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

+ + + + +

ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

+ + + + +

SEC ISSUES WORK GROUP

+ + + + +

TUESDAY
MARCH 10, 2015

+ + + + +

The Work Group convened by teleconference, at 1:00 p.m. Eastern Daylight Time, James M. Melius, Chairman, presiding.

PRESENT:

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

ALSO PRESENT:

TED KATZ, Designated Federal Official
TERRIE BARRIE
BOB BARTON, SC&A
LIZ BRACKETT, ORAU Team
NANCY CHALMERS, ORAU Team
HARRY CHMELYNSKI, SC&A
JOE FITZGERALD, SC&A
TOM LABONE, ORAU Team
JENNY LIN, HHS
JOYCE LIPSZTEIN, SC&A
ARJUN MAKHIJANI, SC&A
DAN MCKEEL
JOHN MAURO, SC&A
JIM NETON, DCAS
DANIEL STANCESCU, DCAS
JOHN STIVER, SC&A
TIM TAULBEE, DCAS

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

(1:01 p.m.)

MR. KATZ: Welcome, everyone. This is the Advisory Board on Radiation and Worker Health, the SEC Issues Work Group.

For our meeting today, we're talking about coworker modeling implementation guidelines, and we also are, because it's related to that sort of by example talking about one of the coworker models for the Savannah River Site. So, when I go through roll call for all Agency-related personnel, please also speak to conflict of interest when we do that. So, let's get started with roll call starting with the Board Members, please.

(Roll call.)

MR. KATZ: All right. So, the agenda is on the NIOSH website, as well as the two documents related to the agenda today. It's guidelines, draft guidelines for coworker modeling, and also Savannah River Site -- a couple of documents

related to Savannah River Site. And, Jim, it's your meeting.

CHAIRMAN MELIUS: Okay. Thank you, Ted, and thanks, everybody for joining us.

We're going to separate the meeting into two parts. The first part we'll talk about the --- it's called Revision 4 of the Draft Criteria for the Evaluation and Use of Coworker Data Sets. And there's a document that Jim Neton and others have put together, but it came out of a number of discussions within this Work Group, and with this Work Group, and NIOSH, and SC&A about how best to approach the evaluation of coworker data sets. So, I believe probably the easiest way we've dealt with these before is if, Jim Neton, you want to walk us through sort of what the updates are. We don't have to go through every detail but sort of generally where you've made changes since the last time, and I think that'll open it up for discussion.

DR. NETON: Okay, Dr. Melius, thanks.

Can everybody see the document on their monitors, or no?

MEMBER BEACH: I have the document in paper form. Do we have to see it on the monitor?

DR. NETON: Well, if anybody's on Live Meeting can they see it?

MR. KATZ: Yes, it's there, Jim.

DR. NETON: Okay, that's all I want to know. I couldn't tell if it got up there. My computer went wild and started making like multiple iterations of the same file.

MR. KATZ: Right, I saw that, but it's there. It's fine right now.

DR. NETON: Okay. So, those are on Live Meeting. I want to just kind of use it as a background template for us to speak from, but everyone should have a copy of Revision 4 that was issued February 26, 2015.

I went back and reviewed the transcripts of the last Board meeting where we

presented Revision 3 and didn't see a lot - didn't receive a lot of comments on that document. Actually, I don't think I received any from the Advisory Board. I got a few internal NIOSH comments, so I took it and revised this from Rev. 3 which was issued October 30th, 2014.

Not a ton has changed here. I did move some things around and added a few new pieces, though. Mostly, the first thing I did was I moved Section 2.3, the old Section 2.3 which was titled, bear with me, "Applicability of Monitoring Data to Unmonitored Workers." I moved it to Section 3.1 because I felt that it fit better there, and I thought it improved the readability, so that just in total moved over there. And then I added some language to Section 3 at the beginning of --- where did I do that? At the very beginning of Section 3 there's some new language, some introductory language. It talks about the finalized coworker data sets and sort of a configuration control

section.

We had some internal discussions within NIOSH and felt that this is a pretty important aspect. It's sort of what you see in epidemiologic research where they would call it cleaning the data set or something to that effect where you go through the data set, especially if it's electronic, and start looking at outliers and things that don't belong there, like maybe chelated samples. You need to do that, but we also need to be very systematic in how we control those various sets so that we can go back in time later and at least figure out what we did to get where we are. I think it's a very important piece of that, so that whole first introductory section was added there. I don't know if you've had a chance to read it. Not very long, but I think it's important.

And, finally, in Section 4, I debated a bit about this. I indicated the last time we met that I need to think about this evaluation of

stratification and what we're going to do about data analysis.

The statistics -- I think in looking at this document, I went back and looked at the original review of ORAU Report 53 which is how to analyze for stratification, and SC&A came back and had five findings -- or eight findings. And I think in this document now I've addressed --- we've addressed at least five of those findings to some extent. Not that we've addressed them, but we've formally put the criteria in here that they believed were lacking in the analysis of stratification, such as the data completeness and such. The three remaining findings that have not been addressed relate to the statistical analysis.

Now, I think that this document itself sort of walks you through a qualitative analysis of a data set such that you really end up stratifying in a lot of locations where we might not have previously. For example, when it talks

about stratification of incident versus routine. That's sort of a --- that is a default recommendation in the document. So, as you go through this you end up stratifying for various reasons other than doing a statistical test.

I do believe, though, at some point we're going to get down to the situation where we have a remaining set that, for instance, is all routine data that we still believe that stratification could be necessary. An example may be reactor operators at Savannah River who were exposed to tritium versus others. And I've outlined in this section now the three criteria where we may --- the three evaluation criteria where we may end up requiring some test of stratification.

There's no way around doing some sort of statistical tests. I didn't want this document to be the holdup in moving forward with the good stuff that's preceded in here, so I took and made the statistical evaluation criteria a little less

prescriptive. I said that it needed to be done, but I didn't include in here the exact statistical test that needs to be done to demonstrate that these data sets should be stratified, so that's where I ended up with this document. That in a nutshell is where we are at this point.

CHAIRMAN MELIUS: Very good, Jim. And, actually, I think I --- I more than think. I do agree with your approach. I'm worried about this becoming overly prescriptive because I don't think that would be appropriate given the, sort of, wide range of situations which we encounter at different sites and so forth. And I think it's very hard for us without specific example, or a set of specific examples to really under --- you know, we don't want to be overly prescriptive because I think we have to look at the situations. And I think, again, like we did with our SEC evaluation documents, I think what we're trying to put forward is sort of what's the general approach, and then what should

be considered in developing and evaluating coworker models, and then those should be addressed in whatever report would come from NIOSH, and then we can evaluate it on a sort of a case by case basis. So, I think the approach you've taken is the best approach.

DR. NETON: Thank you.

CHAIRMAN MELIUS: And I agree, some of the statistical considerations, I almost would think that, you know, it might be best dealing with them on an individual basis. You know, is this --- or something meets the other criteria and you're coming down to where you have to make a statistical analysis as to whether or not the stratification of a coworker model is appropriate. Then we would, you know, address that, you know, as that specific example. I think it's going to be hard to generalize on that because there are just so many different situations that might change our evaluation of that statistical analysis.

DR. NETON: Yes, I agree. I think the first three sections are going to sort of triage out the easier ones that don't --- we will stratify without even the requirement for a statistical test.

CHAIRMAN MELIUS: Yes.

DR. NETON: You know, such as the incident-driven construction trades monitors, ones that are monitored that way versus the overall routine monitored workers. I think it will address a lot of the issues that we've had, but it still does allow for us to get down to the statistical analysis at the very end of the day, if that needs to be done.

CHAIRMAN MELIUS: Yes, and my favorite example is the --- a little bit different than yours, but it's the one of where there's only a few missing data points, a very small percentage are missing. You're sort of using a coworker model to fill those in, then I'm not sure that we need to

worry a lot about the statistical force of that; whereas, if it's a huge gap that we're trying to fill where there's been no data, or very little data collected, then I think we have to give a lot more scrutiny to what we're doing because statistically that's a lot more difficult to do, or may be a lot more difficult to do. It depends on lots of other factors there. But I think we would get that from the beginning of this, so the one through three.

MEMBER ROESSLER: Jim, this is Gen. I'd like to make an overall comment on the paper. I read it in its revised form, and probably from my perspective as an editor, or maybe a has-been editor, I'm always looking for things that have scientific value, and this is so well-written, it's so precise, and it outlines things I think so well with regard to using coworker data.

You know, people can say well, you really can't do it, or you can do it, but this goes through and it outlines the situations where it

could work, and how it can be accomplished. And I'm just wondering if it would have --- could be published somewhere in the broader literature. It would seem there may be other places where this information really would be useful.

