U.S. Department of Health and Human Services
Centers for Disease Control
National Institute for Occupational
Safety and Health
National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Joint Meeting of the Savannah River Site (SRS)
And
Special Exposure Cohort (SEC) Issues
Work Groups
Friday
November 20, 2020

The Work Groups convened at 10:30 a.m., Eastern Standard Time, via video teleconference, Henry Anderson and Bradley Clawson, Co-Chairs, presiding.

Present:

Henry Anderson, Co-Chair
Bradley P. Clawson, Co-Chair
Josie Beach, Member
James E. Lockey, Member
Genevieve S. Roessler, Member
Phillip Schofield, Member
Paul L. Ziemer, Member

Also Present:

Rashaun Roberts, Designated Federal Official
Nancy Adams, NIOSH Contractor
Matt Arno, ORAU
Bob Barton, SC&A
Elizabeth Brackett, ORAU
Ron Buchanan, SC&A
Zaida Burgos, CDC
Grady Calhoun, NIOSH/ORAU
John Cardarelli, NIOSH/ORAU
Nancy Chalmers, MJW Companies
Joe Fitzgerald, SC&A
Roger Halsey, ORAU
Patrick Kelly, SC&A
Joyce Lipsztein, SC&A
Mike Mahathy, ORAU
Jenny Naylor, HHS OGC
Chuck Nelson, NIOSH/ORAU
LaVon Rutherford, NIOSH/ORAU
Tim Taulbee, NIOSH/ORAU

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Proceedings

(10:31 a.m.)

Welcome and Roll Call/Introductions

Dr. Roberts: I'd like to wish everyone a good morning. This is, of course, the Advisory Board on Radiation and Worker Health. And I'm Rashaun Roberts. I'm the DFO for the Advisory Board.

This is the second and final day of the two day joint meeting of the Savannah River Site, or SRS as we call it, Work Group and SEC Issues Work Group.

I want to let meeting attendees on Zoom and attendees who might be participating by telephone only that the agenda and all of the background documents and presentations for both days of this meeting are on the NIOSH website under the Schedule of Meetings if you look under the month of November.

If you've taken a look at the agenda, you will notice that today's session is focused both on SRS and SEC issue Working Group business whereas the first session on November 17 that we had earlier this week was focused mainly on SRS.

So with that said, let's start roll call and conflict of interest as usual. I will let everyone know that in order to sit on the SRS Working Group, members of that group cannot have a conflict of interest for that site. So let's go ahead into roll call.

(Roll call.)

Dr. Roberts: Being that he doesn't seem to be on, let me ask the Work Groups shall we continue?

Member Lockey: Did anybody give him a call?

Ms. Burgos: I'm going to give him a call. This is Zaida.

Chair Clawson: This is Brad. We can go ahead and

continue on.

Dr. Roberts: Okay. Okay. While Zaida is trying to get ahold of him, let me just go through this. So thank you. Welcome again to all of you. I just will go over a couple of additional items before I give the floor over to Brad and Andy if he joins us. They are the Chairs of the SRS and SEC Issues Work Groups, respectively.

In order to keep things running smoothly, and I'd really like to emphasize this, and so that everyone speaking can be clearly understood and we don't need to interrupt presentations, please make sure that you mute your telephone unless you need to speak.

If you don't have a mute button on the phone, press star 6 to mute and star 6 to take yourself off. And I can hear something in the background right now. So if you're not on mute, if you could check your phone.

If you're on Zoom, the mute button is at the bottom lower left-hand corner of the screen. So, again, if you're not the speaker, it's really important for you to check Zoom or to check your phone, especially if you need to attend to another phone call or some other business because there's been some situations where we can hear other conversations taking place, and it's rather disruptive. So please try to be as mindful as you can.

So once again, if you didn't hear earlier, the agenda and the presentations and background materials that are relevant to today's meeting can be found on the NIOSH DCAS website. All of the materials were sent to Board members prior to the staff meeting.

If you were in on the November 17 session, you might have heard some discussion about making a change to today's session. But ultimately, the Chairs decided not to make any changes just for your information.

So with that, I'll check in one more time to see if Andy

has joined us.

Chair Anderson: I'm here.

Dr. Roberts: Oh, hi. Good morning.

Chair Anderson: I'm here. I can't get my video working, but I'm here.

Dr. Roberts: Okay. But you can hear okay. Alright.

Chair Anderson: I can hear you.

Dr. Roberts: Is that correct?

Chair Anderson: Yes.

Dr. Roberts: Okay. Well, you have joined in the nick of time for me to turn this meeting over to you and to Brad.

Chair Anderson: Okay.

Dr. Roberts: Are you ready?

Chair Anderson: Yes.

Dr. Roberts: Okay.

Issue 5: Stratification of Co-Exposure Models (NIOSH "Stratification Refinement" White Paper)

Chair Clawson: Andy, since this is a Savannah River stratification, if it's alright I'll take over on this. I'd like to welcome everybody here today. Thank you for taking your time out of your day so we can work on this. Tim, I believe, you're the first presenter on this so I'll turn it over to you.

Dr. Taulbee: Okay. Thank you, Brad. I appreciate that. What we're going to talk about first here is the Savannah River Site plutonium construction trade workers stratification.

And we're calling it a refinement because this is effectively an expansion or a more detailed evaluation of something that we had done a few

years ago. But it does address some of the questions that came up during the discussions a few days ago on November 17.

So before I get going here, I really want to recognize the ORAU Team. They did the lion's share of this work, and I really appreciate all that they did in pulling this information together so.

I'm going to go over a little bit of background, the evaluation that we did, some more summary and conclusions and then open it up for questions. So hopefully this will go fairly quick.

So from the background standpoint, when we made the construction, or when we made the initial co-exposure model for the Savannah River Site, we did a single co-exposure model where we actually had all construction trades workers and operations workers combined together.

One of the comments that came back was that we should really break out construction trades from the non-construction trades workers. And so we did that. And so in the current revision of OTIB-81, which is the Savannah River Site co-exposure model, non-construction trades workers are broken out from construction trades workers.

This resulted in a further concern that the construction trades workers in the co-exposure model are a combination of prime construction trades workers. These would be construction trades workers working for DuPont and subcontractor construction trades workers.

So the current discussion and the concern is should the subcontractor construction trades workers be combined with the prime construction trades workers into a single co-exposure model?

And our position is that if prime construction trades workers had similar exposure conditions to the subcontractor construction trades workers, then the bioassay data from the primes and thus the intakes

on that data may be used to assign the intakes to unmonitored subcontractor construction trades workers.

It is our position the exposure conditions and the potential for intakes were similar amongst all construction trades workers. And this comes into play where a lot of the what I'm going to call prime construction trades workers were primarily millwrights and what they call at Savannah River Site E&I technicians, electronics and instrumentation technicians. And so they would be doing a lot of the same type of work that Savannah River would bring in subcontractors for. Okay?

So a timeline of these discussions is this kind of started around the 2017 time period. There was a joint SRS, SEC Issues Work Group meeting. And then in August, we had sent out an email memo to Mr. Clawson and Dr. Melius, at the time he was the Chair of the SEC Issues Work Group. And this is where they had asked for additional analysis and clarification.

So in May of 2019, we wrote a White Paper. And that's the topic of today's presentation right now. We entitled it the SRS Plutonium Construction Trades Worker Stratification Refinement. And that's what this presentation is about.

Now what you're going to see next is on November 12 SC&A did a memo review of that White Paper, and Bob Barton is going to talk about that next. And then in March of this year, we wrote a response to SC&A's comments with regards to the information I'm about to present to you.

So this is the sequence. This is how we're getting to this. It really -- the first -- this presentation and the November 12th just didn't make it onto the agenda due to timing type of issues for the last time we met, which was December of last year.

So we're kind of backing up a little to fill in the gaps. Remember, we were all supposed to have a March Work Group meeting that got delayed or actually

cancelled due to COVID and so we're kind of picking up what would have been presented in March. Okay?

So let me start with what we did in this White Paper, what our evaluation was. So our evaluation plan here was to compare subcontractor construction trades workers and prime construction trades worker bioassay for commonly monitored radionuclides onsite over a period of time.

So we looked at possible candidates that we could do this with, plutonium, uranium, mixed fission products or tritium. We had previously done one, a comparison of the tritium and had presented that previously to the Work Group. But the actinides are really the crux of the concern here. And so we selected plutonium to compare from that standpoint.

So one of the other questions we had was do we look at all years or select years? Well, this is a large effort to do. This is not trivial to go through and do this type of comparison and separating people out.

So we decided to evaluate five years through the period of 1972 through 1988 and basically at three year intervals. Okay? And so we honestly started with the end. And 1986 is where there was previous concerns that subcontractor construction trades workers were demonstrating a potential higher exposure than prime construction trades workers. So we started with 1986 and then kind of worked backwards and decided on let's do five years every third year going backwards.

Can we evaluate more years? Yes. We certainly can. But we don't feel that this is necessary. We feel that this answers the question.

So this is the current SRS plutonium construction trades worker model that is in OTIB-81. And I've highlighted here the five years that we evaluated. Again, we started with 1986 and kind of worked back on three year intervals. And so these are the years that we are evaluating.

So the source data for the plutonium co-exposure models is from claimant files. This is the NOCTS data. And that was done -- it was started years ago. Instead of trying to code all of the plutonium logbooks, which would be a massive effort, we felt we have sufficient information in the claimant files to just use the claimant data to develop the plutonium co-exposure models.

However, one of the things we noted when we started doing this is that the data is highly censored for most years and in particular for subcontractor construction trades worker populations. So if you're looking at a lot of censored data at .1 dpm per day, it looks like, well, as you will see on the next slide or so, that virtually all of the data is censored.

To increase the number of uncensored results, we considered an additional source. And this was the plutonium bioassay logbooks. And in these logbooks, the data is actually not censored.

On the individual cards we get from the Department of Energy in processing claims, the data is censored. It will say less than .1 dpm per day typically, but in the logbooks there is the raw result.

So, wait a minute. Okay. So this is the time weighted one person, one statistic plutonium results. And again, the censoring level is .1 dpm. And so this is when we went through and separated the prime construction trades workers from the subcontractor construction trades workers. And I've got the two columns there divided by the blue line of primes on the left and subcontractors on the right.

And what you'll see from this for these five years is that the primes for the 50th percentile were slightly higher than the subcontractor construction trades workers with the exception of 1980. The same holds true for the 84th percentile, except for 1980 and 1986. Okay?

So this is what it looks like graphically using box plots. And the dotted line across the center of the

graph there, that's the censoring level. And so what you see here is that there's not much difference between these two populations, at least from our standpoint in what we were looking at.

What you do see, especially in '83, '86 is that there are a lot more subcontractor construction trades workers. And this is predominantly because we supplemented their data with the bioassay logbooks, and we did not for the prime CTWs.

We had over 30 results for the primes that were not censored. And we could go to the logbooks and instead of trying to randomly select, we just coded them all. Okay?

And so if you look at the numbers here, 65 prime construction trades workers in 1983, 641 of the subcontractors. There are many more than 65 prime construction trades workers at the Savannah River Site. These are actually just the claimants. Okay? So I just want to make that clear here.

This is what happens when you expand the box plots on a log scale that makes them easier to see and easier to see that separation. What you see is that central tendency of the box between the 25th percentile and the 75th percentile. They match quite closely all the way through.

You do see in 1986 that the 95th percentile of the subcontractor construction trades is higher than the primes. Also in 1980 and I believe 1983, too, it's also slightly higher. Okay?

So we're not seeing a big difference in the TWOPOS results. But remember the TWOPOS results are used to develop the intake model. Okay? Those are not directly used when we do dose reconstruction. We use the intake model.

So if you recall what we do from the intakes to determine these intakes is we take the 50th percentile, the TWOPOS data, and we fit it into what this particular case is an example of. And in this

particular case, we're fitting the 50th percentile of the subcontractor CTWs from 1973 to 1978. And this would be for Type M plutonium.

And here is for the latter years, for the 1979 to 1987 time period. And that's what that would look like. It's a higher intake that we would assign. So really the intakes is what we should be comparing here.

And so for Type M plutonium, what we find for the '73 to '78 time period is that the prime construction trades workers have a higher 50th percentile, a higher 84th percentile and a higher 95th percentile. However, from 1979 to 1987, the primes have a higher 50th percentile but a lower 95th percentile. The geometric standard deviation is higher for the subcontractor, showing there is more variability in that time period. Okay? And so this is for Type M.

For Type S plutonium, again, we see the exact same thing. And so in the '73 to '78 time period, the intake is about 100 dpm per day higher for the prime construction trades workers versus the subcontractors. The opposite is true for the '79 to '87. The subcontractors are about 50 dpm per day higher than the prime subcontractors.

So which is more claimant favorable? Well, it depends upon the individual worker as to which time period they worked in as well as what their exposure profile looks like.

So our summary in conclusion is that, you know, over 95 percent of the TWOPOS data results are less than the reporting level of .1 dpm per day. So 95 percent of the data for all construction trades workers is censored. Okay?

We had to go back to the original records in order to make it uncensored to try and

get what these lower levels are. There's no apparent difference between the prime construction trades workers and the subcontractor construction trades workers with regards to TWOPOS. There's no

practical difference between the two groups when intakes are modeled.

So there's really no evidence of a significant difference between the prime construction trades workers and the subcontractor construction trades workers. So our conclusion is that the exposure conditions and the potential for intakes were similar among all construction trades workers therefore combined strata is appropriate. With that, I'll be happy to answer any questions.

Okay. Not hearing any, then let me go and share Bob's presentation. SC&A will --

Member Beach: You know, Tim, while you're doing that I do have one quick question. How can you be sure of the completeness of the data? How can you be sure that all the construction subcontractors are even in the logbooks?

Dr. Taulbee: Well, let me go back up then. Sorry.

Member Beach: Oh, I apologize.

Dr. Taulbee: No, no. That's alright. That's alright. This is important. Let me go back up to that presentation. Why am I not seeing it now? Share. Oh, okay. Let me stop sharing that one and share a different presentation here. There we go. Okay.

It kind of goes back up here to this particular slide, Josie. When you look at 1983 and 1986, I mean, we're looking at 1,000 bioassay of subcontractor construction trades and in 1983, 600.

It kind of runs down to, I mean, is this complete? Was everything -- I mean, this follows on to the discussion from Tuesday for sure. You know, there is a lot of work that is going on in this time period, but just the sheer numbers of bioassay tells us that we're not missing a huge portion, at least that's what it tells me.

Now when we get into these earlier years, '74 and

'77, there could be. But in this time period we also know that DuPont didn't use a lot of subs in that time period. They did a lot of the in-house work themselves.

In 1980 is when they began to ramp up. And that's where we begin to see these large numbers of using subcontractor construction trades. So can we be 100 percent sure? No. But if everybody was monitored, okay, then we wouldn't need a co-exposure model. I mean, that's just a simple fact.

So we know not everybody was monitored. How do we know that we feel like we've got enough data? Oh, it has to do with the abundance of the data here. I mean, 641 subcontractor construction trades workers were monitored for plutonium.

As John showed on Tuesday, over this time period of 1972 to 1990, or 1989 rather, we have 11,000 subcontractor construction trades workers bioassay -- I'm sorry -- amongst 7,000 individual subcontractor construction trades. So it's the abundance of data that gives us some assurance here that we've got a large population that is monitored and that a co-exposure model is reasonable.

Chair Clawson: Tim, this is Brad. One of the things that bothers me on this, now Savannah River is different than any of the other sites. Their maintenance program, everything else like that, they use trades. They use construction trades. That's why you have a DuPont construction trades workers. Those people can go from there, back into the hall and back and forth without too much trouble.

A lot of them stayed there for quite a while. The thing that does bother me is that if you look at the DuPont construction trades those numbers are almost half in some cases what the construction trades is.

To me, I would see that it -- because they are the ones that are doing all the maintenance on the work and maintaining the whole Savannah River Site. And there's not that many numbers there.

Dr. Taulbee: Again, this is the claimants. Okay? For the years 1970 -- all of the black box plots here that you're seeing, these are claimants only. Alright?

The red ones that you're seeing, these are ones that have been supplemented with logbooks. So you really can't compare these two the way that I have. What you should be comparing is just the concentration, not as much the numbers. Because if we were to add in all of the prime construction trades workers here -- and I'm sorry that keeps popping up that way -- for, like, 1983, like I said, there's many more than 65. There are probably going to go on -- somewhere around 300 to 400 prime construction trades workers that could be added in here.

But what you see in those distributions of their bioassays, they're not that different, even with these smaller numbers for the primes.

Chair Clawson: Okay. It's just to me it's misleading a little bit that way and --

Dr. Taulbee: So I'm trying to be clear.

(Simultaneous speaking.)

Chair Clawson: -- Savannah River Site period. And it just kind of was a little bit interesting to me.

Member Lockey: Tim?

Dr. Taulbee: Yes, sir.

Member Lockey: Jim Lockey. What percentage of subcontractors did not have bioassay data again?

Dr. Taulbee: Did not have bioassay data?

Member Lockey: Yes.

Dr. Taulbee: Within this particular population, this one here we just looked at the plutonium bioassay itself. You'd have to look at RPRT-00944 in order to tease that out.

And from there we broke out the plutonium bioassay -- or not the plutonium. We combined plutonium and mixed fission product bioassay. We broke out tritium.

And so the numbers are around -- sorry, I'm being weird here because I don't have the exact numbers right in front of me. But it's somewhere around 40 to 50 percent of the actual claimants that we have did not have -- subcontractors did not have plutonium bioassay for these five years.

Member Lockey: For those five years.

Dr. Taulbee: Yes.

Member Lockey: Okay.

Dr. Taulbee: Of the claimants, between 40 and 50 percent of them that were externally monitored have plutonium bioassay.

Member Lockey: Okay. And you could link those bioassays to specific job tasks?

Dr. Taulbee: To specific trades, not to -- the job tasks comparison was RPRT-0092 that we talked about on Tuesday. And we can only link them for one area. And that was one of the discussions. But this particular dataset is looking at all areas.

Member Lockey: So you linked it to a specific trade.

Dr. Taulbee: Yes.

Member Lockey: So we're comparing trade against trade. Okay. I thought that's what happened, and it confirms what I heard on Monday. But I just wanted to make sure. There's so much data that we have to look at or have looked at that sometimes it makes your head swirl. But your answer is consistent with what I thought you were going to say.

Dr. Taulbee: Okay. Thank you. Are there other questions? Okay. Alright. Now let me try then, Bob, to share your presentation. Alright. Go ahead.

Mr. Barton: Alright. Thank you, Tim. Again, this is sort of our review that came out last fall of what Tim just described, that analysis, which was really a refinement of the 2017 analysis that sort of broached this entire question about stratification.

Before we really get started in here, I would just like to reiterate the caution in that the decision to stratify is really in my mind more of a Site Profile issue that comes up when you've already decided that a plutonium co-exposure model is feasible for all the parties involved, which includes the subcontractors.

And that's why I cautioned that on Tuesday. But there are -- this discussion does provide a good perspective. But I'm not sure we want to belabor it too much because I do see it as more in the Site Profile realm.

But anyway, I don't know if those of you who were on the call a little bit early the way we were going to structure this is that we'll sort of go through my presentation and then pause at each finding and observation and switch over to NIOSH's response so that we don't sort of have all of these things washed out by going full presentation, full presentation and then trying to discuss them all at the end.

So as we go to each one, SC&A will present its finding, and NIOSH will present its response. And I believe the best thing to do at each point would be to have a discussion of that among the Work Group or Work Groups rather. So we'll get started.

Next slide, please. Alright. A lot of these first slides are just, again, reiterating the background of this issue and sort of the timeline that Tim already laid out. So we're going to sort of breeze through these.

But, again, that key question is do subcontractor trade workers have the same exposure potential as primes? And the test that was put to this was to look at available plutonium data, which for the prime contractors was just claimant data and then expanded for certain years for subcontractors. I

believe among those five years it was expanded for three of them, Tim, or was it four? I think maybe it was three.

Dr. Taulbee: It was actually four. I think on my slide there is an error that I actually meant to point out. There are four of the five years we did supplement with the bioassay logbooks. You are correct.

Mr. Barton: Okay. Alright. If we can go to the next slide again, this is sort of just giving the history of how we got there, which Tim has already presented.

Again, this was the conclusion in 2017. And really what gave us the most pause is sort of this notion in here of the exceptions where subcontractors appear to be higher in the original analysis in 2017.

And it was, what? The conclusion was this observation is somewhat supported by the contemporary interviews with subcontractor CTWs. Subcontractor CTWs indicated they were called in for more contaminated work to save the exposure of the onsite CTWs.

And so we saw this and said, well, this would indicate to us that stratification should be considered not just pulling out construction trade workers alone but possibly separating out primes and subcontractors.

Next slide, please. Again, this is just reiterating what the path forward was. I don't think there's anything more to say about this slide other than NIOSH wanted to go back and look at a little bit more data and refine it is exactly as it's called.

Next slide, please. And so Tim already showed this table. And, again, these are intakes that we're looking at, which ultimately is what is applied to a claimant who is unmonitored and needs the co-exposure model.

And we're going to certainly get into this in a little bit but just to call your attention to that last column, the 95th percentile ratio. As Tim pointed out, at the 95th

percentile in the 70s, the prime contractors appear to have higher intakes based on this analysis. But once you get into the '79 to '87 time frame, it's the subcontractors that are higher by about 15 to 20 percent.

Next slide, please. And so this is the refined NIOSH conclusion. Tim just went over this. And ultimately what they're saying is that even though for the different periods, you know, '70 to '78, the 95th percentile for DuPont is higher, as I just said, '79 to '87, subcontractors are higher, again, at the 95th percentile.

And that's due to that higher geometric standard deviation of the data, which you saw that box plot that Tim just put up, especially in those later 80 -- the two later 80 years. You see a lot of subcontractor datapoints that are well above what the highest DuPont construction trades were, again, in those 1980s periods. And, again, this does give us pause as we move forward as you will see in Finding 1.

Next slide, please. And this comes out of the NIOSH original analysis that NIOSH presented in 2017. And the only thing I really want to point out here, and, again, this is the number of monitored claims. It breaks it out by DuPont and subcontractors.

And just if you look towards that 1980, towards the right of the graph, you can see that the number of subcontractors is significantly increased as well as the percentage compared to DuPont. So, again, that's the 1980 period where we observed as the 95th percentile a 15 to 20 percent increase in the calculated intakes for subs versus DuPont.

Next slide, please. And, again, this is essentially the same thing. If you look, again, this is the claimant population, the subcontractors versus all workers combined, again, in the claimant population.

As you can see, it goes from '72 into the late 90s. And it slowly increases through the 70s. And you sort of hit your maximum there in the mid-1980s up to

1990. So, again, this is just sort of giving perspective on the increase in the use of subcontractors during that 1980s period, which I believe was referred to as the late DuPont era in NIOSH's presentations on Tuesday whereas the 70s was referred to as the mid-DuPont era.

So there is sort of a delineation there, which I believe is why in the stratification analysis when calculating the intakes, and Tim, you can clarify this certainly, that's why I believe it was sort of separated into the 1970s and the 1980s for comparison purposes. I don't know if you want to -- or is that correct?

Dr. Taulbee: Actually when we do the intake modeling, we don't consider from that standpoint. We look at what is the bioassay data doing because we're modeling a chronic intake. And so the results were generally lower in the 1970s compared to the 1980s. That was the reason for the break. It really wasn't due to this change in the number of workers.

Mr. Barton: Okay. Thank you for that clarification. But I think it's important to remember -- the reason I put these charts in here, and these were compiled by NIOSH, it just appears that the use of subcontractors increased significantly in that 1980 period. And that's really the only point I wanted to make with those two slides here.

So we can move on to the next one. Alright. This brings us to Finding 1. And I'll read this into the record.

In SC&A's opinion, the conclusion that subcontractor construction trade workers had higher excretion rates and derived intakes at the 95th percentile for the period 1979 to 1986 is significant from the standpoint of considering stratification because the 95th percentile is what is proposed for assignment to unmonitored subcontract construction workers.

And so that's our finding. What we're basically saying here is that, you know, you can look at the medium --

Dr. Taulbee: Bob, we lost you.

Dr. Roberts: Bob? Let me see. He's still talking. Let me see if I can --

Dr. Taulbee: Is anybody able to hear Bob?

Dr. Roberts: I can't.

Chair Clawson: No.

Dr. Roberts: No.

Member Beach: No.

Chair Clawson: I cannot hear him.

Dr. Roberts: I sent him a message.

COURT REPORTER: This is the Court Reporter. I suggest we go off the record until we have him back.

Dr. Roberts: Okay. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:12 a.m. and resumed at 11:13 a.m.)

Mr. Barton: Alright. So as we can see, this is SC&A's finding. And we believe that it's significant to look at the 95th percentile because what we're really talking about is bounding doses here. And so in that box plot that was in the previous presentation if you looked at those 1980s years, at the very top of the distribution, you had a lot of subcontractor results compared to the DuPont.

And if we're really talking about bounding doses here to unmonitored subcontractor workers, I think it's important to be able to look at the 95th percentile. And NIOSH has a different viewpoint on that, which I think we're going to get into.

And, Tim, this might be the time to bounce over to your presentation so that NIOSH can present their view and their response and then we can discuss what's really the appropriate metric to look at.

Dr. Taulbee: Okay. Alright. Let me -- can everybody see the slides here? Okay. So our response to SC&A's finding here, for one thing I want to make clear to the Work Groups is that the 95th percentile is not exclusively used in dose reconstruction. It's a bounding scenario, but we do use it occasionally.

The decision as to what should be assigned is made during the dose reconstruction process, and it's based on the total information in the claim. There are some subcontractor construction trades workers who were never exposed.

