Centers for Disease Control
National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Use of Surrogate Data Work Group
Monday, August 12, 2019

The Subcommittee convened via teleconference, at 1:30 p.m., Eastern Daylight Time, Paul Ziemer, Chair, presiding.

Members Present:

Paul Ziemer, Chair
Josie Beach, Member
James E. Lockey, Member
Loretta R. Valerio, Member

Also Present:

Ted Katz, Designated Federal Official
Dave Allen, NIOSH ORAU
Robert Anigstein, SC&A
Kathy Behling, SC&A
Grady Calhoun, NIOSH ORAU
Rose Gogliotti, SC&A
John Mauro, SC&A
Dan McKeel
Jenny Naylor, HHS OGC
Jim Neton, NIOSH ORAU
John Stiver, SC&A
Tim Taulbee, NIOSH ORAU

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Proceedings

(1:32 p.m.)

Roll Call/Welcome, by Ted Katz

Mr. Katz: So welcome, everyone. This is the Advisory Board on Radiation and Worker Health. It's the Use of Surrogate Data Work Group, and today we're discussing Surrogate Data matters related to -- just drawing a blank -- Allied Chemical Plant, and the materials for today, the agenda and the background readings for today, are posted on the NIOSH website under the Board section, our scheduled meetings, today's date.

So you can go there and see the basic materials and the agenda. And this work group has four Board members. Paul Ziemer. Dr. Ziemer is the Chair, and he's here, and as well as all -- well two of the other members. Loretta Valerio and Josie Beach, and we're waiting for Jim Lockey, but I know --

Member Lockey: Hey, Ted, I'm here.

Mr. Katz: Oh, great. Okay, and we have Jim, so we have the whole work group which is great. None of the members have conflict or they wouldn't be on the work group, but let's for the rest of the people as I go through roll call, please address conflict of interest.

(Roll call.)

Mr. Katz: Okay. Welcome, Dan. All right. And with no further ado, then, Paul, it's your meeting.

Chair Ziemer: Very good.

Mr. Katz: And just to remind everyone to mute your phones except when you're addressing the group. Press Star 6 to mute your phone and Star 6 to turn off of mute. Thanks.

Brief Review of Surrogate Data Criteria, by Paul Ziemer, WG Chair

Chair Ziemer: Okay, thank you, Ted, and welcome, everybody. You have the agenda before you. The main documents for consideration are on the website. Also, if you look at the agenda you'll notice that I've put in, for Item 2, a brief review of surrogate data criteria and I want to go through that very briefly.

The dose reconstructions for this site originally were based almost completely on surrogate data, although since the early days of the dose reconstructions for the site there's been additional data which will be mentioned. But I did want to do a brief review of the surrogate data. I'm not going to spend a lot of time on it.

I'll just reference you to the final draft of the criteria for use of surrogate data was dated May 14th, 2010. So if it's convenient for you to pull that up, you might go ahead and do that, but I'm just going to briefly review the criteria.

To a large extent it's going to be sort of a hybrid now because there's -- new data has become available in the last couple years so that the issue of using surrogate data completely for this site is critical and will continue to be used.

Just to recall, there actually are two types of surrogate data. One is the type of surrogate data that's simply used completely to substitute for the site in question because of the lack of data.

The Type 2 surrogate data is a situation where you're using surrogate data to develop parameters for dose reconstruction and not completely as a substitute for the site data.

Criteria that are the ones that are used to establish

the validity of using criteria data. The first is called the Hierarchy of Data and basically that says that we first must go through the full hierarchy which is individual worker monitoring data, co-worker data and on through the complete look of the site. So you should only use data in this image over data for image if they are available for --

Mr. Katz: Paul. Paul, I don't know, Paul?

Chair Ziemer: Yes?

Mr. Katz: Paul, I don't know if you know you're having problems but your voice is breaking up at times on the --

(Simultaneous speaking.)

Chair Ziemer: You know what, what I'm going to do I'm going to -- I'm on a cell phone so I'm going to move to a different location and I'll see if that helps any.

Mr. Katz: Thank you.

Chair Ziemer: Should I repeat what I was saying or?

Mr. Katz: I think, I mean the last couple sentences I couldn't follow.

Chair Ziemer: Oh, okay. I'm actually going to move out to my patio which will eliminate the blockage of doors and windows and other parts of the building here. Is this better?

Mr. Katz: Yeah. You sound good right now. Thanks.

Chair Ziemer: Okay. Let's try this. One which is where you are using the surrogate data completely to substitute for the other, for the site of interest simply because of lack of data.

The other is where the surrogate data is used to help

develop parameters to use in assisting in the dose reconstruction for a site that may have some data but perhaps not adequate.

There are five criteria to use. One is the Hierarchy of Data. You first have to establish that, well you have, there's the criteria saying that you must go through the availability of, first, the monitoring data, personnel monitoring data, then the process data, source data. And the surrogate data is only to be used to replace data where you have some advantage in doing so that made a big advantage over available data.

Effectiveness criteria is called exclusivity constraints. This surrogate data is used with this available data. You have to establish the --

Court Reporter: Sorry, this is the court reporter. I'm not able to follow this.