DR. NETON: I appreciate those comments, Gen. It's certainly within the realm of possibility that we could do something like that. I hadn't really thought about that. You know, there aren't many programs that do what we do. This is a very sort of specific little niche business that we're doing, but let's think about it.

CHAIRMAN MELIUS: Yes. This is Jim Melius, again. I was going to say there's probably a fair amount written in the epidemiological literature, the occupational epidemiology where people are, you know, developing exposure models and so forth. But really the criteria there are different than in a compensation program.

MEMBER ROESSLER: There may be other

compensation --- I mean, there are other compensation programs ---

CHAIRMAN MELIUS: Yes.

MEMBER ROESSLER: --- so that this might be general enough that it could be used. This is --- it seems NIOSH is putting so much in with the review by SC&A, and the Board, and so on. There's so much effort going into this, and when you come up with something that to me is so well-written and has so many important points in it, it's a shame to just have it buried somewhere.

CHAIRMAN MELIUS: Yes. No, I agree with you, Gen. Other Board Member comments?

MEMBER ZIEMER: This is Ziemer. I'll make a general comment. Again, I concur with Jim Neton's approach on this, particularly on Section 4. I think that's where you've got to land. This is a criteria document where you lay out kind of a roadmap and the individual statistical analyses needs to be very site-specific in almost every

case, so I think this is the right approach. I also would concur with Gen's comment, but probably not a decision this Work Group can make on whether to publish this. But, anyway, I'm very comfortable with what the NIOSH approach here is on this particular document.

CHAIRMAN MELIUS: Well, I don't know, Paul, we're always giving Jim Neton lots of work to do, so ---

DR. NETON: Yes.

MEMBER ROESSLER: It's just a suggestion.

CHAIRMAN MELIUS: No, no, it's good. It was a good suggestion.

MEMBER BEACH: This is Josie. I agree with all the comments. I thought it was well-written, and it explained a lot for my benefit.

CHAIRMAN MELIUS: Okay, thank you. SC&A, you have so many people on the line, I don't

know where to start.

MR. BARTON: This is Bob Barton. It's not so much a comment, but I guess just a clarifying question. During previous discussions on the stratification issue, notably the meeting we had, teleconference last October, it seemed like, you know, based on the transcript and what I recollected from that meeting that the approach is almost --- it's almost sort of a qualitative approach to whether you stratify. And I think the discussion sort of went something along the lines of if you have a legitimate reason to believe that you have two groups of workers that are different, and you have enough samples to build two distributions, and it meets all the other criteria that's spelled out in Sections 1-3 of the Implementation Guide, then just go ahead and build two coworker models, and see where the chips fall.

And then you still have the statistical comparisons for situations where maybe it's not as

clear, or you have a population of workers who are all routine, for example, where you would apply the statistics. But when you had situations such that, you know, for example, I think you mentioned earlier on this call, you know, a routine monitored population versus an incident-driven, that you wouldn't even need to apply the statistics, necessarily. If you have a legitimate reason to believe these two groups are different, just go ahead and build the two coworker models. At least that was my impression. So I guess, one, is that a correct impression? And, two, is it still NIOSH's sort of feeling on the matter?

DR. NETON: Bob, I think you've hit it just right. I believe somewhere in here I mention that --- in the applicability section --- it's certainly our --- oh, yes, here. The second full paragraph on page 9 talks about different sites who have been monitored for different purposes. It talks about construction trades workers who were

intermittently monitored or only when an incident occurred, while those employees involved in routine operations would have been routinely monitored.

In this case, it would not be appropriate to combine the monitoring data for these two groups into a single coworker model that assumes a chronic exposure pattern; rather, the default in this case should be to consider separate coworker models. So, that's definitely prescribed in here pretty clearly, I think.

The idea is that, you know, if we go down this sort of criteria, one, two, three, and then you end up and you say okay, I'm at step four, and I still have what looks to be a routinely monitored workforce, and I have a very wide range of job descriptions, I tried to spell out what needed to be in place to consider stratification, and that's the first three items in here in Section 4 where it talks about first, you have to have accurate job

categories and descriptions for all those workers that make up the data set. There also needs to be some reason to believe that, you know, there's a high-end exposure. And then, third, I put in here that we also have to have some knowledge that there were unmonitored workers in the higher-end job categories, or in this job category.

For instance, it's possible that for a small set of workers that you have a coworker model, all the workers were monitored. Maybe not routinely that way, but it's possible. So, those are the three criteria. And if those three things are fulfilled, then you would consider doing some sort of statistical analysis, but that would be at the very end of the process.

I think what's going to happen, as I mentioned earlier, is we're going to end up having separate models for some workers now that we didn't previously, because you have to evaluate the types of the monitoring programs themselves. That

typically, at least in my mind, has been our major issue. We're comparing apples to oranges, and this document forces you to compare apples to apples.

I don't know if I answered your question. I think I did.

MR. BARTON: No, you did. I mean, again, that was sort of a clarifying question to make sure that at least I was understanding where we were on that.

I guess a follow on, if you had an incident-based monitored population, I mean, maybe this is getting beyond the scope of discussions today, but if you did have --- decided that we have an incident-based population, I mean, would the actual coworker model itself for that sub-population we'll call them, wouldn't it have to change since you're not longer in a situation where you can safely assume chronic exposures over some intake regime time period? I mean, I'm just --- I'm trying to think this through. If you have

---

DR. NETON: Yes. That's going to have to be an implementation issue, but I do agree with you that needs to be considered. A chronic exposure model might not necessarily be sufficiently accurate. It might be bounding in that situation, but it needs to be considered.

Yes, it's not in here, but I think that would have to be taken into consideration on a case by case basis. I just don't know any other way to do it. You have --- you know, if you can ---I think there's some verbiage in here that talks about if you have a very well-controlled monitoring program, a very well-defined project, for example, with some very good monitoring, you know, whether it's good air sampling, good alpha CAMs, contamination control, and you can demonstrate that all the upset conditions would have been detected, you know, maybe you don't need a coworker model in that situation, even though there may have

been an incident. But it's certainly --- all the incidents would have been detected, that sort of thing, so there's a number of different variations on this theme, I think.

MR. BARTON: I was going to say, sort of the corollary to that is like where there were relatively few incidents that occur. We may know there's some but, you know, is it really going to, you know, matter? We know that those weren't extremely high incidents. I mean, I think you sort of got that covered in your criteria but ---

DR. NETON: Right.

MR. BARTON: --- it is going to be ---

DR. NETON: And you also have a situation where you'll have incident-driven bioassay on a project that's short duration, but then you may have closeout bioassay samples on everyone, which adds another dimension to it.

MR. BARTON: Yes.

DR. NETON: But the main message is that

that should not be lumped in with the routine monitored population.

MR. BARTON: Right, thank you. I completely agree with that.

CHAIRMAN MELIUS: Other SC&A comments?

DR. LIPSZTEIN: Yes, may I?

CHAIRMAN MELIUS: Sure.

DR. LIPSZTEIN: This is Joyce. Can you hear me?

CHAIRMAN MELIUS: Yes, we can.

DR. LIPSZTEIN: Okay. I'm going to repeat what's already been said, that this is an extremely good document. We appreciate it a lot. It touches in many problems that we had discussed before, and now we have it written in a very good way, and attempts many of the things that I've seen SC&A had been observed and discussed all along, so it's a very, very good document.

Just one point that I would like to --- I don't know if it could make it more clear,

is when you talked about the missed dose and results below the lower limit of detection, the limit of detection. There is just one paragraph talking about the missed dose, and I don't know if I understood it well. But if I understood it well, Jim, is on page 5, the final paragraph in 2.1. "Finally, the amount of dose that could have been received but not detected by a routine monitoring program must be evaluated to determine the magnitude of this missed dose is within the plausible bounds of exposure received by the workers."

Does this mean that when you have results below the limit of detection, we are going --- what is going to --- the standard would be to apply the limit of detection and not results lower than the limit of detection?

DR. NETON: I think that will take us probably into our next discussion on the trivalent actinide analysis, Report 55. But the idea that I

had here was that if, for instance, you only had the MDA reported for all the measurements, and it turned out that, you know, the missed dose was so large --- and I had in mind here a thorium intake which, as you know, has very poor ability to detect intakes for various reasons, but if the missed dose --- if you tried to just build a coworker monitoring based purely on missed dose and it ended up --- and the samples were very far apart, and you ended up with very high implausible doses, it's not --- it would not be considered sufficiently accurate. That's what I was trying to say.