They did their work onsite. They talked about that they were doing new construction. They weren't wearing external dosimetry. And so we assigned an environmental dose, a minimum exposure, for those particular workers.

There are others who occasionally went into an area. And we've assigned the geometric mean in the 50th percentile. But as Bob pointed out there are some who we would assign the 95th percentile to. So it's not a one size fits all when it comes to dose reconstruction and how this gets used.

So if you go back to the comparison that I was talking about, and the comparison of the TWOPOS and the intakes, the TWOPOS results, the 50th percentile is higher for four of the five years that we compared. The 84th percentile is higher for the prime construction trades workers for three of the five years. But when you come to the intake models, the 50th percentile is higher for prime construction trades workers in both intake periods.

The primes was higher in the second intake period -- or the subcontractor construction trades is higher in the second intake period.

So it really depends upon the individual claim, which is going to be more claimant favorable. But there's no apparent difference that we felt would support stratification on this and that's our current position.

We're not refuting that some of the construction trades workers subcontractors were potentially exposed higher than the primes, especially in the 1980s. But the bulk of the data doesn't, in our opinion, support stratification for unmonitored subcontractor construction trades workers.

And a lot of it goes back to this particular slide in that we look at the totality of the claim. We don't just blindly assign the 95th percentile. There are some that we assign an environmental dose to. And some we assign geometric mean or the 50th percentile so.

With that, Bob, let me bring back your presentation. Actually, does the Work Group -- I mean, probably before we move on we should address questions, right? Is that agreeable, Bob, to both of ours? Okay.

Mr. Barton: Yes. I'd like to hear if the Work Group has any questions and then I do have a comment on this issue, which is applicable not just to this but as sort of a programmatic policy of how we apply these different percentiles and how co-exposure models are actually used in practice because I think it's possible that we over at SC&A are mistaken on what NIOSH's policy was. But we can get into that -- I prefer to open it up to the Work Group if there are any direct questions or comments first. Unless you want me to --

Member Beach: Well, one question I have is, Tim, how do you determine which exposure to assign, the environmental, the 50th, the 95th percentile? Where does that information come from? Is it from the workers, from their bioassay?

Dr. Taulbee: It's a combination of multiple sources when the dose reconstruction is done. And professional judgment plays a role in that. And that's where the Dose Reconstruction Review Subcommittee comes into play.

And they review these claims and go through and look at which decision we made and how we assigned the doses. And, you know, there isn't any, you know,

like I said, one size fits all. It depends on the individual claim.

There could be claims where it's a non-metabolic cancer, and we go ahead and assign the 95th percentile because it's not going to make a difference in the claim decision. And so we'll be overestimating that particular dose.

And then in other ones when you're looking at a best estimate, which is what the Dose Reconstruction Subcommittee focuses on is the best estimate cases, and where that professional judgment is used.

Ms. Naylor: Tim, this is Jenny. But I just wanted to make sure that you could discuss the various factors that the dose reconstructors evaluate when assigning those percentiles.

Dr. Taulbee: Sure. I mean, some of the things that I would be looking at if I was a dose reconstructor would be looking at whether they were externally monitored, which areas that they were working in from that standpoint as to whether I would be assigning the environmental dose or the 50th percentile or the 95th percentile.

I mean, if I've got somebody who only worked around the reactor areas and, you know, they mentioned that they were specifically working in the spent fuel areas, then we might assign the 50th percentile so. Does that help?

Ms. Naylor: That's great. Thank you.

Member Lockey: Hey, Bob. Jim Lockey. I'm looking at this slide, your SC&A Finding Number 1. I'm trying to get my head around what you're trying to say here. What would you propose? That everybody be assigned a 95th percentile? Is that what --

Mr. Barton: No. What I'm saying is that when you make the decision to stratify or not, you want to consider whether there's a group out there at the upper end of their distribution. They're actually doing

more contaminated work and had a higher exposure potential.

So I think when you're talking about purely bounding doses and the decision to stratify, I think looking at the 95th percentile is the metric you want to look at because that's what you're going to essentially apply when you have a worker who you feel is significantly exposed but does not have monitoring records for whatever reason, either they were lost, destroyed or they just weren't monitored and should have been.

So I think, you know, I'm not saying the 95th percentile should be applied to everyone, but I think that when you're talking about the decision to stratify, that is the metric you want to look at.

And to sort of get into that a little bit, I mean, I was looking through some transcripts when we discussed this back in 2017 because, again, SC&A may just be confused. But our impression was that was the metric we were looking at.

So in a 2017 meeting of the SEC Issues Work Group, this is on Page 26 and 27, and I believe this is you, Tim, you had similar conclusions. So we didn't see any systemic difference between DuPont construction trade workers and subcontractor construction trade workers.

There's a few years where plutonium bioassay is higher for subcontractors than DuPont construction trades workers, but it's not systematic. The last five years there's three years where subcontractors were higher and two years where they were lower.

Therefore, we feel that the application of the 95th percentile of the combined construction trades workers coworker model, the unmonitored construction trades worker would be bounding. So even back then, we're looking at that 95th percentile.

Also in 2017, and Brad, you'll appreciate this because this actually comes from a -- I took this out of one of the Fernald transcripts. And the quote is, our general

guidance on coworker models is for a coworker model if someone that is not monitored and is occasionally exposed, they get the 50th percentile. If someone is not monitored but it looks like they are probably regularly exposed, they get the 95th.

But I think that application of the 95th percentile is very important to think about here in the context of applying co-exposure models. Again, our impression was that essentially if, you know, you never really entered radiologically areas, if you were administrative or something like that, or you just worked outside, environmental dose is appropriate.

If you were someone who only occasionally entered radiological areas but weren't really considered a rad worker, per se, then you get the 50th. And if you were a rad worker that was unmonitored, then you get the 95th.

And that's what we get from this quote out of Fernald and that, by the way, was Stu Hinnefeld who said that. And that's on Page 95 of that transcript. So, again --

Dr. Taulbee: I believe that matches what I had said earlier as well.

Mr. Barton: Right.

Member Lockey: This is Jim Lockey. That was my point. I was trying to figure out how you two differed. And I couldn't understand how you were differing.

Member Ziemer: This is Ziemer. Can I comment on that as well? So this actually is an overarching issue. And we've been looking for consistency across all the different sites for this.

So I'm sort of trying to understand Bob, what your point is. Are you saying that maybe the wrong 95th percentile that they're using for those that need to have the 95th percentile assigned? That --

Mr. Barton: Right. My point is that if we're trying to

bound doses to workers, whether it be DuPont or subcontractors, you would want to apply the 95th percentile to workers to bound those exposures. And this is the decision whether we need to pull out the subcontractors that have their own separate distributions for that purpose. And these are looking --

Member Ziemer: You're saying that it may be a different 95th percentile value rather than the combined. Is that my understanding?

Mr. Barton: No. What I'm saying is the analysis shows that in the model 1979 and 1987 period at that higher end, the subcontractors had higher intakes, calculated intakes than DuPont. So if they did not have their own separate model, you'd be applying the DuPont intakes or the combined intakes.

And so when we're talking about, again, this is the decision to stratify and again this is sort of getting back to this is really a Site Profile issue in that it's assumed that co-exposure modeling is appropriate and can be applied to subcontractors that at least for that latter period when you look at those higher end calculated intakes, the subcontractors are higher than DuPont.

And that's really our only point here. Not that, well, they're not 50th percentile according to this sort of scoping calculation is different than DuPont workers.

Now the inverse is true for the 1970s. But in that latter period, the 1980s, it would appear that if you wanted to bound unmonitored exposures to subcontractors, it might be appropriate to pull them out, again, for the 1980s because at that higher end exposure, they're higher than the DuPonts.

Now the inverse is true for the 70s. And that might be very well appropriate that subcontractors in the 70s may, if they had their own co-exposure model, the DuPont would probably bound them.

However, I would caution that when we talked about

job specific bioassays back on Tuesday and specifically plutonium, which is the analyte we're looking at here, SC&A found that the subcontractors on job plans were only monitored or effectively monitored, in other words being on the same job plan as the monitored worker about 65 percent of the time and that's in the 70s.

And actually that's only for '72 to '74 because there was no analysis available for '75 to '79. So we found what we feel are deficiencies in that job plan monitoring in the 70s for plutonium.

Now in the 80s we actually agreed -- we're pretty much in lockstep with NIOSH that the follow-up for job specific M plutonium in the 1980s was around, like, 97 percent. And I think we pretty much agreed exactly on that number.

So while the data appears to say that in that 70s period where you did have fewer subcontractors onsite doing work and that DuPont work might have been higher based on this analysis, again, we found that there were concerns with the job specific monitoring of those subcontractors in the 70s.

And, again, we came up with 65 percent effectively monitored. That's directly monitored via urinalysis or working with someone who would be included in a co-exposure model. So I throw out that caution there. I'm not sure if that answers your question necessarily.

Member Lockey: Bob, Jim Lockey. So are you proposing that -- what you're saying is take the exposure data for the subcontractors and separate it from the primes. Correct?

Mr. Barton: That's the question on the table. And I think it's certainly for the 1980s when we feel that at least for plutonium, the job specific monitoring data is very good. And, I mean, again 97 percent effectively monitored, there's not going to be a lot based on that analysis.

Now, again, that's only one area. But based on the analysis of RPRT-0092, again, this all assumes that co-exposure monitoring for plutonium is feasible for subcontractors.

Member Lockey: I understand that. So if by combining them, you're actually lowering the 95 percent bounding for the subcontractors were if you are separated, the 95 percent bounding for the subcontractors may likely be higher. Is that what you're saying?

Mr. Barton: For the model '79 to '87 period, that's what the analysis shows. And, again, the inverse is true. DuPont at the 95th percentile bounds the subcontractors. But, again, we do have concerns about the plutonium data.

We didn't get too much into the plutonium aspect of it on Tuesday. A lot of the brunt of the discussion was about limitations of the sampling itself, which in the 70s was only '72 to '74 with no comparison available. '75 to '79 in only A area for the entire period. So we do have concerns about whether it's feasible to use a co-exposure model during the 70s.

And then you get into the 80s where we really don't have the same concern for plutonium at least. But then when you look at should we pull out -- if we can do co-exposure modeling, if it's decided that that's feasible during the 1980s, is it appropriate to pull out the subs considering they have increased calculated intakes per this analysis when compared to DuPont?

Member Lockey: And the subs are going to have a higher 95 percent bounding limit if you do it that way than the primes in that time frame.

Mr. Barton: In that time frame.

Member Lockey: So, Tim, can you answer that?

Dr. Taulbee: Yes. I mean, our approach is to combine these two together. They're all construction trades workers combined together. And so the 95th

percentile for this latter time period of say the '79 to 1987 time period would be a combination of this 279 plus 326. So it would be around 300 dpm per day.

So if we were to break it out, you do see this difference here, which would be about 20 percent higher. And we just don't see that this is a reason, you know, a 20 percent difference to stratify off of somebody -- off of people who are -- to stratify these two groups -- I'm trying to use the right -- I'm trying think of the right words here.

For this particular time period, that's what this data shows. The earlier time period, it's the inverse. Okay? And up here, it's, like, 50th percentile, or 50. No, it's about 30 percent.

Okay. We just aren't seeing the value of going through this effort to do it. Can we do it? Sure. We can. But it just -- we feel that combining the construction trades workers together is the appropriate way to go for this.

Keep in mind that when we do our full co-exposure analysis, okay, we are looking at generally over about this time interval, yes, about 10 years is generally and then you see another drop in the values due to bioassay monitoring type of methods.

This is just a further substratification. And I guess we're looking for feedback from the Board, you know, from that standpoint. Is this worth going through and breaking it apart?

Member Schofield: Tim, this is Phil. I've got a question for you. Now this is based on Pu.

Dr. Taulbee: Yes, sir.

Member Schofield: But we do know a lot of those people also were exposed to fission products and americium and strontium, you know, some of these others. So how are you -- are you taking those into a factor or just using -- it looks like you're only using plutonium to make this co-worker model.

Dr. Taulbee: No, no, no.

Member Schofield: Is that correct?

Dr. Taulbee: That's not correct. We only did this evaluation for plutonium. Okay? We did not do this evaluation for the mixed fission products, for the americium or the uranium bioassay. Okay?

This was a comparison to see do we see a difference and should we stratify? That's all that this evaluation was. We have co-exposure models for construction trades workers combined for all nine radionuclides. Okay?

Member Schofield: Oh, okay. Well, that answers my question. Thank you.

Dr. Taulbee: Yes. We just did this separation just for plutonium so that we could do a comparison. What we thought would be an easy comparison, it's not as easy as we thought.

Member Ziemer: This is Ziemer. I have another question in terms of the practical dose reconstruction.

Does the dose reconstructor, it's easy to see where a given worker could have a life -- his lifetime exposure may overlap these different periods. Do they use a 95th percentile value year-by-year when they dose reconstruct?

Dr. Taulbee: Actually what they would do in this particular case is they would assign it -- this is dpm per day. And so this would be on a per day within this time interval of 1979 through 1987.

Member Ziemer: Right. So if you had a given worker, there is a pretty good chance that part of the time his value would be overestimated because he would be in the -- and part of the time it's underestimated.

Dr. Taulbee: Exactly. If you consider a worker that say started in 1975 and worked through 1985, they're going to bridge these two gaps. And in one

case it's more claimant favorable for them to be combined under the combined CTW method and the other part it's better for them to be separated.

How can you make that determination? You know, that's part of why we feel it's better to combine it all together. And, you know, keep in mind that this is the 95th percentile here. So this is the upper bound of what a worker would be exposed to. And we're applying it to everybody who wouldn't be monitored that we feel should have been monitored and was doing significant work in a rad area.

Member Ziemer: And it's already highly claimant favorable to start with.

Dr. Taulbee: Yes, sir.

Member Ziemer: So it's the issue of is it really worth the detail because you're going to end up part of the time going the opposite direction. So what's the point, you know?

Dr. Taulbee: That's our exact position. Yes, sir.

Member Ziemer: I think it makes sense just to use the combined one. But I'm not on the Working Group that makes this decision.

Chair Clawson: Oh, Paul, but this is kind of an overarching issue for all of the sites. This is what part of the issue is we are talking about Savannah River in this aspect.

But what Tim is asking us and also the Board is they want to do this to all of the sites. And this is an overarching issue for every one of the sites.

Member Ziemer: Well, I think the decision on the 95th percentile and 50th and so on, that decision has been made already. So that's not new here. I think the only issue here right now is very site specific on treating this particular situation for Savannah River.

The use of the 95th percentile today as an issue, the overarching issue, I believe, that's already been

applied, is it not, Tim?

Dr. Taulbee: No, it is. But Brad is right here. And what our question back to you is because this is an overarching issue for all of the co-exposure models, what level of detail do we need to go down to?

And that's where this is the SEC Issues Work Group's role, I think, is do we need to substratify amongst subcontractors versus primes for, you know, any site from that particular standpoint?

I mean, there could be times when we run into this exact same scenario at another site. You know, I don't know, Idaho or Hanford or one of the other sites where we run into a time period where if we broke it out we would see a subcontractor pool that would be higher for a few years than the in-house folks and vice versa, like we're seeing here with the '73 to '78 time period.

And that's the question back to you all. We don't see a significant difference here that warrants substratification. And if you go back to the intake modeling, let me pull that up quickly here if I can, and I can't pull it up quickly. Give me just a second, sir.

Mr. Barton: Well, Tim, while you're doing that, in preparation for this meeting, I hope everybody can hear me, I actually ran this series of reports, 2017, the refinement, SC&A's review and then the NIOSH's responses past one of our statisticians, Richard Griffiths. Unfortunately he had a prior commitment so he couldn't be on this call.

But he did provide some comments that are directly related to this and it's that notion of significant difference. And what he said was the determination of no significant difference between the two populations appears to be subjective here.

There's no formal statistical test that was applied to quantify and conclude the two groups are either not different, different or there's a degree of difference in

there. And Richard Griffiths, again our statistician, also noted this is of particular import because we're only looking at a sample of the population under consideration here and not the full population.

So, again, the decision of whether the groups are different or not is somewhat subjective here from SC&A's viewpoint.

Chair Anderson: I mean, and I would just add the other issue is it almost has to be on a specific basis because you may not have sufficient samples to substratify. Here you have a lot of test results so you can consider is it important to self-break out the groups? But in many of the sites, the numbers are not sufficient to be stable enough to allow you to break them out.

So kind of the first decision is how strong does that statistical number need to be to be able to say we should consider substratifying or not. Here this is probably -- maybe Hanford has a similar large number of samples. But this is one that has so many samples that you can consider substratifying.

Dr. Taulbee: And if you look at the combined model over a time period here, this is all of the data. This is the current construction trades worker plutonium co-exposure model.

You'll see that it changes a little bit over time. But the actual model of the intake -- this is the bioassay data. The actual intake doesn't change much because we're fitting all of this data together.

And so when I go back to this particular graph here, there would be additional years in here. And we would come up with an intake that's not perfect. It doesn't go through all of the lines as you can clearly see from this particular modeling.

So this small -- this difference that we're seeing here in the intake, we just don't believe that it is significant enough, if I can use that term, to separate from a practical standpoint.

We disagree with SC&A on that. But, again, you know, if the Work Group feels differently, we can do it. It is possible.

Chair Clawson: Well, Tim, what are you asking the Work Group for period?

(Simultaneous speaking.)

Dr. Taulbee: What I'm asking for is the approval or the okay to combine the DuPont construction trades workers with the subcontractor construction trades workers in our co-exposure models. That's what I'm asking for.

Member Lockey: Tim, this is Jim.

Chair Clawson: Is this only pertaining to Savannah River? Because to me I'm kind of under the impression that this is an overarching issue because I think that we've run into this at almost every large site that we've got.

And I just want to be clear what you're asking for us to do. Because to tell you the truth, as Bob has said already, this is a Site Profile issue. So I just wanted to fully understand what you are asking this Work Group for.

Dr. Taulbee: Effectively the agreement that our stratification method of combining the construction trades workers together is appropriate for this particular site. That's the first thing that I'm asking for.

The second part that you're absolutely right on, Brad, that I'm asking for or I guess looking for is do we need to go through this type of analysis at all the sites, which I hope we don't, or do we have to go through this type of analysis at other sites to demonstrate that it's okay to combine them?

Member Lockey: Tim, it's Jim Lockey. I wanted to follow-up on what Bob was saying. There is no statistical methodology available to determine

whether there are differences in these two approaches?

Mr. Barton: Tim, I think that question was for you.

Member Lockey: It is for Tim.

Dr. Taulbee: Oh, I'm sorry.

Member Beach: You said Bob though, yes.

Member Lockey: No, I said the question is to Tim. But Bob inferred that there was no statistical model available that they could discern that could help us in this issue.

Dr. Taulbee: We looked --

Member Lockey: It sounds like it comes down to a value judgment. Is that correct?

Dr. Taulbee: Yes, it does at this point. And part of this goes back to the initial reason to stratify or not stratify for even construction trades workers. We've looked at using a single model way back in 2015, I think.

We proposed multiple different testing, tests, statistical tests that could be done. We settled on one called the Peto-Prentice test.

This was presented to the SEC Issues Work Group if you recall. And the whole discussion kind of came down to was does it even have sufficient power in order to do this? And power is not the right word there. My statisticians are cringing when I said that. But is it possible to even discern a difference amongst the different groups?

And because we couldn't come to a conclusion then on a statistical testing method, we went ahead for CTWs at Savannah River and said, okay, we'll just stratify a priori and just break them apart now and then we don't have to try and have that discussion.

Well, we've ended up in that discussion now between

DuPont construction trades workers and subcontractor construction trades workers. So that's really the overarching issue of whether we need to use a statistical test and then if we do, what test should we use?

Member Lockey: Okay. So my next point, and this is for Tim, as a practical perspective by combining them, by combining the contractors and subcontractors, if you look at how that impacts an individual dose reconstruction, on some individuals, you're going to have a dose reconstruction that is somewhat lower and in other individuals you're going to have a dose reconstruction that's somewhat higher. You're sort of homogenizing the data. Am I reading that correctly?

Dr. Taulbee: Yes, you are. But the example that I was pointing out, though, is if you consider a subcontractor who started say 1975 --

Member Lockey: Right.

Dr. Taulbee: -- and ended in 1985, he's going to straddle both ways, and I have no idea which way that claim would come out.

Member Lockey: And so I think I understand. So this is really a value judgment for the Board. What we're doing is some people are going to get a dose reconstruction using this combined approach that's higher than probably is truth and then other people are probably going to have a dose reconstruction that's lower and does not necessarily represent truth for that person, but it's been homogenized across the whole group. I don't know where else we can take it. But that's, I think, the end result here.

Dr. Taulbee: Right. But one thing I would point out is the discussion that we're doing right now is at the 95th percentile.

Member Lockey: Right. I understand --

(Simultaneous speaking.)

Dr. Taulbee: This is a --

Member Lockey: But the subcontractors in the late 90s, if we stratify them, they're going to have a higher dose reconstruction because their 95 percent is going to be higher.

Dr. Taulbee: That is true.

Member Lockey: Right.

Member Beach: But there's a judgment call there, too.

Member Lockey: No, that's right. It comes down to, you know, are we averaging out over the whole population and are we okay with that? Because some people are going to have a falsely higher dose than they really got and some people are going to have a falsely lower dose than they really got. That's the end result of this.

Dr. Taulbee: It's the really got part of your sentence there, Dr. Lockey, that I'm having a little difficulty with because we're using the 95th percentile.

You know, in reality the whole distribution is what we believe. Now we're assigning the 95th because it makes it easier to do that. So, you know, there's very few in my mind that are going to be getting, in reality, greater than that 95th percentile of the combined model. I just don't --

Member Lockey: But that 95th percentile, Tim, would change if you stratified it?

Dr. Taulbee: Yes, it would.

Member Lockey: Yes. And you said there's a 20 percent difference maybe, right?

Dr. Taulbee: Right. That's correct.

Member Lockey: So that's what I'm trying to deal with. And that 20 percent now, if you combine them is being leveled --

Dr. Taulbee: Yes.

Member Lockey: -- across that whole population to a certain extent.

Dr. Taulbee: To a certain extent, yes, sir.

(Simultaneous speaking.)

Member Ziemer: Tim, either way, either way at the 95th percentile for an unmonitored worker, you're giving them what is likely completely friendly notes, user friendly notes. In other words --

Member Lockey: Jim Lockey, I agree with that. You know, I agree with that. I'm just trying to --

Member Ziemer: So it's a little more user friendly, maybe slightly so? But it's --

Member Lockey: Is it worth the --

Member Ziemer: In my mind, it's not going to make much difference.

Member Lockey: Yes. Is it worth the effort? And I would say probably not, not worth the effort.

Member Ziemer: But this decision on which to use still looks to me to be site specific, for example, if this stratification thing across the board looked different all the way across, we wouldn't have this question. I mean, it's up and down.

And for a given worker, it's going to pretty much level out between various years. If it was consistently higher and significantly so all the way, we wouldn't have this question. We could say, yes, stratify. But that doesn't mean that would occur on another site.

Chair Anderson: The other thing is the exposures in different time periods of the subcontractors may be different. And that's really what this is saying.

And, therefore, you could stratify in some time periods where I would say that the differences

between the groups in the -- and after '80 you have a great deal more data. And you look at the exposures there between '73 to '78. And we know the quality of that and the areas that were sampled is quite different than that in the 80s.

So the quality of the data and the extensiveness of it in the 80s is much better than it is in the early years. So combining all those and then, you know, we may want to stratify in certain time periods might be -- at other sites that might be what you need to do because it has to do with what kind of work the subcontractors are doing if that's different in different periods.

I mean, the comments made that the subcontractors were brought in for some of the dirtier jobs whether that's true or not, I'm not sure we've established. But that certainly could account for why it's higher, the differences between the two groups are different at some periods of time because of the use of the subcontractors.

Mr. Barton: This is Bob. I would also reiterate that, again, this is sort of a Site Profile issue because all of this -- the question of whether to stratify or not assumes that a co-exposure model for subcontractors is feasible.

And not to completely rehash Tuesday's discussion, but SC&A does still have some concerns about the plutonium monitoring for job specific subcontractors during the 70s, namely we only have that comparison for '72 to '74 for subcontractors and only for A area. There's no analysis for '75 to '79. And just for '72 to '74, we only found 65 percent effectively monitored.

Again, that's the combination of those who actually have records or are on a job plan with someone who has records, which would feed into this co-exposure model. So we have concerns about the data for subcontractors in the 70s whereas in the 80s we do not.

But in the 80s based on this scoping analysis, it

appears that there is somewhat of a difference for subcontractors when we don't have those job specific concerns based on the RPRT-0092 analysis.

I just want to try to keep this in perspective that what we're really talking about is a Site Profile issue that already assumes that co-exposure modeling is feasible for both periods under evaluation here.

Chair Anderson: And also we have to remember this data that's being used is only in the claimants. And so there may be -- and, again, so the claimants are more apt to be people that have cancers. And we don't know is that representative of the whole workforce? And those who file, we don't know are the subcontractors less represented than the claimants because they're not as aware?

Chair Clawson: This is Brad. I would also like to say, you know, all of this is bounding on the completeness of the data. And if we don't have the completeness of the data and feel comfortable with the data and everything else like that, I don't see where we can because I think that we're stratifying what we do have but it may not be the best for either side.

Member Lockey: But, Brad, Jim Lockey. Even if the SEC gets sort of through with the whole Board, NIOSH still has to use this data.

Chair Clawson: And I understand that, Jim.

Member Lockey: So we should make a decision whether on this data we want them to stratify or non-stratify. Don't you need an opinion from us, Tim, on that?