Chair Ziemer: Still breaking, still breaking up?

Court Reporter: Yes, I'm sorry.

Mr. Katz: Yes, just at the very end, Paul, you started breaking up again and so, just the last sentence or two. Do you have earbuds with a mic because that usually works better for me?

Chair Ziemer: I don't have earbuds at the time. I'm just shooting this as is.

Mr. Katz: Okay, yes.

Chair Ziemer: So, in the exclusivity constraints, the surrogate data is used to supplement available monitoring data. You use it -- it's data that's available and you're relying on evaluating the quality and the completeness of the surrogate data as it might apply.

The third one is site or process similarities. That's similarities to the sites, the surrogate data has to be

similar to the site's situation or the process has to be similar. So there's issues of having the data reflect the types of processes and work practices at the site from which you're doing the evaluation.

There are temporal considerations. You have to take a look at the period in question and ask whether working conditions and processes are similar time wise to the surrogate data site and the site under evaluation.

And the last criteria has to do with plausibility. The manner in which the surrogate data is to be used must be plausible in terms of reasonableness of the assumptions made. And there we're talking about both scientific plausibility -- is it scientifically appropriate -- and work place plausibility -- is it plausible for the facility in question.

So, those are the criteria. And in the case that we're going to be talking about today, I believe I'm correct and NIOSH folks can help me here if I'm wrong, but I believe that the original approach was completely use the surrogate data. Is that not correct, David?

Dr. Mauro: Paul, I'm sorry to interrupt you in the middle of your discussion but let me apologize. This is John Mauro. Let me apologize --

Chair Ziemer: Yes, John.

Dr. Mauro: -- for being 10, 15 minutes late. I find myself sidetracked on another conference call that stretched on, so I apologize to everyone for interrupting. I'm online and I'm available to help out at any time --

Chair Ziemer: Yes. Very good. Dr. Mauro: -- for your people. Okay, thank you.

Chair Ziemer: Yes, appreciate you letting us know. We're just reviewing the surrogate data criteria.

Dr. Mauro: Yes.

Chair Ziemer: What we've decided to do in terms of this particular situation, which is, was really the blind dose reconstruction for the site, and originally SC&A had comments early on and the -- I think that was in 2015, and you'll have a chance to talk about those if you wish next, or in a moment.

But we have now NIOSH's approach for estimating the radon exposure which was the case, the situation here for Allied Chemical, which they developed in 2017 or at least the paper came out in February 2017. And that's the approach that they have proposed and they were challenging -- that's that. That is the most recent paper.

SC&A may wish to then respond to that but you also may have some background information relative to your earlier review, which was for the June 2015 review.

But let's go ahead with the NIOSH approach now and --

Dr. Mauro: Yes, Paul, just to let you know we, myself and others from SC&A on the phone have read the reports, the most recent one and --

Chair Ziemer: Yes, I assumed that you did. Right.

Dr. Mauro: Yes. So we're prepared to give the background and also to comment on the current one, the 2017 report --

Chair Ziemer: Very good.

Dr. Mauro: -- by Dave Allen, yes. Thank you.

Chair Ziemer: Very good. So, let's proceed with the latest NIOSH approach, which is actually a couple of years old by now. But, Dave, you want to go ahead?

NIOSH Approach to Estimating Radon Exposure, by Dave Allen

Mr. Allen: Yes. This is Dave Allen. Just enough background to know where we're at, this was, like you said, a blind DR. The point of contention that's still outstanding was the radon exposure.

SC&A did a blind DR and did radon exposure a couple different ways. We did one for the DR and they didn't match up well, which is not too unexpected.

But after some discussions, it was decided at one point that SC&A should see what the radon exposure would be if they used the same model used in Blockson. And they did that in 2015, I believe, and came up with something a little closer to what we had. And then at some point I think the, I may be speaking out of school but I believe the dose reconstruction subcommittee was ready to close this out saying it was, you know, everybody agreed it was, what we did was a bounding estimate.

But then Dr. Melius stepped in and said he wanted to review it based on the surrogate data criteria, and that's kind of why we're here for this particular issue.

After that time, to muddy the waters more, after that time, Jim Neton managed to find some more definitive documentation on the research they were doing, which was something we were lacking. We only knew that the kind of quantities they worked with and it was very small quantities.

Since then, he found this information that the two main studies they were doing was on leech zone filtration and on uranium extraction from phosphoric acid. And we judged that the phosphoric acid came to the laboratory, it would have already been chemically processed and the radium would have been gone from that, so it wasn't really a source of radon.

It would have been the leech field studies, the leech zone filtration studies that would have been the source of radon.

This documentation that he found mentioned that they worked with 150-gram samples, and at another point in there it mentioned that they thought they would need 45 more batches of those samples to run all the analyses they wanted to to verify the analysis they had already run.

So what we did was came up with a rough estimate assuming 150 grams in the laboratory to the point where it just stayed there all the time and reached an equilibrium. And by that, I mean all the radon that would emanate from 150 grams of phosphate ore minus the radioactive decay and minus the air exchanges in the room, in a small room. And we came up with an estimate of what the radon levels would be in the room based on that.