I did not intend, though, to say that we would not use data below the MDA in the analysis of coworker models, and particularly in the OPOS analysis. And that --- I purposely didn't mention that in here. I think that's an implementation issue, and I think we can discuss that maybe at the second part of this discussion. That's why I really wanted to discuss that today, because in my mind

that is the only outstanding issue related to the use of the OPOS technique.

DR. LIPSZTEIN: Okay.

DR. NETON: That's where we're at.

DR. LIPSZTEIN: Okay, thank you.

CHAIRMAN MELIUS: Any other comments from SC&A? Okay, hearing none, any further comments from Board Members or reactions?

MEMBER ROESSLER: This is Gen. I have one comment on Section 4. This is very short and you jump into it very quickly. I think it would help --- this is editorial, I'm sorry, but in that first sentence if the last part were brought up to the beginning to say "the distribution of," so on and so forth, and then list the situations, it would be easier to understand.

DR. NETON: I'm sorry, Joyce, I'm not following.

CHAIRMAN MELIUS: Gen.

DR. NETON: Gen. Where ---

MEMBER ROESSLER: I can just send that to you. It's just a rewording that I think would help.

DR. NETON: The first sentence for situation where accurate job categories obtained for all workers ---

PARTICIPANT: Move the distribution of potentially highly to the front part of the sentence and then say --- give examples, make it clear.

DR. NETON: Oh, yes, sure, that could be a rephrasing of that sentence.

CHAIRMAN MELIUS: Okay.

DR. NETON: Yes, we can do that.

CHAIRMAN MELIUS: Open for discussion, obviously, but what I would like to do is suggest next steps for this document is that we get it to the Board Members, the Full Board, and that we --Jim, if you can present it at the Board meeting, hopefully, we'll get continued engagement on that.

And I think once we tell them it's almost final, that if anybody has any residual concerns or questions they will come up. And we, obviously, already put it on the agenda, so ---

DR. NETON: That sounds good to me. I can distribute this to the Full Board once I --- I'll make this one change the Gen recommended because I do agree with it. I think I'm still going to leave it at Rev 4. I don't want to make a separate revision for a change in a sentence, but I'd be happy to present it. And I'm hoping that we're nearing this, because we're anxious on our end to start to try to implement this.

CHAIRMAN MELIUS: Okay, and that was my next suggestion, and you may have to give this some thought as to the example, but I think it would be helpful to this Work Group, our SEC Work Group here which is, you know, sort of work through this methodology with you, and guidance with you, that we then take and go through an example that would,

you know, sort of follow these guidance in terms of addressing these particular issues.

DR. NETON: Yes, we can do that.

CHAIRMAN MELIUS: And that would be the step to implementation. I mean, so the --- I think it's ready for implementation, in general. I think --- what I'm concerned about is that we make sure that we --- that as you're implementing it, that you --- that we, sort of, reached agreement on what would be the appropriate ways of, you know, outlining this in a document, that when you first present, you know, a coworker model, you would walk through these steps.

DR. NETON: Yes.

CHAIRMAN MELIUS: In terms of what had been considered, and in terms of presenting information. I think that would be --- I think that's helpful in terms of ensuring, you know, sort of consistency, and making sure that there's no --- you know, you're not, sort of, sent back to the

drawing board, or something is missed that people are expecting to see, or to understand better, and you have to go back through and revise the report, and so forth. And I think we could do that in a --- hopefully, in a timely way, which is why I say, you know, let you sort of think about what would be a good example to start with.

DR. NETON: Yes. I was just talking offline with Tim here a little bit. I think Savannah River is the obvious choice to start. I mean, there's other sites but we're ---

CHAIRMAN MELIUS: Yes.

DR. NETON: --- so far along with this site. We certainly won't have this by the next Board meeting.

CHAIRMAN MELIUS: Well, no, I'm not expecting it by the Board meeting. And I would do it, I think, as a --- I think we can do it as a Work Group effort.

DR. NETON: Yes.

CHAIRMAN MELIUS: I don't know, it might take longer, but if there's something that would be between now and our follow-up Board meeting.

DR. NETON: Yes, I don't think the whole thing could be done, but we could certainly start with the pieces and parts of the data completeness, that sort of thing. And maybe that's the best way to approach it, is one step at a time.

CHAIRMAN MELIUS: Yes, that's a good idea.

DR. NETON: Sort through it logically.

CHAIRMAN MELIUS: Yes. And I'm not sure we have to go through the whole --- all the steps, but ---

DR. NETON: Yes, I totally agree. I mean, to me it's sort of like, you know, any new law that's written, no one knows what it means until you try to implement it, and follow it ---

CHAIRMAN MELIUS: Yes.

DR. NETON: --- and it gets tested in

the courts, so to speak.

CHAIRMAN MELIUS: Yes. I also think it would then --- you know, the extent that you have to go back and re-look at previous coworker models, it would sort of clarify the steps for that.

DR. NETON: Yes.

CHAIRMAN MELIUS: And we may come up with some other guidance or criteria that would come out of that. Again, I think you've covered everything well in a general fashion, but you, sort of, never know until you encounter it.

DR. NETON: Yes, and maybe once we do it, then we --- you know, sort of proceduralization can happen a little ---

CHAIRMAN MELIUS: Yes.

DR. NETON: That sort of thing.

CHAIRMAN MELIUS: Other Board Members think that would be helpful?

MEMBER ROESSLER: Yes, I do.

MEMBER ZIEMER: Yes, that makes sense to

me. This is Ziemer.

CHAIRMAN MELIUS: Yes, because I ---

MEMBER ZIEMER: Are you going to present that criteria at the next Board meeting?

CHAIRMAN MELIUS: Yes. I want to get input that any other Board Members have and sort of explain our next steps to them.

DR. NETON: I'm hoping that maybe, you know, the Full Board would see this and agree, and then we could sort of just finalize this sometime shortly thereafter.

CHAIRMAN MELIUS: Yes. No, that's why we'll be asking for it, and so forth. And if you can --- yes, what I would suggest, if you can get the small revision done and then, Ted, if you can get it out to the entire Board with sort of a note to the effect that we're going to, you know --- we're intending to try to finalize this at the Board meeting.

MR. KATZ: Yes, absolutely.

MEMBER ZIEMER: So, do we need a formal recommendation from the Work Group that we are recommending adoption then?

CHAIRMAN MELIUS: Yes, I think that would be in order, I think. I hadn't thought of it ahead of time, but I think you're right, that it would be helpful to have.

MR. BARTON: Dr. Melius?

CHAIRMAN MELIUS: Yes?

MR. BARTON: This is Bob Barton. I actually just thought of sort of a follow-on question on this document. It's broad, it's not necessarily ---

CHAIRMAN MELIUS: Okay.

MR. BARTON: --- the prescriptive type, but it's this notion of, you know, you have to take a look at the actual detection levels of the system and see if you have missed doses that are just completely implausible. Jim gave the example of, you know, perhaps doses based on thorium

monitoring. And I was just kind of wondering to myself if we headed down that road in a specific instance where, you know, all you have is values that are, you know, less than the detection limit of the system, and when you apply missed dose calculations you end up with implausibly high doses. I guess my question is, where do we head to from there?

DR. NETON: Well, I think, Bob, it's probably SEC.

CHAIRMAN MELIUS: Yes.

DR. NETON: Can't do anything with a coworker model. That's usually the pathway towards an SEC if you can't reconstruct the unmonitored workers' doses. That would seem logical to me.

MR. BARTON: Okay. I just wanted to clarify that point because it stuck out a little bit.

CHAIRMAN MELIUS: So, I'm looking for a motion from the Work Group that we move this forward

as a recommendation that the Board adopt this.

MEMBER BEACH: Jim, this is Josie. I'll go ahead and make that motion ---

CHAIRMAN MELIUS: Okay, thanks.

MEMBER BEACH: --- that we adopt the new---

CHAIRMAN MELIUS: And, again, as with anything, it's a living document. All of our documents are living documents we've changed as we've gone along, but I just --- I actually think it would help as much with sort of the impetus to make sure that all of our Board reviews this and thinks about this as we go through it. Obviously, there'll be other opportunities with specific examples, but we'd like to get this closed out.

MEMBER ZIEMER: I'll second the motion.

CHAIRMAN MELIUS: Okay, thanks.

MEMBER ROESSLER: Yes. And I think that by doing that, that puts this in a position for the Board to know that it's an important document, so

we could almost call it required reading.

CHAIRMAN MELIUS: Yes.

MEMBER ROESSLER: If we could that subtly.

CHAIRMAN MELIUS: I can tell former academics.

MEMBER ROESSLER: Can't help it.

CHAIRMAN MELIUS: Should we say there will be a quiz at the end of it?

MEMBER ROESSLER: Yes, right.

