe it is better to say, how do we evaluate certain issues? And what would be helpful for doing that?

We already talked about should we look at an external coworker model and see if that would -- it should be much simpler and maybe that lends itself a little bit more to more straightforward evaluation and sort of helping us look at this issue, and so forth.

And then, secondly, should we do the same or some calculations, or whatever we want to call them, on some of these coworker models for internal exposures that might also help us to decide how we approach this? Because we want to be evaluating the right things and looking at the right issues, and so forth. Every site is different.

But, also, we don't want to waste a lot of time or have time wasted by ORAU or SC&A or NIOSH and everybody involved on factors that aren't going to be important or aren't really going to affect that, or may only affect the models in certain relatively-rare situations, or whatever. And somehow, how do we tie this back into sort of the sufficient accuracy question that we have been trying to wrestle with at the same time?

So, it is more like, I guess, sort of brainstorming and thinking. Some of the sites we are evaluating now, like Savannah River, may be helpful, but also some

of the sites we haven't talked about.

And that would include this issue of the multiple sampling on individuals, and so forth, which I think is something else that we need to sort of think how do we evaluate that or decide whether it is appropriate or not appropriate to use, or does it make a difference? Maybe that is the bigger thing, is to what extent does it make a difference.

Does that make sense to everybody?

DR. MAKHIJANI: Could I ask if Harry has any more comments on the technical things?

CHAIRMAN MELIUS: Well, then, that was the other thing I was going to mention. I am not sure just before lunch is fair to Harry, but --

DR. MAKHIJANI: No, no.

CHAIRMAN MELIUS: -- I'm not sure right after lunch is, either.

(Laughter.)

But at some point I think we should come back, and probably right after lunch, I will say. I will drink caffeinated beverages or something, and we will come back and go through some of -- if he has some issues -- but I think we need to go through the entire presentation. There may be selective things that would be helpful and we should weigh-in.

DR. MAKHIJANI: I think there are three or four slides in there. I can talk to Harry over lunch --

CHAIRMAN MELIUS: Oh, okay.

DR. MAKHIJANI: -- and work it out.

CHAIRMAN MELIUS: And I'm sure John Mauro will have wise words for us also at some point.

(Laughter.)

Silence.

(Laughter.)

DR. MAURO: You baited me because I do have one, but I am not going to bring it up.

(Laughter.)

CHAIRMAN MELIUS: I was just whispering to Ted to call the operator and have them disconnect John.

(Laughter.)

We wouldn't do that to you, John.

DR. MAURO: I am going to save this for later. I have got a nice one for you.

(Laughter.)

CHAIRMAN MELIUS: Yes, usually, your ideas are spontaneous. So, write this one down and remember it.

(Laughter.)

DR. MAURO: You're right.

CHAIRMAN MELIUS: We always used to have fun. You know, when you came to all our meetings, John, we would try to predict what you were actually going to say at the

microphone.

(Laughter.)

DR. MAURO: Did you have a pool?

CHAIRMAN MELIUS: We never knew whether you were for or against.

(Laughter.)

MR. KATZ: Nobody made any money.

(Laughter.)

CHAIRMAN MELIUS: See what happens when you're at a distance, John? Now we can say what we --

DR. MAURO: I miss the action.

(Laughter.)

CHAIRMAN MELIUS: Is lunch here?

MR. HINNEFELD: I'll check.

CHAIRMAN MELIUS: Oh, you'll check?

MR. HINNEFELD: I think it should be here anytime.

CHAIRMAN MELIUS: Why don't we break then?

MR. KATZ: So, I think we will

break for lunch. And how long do you want to take for lunch?

CHAIRMAN MELIUS: Forty-five?

MR. KATZ: Forty-five minutes? So, about quarter to 1:00?

CHAIRMAN MELIUS: Quarter to 1:00 we will be back.

(Whereupon, the foregoing matter went off the record for lunch at 11:52 a.m. and went back on the record at 12:48 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:48 p.m.

MR. KATZ: Good afternoon. We're back online.

Let me just check and see that we have -- Harry, do we have you on the line?

DR. CHMELYNSKI: Yes, I'm here.

MR. KATZ: And John Mauro?

DR. MAURO: I'm here.

MR. KATZ: Great.

Bill can't make it this afternoon.

CHAIRMAN MELIUS: Stiver?

MR. KATZ: How about John Stiver? John, are you on, too, Stiver?

(No response.)

Okay. Well, let's carry on.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: So, Harry, I will go through your slides.

Slide 2, review. It is up here.

DR. CHMELYNSKI: Okay. Slide is on, you say?

DR. MAKHIJANI: Yes.

DR. CHMELYNSKI: Okay. This slide simply points out how we conducted our review of RPRT-0053. We not only reviewed the report itself, but also three documents

that employed the techniques in 0053 to use them to compare construction workers with other workers at the Savannah River Site for neptunium, mixed fission products, and the exotic trivalents.

DR. MAKHIJANI: And I might add, only to the extent that it applied to the statistics method, not in terms of the actual data sets in detail.

DR. CHMELYNSKI: Right. It was only a very narrow issue as to how the comparison tests were applied with these three data sets.

The next slide, which is on page 3, reviews a discussion we had earlier on the use of r-squared for ROS regression. Personally, I think this does relate to the question of sufficient accuracy because the r-squared is not the appropriate measure of goodness of fit here. And NIOSH in their response, as you can see below in bold, also indicated that r-squared was not used to

evaluate the fit of the plots.

But this does raise a pretty serious question. What was used? And when you think about, you know, we are talking in that Monte Carlo simulation plot that you showed two graphs there were 40,002 log-normal distribution fitted using ROS. I wonder how well they did fit. And certainly, the answer that statisticians can see whether they fit wasn't used because there's 40,000 of them. So, I am not sure anything is being used to measure goodness of fit.

Is there any response on it?

MR. LaBONE: I can respond to it, but I would need to go back to Jim Neton's slides.

DR. MAKHIJANI: You have the hard copy.

MR. LaBONE: It's the third and fourth slide where he showed -- in general, the fourth slide shows where the internal dosimetrist would go through and fit to come

up with a chronic intake. And the internal dosimetrist judges the fit, the quality of that fit, as far as does basically that line capture the central tendency of those data points. He does not use r-squared. He does not use any other statistic associated with that fit. It is just basically in his professional judgment does that fit.

And so, going back to the third slide, the third slide is fit by the statistician. And so, the statistician would go through and apply the same process. They don't look at r-squared. They say, she would say, does that line capture the central tendency of data adequately for what we are going to use it for?

And so, it is basically professional judgment that is used in both cases to decide is the fit adequate. Now that is not exercised in 10,000 iterations in the Monte Carlo calculation. But that is when you actually do this, implement

Procedure 53, that is how it would be done, RPRT-0053.

DR. CHMELYNSKI: So, this would apply to the black dot on the Monte Carlo simulation, you're saying, basically?

MR. LaBONE: Yes. This is what we actually saw. And then, the cloud with the confidence, the 95-percent confidence ellipse would be from the simulation. So, yes, this is the black point, except for the one at the middle, which is just the center of the cloud.

DR. CHMELYNSKI: Okay. So, essentially, the answer is that it is the statistician's judgment when he actually does look at it, but in Monte Carlo, then, it is not actually -- there is no measure of fitness of things?

MR. LaBONE: No.

DR. CHMELYNSKI: Okay. So, let's go on, then, to slide No. 4, which is one that we -- I don't think I am going to read

that. This is something we have already talked about quite a bit this morning, representativeness of the data that is available and completeness, representativeness in the sense does it cover all the groups of the unmonitored persons, and completeness in that did we actually get the workers that should have been monitored.

MR. LaBONE: Yes, I agree.

DR. CHMELYNSKI: Those two questions I can't answer, but they are here as findings and we have some responses.

So, go ahead. Sorry to interrupt you.

DR. MAKHIJANI: No, no, I think we did settle this morning that NIOSH is going to do some demonstration about who the monitored construction workers were.

DR. TAULBEE: Well, I think this is part of that checklist --

DR. MAKHIJANI: Right.

DR. TAULBEE: -- that Dr. Melius

was wanting to try to develop within this group.

DR. NETON: This is not germane really to 53. This one precedes 53. And 53 starts with the fact that you have got a monitored population.

DR. TAULBEE: Right.

DR. NETON: I mean, all that other stuff would need to precede 53 before we go into a 53 analysis.

DR. MAKHIJANI: Should I turn the slide?

CHAIRMAN MELIUS: But I think we need to make that sort of explicit.

DR. NETON: Oh, I agree. Yes.

DR. MAKHIJANI: So, should I turn the slide?

DR. CHMELYNSKI: Yes. We can go to page 5. One other point in the bold here. We do still feel it is necessary to examine subgroups of the construction workers, and not just all construction workers as a single

group.

DR. TAULBEE: Which construction workers? I mean, laborers, pipefitters? I mean, a priori is where you've got to try to come up with this grouping that you want to evaluate. So, all of them? Do we go down to junior or to journeymen within each trade? How far do you go?

CHAIRMAN MELIUS: We will come back to that because it is all part of this other issue, but I don't think it necessarily has to be a priori, either, because I think just for the reason you said. We can end up doing lots of comparisons that aren't going to be very helpful and meaningful, and so forth. So, it has got to be sort of a process of deciding. But some of it is going to be driven by the data itself, the nature of these data, because they aren't random samples from a population, and so forth.

MR. LaBONE: But you can't use the data set to come up with your hypothesis

and then test it with the same data set is the problem. So, you are supposed to go through and identify what you want to test ahead of time or use a different training data set and then come and test it.

CHAIRMAN MELIUS: I don't necessarily agree with that, but let's come back to it.

MR. LaBONE: Okay.

DR. MAKHIJANI: It is also the question of professional judgment in this particular area as to what you are going to use --

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: -- based on what work was being done.

Okay. Next, I'm changing the slide, 6.

DR. CHMELYNSKI: Well, I guess we have already started the OPOS discussion, too, and we have had some statements about the variability, and NIOSH does accept that

this procedure would result in smaller geometric standard deviations. And it does raise the question as to what should be done for all the claimants whose cases have been processed so far using any other methodology that didn't include OPOS.

For many years, the idea was to collect all the data and use them as one pool. Now we are saying that that wasn't the right way of doing it. So, again, I think a lot of this boils down to how the data -- to what happens to the data as you go through the process of first modeling the urine concentrations and, then, trying to go on and figure out what the intakes were. And I think those are really the important questions on OPOS, is how the modeling works.

So, I will leave one that one as already being discussed.

The next slide, which is page 7, we also discuss this. It is exactly what the term sampling protocol means. I keep using

that word, but NIOSH suggests that the right terminology is in the approach there in that first box, internal dosimetry monitoring program.

And as long as the workers were in that program, that seems to be enough for NIOSH to make the protocol similar. We are not so sure that you can combine the special sampling that is done due incidents along with the routine sampling. That is comparing apples and oranges to some degree.

Finally, I want to raise a point on page 8, though, about the sampling protocol issue. I think this is in NIOSH's own words, that the CTWs were potentially subject to different bioassay practices than other workers. The CTWs, many of whom are subcontractors, I guess is the right word, commonly submit bioassay samples after suspected intakes and at the completion of jobs. So, there does not seem to be any evidence for a routine monitoring program for

those workers.

DR. MAKHIJANI: And let me just say that we use the words "sampling protocol," and it is confusing. We understand why NIOSH took in the way that they did. But what we mean is the monitoring protocol for construction workers, as is clear from the way we interpreted the NIOSH report.

Should I move on to the next one?

DR. CHMELYNSKI: Okay, page 9. This is identified as Finding 5 in our report. And this has to do with the idea that we only have a fairly-small number of samples in a lot of the comparisons that we are trying to make.

My own feeling is that trying to push out to the 95-percent confidence level when you know you are faced with small sample problems is not claimant-favorable because it tends to diminish the chance we will detect any differences.

NIOSH takes a slightly different point of view, saying that if you carried that to an extreme, in other words, moved to the 50-percent confidence level, would that be better? I am not saying it is worse, but --

(Laughter.)

On the other hand, you know, when this program was set up 50/50 was where the boundary is. So, there's some justification for using alternative significance levels in order to be claimant-favorable.

But the point here is that, if you do make 90 percent for your alpha, you are going to end up with a large beta, which means a Type 2 error, not being able to reject when perhaps you should be.

So, the next slide is the beginning of a fairly-long discussion, and that is on page 10. It has to do, again, with the small sample sizes.

There is a theoretical issue here

about, once you have seen the data, should you use anything that you have learned when you do the hypothesis test. Well, some people are very purist on conducting hypothesis tests and say you can't do any analysis of power after the data has been collected and analyzed. There is sort of a nebulous area where the data has already been collected, but we really haven't looked at it that much.

(Laughter.)

I'm not quite sure the same arguments apply there.

But, on the other hand, I don't know of anybody who is willing to say that you can try a hypothesis test, first off, not knowing what difference you're looking for and, secondly, not caring how much power you have to detect that difference. That is disturbing to me for the reason we will see on the next page.

But, basically, the argument

presented here is that a retrospective power analysis doesn't give you any new information. And I agree. If you specifically use the sentence that is in this box here that includes the words "confidence intervals of the estimated parameters." However, we don't have confidence intervals of the two-sided type. We only have one-sided confidence intervals that you can imply from the hypothesis tests that are being done.