Dr. Taulbee: Yes. However, it depends upon how you define -- or if the Board does recommend the Class, it depends upon how that gets defined.

If you say we can't do plutonium dose reconstructions or plutonium dose reconstructions are not feasible for subcontractor construction trades workers, then no, we wouldn't, you know, because

we wouldn't be able to set a maximum dose.

Member Lockey: Okay.

Dr. Taulbee: So it really depends upon how the -- if you recommend a Class and the Board approves it and so forth, it depends upon how that gets defined.

Chair Clawson: Well, I've got a -- for the Work Group, I've sent out a proposed Class. And once everybody has made their reviews on that, that will come into use.

So really what you're telling us, Tim, is until we define this Class, this is kind of a moot point for right now, are we going to stratify or not?

Dr. Taulbee: Yes. I guess based on that that would be correct.

Chair Clawson: So --

Dr. Taulbee: Okay.

Member Ziemer: Could you put that chart back up that you had on before with the -- yes, okay. If you look at those 95th percentile things, I'm just looking at the '79 to '87 one right now.

The 279 versus 326, I think you've got to understand that this is one of those things where we carry things out to decimal places that are way beyond the significance of the number. The 279 is probably 300. And the 326 is probably 300.

Dr. Taulbee: Yes, sir.

Member Ziemer: You know, plus or minus. Okay? So we have much more significance before us than the actual number is. To me, those two numbers are the same. The same with the 16 and 90. We don't know those numbers that closely anyway. If they were way apart, like, 200 and 2,000, that's very different. But 279 and 326, it's the same number as far as I'm concerned.

Dr. Taulbee: Yes, sir. I agree wholeheartedly with you. And how do we --

Member Ziemer: See, I can't justify stratification on the numbers that are before us here.

Now I do have some other issues I'm going to have to bring up at some point when we get into the definition because there's a downside to the definition of what we use for if we say we can't reconstruct dose with some accuracy.

The downside of that is going to be those individuals who do not meet the 250 day requirement or who do not have a covered cancer. For those individuals if we tell them that we cannot reconstruct any internal dose for them, they're not going to be very happy.

They're going to say, you know what? We have all kinds of internal dose data and even though you say it's not sufficiently accurate, how about if you give me what is there? Take that distribution and give me at least some of that rather than cancelling all my internal dose out because you can't reconstruct your accuracy.

We can expect someone whose claim is turned down on a partial dose reconstruction because we don't give them any internal dose that we're going to have lawsuits. I think we already have some of that type. So, you know, we have a lot of internal dose data. We're saying we can't use that for somebody?

Chair Clawson: Well, I thought we had a statement at the end of that that unless they had personal dosimetry that we would be able to utilize what we did have for that individual.

Member Ziemer: Yes. But you might have someone who has no personal dosimetry.

Chair Clawson: Okay.

Member Ziemer: I mean, bioassay. Well, we don't need to discuss that now. But I think it's going to be

very important if we say we can't reconstruct with sufficient accuracy, we're going to have to address very carefully what that really means, particularly in the presence of all of this internal dose data.

We have a lot of internal dose data and to say that we can only use it if we can tie it in with some work order, that's a stretch for me.

Ms. Naylor: And I also want to just remind the Board that, yes, we do have lawsuits that have been filed against the Department on the partial dose reconstruction issues for a site that has SEC Class, just like what Dr. Ziemer has said. And also Bradley brought out the issues about using their personal dosimetry data.

At the end of that sentence, that boilerplate sentence, they also said that could be interpreted or be reconstructed by using existing models. So if we don't have a method to actually use their data in some way to reconstruct a reasonable dose for them, then we cannot reconstruct those doses because of the SEC Class determination.

Mr. Barton: Tim, you want to clarify that, or should I?

(No response.)

Mr. Barton: If you determine that -- Dr. Ziemer, you're correct, it would be for an unmonitored worker, however, if you're monitored you can use that worker's data to reconstruct doses and any SEC determination would not hinder that.

Member Ziemer: No, no. I'm talking about someone --

Mr. Barton: Unmonitored?

Member Ziemer: -- unmonitored, yes.

Mr. Barton: Yes. Correct. I just wanted to make sure that that was understood. So all the data that we have that is tied to any future claimants would or

could potentially be used for a partial dose reconstruction regardless of any SEC determination. It would simply be those workers who are unmonitored.

Dr. Taulbee: That is correct. But one thing I would point out to you, Bob, is that by -- depending upon what you do with the -- or how you talk about the co-exposure model here that not everybody under an SEC -- in fact only about the additional 30 percent of the claimants fall under that SEC. So there is a large fraction of people who could benefit under a -- using co-exposure model such as this one. So that is an important aspect here.

Chair Clawson: Plus, Tim, it could also go the other way, too, depending on where you're sitting in the --

(Simultaneous speaking.)

Dr. Taulbee: Yes, sir.

Chair Clawson: -- you got it on both sides. So no matter what we take, no matter what stand we take we are all taking a chance that we're not going to do -- get the best for everybody. And we've known that from day one. We are trying to get the best product out to the over -- the biggest group that we can. It is something -- and I understand what you're talking about, Paul, and I deal with this on a daily basis of, what is the best for the majority of the people? Unfortunately, we're not going to be able to give the best to 100 percent of us. We're trying, but it is the nature of the good. This is what they handed us and this is what we deal with.

Ms. Naylor: Brad, I don't think the issue here is about sort of who wins or loses, but I think in designating SEC Class we have to articulate a scientific basis to support this recommendation to the Secretary that dose cannot be reconstructed because that basis is -- what goes up to the Secretary is taken under advisement in making that final decision.

And so if that -- the science that's been articulated

by the Board is really not strong enough and some claimants end up with a partial dose as a result of that, then we have to defend the Agency's action in some way by using the Board's rationale. And that could be very challenging for the Agency to do.

So what I'm asking is just that the Board actually fully articulate what is it that's causing these data not to be good enough to do dose reconstruction so that we are accountable to all the claimants here.

Chair Clawson: Jenny, I understand what you're saying, and I guess that's the million dollar question, but it kind of comes back to what I say, too. We're doing the best scientific possible that we can for the people, and what's going to give them the correct dose, too. Because we're also held under another standard, too. Scientifically is it feasible or not? And that's been in question many times itself. So I understand what you're saying.

Dr. Taulbee: I mean, our -- NIOSH's position right now is that dose reconstruction is feasible for the un-monitored workers using the co-exposure models.

Member Lockey: Tim, Jim Lockey. And that's about using best case situation, about 50 percent, right?

Dr. Taulbee: That is correct. Yes, sir.

Member Lockey: And so, I mean, really then the remaining 50 percent is assumption, I take it. Right?

Dr. Taulbee: Yes, sir, I -- well --

Member Lockey: I mean, we went back and looked at the records at Savannah River to see if there were going to be -- provide us any additional help in relationship to bioassay data that specifically was related to job tasks for the subcontractors.

Dr. Taulbee: Well, that was -- we went back to look at specific RWPs or job plans in order to verify that those workers were monitored or that we felt should have been monitored were monitored, that they were

sufficiently represented in the co-exposure model. Okay?

But the other component to that is, what do we see in the individual claimant files? And we're seeing that -- at least for plutonium, amongst this time interval, that around 50 percent roughly of the workers/subcontractors are monitored. And when you combine that with the much higher percentage monitored of the prime contractors, that that combined model would cover that 50 percent that is not monitored.

Member Lockey: Alright. So what it really comes down to is that 50 percent adequate? I mean, that's a question you even asked on Monday: is that adequate?

Dr. Taulbee: Yes.

Member Lockey: Right.

Dr. Taulbee: We believe that it is. We believe that the combined representation between the two is adequate, keeping in mind that many of that 50 percent that we're talking about that was not monitored didn't need to be monitored necessarily. Okay? Not everybody who went into an area was exposed. We know that at least 20 percent of the subcontractors didn't get an external dosimetry badge. Okay? They didn't even go into an area. So --

Chair Clawson: And, Tim, vice versa with that 50 percent. All that 50 percent there probably didn't have to be monitored either. You're telling us basically to flip a coin and which one comes out the best. It's a 50/50 deal. And I'm not -- I thought that's why we had the SECs. And I still feel this is an SEC for this.

Dr. Taulbee: I guess, how do we want to proceed here, to go on through these, because I guess we're not -- I mean, I've heard from -- at least Dr. Ziemer's opinion on the sub-stratification here, but perhaps

you're -- I mean, well, not perhaps, but, Brad, you're right as far as how this plays out as to whether this is even going to be important that we stratify or whether we even have a model. So, okay.

Chair Clawson: Well, this comes down to how we wrote that.

Member Lockey: Well, Brad, Jim. This is Jim, Brad. That aside, if we're just looking at the question of the stratification versus not, I don't think it's worth -- I would say it's not worth stratifying. I'm just looking at that as a stand-alone issue here. Okay?

Chair Clawson: Okay. I understand what you're saying there and --

Member Beach: Is this a decision that has to be made today? Can we go through the rest of the slides as an informational and then see where we're at after the Board meeting, or after this comes up for a vote?

Dr. Taulbee: I'm okay with that. We could go through the other observation. We could respond to it. Then we could just go through the rest of it and I guess just answer burning questions or clarification-type of questions, if you'd like. That would -- that's fine with me.

Member Ziemer: This is Ziemer again. Could I also ask -- and I don't know who to ask this of, perhaps Andy and maybe Rashaun. I'm not sure exactly what the SEC Work Group's role is in this, whether or not we vote on that or we're just here in some advisory capacity, because I went back and reviewed our responsibilities that we're officially charged with and they are twofold: one is to handle those cases where there is a situation where NIOSH has found that it could not reconstruct dose for one or two people, the so-called 83.14 situations, that we would review those.

And the other was to consider conditions where there's a significant exposure in addition to criticality that could occur in less than 250 days. Those are the

two main things we're responsible to look at.

And I know we've been brought in on some other things relating to SEC, but I'm not sure exactly what our responsibility is other than perhaps giving our opinions on some of these issues.

Dr. Taulbee: If I could remind you of the co-exposure model: you guys had a very large role in that of getting the implementation guide through and agreeing to that. So that's -- this is actually a spinoff of that aspect of it.

Member Ziemer: Yeah, I don't know if the Board actually charged us with doing that or -- it doesn't show up in our official list of responsibilities.

Member Beach: I think that was a -- Dr. Melius back in, what, 2017 or earlier --

(Simultaneous speaking.)

Member Ziemer: Asked us to do that.

Member Beach: Yeah.

Member Ziemer: Yeah. Yeah.

Member Beach: So maybe that definition needs to be updated. Good call, Paul.

Member Ziemer: Well, I mean, we're all glad to give our opinions, but I think the ball is actually in the -- Savannah River's Work Group on how to handle these things, on this particular case, in my opinion.

Member Beach: Well, and I think --

Dr. Taulbee: And actually --

Member Beach: Oh, go ahead. Sorry, Tim.

Dr. Taulbee: Actually I think that's some good guidance here for us from that standpoint, because we are facing a potential for stratification amongst other co-exposure models and I'm getting the impression from the SEC Issues Work Group perhaps

that you feel that it -- the decision to stratify might be based upon the individual Work Groups. Is that -- am I interpreting that correctly?

Member Lockey: I would say yes.

Member Beach: Yes.

Member Lockey: I don't think we can have a one-size-fits-all approach to this.

Chair Anderson: Yeah, I would agree with that.

Chair Clawson: And this is how you got drug into it, Paul, is because they wanted to use this as a test for us of the -- to be able to make an overall, but the thing is, is we can't. Each site is going to be different. I don't think we can pick a one-size-fits-all. I really don't.

Member Beach: Well, I think --

Dr. Taulbee: On the stratification. Yeah, I agree with that.

Member Beach: Yeah, and I think this was --

Dr. Taulbee: That's what I --

Member Beach: Oh. Sorry, Paul. I think this was for us, not necessarily for the Savannah River Site. It was for us to see if it could -- if it was possible based on our procedure.

Chair Clawson: Right. You're absolutely correct, Josie.

Member Beach: Well, the other part of this is we don't usually settle Site Profile issues until after all SEC issues are settled. And I understand this is happening simultaneously, but because you've called for a vote, it kind of derails this and we should just go back to this as informational at this point, in my opinion.

Chair Clawson: Well, right. And that's why I didn't think that we were going to go over this, but I also

have to give due diligence to NIOSH and SC&A for the work they did do. And Tim did want to go over this. And it's good information for us and especially what Jenny brought up to us and stuff, in looking at our proposal of -- for that SEC to be able to make it the best that we can. And I appreciate that, Jenny.

Chair Anderson: Moving right along. Chair Clawson: Right.

Mr. Barton: Okay. Really that Finding 1 is the whole question about whether to stratify or not. The remainder of the findings and observations are concerns SC&A had with the overall method used to get to that table that we've been looking at for the past hour-and-a-half or so.

So Observation 1 is just pointing out that this analysis of whether to stratify or not was only limited to the five years. There is more data out there. They have all of the logbooks, but those logbooks were only used for subcontractors for three of those five years evaluated, or maybe it's four. It's three or four. And one of the things we looked at was that is there a difference by adding in all of this logbook data just for subcontractors whereas we used solely NOCTS for prime contractors, and for subcontractors we use a combination of the logbook data, which is essentially all of the data for those years where it was used and comparing those two.

And so given that was only five years and this is an observation, not a finding, what we're pointing out is, is more analysis may be warranted here given that we saw what we felt was a difference in that 1980 period for the subcontractors. The magnitude of that difference of course is subjective, and as Dr. Lockey pointed, is a value judgment. So that's SC&A Observation 1.

Dr. Taulbee: Okay. Let me do this then. We'll go to the -- sorry for the delay there, folks.

So our response to the observation is that we agree that while additional data would provide a more

comprehensive analysis, the current assessment we felt was sufficient to conclude that further stratification wasn't necessary. The five noncontiguous years cover the DuPont era in the SEC -- during the SEC range in question that's currently being evaluated by the Advisory Board.

Considering the entire set of entire set of analysis including the TWOPOS and the intake results, again we feel there's no apparent difference between the primes and the subs. As Dr. Ziemer had pointed out, just the numbers of the 95th percentile, the 279 versus the 326, they're basically within the precision of assigning or estimating what those intakes are.

Now, let's go back to your presentation, Bob.

Okay. Before we go on, is this working for people for us backing -- going back and forth? Is this okay?

Member Beach: Yeah, is there a way you can leave them both not side by side so it's easier for you to switch back and forth like I think John was doing on Tuesday, or is this the best --

Dr. Taulbee: No, I can try.

Member Beach: I just thought it might be easier for you, Tim, but otherwise --

(Simultaneous speaking.)

Dr. Taulbee: Can you all see my screen now?

Member Beach: Yeah.

Dr. Taulbee: Okay. So there's that one. Let me put Bob's here. And then this is my responses. Okay. We'll do this and see how it goes.

Mr. Barton: Okay. This is moving onto Finding 2, which really has to do with -- we took a look at how subcontractors were identified in this analysis and whether there might be an issue with prime contractors being inadvertently included in the subcontractor population or vice versa.

Now what NIOSH does is they look at payroll IDs and associate certain number references with subcontractors. That's based on the dosimetry records. So what we did is we went in and we pulled 35 random claims from this analysis that were identified by NIOSH's subcontractors and then we went into the computer-aided telephone interviews and the Department of Labor file for those individuals. And what we found is that 13 of the 35 subcontractors, or roughly 37 percent, we found evidence that designating them as subcontractors may have been incorrect. And really the description is contained in Table 3 of SC&A's report. And what I want to do is just quickly go through that.

And before I give Jenny a heart attack, this is only based on what was publicly available. So there will be no redacted information in what I'm about to say.

But again, 13 of those 35 randomly selected subcontractors, we found evidence that suggests they were actually prime. So we have 13 cases and we just assign them an arbitrary letter for each case. And again that's Table 3 in SC&A's memo.

For Case A, again DOL has specified that the covered employees were DuPont, Bechtel, and Westinghouse. They did not specify a subcontractor.

Case B. Again employment was established as a contractor. DuPont, Bechtel, and Westinghouse. We also found a medical report for that individual that listed employer as DuPont.

Case C. Again only DuPont and Bechtel are listed on the claimant's employment form. And the termination form says only Bechtel.

Case D. This person appeared to move between subcontractor and prime contractor for brief periods. So it's a question of which strata they would be in, or potential strata based on the employment time, what time during their employment.

Case E. In the Statement of Accepted Facts by

Department of Labor, claimant worked for DuPont and Bechtel at Savannah River.

Case F. Employment verification indicates contractor rather than the option of subcontractor, which appears on that form.

Case G. Again, the contractor is designated by DOL, not subcontractor.

Case H. This person was associated with the -- a certain corporation that appears to be a subcontractor, but that was changed to DuPont and then Bechtel in April of 1972, which is exactly the period or the start of the period, or close enough to the start of the period that we're looking at. And in that case other information in that file indicated a different payroll number than what was used by NIOSH to definitively place that worker either in the subcontract or prime contractor strata for this analysis.

Case I. There was as Request for Review by Medical Panels. That's the official name of the form. And it affirms employment by the contractors. And a detailed work history that was provided by the Energy employee indicates that the energy employee started with DuPont.

Case J. Again, DOL indicates DuPont Construction. Also other correspondence in that DOL file and correspondence with the EE, that's Energy employee, indicates DuPont. And the interview with the Energy employee also indicates DuPont.

Case K. Again, we had a medical form that was in the '80s that lists DuPont under usual occupation.

Case L. There's a referral document to NIOSH that indicates Bechtel and DuPont, and DOL checks contractor, not subcontractor.

And the last case, the 13th case, the Statement of Accepted Facts lists employer as Westinghouse from

1978 to 2000. Of course Westinghouse didn't take over until the late 1980s, April 1989 I believe. But again another medical record during this period indicates Westinghouse, Bechtel.

So those are the 13 cases among 35 randomly selected cases that were identified as subcontractors, where when we go into the Department of Labor files, that designation may have been incorrect based solely on the payroll ID, which is what NIOSH used to establish whether someone was a subcontract worker or a prime contract worker.

Now it must be noted -- some 13 out of 35, roughly 37 percent, we found evidence that suggests they were actually primes. The remaining 22 of 35 all had evidence in the Department of Labor files that their employment was with subcontractors such as Miller-Dunn or MK-Ferguson, that sort of thing.

What we also did -- so that was sort of one way. We're going to test the subcontractors to see if they're really subcontractors. We also pulled in an additional 25 claims that were designated as prime contractors based on payroll ID and all of those appear to be correctly categorized.

So that's the subject of Finding 2 in SC&A's review and it appears to be a one-way street. We found some evidence that subs might not have actually been subs, but it appears to be 100 percent that those designated as prime were in fact prime.

Dr. Taulbee: Okay. There's a bit of a misunderstanding here between, apparently, us and SC&A as to what we were defining as a subcontractor CTW.

There's two operating divisions at Savannah River. Both had construction trades workers: operations and construction. We used the five-digit payroll ID as the basis for the subcontractors. These were all under what you would call the construction division, if you will. They had specific contracts for electricians -- subcontractor; sorry, for electricians using Miller-

Dunn. For pipefitters, it was BF Shaw. For North Brothers, those were -- those covered the insulators.

But not all of the construction trades workers had a subcontractor. DuPont Construction would hire directly out of the union hall, so they would appear to be a prime CTW, but these are generally temporary workers like a subcontractor. I don't believe that there was ever a subcontractor for the sheet metal workers, which you will see as several of the ones that Bob noted in their listing of 13 there.

So it wasn't specific from that standpoint when they hired out of the union hall. Okay? They could very easily have been as DuPont Construction and work for four months and then they left. They went to another place.

So we called those -- the thing that DuPont did was they included them in the construction trades worker division with that prefix that they had for that job code, or for that particular trade. So there's a five-digit payroll that had a two-digit prefix to it. So we can identify who was a laborer, who was a sheet metal worker, who was a pipefitter. So we can go down to that level of detail from the quarterly dosimetry.

So regardless -- like I said, DuPont assigned these workers that five-digit payroll, which is why we used it that way. The people we are calling DuPont Construction are the people who were until Roll 2. These workers were all typically Roll 4, sometimes Roll 5, and then later it was more Roll 6 toward the end of the DuPont construction, the late DuPont era.

So the DuPont Construction that we're referring to are the maintenance mechanics and the E&I technicians. And those were Roll 2. They did not have five-digit payroll IDs. They were the ones who were solely DuPont, which is what Bob noted there whenever they did that check of the DuPont people. There was no other subcontractors for them.

These are people who were under Roll 2. They were

-- some sites might refer to them as technicians, but these were actually maintenance mechanics, building mechanics and E&I technicians. So they would be doing some of the electronics work. It depended upon what was going on and somewhat dealing with Davis-Bacon-type of rules of how much would be spent on a particular job.

Those are the DuPont construction folks, the Roll 2 folks. They do not have a five-digit payroll ID. The five-digit payroll ID folks: those could have been hired out of a union hall or one of those other subcontractors, so you will see the mix that Bob is displaying there. We believe the five-digit payroll ID is the best indicator of these subcontractor construction trades workers that would put that whole group together, your temporary transient workers, as I believe I've heard Joe refer to them. Questions?

Mr. Barton: Brad, you're on mute, if you were trying to say something.

Chair Clawson: Yes. Thanks, Bob. But you're not 100 percent.

Here's one of the things we found out in the interviews and talking with people: I've always told you that Savannah River is a unique site because for their workforce for their maintenance and everything else like that, they use the trades. There are some trades that have been there for 25 years, but the thing is it's not uncommon for them to be working for DuPont for six months, all of a sudden drag up and go onto a construction site and still be on Savannah River. And they said that their numbers never changed. One of them had worked on construction for two-and-a-half years and then went back to DuPont as a maintenance person for them.

Dr. Taulbee: That is correct. And those people were all given that five-digit payroll ID. The DuPont folks that I was talking about, the E&I technicians, I do not believe that they were the ones they were bouncing back and forth. The five-digit payroll ID out of Roll 4,

they were the ones bouncing back and forth.

Chair Clawson: Okay. Because one of the big drivers on this -- and this is what all of them have told us -- Savannah River paid X amount of dollars and if a construction job come onto Savannah River, they got almost a $5 an hour raise. So this is where a lot of this jumping would always come off to. And I don't think that they really changed a lot of those numbers in that.

But that's neither here nor there. They're all considered construction trades. And it's just -- that picture that you're painting, it looks fairly good, but I think it's got some flaws to it.

Mr. Barton: Should we move on?

(No response.)

Mr. Barton: Sounds like it. Moving on to Observation 2, and this -- just kind of reflected -- it's an observation -- that additional data was quoted from the law books just from subcontractors for 74, 83 and 86, I believe. And all other evaluated data was based solely on the claimant records. And we did some rudimentary analysis of that to see if there's any bias, and there was some indications of that. Not huge. But we wanted to point it out and say, you know, if -- if the Work Group wants to sort of flesh this analysis out a little bit to get a better handle on it -- to actually go back and code that logbook data, then you'd be looking at the full population of workers rather than sort of mix and matching NOCTS data, which is -- it's only NOCTS for primes. And then subs is a combination for some years. So this is a question of whether it's worth it to go back and code those plutonium logbook raw results.

And one thing I'd point out here is that the co-exposure model as currently formulated only uses the claimant results. Whereas, for plutonium -- and those are often censored. So when you have the censored values, you really have to -- you can just go back and pull the claimants out of the logbooks.

But I'd also point out that for -- for something like americium, NIOSH pulled all of the data for the entire site, coded it, and that's how they based their co-exposure model. And we have those same logbooks for plutonium. In fact, often the -- they're the exact same logbooks as -- as the americium logbooks. So I guess I question why that data just wasn't coded because they're the raw results. They're -- they're better because you don't have the -- the censored results, and you have a full sample of the exposed population. But again, this is just -- it's an observation about how data was sort of selectively coded based on limitations of what was found in the actual claimant database for subcontractors.

Dr. Taulbee: Okay. Is that the completion of that one?

Mr. Barton: Yes.

Dr. Taulbee: Okay, alright. Alright, give me --

Member Beach: I am trying the hand-up method instead of interrupting.

Dr. Taulbee: Oh, I'm sorry. I can't see you right now.

(Laughter.)

Member Beach: Oh, well darn it.

Dr. Taulbee: There.

Member Beach: My question for you was, the suggestion of coding all the logbooks, can -- is -- I know I read several reports. Is that part of your report -- that you said it would take years? Or can you break out the logbooks -- do you have them in hand at NIOSH at this point? And what --

(Simultaneous speaking.)

Dr. Taulbee: Yes.

Member Beach: -- sort of effort are -- are we talking about for that?

Dr. Taulbee: We are talking years to try and code. We do have them in-house. That's how we've gotten -- and can go back and look at some of this data in more detail. We captured all of the logbooks for all of the radionuclides at the Savannah River Site. So those are all in the SRDB. You can go and look at them. So they're all out there.

But coding all of those handwritten logbooks, for the time period up through 1989 -- actually, through 1990 -- is just a tremendous effort. What we've done is we've taken -- when we get a claimant -- when we get a claim, we take their bio-assay card that's part of the Savannah River documentation that they provide with us -- provide to us. And that gets entered electronically when we're doing the dose reconstructions. We took that database and that's what we used to develop the co-exposure models. Instead of going back and taking years to code all of the data.

And -- and you see how long that that's taken us to do -- taking that electronic data. So it -- this is a -- this -- that would be a multi-year effort.

Member Beach: Okay. And I've got one more follow-on, the hypothetical question. If the SEC does get granted through 90, does that change the -- the logbooks that would need to be coded if we decided we would like all those coded. Would you just go from '91 on? Or would you still have to do the full time frame?