CHAIRMAN MELIUS: And those are your first --- day one of our meeting. I'm not sure what the --- you have to buy us breakfast or something if you fail, or something like that. I'm assuming since I've heard from everybody that we all agree, so the motion passed. So, Ted, could you do that communication after getting ---

MR. KATZ: Absolutely, yes.

CHAIRMAN MELIUS: --- the document from ---

MR. KATZ: Yes, and I'll do that communication. I'll let them know that the Work Group is recommending this for adoption, and you'll be putting that to them in the meeting.

CHAIRMAN MELIUS: Good. Okay. I think we're ready to move on to the second part of our agenda, which is dealing with the --- it's an SC&A report on the ORAU Report 0055 on, I call it the exotic nuclides report. It sounds a little sexier than just comparison of exotic trivalent radionuclide coworker models. So, we have that review, and I think we focused --- I believe it was 8-13, if I remember right, in specific parts. And then yesterday or Friday, I can't remember which, Jim Neton also sent us out --- it was a draft of some of the responses to a different special exposure Evaluation Report that ORAU and Tim Taulbee put together. And, again, there were specific parts of their response, numbers 13-16, 19 and 20 that were sort of NIOSH's response to the,

sort of, the same issue that came up with a different report.

So, Jim, I don't know how you wanted to walk through this part.

DR. NETON: Yes, I'll try. This has been going on for a while, so it's a little bit convoluted, but I'll try my best to explain where we are, what we want to do here.

It turns out that SC&A had reviewed Addendum 3 to the Savannah River Site Evaluation Report some time ago, and I had that written down but I can't find it immediately. Here we go. It was back in 2012 where SC&A reviewed Addendum 3.

Addendum 3 had a number of issues it dealt with, including the tritium reconstruction. It also talks about the trivalent actinide model, and SC&A in their review came up with a number of findings on that trivalent actinide model. In the meantime, NIOSH has issued Report 55, which was the trivalent actinide model, sort of the

formalization of what was in the Evaluation Report. And SC&A reviewed that document, and not surprisingly they came up with the same findings in the area of what we want to talk about today, the six findings.

I will say that I looked through all 18 findings, I believe, and it looks to me like findings 1-7, Report 55, really relate to issues that are related to the coworker model, and will in one shape or form be dealt with when we revise the coworker models in response to what's in the MDA, so I feel pretty good about that.

And then you're left with these 8-13 findings that really --- and I want to talk about these today because I mentioned sort of our last area of discussion on the interpretation of individual measurement values that go into coworker models. And, specifically, these findings deal with data below the MDA. All five of these findings actually --- all six of these findings are

in that general area. I'd just like to focus on that a little bit.

In the trivalent actinide set, there are two kind of sets of data. There are the logbook entry data, and then there are the OPOS values that were calculated from the logbook value, so you have a person that may have been sampled three times in one year, in some cases she'll have one analysis that was run 10 separate times to get 10 values, but that's one urine sample. And then there may be two more samples that were taken during the year. Well, then you have actually three values that will go into the OPOS calculation. The value that was run 10 times on that one sample is kind of a different situation, but it's --- SC&A is still discussing the use of values below the MDA, and I think it's good to start with the repeat measurements, the repeat analyses of the individual samples. To me, it's the simplest case to start with.

In those repeat measurements, we have values that are below the MDA in many cases, and what we've done, our approach is to use all those values to calculate the average, and then that average value would be the OPOS --- one of the values that goes into the OPOS calculation.

SC&A seems to be arguing that you can't use those values that are less than the MDA, but I strongly believe that at least in this case you should, because if you don't, you end up having a biased estimate of the mean value.

I put forth on the screen our response to Finding 13, which is the same as Finding 8 in the Review of Report 55, the same finding. And I wanted to highlight our response where there's a NUREG document, NUREG-1156 that specifically addresses this issue. And it's pretty clear if you read the couple of paragraphs that we've excerpted from that document that you should use values below the MDA to do mean value calculation. There's

meaning in those values, so that's our position.

Now, that's for the repeat analysis of the individual --- of a single sample. We extrapolate that and also use value below the MDA when you're calculating the OPOS value that uses multiple samples. And I believe that's also correct, but I'd like to start with a simple analysis where you've done say 10 analyses of the same sample. I appreciate, you know, SC&A's discussion on why we wouldn't use those 10 values to calculate the mean value.

Am I on mute?

CHAIRMAN MELIUS: No, you're not on mute.

DR. NETON: Maybe I confused everybody.

CHAIRMAN MELIUS: No. Anybody from SC&A want to respond?

MR. BARTON: Sure. This is Bob Barton. Yes, Jim, as you know, I mean, our original concern going down to the fact that we were even seeing

negative OPOS values in some situations. Now, that's largely --- at least the negatives part of that is addressed in the most recent Report 53, which basically instructs that if it's negative, you're going to set it to a censored value of less than zero. So, that is how the negative values are being adjusted.

We still sort of question --- you know, like I understand what you're saying about, you know, these values may have some meaning, but in the context of an actual dose reconstruction, we still have concerns about that. And I was kind of thinking about it, I was trying to put it in sort of simple terms to, kind of, get out of the weeds a little bit and see if, you know, it makes a little bit more sense from a broader view. And this is sort of how I thought about it.

We all agree that the gold standard for coworker modeling would be if we had the wherewithal, the time, and the resources, is that

we'd reconstruct every monitored worker's intake, and from that we develop a distribution of intakes. And from that distribution of intakes, we would be able to assign some level, whether it be 50th or 95th of intake values, but we've agreed that that's just simply not feasible. So, in actuality what we're doing is we're taking all these monitored workers and almost assuming that their OPOS values belong to that one monitored worker. You see what I'm saying? You know, it's a surrogate process, obviously. That's the very nature of coworker models.

So, when we take these data points, the raw data and calculate an OPOS value, and then you have, say a 50th percentile OPOS value for each period you're looking at, each year, and then we're going to go ahead and run IMBA to fit that to an intake for a chosen intake regime, and then we get whatever the intake is based on those bioassay samples, which we're assuming belong to the single

unmonitored claimant.

But if you go and look at an actual dose reconstruction, never are values that are less than one-half of the MDA, at least that I've seen, used in an actual dose reconstruction. If you have a claimant who was monitored for let's say plutonium, and all of their results are zero and negative and, you know, less than one-half the MDA, the procedure is you assume on that last day of sampling a value of one-half the MDA, and then you calculate a chronic intake that will result in that bioassay sample, the last bioassay sample to the claimant. So, in an actual individual dose reconstruction we're not taking these values, to my knowledge, and I might be wrong on this, and using them at face value. We are, in fact, truncating them at some sort of potential level, in most cases it's one-half the MDA.

So, for my money I'm wondering why would we do it differently in the coworker setting where

we're really trying to do the same process but using surrogate data from the entire monitored population?

Now in the case of this SRS exotics model, when you look at the derived excretion rates which are based on the OPOS, and they're in TIB-81, and you look at the 84th percentile for the period of interest, I believe every single one of those data points at the 84th percentile excretion rate is less than the minimum detectable activity. Not all of them are less than one-half, but a lot of them are less than one-half. So, what you have is you have a distribution of OPOS values, the worker excretion rates for the monitored population that indicate that the dose was missed. So, I mean, I guess we're wondering wouldn't it be more appropriate to assess the missed dose based on just the bioassay samples we have?

You would still be using, potentially using those negative, not negative but less than

MDA values in developing the OPOS, but when you go and start picking off percentiles by year for the entire monitored population, if those samples are indicating the monitored population has missed dose because of whatever reasons, limitations of a detection system or whatnot, then if the monitored population will be getting missed dose, I don't see why the unmonitored population who should have been monitored wouldn't also be assigned missed dose.

DR. NETON: You raise a good point, Bob. A couple of things. First, you're right that we have decided, and we did revise Report 53 to not include negative values in the OPOS calculation. And that was done principally because we implemented the, you know, the backwards time-weighted average approach, and it didn't make much sense to start integrating over a short period of time for a negative intake, so I do agree with that. And I think we're on board with that concept.

But as far as how we do individual dose reconstructions and missed dose versus developing coworker models, I think they're two separate issues. You're right that we will always use probably the MDA over 2, I'm guessing, as the best estimate of the intake, or the best estimate of excretion in an individual dose reconstruction, but when you're dealing with a coworker model, you're talking about potentially hundreds, if not thousands of data points of OPOS values. And those tend to even out over time over the large group of data when you're putting them together, so that you don't want to start having biased estimates of intakes in these coworker models.

You know, there's --- you know, if you just --- it's a distribution, just as you said, it's not an individual dose reconstruction itself. So, the distributions themselves when you piece them together will on average come out with a less biased model.