We then turned around and did the same thing with the full 45 batches or basically 45 150-gram samples, and obviously that ended up being 45 times higher.

And towards the end of my paper there's a table that mentions five different estimates that have been done on this site as far as the radon goes.

The first two are the estimates that were done that I just mentioned, the first one being the 150-gram, you know, one sample; the second one being 45 samples all contained in a room at the same time. The third one was a little lower and that was the one from SC&A based on the Blockson model for radon emanating from phosphate ores. The fourth one is what we actually used in the dose reconstruction. That was we used a 10 percent of the OTIB-43 value, the 95 percentile OTIB-43 value, which was OTIB put together based on exposures at Phosphate-4, or at Phosphate-9.

The last one Jim Neton put in there was, he mentioned some samples that were collected at Blockson and simply took 10 percent of the largest sample, and it ended up being right in line with many of these others.

And if you look at the table, you can see that everything is pretty close, or several of them are pretty close in line. There are -- none of them are way outside the others. The largest one being the one we had used in the dose reconstruction, which was 10 percent of the phosphate ore value. But it's only a little more than double what we got with a couple of these other estimates.

And the white paper concluded with it seems based on that the estimate we did was reasonable. Not, it was bounding but not unduly bounding and we were, at least at this point, planning on sticking with that estimate. Did you want anything else on that, Paul, or?

Chair Ziemer: No, that's fine. Let me, and actually I'm back in my office now, so I'm wondering if you can still hear me okay?

Ms. Beach: Better, yes.

Mr. Katz: Yes, you sound much better, Paul.

Chair Ziemer: Okay. So, what you're proposing is basically the surrogate data approach, but it turns out that its estimate is about double what you get from using the X? Do I understand that correctly?

Mr. Allen: About double from what you get with one of those estimates, yes, or a couple of those estimates.

Chair Ziemer: Yes. Yes, well, your 45 sample estimate comes out 00042 and your OTIB-43 estimate comes out 00093, so it's complete

surrogate. It's higher value and it seems to me it was logical to say okay, that's on me. You're not really using in the sense the --

Mr. Katz: Sorry, Paul, we couldn't hear that. You're not using the what?

Chair Ziemer: You're still proposing to use the surrogate data, which gives you the 00093 value. It's OTIB-43 right?

Mr. Allen: Yes, that's what we stated at the end --

Chair Ziemer: That's what you used before and that's what you're proposing to continue to use. And I'm saying it appears that it's about double what you get if you used the actual data for 45 samples.

Mr. Allen: Yes.

Ms. Beach: So, Paul, let me -- can I ask a question?

Participant: Excuse me.

Ms. Beach: Paul, this is Josie.

Participant: This is --

Chair Ziemer: Somebody's asking a question? Josie?

Ms. Beach: Yes, this is Josie, Paul. I wanted to ask, so if you're going to go with the 043 OTIB, that data is in, was gathered in the late 80s and 90s, so it doesn't really fit the criteria as the same time frame either. So, and I don't think we ever settled the surrogate data question. Is that correct?

Chair Ziemer: Yes. Well, that's correct. At least that was Dr. Melius' question, I think. One of the questions on the time frame is not that has to be the same time frame. The question is whether or not the methodology or either the approach is different in different time frames.

A lot of this is just based on radon emanation and some basic types of extraction and I think that they were assuming, and, I guess, Dave, you should speak to this, that that part of it has not changed in time.

Mr. Allen: Right. Well, I mean our estimate in this white paper is based on the idea if you have phosphate or with some percentage of uranium in it, which is essentially the same radon source you would get in the phosphates mines. It's just a heck of a lot more quantity in the mines.

The assumption then is that the laws of physics didn't change from the 50s to the 80s and you end up with a similar --

Chair Ziemer: Right.

Ms. Beach: Except the facilities are, one's in the south and one's up further north isn't it?

Mr. Allen: Right. That was a big question, was the phosphate mines are essentially open pits mines in Florida; whereas Blockson, if you noticed on there, is a building in the Chicago area, essentially in Illinois.

Ms. Beach: Right.

Mr. Allen: And you end up where, as Jim pointed in this white paper, the maximum or the values you get for radon measurements at the Blockson were fairly similar to what you would get at the phosphate mine. That essentially is that factor of two difference so, it seems like though that might make a difference, it seems like it really didn't between Blockson and the phosphates mines.

Dr. Mauro: Can you --

Ms. Beach: But we're also talking -- go ahead, John.

Dr. Mauro: Yes, I just got -- clarification, I thought the work that was in OTIB-43 is not the mine data

but you looked at all of the data from FIPR, you know, the Florida research work.

And there's a lot of different categories of where radon was measured -- everything from the mines to the processing plants to the stacks, outdoor stacks. And the most applicable set of data would be the processing plants.

And that there was an issue at one time, and we're prepared to talk a little bit about this, is that the phosphate processing plants, which is the most analogous to places like Blockson and Allied Chemical where they're, as you said, the chemistry, the wet chemistry phosphate process, really hasn't changed, sort of the same thing they've been doing forever.