(Simultaneous speaking.)

Dr. Taulbee: To come up with what? Go ahead.

Member Beach: The co-worker model.

Dr. Taulbee: Depending upon what you would define -- or how you would define that, what the dose reconstruction infeasibility was, we would likely still just use the claimant data that we have because we have a large amount of claimant data. We've been focusing here -- these numbers are specifically on

subcontractor construction trades workers. When you look at the full population that comprises the co-exposure model for non-construction trades workers, it is significant. It is much, much larger. So I don't -- we don't have any plans to go through and code all of the -- the logbook data.

Member Beach: Okay, thank you.

Mr. Barton: And if I could just comment here. On the second bullet there -- the TIB-75, I'd just point out that that document is still technically under review. In fact, I checked the BRS yesterday in past discussions, and Finding 4 from that review of TIB-70 -- I'm just going to read what Finding 4 was, which is still open. No analysis of uranium or plutonium exposure at SRS was possible because the available hard-copy data have not been reduced to electronic form. And then it goes on to talk about uranium and fission products being the same and that -- OTIB-75 includes the comparison, essentially, for -- only for tritium and then only from 1991 to 2001.

So while it does say here that you can absolutely use claimant data sets to represent the fully exposed population, I think that's still under discussion. And Finding 4 we did include in our review of the co-exposure models, I believe in Attachment B. So that's still open and under discussion. So -- and I am not sure that that's been settled yet. And that's my only comment on those response.

Dr. Taulbee: Okay. I would say that, keep in mind that OTIB-75 was designed to take current data sets that were already ready, that could be used to evaluate, and that was what was done. And you're absolutely right, Savannah River, we have not coded all of the plutonium. And we didn't have anything other than the tritium at that time period.

We have since obtained some of the electronic data from Savannah River from the post-1990 time period. But again, the OTIB-75 I believe is under the Procedures Work Group. But our current basis is that OTIB-75 provides the justification of why a claim --

work claimant population represents the same exposure potential as the non-claimant population. And until demonstrated it doesn't, that -- this is our basis.

The inverse is true -- that if we use the entire population, that that would represent any future claimants that we have. So that's our response to -- you know, your observation, you know, back here about a potential bias. We don't see any evidence of that when you look at it between a full data set and a claimant population. As long as the two are sufficiently large. Questions?

(No response.)

Dr. Taulbee: No? Okay. Bob?

Mr. Barton: Yes. Okay, so moving on to what's known as regression analysis. And just to kind of go through these -- there's a couple of slides and then we'll get to what the findings and observations were associated with that. So NIOSH noted in their analysis that the hard copy data often only contained an un-normalized bioassay result. And that would be activity per a disc, rather than a normalized result, which would be activity -- in dpm, not counts, but disintegrations per minute, personal volume -- usually per liter, or per 1.5 liter.

So what NIOSH did when it -- so, Tim, you can describe this a little bit better, is when you had this un-normalized disc result, they said alright, what we're going to do is we're going to fit a linear regression line through all of the results where we have an un-normalized result and a normalized result and come up with a linear formula that apply to bioassay that only has the un-normalized result to essentially calculate what the volumetric sample would be.

In any case, NIOSH assumed a linear relationship calculated for each year under analysis to convert any hard copy data that was un-normalized. And again, that would be a dpm per disc result. But we

don't know what the actual concentration would have been back to urine results, because it just simply wasn't normalized. You can go to the next slide, please.

Actually -- let's see. Okay. This -- this also gets into a QA finding, but we actually notice situations where a dpm per disc result was actually listed as zero, or possibly even negative. But that normalized result came back as sometimes a positive result. We question whether the linear regression really has a meaningful numerical relationship to try to convert these un-normalized results to a normalized result in per volume of urine. What we found -- and that was Observation 3.

We also found that some of these data pairs that we looked at -- and they only piqued our interest because, again, this is either a negative or zero measurement on the disc, and somehow the site was coming up with a positive normalized result, which doesn't make a lot of sense but in those -- those specific situations we -- we followed up, went back to the logbooks and found that in some cases it was transcription errors into the electronic database. Sometimes they were just very difficult and hard to interpret. Sometimes there were legibility concerns that would explain why -- why we saw some of these, again, very unusual results.

So it was really two issues here. Can we use -- can we create a meaningful linear relationship between the activity on a certain disc measurement and what the normalized result would have been in cases when we only have disc measurement, and the site didn't actually provide a normalized result. And based on just looking at some of those -- again, some of the really abnormal ones, with the negative or zero measurement on the disc and coming up with a positive result, we wondered -- especially when some of them were discovered to be transcription errors, what quality assurance was applied to this data set as would be done -- because we're trying to figure out whether to stratify the co-exposure model. You

know, what quality assurance do we have that the added logbook data that was transcribed here is entirely accurate to make a determination on whether we should stratify or not? And that was SC&A's Finding 3.

I mean there is -- one of those such linear regressions that was used. The orange dots are essentially what the linear relationship is calculated to be and the blue dots are the actual observed results where we have a dpm per disc and a normalized result. Now this is truncated, which is noted there at the bottom and was noted in the NIOSH response, but I would point out that this shows essentially 95 percent of the data, or if you include records from one chelated individual, it actually drops to about 92 percent of the data just because there is some not shown that were essentially higher than what we have here. Next slide? Okay. I think you're up, Tim.

Dr. Taulbee: Alright, let me go back up here. I think it's Finding 3, right? Okay. So I want to just quickly go back and -- you know, the goal here was to investigate whether there is any evidence that we should further stratify the population. So it's not intended to be a full co-exposure analysis. Again, we picked a few years so that was could do some comparisons and see, does this make a big difference that would warrant a stratification. We did not do full quality assurance tests that were performed on this, nor do we feel it was warranted. That would have added months and months of time to do this. So it was developed solely to evaluate whether further stratification was needed.

We recognize that the dpm per disc to dpm per 1.5 linear regression is not perfect, okay? Some of the data deviate due to suspected miscalculation of the original data -- transcription errors, as Bob pointed out. Chelation, and -- but a lot of this is due to different aliquot sizes, okay? That's actually one of the bigger drivers that we believe is -- well, actually from what we can tell, is the cause of this. One of the

things I want to point out with this dpm per disc to dpm per 1.5 regression is that we looked at a very large range here. And what SC&A expanded there -- and as Bob mentioned, it's truncated -- but that's the relative scale there, is that little red box that we see here.

Okay, so if we blow that up, this is what you see. This is the duplicate of Bob's graph. What we've added is we've twisted it -- or changed it a little. I shouldn't say twisted. Changed it to highlight who was chelated. And what you see -- that red line -- that whole separate regression going on is somebody who was chelated due to a different aliquot size -- different volume size. And so we didn't use that data at all in our regression, okay? Those were pulled out. The regression was done.

And so this is what the regression really looks like that was used. Now we could go through and we could change -- or, not change, correct all of the aliquot-sized variations and so forth. And many of these lines -- many of these points -- would end up down here on this line. But I really don't think -- and none of us believe at NIOSH and ORAU -- that this regression is going to change much by making those corrections. I mean, the regression is very strong from this region. And -- and so making these corrections and changes -- we just don't think it's going to change that regression line at all. And what we did was we applied this regression to those results where we only had the dpm per disc value. We applied the regression to get a dpm per 1.5 liter to substitute the less than 0.1 value that was recorded as their final result.

Okay, so this was to fill in for censored values. That's all that this was. We know the results were less than 0.1. We were trying to, within those box plots, figure out where that 75th percentile, where that 85th percentile was. That was the only goal here -- was to try and reduce the amount of censored results that we've got to improve what the TWOPOS value was. So that's -- that's our response to this. Questions?

Mr. Barton: Well, I have two comments, if there aren't any direct questions right now. Again, I spoke with one of our statisticians in preparing for this meeting. And I think it's just the -- this is the first time I've ever seen this method used to take an un-normalized result and normalize it. And so it certainly gave us pause.

One of the things our statistician said that, you know -- you -- regression methods to essentially expand your sample size is you get a bigger sample size. And that's -- can be a valid statistical technique. However, this adds uncertainty when you do that. And so that -- any uncertainty associated with using this type of a method needs to be appropriately considered in any -- any modeled numbers that you get off that.

Also we note that in these regression analyses there was really no metric used, such as an R-squared value, to say how good of a fit these regressions actually were. They're essentially just a visual of how well it fits. And I am going to read this, not -- my statistics aren't that great, but I am going to read exactly what our statistician said. He's -- in response to my question about there being no R-squared values. And he said, if we really want to assess NIOSH's regressions, in addition to R-squared values, we want to look at regression coefficients and tests of significance for those from residual plots and information on leverage as it pertains to outliers. I can't say anything other than -- than quoting him here. And again, I apologize, he had a -- he was not able to join us today for -- he just had -- he had other obligations that were set well in advance and so he couldn't join us. But that -- that was his comment.

Now the other part of this -- they -- I tried to get a handle on how often was there an un-normalized disc result where we really had to use this regression analysis to fill in the normalized results so that we can add it to the sample size for evaluation here to determine whether things should be stratified or not? And so I went into the raw data provided by NIOSH. And I looked at all the individual disc results and

normalized results, and I counted up -- literally counted up how many times I saw a disc result without a corresponding normalized result, in which you would -- NIOSH is proposing to use this regression formula to sort of fill in the blanks. And by my count, it was only 1.6 percent of the entire measurements had a dpm per disc result and then did not contain a normalized result.

So this entire discussion may be sort of moot here since we're only looking -- this was only applied to what we see as a very small portion of the data. But we do have those concerns, as I stated, from our statistician about using such a method as regression to sort of expand the data set if it's -- is intended to be used in any future situations. But like I said, I am a second point, it really doesn't appear to affect much here as it's only 1.6 percent of the -- of the data pairs -- or unpaired, essentially.

Dr. Taulbee: I guess my comment to that would be if, you know, that's the case, then why are these findings and not observations? If -- if you don't believe that it's going to have a major impact on the analysis?

(Simultaneous speaking.)

Mr. Barton: Well, arguably yes, we do have technical issues with using this type of approach to fill in the results. But really, it's a finding because we don't want to necessarily see it used going forward unless, you know, these additional uncertainties are considered and also a real discussion -- and quantifiable discussion of outliers that are viewed and what affect this has on the overall data set. Again, it was in prep for this meeting that I said, alright, let's see -- you know, how often do they actually use this? Because in the NIOSH report, it seems to indicate that they needed it for a lot of results. They said, well alright, are we talking about 50 percent of the results? You know, 60 percent of the results? And as it turns out, it's 1.6 percent of the results. And that was done, again, in preparation for this meeting, to

try to get more perspective on it.

We did not do this in the original review. We were essentially going on what NIOSH said that -- and I think it's in your response there that, you know, a large portion was indicated. So we assumed it was a large portion. But upon review, it does not appear to us to be a large portion.

But we do have technical issues with using a regression method, if in fact it will ever be used in the future.

Dr. Taulbee: It might be, I don't know. Okay. Next finding?

Mr. Barton: We already -- we really already discussed finding four -- finding three and four, were again, about this regression analysis and whether it's technical justified to be used. And again, in this situation, as it turns out, it wasn't a large portion of the data set, as it was indicated. It's a very small portion of the data set, so it does not affect the results here. But again, we -- we have technical concerns if it's going to be used in the future, which I believe I -- I basically indicated this was the first time but you're unsure if it will be used in the future. So this is really a cautionary finding, or if it's used in the future, we've got to be really careful with it.

Dr. Taulbee: Okay, let me pull up my -- our response to that then.

(Simultaneous speaking.)

Dr. Taulbee: I said it greatly reduced the number of censored data for this analysis. I am actually questioning your one percent, but I'll -- I have not looked at the data in that detail, but I won't question it here. I do question internally, but -- I'll -- I'll take it that that's what it was.

But although not perfect, the vast majority of the data fell on a straight line over a very large range. And that's -- that's the driver for the regression. We

-- like I said, we could make further corrections on aliquot size, but we don't believe it will significantly change the regression, so we don't believe that this is -- worth doing, effectively. It's just -- for this type of analysis, if this was going into a co-exposure model, absolutely. We would have done all of the QA, everything associated with it. But this was just a comparison of whether to stratify or not. That's it. Okay.

Mr. Barton: Okay, just to sort of sum up what our review was here is -- the refined analysis is limited to a handful of cases in five of the years in that DuPont era. Again, we talked about the payroll ID numbers and are they alone sufficient to designate a subcontractor versus a prime contractor. But we point out that quality assurance -- in the period -- at least, it's not discussed in the report and certainly, it doesn't appear to be the level of a co-exposure model. And I can understand NIOSH's position on that. This was -- this was meant to be an analysis on whether to stratify. But you know, when we're talking about essentially calculating co-exposure intakes, I mean, it seems to me that you need some assurance that the data set that you coded is -- is acceptable.

Again, we just talked about it that we question the use of linear regression to be able to convert those values that are un-normalized into a normalized result. And there -- there are certainly some -- two qualifiers there about what needs to be considered if you're going to use that in the future. And that includes the uncertainty added when you do that sort of thing.

And then, again, this goes back to the Finding 1 where that -- the 95th percentile subcontractors had higher intakes by roughly 20 percent in that 79 to 87 area. And that's the period when there was significantly more subcontractors being brought on site -- at least, when you look at the claimant population. A minimum of subcontractors there. And that's shown even in comparison to the total worker population. So you have more subcontractors on site,

and at the 95th percentile, you have slightly higher intakes calculated again, in the -- that 1980s period.

So I -- in summary, we don't agree that this NIOSH analysis necessarily demonstrates that sub-CTWs and prime CTWs are definitely part of the same exposure strata and thus don't need to be considered for stratification. Again, it was in that 95th percentile comparison and also some drawbacks to the analysis, which I fully understand that to rectify some of these issues would take considerable work and it's certainly not SC&A's position to comment on resources and what's important to do, and what's not important to do. That's entirely, obviously up to the Work Group and, you know, NIOSH's own resources. So the fact that -- I think NIOSH agrees that were there time, they certainly would have done much more. But it sounds like the resources and time is cost-prohibitive.

So that's -- that's the summary of SC&A's review. Oh, and we did propose a path forward. And that was to expand the analysis to the remaining years in the SEC, at least for the DuPont era, which we're really looking at. And really the DuPont era alone because that's only where the co-exposure model covers. It ends in the late '80s for most things -- 1989. And it's suggested that co-exposure intakes from that DuPont era could be perhaps extrapolated forward and used for the 90s. I am not sure if that's still NIOSH's position. But again, our proposed path forward was to go in and get that logbook data and you'll have a much better idea -- you'll have more granularity to make a determination on whether stratification is necessary.

We felt that -- that report should document quality assurance that was done on the transcribed data set. And either correct -- correct those or, if there's an unacceptable number of transcription errors or what have you, that -- that you might have to go back and re-code, which -- not to give a preview of coming attractions, but when we get into the -- an americium discussion on the next item, that's exactly what

NIOSH is going back and doing. Though -- and that's for a co-exposure assessment, which again, this is not necessarily a co-exposure assessment.

The exercise is to act as if it is to see if there is actually a difference between the two populations. And also, the issues that we found with identifying subcontractor designations -- and then the partially explained qualitatively in the NIOSH response. But again, DOL, when confirming these people's employment, considered them contractors. So the question is whether payroll ID alone is enough to be sure that all of these workers were actually subcontractors -- or subcontractors instead of prime contractors.

And we recommend not using regression methods for samples with un-normalized results. In this case, it really doesn't matter because even though -- at least our -- our count of the raw data provided by NIOSH when we looked -- unpaired measurements was quite low. Often you wouldn't have the dpm per disc, all you had was the normalized result. So -- and again, in preparing for this meeting, I had our statistician take another look at NIOSH's response and essentially he came out with -- again, this is Richard Griffiths who -- who I had do the first secondary review and check my work -- he said, well you can use regression, but there are a number of caveats including taking the -- count the uncertainty when you do that, and explain any variance in that result when you use a -- a linear -- linear model. And I believe that's my last slide, but -- okay, here are the references that I cited and then sort of the concluding slide here.

Dr. Taulbee: Okay. Alright -- yeah, that's pretty much it. I -- just from NIOSH's standpoint in wrapping up, the whole methodology was to do a simple comparison to see whether we should further sub-stratify and -- and that was the -- that was the goal with this particular analysis. So I'll leave it at that. Any questions?

Chair Clawson: Any Board members for the SRS have any questions?

(No response.)

Chair Clawson: Okay.

Member Lockey: Brad, I just have one comment. This is to Bob. Bob, I -- when I listened to your summary, I didn't get an idea of level of importance of your points. Some of them were, for me, were not really -- reach a level that I would consider important. Are there any of those there that you feel were overwhelmingly important and have to be addressed?

Mr. Barton: I think it's -- it comes down to the question of whether we're going to stratify here. We have some current concerns with the method that came to these numbers. But at the end of the day, the method that was used and the -- the intakes that were calculated -- we saw that difference in the '80s for subcontractors. So that certainly raises the question of whether there are differences between the two populations for us. And again, that's a value judgment. But that's really the name of the game.

We saw higher intakes at the 95th percentile, and so we felt -- if we're going to conclude that they're the same population, we might want to do a little bit more work to have more granularity making that determination, including a more robust quality assurance method and going in, grabbing more of the logbook data and perhaps more years.

Member Lockey: Do you actually think that would influence and make it other than a value judgment at some point in the future? Do you think that would really have an important impact on that?

Mr. Barton: Well the only way I think that it wouldn't be a value judgment would be if you put in enough data and there was a statistical test that you could apply to it. I'm not sure what that would be. Again, I'm not a statistician and our statistician was not

available for this call. But I mean it would be -- I think you'd have a better idea, certainly. But again I -- the numbers we see here -- it just -- it seems like there's -- there's reason to think that maybe there is a difference between the two populations and certainly more robust analysis, I think, would bear that out. Or at least, give us an idea of what's out there. And in turn, you then end up with a more robust -- robust plutonium co-exposure model. Because now you wouldn't be using just the NOCTS database, necessarily. You would be using the entire site population.

Member Lockey: Okay, thanks.

Dr. Taulbee: Can I -- if there's no questions, and before we move on, can I propose we do a break?

Chair Clawson: No, this is how we keep this wing down. Yes --

(Simultaneous speaking.)

Member Beach: I second that.

Chair Clawson: Hey --

(Simultaneous speaking.)

Chair Clawson: Let's take a ten-minute break, if that would be alright, Rashaun?

Member Lockey: Brad, let's make it 15.

Chair Clawson: Oh my goodness.

Dr. Roberts: Yes, I think a longer break is -- would be helpful. So 15 minutes. So we come back here at about 1:15 Eastern.

(Whereupon, the above-entitled matter went off the record at 1:01 p.m. and resumed at 1:15 p.m.)

(Roll call.)

Dr. Roberts: Okay. Very good. I think we've got everybody, so we can continue with the agenda.

Dr. Cardarelli: So Rashaun, I'm assuming that's my cue. Okay.

Dr. Roberts: Yes.

Issue 6: Status of Open Issues on SRS Co-Exposure Model (OTIB-0081 Rev. 4)

Dr. Cardarelli: Okay. This presentation is going to be, hopefully, fairly quick. I'm just going to be talking about the status of the various findings and observations that have been made by SC&A on OTIB-0081, Revision 4.

This spans 13 concerns which -- we'll call them concerns. In September 2019, there were six findings. And then they were changed to five findings by March of 2020. And that one finding became an observation, which caused our observation numbers to go up by one.

As you can see in the sub-bullets, Finding 1 is the only kind of remaining open. And a presentation, detailed presentation will be following this talk.

Findings 2 and 3, we are recommending closing. And Findings 4 and 5 were closed in the last Work Group meeting last year.

Only Finding, Observation 7 was closed last year. But Observations 1, 2, 3, 4, 5, 6, and 8 we are recommending to close.

And I will start with Finding 1. And I'll just read this for the record.

Although SC&A recognizes that the incident-based sampling involving chelation is not considered in final coworker modeling, the removal of DTPA-influenced samples from consideration in the analysis of the high variability observed in the trivalent actinide bioassay results has not been justified sufficiently.

Evidence suggests that the variation among DTPA and non-DTPA samples is nearly identical. Furthermore, OTIB-0081 has not provided any

reference to justify the assumption that DTPA causes heterogeneity among a single urinalysis voiding.

The status remains open, and we will have a presentation on this following this particular talk.

In summary, though, NIOSH agrees that the SC&A -- with SC&A that chelation therapy is not a source of variability in repeated counts of a given planchette.

We do not agree with SC&A that the observed variability in the repeated counts prohibits the use of our -- of this bioassay data for developing co-exposure models.

And there's no definition for high variability. We believe it's a subjective decision. Research on this is, on this issue is currently being performed by NIOSH. And Dr. Taulbee will be presenting what we have on that right after my presentation.

So Finding 2, this one, the status is recommending closing. But to read it into the record, use of imputed values that are less than one-half of the minimum detectable activity, the MDA, raises a fundamental fairness issue in that monitored workers who have bioassay results that are less than the MDA are assigned a missed dose in accordance with ORAUT-OTIB-0060, which is the Internal Dose Reconstruction document.

Our response to that is SC&A's memo dated on June 3, 2020, and it's in the SRDB database, the number is 182225 and it's entitled Review of the Multiple Imputation Methods Applied to Censored Bioassay Data Sets, concluded, quote, the use of the multiple imputation in evaluation of bioassay data sets with censored results is technically appropriate, scientifically defensible, and likely of small practical significance when considering its effect on resulting Probability of Causation calculations.

As a result of this -- that was unquote. Therefore, as a result, NIOSH is recommending closing this observation.

Finding 3, which is basically a discussion about claimant cutoff for data, it was originally Finding 4.

But to read it into the record, the coworker analysis uses the internal monitoring for claimants for which data were available to NIOSH in approximately August of 2011. There was around 4,000 claims.

Since that time, approximately 2,000 additional claims have been submitted that could be used to augment the coworker data set. Inclusion of these data would be especially important for the two contaminants that required a combination of multiple years for analysis due to lack of sufficient number of data points, specifically uranium and cesium.

NIOSH is recommending closing this particular finding based upon the transcripts of the December 5, 2019 Work Group meeting, specifically on page 165. It was decided not to pursue the inclusion of this additional data.

However, we could not find in the transcripts where an official vote was taken. Therefore, NIOSH believes this finding is closed. But we would like confirmation from the Work Group.

Finding 5, which was -- or Finding 4, which was originally Finding 5 in the September document, classification of a machinist as a non-CTW in OTIB-0081 is inconsistent with its classification in OCAS-PER-014, which is entitled Construction Trade Workers.

This status has been closed by the Work Group as a result of the votes that were taken in the December 5th Working Group. And I provide the pages 145 to 146 in the particular transcripts there.

Finding 5, which is entitled Construction Trade Worker Misclassification Evaluation, this was originally Finding 6 in September of last year's document.

And it states, a target sampling comparing the OTIB-

0081 strata designation, construction trade worker or non-construction trade worker, against two alternate sources for identifying worker job classifications indicated that just over nine percent of the entries appear to be in conflict when comparing the NIOSH and SC&A analyses.

Again, this is a closed finding, same pages that we mentioned in the last one.

So, Observation 1, multiple imputation, to read it into the record, while the multiple imputation method is mathematically correct, it has the potential to result in biasing the simulated bioassay results unnecessarily low.

Alternate approaches, such as the maximum possible mean method, which replaces censored data with the actual censoring limit, or alternatively one-half the censoring limit, would solve the issues associated with data sets containing a large number of censored values in a claimant-favorable manner.

We recommend closing this particular finding based upon the SC&A memo, which is dated June 3, 2020, and the SRDB database, again, the number is 182225, where they reviewed the use of multiple imputation methods applied to censored bioassay data, where they concluded that the use of this approach, multiple imputation, is technically appropriate.

For Observation 2, it's just a kind of continuation of this multiple imputation discussion. We recommend closing it.

But the observation itself states, a scoping assessment concluded that while intakes and doses are significantly higher using a missed dose approach in most of the sample calculations, the overall effect of the resulting Probability of Causation values was relatively minor.

And in most cases, the coworker derived Probability of Causation bounded the missed dose evaluation.

This appears to be due to the effect the statistical distribution has on the resulting Probability of Causation values, mainly the use of the triangular distribution for missed dose evaluation versus a log-normal distribution for coworker data.

Our response in, or our justification in recommending closing this particular observation is SC&A noted that the calculated intakes and doses differed between the multiple imputation method versus the limit of detection divided by 2 method, but concluded that the overall effect of the Probability of Causation was relatively minor. And in most cases, the co-exposure derived Probability of Causation bounded the missed dose evaluation.

And again, we referenced the SC&A memo, which was dated June 3, 2020, as the justification for closing out this particular -- or recommending closing this observation for the Work Group.

Observation 3, multiple imputation specifically targeted on uranium, it was originally a finding. This was the one that was changed to an observation.

It states, the sample comparison of co-exposure intakes to a missed dose method for uranium showed that the co-exposure model derived intakes were a factor of 4 or more higher than the missed dose approach.

This illustrates the potential for inequity between the treatment of unmonitored workers assigned coworker intakes and monitored workers with results less than the detection limit in some situations.

We recommend that this be closed, and it's based upon these justifications. We acknowledge that using the multiple imputation method the censored values can be higher or lower depending on the uncensored or the -- uncensored data. These would be the results that are above the detection limits.

Further, in the case of uranium, there are multiple censoring levels over time, and that the relatively

high censoring level for some data explain the increase in intake results.

In contrast, missed doses is based exclusively on data that are less than the minimum detectable activity. The resulting intakes use a triangular distribution encompassing the full range of possible missed intakes from zero to the minimum detectable activity.