Now, as far as affecting people's dose reconstruction, I would say that you've got to look at the population we're trying to reconstruct, the unmonitored workers. Now, there's various reasons why people were unmonitored. In the extreme case, though, maybe a worker was --- should have been monitored and they lost his bioassay records and he was highly exposed.

I would suggest that truncation --- use of data below the MDA would not affect the 95th percentile, very little in those cases, so those workers would not be disenfranchised by use of this --- use of the values below the MDA.

The second point I bring up is that the MDA is really not the value that should be used in evaluating the data points because that's an a priori statistic. That value is calculated prior to having done any measurement. Once you've done a measurement, you need to implement the a posteriori statistic which is the decision level.

It's called other things but let's call it the critical level, decision level. That's typically one-half of the MDA, but there is value below even the decision level.

Again, if I took a blank --- a person had no plutonium in his urine, he was never exposed, and I measured it 10 times the subtracted background, I would expect on average half of the value to be negative, half of the value to be positive, and the mean value to be zero. If you do not do that, if you just only accept the positive values, then you're going to bias the result high. Typically, it just makes sense to us that that's the way we deal with these averages. And we don't use averages in individual dose reconstruction.

I would go back, though, and --- I tried to focus on these repeat measurements of the same sample because I think it's most clear in that situation, though. If I measure the same urine 10 times, I take 10 aliquots of the same urine and

measure it, and let's say it was a control, the average value has to be zero if it was not exposed. And if I don't use the data level below zero, then I'll get the wrong number. And that's very clear in this situation where you've got multiple analyses of the same aliquot, or multiple aliquots of the same sample.

MR. BARTON: Well, yes, I know you maybe perhaps didn't want to get into it today, but part of these findings are a corollary to the findings about observations we had where samples that were --- are aliquots of samples that were well above the MDA still showed a lot of variability which is, of course, an adequacy concern. But, no, here's I'm talking about, it's almost a question of parity. I mean, I under --- it almost seems like we are biasing towards the monitored worker, which to some extent makes sense.

DR. LIPSZTEIN: Bob?

MEMBER BEACH: Yes, I'm sorry, go ahead.

DR. LIPSZTEIN: No, no. I'm interrupting you, but I just wanted to say that in all my years of lab work dealing with urine samples which was the gaze of SRS that we were discussing, it's very rare that you really have below zero results. You generally have sort of --- if it's below the MDA, it's below the detection limit, you'll have something which is denied of the instrument. Very rarely you are going to find those results that are below zero.

And another thing that I was going to say is that we are working with claimant-favorable assumptions, so I wanted to read a text from NCRP-164 which --- because NUREG-1156 is from '87, and NCRP-164 is a more recent one. And that's what he --- the document says about bioassay data less than the limit of detection.

It says that bioassay data less than the limit of detection can lead to biases and they affect doses in values weight and things in excess.

This is because that's the main reason we are looking at the urine samples, because we want to determine the dose. So, what NCRP-164 says is that the biases are under --- it's underestimated if data less than the limit of detection are set to zero, overestimated if data less than the limit of detection are set equal to the limit of detection, overestimated if data less than the limit of detection are ignored, and only data greater than the limit of detection are used, and biased by an uncertain amount if the data less than the limit of detections are set to an arbitrary fraction of the limit of detection."

So, no place here is talking about the numbers that are less than zero.

You know, the underestimate is already written here very specifically, "The bioassay data is underestimated if data less than limit of detection are set to zero." Imagine below zero.

So, what NCRP-164 suggests is that it's

to do a cause between zero and the LOD, the limit of detection. And if you want to be, you know, claimant-favorable, use the LOD because it overestimates -- or some number in between, but then there are the uncertainties undetermined, the bias is very undetermined.

DR. NETON: Joyce, I think --- I don't disagree with what's in NCRP-164. I didn't hear anything in there that said we couldn't use values, measured values that were less than the detection limit.

DR. LIPSZTEIN: I'm not saying less than the detection limit. You are calling negative values, the ones below zero, but that's an important distinction.

DR. NETON: Well, we're not using negative values in the OPOS calculation any more. That ---

DR. LIPSZTEIN: Okay, so that's good. Okay. That's one point of discussion.

DR. NETON: But we are using ---

DR. LIPSZTEIN: We don't want negative below zero results. So the results will be between zero and the limit of detection. Right?

DR. NETON: We will not use a bioassay value average that is less than zero in the OPOS calculation. That is true. But we still believe in the value in data points that are less than the detection limit, because when you're doing averaging one needs to use all the data to calculate the average value, whether it's an OPOS time-weighted average, or whether it's the average of 10 repeat measurements of the same sample. You still ---

DR. LIPSZTEIN: Don't you agree that if you have values below zero, then suppose there is something --- in other words, it's below even the noise of the instrument, it's very rare that you will have --- we got this at SRS because I don't believe the data there is good. I think the

difference ---

DR. NETON: I've measured a lot of samples of environmental samples, plutonium in human autopsy samples, hundreds, and I can tell you for certain that many values were below zero because people didn't have any plutonium in their system.

So, 50 percent of them --- not 50 percent, but a large number of them -- ended up being less than zero just by the way, you know, you subtract background. I mean, if it's background and you measure it 10 times, background is going to be below zero half the time, it's going to be above zero half the time. That's just the way it works.

DR. LIPSZTEIN: I'm not --- okay. I never went into this situation. I always have numbers that are a little bit more zero. But anyway, they can't have negative intake, so either zero or some number above zero. Right? So, when you translate it into those, it can't have a negative

value.

DR. NETON: That's exactly what we're doing.

Well, I guess I'd like to look at 164 because I don't have it in front of me, but I didn't hear anything in there that contradicted what we would be doing, or what we're doing.

MR. BARTON: Well, I think --- this is my rudimentary understanding of the passage Joyce read -- but I think what they're saying is that when you have samples that are less than the detection limit that you really want to use more of a probabilistic curve ---

DR. LIPSZTEIN: Exactly.

MEMBER BEACH: --- which I believe in the program is a triangular distribution. If your minimum is zero, your mode at one-half, which you mentioned is probably the decision level, and then the maximum of the triangular is the limit of detection. So that's sort of, I guess, a sampling

way to do it, but the easy way to do it just say, okay, we'll assume it's one-half the MDA, which, like I said, is done in dose reconstructions.

Which leads me back to something you said. You said, well, yes, we use that in individual dose reconstruction, but it doesn't apply to coworker modeling. You know, we all agree that the best way to possibly do a coworker model is to a best estimate dose reconstruction, which would not use values that are less than one-half the limit of detection.

DR. NETON: I don't know. We disagree here, I guess. I'm not sure where we --- we're not going to solve this, I guess, this afternoon on this call.

DR. TAULBEE: I think this is kind of an important part for us ---

DR. NETON: Yeah.

DR. TAULBEE: --- the coworker models to move forward on that next step as you're running

them, Dr. Melius, is taking it -- starting to go through it. You really need to come to some type of an agreement with regards to how we calculate the OPOS.

MEMBER BEACH: Well, it may not come to that, actually. I mean, if you think about it, if you use the raw data set, taking out the negatives for the reasons you stated, using pre-weighting, it just really mucks things up. I mean, you could still calculate your OPOS value but, I mean, if you look at it and you see that the OPOS value for a given year at whatever percentile is less than half of the limit of detection, I mean, it just seems logical to me that you would assign a missed dosage. Because your monitored population is simply indicating that they would receive missed dose. And, in fact, that's what they're going to be getting in their own dose reconstruction. Of course, we can't do dose reconstruction for all of them.

DR. NETON: If you have a thousand measurements, you can actually almost calculate what people were receiving. I mean, they weren't receiving missed dose. You have a lot of data. If you have 84 percent of your values below the MDA, I can guarantee you statistically it's not possible all those people receiving the MDA. It's not possible. They could not all be at the MDA and --- it's not statistically possible.

MR. BARTON: No, I understand that. You're saying ---

DR. LIPSZTEIN: That ---

MEMBER BEACH: Go ahead, Joyce.

DR. LIPSZTEIN: That's exactly what NCRP-164 says. If you put everybody equal to the LOD, you are overestimating the data. But if you put everybody, you go to zero, you are underestimating it.

DR. NETON: We're not. We're estimating the best statistic we can, which is an unbiased

estimate using the data that was measured. Once you've done a measurement, I have a value. All you can say, if it's less than the decision level, is that I'm 95 percent sure that it wasn't a real sample. That's all you can say.

DR. LIPSZTEIN: I think we're saying the same thing. I don't know.