On the next page, we will see an example, on page 11, of let's say we did a hypothesis test on data that had the same variability, and here is one case where we had a large sample size -- that is Case 1 on the bottom -- and another case where we had a small sample size, and that is Case 2 on the top.

Both of these, the 95-percent confidence interval for delta includes the value of zero, which means that no

significant difference could be found. However, the upper case with the small sample sizes shows that the confidence interval for delta extends all the way up to perhaps 300. Again, we don't know what we are measuring, so the units aren't on this graph.

But the point is that, even if we don't do power analysis, at least if we saw the confidence intervals, we would have some feel for how well we were able to estimate delta. And if we had that feel, then the next question we would come back to is the same one we had earlier: how large of a delta are we willing to accept? Is the graph on the bottom what we want or is the graph on the top what we want? And that depends on whether 300 is the biggest difference we are willing to accept or maybe 50.

So, the confidence interval is just another way of expressing the hypothesis test and they have the same questions that are raised. I don't think you can do either

of these. You can't interpret the confidence interval. You can't interpret hypothesis test unless you have some feel for how big of a delta that test could detect and how big of a delta you are willing to accept.

Following on page 12, there are some other statisticians who do recommend carrying out power calculations based on if there are statistics. One is Gelman, who is a Bayesian, and Bayesians tend to have heretical views toward hypothesis testing in general.

But even EPA takes this same approach on page 13, where their guidance for data quality assessment, which is a little different process than data quality objectives -- data quality assessment is what happens at EPA when the QA people go in and look at what was done.

And what they are saying here is that, yes, you have to look at the variability that you actually observed in

order to confirm you had a large enough sample size. And this was instructions for the WRS test, which is a little different than Peto-Prentice. But at least it is an indication that a lot of people think it is not so bad using the analysis.

NIOSH's point of view on this is a very purist and theoretical view of hypothesis testing, which is that you can't do power analysis if you have already done the data collection. Or, rather, it is not important to do. Well, we still feel it is important.

And I guess we should stop there because I would like to hear some feedback on what these power issues boil down to. Should we do them or shouldn't we do them? Are we going to figure out how big a delta we are willing to accept or not?

MR. LaBONE: This is Tom.

Let me start with basically a description of what we are trying to do. And

that is, we are doing this test to make a decision: should we use a stratified model or unstratified? So, basically, our two paths forward are fixed. And so, we are just doing this test to decide that.

And so, my argument about the small sample sizes is that that argues to use the unstratified model. Basically, you are saying we don't have enough data. If I can't see a difference when I do the tests, what makes me think that I can develop a reasonable model with that same set of data?

And so, we are not trying to prove a drug works or doesn't work here. What we are trying to do is which path do we take, stratified or unstratified. So, that is the first thing that it comes down to.

All of the EPA guidance and everything that you have in here about power presupposes, and it is implied in it, that you can go get more data. And so, EPA says, test this, and if it is not powerful enough,

go back and get more samples. We can't go back and get more samples.

And so, that is why I think we feel that it is kind of meaningless. We are given a data set. We can't improve it. It is what it is. We do the test and then we make a decision depending upon what we get.

So, in that process it is just, you know, if you go back and say this is not powerful enough, all that means is that we are just going to use the stratified model.

Tim?

DR. TAULBEE: Let me interject there because you just said something that I am not sure we have actually investigated from one standpoint. In some cases you're right, the data we have is the data we have. We can't go get the code back and get more data. But there are other cases where we can. We are using the NOCTS data set because it is more readily available, but there is more data available at the sites to where we

could go back and get them.

In the case of the americium, curium, californium, there isn't any more. We use the logbook data. In the case of plutonium, uranium, strontium, mixed fission products, there's a lot more data that we could go back and get. So, I think it depends upon the particular standpoint.

From that, what are your thoughts on, if we are dealing with a limited data set to start with that we know there is more data, is there any benefit of doing a power calculation then?

MR. LaBONE: Just like Harry said, you do what is practically significant, what effect is of interest to us. Take a look at those confidence intervals, and if that value falls inside that confidence interval with zero and you can get any more data, then, yes, we should go get more data. I mean, again, you would have to give me that number that is of significance first.

DR. NETON: That brings up a whole other issue about --

MR. LaBONE: Yes.

DR. NETON: -- the cost and the time.

MR. LaBONE: Yes.

DR. NETON: I mean, that's --

DR. TAULBEE: But that kind of plays into the role of just taking the external dose example of -- you know, that data is readily available. And if we could decide on a value that is of significance to help us with the internal --

DR. NETON: Yes, yes.

DR. TAULBEE: -- then we could apply this.

DR. NETON: We could flesh that out a little bit, but, yes, I tend to agree with you.

DR. TAULBEE: Yes.

DR. NETON: I mean, there is a reason we used the NOCTS --

CHAIRMAN MELIUS: What would be the gain from adding more, getting more databases? Yes, there is a cost to it, but is that cost worth what you will get out of it, which is sort of what you were talking about earlier, Jim, in terms of how much of a difference would we see, and so forth. Maybe we can predict that with some capability or something. Again, it comes back to what level are we interested in.

DR. NETON: Well, but you should be able to predict how much more data you need, right?

MR. LaBONE: Yes, yes. Absolutely. Yes.

CHAIRMAN MELIUS: That is usually the purpose of the power --

MR. LaBONE: Yes, but that is the a priori. You design it, yes.

CHAIRMAN MELIUS: If we are going to get -- I think there's more samples. There's all kinds of --

DR. NETON: There is a significant difference value that we are, hopefully, going to talk a little bit about later.

MR. LaBONE: Yes. Anyway, if we can get more data, then what Harry is saying is correct. It is just usually when we get this, we assume that we can't get any more data; this is it.

DR. NETON: That is often the case, more often than not, I would say. Only in cases where we are going to do the NOCTS data, and we use NOCTS data for a reason, because the data were there, but they are not coded. It is not readily available. It would take a monumental effort, if not years and hundreds of thousands of dollars.

Anyway, that is probably the subject of a different discussion.

DR. MAKHIJANI: But in the case where you cannot get more data, which is the case that you have already gone to the

logbooks, and so on, as Tim was talking about, and you still have a small number of samples, which is the case, say, with the neptunium data, there are two alternatives. There are three alternatives.

You can always decide we don't have enough data. The amount of data is inadequate, and then that is a question for the Board to decide. And that is an example that Stu was talking about earlier. They had some data and it was kind of evident that the data is inadequate.

MR. LaBONE: They had a systematic inadequacy there.

DR. MAKHIJANI: Yes, right.

MR. LaBONE: Yes, yes. I mean, it was --

DR. MAKHIJANI: Basically, one of the issues that has concerned us -- and I'm sorry Joyce isn't on the phone, but I will try to represent the situation as best I can for the team -- is that construction workers

were thought to be not at routine exposure potential. So, they were only monitored when incidents came to light. But that may not actually be correct.

So, it may be a parallel situation or it may not be. We don't have a definitive conclusion about that. But, certainly, we have put this issue on the table in both the reports, the analysis of actual data that we have put on the table for you, more so with the neptunium than with the thorium.

DR. NETON: I would agree with you that, if it could be demonstrated the construction workers were on an incident, a certain fraction or a fraction of the construction workers were on an incident-driven bioassay, not part of a regular monitoring program, then that would be not appropriate to incorporate that data into the overall routine monitoring data. I think that is true.

DR. MAKHIJANI: But that is what NIOSH has said itself.

DR. NETON: Well, I saw that.

DR. MAKHIJANI: Right.

DR. NETON: And it kind of made me take some pause on that comment --

DR. MAKHIJANI: Yes.

DR. NETON: -- because, you know --

DR. TAULBEE: That's not the case, though.

DR. NETON: Okay. If you really have an incident-driven program, there is a separate -- well, okay, I just would agree with Arjun's point that, if there is this sort of dichotomy in monitoring, you know, incident-driven versus routine, I am willing to accept the routine with incident inside of it, sort of a different situation.

DR. TAULBEE: Right. I agree with that.

DR. NETON: That would only tend

to bias the results high, but they are still on a routine program. But if you only have incident-driven, then I have got some concern there.

MR. LaBONE: I can't comment on Savannah River, but, in general, the question is, did you adequately characterize the intakes? The actual monitoring program is really not significant.

DR. NETON: Yes, yes.

MR. LaBONE: It is, did you accurately characterize the intakes that the people had?

DR. NETON: And demonstrate that the only time there were exposures was when there was no incidents.

MR. LaBONE: Yes. For example, you could have a job-specific-driven monitoring program that only when they went in and did work were they monitored when they came out.

DR. NETON: Well, that's not

incident.

MR. LaBONE: No, but if there are different types of programs, and you can't look at these names, it is, again, did they adequately monitor them? Did they capture the intakes if they occurred?

DR. NETON: Agree, agree.

MR. LaBONE: And independent of site, that is the thing that is important. And if you did that, then you can combine all that data.

DR. NETON: Right.

MR. LaBONE: And that was the comment that we made. But you have to judge did you capture all the intakes.

DR. NETON: Okay.

DR. MAKHIJANI: Are we done with 13, Harry? Did you get the feedback that you were looking for?

DR. CHMELYNSKI: I think it is also going to be hard to resolve that kind of issue as to exactly who was monitored for

what reason.

If we go on with the slides, I think -- what are we on now?

DR. MAKHIJANI: Fourteen. We are on 14.

DR. CHMELYNSKI: Fourteen, right. This is the discussion we just had, I think, that if the data are already there, why are you doing the power analysis. I think we have already discussed that.

DR. MAKHIJANI: Fifteen.

DR. CHMELYNSKI: Okay, 15. Yes, again, Arjun mentioned that we have done these studies, and we looked at the data for a set like neptunium and we do see the number of samples that are there. And we did some simulations to look at how well one would be able to discriminate between the two groups of workers.

And it seemed to us that, even under ideal conditions, using pure log-normal distributions, even if you don't have any

non-detects, you still wouldn't be able to see reliably a difference of factors of 4 to 10.

And this particularly happens when you get up to the GSDs at around, of over 3, 4 and 5 or so, which are very common in this data set. Once you get up that high, it is very hard to find evidence that the tests will be able to detect anything that is in this range of factors of 4 to 10.

Now there are some other simulations reported in NIOSH's response in the Appendix A. And as far as I could tell, none of those had any high GSD values. So, I think 3 was the highest.

So, what those graphs tend to show is that the Peto-Prentice Test and Gehan Test, which is pretty much an WRS test unless you are dealing with a lot of ties -- I'm sorry, but when you have non-detects, you do have a lot of ties. So, that is probably why Gehan is used as a basis here.

Even though both tests do about the same, the Peto-Prentice Test is a little better in those simulations, probably not enough to write home about, but a little bit better.

On the other hand, again, we don't know that we can detect any of these differences that are pretty large, in my mind, for a factor of 4.

So, we leave that again to this issue of how large of a sample you are going to need is going to be dependent on how big of a delta you want to detect.

DR. NETON: This is Jim. I just had a thought, and it could be totally wrong, but I am going to throw it out there anyway.

(Laughter.)

It seemed to me, if you have a GSD that is in the 4 and 5 range, that is going to drive a very high 95th percentile. I mean, clear. And we are assigning the 95th percentile based on a GSD of 4 or 5.

So, wouldn't the stratified data set, to make a difference in the 95th percentile, have to be a difference of a GSD of 4 or 5 higher than the mean to make a practical difference in the distribution that we are assigning at the 95th percentile? Do you know what I'm saying?

You know, we are way out here, a GSD of 5. We are saying we are giving this guy a GSD of 5 difference from the mean. And so, for a stratified coworker data set to make a practical difference up here, to change that number, it would have to have a very large difference in the geometric mean. It is almost like it would be impossible to change that number substantially unless there is a huge difference in the data sets.

Am I wrong on that?

CHAIRMAN MELIUS: No, I don't think you are wrong. I was going to say I think there is a relationship there.

DR. NETON: But we can't detect

very well.

CHAIRMAN MELIUS: Yes.

DR. NETON: But, at the same time, you don't need to because you are already way out here on the distribution. To make a change there, you have to have a huge difference.

CHAIRMAN MELIUS: Yes, but anytime we are way out there and applying it to a larger population, you start to worry is that plausible. You know, you would just take care of the tail.

DR. NETON: Well, no, but that is what we do with the 95th percentile, what we assign for people who could have been heavily exposed. And that is what we are saying.

CHAIRMAN MELIUS: Well, see, that is a key difference. You are saying you are applying it to everybody, is what you actually --

DR. NETON: Well, not everybody.

CHAIRMAN MELIUS: No, I know.

And, see, I think that is another thing we need to think about and take into account. Because if we are segmenting that, or whatever you want to call that, you know, some people get the 95th, some people get 50, that makes some difference in terms of how we are approaching this, yes.

DR. NETON: But the end result would be, if we stratified it and it was lower, they would receive a lower, construction workers would receive a lower dose than they are already getting. I mean, that would be the end result. I am not sure we are going to spend a lot of energy to do that.

CHAIRMAN MELIUS: No, no.

DR. NETON: But I need to explore that concept because I really do think that, with large GSDs, you would have to have huge differences to drive the change in the 95th percentile.

CHAIRMAN MELIUS: But that also

comes back to how do we distinguish, then, who gets the 50th and who gets the 95th.