But I think you're, correct me if I'm wrong, but the measurements that you used as your, the foundation is really the radon measurements in the processing plant as opposed to the mines. Correct me if I'm wrong.

Mr. Allen: I really don't have that information. You're talking about OTIB-43 right?

Dr. Mauro: Yes. Yes. I'm going back to OTIB-43 and, which draws, you know, has your surrogate data. And what I'm saying is I believe your surrogate data is based not so much on the mines but on processing plants.

Because, you know, when you go to looking at other processing plants up north where they have a closed building, where you'd want to, where they're doing the same process, the wet, the sulfuric acid digestion, you know, the whole thing that we're familiar with.

The analogous circumstance would be the processing plants that were used in Florida. We have tons of measured radon data for different aspects of the whole life cycle. The most important and most

relevant of which of course, is the processing plant itself as opposed to the rock mines. And I just wanted to bring that up because that was my understanding of OTIB-43.

Mr. Allen: I, as you say that, John, I believe you are correct. I didn't look that up off the top of my head. I don't remember off the top of my head, but that does sound correct.

Dr. Mauro: Yes, and I have a --

Mr. Allen: John, say this is --

Dr. Mauro: Later on I have a lot to say about that but I wanted to give a little clarification to that. It's important.

Chair Ziemer: Well, you're right, John. If you look at OTIB-43, you'll see that there's a compilation of a lot of different studies and it has everything from the tunnels into the processing plants and so on.

Dr. Mauro: Yes.

(Simultaneous speaking.)

Mr. Allen: Okay, this is Dave Allen.

Chair Ziemer: Somebody else was -- yes, Dave, go ahead.

Mr. Allen: I'm sorry, I just wanted to say something else about the surrogate data and the criteria. When we were looking through this and trying to prepare for this meeting several years ago, actually, when Jim found this stuff, it occurred to us that it's not clear any, you know, a bounding estimate would ever actually pass the surrogate data criteria. It's not clear if it was intended to apply to a bounding estimate because the criteria requires the equivalent of working conditions, source terms, processes. And it's hard to come up with a bounding estimate that's

equivalent to what the surrogate data was, so to us it wasn't clear if this criteria actually applied to something that everyone agreed was bounding.

Chair Ziemer: Yes, okay. Other comments or questions for NIOSH?

Mr. Anigstein: This is Bob Anigstein. I just wanted to make a clarification or perhaps I didn't understand. Paul, you referred to that sample, to that study using the 45 150-gram samples of data. It was actually a model, correct me if I'm wrong, if I'm misinterpreting it, Dave, a model of what is the maximum you could possibly expect by using extremely conservative, extremely limiting and not -- this is not a pejorative scene, but not realistic parameters like 100 percent emanation from the ore of radon, a very small room, so --

Chair Ziemer: All right, well --

Mr. Anigstein: At least the reason was --

Chair Ziemer: Yes, you're correct, Bob. It's not that, it is that they had source term information, the 150 grams. That is, in a sense data.

Mr. Anigstein: It is. But the radon concentration --

(Simultaneous speaking.)

Chair Ziemer: In other words, it was the 45 runs were actually made, but they made the assumption that perhaps they all weren't made and therefore they would, the source term would be 45 times that. That's my understanding of it.

Mr. Anigstein: Yes, that's my understanding also. But the actual radon level were not measured.

Chair Ziemer: You're very correct. But knowing the source term and making some assumptions, I should think they're, as I understand what they did, the

effort using the room size that they did, which was rather small, would maximize the concentration.

Mr. Anigstein: Yes.

Chair Ziemer: A lot of assumptions there of course, yes. Other questions or comments?

Mr. Anigstein: But excuse me, if I could point out in contrast, where to show the variability depending on further variability of the model, of the modeling. The model, which is, Dave, perhaps I'm jumping ahead, out of turn, so stop me, somebody stop me if I'm wrong, if I'm out of place.

Incidentally I just wanted to notify everyone, I have to, I was brought into this after the date and time were chosen, so I have to leave at 2:30. I have an appointment.

Chair Ziemer: Okay.

Mr. Anigstein: I have to get my sitting in time. Because in contrast to the Dave Allen's model of our work in regulatory meetings, we were asked back in 2015 by the DR subcommittee to, or we volunteered -- anyway we were directed to use the source term information available then in conjunction with the model we had developed for Blockson to come up with a concentration.

And the source term, we didn't have 150-gram samples --

Chair Ziemer: Right. That was before that was available. Right.

Mr. Anigstein: Yes. So the source term we used was an estimate from an interview of a former worker who said, well, it's not more than two to ten pounds of uranium -- not ore. Two to ten pounds of uranium were extracted and that translates, based on the

concentrations of radium -- of uranium in the ore, that translates to approximately, if you assume this is an annual amount, to approximately 50 tons of uranium as opposed to 150 grams times 45 at that time.

Chair Ziemer: Right.

Mr. Anigstein: And nevertheless, by using the ventilation rate, using the detailed model developed for Blockson with the emanation coefficient, the processing, the size of the building and the ventilation rate, we came up with about 30 times lower than the estimate for the 150-gram samples.