DR. NETON: I think we are. I think, if you look in OPOS, it kind of works out where, you know, there will be a period of time where the one OPOS sample will be less than the MDA, but then for another monitoring period it'll be maybe greater than the MDA. But you can't compare the OPOS value to the MDA; you have to compare individual samples to something. And I think we use the individual results if we have them, because if you ---

DR. LIPSZTEIN: Yeah, you are going to use the individual results, but you are not going to use below zero results.

DR. NETON: For an individual OPOS

value, that's correct. Or not an OPOS ---

DR. LIPSZTEIN: Now, to calculate the OPOS you're not going to use below zero results. Is that what you are saying?

DR. NETON: There will be no results in the OPOS calculation below zero. That's correct.

DR. LIPSZTEIN: Okay. Okay.

DR. CHMELYNSKI: This is Harry Chmelynski. I'd like to make a comment also on this discussion, which is: the reason why we're seeing these negative numbers is because we made up the procedure where we think we know what the background that we ought to be using for this measurement is, and we subtract and, hey, we get a negative, now we're going to pretend that those negatives mean something.

I find it very hard to believe any of this discussion unless I know how the background varies from individual to individual, and how well it was measured, and what did they actually do to

get those negative numbers.

DR. NETON: Well, we have the procedure at Savannah River. I could show you that. But I want to go back to the example of the repeat measurements of the same sample, though.

DR. MAKHIJANI: This is Arjun. Could I say something on the OPOS question, as a general matter, not Savannah River, before you move on, please?

CHAIRMAN MELIUS: Sure. Go ahead, Arjun.

DR. MAKHIJANI: Jim, I think you and Joyce were saying different things. Joyce was asking whether you're going to use negative values in your calculation of OPOS. And I heard you say that you would not have negative OPOS results. Those are two different things.

DR. NETON: What I meant to say, Arjun, was we would not use zero values in calculating an OPOS result.

DR. MAKHIJANI: So, maybe it was my understanding, but you're saying that any negative result would not be used in the OPOS value calculation.

DR. NETON: Correct.

DR. MAKHIJANI: Thank you.

DR. NETON: That's already in the procedure. We revised the procedure a while ago to state exactly that.

DR. MAKHIJANI: Thank you.

DR. CHMELYNSKI: Arjun, I'd like to point out that I'm not quite sure that everybody --- I'm sorry, am I on mute now?

DR. NETON: No, you're live.

MR. KATZ: Harry, we hear you.

DR. CHMELYNSKI: Okay. There's two ways to say that it's not being used in the OPOS calculation. You can say that it's not being used in this time-weighted averaging, or you can say it's not being used at all in the OPOS calculation.

Well, if you're going to use them when calculating individual day and time averages then you're still using them in the OPOS calculation.

DR. NETON: Well, yeah, let's talk about that. I mean, if we have an individual value, an excretion value, one measurement, and it's less than zero, it would not be used in the calculation. It would be zero.

But I want to get back to the --- this is sort of unique to this trivalent actinide data set where you have multiple measurements of the same sample. That's a very different situation. You've taken the same sample, I've taken, say, five aliquots and I chemically processed it five separate times and measured it five times. It's the same exact sample. That sample has to follow some distribution, and if you throw away the negative values in that analysis, you're throwing away usable data.

Now, if that average value comes out

less than zero, we wouldn't use it as less than zero; it would be zero. But this is only probably going to occur in this example of the trivalent actinides. I can't think of any other data set -- there probably are -- where we have multiple measurement of the same sample.

Okay, maybe plutonium at Savannah River. But, to me, if I measure something ten times to get the meaningful average, if I did the same analysis ten times, I have to use all the data. That just makes common sense to me. How could it not?

DR. CHMELYNSKI: If we talk about, then, the use of OPOS as a time-weighted average, are you saying that if I use these negatives on a given day and they do give me a negative OPOS value, what are we going to do with that value? I think I understand you to say we're going to set it to zero?

DR. NETON: For an individual measurement that goes into the OPOS calculation it would be set to zero. That's correct.

DR. CHMELYNSKI: Why not the MDA?

DR. NETON: Well, less than zero, but effectively we would be using zero.

DR. CHMELYNSKI: But why not the MDA?

DR. NETON: Because we're using the actual results, the values that are --- we're using results that are less than the MDA in the calculation of OPOS. The MDA is an a priori measurement. It's established before you ever measure the sample. Once you measure the sample, it's a different number. It's the decision level, not the MDA, so ---

DR. CHMELYNSKI: So you're saying it's a number --- it could be any number greater than zero.

DR. NETON: Yes. Yes.

DR. MAKHIJANI: This is Arjun. Let's take another example than radiation. Suppose you make ten length measurements and then you have two negative measurements. It's impossible. You have

to throw out physically impossible results from your average. You cannot use physically impossible results in creating an average because it makes the average meaningless, I think.

DR. NETON: No, that's not a good example, Arjun. You're assuming you have a positive measurement to start with. If you don't have any length at all, you measure it, sometimes it's going to be minus-.1 inch, sometimes it'll be plus one. It's the net value you're looking at. If I have a ruler and I measure one inch, and then I measure it ten times and I'll get 10 measurements, sometimes it'll be 9.9 inches, sometimes it'll be 0.1 inch. I have to average all those values to get the true value, which is one inch. If I don't, if I throw away everything that's less than one inch, it's going to bias the value. It's a net value that you're talking about here, net above background. You measure background.

DR. MAKHIJANI: I can't agree. Anyway,

doesn't ---

DR. NETON: You tell me if I measure one inch, and I measure it ten times, you're always going to have values that are larger than one inch.

DR. MAKHIJANI: No, no. You should have always values greater than zero.

DR. NETON: No, not if I subtract them. I want to get the net measurement. I have one inch, and now I measure something else, and I say is this bigger than that one inch? And I measure it, and it's exactly one inch, I'll get a distribution about the one inch. I subtract the two, and I get zero with a distribution about it. It's statistics, that's the way it works.

DR. LIPSZTEIN: Yeah, but your --- I agree with it, but you are going to underestimate the data when you use ---

DR. NETON: No, you won't underestimate the data. You'll get closer to the real value.

DR. LIPSZTEIN: No, I don't think so. I

think you are sometimes underestimating the data.

Anyway, let me come back to SRS, the repeated measurements. Our problem is much bigger than having negative values. The problem is that the difference in these results are so big that you can't really use them. It's not something that is around the detection level.

DR. NETON: No, that's another issue, Joyce.

DR. LIPSZTEIN: Yeah, yeah. Well, right. And you'll have that on the draft.

DR. NETON: That's a different situation. In fact, I think it's somehow related to chemical recovery of the measurement technique, myself, but that's ---

MR. STIVER: This is Stiver. I might be able to jump in a second here. It seems like we're kind of conflating a couple of different concepts. I think what Jim is talking about really is the idea of a null distribution where you're doing multiple

sampling with your accounting system. And you're going to get a distribution, if you do a normal distribution, centered around zero.

And I think Arjun seems to be talking more about the situation where you actually some positive analyte that may be --- you know, it's greater than zero but may be less than the detection limit.

So I can kind of understand Jim's point of view when you have multiple aliquots of a single sample. You're basically --- you know, if there was nothing in there whatsoever you'd expect it to be zero. If it was a little bit more than --- you know, you might have a few negative values, you'd have quite a few more positives.

You're kind of getting into a situation where you're moving away from that null distribution and into a situation where you have something that's less the MDA, maybe, but still greater than zero.

DR. NETON: Well, I think we're on different sides on this. I don't know how to proceed. Maybe we need to ---

DR. LIPSZTEIN: You said you were going to take a look at NCRP-164, I think.

DR. NETON: Well, I can look at that, but I just don't see us agreeing on this phone call. I mean, we both spoke our positions and it's relatively clear, I think.

DR. LIPSZTEIN: Okay.

DR. NETON: I'll look at 164. I don't know that it's going to change our opinion, based on what I think you read.

DR. LIPSZTEIN: It clearly says you underestimate the dose if that's less than the limit of detection ---

DR. NETON: Yes, for a single sample that may be true, but when you take averages, that's a different situation. That's what I'm trying to say. When you're taking average values, you will

bias your results high if you throw away values that are below the detection limit. I don't know. It's what I learned in my first year of graduate school. I don't think it's wrong, I'm sorry.

DR. MAURO: This is John. I'm conflicted on SRS, but I want to raise a question which is more generic, that Arjun asked, and I think I want to ask it again in a different way. If I have a person that has quarterly urine samples and one of them --- and you want to do your OPOS on that, and we know the procedure.

Now, if one of those urine samples comes back negative, are you going to assume that negative number is not negative, but it's zero, when you do your OPOS calculation?

DR. NETON: That's correct.

DR. MAURO: You've answered my question. I, for one, from a purely theoretical basis and from the same statistic course that you've taken, I think that's the

claimant-favorable way to proceed.