DR. NETON: Well, yes. Well, that is not a coworker, I mean, that is not a stratification issue. That is a sort of way we do business, dose reconstruction.

CHAIRMAN MELIUS: Well, but it has the same impact. I mean --

DR. NETON: Well, yes. Yes, but it is a different issue, though, I think. I didn't think that the issue on the table was getting rid of the 50th and the 95th. It was deciding what the appropriate distribution was to be used to assign the 50th and 95th percentiles. That is what I thought we were talking about.

DR. MAKHIJANI: No, I don't think it is a distinct issue. I agree with Jim on this.

Because you may argue that the 95th percentile and the GSD is high, so big

that it will cover the most exposed workers, a large fraction of them.

DR. NETON: Yes.

DR. MAKHIJANI: But you can't argue the same for the 50 percentile. To figure the people in that box, you have to know is the 50 percentile the construction workers. You know, how do you know -- how are you going to decide which construction workers are comparable at the clerical workers?

DR. NETON: All construction workers are going to fall into the 95th percentile. I don't see how they wouldn't. That has been our way of doing business for a long time. These guys are workers that are in the radiation-exposed areas working. And the 50th percentile, remember, is not a fixed point. It is a full distribution. We are acknowledging there is uncertainty.

DR. MAKHIJANI: Yes, I understand that.

DR. NETON: So, I think between those two you have sort of bounded the exposures.

CHAIRMAN MELIUS: But I think it is more than bounding. Especially as we are trying to do these kinds of comparisons, the applications, the coworker applications, I think we need to sort of be careful about it.

DR. NETON: I am trying to figure out, if we teased out a construction worker coworker model, strata, then would we use the 50th percentile, the full distribution? Would that be more appropriate because that is the representative distribution of that --

MR. LaBONE: You would not use the 95th.

DR. NETON: I wouldn't use the 95th because now I would have a distribution, and we can do that, but I don't know. I could see only numbers going down, doing this type of analysis.

CHAIRMAN MELIUS: Yes, but saying

what distribution is appropriate, I mean that should be the goal, not does it go up or down.

DR. NETON: Well, but, at the same time, we have already demonstrated that it is very hard to tease these out because there are small numbers, and it is hard to show the difference, the significance. I mean, so in a way it is what it is. These are the data sets we have, and then we are bounding based on a plausible upper bound.

I mean, I don't know. We can talk more about that.

DR. MAKHIJANI: Should I move to the next one, Harry? Or did you have more comments?

DR. CHMELYNSKI: No, I don't. But I see on the next page, on page 16 -- let me just back up a second. Page 16 is titled, "Finding About Worker Changed Jobs". And indeed, that was a concern of ours, and especially one of Joyce's, I think.

Since we are already saying we don't know much about who did what, it is hard to tell whether you are doing this right or not in terms of throwing people into one group and the other group, since we know that some construction workers start becoming regular workers. That fouls up the comparison once you start having people cross the line between the two groups in a given time period.

However, I thought it was interesting to see down in NIOSH's response that they point out, again, that to stratify these models, you have to be able to assign people to a meaningful job title. Well, I don't know how exactly specific those job titles have to be.

But the point is that here we are pointing out that it is a hard task to do that. And yet, on the other hand, just moments ago, we hear that, "Oh, we are going to give those guys the 95th percentile." Now

if that is going to be applied to all construction workers, that is one thing. But when you start trying to think about the subgroups, we are not even sure which ones we could put in there.

So, I guess what we are trying to say here is both. If we don't know what they are doing, what jobs they are doing, but, yet, when we get around to dealing with this issue, we will know what kind of jobs they are doing, I guess that is reasonably uncomfortable.

DR. TAULBEE: I think this really depends upon the site. You know, RPRT-0053 was designed to be generic, and there are some sites where we can get down to meaningful job titles on virtually everybody, and there are other sites where we cannot, where we can just basically categorize them as the construction trades or non-construction trades. So, it really varies between the different sites as to what level

of data we have in order to categorize people.

DR. MAKHIJANI: This is just a question/observation. At Savannah River Site we have job titles on everyone.

DR. TAULBEE: Yes.

DR. MAKHIJANI: So, they are part of the worker records. But we don't necessarily have a meaningful amount of data corresponding to every job title. So, we can't necessarily develop.

So, if you have, you know, 12 job titles for construction workers, we have those job titles. They belong to the site.

DR. TAULBEE: Yes.

DR. MAKHIJANI: And there were specific types of work they were generally doing, you know, carpenters, electricians, whatever. But we don't necessarily have enough data to put them in an exposure matrix.

DR. TAULBEE: We don't have

enough monitoring, internal monitoring data --

DR. MAKHIJANI: Right. That's what I mean.

DR. TAULBEE: -- for some radionuclides.

DR. MAKHIJANI: Right.

DR. TAULBEE: Other radionuclides we do.

DR. MAKHIJANI: Right, right.

DR. TAULBEE: So, some of them, that is why you end up with the small numbers. But take plutonium, for example; there is thousands of results. You won't run into any of these small numbers of workers issues.

DR. MAKHIJANI: Right, and we haven't argued about plutonium or uranium, precisely because of that, I think, because we recognize that there are large numbers of data.

DR. TAULBEE: But the same

general type of work of a construction trades worker going into a plutonium facility or a californium/curium facility, which were smaller than the plutonium facilities, their same type of work is actually similar, the type of work that they would be doing and the monitoring associated with it, compared to the operators.

So, you could do a comparison of the plutonium from that standpoint of do pipefitters come up higher or just construction trades in general come up higher from that standpoint. That could be informative from that standpoint.

DR. MAKHIJANI: It could be, yes, I agree.

CHAIRMAN MELIUS: So, you haven't done that?

DR. TAULBEE: No, we haven't gone and collected all of that data.

CHAIRMAN MELIUS: Okay.

DR. TAULBEE: We used NOCTS

because we had 4 to 5 hundred per year. So, we didn't bother to go get the thousands --

CHAIRMAN MELIUS: Okay.

DR. TAULBEE: -- for that comparison.

DR. MAKHIJANI: Should I move to the next one, Harry?

DR. CHMELYNSKI: Yes, please.

All right. We are on page 17. Now we get into the statistical discussion, I guess, although I am not sure how long we want to drag this out.

(Laughter.)

But I still feel that we have to know what the power of the test is. I don't care if we are doing it on retrospective data or not. I think that, if you deal with this small of sample sizes, it is hard to trust any hypothesis test result.

And I think that in the response here that NIOSH made, I think they also recognize that you have to be able to define

the size of the effect, as we have said several times now, in order to figure out whether there is a difference and whether the test has any power to detect that difference.

Lacking a measure of what we think is sufficient accuracy, we are left doing hypothesis tests that sort of tell us some random numbers sometimes when we get very small samples. And we are trying to base important decisions on those random numbers here, it seems to me.

So, if we go on to the next page, continuing that same line of thought, NIOSH has done a lot of research here in figuring out what is the right test to do when you have less-censored log-normal data. Now, of course, we don't know it is log-normal, but we do know we have non-detects. So, it pretty much fits into that.

Now just knowing that the Peto-Prentice test is the most powerful test available for these kind of data doesn't tell

us what the power is. And I am still maybe the old school. I want to know what the power is before you tell me what the test result is, because test result doesn't mean much without that information.

Now, getting down to the specifics, so what we are talking about is, is 30 samples going to be enough? That is what NIOSH stated. I am not quite sure how they came up with that number, although I have seen it quoted in some other places, too.

When you think about all the different kinds of distributions with all the different GSDs, it is hard to believe there is any single sample size that would be appropriate across all these different comparisons we are trying to make.

And I think one has to sort through them and start thinking how big a sample we are going to need to detect how big of a difference. The simulation results that

we report on page 19 we reported last time. Some I kind of elaborate on them.

But, basically, the gray area on that table shows where the Type 2 error rates are low, at least low enough for my mind. Maybe some people go on down to .05, but I am willing to get them down to around 10 percent or so.

And if I am using an alpha of .05 and I happen to apply it to some data where both of them have a GSD of 4, I am already up to a 15-percent error rate. And then, 5 and 6, we start getting even much higher error rates. And again, we have the graph that shows the steepness at the .05 level in this curve, rising almost up to 35 percent. Thirty-five percent of the cases we were not able to reject the difference that we know was there.

Well, in this case, again, no matter how many simulations you do, you can't cover all the cases. So, maybe this isn't

sufficient to say that this is always bad. But we certainly haven't found any simulated results that show us that it is a good one.

DR. MAKHIJANI: Well, could I add to that, Harry, we actually gave examples from actual data in the thorium report, and Harry did an analysis for four years. In all cases, there were more than 30 data points. And we showed that, depending on the ratio of GMs and GSDs, that sometimes you could have fewer data points, more than 30, like I think 38, in which it looks like the analysis was good, that you could actually make a good comparison, keeping both effects of error down. Sometimes you could have far more data points, but because of the way the GMs and GSDs are related, 60 or 70 data points may not be enough to give you a result with some confidence.

And we don't have the details here, but I think this little strip chart is illustrative of the actual cases that we

analyzed with more than 30 data points. This uses exactly 30.

Sorry, Harry.

DR. CHMELYNSKI: Oh, no problem.

Are there any other questions on that? We are pretty much wrapping it up here.

CHAIRMAN MELIUS: Where does the 30 come from?

MR. LaBONE: The 30, we were always taught 30.

(Laughter.)

No. The question is sometimes you will have 30 data points and the entire population was 100 people. So, you are sampling a good portion of the population.

CHAIRMAN MELIUS: Okay.

MR. LaBONE: Other times you don't know. Sometimes it is all uncensored, which is good, solid data.

CHAIRMAN MELIUS: Right.

MR. LaBONE: Sometimes it is

censored. And so, actually, that 30 is attempt to make sure somebody doesn't try to go through and do a model with two points.

CHAIRMAN MELIUS: Yes. Okay.

MR. LaBONE: Okay? So, it is more of a thing, and again, all these analyses are done by statisticians. That is written into the report. And they are supposed to look at this and make a professional judgment, is what I am turning out nonsense?

CHAIRMAN MELIUS: Okay.

MR. LaBONE: Because the data are just -- there is no data here. There is only one uncensored data point, for example.

And so, it was just a general guideline to give the statisticians someplace to start. And so, that is kind of like where it came from.

CHAIRMAN MELIUS: Okay. That is sort of what I assumed.

MEMBER BEACH: What I am

wondering, does the percentage ever play in that? If you have 100 people and you have got 30 samples, that is a pretty good percentage. But if you have 1,000 people or 3,000 people and only 30 samples, then your percentage goes way down.

MR. LaBONE: What they taught us in sampling class is that one sip of a well-stirred pot of soup is sufficient.

MEMBER BEACH: Is sufficient?

MR. LaBONE: So, it depends upon --

MEMBER BEACH: It depends on what is in the soup?

MR. LaBONE: No, is it a random sample? Did you collect from -- yes, is this a random sample? Is it a good sample versus -- once you get to, I guess, a certain size of sample, the population size really doesn't matter that much.

MS. CHALMERS: As long as it is representative.

MR. LaBONE: As long as it is representative, yes.

MEMBER BEACH: Okay.

MR. LaBONE: So, it is not exactly proportional, like you might think.

CHAIRMAN MELIUS: You can characterize the mean income of the United States by interviewing 10 people, or whatever.

MR. LaBONE: Yes, yes.

CHAIRMAN MELIUS: Yes, yes.

MR. LaBONE: Political polls.

CHAIRMAN MELIUS: Yes, yes, right. Yes.

MR. STANCESCU: Actually, you can do this test. I mean, EPA is doing the Gehan test, which is like a slightly different version of Peto-Prentice, with 10 samples in each group.

But, you know, depending on how much censoring you are -- we wanted to be confident that we have enough power to detect

the differences. So, 30, we thought maybe a 30 or 4-percent censory, we think is good enough to detect the difference. We put these power curves at the end just to show that the power of the Peto-Prentice Test is enough to detect these differences.

I mean, it is very hard probably to agree what is enough power. I mean, most of that, sufficient, I want to say 80 percent is enough. I mean, we are not doing a clinical study to get 99 percentile. So, it is probably very hard to agree what is appropriate power here.

MR. LaBONE: I think I'm sensing the primary disagreement is based on whether you can or cannot go back and get additional data. I don't know what Harry thinks about that. But, again, if you cannot go get more data, to me, this doesn't get us anywhere. Whereas, if you can go get more data, then, yes.

CHAIRMAN MELIUS: Well, I also

think it is a question of how it is applied. So, it is what use is being made of this and what are the implications of that for dose reconstruction, which, again, isn't a fault of the statistics, or whatever, but that is what helps us to understand it, and so forth.

At least now I know 30 isn't a Holy Grail that I had missed someplace because my education is so --

(Laughter.)

MR. LaBONE: When normality kicks in, yes.

(Laughter.)

DR. MAURO: While listening -- this is John -- while listening to this conversation on the reason for 30, and I went online.

(Laughter.)

And it is really funny to see what this says. That the only reason 30 was regarded as a good boundary was because it made pretty students' T tables in the back of

textbooks that fit nicely on one page.

(Laughter.)

I just found that on the web.

DR. NETON: I wouldn't believe everything I read on the web.

DR. CHMELYNSKI: It must be true if you saw it on the web.

DR. NETON: That's right.

(Laughter.)