And we point to the same SC&A memo dated June 3rd that helps justify the recommendation we feel warrants closing out this particular observation.

For Observation 4, which is the difference in the number of trivalent samples, this was originally Observation 3 in September of 2019.

It states, available trivalent logbook data show notable differences with the number of reported samples taken in 1980 and 1982. These years and any changes in operations are not discussed specifically in OTIB-0081.

However, it is noted that a future NIOSH report on americium exposure potential at SRS is pending that may address the apparent gaps in the data.

We recommend closing this based upon our NIOSH response, which is in the SRDB. The number is 182704. And we provided this to the Working Group on August 11, 2020 regarding the completeness of the trivalent logbooks.

This particular slide provides an example showing the difference of two separate measures of the same type of data coming from two different sources -- I'm sorry. One comes from the HPS Summary Reports, and the other one comes directly from the americium logbooks themselves over the 15 years where the concern has been raised.

And the real metric here is the cumulative number of samples that have been reported over those 15 years. Ranges, it's up over 11,000. And the

difference between that is 140 of the two different metrics.

We feel that this sufficiently explains the completeness of the trivalent samples for americium.

Observation 5, a statistical comparison of stratified groups, this was originally Observation 3 in September 2019.

So Observation 5, OTIB-0081, does not provide a statistical comparison of the two stratified groups as prescribed in the coworker implementation guide. The various coworker models were stratified based upon a priori assumption that exposure potential between construction trade workers and non-construction trade workers was different.

We recommend closing this. Based upon the transcripts from the December 11th meeting on page 129, it shows that SC&A states, quote, and so the status of this is there's really no action required. It's just, it's there to note the fact that the coworker guidelines say that you should perform a statistical analysis after you stratify the groups to see if they're truly different.

For Observation 6, quantitative assessment of the job plans, it was originally Observation 5 in September 2019.

And it states, SC&A acknowledges that there are inherent difficulties in correctly associated workers, individual workers with the correct construction trade worker versus, or slash, non-construction trade worker strata.

This is particularly true for job titles that could potentially be included in either stratum.

SC&A suggests a scoping analysis in which such broader -- such borderline job titles are removed to ascertain the effect of the resulting distributions. Such an analysis would help determine whether current strata designations are sufficient or a more

rigorous approach to individual job classification is warranted.

We're recommending closing this particular observation based upon a White Paper that we've entitled The Savannah River Site Plutonium Construction Trade Worker Stratification Refinement, which was dated May 28, 2019. This was the presentation that Dr. Taulbee just gave prior to this presentation.

NIOSH, it states, quote, NIOSH believes it's reasonable to combine all construction trade workers into a single strata for assignment of intakes in the SRS internal dose coworker study, unquote.

Of course, SC&A disagreed in their review, which was dated November 12, 2019, and suggested additional analyses.

NIOSH's responses to SC&A comments dated in March 4, 2020, which were in the SRDB, and that number is 179903, concluded that the -- that, quote, the final conclusions that substratification is not necessary remains unchanged, unquote, and notes that additional coding and analysis would take many months, if not years, to complete.

So we're recommending that that one be closed based upon on that information.

Observation 7 has already been closed. And I will save us the time for reading all of this information in there. But it had to do with the sensitivity analysis of misclassification. And it was voted to close in December 5, 2019 on pages 145 to 146.

Observation 8 is based on the error rates dependent on payroll ID, which was originally Observation 7 in 2019.

And it states, the results shown in Attachment A of OTIB-0081 demonstrate a high degree of confidence that the acceptable error rates are within the goals established for each test.

However, this conclusion is dependent upon the assumption that the payroll ID issues identified would not affect the resulting coworker distributions.

And it's referring to Section 6.5 in that report.

We're recommending that this particular finding, or observation be closed. This was a data validation issue. The payroll prefix issues have no effect on the construction trade worker or non-construction trade worker coworker distributions.

The Work Group did discuss this on pages 146 through 150, and the December 5th transcripts indicated that there was agreement by all. This was a non-issue, although no vote was taken.

Page 134 of the December 11th transcript has SC&A considering this observation closed, and therefore, NIOSH recommends closing this observation just for -- to clear the record.

That would conclude the summary of the 13 concerns raised for OTIB-0081. Any questions? Okay. Well, what I might do now is turn this over to you, Tim.

Dr. Taulbee: Actually, no, we'll go to Bob next, because he's going to give a summary of the --

Dr. Cardarelli: Okay.

Dr. Taulbee: -- I believe the trivalent. You are next on the agenda, correct, Bob?

Mr. Barton: That's correct.

Dr. Taulbee: Okay. Before we move on, though, I would ask Brad and Dr. Anderson, actually I guess more Dr. Anderson, Henry, on this because this is more from an SEC issues Work Group with regards to the OTIB-0081. It was primarily your Work Group that was closing out those particular findings and issues on OTIB-0081.

We noted several locations here in John's presentation where a vote wasn't taken. My question

to the Work Group is, do you agree with our recommendations of closing the ones that were identified and leaving the variability issue open, or do you want discussion on those issues?

Chair Anderson: Committee members, what do you feel?

Chair Clawson: Well, first of all, this is Brad. So this seemed like to me that this was all SRS issues.

Chair Anderson: Yeah.

Chair Clawson: So this really comes down to the Savannah River Work Group, Tim. I don't think it's the SEC people. I think this all pertained as -- am I correct in that?

Dr. Taulbee: You may be. I was trying to recall the actual discussions of the issues that were closed, like multiple imputation were a global type of issue, not just a Savannah River.

While it pertained to the OTIB-0081, you're absolutely right. But I believe that was an open one that was for the SEC issues. But either Work Group, I don't care. I apologize.

Chair Clawson: Well, I understand what you're saying. But I do not, as a Savannah River Work Group, want to close something that is an overarching issue that the SEC group is working on.

I can for SRS but not for the Work Group. So that being said, I'd like to be able to go through each one of them and the SRS Work Group close them or remain open, whatever.

Dr. Cardarelli: Excellent. Bob, can you let me share my screen? I'll bring them back up.

Mr. Barton: Sure. If I may just comment here, though, in SC&A's view there's really only three issues that came out of this. There's trivalent variability, which is the next item discussion. There's multiple imputation, which is a global issue, which is

the item after trivalent variability.

And the only other one that I, in my understanding, that wasn't actually closed out, I guess we don't have the language that it was closed out, related to differences by year that we saw in the number of reported americium results versus the number we had in hand.

Now, that was partially resolved during the Work Group. If you go back to the transcript, there was an indication by [identifying information redacted] that she received a note from the ORAU team that they had documentation to explain why there might have been a little bit of variation by year where you had a section where it seemed (audio interference) less data points and then subsequent years had significantly more data points and that there was, I think they were trying to hunt down the documentation of why that happened.

But the explanation was essentially that the bioassay lab just had a, for whatever reason, a really large backlog of these samples. So, even though the samples were taken in a given year, they actually weren't analyzed until a couple years later.

And it looks like the documentation wasn't found. However, the analysis that NIOSH presents here, I mean, I think it's pretty compelling. So I wouldn't have a problem closing Observation 4.

And like I said, the only other two open issues regarding the TIB-0081 review is bioassay variability and multiple imputation, which are the next two items on the agenda.

(Simultaneous speaking.)

Chair Anderson: Just for me, just to comment further, I thought in December the focus was on the Savannah River determination. I think NIOSH and, Tim, you were interested in expanding it out into kind of a global overall thing, but I think our group was not yet prepared to say it is an overarching issue.

I think we were using this as an example of could a coworker model be developed as opposed to since it could be done for SRS that that then became a global application to all sites. I think we're focusing on individual sites right now.

Dr. Taulbee: Okay. Then, I'll leave it to Brad then as to --

Member Ziemer: Brad, could I comment? This is Ziemer. Brad, could I comment? Ziemer here.

Chair Clawson: Sure, Paul.

Member Ziemer: Yeah. And these are all findings or observations on OTIB-0081, which I think is an SRS document. So it seems to me it's appropriate for the SRS Work Group to deal with these particular issues.

Chair Clawson: Okay. I just wanted to make sure, Paul, because that's why we actually brought you guys in is because of the implementation of this, it would become a site-wide profile.

Member Ziemer: Right.

Chair Clawson: So, Bob, what I have to ask from you is your recommendation on which, if there's any at all that need to be -- remain open, if SC&A has not got a satisfied response back, which at this point I'm not seeing any.

So you're proposing to the SRS Work Group to be able to have 1 through 5, is that correct, closed?

Mr. Barton: I think it's, again, there's three open issues. The one concerning the sort of discrepancy between the number of americium bioassay results taken or reported and the number we have in hand, I think SC&A is satisfied with that answer. I'm not sure we need to go into it further.

(Audio interference) shows that there's not a huge necessary gap. And it can be explained by a backlog. There's a -- there's what appeared to be a gap. And we have significantly less samples in hand, and then

subsequent years from that what could have been a gap, where we have significantly more samples in hand than what was reported by the Health and Safety Department.

NIOSH was looking for documentation of that. But, instead, the quantitative analysis I think satisfies that.

And again, the only other two open issues from SC&A's view, from that TIB-0081 review, are the next items on the agenda. So --

(Simultaneous speaking.)

Dr. Cardarelli: We can go through these.

Chair Clawson: For Findings 2 and 3, we're recommending closing.

Mr. Barton: Well, the imputation findings, sure, we can close them because, unless, you know, we have a presentation on that very issue, which is global. So it would involve the SEC Issues Work Group, too. And again, that's a discussion item for this agenda sort of outside of this summary presentation that John --

Chair Clawson: Bob, I understand that. But what I'm looking at is strictly for SRS and how it implements into the SRS group.

Now, if it becomes a global issue, which many of these things end up into, that is still open for discussion. But my understanding for Savannah River Work Group, that this one is closed.

Mr. Barton: I think that's accurate. And again, it's --

Chair Clawson: I think 2 and 3 were closed, correct?

Mr. Barton: I'm sorry. I was speaking over you. Can you say that again, Brad?

Chair Clawson: Findings 2 and 3, we're recommending closing. Bob, you're on mute.

Mr. Barton: NIOSH is recommending closing based on a memorandum that SC&A produced from earlier this year that has not been discussed yet.

So, ultimately, again, not to preview coming attractions too much, we can -- we're fine with closing them if the Work Group is satisfied with SC&A's conclusions regarding multiple imputation, because essentially we come out and (audio interference) as saying, you know, we think it's a valid statistical method to deal with what's a very difficult situation when (audio interference) number of censored bioassay results.

So I think NIOSH is saying, look, SC&A did their review (audio interference) 96, which is the global issue for using multiple imputation across the entire program. And SC&A came out favorably in its review of that. So that would mean that we're in favor of using it at SRS under the context of the OTIB-0081.

So, I mean, we're fine with closing it out to save time since we've already burned up a lot of the day here. We're fine with that, or we can go through that report and what we found to satisfy both SEC and SRS Work Groups that multiple imputation is okay.

Now, trivalent variability, that's Finding 1, is really tied directly to SRS and SRS-specific data, which is the next agenda item --

Dr. Cardarelli: Right. And that one's remaining open.

Member Lockey: Brad, Jim Lockey.

Chair Clawson: Yeah.

Member Lockey: There were some, I think John also said there were some other either findings or observations that he felt were closed, but there was no vote. So do you want to go back and just briefly have him go through it and pick out those ones we need to have a vote on so we can get past it?

Chair Clawson: Yeah, I don't see any other way of doing it. But let's just go back --

(Simultaneous speaking.)

Dr. Cardarelli: Alright. So multiple imputation we just talked about. And we recommended closing for that statement. And, obviously, we'll have a presentation on it later. So we're recommending closing based upon SC&A's context that was just described.

Chair Clawson: Okay. SC&A, your feelings?

Mr. Barton: I have no objection. Like I said, our review of the imputation method in general was favorable, and that we agree with NIOSH that it's appropriate to use absent any other better method that could be employed on this, so I am okay with closing it.

The question is do you all want to see the presentation on how we got to the same place and essentially agree with the NIOSH methodology? Again, that's the -- it's one of the items on the agenda, but I mean, the fact that we come out in the same place, maybe it's worth saving time to simply close it or we can have that discussion.

Member Lockey: Brad, I'm going to recommend that we close this as it applies to SRS.

Chair Clawson: Okay, I still want the discussion. I still want Bob to be able to do it, for Board Members of SRS to be able to close this. I recommend closing it. Jim, you recommend. Phil?

Member Schofield: Yeah, I'll go with closing.

Chair Clawson: Okay, let's go to the next one.

Dr. Cardarelli: This one is simply -- there was no official vote taken, but there was an understanding that this was likely to be closed.

Chair Clawson: Okay, NIOSH, your feelings on this? Were you satisfied with this?

Member Beach: You mean SC&A?

Chair Clawson: SC&A, I'm sorry.

Mr. Barton: Yeah, I'm kind of surprised that it wasn't officially closed back in December because, you know, the Work Group, I mean, they acknowledged the fact that these additional claims exist, but did not feel that it was worth the time and effort to go and capture that data to supplement their co-exposure models and the Work Group agreed, and so I'm surprised it's not closed as it states here.

Chair Clawson: Well, and they said that in there, they couldn't find an official one.

Mr. Barton: Right.

Chair Clawson: So, today we'll make it official from the SRS Work Group. I recommend that we close Finding 3.

Member Lockey: I agree.

Chair Clawson: Phil?

Member Schofield: I agree.

Chair Clawson: Okay, Finding 3 is closed.

Dr. Cardarelli: Finding 4 has already been closed. Finding 5 has been closed. Observation 1, we recommend closing this one because it's associated with multiple imputation and we're referencing the SC&A memo.

Mr. Barton: And this ties directly into Finding 2 that we just discussed if we want to close this out as the SRS --

Chair Clawson: SC&A, you're good with this?

Mr. Barton: Yes, SC&A does recommend closing.

Chair Clawson: With the understanding that it's pertaining to SRS Work Group, I recommend that we close this issue. Jim?

Member Lockey: I concur, Brad.

Chair Clawson: Okay, Phil?

Member Schofield: I'm for closing it.

Chair Clawson: Okay, let's go on.

Dr. Cardarelli: This one is just a continuation of multiple imputation and we recommended closing it for these reasons.

Chair Clawson: Okay, and this is the one, Bob, we have a presentation for you on later on?

Mr. Barton: That's correct, this and the previous, yeah.

Chair Clawson: For SRS, I recommend closing this Observation 2. Jim?

Member Lockey: I concur.

Chair Clawson: Phil?

Member Schofield: I agree.

Chair Clawson: Okay, Observation 2 is closed.

Dr. Cardarelli: Observation 3 is multiple imputation again applied to uranium. We are recommending closing again based upon the same type of SC&A memo June 3, 2020.

Chair Clawson: Okay, for Savannah River, I recommend that we close too. Jim?

Member Lockey: I concur.

Chair Clawson: Phil?

Member Schofield: I concur with that.

Chair Clawson: Okay, the next one?

Dr. Cardarelli: Observation 4, we believe this was closed, but we're recommending closing it based upon the information that we provided and the

information that was just described by SC&A.

Chair Clawson: Okay, Bob, you're good with that?

Mr. Barton: Yeah, SC&A concurs, the only comment being that we were kind of hoping for documentation that was indicated to exist, but we think that the additional analysis provided by NIOSH, and that if we're missing anything, it's less than a one percent difference. We're satisfied.

Chair Clawson: Okay, I understand. Thank you, Bob. Okay, I recommend closing this. Jim?

Member Lockey: I also agree.

Chair Clawson: Phil?

Member Schofield: Yeah, I agree.

Chair Clawson: Okay, that one's closed.

Dr. Cardarelli: Observation 5, statistical comparison of stratified groups, we're recommending closing based upon the discussion on December 12, and I've read it into the record, so you can look at the screen here and discuss how you want to do it.

Chair Clawson: Bob?

Mr. Barton: Yeah, I believe that's my quote there at the bottom, the third bullet. There was no action that SC&A recommended as a result of this. It was really for informative purposes. It's an observation for the Work Group just to point out that SRS stratified a priori without any sort of statistical verification (audio interference) this being not subcontractors versus prime contractors, but just operational workers versus construction workers as a whole were stratified a priori.

There was no statistical analysis done as is indicated should be done in the co-exposure guidelines, but NIOSH basically elected to stratify it anyway.

So, that was just for informational purposes and it

has my quote there at the bottom. I'm pretty sure that's me.

Dr. Cardarelli: Yes.

Mr. Barton: No action required, so we are okay with closing that.

Chair Clawson: Okay, I recommend closing this. Jim?

Member Lockey: I agree.

Chair Clawson: Phil?

Member Schofield: I agree.

Chair Clawson: Okay, that one's closed.

Dr. Cardarelli: Observation 6 is the quantitative assessment of job plans. We do recommend closing this based upon the White Paper that Dr. Taulbee just presented to us earlier. This is coding additional data.

Chair Clawson: Bob, what's your --

Mr. Barton: I mean, this is really subsumed under the discussions we just had this morning, which is sort of an ongoing thing.

So, I think for the purposes of the OTIB-0081 review, I think it's okay to close it because the issue is sort of being carried forth and will be dealt with after any SEC determinations are made, so it's really been sort of pulled out of the OTIB-0081 review and is its own separate item.

Chair Clawson: I understand. So, I can close this without creating a problem later on? This was my issue. You know, it's ongoing somewhat, but it's out of the, like you say, it's out of the 81 profile. Is that true, Bob?

Mr. Barton: Yeah, I think we can safely close it in the guise of 81 because it's still being dealt with under the plutonium stratification subcontractor discussion we just had.

Chair Clawson: Okay, with that being said, I recommend we close that. Jim?

Member Lockey: I agree.

Chair Clawson: Phil?

Member Schofield: I agree.

Chair Clawson: Okay, closed.

Dr. Cardarelli: Observation 7 has already been closed, so we'll move to the, I think the final one, error rates dependent on payroll ID, which is Observation number 8, and we have recommended closing this.

Chair Clawson: And SC&A's feelings?

Mr. Barton: Well, again, this is another one that I'm surprised that it wasn't formally closed, but as it said there in the third bullet, the Work Group discussed it pretty thoroughly back last December, and as it indicates and this is my recollection as well is that it was a nonissue, so I think it's okay to close.

Chair Clawson: Well, that was my thought too, but if you remember, that was a pretty big discussion and it went on for quite a while, so I recommend to the SRS Work Group that we close this. Jim?

Member Lockey: I agree.

Chair Clawson: Phil?

Member Schofield: I agree.

Chair Clawson: Okay.

Dr. Cardarelli: Thank you, Work Group. That concludes this presentation, and I appreciate the vote for closures. Just a brief summary, I'll go back to this first slide here.

Everything that we had recommended closing did get official votes for closing, and the only remaining open item was Finding number 1 which we will move

to the next topic on the agenda for Dr. Taulbee to present and discuss that particular finding.

Chair Clawson: Thank you, John. I appreciate that, and Bob too for weighing in on this. One of the things I want to always remind everybody is there's a lot of times that we do not sometimes come to complete closure, and it's good to sit down like this and be able to take them one by one and discuss them and close them. I appreciate that. So, with that being said, we'll turn it over to Tim.

Dr. Taulbee: Actually, it goes to Bob.

Dr. Cardarelli: Oh, Bob, sorry.

(Simultaneous speaking.)

Chair Clawson: You guys directed me the wrong way.

Dr. Cardarelli: I did that. That was my fault, sorry.

Chair Clawson: Okay, Bob?

Mr. Barton: Let me just get the presentation up here. Okay, I know I saw Joyce had joined us. Patrick Kelly, are you still on the line? You may be on mute. Patrick Kelly? Alright, well, hopefully he will join us later on.

I'll be giving this presentation, but really sort of just really drove the car to get our subject matter experts here, which is Patrick Kelly, our guru on radiochemistry, and Joyce Lipsztein, who is our expert on internal dosimetry.

So, I'm going to go through this presentation and then I'll let any questions the Work Group has be handled by them, hopefully. If I need to make a side call to get Patrick back on the line, I'll certainly do that.

Alright, so let's go through this issue, a little bit of background on the implementation guidelines, and these were really what were voted on by the Board last December as appropriate, so they went out of draft form and it is now the procedure on how you

evaluate co-exposure guidelines.

And one of the core tenets of that is data adequacy which really asks the question does the monitoring method being applied, so the measurement techniques, chemical recovery, the numbers we get from a monitoring result, does that adequately reflect the exposure that we're trying to reconstruct?

And this comes actually right out of the co-exposure guidelines and it's directly applicable to this issue of trivalent variability, which we'll obviously get into what our concerns are there.

But this comes from the co-exposure (audio interference) that says when paired measurements are available, the prevision between measurements should be examined. If widely different results from the same aliquot are observed, the effect this might have on the usefulness of (audio interference). Is someone trying to speak?

Chair Clawson: Hey, Bob, hold on one second. Somebody needs -- there are several people that need to mute their phones. We are hearing them. Check to make sure that you are muted. We're hearing a lot of background noise. Thank you.

Mr. Barton: Okay, thanks, Brad. So, as far as this specific issue at SRS in the guise of the co-exposure guidelines and what needs to be evaluated, SC&A first brought up a concern over what we saw as significant variability among disks of the same sample.

And what this really means is often at SRS, specifically for americium, but sometimes for plutonium, they would basically take a sample, a single voiding, and break it out onto a number of disks, at least this is our understanding to date, and then measure those disks.

And you'd expect that when they normalize those results to get back to an activity per volume in that urine sample that was split up and measured several

times, that you'd have reasonably close values, especially when looking at results that were well above the detection limits.

So, we first brought this up in September of 2013. It was part of the review of Addendum 3 of the SEC Evaluation Report. In February of 2014, we released a memorandum, and all of these documents are available on the website, by the way.

And we dove into it a little bit more and we provided 188 individual examples from among those samples that were above the detection limit that we saw variability that we felt was concerning, so that was all the way back in 2013 and 2014.

And so we fast forward and this was brought up again, and this was Finding 1 that we just discussed as part of the OTIB-0081 review, and at that time, the joint Work Groups requested that SC&A really formalize our position and sort of distill down all of the issues we had with it, including the longer memo in February of 2014, and really just summarize where we're at from a technical standpoint and really just get at what are our concerns, and there were also some specific questions asked by the Work Group at that time to investigate, which we'll get into.

So, one of the things we did in putting together our most recent memorandum, which is available on the website under the SRS work site -- I don't believe it's posted necessarily on the meetings page, but if you go to the SRS specific page, you can find it there along with all the reports that John had mentioned and given the SRDB numbers in the previous presentation.

I checked. Those are all available online, so you don't necessarily need to have access to the CDC system to see all of these different documents.

So, we revisited the 188 examples from our 2014 analysis basically to assure the sample was taken from a single voiding. In other words, it wasn't a separate voiding possibly taken later that day or

possibly the next morning and combined with the previous sample the night before, that sort of thing.

We wanted to make sure there was no indication on the logbooks that the sample was actually invalidated, either it got contaminated or lost in process. Those are certain examples of why you would think that the sample is just not good and shouldn't be included in any case.

And so that 188 got reduced to 145 that we feel are still valid examples of these multiple measurements above the detection limit where we see significant variability, and what we found was on average on these samples, you see plus or minus 50 percent on the different aliquot measurements when you compare it to the average of all of the ones for that single voiding.

So, one of the big questions is what does this really matter in terms of dose? Well, if you go back to that SC&A 2014 report, there's a Table 12 which provides a scoping calculation of potential doses at some example bioassay levels of doses to the critical organ, which for americium is the bone surface.

So, you can refer to the extracts, or we're going to refer to the extract from that 2014 report on the next slide. It's important to note here that these dose calculations were based on an assumed chronic intake over one year and that the urinalysis result, which again is hypothetical, is performed at the end of the intake period.

So, this is just to get a sense of how much does the dose really vary when you're talking about plus or minus 50 percent on these individual measurements? So, what does this variability really mean?

So, this is a fairly simple table, but to the far left, you have some examples of bioassay levels, so consider these perhaps -- you know, consider these as examples of what a claimant might have in their file based on measurements that can vary significantly in our opinion.

So, you can see at 0.3 dpm per 1.5 liters, which is essentially dpm per day, the 30-year committed dose is about 20 rem to the bone surface. Now, if you double that, it's proportional. If you double that, you really double the dose.

So, what we're just trying to show here is the significance of this variability when you take these individual measurements by themselves without averaging them, and the effect that would have if you just took a single measurement and evaluated that versus taking multiple measurements and averaging them, how much of an effect this could have potentially on calculated doses, and again, this is based on a one-year assumed chronic exposure to americium with a bioassay result submitted at the end of that year.

So, back in 2019, in December, NIOSH provided us with two technical reports to hopefully assuage some of our concerns here about the variability that we were witnessing in these samples above the detection limit.

One of them was Determination of Actinides in Biological Samples with Bidentate Organophosphorus Extractant, and the other one was an article about two californium inhalation cases.

So, we reviewed those documents, both Joyce Lipsztein and Patrick Kelly, who hopefully is on the line now, and basically the conclusion when they reviewed those documents was that there's general methodologies and they are illustrative of the process, but the technical questions we have still regarding this dataset and the variability we see were not really adequately answered without some additional information provided beyond those two documents.

So, we have several specific technical questions here and I'll read these into the record. These are the types of questions that, you know, we hope to get some answers on to give us a little more confidence

that what we're observing is, in fact, okay, and that the data is adequate to reflect exposures to americium.

So, are the multiple aliquots actually from the same sample and a specific void? That's our understanding right now, but the question might be is that actually the case, because that might explain some of the variability.