If your OPOS ends up, at the end of the process of doing this, which is less than one-half the MDL, let's say you end up with that as my OPOS number for that person for that year, you're going to use that less than --- it'll be someplace within zero --- if you do that, that means the number that you're going to use has the single value that represents that person for that year, it'll be someplace between zero and one-half -- well, it would be someplace between zero and the MDL.

However, it's very possible that it could come out at some level that's less than one-half the MDL. Are you going to use that as your OPOS value? Not zero, but it's not one-half the MDL either, it's someplace in between there. Is that what you're going to use?

DR. NETON: Yes.

DR. MAURO: Yes. Okay, so it's possible that, in the development of your OPOS value for a

single person, that the outcome will never be zero. Well, it'll never be zero, but I guess it'll be some --- it could theoretically be someplace between zero and one-half the MDL, and you will use that value.

DR. NETON: That's correct.

DR. MAURO: Okay. I just wanted to understand your position. Now I understand it, and I'll leave it to everyone else to decide whether they're comfortable with that or not.

MR. BARTON: Well, you know, I certainly --- I think I understand where you're coming from, Jim, and I think you understand the position here, that in any given year, if the upper percentile of the average urine concentration for the monitored workforce in a given year -- for the sake of argument we'll just say the 50th percentile, that's most often implemented.

At the 50th percentile of the monitored worker population, you would have an annual average

urinalysis result that is less than one-half of the MDA. I simply feel that the claimant-favorable thing to do in that situation, even though the calculations completely reflect the numeric results of the data we have, I think when you go to reconstructed dose from that 50th percentile annual average urine sample, that you should be applying it at likely the decision level because that is consistent with individual dose reconstruction procedures.

I guess that's my piece. I don't want to harp on it too long.

DR. NETON: Remember, Bob, we don’t assign the 50th percentile, we assign the 50th percentile with the geometric standard deviation of the distribution with a minimum of three. There's where additional --- you know, it’s not favorableness, but we try to account for the uncertainty in our value. So, whatever that value comes out you're going to have a GSD at a minimum

of three, if not five, or six, or whatever the distribution ends up being. So, that's what we do.

If you all of a sudden say I can't have anything less than the MDA, and then I start putting GSDs of five on top of it, you start getting into, I think, some silly statistics. You're putting statistics about values that were sort of contrived to begin with. We're dealing with averages here, not individual samples.

CHAIRMAN MELIUS: This is Jim Melius. So, my question is, how much of a practical difference is this going to make?

DR. NETON: That's a good question, Dr. Melius. I don't know.

CHAIRMAN MELIUS: Yeah, and I'm not sure we can know until --- you know, it depends on what situations we encounter.

MR. BARTON: Well, it could be considered comparable to the urinalysis values in OTIB-81, which were calculated based on just a

standard OPOS, not the time-weighted. So that's obviously going to change things. Setting zero OPOS values, or negative OPOS values to zero, is going to change those numbers, but based on how they stand right now, the 50th percentile and the 84th percentile OPOS urinary excretion rates are well below the detection limit. And most of them are actually below one-half the detection limit, or as Jim referred to it, the decision level.

So, I mean, the way the data stands now, what we're applying is going to be intakes based on urine results that are much less than one-half the detection limit.

Now, that could change based on, you know, normalizing negative values to zero and such. We really can't know at this point.

DR. NETON: Right.

DR. LIPSZTEIN: When we have, for example, as the case of SRS, when we had the americium-241 on the disk samples, a result equal

to the limit of detection, which is .3 dpm, would result in a dose to the bones of the face, a 20-years dose to the bones of the face of around 14 rem. So if you use half of it, it would be 7 rem. So it may make a difference for nuclides like americium.

DR. NETON: Yeah. You know, you have to look at these situations where people aren't really exposed very much. And like Bob has pointed out, a large percentage of the samples are less than the MDA, many more than above the 50th percentile. You still have to extrapolate back somehow to figure out what your 50th percentile value is, and we've been doing that by extrapolating backwards, you know, fitting the distribution to it and saying here's the 50th percentile.

DR. LIPSZTEIN: I understand. I was just answering what, in practical, does it mean. I think we've come, you know, to the way you have pointed out in the draft, that sometimes the detection limits go to unrealistic doses, or could not. In

realistic terms, in terms of dose, for example, it could make a big difference depending on the nuclides. And, of course, on the limit of detection. So, in practical terms, it could be meaningful.

DR. NETON: Yes.

MR. BARTON: Could I ask, maybe someone on the NIOSH side, I don't know this off-hand, but you kind of mentioned that perhaps the data set that we're using here, the trivalents, might be a rather unique situation.

How often do we actually have these raw data measurements, as opposed to them simply reported as less than the detection limit? Because the reason I point this out is we looked at individual claimant files provided by DOE of monitored claimants who are in this database, and those logbook files that contain the raw results weren't even included. So I would assume it would be included in the dose reconstruction.

I'm just curious as to how many situations do we come across this where we have raw data points that sort of run the spectrum between zero and the MDA, in which you would be calculating OPOS results that would really run the gamut between zero and the MDA.

I don't know if that's information that's on hand, or if this is a special situation, or this is something that we might encounter somewhat frequently?

DR. TAULBEE: It really depends upon the sites. This is Tim Taulbee. It really depends upon the site where we're working on a coworker model. And it will completely run the gamut. You are absolutely correct. In some sites all we have is, you know, a less than value, and we have no other information, in which case, from the OPOS standpoint, we treat it as a censored value.

But at some of the sites, thinking of INL, for example, we have the original worksheets,

like we do at Savannah River, where you can go through and you see what the background value is, and you see what the gross count value is, and you've got a net value count.

So it really runs the gamut across the facilities and the sites as to what level of detail that we have. So I really can't give you a better feel than that. You know, I can name two big sites where we do have it, but other sites I'm sure we don't. Sorry.

MR. BARTON: I'm looking at RPRT-0053, and maybe this statement, either I'm not understanding it, or it's an error. I can throw it up on the screen if people want, but it's in Attachment C on page 43. And Attachment C, it's Time-Weighted OPOS Method, and it says, "The OPOS method was designed as the MPM, the Maximum Possible Mean, of the face values for all censored and uncensored excretion results for one person in a year. By face value of a measurement, it is

understood that measurements reported below the censoring level are replaced by the value of the censoring level."

And I look at that, and on first read it sounds like we're talking about exactly that: you have numerical values, even if they're below the censoring level, which the censoring level in this case is 0.3. That's even on the logbook cards, it's the report value. You have your individual disk results, you have your normalized disk results, and then the final column is reported. And if the average of those normalized disk results was less than the MDA, it was reported as less than 0.3, and that's what's contained also in the claimant records.

So, based on that sentence, it would sound like the censoring level could be considered .3, or it could be considered the decision level, or half that at .15. And that values less than that, based on the opening sentences of Attachment C,

seems like the intent was in fact to assume those values are at some censoring level, which in this case could either be .3 or .15 depending on whether you want to use the MDA or decision level.

DR. NETON: I'm confused by this. I'll be honest with you.

DR. TAULBEE: Bob, one thing, and I don't --- I'm trying to figure out if this was playing a role into why we wrote that in there. There is MDAs, there's decision levels and there's reporting levels, as well. So, one of the things I know, at some facilities, we'll have data that is actually above an MDA but below a reporting level, where reporting level is considered a significance level. And so what you'll see in some of the records will be like a less than what the reporting level was. So, I'm not sure, I'm thinking this is ---

DR. NETON: I think what we're seeing here is the difference between OPOS and

time-weighted OPOS. If you look at the next paragraph. Sorry, Tim. It says, "In a time-weighted OPOS method, the computed statistic is defined as the maximum possible weighted mean of the face values for all the censored and uncensored results."

MR. BARTON: So you're saying in the original OPOS value we would have reset values below the censoring level, but in the time-weighted we're using them as-is?

DR. NETON: I don't know if that's true in the original OPOS. I haven't thought about the original OPOS in a while. We don't intend to use it unless there's no other way around it.

Can someone from ORAU speak on this? Because I don't remember what the approach was. Nancy or Tom, since this is not an SRS-specific question.

MR. LABONE: Can you summarize the question? This is Tom LaBone.

DR. NETON: Yeah, Tom. I'm looking at Attachment C, which was part of the revision to RPRT-0053, and it says, when it's talking about calculating an OPOS value, not the time-weighted OPOS. It says, by face value of a measurement it is understood the measurement reported below the censoring value are replaced by the value of the censoring level. I don't recall. I'm not sure why that's in there.