DR. MAURO: You know, I had to do it.

(Laughter.)

MR. LaBONE: No, a lot of thought went into the numbers because every one we came up with Tim said, "Can't you go lower?"

(Laughter.)

You know, "What about 29?"

(Laughter.)

DR. MAKHIJANI: Harry, do you want to comment on that?

For my part, I would agree with what Tom said. If you have very small

numbers, you are in trouble, and that so long as 30 is a guideline, rather than some hard-and-fast number that fell from the sky, acknowledging that sometimes more than 30 may not be enough --

MR. LaBONE: Especially if you go back and do the analysis that he is talking about, you may demonstrate that it is not enough, yes.

DR. MAKHIJANI: Harry, did I misstate anything?

DR. CHMELYNSKI: No, no.

DR. MAKHIJANI: Okay.

DR. CHMELYNSKI: I think that this issue does get down to the very core of what is going on in terms of -- I guess the way you said it earlier was the way I think, too.

There are really three outcomes here. One is the test can tell you that they are different. The test can tell you they are the same. But then there is the case

where you don't have enough data to answer the question. And I just keep feeling that we keep beating our head against the wall trying to say, "Oh, we can answer this question," when, in fact, the statistics doesn't give you the answer if the data set isn't good enough.

DR. MAURO: This is John again.

I am listening, and please shut me down if I am going someplace where I shouldn't go.

But I think the dilemma is this, and it comes from my experience in doing blind dose reconstructions: we are trying to standardize the process, streamline the process that will help dose reconstructors deal with the limited data that might be out there.

And just let me say that, when I am doing a blind dose reconstruction, and I am just confronted with the person and a whole bunch of data and a lot of history of

the site, and that sort of thing, and I am doing my dose reconstruction, a difference that makes a difference is if I think it is possible that a person could have gotten an intake or an external exposure that is of such a magnitude that can make it a 50-percent Probability of Causation.

So, it becomes a case-by-case problem. And so, in a way, the answer to the question, you know, statistical power and level of uncertainty and confidence levels, and you are trying to decide that upfront, I don't know if it is possible to do that because it only has, the question only has meaning when it is applied to a real case where 100 millirem may make a difference.

So, I guess all I am saying is to bring it back down to earth in my world, what I call the "common-sense world" of doing dose calculations, what I do is I actually look at a person. Then, I look at all the data at that site that is available to me. And I

say, is it possible that this guy could have gotten a lot higher exposure because of his work and because of data we have regarding him, the time period, what he did, and the other records? And it almost becomes one where you are doing the diagnostic, you know, where you have to use a certain degree of judgment and ask yourself the question, is it possible that this guy could have had this much intake? Because that is what you are going to need to get him over 50 percent.

In a way, I am making an argument that, to a large extent, this is a dose reconstruction program, but to a certain extent it is really a compensation program. And the two sometimes are problematic. Sometimes you really can't reconstruct the dose, but you probably can make a statement that it looks like it is virtually impossible that this guy could have gotten more than 50 percent.

And then, right now,

unfortunately, the conversation we are having is we are trying to come up with all of the statistical tools that will allow us to go through a process that will get us where we want to go to make a good decision. And I don't think in the end you can accomplish that. I think in the end the question becomes, on a case-by-case basis, have you done the right thing by way of this guy in terms of trying to assign the highest-plausible exposure? And I don't know if you could standardize that.

And I know it is a little blasphemous to raise it this way, but I think we are in a place that maybe we can't solve this problem.

CHAIRMAN MELIUS: There goes the SC&A contract.

(Laughter.)

MR. KATZ: It's up in December anyway.

(Laughter.)

DR. MAURO: I was afraid of that. I wasn't going to call in.

(Laughter.)

CHAIRMAN MELIUS: I'm sorry, John, I couldn't resist it.

DR. MAURO: I know.

CHAIRMAN MELIUS: You went from common sense to a Ouija board I thought there for a while.

(Laughter.)

DR. MAKHIJANI: Do we have any more? I think we are done. Yes, I think we are pretty much done.

CHAIRMAN MELIUS: John, you finished us off.

(Laughter.)

DR. MAKHIJANI: Harry, did you want to go further? I think we are done with the analytical comments, right? Did you want to go through the rest of the slides?

DR. MAKHIJANI: There are several recommendations concerning one-sided versus

two-sided tests.

DR. MAKHIJANI: Yes.

DR. CHMELYNSKI: And, in fact, I do like the idea that NIOSH throws up here about testing for a difference which has a practical significance rather than one that has a statistical significance.

DR. MAKHIJANI: That is slide 22, right?

DR. CHMELYNSKI: Slide 22, yes. There is a formalism here for doing a test where it has the null hypothesis that, indeed, there is a difference. And then, the alternative is that, no, there is not a difference. I am not sure I would require that, for all X, then, at least one X should necessarily be in there, but I will have to think about that, the way this is phrased.

But this is pretty much what we were asking for, which is, could you turn it around? Rather than making the assumption they are the same, can we assume they are

different and, then, look for evidence in the data that causes us to abandon that position?

So, I do think this is a positive step, trying to look for the significant difference. But I will point out that they have a "D" in there. So, it has the same problem of the other three discussions we have had. Someone has to figure out how big a difference is important to find.

And not being able to do that leaves me wondering why we are doing hypothesis tests if we don't know what it is we are looking for.

MR. LaBONE: We are doing the hypothesis --

DR. CHMELYNSKI: That's the end of my discussion.

(Laughter.)

MR. LaBONE: We are doing the hypothesis test because, again, the whole purpose of RPRT-0053 was to say, should we stratify or not? So, again, we have this

binary decision to make. And so, it was, what is your technical basis for making decisions to stratify or not stratify?

And so, again, we looked at this equivalence test early on, but, again, after talking to a number of people and we could not come up with practical significance, we just had to move away from it and just go to statistical significance. That is why we put it in there.

I think we understand what you are asking for. It is just we couldn't do it. We didn't know how to do it.

DR. CHMELYNSKI: Well, I don't, either, I have to admit.

(Laughter.)

MR. LaBONE: Yes. We agree.

(Laughter.)

Yes, it is a subject matter decision. It is not a statistical decision. Yes, yes.

CHAIRMAN MELIUS: But I think if

we were able to take on that issue in some way, that the statistics could be much more helpful.

MR. LaBONE: It will fall way out of the --

CHAIRMAN MELIUS: Yes, yes. I think that is sort of the bottom line, not that we have to give up, but the fact that we would get more information and be able to -- maybe another way to look at it is we would have more agreement and better ability to look at different situations and agree on how to approach that, and so forth.

Tim, you had a --

DR. TAULBEE: Couldn't we kind of take a step back and get away from the internal for a minute and just look at the external? Is there any way we could come up with a practical difference that everybody could agree with on the external? Then, we could apply these methods and see how they come out.

CHAIRMAN MELIUS: Yes. No, I think that should be our next discussion. And I confess it has been a long while since I have even looked at an external coworker model. I don't know --

DR. TAULBEE: If you go back through Tom's breakdown of how we get to dose --

CHAIRMAN MELIUS: Yes.

DR. TAULBEE: -- we are already at the end at that point --

CHAIRMAN MELIUS: Yes.

DR. TAULBEE: -- with the external. So, we have a badge --

CHAIRMAN MELIUS: Right.

DR. TAULBEE: -- associated with the people. So, we get rid of a lot of these other censored data type of issues associated with that. And if we can come up with a difference that everybody is comfortable with, then maybe that would help inform this.

CHAIRMAN MELIUS: And we have to

come up with a name for that difference, so we don't cause shockwaves, or whatever.

(Laughter.)

MR. LaBONE: De minimis is probably not a good word.

CHAIRMAN MELIUS: Yes, de minimis is not a good word, you know.

Let's figure out what number we want to -- what would be helpful, and then we will appoint another Work Group to name it, though, something. I don't know.

(Laughter.)

People have been clamoring for more Work Groups, and Wanda will volunteer; I guarantee it.

(Laughter.)

DR. TAULBEE: And DOE and NRC have effectively defined 100 millirem as their basis for monitoring people.

MR. LaBONE: That's true, yes. But that's not a good reason to choose it for this.

DR. MAKHIJANI: You have to throw some numbers out there.

MR. LaBONE: That is true.

DR. MAKHIJANI: I think it is good starting point in thinking about it.

CHAIRMAN MELIUS: And the basis for that is?

DR. NETON: I'm not aware of a basis for why it's 100.

DR. MAKHIJANI: It is 100 millirem is background? Is that probably the basis for it?

DR. NETON: No, no. What's external background, about 100, right?

DR. MAKHIJANI: External, natural background without radon --

DR. NETON: It's about 100.

MEMBER ROESSLER: What are these millirem units you keep using?

DR. NETON: I refuse to move over. Sorry.

I think it could be sort of an

increment of a natural background. Because if you have -- I haven't looked at the tables in a long time; they have changed, but it is about 100 millirem internal, 100 millirem external, and throw radon in there, which is another 100 or so. Three sixty comes to mind in total.

CHAIRMAN MELIUS: What about for what we talked about earlier in terms of -- I think we tied Probability of Causation. So, the model we are using, I think it may be more useful, maybe not.

And so, we talked before of taking sort of -- you know, what would make this substantial or some difference in the reconstruction for a radiosensitive cancer, leukemia? We talked about 500 or a rem.

DR. NETON: Oh, for a PoC of 50 percent?

CHAIRMAN MELIUS: Yes, yes.

DR. NETON: About a rem, I think. You could get the 500 under some very

extreme --

DR. TAULBEE: Oh, I wouldn't say you could get to the 99 percentile out of 500 millirem, but I am saying that where it could really begin to make a difference is if somebody already has a few rem type of scenario. Then, 500 millirem would kick them over. If you were to see it at the 45th percentile for leukemia, it would take about 500 millirem to get them over the 50th percentile.

DR. NETON: I don't know. I mean, there's all kinds of different permutations that you have to look at. That's the problem. But I think 100 millirem would not move things because it is not a linear scale, right?

DR. TAULBEE: No, it is not a linear relationship.

DR. NETON: Right.

DR. TAULBEE: And 100 millirem wouldn't move it very much. We haven't done

that calculation, but, I mean, that's something we could look at and see.

DR. NETON: What if we look at a few different ones with the external, 100, 500, 1 rem?

DR. TAULBEE: We would have to come up with some various combinations of scenarios that we think are sort of maximizing that difference somehow, although one could always -- I don't know. It would be hard to -- I wonder if there is a way one could computerize this and come up with a maximum, you know, a sensitivity analysis almost of some sort.

MR. KATZ: Well, you don't have to use the very worst case. You don't have to base this on that. You just need to find something that is reasonable as a case of concern.

DR. NETON: Yes.

MR. KATZ: I mean, it doesn't have to represent the very worst case.

CHAIRMAN MELIUS: Not the worst case, but it needs to be --

DR. NETON: Pretty close.

CHAIRMAN MELIUS: -- close to a worst case because you don't want to dismiss it if it is --

MR. KATZ: No, no. I am just saying Jim is saying, you know, you can never think of all the permutations that could make for a worst case.

CHAIRMAN MELIUS: Yes.

MR. KATZ: And you don't have to get that far, I don't think.

CHAIRMAN MELIUS: No, no.

MR. KATZ: Just sort of a reasonably-bad case, whatever, it seems like would be more than adequate because you are talking about developing a coarse tool in the first place.

DR. NETON: One thing we do have is a 40,000 completed dose reconstructions, so we could add 100 millirem. How many are

under 50 percent? I have forgotten. But the ones over 50 obviously wouldn't come into play, but the 30 percent or 60 percent that are under 50 percent, you could almost look at those.

CHAIRMAN MELIUS: Or look at the ones 45 to 50.

MR. KATZ: Take 45 to 50.

DR. NETON: Oh, yes, yes, that's true, yes. Yes, take the ones that are closest, so you get the 100 millirem. And that is about as representative of a sample as we are going to get of what we have dealt with. I am not sure if there are issues doing that or not.

DR. TAULBEE: If you had one line of 100 millirem --

DR. NETON: No, no, no. I'm talking about using real data to -- I don't know why; I worry about a lot of things.

(Laughter.)

That's my life.

CHAIRMAN MELIUS: Just don't send out letters.

(Laughter.)

DR. NETON: Well, I mean, I am just thinking if we have the definitive list, or not definitive, but a very good representative listing for distribution of potential effects.

MR. KATZ: That seems like fairly compelling.

DR. MAURO: Jim, I think that is a great idea. I mean, what is the smallest dose that could be added to the 40,000 that would bring someone that was under over?

DR. NETON: It wouldn't be 40,000. It would be the ones that are under 50.

DR. MAURO: Right. Exactly.

DR. NETON: It would be 60 percent of our cases.

DR. MAURO: The 30 percent or so, right. We are talking only 10,000. I think

about 30 percent out of the 40,000 have been compensated, on that order.

CHAIRMAN MELIUS: But I am not sure we want to go through and try to find the smallest dose.

DR. NETON: Yes, that's true.

CHAIRMAN MELIUS: There is sort of a practical --

DR. MAURO: Yes. But the idea I like.

CHAIRMAN MELIUS: Yes.

DR. MAURO: I mean, at what point does it make some sense to make some changes to the compensation decisions? We have such a history of data. That is a practical way to do it, yes.