Were the aliquots taken from what appeared to be different fractions of a sample based on the observable attributes or was there chemical difficulties attributed to nonhomogeneous samples in the interest of representativeness?

If the multiple aliquots were taken, can we assume that they are the same or equivalent volumes? So, you know, what are the volumes out there and how does that factor into what we're seeing?

What is the technical basis for this analytical approach that was used at SRS and where is this necessarily referenced in the analytical protocol, which for SRS, we found one for 1987. I believe there was one in 1993. However, I don't think we were actually able to find that level of detail prior to that.

And sort of regardless of what the multiple counts represent, is this approach adequately represented in the method's uncertainty, the uncertainty in the measurement? When we're averaging all of these things, is that uncertainty really accounted for?

And the real question is how much variation between the disks is actually acceptable such that a simple average of all of the values from what we believe is a single voiding is actually representative of the exposure?

And what was the acceptance criteria for the degree of variability at SRS? Was it, you know, don't exceed 50 percent at a given level?

These are the types of questions that would really

help us understand what we're seeing, what we observe as anomalies, to give us confidence that these samples that we have are adequate, not only for use in a co-exposure modeling setting, but also for individual dose reconstructions.

So, some examples of additional information that would really seek to answer some of those technical questions on the previous slide would be formal SRS or laboratory calculations with all of the terms identified, the volume, the counting efficiency.

So, that would be counts per disintegration because, you know, when you measure something, you'll get counts per minute, but you have to convert that based on various efficiencies, chemical recovery, to get to disintegrations per minute, and so that's information we would certainly be interested in, the chemical yield, the target analyte percent recovery based on the tracer or some other technical reason, and the overall measurement uncertainty that was considered by the site.

Also, you could have possibly written instructions explaining the technical basis, practice, and procedural controls regarding when you do multiple counts, how many times you do multiple counts, and why you might not do multiple counts of the same sample.

Prospectively determined acceptance criteria for the performance samples analyzed with each batch, you know, what were the performance criteria for blanks and spikes?

And also objective evidence that the laboratory had predetermined acceptance criteria for the performance of the samples and that these criteria were technically appropriate and were, in fact, applied to these routine bioassays.

There's also some concerns that arose when Patrick Kelly did his review of some of these logbook examples and they are about batch spike samples.

Spike samples are a routine aspect of the analytical process and we'd like some evidence of the laboratory ability to quantify that target analyte and identify any potential systemic biases in the analytical protocols based on these spike samples.

Because what we observed is that sometimes the spike sample recovery would range from six percent to over 100 percent, and in some cases, you got zero percent recovery in the spike sample, but these were deemed by SRS as still okay to report. Somebody did sign off on the page, but we're really not sure what the criteria was for accepting these measurements.

One of the questions that the Work Group asked us back in December was, well, you observed variability, but how does that actually -- I mean, how much is too much? What comparisons can be made to other facilities and such?

So, we did some literature search, and so we only found that, the precision at SRS, we could only find documentation in 1987 and they had it at plus or minus 19 percent, and that's at a level of 13.6 dpm per day.

In our review in 2014, we identified aliquot examples that were above the 13 dpm per day range, and they could range anywhere from 16 to 246 percent of what the average value was that was reported.

We got some NCRP documentation. Again, this is much later in the period than in the period that we're talking about. This is in 2009 from Report 164.

And they had 18 individual laboratories perform actinide analyses and the optimum conditions were determined to be less than 25 percent, and the purpose was really to see if you're above that level, what can we do to improve the precision at your individual laboratory?

And again, this is based on the 2009 report, but also that 25 percent is at a value much lower, about a factor of five lower than what the MDA was for SRS,

so it was a precision of 25 percent at much lower levels, which would be expected as measurement methods improve into the 2000s.

And again, I remind that the SRS detection limit was 0.3, so you can compare that to 0.06, which were the optimum conditions, and one thing that report actually found was that on average for those 18 laboratories, it was plus or minus 30 percent, and that's at a level of 0.006 dpm per day, so now you're a factor of essentially 50 below the SRS detection limit we're talking about.

There's also a quote from that report and I'll read that into the record. In addition to the normal counting uncertainties due to counting time, detector efficiency, and counting background, the parameters influencing the uncertainty of the results include heterogeneity of the material being analyzed, reagent blanks, and chemical yield, tracer recovery.

The uncertainty due to the heterogeneity of the material is calculated as the standard deviation of the results from repetitive measurements of several subsamples randomly taken from the bottle and analyzed under the same experimental conditions. It has been estimated to be equal to five percent.

So, again, this is you take one sample. You break it out into several different planchettes or disks as it were at SRS, and they found that heterogeneity of the urine itself was around five percent. Again, that's from the National Council on Radiation Protection and Measurements.

So, what do we conclude from this? We still don't feel that a sufficient explanation has been provided to explain why we're seeing some of this variability at levels far above the detection limit when measuring the different aliquots of the same sample.

Again, in comparison to what we could find in the literature about other acceptable or observed variability, at SRS, they reported a precision level of plus or minus 19, and then there were the other

analytical laboratories which I just discussed that were part of that NCRP report.

And what we still find is that we simply don't have the documentation or other objective evidence to really understand what those trivalent bioassay represent and verify that they are, in fact, technically accurate to be able to use in both the co-exposure model, but also for individual dose reconstructions.

In our memo sort of summarizing all of this, we did suggest a path forward, and this would be to try to capture any benchtop procedures that were in use at SRS in the analytical laboratory. This might really help us understand what they did. You know, what were the procedures? What was the acceptance criteria and things of that nature?

And also documentation about the quality assurance criteria that was in place at SRS, this would be just additional information to give us confidence that even though we see variability, that the results are essentially okay. They are adequate to quantify, again, the exposures we're trying to reconstruct, which is mainly americium in this case.

And the third bullet, I don't think I did this one yet, but the third bullet was, and this one might be very helpful, is to interview some of those workers who worked in analytical chemistry so that they can explain, you know, what it is they did and what the procedures were beyond sort of the general methods that are described in the documents provided by NIOSH back in December.

And so since our 2020 memo, I actually went into the claimant database and looked through CATI reports for potential candidates who might have worked in the analytical laboratory and I was able to find at least 11.

Now, some of them started work very early in the '50s and worked, you know, through the period we're interested in, but they might simply not remember what's going on or might not be available for

interview.

But some of the candidates that we identified actually started work in the 1970s and 1980s and might still have that institutional knowledge about how these bioassay samples were analyzed, what performance criteria there was, and basically how we got from a urine result to the reported results in these logbook samples which are currently being proposed to form the basis of dose reconstruction in co-exposure.

These are the references. I cited a bunch of stuff in there, so I wanted to make it easy to be able to look back. As you can see, many of these reports are available right on the website and you can see them just through that link, so that's just for people's edification.

So, with that, I'd certainly like to accept any questions which -- let me just ask again. Patrick Kelly, are you with us right now? Patrick, are you on the line? Okay, well, maybe I should give him a call, but we do have Joyce Lipsztein on the line, and we can either take questions now, or I know NIOSH has a response. We could wait and have the discussion then, whichever.

It might be beneficial to do it that way just because I can give Patrick a calright now and I hope I can get him on the line for that discussion if that's amenable to everybody.

Chair Clawson: Bob, this is Brad. I'd like to have NIOSH give their response if that would be alright. I agree with you.

Mr. Barton: Okay, very good.

Dr. Taulbee: Okay, this is Tim and I'm going to share my screen now or share that box. Can everybody see the presentation okay?

Chair Clawson: I can.

Dr. Taulbee: Okay, great. Alright, so this is our

response to the SC&A memorandum from earlier this year, and I certainly want to acknowledge my coauthor on this presentation, and she'll actually be presenting some of these slides, and that's Dr. Nancy Chalmers from MJW Companies working under the ORAU contract.

And so one of the things that we noted here, kind of an overview, is SC&A kind of has two primary issues. One is dealing with the high variability context and then the other is dealing with the procedures, and that's how we've kind of broken this presentation into our parts.

And then Dr. Chalmers is going to talk about the metric to define variability, and then we're going to wrap up with a conclusion. Then I'm going to introduce a new data issue with regards to the americium and our path forward with regards to that, so that's an overview.

So, Bob had gone through a lot of this, the background and the discussion timeline. What I want to kind of focus on is more of the recent time periods of the NIOSH response back in November of 2019, about the americium results are averaged, you know, four times in the co-exposure modeling.

So, even though there's this variability, we do have where we developed the time-weighted OPOS and then we do the intake modeling.

So, you know, doing the dose calculations directly off of the bioassay is done for individual claims, which Bob did bring up, and actually the context that this was originally raised I felt was more under the co-exposure, and so that's where we had focused in the past, but the variability does apply, you know, to the individual claims from that standpoint.

But we're still taking an average, and so, you know, the overall variability of the original data when you take an average of an average, you know, it's much smaller than what you're considering here, and when you're doing a bioassay fitting for an intake type of

modeling, you know, you're looking at more than just one individual sample.

Especially for many of these that are large, these are intakes. These are multiple samples from multiple people, or not multiple people, same person, multiple samples, and several of them are in the same day type of scenario, and so for the co-exposure models, we will sometimes combine them into that time-weighted OPOS.

Alright, SC&A's response in June implies that the acceptability of variation should be judged without consideration of its use, and this is something that we disagree with and I'll get into that in a moment.

And so what I'm presenting today is the additional response that we released late last month, October 21, so that's the focus of this presentation.

So, with regards to the high variability, the context is crucial, okay, for an example, variability in emergency monitoring after an incident versus variability in routine monitoring.

The measurement's acceptable variability is tied to its use, okay, and so that's something that I wanted to point out here, and along those lines, I want to consider the seven examples in SC&A's Table 1 of their report.

Okay, five of those seven examples are for one worker involved in a single incident, alright, and the five examples were all small aliquots of 10 to 30 milliliters compared to 300 milliliters, which is what the routine sample typically is, so these are much smaller, and so you're comparing a small aliquot versus a large aliquot.

We don't have evidence of this, but I can tell you from personal experience of running a counting laboratory that samples can be counted for different times, especially under an accident or incident scenario where the health physicist and the medical officer or doctor are trying to decide whether to chelate

somebody.

They're going to be getting results as quick as they possibly can to try and make those decisions, and so were they really all counted for the same amount of time? My best guess is the smaller aliquots probably were not, and given the activity levels, I can almost guarantee that they were not.

But one of Bob's indicators was perhaps we should do some interviews and talk to people, you know, was that the case? That is something that could be clarified from that standpoint.

From the standpoint of a co-exposure model, these five examples would contribute to one TWOPOS result in the co-exposure model, and if you're using these five examples to fit a bioassay to estimate the dose for that individual person, you're going to be looking at all of them and trying to do an excretion curve or looking at what that is and back extrapolating to what that maximum intake is. So it's not an individual sample that is contributing to what we would assign for an intake and subsequent dose, okay.

Furthermore, this particular worker where these examples were brought up by SC&A was chelated, so the data weren't used in our current americium co-exposure model at all, alright. They were taken out from that analysis.

So, let's look at the remaining two in the table of examples from SC&A. One of the workers was also involved in an incident and was chelated. We actually found this was an error in our co-exposure model in that they should have been removed from our co-exposure model.

They did a payroll ID change that resulted in an inadvertent exclusion of pulling them out, and so they ended up with this chelated data in our co-exposure model. We have since fixed that coding error.

But again, this was a sample that was nonstandard as well. It was not 300 milliliters. It was 210 milliliters, much closer than the much smaller samples I previously discussed.

So, let's look at the final example that was provided. The remaining variable example was actually flagged by the radiochemist in the logbook and there's a note in the margin that this sample, this particular result is suspect and they requested a subsequent follow-up sample.

A subsequent sample was collected and analyzed for that person. We went to a different, actually the same logbook, but several weeks, I think maybe a month or so later, and the follow-up result was below the reporting level.

So, it was flagged by the laboratory, this high variable sample. It was also much higher than the others and they flagged it for follow up. So, to us, this demonstrates that they were paying attention to what the samples were, and what the results were, and doing appropriate follow up.

I would like to emphasize that those examples we don't feel are representative of the americium co-exposure model, and so to draw conclusions based upon that, we don't think are appropriate.

So, now I want to get to the next kind of component of this is the response from SC&A attempts to define excessive variability and they use two reports basically, the 2003 optimization of monitoring for internal exposures, the OMINEX bioassay survey, and then the 1987 SRS DuPont standard operating log, DPSOL, 47-206.

Both of these documents were reviewed in detail in Appendix A and B of the memo. I'm just going to give some brief details here. If you want more details, please go and read that, and if you have questions, let us know and we'll be happy to go further on that.

And SC&A referenced the NCRP Report 164. Well, the

full OMINEX report notes that this is optimal condition of less than 25 percent uncertainty for a sample containing one millibecquerel. In our opinion, this is an arbitrary value established by the authors for state of the art methods in 2003.

Less than half the labs were able to meet this standard using alpha spectrometry in the 2003 era. So, we don't really feel this is appropriate to try and apply to the americium monitoring that was done in the 1970s and '80s, and '90s at SRS.

In DPSOL 47-206, they do provide some precision levels, precision criteria of plus or minus 19 percent at the six picocurie level per 1.5 liter, which is 13 dpm as Bob pointed out. This is at the 95th percent confidence.

Now, this is a minimum quantifiable value. This is not a minimum detectable value. This is a measure of what the process capability is, and the process was capable of analyzing americium at a level of 13.3 dpm per 1.5 liter with a coefficient of variation of ten percent.

This is not inappropriate as a QA criterion for individual analytical results. There is many other things that are going into this. This is what the process generally was.

As I pointed out earlier, if you change that sample volume size, if you change the counting time, if you change these other variables, that value of plus or minus 19 percent will go up. Of course, if you increase counting time, it will go down.

So, this is what their standard process was, okay? This wasn't something that they graded against. Go back to my initial discussion of emergency situation for many of these samples versus your routine counting.

If you look at ANSI N13.30, the current performance criteria for radiobioassay, it defines acceptable variability only for high-level testing samples used in

the DOELAP accreditation, and there they give, you know, a minimum testing level which is actually much higher than what that SRS MDA is.

So, again, the variability is really not defined for these lower samples. It doesn't apply to sample specifics.

So, our conclusion is there's no generally applicable quality criteria for variability that can be applied to an individual analytical result generated in an occupational radiobioassay program, and if there's no criteria that can be applied today, then we really can't apply criteria in earlier time periods.

So, now let me talk a little bit about procedures here and this is the -- going back to our implementation guide where one of the things Bob quoted there was that we should be, there should be a review of the sample collection methods, any chemical processes employed, and the radiation counting equipment used, and we've done that, okay.

Have we done an extensive review and documented absolutely everything? No, we did a summary though in OTIB-0081 where we described these different things. We feel the level of review of historical documents referenced in OTIB-0081 fulfills this requirement.

SC&A appears to suggest a much higher level of scrutiny is required and that the level of review performed to date is inadequate. SC&A listed some documentation they would like to see. We acknowledge these documents would be helpful, but we don't know that they're necessary. We don't believe they're necessary.

There is difficulty in obtaining the information, locating it, vetting it, properly interpreting it, locating and properly interpreting all of the relevant procedures and QA records, especially in the pre-DOELAP area.

The radiochemist reviewed the logbooks as a mean

of sample-specific criteria where the variability is included, that they were met, that these are good results, and so that's what we really rely upon here.

One other topic I'd like to briefly touch on is americium recovery because SC&A pointed out that the recovery values were quite, well, they said they were too variable, implying that the data appeared to be too variable for use because it ranged from zero to 116 percent.

Well, we went back to SC&A's source of one of the logbooks that they listed from 1981 to 1986 and we pulled out all of the spikes within that logbook, and there were 263 batches that were done within that logbook and we looked at all of the spikes and what the recoveries were.

And this is a histogram off to the right of what those recoveries were with percent across the bottom, and yes, it does range from zero to 116 percent, actually up to near -- I want to say there was one that was 120, but the typical range for recovery is about 25 to 120 percent.

And in this particular case, 255 of the 263 recoveries were within that range, so 97 percent of the data are within the range of 25 to 120 percent recovery, each batch this recovery is applied to.

So, really if it's ten percent, that means those results are going to be biased higher, much higher than, you know, it could be in reality for the individual samples.

Only three of the batches had a recovery of zero percent, okay. That's one percent of that dataset within that time period, and this is just one logbook within that time period.

There are several logbooks. Some of them are plutonium and americium combined analysis. Some of them are just americium logbooks. Others are americium -- I'm sorry, americium, plutonium, and neptunium, so this is just one logbook.

Our general conclusion is that the original bioassay results of record at the site that are used to demonstrate the compliance with the regulations that appear in the individual records for the individual claimant that we used for dose reconstruction are the best available data that can be used for the co-exposure models.

A limited review of that data is performed as a confirmatory measure. We don't go into the details of every single one. This would be incredibly time consuming to do.

And with that, I'm going to pass it over to Dr. Chalmers to discuss the metric to define variability.

Member Lockey: Tim, this is Dr. Lockey. Can I ask you a question before you do that?

Dr. Taulbee: Yes, sir.

Member Lockey: Go back two slides for me, would you? Right there. So, the typical recovery range was 25 to 120 percent, and 97 percent were in a typical range. Is that --

Dr. Taulbee: That's correct, 97 percent of the recoveries were within that range of 25 percent to 120.

Member Lockey: And there was three with one or zero percent recovery?

Dr. Taulbee: There was -- three of the batches indicated a zero percent recovery, yes, three of the 263 batches.

Member Lockey: So, I'm going to go back and ask Bob. Bob, was this data available to you also in this way?

Mr. Barton: Well, I guess I also had a comment on the presentation. This response was provided about a month ago, I think it was late October. Unfortunately, it did not clear with DOE to the point where I could share that response with our technical

experts, Joyce Lipsztein, and I hope -- Patrick Kelly, I think I see your number there, so hopefully you're on. I do have --

Mr. Kelly: Yes, I'm on.

Mr. Barton: Oh, great, great. So, they've only had basically a little over one week to really look at this, so we haven't had much of a chance to digest it, but one question I have on this slide is it says typical recovery range is 25 percent to 120 percent.

Tim, are you saying that that's what was typically observed in the logbook data? Is that correct or are you citing industry wide standards on what the typical recovery would have been?

Dr. Taulbee: I don't know that I'm citing any standards from that standpoint. It more has to do with this is kind of an acceptable or generally thought about range when you're doing recoveries in a chemical laboratory for an analyte.

At least that's my experience. I mean, others may have different, I don't know. I mean, Patrick may have a lot more experience along that line than what I do from that standpoint.

But what I'm trying to say is that 97 percent of those batches fell within that range and you can see on the histogram there that, you know, it kind of peaks at around 75 to 80 percent recovery. It's kind of a normal distribution as one would expect with recoveries.

Member Lockey: So, I guess the question I'm asking when I look at SC&A's comment above that, when I see zero to 116 percent, that's alarming to me, but when I see what you're saying, that's not alarming to me, and I just want to know, Bob, was that data available to you when you came up with this slide originally?

Mr. Barton: Well this is NIOSH's slide based on their response, which again was -- a preview DOE version

of it was available late last month, but again, our technical people have only had it for about a week.

I don't know if we want to have Patrick comment on this right now or we can wait until the end of the presentation and circle back, or we can handle this --

Dr. Taulbee: I would like to interject that this is from the SRDB, so this is an SRDB logbook, so, yes, in my opinion, the data was available to SC&A.

Now, we had not analyzed it in this manner. We analyzed it to respond to your comment because from our looking at the typical recoveries when we went through, I was like no, I'm typically seeing somewhere between 60 and 80 percent, and so we went through and we pulled those batches out, which SC&A could have done.

This logbook was captured multiple years ago, and so that was what we did to address SC&A's comment about zero to 116 percent because like you, Dr. Lockey, that caused me some concern as well and it just didn't jive with what I had recalled seeing in those logbooks.

Member Lockey: Well, I guess my question is that if this was readily available in a logbook, this is data I also would have expected SC&A to present, okay.

I would have liked to have known that one percent represented three out of 264 because that would have given me a different perspective on this range.

Mr. Barton: And we're talking about the spike recoveries here. I'm not sure, Patrick, do you want to comment on this?

Mr. Kelly: Sure, I would be happy to.

(Simultaneous speaking.)

Mr. Kelly: Yes, I'd like to point out that we're talking about data, in this case from one logbook of many. The examples I chose which were then worked up

were examples I chose just at random by looking through a logbook.

We did, I think, have accessible all of the information that everybody else had. I don't know offhand how much that is, but there were many logbooks. This was one example I chose at random.

It was not intended to be comprehensive, but rather to indicate a degree of variability that I was trying to understand for my own edification to assess the validity of the method.

And this is, the data that were worked up in this one, the histogram of the SRS spike recoveries from 1981 to 1986, those are values from one logbook of which I believe there are 13 or 14.

Again, I chose a group of values because they represented a fair amount of variability. It was not intended to be comprehensive or to be representative of every value that was included in all of those logbooks.

Member Lockey: But you looked at the same logbook that Tim's group looked at, right?

Mr. Kelly: I assume so, yes. I did look at this logbook. I looked at a good many logbooks. I can't tell you exactly how many, but, yeah, I was, I assume -- I'm just looking over my notes. I assume I did, yes.

Dr. Taulbee: This logbook selection was the one that was referenced in SC&A's memo with that range of zero to 116 percent.

Member Lockey: And so the data you looked at is how you came up with the range of zero to 116 percent, but what you didn't do, or at least didn't present to us, that that zero percent was three out of 263.

Mr. Kelly: I did not present that. You are correct. Again, I was looking to understand the degree of variability in the method. This is one logbook.

There are other logbooks that I believe have

examples of variability as well, and I would caution us from assigning the values that are in this one histogram to the entire dataset over all of the logbooks. I mean, it may be correct. I just don't think that we have done that yet.

Member Lockey: No, and I understand that different logbooks will present different data, but I think for completeness sake, it would have been extremely helpful for me is that when you present the zero to 116 percent, you would have put some kind of degrees of how was that zero to 116 percent distributed.

Because zero to 116 percent is very disturbing, but when I look at the lower part of the slide for this particular logbook, for this particular analysis, it's not disturbing.

Mr. Kelly: Well, I take the point and I think it's a fair one. I would say the logbooks presented with me or presented to me with some degree of difficulty in terms of understanding exactly what I was seeing.

As Bob said earlier, we got this response, and upon seeing this, I thought, oh, this is worth taking another look at. I have not done that between when we got this response from NIOSH and now.

Member Lockey: Okay, well, thank you.

Member Schofield: This is Phil Schofield. I got a question. You said this, the samples were put on a disk of some type and some of these could wait. If I understand correctly, it could be up to two years before they actually process some of these samples. Is that correct?

Dr. Taulbee: Two years is a bit long. I don't believe that that's the case. I have seen six to nine months and maybe a year. I'm not for sure on that, but yes.

But what they would do is not necessarily put them on a disk, is they would save the sample, save the urine sample and, you know, there would be a

backlog and then they would process through. Does that make sense, Phil?

Member Schofield: Okay, yeah, because I was going to say if you put them on a disk and, you know, depending on a number of factors, you could actually lose part of that sample and then your numbers would change than if you had processed it in the first, you know, few days or something, or weeks even after they received it.

In other words, they took a sample and then they, instead of just putting it on one of these disks or whatever they particularly did, and then it just sits there for a long time. So, yeah, that gives me a little more confidence.

Dr. Taulbee: Okay, thank you. Alright, are there other questions? Hearing none, Nancy, go ahead.

Dr. Chalmers: Alright, thanks, Tim. So, what we're trying to do here is define a metric to assess variability. We've talked about high variability and excessive variability, those sorts of things, but ultimately we need to settle on a statistic to define variability.

And so what I'm going to walk you through sort of is the history of what's been proposed over the years, I guess, back and forth between SC&A and NIOSH, so we'll start with the February 2014 SC&A response to OTIB-0081.

SC&A had a table with 188 values called out that were chosen subjectively and they highlighted some of those results in green and called them inconsistent disk results, which I don't think the inconsistent part was ever defined there, and so that's obviously subjective, so that one is not a metric necessarily the way they initially called these values out.

So then November 22, 2016, ORAUT-OTIB-0081 Rev 3, this is the previous version, NIOSH proposed the use of CV, also known as the coefficient of variation. I believe we've talked about it a little bit.

Some folks in other fields may know this as the relative standard deviation, but it's basically just a standard deviation of those multiple counts divided by the absolute value of the average of those counts.

And one way to look at that, which is in Rev 3 of OTIB-0081, is to plot the coefficient of variation versus the absolute value of the average, and you can sort of look at those values and they have a distribution as you would expect, so you take a look at that plot in OTIB-0081, Rev 3.

And then in September of 2019, SC&A response -- oh, can you flip the slide, Tim? Sorry. September 2019, SC&A review of OTIB-0081 included a log-log plot of the coefficient of variation versus the average, so what we were just talking about except it's on a log-log scale and they did it for average values of 0.32 dpm per 1.5 liter or greater.

You know, we would say that for proper assessment, we should use all average values, but SC&A also mentions in the text of that document that the coefficient of variation is commonly used as a measure of variability.

And then in November of 2019, the NIOSH response, we didn't propose a new metric then because we believed the CV that we previously proposed is the appropriate way to look at this.

And then in the most recent June 2020 SC&A memo, there is sort of another type of metric they included there. One of the examples was 145 samples had a range greater than plus or minus 20 percent of the average value.

From my experience, that's not a well-known metric and they didn't reference sort of what that is, what it's called, why consider it in that way instead of the coefficient of variation. So, can you flip the slide, Tim?