So it just shows the variability, depending on what assumptions you make about the site of the building. I was using the Blockson building with a 20,000 cubic meters --

Chair Ziemer: Right.

Mr. Anigstein: -- as opposed to maybe 20 cubic meters, so it's ten by ten by eight feet and also, however, a higher ventilation rate based on some industrial buildings, data on industrial buildings.

So I'm just throwing this in to show the range of parameters. And also I'd like to make one other comment to supplement what Dave said about the -- I just changed screens here -- about the measurements as Blockson.

There were two other measurements, two other sets of measurements that are mentioned in the updated -- the Blockson TBD was updated since the original work was done on Blockson.

And one statement is that the FUSRAP measured .0061 working levels, so it's a little higher than the .0042 that was measured by the Owens Survey, and by one, almost one and a half times higher.

And then also the assumption made in the TBD for doing, for modeling radon during the residual period assumes that in 1960, which was the last year of the operational period, the value, the radon value was .0083 working levels. So we basically have three numbers from Blockson --

Chair Ziemer: Yes.

Mr. Anigstein: -- .0042, .0061, .0083. So all of these are pretty much, this is what -- I'm speaking for SC&A, mainly it's myself and John Mauro -- all of these are pretty much in the range of the .0093 from the OTIB-43. So --

Dr. Mauro: Is that .00 -- is that -- I think it's three zeroes there? Is that right?

Chair Ziemer: It's three zeroes, triple zero.

Mr. Anigstein: Right. Yes.

Chair Ziemer: Yes. Well --

Mr. Anigstein: Actually, excuse me. It's two zeroes was the 95th percentile and then they divided by ten to account for the much smaller source term.

Chair Ziemer: Yes.

Dr. Mauro: Thanks. Thank you.

Chair Ziemer: Well, actually, Bob has a presentation for the SC&A, so let's go ahead and flesh that out a little. First, Kathy, were you going to do some, give us some background information before the others got into the details? Is Kathy there?

Dr. Mauro: I was speaking -- this is John -- I was speaking to Kathy before the meeting. I'm not sure if she's able to be on the line or not.

Chair Ziemer: She was on the line earlier.

Dr. Mauro: Oh, she was. Oh, okay. Well if she's there certainly, but one of the things we talked about --

Chair Ziemer: I don't know if she's still there. Kathy, are you there? She must not be there now. But I did get an email from her that she would be on the line. Is she there?

Ms. Behling: This is Kathy. I'm on. Yes, I am.

Chair Ziemer: Oh, okay. Yes.

Ms. Behling: Actually I came back between David Allen and Bob Anigstein. They have provided the background information that I was prepared to speak on.

I just want to touch on making the subcommittee aware that obviously this is work that was done initially on a blind dose reconstruction and --

Chair Ziemer: Right.

Ms. Behling: -- there were several methods used, so everything I think that I was going to tell you has been talked about. But thank you for asking if I had anything else to contribute.

(Simultaneous speaking.)

Chair Ziemer: Yes. John and Bob, then, do you want to specifically respond to the cited paper by NIOSH?

Dr. Mauro: Yes, this is John. I mean, I'm be glad -- Bob and I did have a chance to talk --

Mr. Anigstein: Go ahead John.

SC&A Comments on NIOSH Approach

By John Mauro

Dr. Mauro: -- thanks Bob. Yes, let me, I think to go to Josie's the heart of the question. Surrogate data.

We all understand the background now. And you have to ask yourself the question, all right what we're doing is we have data from FIPR for processing plants, which is basically OTIB-43.

Now interestingly enough, we have data from Blockson and there is parity in that measurements are Blockson and the measurements for the processing plants at FIPR.

And the measurements are, quite frankly, from Blockson and from FIPR were in the same decade, I believe. So in terms of the, so in a funny sort of way what we have is, even though the processing plants at, and this was an issue way back when, the folks have been around for a while remember.

One of the issues I brought up originally when I was concerned about using FIPR as a surrogate for Blockson had to do with -- well, one building is opened. The building's in Florida. These are processing plants. These are open buildings.

And here we have a situation with Blockson and also Allied Chemical which are close. Boom. We have ourselves a potential surrogate data issue.

And the other potential surrogate data issue is the Allied Chemical building was clearly smaller than the Blockson building and it was decades earlier when the operations took place compared to when the measurements were made, both at Blockson and at FIPR.

Okay, so that is the essence of the surrogate data issue, and now I'm going to give you my conclusion and then I'm going to tell you why. I don't think it's an issue, okay.

I think what was done by the use of OTIB-54, the use of the factor of ten and, in fact, is acceptable, notwithstanding the surrogate data issues that we

always tried to test. And let me explain why.

Ms. Beach: Hey, John?

Dr. Mauro: Yes?

Ms. Beach: Before you do that, you just brought up OTIB-54. Is that --

Dr. Mauro: No, that should be then 43.

Chair Ziemer: You meant 43, I assume.

Ms. Beach: I want to make sure. Thank you.

Dr. Mauro: Oh, no, I apologize. If I said 54, it's just a slip. It's 43.