MR. LABONE: Well, what that means is that if you have less than 10 that's reported to us and we go to average it, we basically lose the less than ---

DR. NETON: Oh, that's right, that's right. It says, "reported below the censoring level."

MR. LABONE: Well, if you haven't reported below the censoring level, then you don't have to worry about the censoring because you have the actual value.

DR. NETON: That's what I'm saying, that's not what this sentence appears to say. That's what's bothering me.

MR. LABONE: I don't have it in front of me.

DR. NETON: Yeah. But at any rate, Bob, the concept was that if we had the actual value, we would use the actual value.

DR. TAULBEE: Tom, are you on Live Meeting?

MR. LABONE: No.

DR. TAULBEE: Okay, never mind.

DR. NETON: Anyway, the idea, Bob, is that we would not use the value below the --- if you have the actual value, it would be used in either situation. I'm not sure, that sentence does not seem to say that, but that's not what we're doing.

DR. CHMELYNSKI: It would seem to me that the term itself, maximum possible mean, says

that that's exactly what we should be doing, is replacing anything with a face value below the limit of detection with the value of the censoring level.

DR. NETON: What we're doing, Harry, is we're replacing -- anything that's a less than value is replaced with that value itself. In other words, if it's less than .3 we would use .3 in the calculation.

DR. CHMELYNSKI: Well, what if it says on --- to the column to the left of less than .3, if it says .2, that's the case we're talking about.

DR. NETON: Right. We would use .2 because we have the actual measured value.

DR. CHMELYNSKI: Well, then why would you call it the maximum possible mean? I mean, just because they quote some number less than the limit of detection, it doesn't mean that number means anything.

DR. NETON: It's the measured value, and

when you're taking averages of measured values ---

DR. CHMELYNSKI: How can you use the measured value below your limit of detection? It's not a measured value, it's a created construct that you decided to call a value.

DR. NETON: Harry, if you have ten measurements --- I'll go back to my ten measurements -- of the same sample ten times, you would not take the mean of all those values to get my average value. You wouldn't do that. If I had ten ---

DR. CHMELYNSKI: Well, why are we --- excuse me. Then why are we using the word ‘‘maximum possible mean’’?

DR. NETON: What?

DR. CHMELYNSKI: Why are we using this catchphrase, ‘‘maximum possible mean,’’ if indeed it is such a subtle difference?

DR. NETON: To replace all of the values that are less than --- that are listed as less than

the MDA with the MDA if we don't know what the measurement was. That's what we're doing.

DR. CHMELYNSKI: I understand what you're saying you're doing, but I would get rid of this term, ‘‘maximum possible mean,’’ because I think that measure value has nothing to do with the value that could have been measured. We could have had any number between zero, negative, up to the limit of detection. You just happened to get that one number.

DR. NETON: Harry, if that's the only objection, I would be happy to do that, and then we can move forward.

DR. CHMELYNSKI: Anyway, yeah, you're right. We've beaten this to death, so I'm going to lay off.

CHAIRMAN MELIUS: This is Jim Melius. Can I suggest a way forward?

DR. NETON: Please.

CHAIRMAN MELIUS: Okay. And there's

some, I'll say, urgency here, but we need to be expeditious about this, I think. In responding to what Tim was saying before, we do need to be moving ahead on Savannah River, and that's obviously going to be affected by the new set of guidance that we will be talking about at our Board meeting in a couple of weeks, that we also want to pick an example to sort of test the guidance, or I guess pilot test the guidance may be the way of putting it. And we had talked about possibly that being Savannah River, but I think Jim and NIOSH staff need to think about what would be the best one, an appropriate one to use, and so forth.

So, what I would suggest we do is that we --- well, the other thing that --- this Work Group will be meeting sometime in the near future. I'm not sure exactly when, but we also have one other task we need to deal with based on when an SC&A report comes out having to do with the Dow Madison site, so we will be scheduling meetings,

anyway.

What I was thinking of is when we're in the State of Washington in a couple of weeks, everyone will have had time to think about this issue more, maybe clarify things, and we can either come back to it in a Work Group, but I think we need to be able to at least give NIOSH enough --- if the pilot of the guidance is going to involve looking at a site where this issue is going to come up, I think we need to be able to give NIOSH some guidance on going forward on that.

So, I guess my suggestion is we, when we're out by Hanford, that we talk and sort of figure out specific steps at that point in time. It'll give everyone a chance to think about, one, NIOSH, what would be the appropriate pilot. And, secondly, to what extent it's going to involve or not involve this issue.

And I think we're going to need to figure out a schedule to expeditiously resolve this

issue, if we can. But I think we all need to think about it some more and decide. Does that make sense to the other Work Group Members?

MEMBER ZIEMER: Yeah, that's fine with me.

MEMBER ROESSLER: Fine with me.

MEMBER BEACH: Yeah, that works for me, also.

CHAIRMAN MELIUS: I mean, I think the discussion has been useful. I'm not sure it's readily resolvable, but we usually manage to resolve these things.

DR. NETON: Dr. Melius, do you suggest that I bring this up as part of a discussion point to the full Board, or we just reserve that as a sort of internal deliberation for the Subcommittee -- or the Work Group?

CHAIRMAN MELIUS: I would think the latter, but ---

DR. NETON: Yeah, I guess until we have

a path forward maybe it's not ---

CHAIRMAN MELIUS: Yeah, I mean, I just think it's hard --- I mean, it's hard to discuss this even on the phone. I think it's just one of these issues that ---

DR. NETON: Yeah, I agree.

CHAIRMAN MELIUS: --- an in-person meeting is better, and with some more examples, and sort of agreement on what documents we're going to see and so forth. I mean, it's a little hard ---

DR. NETON: And that's why I wanted to bring this one up specifically today, because in my mind it's the last hurdle.

CHAIRMAN MELIUS: No, I fully agree with looking at this, but I'm not on the SRS Work Group, and so, you know, some of this, it's the first time I'm seeing some of this.

DR. NETON: Yes, exactly.

CHAIRMAN MELIUS: And I don't know about all the others involved, between the conflicts and

everything. So I don't think it needs to be there, I mean, at the Board meeting presented, but I do think we sort of need to figure a step forward.

And, John Stiver, if you can talk to your group and sort of think about this some more also, it would be helpful.

MEMBER ROESSLER: Jim Melius and Jim Neton, this is Gen. It would be helpful to me to see the pertinent pages in NCRP-164 that Joyce was reading from. And I looked on my shelf, I don't have it. I think it's one of those that's online only. So if you find those pertinent pages could you forward them to the Work Group?

DR. NETON: Is that the uncertainty in bioassay --- I mean, internal dosimetry?

DR. LIPSZTEIN: Yes, that's the one.

DR. NETON: I've got it here somewhere.

MR. STIVER: I know we have that here at the office. This is Stiver.

DR. NETON: Yeah, I don't have it on my

shelf right now. We could get that out. Joyce seems to have it handy. Actually, maybe SC&A could send out that page?

MR. STIVER: Yeah, I think we might even have the electronic version. I'll have to check.

CHAIRMAN MELIUS: Good.

DR. TAULBEE: Can you submit that to the SRDB?

DR. NETON: Well, he could submit it to us, I guess. I don’t know. It’s probably too big to email. We’ll figure it out.

MR. BARTON: I'm having a hard time hearing you guys. You're kind of breaking up here.

DR. NETON: Okay, sorry. Yeah, we'll take a look at 164. I suspect that it's only a paragraph or so in there, and my gut feeling is it's not specific to what we're trying to do here, but we'll look at it.

DR. LIPSZTEIN: It's Chapter 4.

CHAIRMAN MELIUS: Okay. I think we can

adjourn. Ted, any further ---

MR. KATZ: No, all good.

CHAIRMAN MELIUS: I wanted to make sure you're still here, Ted.

MR. KATZ: I'm still here. Riveted.

CHAIRMAN MELIUS: Riveted, good. We riveted you to the floor. Right.

Anyway, thanks, everybody. I mean, I think it has been helpful, even if we didn't reach full agreement. We did reach agreement on the other document, so that's good.

DR. NETON: I thought the first part went swimmingly well.

CHAIRMAN MELIUS: Not unexpectedly, the second part is difficult.

MEMBER ZIEMER: Well, we're halfway there, anyway.

CHAIRMAN MELIUS: Yeah. And I do think it's progress. Anyway, again, thank everybody for taking the time and joining in, and many of you I

will see in Hanford in a couple of weeks. And some of you I think we have a Hanford Work Group going in a couple of weeks just before the meeting also.

MEMBER ZIEMER: Right. Okay.

CHAIRMAN MELIUS: Okay, thanks, again.

MR. KATZ: Thanks, everybody.

(Whereupon, the above-entitled matter went off the record at 2:43 p.m.)