CHAIRMAN MELIUS: And I think if you limited yourself, I mean, if you limit yourself to more radiosensitive --

DR. NETON: Yes, we would pick some cases, the ones that were 40 to 45.

CHAIRMAN MELIUS: Yes. Yes.

DR. NETON: Interestingly enough, see, that doesn't factor in the -- what am I trying to say here? When you get to things like internal dose, there is not a one-to-one incremental increase in the organ dose based on increase in the inhalation rate because the organs have different simulations.

DR. TAULBEE: But if we can't do this for the external, there is no way we can do it for the internal.

DR. NETON: That's true. Yes, yes. No, I will grant you, yes. And what I am saying is it would be less of an effect from an internal exposure because it would only affect those organs that assimilate the material. And you could limit the test cases to those situations like lungs and liver, and whatever.

I think it is worth pursuing.

CHAIRMAN MELIUS: Yes.

DR. NETON: And we never thought -- I mean, we talked about doing

something like this, but this just sort of popped into my head.

Of course, you know what is going to happen. The data are going to be somewhat ambiguous. It doesn't make an effect for 99 out of 100 or something like that.

MR. KATZ: But it sounds like a useful task.

DR. NETON: It's a start. It's a start. I'm willing to try this.

CHAIRMAN MELIUS: It's a benchmark we can -- so we are not trying to do something. And it has applications elsewhere, which is why I think we need to put some thought into doing it, not just pick a number out of the air arbitrarily.

And then, at the same time, I think it would sort of help frame this situation. And I think it is the only way we are going to get by this coworker issue, at least in a way that we can -- how to say it? -- be consistent from site to site and

understand how to weigh different factors, and so forth.

DR. NETON: I also like the fact that it happens to coincide with increments of background to some degree. I mean, you have distribution in the background. I mean, a person in Denver versus a person here. I mean, so that is all kind of built into the general background. It is not a good reason, but it is another component of that.

DR. MAKHIJANI: Well, I'm not so sure about that. I'm not so sure about that. Because what I was going to say is that we have got to make an assumption that background doesn't cause any cancer. It may cause 1 percent of the cancers.

DR. NETON: Yes, but it is not DOE-related.

DR. MAKHIJANI: Yet, not DOE-related, no. You said that it would help with communication to the public.

DR. NETON: Oh, no.

DR. MAKHIJANI: And then, you add the radon, and so on.

DR. NETON: I agree.

DR. MAKHIJANI: You know, EPA says a certain number of cancers from radon.

DR. NETON: Yes, when you are on a threshold --

DR. MAKHIJANI: Yes, right. So, I think proceeding on the practical, I think a different approach to how to present this.

But, Harry, did you have a problem with where we're headed?

DR. CHMELYNSKI: I'm sorry. That is exactly where I think it needs to be done. This is how big of a difference are we looking for. I think you have to translate it down into risk in order to standardize that difference over sites.

DR. MAKHIJANI: Okay.

DR. NETON: So, the question is, if you add 100 millirem, would that be your lifetime dose, not your lifetime, but your

worker dose?

DR. TAULBEE: I would say 100 millirem in one year, which would be what point in relation to the cancer where it would have maximum effect on the latency, the latency curve.

DR. MAKHIJANI: Some homework could be done.

DR. NETON: Yes. Yes, you don't want to add 100 millirem the year before everybody got their cancer because it is going to be zero effect.

DR. TAULBEE: Yes, do it the first day of employment.

DR. NETON: Yes.

DR. TAULBEE: I mean, the only one that is going to decrease is the leukemia, and that one you would have to try to figure out.

DR. NETON: Well, we would have to outline the parameters.

CHAIRMAN MELIUS: Yes, we don't

want something just very extreme, I think.

MR. LaBONE: Well, I think you should really carefully think very hard about how you are going to do it, and then do it. Don't play with it and iterate until you get the answer you want.

(Laughter.)

I mean, don't tinker, you know.

CHAIRMAN MELIUS: Design the study.

DR. NETON: Design the experiment upfront. I totally agree with you.

MR. LaBONE: Yes.

DR. NETON: You have to define your parameters. I am not saying that we know and then move it around.

MR. LaBONE: Okay.

MR. KATZ: But you could have several starting points in mind and could test them all. I mean, you could have more than one in mind, construct in mind, and test it.

DR. NETON: Yes. Well, I think we would have to develop a test plan, and then maybe even get it vetted to some degree with others, just so we aren't accused of doing exactly that, like rigging the experiment or whatever you want to call it.

MR. LaBONE: Well, again, you get your training data set and then your test set. So, you can play with the training set and then --

DR. NETON: But can we do a power calculation?

(Laughter.)

CHAIRMAN MELIUS: I mean, you are going to be collecting more dose reconstruction.

DR. NETON: We can always get more, right? Well, I'm game for doing this experiment.

MR. LaBONE: In the game plan, are you game?

DR. NETON: Yes, I haven't heard

Stu say anything.

MR. HINNEFELD: Oh, well, yes, I mean, if the Work Group wants us to do this task, we will take it on, recognizing all of the priorities we face and then the monetary restrictions.

It occurs to me that we are talking about here a coworker model, right? We are talking about can we build a coworker model, which then will be applied to unmonitored work.

DR. NETON: No, no, no.

MR. HINNEFELD: No, that's not what we're talking, not this exercise.

DR. NETON: Oh, yes. Yes.

MR. HINNEFELD: I am talking about our broad discussion.

DR. NETON: Yes.

MR. HINNEFELD: Our broad discussion today was, can we acceptably build a coworker model to apply to unmonitored workers? And in order to do that, we have

this population of monitored workers, many of whom are probably completely monitored.

So, if we reach the conclusion that there is not a way to build a coworker model for those unmonitored employees, the logical conclusion is that the unmonitored employees would go in an SEC, while the monitored employees, who are quite likely the more highly exposed, will go through dose reconstruction. I mean, that is where this decision could lead.

MEMBER ROESSLER: And that seems like such an unclear --

MR. HINNEFELD: That is why I brought it up.

MEMBER ROESSLER: When I think about that, it is just --

MR. HINNEFELD: How do I go to my Director and say, "So, we have concluded that there is not a way to build the coworker model. So, these people who were not monitored, we cannot reconstruct their doses.

And so, we are going to recommend an SEC Class for those. But the people who were completely monitored, we can do those dose reconstructions. And so, those will have to undergo dose reconstruction"?

So, that is the outcome of rejecting, of saying there is no way to do a coworker model. Am I wrong on that?

CHAIRMAN MELIUS: Well, I don't think that we're talking about that at this point.

MR. HINNEFELD: Okay.

CHAIRMAN MELIUS: I don't think that is even on the table at this point. I think what is on the table right now is what are the best ways of doing coworker models and how does it have to be done.

MR. HINNEFELD: Okay. That's good.

CHAIRMAN MELIUS: And then, how do we deal with stratification and other issues, which, again, may mean that certain

strata may not end up -- may end up in the SEC or something, which is sort of what happened at Fernald. It may not be because of the statistical issues. It may be because of just lack of data, and so forth.

But I think we are more likely -- sort of what is the best way of constructing and evaluating coworker models?

MR. HINNEFELD: Okay.

CHAIRMAN MELIUS: And I don't think we are at the point to even --

MR. HINNEFELD: Okay.

CHAIRMAN MELIUS: At least I'm not.

MR. HINNEFELD: That is just one thing that worries me when I think about it.

CHAIRMAN MELIUS: Yes.

MR. HINNEFELD: And then, I always worry when we talk about getting more data because just resources being what they are, if we can accomplish what we need to accomplish without -- when I say getting more

data, I mean going and capturing all the monitoring data which we then have to code and go enter and build our database from additional data. That is almost always a long effort, and that almost always gives me pause.

CHAIRMAN MELIUS: But I think this is also a way of evaluating how much -- do you need more data? How much more do you need?

MR. HINNEFELD: How much more do you need?

CHAIRMAN MELIUS: And then, you are going to be able to say that is going to cost "X". Is that feasible or not feasible?

MR. HINNEFELD: I don't have any objection to the course of action that we are embarking on. That is not what I am worried about. What I am worried about is ultimately some of the things I heard discussed today.

CHAIRMAN MELIUS: Yes, and I think that's sort of the resource issue. I

think it is sort of better than putting -- unless we have a good way of evaluating these models, then we are going to be in the situation where the Board and NIOSH may disagree.

And then, the letter is going to be what I described. It is going to be saying, you know, NIOSH has sufficient data; there is sufficient data to do dose reconstruction, but NIOSH doesn't want to get it.

MR. HINNEFELD: Go get it, yes.

CHAIRMAN MELIUS: Or can't afford it, or whatever, something like that. I don't think that is where we want to be.

MR. HINNEFELD: Yes.

CHAIRMAN MELIUS: I mean, it is in some sense a practical outcome of what is going on.

And we are not going to have a good -- "Well, how much more data?" How are you going to say it? Well, you are going to

go talk to John, and is it going to cost a million or $50,000 or --

MR. HINNEFELD: Yes.

CHAIRMAN MELIUS: -- a billion, or whatever?

I think the issue we need to be careful with here is just sort of the communications issue in terms of how we describe what this is doing.

But what I would hope is that it is something you can do relatively quickly, and then say we would have a Work Group call to discuss it. I am not even going to try to pin you down to a timeframe right now.

DR. NETON: Yes, I have no idea. It is going to require some programming efforts on our part. When I always speak with programmers, I get yelled at.

(Laughter.)

CHAIRMAN MELIUS: But I would hope we could do it relatively quickly because I don't think we need to spend,

should be spending a lot of resources on it, because I don't think we are trying to be that exact or specific, or whatever you want to call it.

MR. HINNEFELD: Are we clear on the task that we have got coming out of here in terms of using external dose and some existing cases we have, in the like 45-percent range, about that? How many of those are we going to do? Actually, first, we are going to do it by the sampling method.

DR. NETON: Yes, you've got to plan, yes.

MR. HINNEFELD: Design the task.

CHAIRMAN MELIUS: Yes, we want to do a technical call, or whatever we want to call that to --

DR. NETON: Everyone might have a different viewpoint there as to what may or may not be appropriate. I don't know.

MR. HINNEFELD: Okay. So, the first thing we need to do is design the task.

DR. NETON: Right.

MR. KATZ: And we may be able to just circulate that up --

MR. HINNEFELD: Yes.

MR. KATZ: -- and get written comments back.

DR. NETON: Exactly. We can put it out there.

MR. HINNEFELD: Okay. Okay. We should be able to do that relatively quickly.

DR. TAULBEE: And if we come up with a value, then your step two would be to actually for the external do a coworker, stratify it, and see if we see a difference. That is step two.

CHAIRMAN MELIUS: You circulate the plan. You need to implement the plan. We have a call, first of all, to sort of go over it. And then, we can talk about the next steps, which I think are just what Tim is describing.

DR. NETON: I was also going to

ask -- I'm a little confused, not confused, but I am concerned about how this is going to play out. So, we end up with -- let's say, for instance, that the ideal situation is we find no difference or no practical difference at 100 millirem with these test cases. So, then, we are going to use that as our sort of benchmark to compute or evaluate significance of difference between coworker models, right? Stratification? Is that the case?

So, let's say in one year, 1976, we have a geometric mean of "X" for all workers and a higher value for construction workers. Do we just compare those and say, is there a 100-millirem difference? I mean, what are we doing here? Are we just doing a statistical analysis?

The test is going to be the same. It is not going to be able to see -- it is not going to have much power because of the numbers, right?

MR. LaBONE: Yes, but if you

don't have sufficient power, then you fail; you basically say they're different and you stratify. So, if you don't see this difference --

DR. NETON: You can't see 100 millirem --

MR. LaBONE: You would stratify.

DR. NETON: -- you're going to stratify.

MR. LaBONE: If you can.

DR. NETON: Well, yes, that's a pretty low bar.

MR. LaBONE: Yes. But you have to get the job exposure matrix, though, or something like that.

DR. NETON: Well, that is the other, you know, the implementation --

MR. LaBONE: Yes.

DR. NETON: -- is still kind of fuzzy.

CHAIRMAN MELIUS: Yes. I mean, that's why I don't think you take the one

case that would take the smallest increment to get over the top, and then we pick something that is more reasonable.

MR. KATZ: But how does that say it is a 100 millirem -- how does that relate to what you were talking about before as what is really a substantial difference? Because when you are modeling, you are dealing with taking into account all of that uncertainty of the GSD, and so on, how does that relate to that? I'm sorry.

DR. NETON: It is more complicated when you start applying this to internal. This is external, and Tom and I were talking. If you can't do it for external, then there is no chance for internal. But, at least if we can agree upon a value of some type as our target, and who knows, maybe it is more than 100 millirem. I don't know.

CHAIRMAN MELIUS: But getting back to Stu's concern, you know, if we can't

do it for external, it doesn't mean we throw out coworker models. I think it is sort of what is our ability going to be to sort of -- how do we go about evaluating the stratification issue?

MR. HINNEFELD: I kind of followed that. I kind of followed the discussion.

CHAIRMAN MELIUS: Yes.

MR. HINNEFELD: So, I kind of know what we are looking for here.

CHAIRMAN MELIUS: Yes.

MR. HINNEFELD: I did take statistics, and I do remember half of it.

(Laughter.)

DR. NETON: All right. This we can do. I think we have got a shot at doing something here that is of use.