Ms. Beach: No worries. Okay. Thanks.

Dr. Mauro: Yes. Good. Okay. What we have here is something that's, first of all is very important. The issue before, the original issue, that open building closed building was an issue.

That issue has now been resolved and that, holy mackerel, look at this, the measurements made in the open buildings, processing buildings in Florida are coming up with concentrations of radon and progeny that are in parity with Blockson.

So all of a sudden we see that. So, oh, okay. So all of a sudden that original issue that was of great concern, now we have data, we have information, the measurements made at Blockson at about the same time.

And timing, by the way is, in my opinion not an issue because the wet processing of phosphate which is all we're really talking about, has been the same forever, you know, the way in which you process phosphate ore, it's been going on forever.

Now, which brings us to timing. Okay, so the first thing I want to point out is the issue, surrogate issue related to open versus closed just went away, okay. Because we now have demonstrated that in theory originally we were worried about it but now with the Blockson data we could say, that's not a really important issue because they appear to be and they were all pretty low, by the way.

We're talking about concentrations of radon and progeny that are background. I mean, that's where we are, which is interesting. But that's the truth.

Ms. Beach: So John -- John, this is Josie.

Dr. Mauro: Yes?

Mr. Beach: Can I stop you for just a quick sec? Where does the Blockson data come into O-43?

Dr. Mauro: No. I'm only bringing up a point of one of the issues had to do with surrogate data from the OTIB-43 --

Ms. Beach: Right.

Dr. Mauro: -- the measured data for open buildings.

Ms. Beach: Okay. So, that was your original --

Dr. Mauro: That was original-original and, by the way --

Ms. Beach: Okay.

Dr. Mauro: -- that's also an issue as applied to Allied Chemical. That's a closed building too. So what I'm trying to say is --

Chair Ziemer: Yes, it's pretty --

Dr. Mauro: -- what --

Chair Ziemer: The 43 is pretty much Florida stuff.

Dr. Mauro: Yes. I think -- yes?

(Simultaneous speaking.)

Ms. Beach: Okay. I -- going back and forth between the 2015 and then the O-43 is just, I want to make sure I understand. Thanks.

Dr. Mauro: Yes, I want to, please stop me at any point because I think, in my head, conceptually, I've come, I'm at a point where I'm comfortable and I'm trying to explain why. And one had to do with the open facility in Florida, processing plants and closed buildings elsewhere such as Allied Chemical and Blockson.

And that was originally the starting point for one of the surrogate data concerns. I believe that that issue has gone away now simply because we're seeing that the measured, the measured values in the open buildings in Florida, OTIB-43 and the closed building, in this case Blockson, their numbers are comparable and they're very low.

And now what's the other issue? The other issue is timing. We're talking about measurements made both at Blockson and at FIPR, Florida. And well, one were made, I guess, decades later.

In other words, both measurements are made -- you folks -- I remembered that they're relatively recent compared to when Allied Chemical operated, which I believe was in the 50s. There's your timing issue.

Well I would argue that when it comes to phosphate ore processing, timing is a non-issue because there's nothing about the nature of the processing that is, that really changes over history.

The same digestive mechanisms are at play. So, I think that timing in terms of things may have changed substantially, doesn't apply.

And then it brings us to one last issue. It has to do with the size of the building and the amount of material. The size of the building at Allied, smaller. The amount of material is orders of magnitude less by way of throughput of ore, maybe a 1,000 times smaller. You folks have the numbers on your fingertips, probably, right there.

Now so, in my mind, using concentrations as your starting point, which is surrogate, which you're are either FIPR, which is OTIB-43, in other words, OTIB-43, its foundation is FIPR data.

It has been validated. Now that yep, you can apply FIPR data open buildings to closed buildings.

Ms. Behling: It seems like they're saying on the right, and then it's on the left?

(Simultaneous speaking.)

Dr. Mauro: I'm sorry?

Chair Ziemer: Kathy, I think you're off mute because and we're hearing you.

Ms. Behling: Okay, sorry. Sorry. Go ahead.

Dr. Mauro: Okay. Now so, what is then you say to yourself, okay notwithstanding the model that, I'm sort of putting it in the parking lot right now, the model that David Allen used to try to cut the deal to come to say well listen, let's make this little room, put all the activity in the room and let it, I mean, to me that's a very, very bounding, unrealistically high-bounding analysis to make such an assumption.

So, let's just put that apart. I'm saying something different. I'm saying you could take either the FIPR data or the Blockson data and say to yourself, do I want to use that for Allied Chemical.

And I said, it would be really, really an overestimate,

and the reason being the throughput of ore is, you know, you have the numbers there, but if I recall we're talking a thousand times smaller. So what do you do?

You say, listen, let's just, you know, and we realize the building is smaller also. And here's where a little bit of what I call let's not over-analyze the problem. They divide it by ten, they said.

And to me they could have divided by a thousand. But they divide it by ten because of the throughput difference and they're still coming -- now stay with me. Now what I believe that does is it gives you a working level or a radon concentration in Allied Chemical that's probably overestimated by at least a factor of ten.