So, what we're proposing is to use this coefficient of variation versus the mean plot. We initially proposed

it back in 2016. SC&A used a very similar version of that same plot in 2019. It's a common, well-known metric. You can go Google it and learn all about CV if you'd like.

And we can use that plot that I described to assess variability and it eliminates for us the use of these subjective, and unjustifiable, and not referenced, and all of these other things which we've talked about these other metrics, so that's it for the metric. Back to you, Tim.

Dr. Taulbee: Are there any questions for Dr. Chalmers? Okay, hearing none, I'm just going to wrap up here with the conclusion.

So, with regards to the high variability, we don't feel there's any general, no generally applicable criteria for variability that can be applied to individual results today.

If there's no such criteria today, then there really wasn't any in the previous years that these logbooks are covering.

Generally, the bioassay result of record is used to demonstrate the compliance and are considered our best available data. We do a limited review of the data when we go through and do these co-exposure models as a confirmatory measure.

It's not rigorous, but as Nancy pointed out, the coefficient of variation is the proper variability metric and we will be using it moving forward. Are there any questions there before I go on to the new data issue? Because this one's kind of important.

Okay, well, one of the benefits of the SC&A review here is that during our review and answering their questions, we did identify several new concerns that prompted some further evaluation, and so this got us to go back and look more closely at this data.

Our evaluation found that many of the high variable results were not necessarily variable, but had some

undesirable characteristics that unfortunately could impact our co-exposure model, and I'm going to talk about three of the examples here that we came into.

Well, I guess before I go into these three examples, keep in mind that one of the things that hasn't been considered, but I believe made it into SC&A's list of potential topics that can affect variability is sample aliquot size.

And as I noted earlier, many of these aliquots, many of these samples or flags that SC&A had pointed out certainly have smaller sample sizes.

So, they're not following the standard method that one would consider, and so one would expect the variability to be higher than your typical routine result within those samples.

But some of the examples that we found when we went through and investigated some of these caused us some pause, and so I want to talk about those.

The first one is that we noted that some of our samples in the database, that spike samples were inadvertently included with the individual results, and this was a surprise to us because what ended up getting coded here -- and I'm going to try and zoom in. Actually, let me leave it out here for just a second. Can you all see a pointer or the crosshairs on your screen?

Member Lockey: Yes, I see it.

Member Beach: Yes.

Dr. Taulbee: Okay, so what you'll see here is this is an individual sample, and you'll see this little bracket that indicates that it's the same sample, and you go across here and it's all the same sample.

This is the bottle date, the date it was received, the area. This would be that person's payroll number, and you go through here and this is the dpm per disk and the dpm per 1.5 liter, and then this is the

reported result. Okay, and so for this one here it would be less than 0.3 dpm per 1.5 liter.

Now, if I zoom in here, and hopefully you can see when I zoom in, you'll see that the result here was zero and then the lower result was 3.536 for americium. We coded these together inadvertently because they were the same sample, same date.

And what wasn't noted was this note down here at the bottom that samples three, seven, and 11 were spiked with plutonium. The plutonium spike was 1.25 dpm and later spiked with americium at 4.96.

So, all three of these particular samples here were spiked, and so they were included in our database and they should not have been, and so when you're looking at zero versus three, we're going to come up with an average of around 1.7, something like that because it was 3.5, and you're going to compare that.

Well, one sample was zero and one sample was 3.5. This has a high variability associated with it. Well, the one should never have been included, and we certainly recognize this.

So, including this in the database, this would have a biased high-type of result because we included spikes where they shouldn't have been, and so by removing them, the overall co-exposure model would decrease.

We don't know how many of these are in there. We don't think there's very many. This was a very rare scenario. Typically down here, samples 18, 19, and 20 would be the blank and then two spikes. That was what we typically saw, so this was an unusual entry.

The other example error I'm going to say is an extreme-typo example, and here is an example where the values were entered into the database as 3.59, 92.07, and 4.3. When you look at this, this is 3.59 running diagonal, 2.07, and 4.3.

So, clearly when you average these and look at the variability amongst this sample, you would come to

a conclusion this is incredibly variable and there's something wrong when, in fact, there isn't. This is another example of the co-exposure model would be biased high inadvertently.

The third example is an example of misinterpretation of the data. Occasionally, not always, when the aliquot size was non-standard, an additional multiplication factor was needed to obtain the reported dpm per 1.5 liter.

The top of this column was actually labeled as dpm and this column over here was the dpm per 1.5 liter. So, to get to 31, you had to take the average of 18.2 and 23 and multiply it by 1.5 to get to 31, so this is that sample volume difference.

So, in this case, the coded result underreports the true value, okay? This would be -- we would be including 18.2 and 23 into the database when we should have been including 18.2 -- yeah, 18.2 times 1.5 into the database, 23.0 times 1.5 into the database.

So, the bottom line here is we've got some issues that were discovered in August of this year, the extent and the bias. The bias is in both directions. We're seeing some cases where it's higher, some cases where it's lower. There's no clear impact on the result for the co-exposure model.

So, what we've done is we've started recoding all of the americium-241 data. That was initiated in late August. What we've added to this is an additional Health Physicist Quality Assurance step to each result to ensure the appropriate interpretation of the data.

Now, this HP Quality Assurance step is done when we do dose reconstructions, okay. That's the health physicist's job is to look at that data and make sure that the data was coded properly and that the results are there.

So, this really isn't a problem with doing dose

reconstruction at all. The health physicist checks this. It wasn't checked when we coded the americium data, putting it into the co-exposure model.

We did checks of the data, and if I can go back up two here to this particular one, what was checked was this dpm per 1.5 liter. Yes, that value is zero. Yes, that value is 3.536, not how it was interpreted and put into the co-exposure model.

This is why we've gone back, recoded the data, and are having that health physicist make sure that that result should appear, and so this is a case where the data coder enters the data and a health physicist checks each result.

The good news is we've been working on this since August, and as of the beginning of this month, 12 of the 13 logbooks have been recoded, and I can happily report that earlier this week, the coding was complete on the aspect of the data entry side.

The health physicist's QA of that data is finishing up and is expected to be completed early next month. Once we do this, we will rerun all of the americium-241 analysis and update the co-exposure models in OTIB-0081.

At that point, we can evaluate this coefficient of variation. We can reevaluate it, plot the curve of the coefficient of variation that Dr. Chalmers was talking about, and do the comparisons at that point.

So, I wanted to give this update. This is our path forward with regards to this based upon the further investigation of it. So, with that, are there any questions?

Dr. Lipsztein: I would like to make some observations if possible. Can you hear me?

Dr. Taulbee: Yes, we can hear you.

Dr. Lipsztein: Alright, I would like to make some observations. I think the ultimate objective of the

coworker model is not to average results so they don't have a meaning.

I think the ultimate result you want to get from this work is the dose, and for me, the dose is the most important thing, and also, of course, the analytical chemistry procedure that was applied.

And it makes me very nervous that you gave an example of seven points when your coworker, I don't remember her name, Nancy, was talking just about one of the table that you presented with 188 results in 2014 when about at least one-third of them had very different results on the disks.

So, you have results on disk and then you have reported result, and those results on disk, whether they were routine results with very low activity, or whether they were follow-up results with very high activity, or whether they were labeled with special and had very high results, or whether they didn't have any label, many of them have activities -- the same urine samples as I understand, and you are going to see that they are all from the same urine samples.

They have disk results that have results that are three times one of the disks, four times one of the disks, five times one of the disks, and this implies in the dose that is two times, three times, five times higher from one disk to the other.

So, you have to remember that respectively, what you think we have now as variability, we cannot have something that we have to be objective of calculating the dose for the worker, and we have for the same worker and the same sample these results that have a difference of five times, three times, two times, one.

So, I don't think it's fair for the worker, and they have been waiting for this for 70 years. That's when we first talked about this variability. It's not the variability that you are going to do it through a graph or something. Just think in terms of the dose. Is it

fair for the worker?

Again, we have results that are, from one disk to the other, five times with those results, five times, four times, three times because you know that the dose is proportional to the urine sample results. Now, of course we will have to wait until you review all the disks and see what is happening.

And the second thing is that when we ask you for what chemical procedure was done, what was the analytical procedure, you gave us a paper with some methods that required 250 ml. So, I don't think you can do something with ten ml or 50 ml. It's not good chemistry.

So, I think we have to go back and see what's happening. You cannot, you know, average disks that would give five times the dose with something than the other disks. That's it.

Dr. Taulbee: If I could respond to that, I understand what you're saying if you think about it from a single dose or a single sample, but many, many, many of these results are from the same individual from a single incident, okay.

When I go through these logbooks and I see, you know, a whole listing of the samples together, they're from the same individual and they're repeated samples for that individual, but even on the individual ones where you talked about that ten milliliters, that you don't think you could do that, I disagree.

When you're in an accident type of scenario and you're trying to get a quick result, those were included in there, and so they would take a small sample and they would put it on a planchette, and some of these are very high activity because they got a very large intake.

And so you're going to see some of this variability that is in excess of what your routine sample would be. Using just a single routine, yes, they're disproportional, but most of these that I'm seeing are

from an incident type of scenario.

Dr. Lipsztein: May I? I saw this on routine samples, on samples -- and we gave you a list of the routine samples already in that paper, samples that have very low activity, and we saw this in samples that were a little bit high, but the person was not considered an accident and didn't have a follow-up.

So, we see this in every kind of sample, and even routine, even the ones that are written routine and have small activities, you can't say, oh, I have a 50 percent variability, it's okay, but 500 percent, 400 percent, that's too much.

There is something wrong with the methodology. I have run also a laboratory for many years, and of course I'm an internal dosimetrist, so what I want to know, the result is in those.

So, and I think the objective here is to give a dose, to see if the worker can have compensation or not, and if you cannot say if the dose was 100 millirem, or if it was 50, or if it was 200, then you cannot use this data for compensation analysis.

Dr. Taulbee: Okay.

Dr. Lipsztein: I don't think it's claimant-favorable to do this, no, and not fair.

Dr. Taulbee: I believe that you're pulling out some of the extremes, but I can't demonstrate that at this time until we look at the most current recoded data here.

Because I'm concerned we're running back into the same discussion that we had with the recovery, that this affects an extremely small portion of the data, but I just can't demonstrate that at this moment --

Dr. Lipsztein: Okay.

Dr. Taulbee: -- but we hopefully can.

Dr. Lipsztein: Okay, we'll wait for it.

Dr. Taulbee: Thank you. Other questions?

(Simultaneous speaking.)

Dr. Lipsztein: -- the dose in relation to the question.

Dr. Taulbee: Are there other questions?

Mr. Barton: I have a comment if this is a time to bring it up or the Work Group can ask questions.

Mr. Kelly: Bob, may I make a comment?

Mr. Barton: Sure, I guess. It's not my meeting, but go ahead.

Mr. Kelly: So, I had a tremendous amount of difficulty understanding what I was looking at in terms of the logbooks to see this additional issue that comes up, you know, the previously unidentified one, I can understand that.

So, I'm a radiochemist and when I look at this, I don't really know what they did. I don't know where they get a chemical recovery for americium.

You know, there's no spectrometry, so there's no tracer. Do they assign a chemical recovery based on the spike, or batch, or whatever? I don't see any indication of that.

So, what I try to do is I try to find information that will convince me one way or another about what happened, and when I see this -- and perhaps I'm not being comprehensive at looking at everything, that's entirely possible, but based on everything I did look at, I still don't know what they did. It's not clear to me what kind of a radiometric instrument was used, what procedures, et cetera.

So, I have less concern with the issue of the variability, although I acknowledge that and it's interesting to hear that discussed, but my concerns go more to whether as a whole this body of information is adequate as objective evidence of a controlled process to produce something that was

quantifiable.

Chair Clawson: Who was that that was just speaking? I'm sorry. I didn't recognize the name.

Mr. Kelly: Sure, I'm Patrick Kelly. I work with Bob and Joyce for SC&A.

Chair Clawson: Okay, I just wanted to know who was talking.

Mr. Kelly: Sure.

Chair Clawson: Because to tell you the truth, I'm pretty well confused myself right now of what we've actually got here.

Mr. Kelly: Right, and that's my main point. I don't -- and the fact that there were logbook pages and that they're signed by someone, or that they had a program, that's all fine.

I mean, I think that's certainly good, but for me, in all candor, I'm probably applying a slightly higher degree of technical rigor to it, which may not be appropriate for this program, and if so, then, you know, that's fine, but that's just a little bit of orientation as to where I am coming from with some of the things I have written, or that I might have said or will be saying.

Member Ziemer: Could I comment? This is Ziemer. I assume those logbooks don't include all of the procedures. Wouldn't that be correct, Tim?

Dr. Taulbee: That is correct. They do not.

Member Ziemer: If the radiochemical procedures are elsewhere, maybe they should be made available to -- Bob Barton, to your colleagues. I think SC&A has access to what those radiochemical procedures were, so that would be useful for the radiochemists to look at if they hadn't.

Mr. Kelly: Yes, I saw that there were procedures. It's not clear what procedures were used exactly when,

over what time periods, nor is it clear how the recoveries are determined for the specific analytical protocols.

I don't -- you know, there is no spectrometry, and of course as you all know, you know, this is not just americium. It's all trivalent actinides, so that's fine, you know, americium, curium, californium, perhaps some thorium if that should be in there.

You know, so I look at this and I saw the procedures, but I still don't have a good sense based on this what we are really looking at in terms of the data.

Dr. Taulbee: Okay, I'm not sure. I mean, we can have our folks, you know, go over this more. You know, if you want to do, you know, the interviews of the radiochemists at the time, I mean, that's up to you all.

I can tell you from my read on the logbooks in particular, to me, the spikes and blanks were fairly understandable of what they were doing from that standpoint.

Now, the actual chemical process going through to do all of that, no, I don't -- I'm not a chemist from that standpoint, but it sounds like that you are and somebody who could understand all of that.

And again, that's where I would point to those papers that describe the process because they were more inclined to publish things like that versus having written down procedures on their methods within the radiochemistry laboratory. Those are things that they left to the radiochemists to do, so that's really all I can answer at this point.

But again, this is an open issue, Brad, just to circle back here. We just finished coding the data. Let us get it into a better quality review and in a form that we can present back to the Work Group, is kind of where I would like to go from this point forward with regard to the numbers.

Chair Clawson: That would be nice because right now, I'm really questioning even what we have, and it sounds like I'm not the only one that's questioning that. So, we'll have to address that and go from there, but we'll wait for your report to be able to be issued to SC&A on this then. Is that correct?

Dr. Taulbee: That's my standpoint, yes.

Chair Clawson: Okay.

Ms. Naylor: And this is Jenny. I'm also wondering if this is something that SC&A just needs to sort of have an internal pow-wow and sort of understanding or articulate to us what additional resources that you need to sort of help you understand what goes on in these logbooks and what other procedures or documents that you need.

Mr. Barton: Well, this is Bob. I think that a technical call, as we usually refer to them, could be warranted where we can send in writing certainly some clarifying questions and see what the NIOSH staff knows directly about our specific questions.

That might be helpful. I do agree we need to allow NIOSH to go in and recode the data and see how that affects this issue of variability.

I will say that, you know, we didn't do our own independent compilation of the logbook data. We were operating off of an electronic database that NIOSH had produced themselves. So, when we show this variability, we were working off of what was transcribed, which it sounds like there might be some errors in it.

So, to the extent that this coding effort and review by a health physicist of each new coded data point clears up some of our concerns, we simply don't know until that work is done.

One other comment I had, because one of the major points made in NIOSH's response is that, well, listen, at least in the guise of a co-exposure model, you're

taking these disk results. You average them. You might average more than one sample in a day for the worker.

Then you come up with a TWOPOS value for that worker for that year and you fit that to a distribution, and then you plug that into, you know, IMBA to come up with an intake rate over a range of a number of years, and so in the end, this variability essentially gets washed out, which I'm not arguing against that point, but I sort of disagree with that as an explanation.

I think you have to be able to explain sort of these variances that we point out and the adequacy of the data as a whole at the outset before it goes into the co-exposure machine.

We all agree on the machine, but I guess the old adage is that if it's, you know, bad or questionable going in, then what you get out is still bad and questionable.

So, I do disagree with the point that none of it really matters because it's all getting averaged so many times and fit to distributions that the end results, the variability will not affect. Obviously, that will not apply to an individual necessarily, but I think we need to get a better feel.

I mean, we're not saying that this data is necessarily bad. Our point is that we have several concerns that we don't feel that we have sufficient explanation or documentation of to give us confidence that it's adequate for these purposes.

And frankly, we point back to the co-exposure guidelines. This was the issue of why Dr. Neton put in that line about if you have multiple measurements of the same aliquot and they're showing widely different results, then their use in dose reconstruction really needs to be considered.

I understand that samples involved in chelation would be removed from the co-exposure guidelines,

but that does not necessarily explain the measurement method itself, and as NIOSH has agreed at the last meeting in December, that chelation is not a factor and does not explain the variability.

So, while I understand they're not using the co-exposure model, we still don't feel that we have had sufficient explanation for what we're seeing and what gives us pause here.

Again, we're not saying the data is necessarily bad, but if there's more information out there, we want to understand, as Patrick Kelly put it, what did they do and is that actually acceptable under the auspices of this program, and that's where we came up with our path forward which would involve some form of data capture at the site.

Now, Tim, you'd know much better than I what's potentially out there, and I think in the actual written response from NIOSH, you indicate that that information simply is not available, that perhaps you've already looked for it, looked through the EDWS system for evidence that that information is out there that might be beneficial to us.

So, I don't know what's out at the site. It could be that that information is simply gone forever, in which case we're left with what we have.

And again, the other aspect of that would be maybe we can talk to a few of these radiochemists and find out, and get real perspective on what they were doing out there.

Dr. Taulbee: The latter one there is probably your best path from that standpoint to try and locate additional procedures. We have located some procedures. They're in the Site Research Database and we've looked at those, and some of them are cited in the OTIB.

But further details on what it is they're doing, I believe, to answer some of Patrick's questions, your

potential path would be then to talk to some of the radiochemists from that standpoint -- from an interview-type of standpoint, and then they could also point you to what methods that they used.

I know, out at INL we learned from that particular site that the early procedures were -- not where they were actually documented in individual notebooks that they used, and there'd be one radiochemist that specialized in alpha, and one that specialized in others.

And so, they were the ones that did the analyst. These were typically doctoral-level radiochemists, and so they analyzed the samples themselves.

So, that might be the best path to go fastest forward from that standpoint. But I would urge you to look at, when we get the data, how it's been checked, as to is this still a significant issue with you all. Okay.

Mr. Barton: I agree completely. We need to see what you all produce.

Dr. Taulbee: Okay. And we will do that.

(Simultaneous speaking.)

Member Ziemer: Tim, this is Paul. I think Dr. Chalmers' suggestion on use of the coefficient of variability is really a good one, and that the SC&A also should take a look at that as they find that, as we think of the variability in these samples.

I'm sure that we have sort of an agreed-on -- in looking at that. I know that that variability has been bothering everybody. I like that suggestion that Dr. Chalmers had.

Dr. Taulbee: Excellent. Okay, and that's what we plan on doing in our response back to you, Brad, and the Work Group and SC&A with regards to this dataset.

Chair Clawson: I understand. As we get into this a little bit, though, I think that we do need to have a technical call with SC&A so that we're all on the same

page of what we're requesting to be done, what's going to help us. That's always helped out in the past. That good, Bob?

Mr. Barton: Yes, actually. Well, on Wednesday when we were discussing this internally at SC&A -- and that was the point where we weren't even sure if this was going to be still on the agenda -- but that was the sense of what our path forward was going to be, if it wasn't going to be on the agenda, was to formulate clarifying question, and we can see what we do know, what we don't know, and how that does it does not meet some of the concerns that we've laid out.

Dr. Taulbee: If you could forward us those questions ahead of time before the call, that would be much appreciated.

Mr. Barton: Absolutely.

Chair Clawson: Okay, that sounds good. I'd also like to just be able to listen to it, because I'm going to be right honest: you guys have got me pretty confused right now.

Dr. Taulbee: Sorry.

Chair Clawson: So, is this a path forward that we have to go now?

Dr. Taulbee: Yes, sir.

Chair Clawson: And NIOSH and SC&A both know what is required of them in this path?

Dr. Taulbee: NIOSH is clear.

Mr. Barton: Well, I guess from SC&A, we could use clear directions for the path forward, but it involved data capture. We're trying to find benchtop procedures, or the notebooks that can give you examples at Idaho.

I don't think we're going to do that yet. Or even if it's worth tracking down radiochemists yet until we see what that does in the recording of the data and the

review by health physicists, modification of the co-exposure model, and what they could do statistically with the coefficient of variation.

And then, I think SC&A core action item is to put together a list of clarifying questions for use in a future technical call, so that later on what we know, we know. And what we really should know, or what information is truly unavailable to us.

COURT REPORTER: Can I interrupt? There are two telephone callers, area code 314 and 817, who need to mute their lines. They are interfering with the conduct of the meeting.

Chair Clawson: I appreciate that. I was going to bring that up myself there.

Okay, so it sounds like the bulk of this is actually on NIOSH. And once NIOSH gets a little bit there, I guess the only thing I don't want, Tim, is to go through this whole process and then end up with more questions.

As we get a baseline here for it, I would like SC&A to be able to see the reports of this data that we've got, so that they can get their questions put in there too.

Maybe a technical call, one or two technical calls, may be in store for this. But I think that would be the best path forward.

Dr. Taulbee: I concur. I would ask that, instead of SC&A waiting until we get our report out, if you've got questions now about the bioassay and how to interpret the logbooks, if you could write those now to us, that would give us a little extra time to be working on it while we're doing the other.

So, that would be helpful to us, to work them in parallel, to join to a technical call that would be a little more productive, if that's okay.

Mr. Barton: I agree with you, Tim. We'll put those together. That's our action item going forward. We

won't wait for your report to put that together.

Dr. Taulbee: Okay, great. Thank you. Alright, are we ready to go onto the last topic?

Chair Clawson: Sure.

Dr. Taulbee: Okay. If I'm reading the agenda correctly, I'm going to give a brief primer, which is really just a reminder of the multiple imputation method, and then turn it over to Bob for the remainder.

So, this is just a brief primer on the multiple imputation process that we go through. And as we've been talking about earlier, the multiple imputation method is a better and more statistically appropriate method for estimating censored data, compared to the traditional LOD over two that we've used at the beginning of this program.

As the Dose Reconstruction Program has evolved, new, more robust statistical methods we believe can and should be expected to replace the initial methods and assumptions.

It's well-known that external dosimetry and bioassay data tend to follow log-normal distributions, and so we're trying to take use, or trying to apply those types of methods to improve our dose reconstruction methods.

One of them here is the multiple imputation method, so I'm going to go through this. There's basically five steps here.

And the first step that we do when we're doing multiple imputation, is a regression on ordered statistics of all of the bioassay data for a given year. Okay?

So, we lump it all together. And sometimes we do combine years, but generally, it's on a individual year. So, to keep it simple, that's how I'm going to talk about this.

And so, this effectively -- this regression creates an imputation model. We then use the imputation model to estimate and replace the censored data for an individual's data that are censored. Okay?

So, we take this imputation model, and let's say a person has a total of five bioassay results and three of them are censored. Okay? So, we will use this model -- this regression -- to estimate what those three results are that are censored.

We'll take that then, those five results, and we'll calculate a time-weighted one-person, one-statistic -- a TWOPOS value -- using the individual's data, which can be a combination of the uncensored data and the imputed data. Alright?

So, we repeat this process for each individual in that particular year, to obtain the first TWOPOS imputation. So, we're repeating steps two through four. We're doing this for each individual.

Then, we repeat steps two through four for the second imputation and the subsequent TWOPOS imputation. So, graphically, what this looks like is here.

This is the SRS imputation model for 1969. And what you'll see here on the left is the imputation model. This is all of the positive bioassay data for plutonium in that particular year. This is the regression on the ordered statistics.

So, for the first TWOPOS imputation -- that's the graph here now on the right -- this is all of the people. On the left was all of bioassay in 1969. On the right is all of the individual workers, all of the individual people. And so, you see that the end total goes from 892 down to 295.

And the color coding here is more for your benefit to understand this. The black dots up here at the top -- the upper end -- these are people who all of their bioassay was not censored. Okay? One hundred percent of their data was not censored.

The red dots here is where an individual worker has between -- well, less than 50 percent of their data was censored. So, somewhere between zero and 50 percent of their data was not censored.

And then the orange dots, as you're working down through here, is where between half to 99 percent, let's say, of their data was censored. Okay? We got 50 percent to 100 percent.

And then, the yellow is the people who all of their data was censored. So, all of these yellow dots is where their data was censored. We went to the imputation model and estimated what their result was. Okay? In the calculation of the TWOPOS.

So, this was the first imputation that came out. We then repeated that whole process, that step 5, over and over and over again, to where this is what we end up with. And this is all of the gray.

All of these are the multiple imputations, so you begin to see the banding or the spreading of the data at the ends. And we fit then the regression here to come up with that TWOPOS value for that particular year. So, this is what the imputation model's doing.

Now, keep in mind, this is TWOPOS. So, we're using the 50th percentile -- this is the 1969 data that I'm showing you here for non-construction trades workers -- this would be the DPM per-day value -- is .036.

And if you go up here, you see the geometric mean is .036; that's the 50th percentile. And the GSD is 3.142, from this particular model. And there's the GSD. So, the 84th percentile here is .1136. This would be 296 individuals.

But that's just for the TWOPOS data. But what I want to remind you of is that we take that particular data -- the TWOPOS data -- we use the 50th and the 84th percentile, and then we do the intake modeling for that co-exposure model. And in this particular case, the value we're looking at here is this 1969 datapoint

up here at .36.