CHAIRMAN MELIUS: I have a very practical question. What's the timeframe for people getting to the airport?

MR. KATZ: We have a range

of -- who's our earliest?

MEMBER ROESSLER: You are.

MR. KATZ: 6:00.

CHAIRMAN MELIUS: What I was going to propose is we take another 15-minute break, come back, and spend a little bit of time, some time, going over sort of what are some of the other coworker, some of the other issues related to the evaluation of coworker models that we ought to be thinking about. And it would be, again, the idea of coming to a set of guidelines to how we evaluate. I don't think these would be as sophisticated or statistically-oriented as before. But I think they do weigh into that.

And I have put together sort of a list here. I think we can add to it and talk about that.

MR. KATZ: Okay. So, we will break until 25 after, around there.

CHAIRMAN MELIUS: Yes.

MR. KATZ: I will put the phone

on mute, and we will back with you soon.

Thanks.

(Whereupon, the foregoing matter went off the record at 2:09 p.m. and went back on the record at 2:26 p.m.)

MR. KATZ: We're back. We're back to discuss other matters, related matters.

CHAIRMAN MELIUS: And now that Stu is gone, what would you like to talk about?

(Laughter.)

So, what I thought would be worth spending some time on is sort of what else is part of the evaluation of coworker data sets or should be part of the evaluation of coworker data sets. And I don't even know if there is any sort of technical document on this or not. I know it is not what 53 was intended for, though I think you ended up touching on it, and certainly in the back-and-forth with SC&A and sort of what we have

talked about even here today with it.

And then, there is also sort of a side issue -- maybe we can get that out of the way first -- which is related, but that is the multiple sampling problem, OPOS, I guess, as opposed to opus.

(Laughter.)

And what I was thinking of doing, suggesting for that is triaging that to the Savannah River discussion. Because aren't you going to be -- hopefully, there is a Work Group on Savannah River. Is that scheduled yet?

MR. KATZ: Not scheduled yet, no. It is not scheduled yet.

CHAIRMAN MELIUS: Okay.

MR. KATZ: We will need one this fall.

CHAIRMAN MELIUS: Is it better to do that in the context of -- because you have raised some other --

DR. NETON: I think there is some

work to be done there.

CHAIRMAN MELIUS: Yes.

DR. NETON: I guess I personally would like to hear what SC&A's opinion might be, what they could offer, and what might be a better approach than OPOS. I mean, I don't know that -- I don't have a sense that SC&A is arguing that we shouldn't do something. I don't think you're saying that we leave the data as we used to and use all 50 samples on one person and the cumulative probability distribution.

I have a sense that you probably would agree that that is not appropriate. I don't know.

CHAIRMAN MELIUS: Or another alternative, I mean, again, I don't want Arjun or Tim or anybody to be put on the spot. I think my understanding was that there were other OPOS issues that were raised, came up in the Savannah River review, the recent ones, and so forth.

And we can deal with those. We can do that next time we have the call of this Work Group, and sort of deal with them in that context. Or we can let them be dealt with directly in the Savannah River Work Group as they come up there.

What is the easiest way of doing it? Because I guess initially we need to evaluate it, but we need to evaluate it sort of more systematically than just as it relates to stratification. That is what I am trying to get at.

DR. NETON: But I guess I need to figure out whether -- you know, there are implementation issues that have been identified in the Savannah River, as far as I know, but the overall concept of OPOS needs to be decided one way or the other or discussed.

And I have not seen an SC&A argument that says it is not valid. I have seen issues by saying they are concerned

about the implementation of it, but I have not seen any real discussion as to, if it is not valid, then what is better. Because it is not just enough for me to say, well, that's no good. That would imply, then, what we have done in the past is better. And I certainly don't think that is the case.

DR. MAKHIJANI: Well, we haven't considered the question of the alternative carefully. We have certainly raised some issues.

I don't know if John Stiver is on the line. But, you know, Joyce has been very much in terms of internal dosimetry and how the data are handled, and she has been very central to both the Savannah River reports that we have produced.

So, I think if the Working Group charges us to say, "Well, you know, you have raised some concerns with OPOS. What do you think should be done? Or do you think that individual data are better? If neither is

very good, then what is your alternative?", it is something certainly we can take back and look at. Or maybe we should have a Work Group meeting first, and then take that back. I don't know what you would prefer.

CHAIRMAN MELIUS: Or maybe it is to have the Work Group charge SC&A with doing -- I don't necessarily think it would be a very long report, but just a report summarizing what some of the concerns are about OPOS, and maybe let's not say "solve it" or an alternative, but at least flesh out those implementation concerns as well as the statistical sort of concerns about it that came up in this stratification review. I mean, I think it is already in the stratification report pretty much.

MEMBER ROESSLER: But it would also have to have an alternative, too, I think, because we have heard the concerns. A summary of it would be helpful, but I think we would want to --

CHAIRMAN MELIUS: Well, yes, but I would rather discuss the concerns and make sure we, as a Work Group/Board, sort of agree that those are our concerns and that we need to address them.

I don't like to charge SC&A with fixing things. Because, then, we end up in the position of then essentially charging ORAU and NIOSH with reviewing the fix, and it just gets -- it is a little bit awkward. And I think we should do it stepwise. I don't think this is -- it is not like we are going to make some changes immediately.

Josie?

MEMBER BEACH: So, Jim, in following with the reports, SC&A put in their evaluation, and then NIOSH responded, and I think it would be helpful, too, if SC&A went back and responded to some of the comments in this report.

DR. MAKHIJANI: What occurs to me, both from what Jim said and what you just

said, Josie, is some of the issues came up when we actually looked at the implementation, and some of them came up in the course of the statistical review.

And I think it would be useful, as you said, to put all the OPOS concerns --

MEMBER BEACH: In a matrix or --

DR. MAKHIJANI: -- in one document, so the Work Group can look at it and its integrity and say this is where we are with this particular approach to compiling the data and addressing it for dose reconstruction or coworker models in general.

DR. TAULBEE: Yes, and I think in this Work Group it seems to make more sense because this is a mobile issue.

CHAIRMAN MELIUS: Okay. Fine. Okay.

DR. TAULBEE: Any other coworker model.

CHAIRMAN MELIUS: Okay.

DR. MAKHIJANI: We could

certainly do that as a next step. It won't be a huge thing because --

DR. TAULBEE: Yes, yes.

DR. MAKHIJANI: -- we are not having any new analysis, basically, to gather. And that way, we can get Joyce's input --

DR. TAULBEE: Yes.

DR. MAKHIJANI: -- and, of course, John Stiver's input, you know, the input of all the people on our team who have been involved with this issue.

MR. KATZ: But I think it would be doing more than summarizing what they have. They would be integrating what they have learned in this discussion, too.

CHAIRMAN MELIUS: Yes, yes, yes.

DR. MAKHIJANI: And to address Josie's point, you know, we have gone through SC&A's report, what we have discussed today, and we can integrate some of our responses. Obviously, we don't disagree with everything

necessarily.

MEMBER BEACH: Sure.

DR. MAKHIJANI: I thought Harry made some of that clear, but --

MEMBER BEACH: Well, and NIOSH brought up some points that they didn't feel like SC&A addressed in their writeup. That maybe needs to be looked at.

DR. MAKHIJANI: But my question would be, do you want that all in the same -- because if you want, then, an OPOS kind of framework, because OPOS is a pretty huge issue --

MEMBER BEACH: Yes.

DR. MAKHIJANI: -- because you are proposing to go back and redo all those other coworker models. So, I think it is a very big deal in terms of the amount of effort and work involved and redoing all the dose reconstructions, and so on.

So, my sort of tentative suggestion for your consideration would be

that, if you want more of a response than the slides we have just gone through and the discussion we have had for the record, that we respond to the work that NIOSH, the response that NIOSH has given and some commentary on that separately from bringing the OPOS concerns into one document and discussing that as such, so that you can arrive at a conclusion. We can do it in the same document, whatever you prefer.

DR. NETON: Well, I think that OPOS would be good to be summarized in one document, yes. But the other concerns I think can wait until we flesh out this practical significance issue because I think that is going to drive a lot of what happens in our disagreement. You know, these statistical tests and all this power calculations stuff is all dependent upon what this practical significance comes out to be.

DR. MAKHIJANI: Yes.

DR. NETON: And those issues, in

my mind, are very much up in the air until we come to grips with the practical significance. So, I don't know that it would be helpful for us to get a counter-response to SC&A's --

DR. MAKHIJANI: I agree with you, Jim, because, really, there are two big bins of problems. One bin is the OPOS-related bin, and the other relates to can you decide whether these distributions are the same, you know, and whether we should stratify or not. And do we have enough samples? What is the delta that they are looking for, and so on.

I mean, I don't have the whole universe of things in front of my eyes right now, but those are certainly two very big bins in which you can put the issues that we have raised. I agree with you.

DR. NETON: I think summarizing what your current thinking on OPOS --

DR. MAKHIJANI: Yes.

DR. NETON: -- in light of what

we have discussed and what we have commented on, and what you have learned --

CHAIRMAN MELIUS: What we have seen and commented on the SRS reports --

DR. NETON: Right, right.

CHAIRMAN MELIUS: -- yes, that would be helpful and I think useful for us, as long as there is enough overlap, so that we are not -- I don't want to hold up SRS.

DR. MAKHIJANI: Tim has our report.

DR. TAULBEE: Yes.

DR. MAKHIJANI: I mean, there are a couple of issues with SRS, actually. One is that you have two reports from us. And presumably, you are preparing some kind of a response or I don't know what.

DR. TAULBEE: Jim?

(Laughter.)

DR. NETON: I haven't really gotten into them yet.

DR. MAKHIJANI: Okay.

DR. NETON: Yes, we will certainly respond, but I'm not sure to the extent there is overlap, though, between what we have talked about today and what is in those reports. I mean, they are not really separate --

DR. MAKHIJANI: There is a lot of overlap, but there are also particular issues related to the Savannah River Site and that data set.

And since in the neptunium report there is a particular dose reconstruction method for using whole body data, and a lot of concerns that were raised with that --

DR. NETON: Okay. Well, to the extent we can answer that --

DR. MAKHIJANI: Okay. Yes.

DR. NETON: -- and then, I think as Dr. Melius starts enumerating these other issues, that may help us figure out where we are heading with the Savannah River. I mean, what needs to be described in more detail in

order to apply a coworker model, because right now there is no guidance. The coworker model, the only guidance we have is how to fit a log-normal distribution to a data set really. I mean, that's it.

And so, hopefully, we will enumerate some things here that need to be fleshed-out to provide guidance as to how we need to demonstrate that the data -- see, it is one thing to say the data need to be stratified because there is a statistical difference or practical difference. But my other opinion is, are those people that weren't monitored really representative of the ones that were monitored? They may be lower exposed.

DR. MAKHIJANI: Yes. I mean, if you look, I think the most recent report in my mind, if you look at that report, you will see a lot of findings are not dependent on OPOS and the concerns of that. I think you must have at least taken a quick look at it.

They apply generally to the data set and the approach to dose reconstruction and sufficiency, and, you know, how you apply americium to thorium, and whether you can and when you can, and so on.

DR. NETON: Well, we can address --

DR. MAKHIJANI: Yes.

DR. NETON: -- we can start to address that.

DR. MAKHIJANI: So, I mean, it is up to Mark and the Work Group as to the sequencing in which you want to do this. I mean, it is fine with us.

CHAIRMAN MELIUS: Hey, we got here first.

(Laughter.)

DR. TAULBEE: There is the G2K that came back, because I was tossing it to you.

DR. NETON: Oh, oh.

(Laughter.)

There are numerous loading issues at the current time because of the sequestration. I mean, there are prioritizations going on. Right now, to be honest with you, Rocky Flats is driving the boat as well as the Kansas City plant and a few other sites that are more critical at this juncture.

I don't know. We can put it on the list, but we are going to have to discuss that with our contractor to see where the funds --

CHAIRMAN MELIUS: And as you discuss this, since we are going to Savannah River in March, my recommendation is that we aim to move this up on the --

DR. NETON: We will.

CHAIRMAN MELIUS: Yes, yes, yes.

DR. NETON: We will, but right now all eyes are on Denver at this point.

CHAIRMAN MELIUS: Well, yes, but in three weeks we can look the other way.

(Laughter.)

DR. NETON: Maybe.

CHAIRMAN MELIUS: Or whatever. No, I understand.

DR. NETON: To the extent we can, we can try to address the issues that are not OPOS-related and more generic.

CHAIRMAN MELIUS: Yes. Again, I have read the report. I think they raise significant issues.

I feel like Oprah. "You really should read this book."

(Laughter.)

DR. MAKHIJANI: One point I would just like to clarify is earlier I thought Tim agreed to look at this whole question of actually how the OPOS data were compiled and how the censoring was done or not done.

DR. TAULBEE: Yes. We actually looked at that over lunch. And, yes, the implementation was not per procedure, and we are going to go back and redo that.

DR. MAKHIJANI: Thank you.

So, that resolves a pretty big --

DR. TAULBEE: Yes.

DR. MAKHIJANI: Is that across the board or is it only in the americium? Because we only looked at the americium.

DR. TAULBEE: It is in the neptunium.

DR. MAKHIJANI: It is also in the neptunium?

DR. TAULBEE: Yes, it is in the neptunium, too.

DR. MAKHIJANI: Okay.