In other words -- but they just divided by ten and here's a very important point. So what they've come up with is what I believe to be an unrealistic overestimate of what the concentrations might have been in Allied and, still, you're below doses that are compensable. I mean, that's where I come out.

I say see, in my world when you use an efficiency approach or a bounding approach or an overestimate approach, that's always okay as long, because it's an efficiency method and, certainly correct me because my recollection of some of these things goes back a lot of years and a lot of, you know, water has flown under the bridge, you know.

But I believe it's okay to do that, overestimate, when in the end you still are not compensating. If this was compensated, I would say we've got a problem. I mean, you just can't throw a big number, but you can throw a big number at something that everyone would agree is a big number and you're still not compensating? Well, problem solved.

So, that's my take away on, yes, there are surrogate

data issues that are at play here, all of which I believe can be reconciled. And I just went through my story of why I've come to a comfortable place. Why NIOSH's approach is fine.

By Bob Anigstein

Chair Ziemer: Thank you, John. Bob, do you have additional comments on the SC&A's position? Is Bob still there? Not hearing him.

Dr. Mauro: By the way, Bob is not, I mean, he may have left I'm not sure or maybe he's on mute. We, Bob and I --

Mr. Anigstein: I'm here.

Dr. Mauro: Oh, okay. Bob, you're back. Good. Yes. Bob, there was --

Mr. Anigstein: Yeah, I'm here. What's the question?

Chair Ziemer: Did you have additional comments, do you have what John -- I take it that SC&A's position is that you are comfortable with NIOSH's approach?

Mr. Anigstein: Yes.

Chair Ziemer: Even though --

Mr. Anigstein: I would simply take a slightly different take on it than John did, and that is the three measurements, three sets of measurements at Blockson would probably be a better surrogate than the FIPR data.

But since it's, they're consistent within a factor of two, I think the FIPR data the way it was used was the 95th percentile, so obviously it should be higher. If it was consistent with Blockson it should also be higher because we don't have 20 measurements.

So I think the surrogate data isn't quite clear,

whether that's the exact correct number but certainly, in this instance, it's certainly bounding. It's unlikely that the radon exposures at Allied were higher because quite frankly they were much lower.

And as John said, for the purpose of denial of the claim, it's accepted. The denial for quote is acceptable. I mean it's a difficult, do to discuss your data it's a difficult problem. I think NIOSH did the best that could be done with it.

Chair Ziemer: Yes. Remind me, Dave Allen, what, with the NIOSH concentration values, what would an annual exposure turn out to be for the worker? Wasn't in a couple millirem range?

Mr. Allen: Well, these working level, the working level values are actually put into IREP as an exposure model when it comes to lung cancers.

Chair Ziemer: Yes.

Mr. Allen: So it's actually put in as working levels and we produce a POC. We don't actually get any dose.

Chair Ziemer: Yes. So you don't actually produce a --

Mr. Anigstein: Paul, I believe that NIOSH is using the UNSCR approach, which is, for radon, they use the data on incidence of lung cancer and relate it to radon concentrations and they skip the dose calculations. So we go directly from working levels to --

(Simultaneous speaking.)

Chair Ziemer: Yes. Yes, I was trying to get a feel for how it would compare to a significant lung dose if you were to go to, say a millirem value. But I guess you don't have a specific number that that would translate to.

But these concentrations compared to normal

backgrounds in homes, which are in a few working level months' value are really low.

Mr. Anigstein: Well, there is a little light cast on it because John Mauro, earlier on, back in 2015 did, in fact -- and probably Kathy helped, was also involved -- in doing a IREP run based strictly on four picocuries per liter, which would --

Chair Ziemer: Yes, which was the Environmental Protection Agency value recommended for upper limit for homes before you could --

Mr. Anigstein: Right. And that corresponded to something like a 60 percent POC. Chair Ziemer: Yes.

Mr. Anigstein: Ignoring all other source terms or other sources of dose to the lungs.

Chair Ziemer: Yes.

Dr. Mauro: You make -- yes, I think it's important to point out that when I did that, back then, we were in a funny place. Said, listen, John, he asked me, you know, what kind of levels might be there?

I said, well, you know, we don't know and I said, well one thing I know is that my basement has one picocurie per liter. Where I'm sitting right now.

And I know that EPA set a limit and people are fixing homes all over the country. Got data from all over the country that's on the order of one to four picocuries per liter. Occasionally you have a higher -- buildings.

So I went down that road and then unfortunately, interesting enough, and this was brought out by Dave, and he was right, is that well, you know, yes, we did, but you know, the radon levels in these buildings from the ore processing doesn't approach that. And he was right.

And so I went down a road that was at the time I thought was reasonable, but it turns out it's not a good approach. The right approach is to say, wait a minute, no, no, no, let's look at what the measured values are in real operating plants. And it's an interesting observation.

Now I would be the first to say that those measurements that they made in FIPR, that might very well be background, you know, I mean, so that's where we're operating at.

We're operating at background levels that everyone -- you sitting right where you are, where you are right now, it's probably what you're getting, you know.

So what I'm getting at is that notwithstanding a lot of the struggling we're going through is to say, well how do we deal with the surrogate issue. And I explained to you my rationale why I think the surrogate issue has been taken care of.