And so, we're lumping the -- this would be '69, '68, '67 and 1970 -- into one band and we fit an intake to that to come up with our intake model. Alright?

And the intake model is what we use for the dose reconstruction. Alright? Not the TWOPOS values. TWOPOS values are used to come up with the intake model.

And in this time period of 1967 to 1970, we do this for the 50th percentile, we do this for the 84th percentile TWOPOS data, and then we calculate what the GSD is. In this case, it's 3.49.

And from this 3.49 then, we calculate the 95th percentile, which we were talking about much earlier with the stratification discussion, that is then one of the parameters or choices that we could use for a dose reconstruction. If this GSD is less than three, we round it up to 3.0, because that's our minimum uncertainty that we use from these TWOPOS values. And you see that for the 1955 to 1966 data, in order to get that 95th percentile.

So, this is just how this multiple imputation is used. Normally, the 50th percentile, with the full log-normal distribution, will be assigned to workers who've been exposed to greater than environmental, but less than a typical operations or considered high-potential exposure.

Workers considered to have the high potential for exposure may be assigned that 95th percentile. And again, this is all determined on a case-by-case basis by the dose reconstructor, using professional judgment.

So, with that, is there any questions on the multiple imputation, before Bob takes off, of the method?

Okay. Hearing none, Bob, it's all yours. And we can't hear you. There you go.

Mr. Barton: Yeah, just took myself off mute. Let me get my presentation up here.

Okay, I'm going to give just a little bit of a back story of the discussions back in December and how that's evolved over the past year. A lot of the heavy lifting was done by Dr. Carl Gogolak, who is on the call. And I'll give the presentation, but he's available to answer any questions you might have.

So, again, background, Kimberly just went through it, so that this is going to be really quick. But a lot of these datasets we deal have a large number of censored results. That's results of less than some detection limit, decision level, or some other predetermined threshold levels. All you'll have for bioassay result is less than some value.

So, the true value of that bioassay datapoint is somewhere between zero and that censoring level.

Co-exposure modeling -- again, I refer to it as the machine in the previous presentation, which we all agreed on -- but it requires statistical interpretation so you can fit these data in different distributions. Typically, it's the log-normal. We point out that some datasets have very large portions of censored data.

So again, the multiple imputation. Again, this is really just summarizing what Tim went through. NIOSH developed the methods to impute or infer censored data based on the positive results in the dataset, and this is all documented in Report 96, Multiple Imputation Applied to Bioassay Coworker Models, from 2019.

And the first application they actually saw of it in co-exposure models was for SRS, and that's the TIB-81 discussion that we had previously this afternoon.

So initially, our concerns when we saw it in the SRS co-exposure, we had one finding and one observation directly related to the use of that.

And what we saw was that when imputation was

used, we were getting estimates of the co-exposure bioassay results that would be modeled for the co-exposure intakes that were often much less than one-half of the minimum detectable activity.

And we noted that, well, you know, missed dose approaches, if you had a worker who was monitored and had a censored result, we treat it differently. You assume one-half the MDA.

Again, this was Finding 2. So, that raised our eyebrows. We hadn't reviewed Report 96 in its entirety yet, but we're looking at the results and saying, wow, you're getting some really small results, again compared to that one-half the minimum detectable activity, which immediately raised flags with us.

There's Observation 1, the method is mathematically correct but has the potential to bias results low, and we note that in that observation.

The previous method, called the maximum possible mean method, may be preferable. And that maximum possible mean method would essentially replace or substitute that censored result at the censoring level.

So, if the bioassay result was less than three, we were just going to assume that it's three. That was the previous method prior to imputation.

So, again, we discussed those findings and observations related to the SRS co-exposure models back in December of 2019 at the joint meeting of SRS and SEC Issues. And at that time, we were tasked with performing a broader technical evaluation, essentially tasked with reviewing Report 96, which details how this entire process is done.

So, this past June when we delivered a technical memorandum, Review of Multiple Imputation Methods Applied to Censored Bioassay Datasets -- and that was in June, and again, Dr. Carl Gogolak who is on the call -- thankfully, all the technical

review and literature review of this method as a statistician, as I would fall woefully short myself.

So, some relevant literature that we found related to this -- and I really love the title, the Helsel 2009, Much Ado About Next To Nothing, Incorporating Non-Detects In Science -- and these are two quotes from that work. The first one I'll read into the record.

In general, do not use substitution. Substitution is not imputation, which implies using a model, such as the relationship with a correlated variable, to impute or estimate the value.

The second one is, method of valuations for estimating a mean do not necessarily carry over to the more difficult issues of how to compute interval estimates, upper percentiles, correlation coefficient, regression, slope and intercept.

There's more work from Helsel, and this is actually from 2020. And it's actually titled, Why Not Substitute 1/2 Detection Limit for Non-Detects. And Helsel 2020 notes, this creates problems of what he terms invasive data.

For example, the artificial lowering of the standard deviation, which of course is going to affect your upper percentiles and how the data is ultimately used in co-exposure modeling.

And he also noted that using substitution, such as one-half the detection limit, may create artificial trends in the data that do not actually exist.

And these problems are especially problematic for datasets with multiple censoring levels. For example, if you have bioassay methods, the limit of detection improved over time.

So, some general technical comments that we have. Again, it's in a technical memorandum, which is available under the SRS website. I don't believe it's posted on the Meetings page, but if you go to SRS, you'll find it towards the bottom on all these White

Papers and discussion papers related to SRS.

So, just three real technical comments here, based on our review, is that multiple imputation uses information in the detected data, if that's in the positive results, to generate values below the detection limit.

Co-exposure modeling generally assumes a common log-normal distribution. Detected and non-detect data come from the same distribution.

Therefore, imputation uses more of the available information in the dataset than a substitution approach would. So, in that sense, imputation is statistically preferable.

Unquestioned is, when you get to a point where you just have so much censored data that imputation really doesn't make much sense.

I'm probably going to mess up this name but I'll try it. Krishnamoorthy, et al., a 2009 document, suggests that the performance of any imputation model is really more dependent on the total numbered of censored results you have, than on the proportion or percentage of censored results in a given dataset.

And SC&A agrees with that. And we don't recommend any universal upper limit on the percentage of censored results for that reason. It's really about the total number, not the percentage.

So, it's sort of variable on the size of the dataset there. And so, each time we use this imputation method, you've really got to evaluate it individually, again with the emphasis on the total number of uncensored results when applying imputation. And we provide one very basic example.

In other words, if you have a dataset of ten and only one of those ten results was above your detection limit and the other nine were censored, using imputation may be problematic. Whereas, if you had

a dataset of 100, and ten of them are positive above the detection limit and the other 90 are censored, then it may be okay to use imputation. So, we just offer that caution there.

There were several cases -- and this is a topic for NIOSH's consideration. It's not a finding. I guess you could consider it an observation, although we didn't put it in as such in our review, we just basically had a conclusion.

But NIOSH may want to consider this because we noted that several examples in Report 96 indicate a mix of positive and negative values, i.e., some values do not have a log with which to use.

A document from way back in 1957, Aitchison and Brown, discuss an alternate distribution called a delta, which is really a mixture of log-normal and a discrete probability at zero.

Dr. Carl Gogolak, who did this review, in 1986, actually describes methods for estimating the three key parameters, the delta, the mu and the sigma.

So, we offer this up, that NIOSH may want to consider the delta distribution when using imputation methods when a large portion of unexposed workers are mixed with a much smaller proportion of exposed workers.

Alright, what does this really mean in terms of dose reconstruction? So, SC&A 2020A, which was a revision to our coworker model review, which was discussed last December, the change was basically to change one finding to an observation and add some clarifying language as a result of December, so there's not a real big change.

But essentially, in our original review as well, we did some scoping calculations to compare how does these imputed values, which I noted earlier, could be much less than one-half the MDA?

If we do some sample calculations and compare that

method using imputation to a standard missed dose approach, what do we see? So, we did evaluations for strontium-90, cobalt-60, neptunium-237, plutonium-239, and uranium-234.

And what we found when we did those comparisons of this imputation method and the missed dose method, is that intakes and doses calculated are much higher from this -- well, not much higher, but appreciably higher, when you use the missed dose method.

But actually, when you carry the calculation all the way through to a resulting Probability of Causation, there's really very, very little difference that we observe. And that was Observation 2.

Also, we found that, specific to uranium when we did this, the imputed co-exposure values were actually -- and when I say values, I mean the doses here, were actually a factor of four higher than the missed dose approach.

So, you can only see smaller values, compared to the MDA or one-half the MDA, using imputation. The doses are higher from this but the imputed co-exposure doses are either very comparable or, in the case of uranium, were actually bounding on the missed dose approach.

And you say, well, how can that be? If the intakes and doses are so much higher from missed dose, why is there no follow-through effect on the Probability of Causation?

And what we hypothesize here is that it's really the effect of the uncertainty on Probability of Causation when you're applying a co-exposure assignment.

So, in essence, when you look at missed dose, you calculate a dose, but then when you calculate the Probability of Causation, you're using a triangular distribution, with the dose being the mode, the minimum at zero and the maximum at censoring level itself.

And this is just a note on 95th percentile. I don't want to get into this too much because we talked a lot about that this morning.

But what I note here is that if you use the 95th percentile of these co-exposure models, you're likely looking at the uncensored portion. That is the actual positive results feeding into that upper percentile.

I mean, if you had just an incredible number of censored results, that may not be the case, but it would be logical that if they're going to apply the 95th percentile, imputation wouldn't even really factor in all that much.

So, just to summarize our technical evaluation of the method multiple imputation as a whole, because this was first applied at SRS, but it's really to be applied at all of co-exposure models going forward. And so, we have a number of bullets here and I'll read them in.

Multiple imputation is mathematically correct, an accurate method for assessing censored bioassay data in the absence of other information. For example, raw data measurements, if they're available, which was the case at SRS for at least plutonium and americium.

We also note that the total number of uncensored results, rather than the percentage, should be used when you evaluate what the appropriate statistical method is and whether multiple imputation should really be used.

So, again, it's the total number that you have that are positive to infer the ones that are censored, rather than just the percentage. And that was that really simplified example I gave earlier, where you have one out of ten uncensored results versus ten out of 100 uncensored results.

One out of ten may be problematic, ten out of 100 might not be, even though that's the same percentage. It's the total number.

I mentioned the delta distribution as one option they may want to consider as integrating into their methods for co-exposure when you have large proportions of unexposed workers mixed with a much smaller proportion of exposed workers.

And that would be the situation when sometimes the log-normal fits are really less than ideal.

And we noted, again, substitution as described in Helsel in comparison to imputation has many analytical drawbacks, such as the artificial lowering of the uncertainty of the geometric standard deviation.

And then, finally, what is the effect on actual dose reconstruction? And as I just went through, scoping calculations indicate very little practical difference in Probability of Causation values, when evaluated at 50th percentile.

And I described that that's really because of the effect of applying uncertainty to co-exposure assignment, whereas it's a completely different approach for missed dose.

And then, that note about unmonitored workers can be assigned the 95th percentile, which is likely reflective of the actual monitored results. Imputation would have less of an effect on that.

So, in summary, conclusion, SC&A finds that the use of multiple imputation and evaluation of bioassay datasets, the censored results, is technically appropriate, scientifically defensible, and likely of small practical significance when considering its effect on the resulting PoC calculations. And here's all the references that are provided in there, including the Helsel papers.

Some of them are available online. And again, the NIOSH co-exposure model, which is going to be revised at least for americium, but Rev 4 is available on the website. And then, our actual technical review of Report 96 is there as well on the SRS page, but

you have the link right there. That's that last bullet.

So, if there are any questions, I know Dr. Gogolak is on the line. I don't know if he wants to add anything to the presentation I just gave, or we can field any questions that the Work Group might have.

I'm glad this one went last, because it's lot easier one. There's very little disagreement, just the one technical suggestion for using that delta distribution in certain situations.

Chair Clawson: Are there any questions from members of the Work Group?

Member Lockey: Well, it sounds like there's agreement.

Member Beach: Yeah, Brad, this is Josie. I don't have any now.

Chair Anderson: Just a quick question. For some of these elements, you'll have a background exposure level. So, with imputation, you put assigned values that are going to be -- you will assign at least some values that are going to be lower than what is the background exposure levels for individuals.

Dr. Taulbee: Is there a question?

Chair Anderson: Well, I was wondering if, then, one could assume you would not impute below what background level exposure is.

Dr. Taulbee: Yes. I believe that's correct.

Chair Anderson: I don't think that's in your model. I mean, now we're really getting into -- I mean, don't spend time, I'm just saying that. It seems to be one thing I would --

(Audio interference.)

Chair Anderson: -- where there is a background level.

Dr. Taulbee: Right.

Chair Anderson: And you're assuming their work environments are cleaner than what the background is, and for some of these, that may not be true.

So it's just a word of caution more than build it in, but you need to be aware in some instances for some datasets that may be where the imputation, when it seems to be very low compared to the other methods.

Dr. Taulbee: Okay. Understand. Thank you.

Member Ziemer: Question, Tim, or Bob, I guess, or both. This is Paul. I assume this is sort of universal. This is not just Savannah River. This is an approach you're planning to use throughout the whole system. Isn't that correct?

Dr. Taulbee: That is correct. Yes.

Member Ziemer: Yes.

Dr. Taulbee: For both internal and external.

Member Ziemer: I don't know if we have to approve it at all. I think it sounds fine and looks like both SC&A and NIOSH are in agreement that it's an appropriate approach. I'm certainly good with it.

Dr. Taulbee: Thank you, Paul.

Chair Clawson: Well, that brings up a question, though. Is there anything, as the SRS Work Group meeting, because this is kind of the difficulty that I've been having, is some of these are overarching issues, but they pertain only to SRS too, so I just want to make sure, is there an action that we need to take on this, Tim or Bob, as the SRS Work Group?

Dr. Taulbee: This is Tim. I don't believe so, because I believe from the SRS standpoint, you close them out earlier, as you went through with John, on the OTIB-81. And so, really, I believe everything's closed from SRS. Do you concur with that, Bob?

Mr. Barton: Yeah, that's what we went through with

John's presentation. And we sort of perfunctorily closed them out. Just based on this presentation that we're about to give, there really isn't any disagreement on the use of imputation.

So, while we had some concerns about the results we were seeing in that co-exposure model, we decided, you know, it just really doesn't have a practical difference compared to missed dose when you're talking about Probability of Causation, and we find it to be technically accurate.

When Dr. Gogolak did the research, to really look at the model as a whole, not just for SRS, but the entire complex, the entire program, we're in agreement with NIOSH that we think that this, while not perfect, it's the best currently proposed method for dealing with this, and we don't have a better suggestion, and we think it's probably an improvement over what was there before from a scientific standpoint.

(Simultaneous speaking.)

Mr. Barton: I'm not sure if that answers your question, but we did close those out earlier in the day when John was going through the update on TIB-81, because of this session that we're about to have.

We closed them then, but I think we would have come back and closed them anyway, just based on our agreement with Report 96.

Chair Clawson: And I appreciate that. I just wanted to make sure that we captured them all, because there were some questions at the beginning of this that you thought we'd -- NIOSH thought we'd closed them, but there wasn't anything, and so I just wanted to make sure that we're correct on all of these.

Chair Anderson: The only other thing I would add, you did raise the question and there isn't -- no one agreed on cut point, and that's on the number of detectable occurrences in a dataset before you can use imputed values.

I'm just going back to my environmental health days with VCVs, and then wanting to sum up all of the conjoiners. In some of the conjoiners, you won't detect them all.

And so, how you can end up with an exposure that's all made up, basically, because you're adopting one-half the limit of detection, some imputation there, it might be very helpful.

So, I think we just have to, again, not routinely do things without thinking about the datasets that we're applying this to, would, I think, like here you have so many in the dataset that are really -- it's not an issue, other than to comment how many there are that are detectable in the system.

Dr. Taulbee: I agree and understand.

Chair Anderson: And that would also be an argument for not going into the subgroups, because you can end up with small detect numbers in all the subgroups.

Mr. Barton: Yeah, Dr. Anderson, in response to that, I think, as we pointed out in our paper and in the presentation, I think these have to be looked at on a case-by-case basis whether imputation is truly appropriate.

In a situation where there's all censored results, I'm not sure how you would impute anything anyway. But yeah, I think that's a case-by-case basis.

So, this is going to be used in other sites. So, I guess (Audio interference) your evaluation, the appropriate --

Chair Anderson: The problem you want to avoid is you don't want to think about it, make a decision, rather than simply you push the button like you do now in running your SAS statistics and you get 75 pages of numbers and statistics, and really are irrelevant to what you're doing. You just have to be sure you're thinking about what you're doing.

Mr. Barton: Point taken.

Dr. Taulbee: Agreed.

Chair Clawson: Okay, do we have anything else that needs to come before the Work Group, or for the overarching work? Do we have anything, Paul? Is your group fine?

Chair Anderson: We're going to leave it all up to you, Brad.

Chair Clawson: Well, I appreciate that, Andy. I've still got a lot of questions, but I will wait for those reports to come out.

I was going to -- if we have no more further business, I was going to see if the petitioners had anything that they'd like to be able to say, but I want to make sure we had covered everything that we need to in this session.

Issue 7: Petitioner Comments

Tim? Bob? Joe? Is there anything more that needs to come?

Dr. Taulbee: The only thing that I have is, what do you need from NIOSH, or what do you plan for the Board meeting coming up in December? And I don't know if you wanted to wait until after the petitioners talk about that, or what is it that you are requesting from NIOSH to support that meeting?

Chair Clawson: Well, right now, and I appreciate -- I do have out to the Work Group right now some wording for the SEC for Savannah River. But I wanted to get their input before we send it to you.

I think it's going to come down to that, in this Board meeting -- and, Rashaun, you're going to have to chime in on this one -- we've got to bring the full Board up to kind of where we're at, where and why we've gotten where we did.

So, I figure that there'd be about a 30-minute

presentation from each side explaining where we're at, what we're doing, and why we've come to this point. And so, that's kind of what I'm expecting from both sides.

Issue 8: Work Group Discussion

Member Lockey: Hey, Brad?

Chair Clawson: What, Jim?

Member Lockey: I agree with you, but I don't think 30 minutes is going to be an adequate amount of time.

Chair Clawson: Well, we could put another two or three days on to it if you'd like.

Member Lockey: No, I don't want to do that, Brad. I just don't think 30 minutes. I would say this is probably going to take the afternoon at the meeting. So, I don't think 30 minutes in discussion is going to do it because I think there's a lot of different issues here that I think we need to bring in front of the Board that we need to allow time for people to really understand our process and our thinking as thoroughly as they can in the time limit we have.

Dr. Roberts: I'm sorry to interrupt. Right now there's an hour-and-a-half allocated on the agenda for SRS. How much more time would be appropriate?

Member Lockey: I would say a total of three hours. That's what I would say. And if we get through it faster than that, that'd be great.

Dr. Roberts: Okay. And while I'm on, there's someone with the phone number ending in 661, I keep hearing typing, or some interference in the background. So, if you could mute, please.

Member Ziemer: I don't know. Three hours seems like a long time for this.

Member Lockey: Well, Paul, you were saying that some of the presentations we heard on Tuesday,

you'd like to see presented also at the Board meeting. So, that's why I was saying that. But if you don't think that's important, I'm okay with that.

Member Ziemer: Well, my thought is, at this point we still have, I believe, SC&A needs to cover why they believe dose reconstruction cannot be done, and NIOSH should explain why they believe it can be done, because that's really the decision, aside from the issue that this has gone on a long time.

You can end the time issue either way. But in fairness, the Board needs to hear both viewpoints. And then, to have the recommendation from the Work Group as to why they have determined that they recommend an SEC. But the Board needs to hear both sides of the issue, certainly.

Chair Clawson: And Paul, when I made the comment about time, time, you're right, doesn't play into it. But I just want to remind everybody that it has been a long time --

Member Ziemer: Oh yeah. Yeah. Well, I understand that, Brad.

Chair Clawson: And it comes down to --

Member Ziemer: And we're not going to make the decision on that basis. I want to make sure in the record that the Board -- and I think Jenny has stressed this -- the Board has to make it very clear why they are going in a particular direction, because that has to go through the Secretary and on up through the White House.

Chair Clawson: And I understand that. I will tell you, Jim, what I was looking at. And that's why I said at least a half-hour.

Hit the high points on this. We could go into -- well, let me ask both sides of it. How much time does SC&A and NIOSH feel that they'd need to do a brief description of where they're at?

Because this comes down to data completeness, period. And so, all the other stuff we'll have to deal with. But it comes down to that one issue.

And that's why I feel that we really don't need that much more time. But I also want to make sure that each side has adequate time to express what they want to.

Member Lockey: Well, Brad, I agree with you about we're not going to -- spending another year on this is not going to be helpful. But I just want to make sure that there's enough time with the Board that everybody understands that this is as far as we can go with this in regard to data completeness, and this is how our subgroup made the decision.

Chair Clawson: I understand. I do.

Member Lockey: Okay.

Chair Clawson: Josie?

Member Beach: Yeah, I was just going to say the Board members need to have enough time to ask questions and have their questions answered so the Board members feel comfortable.

Because they're not enmeshed in this data like the SRS Work Group and maybe the SEC Work Group is. So, you need enough time for that.

Dr. Taulbee: I would like to propose, back to what Dr. Lockey was saying, of setting aside a three-hour interval. And I know that sounds long, but keep in mind we've been going at this now for almost six hours.

But the reason I would propose this is if you look at the current agenda, on the second day we run from 1:00 to 4:15, which is three hours, to where the other agenda items could be moved up to Day 1, and then SRS could be all day on Wednesday, December 9, and it would fit within that and it would be the last agenda item, and we run as long as we can, or as

long as needed for the Board.

I can certainly wrap up our presentation. Thirty minutes is pushing it, but I can certainly do it 30 to 45 minutes, not a problem. I don't need to go longer than 45 minutes. Just thinking of some of my past presentations.

And if SC&A was the same, that would be an hour-and-a-half, and give the Board an hour-and-a-half to decide. And if they finish up early, then the meeting's over. There's nothing else to wait. There's no dead time. Just my suggestion.

Chair Clawson: And that's a good suggestion, too. Well, I figure we almost have more than half the Board members right now on this phone call.

Member Ziemer: I was going to say that. Fortunately, a good fraction of the Board is already up to speed on it.

Chair Clawson: Up to speed on it. So, I agree with that. Let's do that and put it there. It's just I want the petitioners to be able to have an opportunity to have their voice heard on this too, especially where we're coming into it like this.

And so, that's why I was just holding for a more precise time. But that's fine with me. Would that work with you, Rashaun?

Dr. Roberts: Yeah, I think that's an easy enough adjustment to make. I'll work on moving some items and things around. But it should be possible to accommodate what's being recommended for at least the three-hour block.

Mr. Fitzgerald: Yeah. Brad, we'll aim to -- quite independent of what Jim just said, I thought 45 minutes was probably about right. So, that's an hour-and-a-half.

That's half the time would be presentations, and the other half would be discussion and questions.

Chair Clawson: Okay.

Member Lockey: Plus, Brad, the other thing is, I suspect the wordsmithing on this letter is really going to have to be very precise. So, I think that's going to take us a little time.

A lot will be done before the meeting, but I suspect there will be additional suggestions or changes actually at the Board meeting too.

Chair Clawson: Okay. You kind of blurred out there at the end of it. I think I fell asleep. But no, my feed was going out of there.

Member Lockey: That's because you're in Idaho.

Chair Clawson: You're absolutely right. And if you've read it, it is pretty precise.

Member Lockey: It is very precise. I have more comments to send you now after today. And I think as I drive to Utah, I'll have even more.

Chair Clawson: Oh, great. Okay. Well, I want to tell everybody how much I appreciate all of the work. I know that we laugh and joke and we poke a lot of fun, but this has been a lot of work.

And I know that everybody here has the best intentions for the petitioners, for our government, for everything. And I just wanted to say thank you. And I appreciate the professionalism in which all of you have demonstrated in this.

And it's been a long time and I really, truly appreciate it. Rashaun, she's only got the last few hours, not the last 13 years that we've been doing this. So, it is what it is.

But is there anything that needs to come before the SRS Work Group as a path forward? Does NIOSH need any further direction on what is requested of you on the sampling?

Dr. Taulbee: No. We are clear as to what we need to

do and we will prepare a presentation of why we believe dose reconstruction's feasible, and look forward to presenting.

Chair Clawson: Okay. That being said too though, a little bit earlier there was, on the sampling of -- what was that? I think, was it with 81 that we had the discussion on the -- yeah, whatever.

You guys will figure it out. We'll go on from there. So, is there anything that needs to come before the Work Group? If you would get in to me your comments on the wording for this so I can get it sent up to NIOSH and other members, I would appreciate it. With that being said, is there any -- do we need to bring anything else up at this time? That being said -- what? Go ahead.

Member Ziemer: Enjoy Thanksgiving.

Dr. Roberts: Brad, I just wondered about the petitioners, offering the petitioners comment -- time to comment now.

Chair Clawson: If any petitioners are the phone would like to make a comment, now is your opportunity.

Not hearing any, Rashaun, I would say that this meeting's adjourned for the day.

Adjournment

Dr. Roberts: Yes, I agree. And I would just like to echo the appreciation that you expressed for NIOSH and SC&A and the Work Group members for working hard in this meeting, and for all the materials and the work that SC&A and NIOSH worked to develop.

Just much appreciation for that. And I'd like to send a special thinks to Dr. Cardarelli, who really played a crucial role in making sure that we had all the materials and presentations together.

So, I really do appreciate his coordination. So, with that said, happy Thanksgiving everybody, and thanks a million.

Chair Clawson: Okay.

(Whereupon, the above-entitled matter went off the record at 4:08 p.m.)