DR. TAULBEE: But they ended up applying the -- when you have a negative value and you chalk it up to the protection limit that should have been done before OPOS was run --

DR. MAKHIJANI: Right.

DR. TAULBEE: -- but they did it after OPOS was run.

DR. MAKHIJANI: Right. And it

made a very huge difference.

DR. TAULBEE: So, that's where we're at. We don't know how big of a difference it makes from that standpoint, but we will look --

DR. MAKHIJANI: In some years it won't make a difference, and in some years it will make a pretty big difference, according to the compilation that we did. Bob Barton actually did it.

DR. TAULBEE: Okay. But, yes, we recognize that that was --

DR. MAKHIJANI: So, that is at least resolved?

DR. TAULBEE: Yes.

CHAIRMAN MELIUS: Good. So, we made progress.

DR. TAULBEE: Yes. Yes, we did.

DR. MAKHIJANI: So, our one takeaway is to give you sort of an integral report on OPOS.

CHAIRMAN MELIUS: Yes. I'm

trying to remember what the acronym means.

(Laughter.)

DR. TAULBEE: One person, one sample.

CHAIRMAN MELIUS: Yes, I know, but -- all right. It is not intuitive in my world.

(Laughter.)

MEMBER ROESSLER: I thought it was one of the best ones.

DR. TAULBEE: Me, too, but, then, again, we are health physicists.

MEMBER ROESSLER: Yes.

(Laughter.)

CHAIRMAN MELIUS: Yes, but you start with a person with multiple samples. That is why maybe it should be "OPOMS" or something.

(Laughter.)

Or make one sample for multiple.

DR. NETON: Something like "OPOR," one person, one result.

(Laughter.)

CHAIRMAN MELIUS: Yes. Maybe we can translate it to German, make it real long.

(Laughter.)

You can tell we are all doing good here. It is late in the day.

So, actually, my list for sort of other coworker issues, I think one issue that -- I think it is very general -- is sort of when do we apply a coworker model. How much sampling data does there need to be available? It is sort of the 30 issue, but it is applied -- is it 30 out of 100 or 30 out of 10,000 people, persons?

And again, that doesn't have a simple answer, but I think it is sort of a general guideline going forward. So, I mean, that is one of the things that I think we need to look into.

And then, it is for each of those -- I mean, I think we have already

talked about it at greater length here today -- sort of representativeness. What do these sampling data -- you know, how representative are they and what do they represent in terms of exposure potential?

And then, of those, of the different exposure potentials they represent, what data is available; what data is missing on those? I mean, I think we have talked at this at length on the sort of routine versus incident-driven, or whatever, for construction workers and others.

And as I was making notes, sort of doing this under stratification, but it is really part of the evaluation. I think the thing about how do we decide what to stratify, and we have already used a priori to stratify on year. That, I think, has been the general approach. And that is somewhat arbitrary, but it may make sense in terms of production and changes within a facility, and so forth.

How do we do it based on job assignment or task? Again, it is somewhat limited by what information we have on that and what is readily available as opposed to what is maybe not so readily available.

And then, this question where sort of Tom and I sort of went back and forth on it a little bit. When we have limited data on a site, I just wonder if we ought to be sort of looking at the data. We are not going to be able to determine a priori or we may not recognize a priori what may be important strata or significant strata that ought to be looked at.

And so, I do think it takes some, in some cases it takes looking at the data and seeing what appears to be different about that data or the characteristics, what information we do have, or something.

Because I think it seems to me that in going through all the various sites we looked at, many sites we have come up with

sort of anomalies, and so forth, that you may not have expected because we didn't have complete information, particularly on some of the older sites, and so forth.

And so, I just don't want to get totally trapped by saying you have to have a priori strata decided on; you are going to test those. There ought to be some judgment involved in that and some attention to the data.

And I don't think you can look at -- I don't think any person looking at the data, to look at what is available in terms of construction or incident data, I don't think you look at that without sort of having some sense of what is in there, a judgment. You know, just who's high; who's low.

And so, I think you naturally pick up on that. You get it from interviews. You get it from the reports, various reports, that are done, what types of exposures they decide to -- or the processes they implement

greater controls on, and so forth.

So, again, I wouldn't throw that out completely, but at the same time I think there is probably a set of a priori types of things that you would stratify and which would be, to some extent, building or process, where they are working job assignments, tasks, and so, again, to the extent that those are available, and so forth.

Does that make any sense?

DR. NETON: It does where we have the data. But I thinking that a lot of our coworker models are just based on CEDR data, de-identified data.

CHAIRMAN MELIUS: Right.

DR. NETON: There is nothing we can do other than say this is the distribution that we have for the site. We can go back and look at the site procedures, documents, and such, to try to figure out who was monitored, but we will never be able to

construct any kind of coworker stratification out of that because we don't have any information as to who was who.

CHAIRMAN MELIUS: And again, I am not recommending this, but what if you have the situation where you have essentially a de-identified data set, but you also have, you know, it's computerized, readily available, and you also have a paper data set that has more? Do you go and take a sample of that more detailed? And we have struggled with this.

DR. NETON: You can always go back and look and see what we have.

CHAIRMAN MELIUS: Yes, which is usually what we do as a second step --

DR. NETON: Right.

CHAIRMAN MELIUS: -- in terms of what does NOCTS tell us about the data, who was monitored and stuff.

DR. NETON: Yes.

CHAIRMAN MELIUS: I understand

where you're coming from.

And I'm not thinking that any of these haven't already been done or the information isn't available or you haven't thought about it before. I think, basically, you're applying sort of a somewhat new approach to what you have already done.

And again, I am not familiar enough with what you have done in terms of external monitoring to --

DR. NETON: It is very basic.

CHAIRMAN MELIUS: Yes.

DR. NETON: The geometric mean, standard deviation of --

CHAIRMAN MELIUS: Okay. Don't tell me that.

DR. TAULBEE: But it does inherently have OPOS in it --

CHAIRMAN MELIUS: Yes.

DR. TAULBEE: -- because each person's percentage refers to year.

CHAIRMAN MELIUS: Yes, yes. No,

no, it avoids OPOS.

DR. TAULBEE: Yes. OPOS is no longer --

CHAIRMAN MELIUS: Yes.

So, that was the general list I had on that. Are there others? I mean, I know there are others.

DR. TAULBEE: I came up with an initial checklist of things that --

CHAIRMAN MELIUS: Okay.

DR. TAULBEE: -- I thought, thinking about the Savannah River one, and what things would help perhaps to give you all confidence of the sampling program. And that is to look at the bioassay monitoring procedures.

CHAIRMAN MELIUS: Yes.

DR. TAULBEE: Who was sampling, who wasn't.

DR. NETON: I'm sorry?

DR. TAULBEE: Look at the bioassay monitoring procedures --

DR. NETON: Yes.

DR. TAULBEE: -- and how those changed over time, because they do change.

The incidents that have been documented, do you see construction trades workers in these incidents and annotations of what their bioassay was indicating that they did followup?

And the one that I wanted to really kind of focus on a little bit, or at least get some discussion on, is the population size to the potential for exposure, because some of these radionuclides that are exotics, the whole site wasn't working with. You are looking at a small group of people of 30 to 40 people that were working with it. And if you have a bioassay and it is half of that population, well, then, it is a pretty reasonable sampling for that group. Or if you have 100 percent of the people who are actually doing the work, then, even if you have a small sample size,

it is okay.

DR. NETON: That gets into, then, you should be able to identify who worked in those areas, in addition to the ones that were sampled.

DR. TAULBEE: That's right.

DR. NETON: Because, if you can't do that, then you end up in the scenario where you have to apply it to the entire site and it becomes, in my opinion, unrealistic at that point.

CHAIRMAN MELIUS: Yes. Going back to whatever, our significance level, or whatever we are going to call this, that may be one way. Do we apply it? How do we apply it? So, what should the application be in those instances? And if we are going to apply -- should we apply the 95th or even the 50th to the entire population? Or do we have 30 of 40? What is fair? I mean, that really is a consideration.

Somehow applying that to the

whole, that assumption to the whole 20,000, or whatever --

DR. MAKHIJANI: The trouble with exotic radionuclides, I agree that 6,000 workers weren't working with thorium or neptunium, and so on.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: They were pretty defined pieces of work that were being done. The difficulty, to the extent that we have looked at many worker records and gone into worker files, and so on, in the course of producing the reports, unfortunately, the worker files don't seem to contain -- they contain locations about the radionuclides that are monitored. So, if you are looking at thorium, you won't find any notation about thorium because thorium wasn't being explicitly monitored, even though we agreed with NIOSH that thorium would be contained in that, in the bioassay sample.

Or neptunium, where initially you

had some neptunium notation, but, then, later on, you are trying to infer neptunium from other radionuclide whole body data. So, you don't have neptunium notations in the work record. So, it is actually very difficult to know how many workers, to identify the workers who are working with neptunium.

DR. TAULBEE: Well, yes and no. It depends upon the facility, again.

DR. MAKHIJANI: Yes.

DR. TAULBEE: And this is a case where --

DR. MAKHIJANI: And maybe this is a problem for you to sort out.

DR. TAULBEE: There are organizational charts that identify by building. Take 235F, where they are working with the neptunium making billets, there is a breakdown of how many workers were in that building, for example. So, you do know what was the general population that was in there. You don't know how many construction trades

would be moving in and out. But, if you have got a population of -- and I am just throwing numbers out here -- of 45 people in that facility, and you have 30 neptunium OPOS type of results, and then you have an additional -- I don't know -- maybe 10 to 20 construction trades workers, it doesn't seem unreasonable to me that the construction trades wouldn't outnumber the number that was in that facility. It would be some fraction, but that could be quite reasonable.

So, it really depends upon the facility. But, as Jim was pointing out, most facilities we don't have that level of data. At Savannah River we happen to because of access to their database systems, but other facilities this would be very difficult to do. I don't think I could do it for Oak Ridge.

DR. NETON: I would say it is almost impossible.

MR. KATZ: Can I ask you, Jim,

your plausibility issues? So, say you have monitoring on 20 -- there were only 40 people doing it -- you have monitoring on 20. So, you think that is pretty good representation for the 40. But, if you can't identify the other 20, it could have been any of the rest of the thousands --

DR. TAULBEE: No, no, that's not true.

MR. KATZ: No, I'm not saying SRS. I was just being more generic than that.

DR. NETON: Well, you're talking about construction trades or --

MR. KATZ: I'm just saying what you were saying. I'm just going along your lines. You're saying you have 20. There were only 40, but, then, can you apply it to a thousand? Is that plausible to apply it, you said, to a thousand other people?

DR. NETON: I'm talking about other --

MR. KATZ: Whatever, 1,000 at the whole site, whatever, or 10,000, whatever it is.

DR. NETON: Everybody, secretaries, and --

MR. KATZ: But here is my -- and you probably could knock out secretaries -- but here is my question: I mean, you have two choices. You can either apply it to 5,000 people, whatever it is, knowing just because you can't identify the other 20 of the 40, or what do you do? Do you make an SEC for the whole site? I mean, that is more ridiculous in a way.

DR. NETON: But that is what we do.

CHAIRMAN MELIUS: We do the coworker model, and it is feasible, and then, we can apply something to everybody on the site.

MR. KATZ: Yes.

CHAIRMAN MELIUS: I mean,

whatever it is. But if we can't do the coworker model, if we reject the coworker model, then everybody is in the SEC because we can't put anybody -- yes.

MR. KATZ: Right. If you can't do a model, yes. What I was saying is what he was saying. You have 20. You know only 40 people did it; you monitored 20. So, you think 20 is probably a pretty good representation of 40. Then, better to apply that basically, that model you make from 20 of them to the whole site, even though, obviously, you know 5,000 of the people weren't involved, than to make the whole site an SEC based on --

(Laughter.)

DR. NETON: Well, we have done that. I mean, that is not --

MR. KATZ: Well, not that specific situation where you have had -- knowing that we have done it where we weren't able to estimate --

DR. NETON: Exotic radionuclides have been, outside of thorium, probably the most popular way to get an SEC. I mean, all the National Laboratories, how many people were exposed to fission products at Los Alamos National Laboratory on a regular basis? And you say, "Well, we don't know because there were small, little pockets of research going on."

MR. KATZ: But, see, we don't know. That's what I'm saying; you don't know. But, if you know there were only 40 people involved --

DR. NETON: Well, if you knew definitely there were 40 people, and you knew the names of those people --

MR. KATZ: I'll tell you, with a lot of the exotic cases, you don't know what that population was. You know it was small, but you don't know what it was. You don't even know the boundaries of that population, and that's different than actually knowing

you have 40 people in this building who were exposed, and you don't know anything for anybody else.

DR. NETON: Well, here's typically how this unfolds, though. I'll just be honest. Okay. We know that it was 40 people, and we have a list. You know, we show here's the 20 people that worked with this, and we can reconstruct all of them.

But, then, you have a situation, well, maintenance workers went in there to clean up the hoods and all that kind of stuff and the trash collectors.

MR. KATZ: Yes.

DR. NETON: You have another population of worker that you just can't put in time and space in those areas. And then, it is just a house of cards; it kind of falls apart. And then, we make it an SEC because we don't know with any certainty who could have frequented those areas, aside from the fact that we know that there were certain

people that were more highly exposed.

MR. KATZ: Right.

DR. NETON: I mean, they were the ones that worked with it, but we just don't know who to assign it to. So, then, you end up making an SEC out of it.

DR. TAULBEE: Why can't you assign it to everybody who was there on the site? Or every monitored worker, everybody except all the secretaries and the --

DR. NETON: You know, you get some very, very bizarre scenarios. Like you say, okay, I have exotic radionuclides, curium, neptunium, americium, plutonium. And I am going to assign exposure to everyone on site for those nuclides, but only pick the one that gives the highest dose to that particular organ to develop cancer. It becomes a very contorted way of doing business.

CHAIRMAN MELIUS: But the alternative is also contorted.

DR. NETON: Yes. No, that is what I am saying.

CHAIRMAN MELIUS: I mean, it is not an easy answer, yes. And I think it is different -- I think Tim's original example was you could identify 40. You could identify the 40 and you had the 20.

MR. KATZ: Right.

CHAIRMAN MELIUS: And then, there is an additional 20 maintenance workers, whatever, some unknown number, but defined number, but maybe a small number. I think all those situations are sort of somewhat different.

DR. TAULBEE: But I think if you start going through this kind of checklist of documenting the procedures, documenting the incidents, documenting population size, documenting the potential for exposure and the size of that population, I think that gives a weight of evidence of whether this coworker model is appropriate.

DR. NETON: Well, then, you also have scenarios where you know that this -- I can't think of a specific site -- but you know that this occurred on several occasions, but if you go and look at the inventory over the entire operating history of the plant, there has been large, fairly-large quantities of the material throughout time. And maybe workers recall that this happened at other times.

MR. KATZ: Yes, but those all seem perfectly valid then. It is ambiguous --

DR. NETON: Right.

MR. KATZ: -- what your outline of the problem is. It is ambiguous how large the scope of the problem is. That seems like an easier matter for saying, okay, so it's an SEC. We don't know how big this problem is.

DR. NETON: Yes, yes, yes. I hear what you're saying. I agree. If it is a very confined and well-defined operation

and you can nail it, sure. But, in practice, that doesn't happen very often, is what I am saying.

MR. KATZ: Okay. Okay.

DR. NETON: I have not seen that sort of a neat, tight package very often in these 50 sites. Maybe Savannah River is one of them in certain cases. I don't know if the whole -- I mean, I hope we are right in what we have done.

CHAIRMAN MELIUS: So, what if you had five maintenance workers that got sampled? Do you make a coworker model from them and apply it to the rest of the site? I mean, there's lots of --

CHAIRMAN MELIUS: I'm comfortable with saying for the trades workers, to assign them to the 95th percentile of dose, because that is what we do for production workers that weren't monitored. We say they worked in harm's way, so to speak, working with unencapsulated materials, and I don't know

what they got, but 95th percentile is bounding. I'm okay with that. But assigning the 95th percentile to the whole site or the 50th percentile, I don't know, it just doesn't --

CHAIRMAN MELIUS: What if it is a security guard that walks around the site and works there for -- you know, not assigned to a building, but he works there for 30 years. Do you come up with a probability of them being in that building?

DR. TAULBEE: I would assign them to the 50th percentile.

CHAIRMAN MELIUS: Or even lower. I mean, how long have they been there, 15 minutes a day for --

DR. NETON: GE, even the thorium in one building for a few years on one site, couldn't figure out who went in and out of that building with any degree of confidence.

MR. KATZ: Right, but, again, you do not have a nicely-defined --

DR. NETON: And again, like I said, that is more typical --

MR. KATZ: Right.

DR. NETON: -- of the scenario.

MR. KATZ: Right.

DR. TAULBEE: But, if we could have found security clearances, we could have found that data. Then, you could have defined the Class.

DR. NETON: Absolutely. So, yes. Yes.

DR. TAULBEE: Because they wouldn't be able to go into the building without a clearance.

DR. NETON: Right.

DR. TAULBEE: That would have made it easy.

MR. KATZ: Right.

DR. NETON: It's not easy.

CHAIRMAN MELIUS: Okay. Did we make it through your list, Tim?

DR. TAULBEE: That was it. That

was what I had for my list of things that I think -- would you all be in agreement with? We can document that, that that would imply, show that a coworker was appropriate.

CHAIRMAN MELIUS: Yes, yes. No, I think those are the kinds of things that ought to be evaluated. Let's say we need to evaluate those issues, yes.

DR. NETON: I don't want to assign us more work. But I do believe that we should probably develop some sort of guidance from within DCAS about how this works, because we have been doing it sort of ad hoc, apparently. And if we put together -- it doesn't have to be a long document, but just some sort of a TIB, or whatever, that says here is what you need to consider when you are developing coworker models beyond the fact that you can fit a log-normal distribution to the data set. And here's important things that need to be either demonstrated or discussed, or

something like that. I think that would help. I'm not sure it solves it.

DR. NETON: Do you, we, whatever, have guidance on evaluating representativeness?

DR. NETON: No.

CHAIRMAN MELIUS: Because, to me, that has sort of been the key. It is the one that we seem to have the most, I won't say disagreement, but difficulties coming to terms with.

So, again, a lot of it is site-specific, but, again, I think that in some level of detail is worth fleshing out.

DR. NETON: Yes, I agree.

CHAIRMAN MELIUS: Because that is a real --

DR. NETON: Yes, this comes to mind. You know, we are trying to figure out right now where to fit an end date for Rocky Flats. We have an SEC. Well, when did they become capable of demonstrating of who was

exposed and who wasn't?

It turns out there is a lot of good procedures out there, we are finding now, that show that they had some very serious thought that went into who was monitored and why. This is more modern-era-type stuff. But, after '92, for example, very serious consideration as to who had the potential to receive 100 millirem, and they were very serious about following that path.

You are not going to find that in the real early years, but maybe something like that that you can hang your hat on and say the highest-exposed workers were monitored, and not only did the procedures say it, but we have evidence of that.

Because I suspect that in many cases it is not going to be representative; it is going to be an overestimate because people that were for the highest exposures were monitored, not people with the lowest.

CHAIRMAN MELIUS: Yes. So, it is

representative of what? I mean, how do we --

DR. NETON: And that has sort of been our -- you know, maybe we have just been sort of assuming that all along without really documenting it.

DR. TAULBEE: I don't know whether assuming that, but it hasn't been documented.

DR. NETON: It hasn't been documented. We have seen evidence of it in the documents we're looking out without --

CHAIRMAN MELIUS: But I think a lot of it is how far do you have to go. How many interviews, how many documents?

DR. NETON: Yes. No, I agree.

CHAIRMAN MELIUS: And again, it is not the number. It is not going to be 30 --

DR. TAULBEE: It is a weight of evidence.

CHAIRMAN MELIUS: It is weight of evidence.

DR. TAULBEE: And you could take external monitoring at Savannah River and, then, look at our claimant population. Eighty percent of the claimants have some external monitoring data. Twenty percent do not. So, from the external coworker model, we are applying this model that we developed to the 20 percent that weren't monitored if there is evidence that they worked in a process area. If they were a secretary in one of the administrative buildings, we don't assign them. We assign an admin or an environmental type of dose.

But when you look at the preponderance of evidence of 80 percent of the claimants have this monitoring data, well, that is pretty significant.

CHAIRMAN MELIUS: And I don't know. That is the earlier statements. How much is enough?

DR. TAULBEE: Exactly.

CHAIRMAN MELIUS: Yes, yes, yes.

You know, we take a sample of five and come up with a good estimate. And actually, we usually have others. But if we have that on somebody in the residual period, and so forth, we probably don't even have that on some of these residual periods. But, if we did, we would be very content.

DR. NETON: Radioactive materials, outside of DOE, we never had any monitoring data.

CHAIRMAN MELIUS: Yes. You and I had a back-and-forth about one of the residual periods. It sort of depends on what kind of work they did there. Maybe you had a security guard that was going around the fence, and whether he or she ever went over the fence --

(Laughter.)

MR. KATZ: So, is somebody going to draw up a list, a sort of framework for this?

DR. NETON: What do you mean, for

the guidance stuff?

MR. KATZ: Yes.

DR. NETON: Yes, we will put together a list. We will start with a list or a topical outline.

MR. KATZ: Yes, an outline sort of thing.

CHAIRMAN MELIUS: Yes, do a topical outline.

DR. NETON: Things to consider.

CHAIRMAN MELIUS: Maybe an extra layer of detail on like representativeness and some of the other --

DR. NETON: Sort of an annotated outline.

CHAIRMAN MELIUS: Yes, yes, that would be --

DR. NETON: Yes, we can do that. I can have that. It won't be before the Board meeting, I can guarantee you.

CHAIRMAN MELIUS: Yes.

I think it is related to this

whole issue, but it is also, what assumptions are we going to make about -- you know, it comes out of the representativeness, I guess, is where I was thinking of this. But what do we assume about a monitoring data set? Do we assume that it is representative? Do we assume it is routine versus do we assume that it is the highest exposure, and so forth? Because that is really --

DR. TAULBEE: It has to be evaluated before you use it.

CHAIRMAN MELIUS: I know, but, yes, we tend to approach it with, I do not want to call it bias, but certain assumptions about it, and so forth. What amounts of information do we need to evaluate? Or do we assume that they are stratified and have to show that they are not? I mean, it is another way it came up. Now I think we have got that solved.

MR. KATZ: I think it is covered.

CHAIRMAN MELIUS: We have got

that covered. But I think in terms of the other, I think we have to think that through. Again, it is a point of evaluation, how much information you need, where you get the information, and then what you make of it.

Anybody else have thoughts?

DR. NETON: I'm thought out.

(Laughter.)

CHAIRMAN MELIUS: I know. I think we all are.

DR. NETON: Yes.

MS. LIN: To be clear, the Board is doing a checklist, and then NIOSH is doing an internal bound?

DR. NETON: No.

Is that Jenny?

MR. KATZ: Yes, that's Jenny.

DR. NETON: Yes, Jenny, I think NIOSH is going to develop a topical outline that sort of incorporates these items that we have discussed, both Tim's checklist issues and what Dr. Melius pointed out.

MS. LIN: Okay.

DR. NETON: Sort of path forward on how we are going to demonstrate that the data -- how we are going to evaluate whether stratification needs to be considered or when --

CHAIRMAN MELIUS: It is really how we approach coworker modeling. I think that is really what we are --

MS. LIN: Yes, I got that part. I just wasn't sure what product are we going to see from the Board and from NIOSH. I don't want to be like coming back from a one-year deployment and there's like a bunch of documents.

(Laughter.)

MR. KATZ: No, no, no. This will all be finished before you get back.

CHAIRMAN MELIUS: We're going to keep you on the email list. You're going to keep getting -- keep a big hard disk drive.

MS. LIN: Yes, well, I look

forward to it. I need some reading materials, and maybe they will put me to sleep.

CHAIRMAN MELIUS: Yes, you will be bored over there.

(Laughter.)

MEMBER BEACH: And then, SC&A is going to bring the one; that is just one action, the OPOS.

DR. NETON: And then, we have got the additional action to look at our NOCTS data set, look at the practical significance issue, which in my opinion is probably a higher priority than anything we are doing yet. Or maybe not.

MR. KATZ: Okay. I think we're set.

CHAIRMAN MELIUS: I have one final. My understanding is, Jenny, October 1 is your --

MR. KATZ: It has been pushed back.

CHAIRMAN MELIUS: Pushed back?

MR. KATZ: The 15th.

CHAIRMAN MELIUS: The 15th?

MS. LIN: Yes, it's the 15th, but I will be leaving my civilian post a few days early, so I can pack and drive down.

CHAIRMAN MELIUS: Aw, come on.

(Laughter.)

You're not going to come to Denver? You're not coming to Denver?

MS. LIN: No.

MR. KATZ: Basically, just before Denver.

CHAIRMAN MELIUS: I know, just before Denver, how convenient.

MS. LIN: Yes, I know. So sorry.

CHAIRMAN MELIUS: Do I have to call the Defense Department to get this delayed another week?

(Laughter.)

MS. LIN: I can't do this. I have already negotiated with them.

CHAIRMAN MELIUS: Oh, okay.

MS. LIN: But if you guys ever do a Board meeting in D.C. again, then I can book a tour at the Pentagon for you guys.

CHAIRMAN MELIUS: That would be cool.

MS. LIN: Yes, and we can go golfing at the Andrews Air Force Base. Maybe you will run into President Obama.

(Laughter.)

CHAIRMAN MELIUS: And you will see John Howard. He [identifying information redacted]. I found that out as I was going to the airport the last week.

MS. LIN: Yes?

CHAIRMAN MELIUS: He was on the Metro with me. He got off first. So, don't be surprised.

MS. LIN: I know, right?

CHAIRMAN MELIUS: I didn't know he [identifying information redacted].

MS. LIN: Yes, he was

telling me there are actually a bunch of people working at the Pentagon who [identifying information redacted].

CHAIRMAN MELIUS: Okay.

MS. LIN: Are we still being transcribed?

MR. KATZ: Yes.

MS. LIN: Isn't the meeting over yet?

(Laughter.)

MR. KATZ: No, we're being transcribed.

MS. LIN: About where John Howard [identifying information redacted]?

CHAIRMAN MELIUS: I think the Pentagon is pretty easy to identify, right?

MR. KATZ: We can be adjourned at this point for the transcription's purpose.

(Whereupon, at 3:16 p.m., the meeting was adjourned.)