But at the same time, Paul, we're talking about levels that are comparable to the levels that we're all exposed to all the time indoors and that has to be kept in mind. You can't lose sight of that perspective, so, on both levels.

And, by the way, interestingly enough you're coming up with POCs that are pretty high. It goes to show you radon is, it doesn't take very much to be a problem.

We're all living our lives in the level of radon concentration that's -- now I'm being a little speculative -- knocking on the door of a level that could theoretically be argued can cause lung cancer at a, exceed a POC of .5 and we're all living at that.

And so radon, it doesn't take very much radon to be a problem. But I think in this case we're showing that,

you know, they put an upper bound, a reasonable upper bound and we're still coming in with a POC that's below .5, and I think that's where the story ends.

Chair Ziemer: Yes. Well, I think, is it fair to say the bottom line for SC&A is that you accept NIOSH's approach? Is that a fair statement?

Dr. Mauro: Well, I think speaking for SC&A the answer is yes.

Work Group Discussion and Recommendations

Chair Ziemer: Okay. Thank you. Let me ask the work group. Jim Lockey and Ms. Valerio, Ms. Beach, any questions for SC&A or for NIOSH? Further clarity or -- go ahead.

Member Lockey: When I was looking at the levels and sort of doing what John did, is these levels that we're talking about really are not of, I would say of clinical significance from a physician point of view. In other words, I would not consider this an injurious exposure at those levels.

Chair Ziemer: I want to ask Ted -- Ted, does this subcommittee need to make a specific recommendation as to whether or not surrogate data criteria are met or do we simply need to make a decision on whether we endorse or accept NIOSH's approach for using OTIB-43 in the dose reconstructions for this site?

Mr. Katz: Yes, I think, Paul, you just need to make the general recommendation that there's not a surrogate data issue here, if that's what I'm hearing correctly and the methodology is fine. And that then settles matters generally and then it also allows the dose reconstruction subcommittee to close out its case.

So, it would be a, and your recommendation really is a, I mean your finding I would say not a recommendation, is just a finding that you then send back to the DR subcommittee.

But it would also, it would also stand for, you know, this work group's position, should this ever come up, I don't see that it necessarily will but if there's a site profile review for this for the Board to consider then that would --

Chair Ziemer: Yeah.

Mr. Katz: -- that would just be included in that site profile would be for your recommendation to the Board. Yes.

Chair Ziemer: Thank you.

Ms. Beach: So this is Josie. It would seem to me that we would need some kind of a write-up. I know we've had this discussion and maybe the transcript will be write-up enough on the surrogate data issue and the parameters of the Board's surrogate data issues being met to follow along with this. Is that not true or --

Mr. Katz: Yes. I think and then just a fairly brief memo referencing the transcript and just the most salient points, like a very brief paragraph from this work group would be adequate.

Chair Ziemer: Well, Ted, I would like something on that.

Mr. Katz: I'm sorry, Paul, I couldn't hear you.

Chair Ziemer: I would like to see something written from SC&A that identifies what John has told us, John and Bob have told us. And we could have that in the record as well as in the transcript, but, you know, a brief white paper or memo indicating I think basically

what John summarized for us.

And then we could maybe close this out well, would we need to do that in-person or I mean, by phone or can we do it, just, agree to do it after we get that?

Mr. Katz: So I don't, I think you can, I mean if you all conclude this is your conclusion, I don't think you have to wait for that. I think you can have, absolutely, and I think it's a good idea for John to write a summary memo that references this call as well and what was discussed and what SC&A's ending recommendation was.

But I think that the work group can act on it. You don't need another work group meeting to act on it because you already all concluded it.

Ms. Beach: Well --

Mr. Anigstein: This is Bob. Can we, can we wait for that until we get the, at least a rough draft of the transcript because it's a lot easier working from the transcript than just working from memory?

Mr. Katz: Yes, yes. There's no reason why you can't. Yes.

Ms. Beach: Well --

Mr. Anigstein: Okay. Paul, could you --

Chair Ziemer: Another question?

Ms. Beach: Yes, this is Josie. I do have one more comment. But I can wait for Bob.

Chair Ziemer: Yes, go ahead.

Ms. Beach: Well, Dave said something earlier on, Dave Allen, about how, about the surrogate data and how it's supposed to be met.

And so it, and I don't want to put words into Dave's mouth but, that it was, something about it being impossible to meet this criteria. Dave, do you remember what you, exactly, said? I think it's important --

Mr. Allen: I'm sure I don't remember my exact words but what I was trying to say was some of that criteria says you need equivalent source term processes, conditions. And that just doesn't seem to apply to a bounding estimate.

I think John and most others have come to that conclusion, that this is a bounding estimate. But I'm not sure how you judge this against that criteria unless maybe you substitute the word bounding for equivalent. It just doesn't seem like that criteria will work well for a bounding estimate.

Chair Ziemer: One of the things about bounding is that it makes assumptions that are sometimes unrealistic which takes you, in a sense, that says you're not really going one for one as a surrogate but you're doing, you're overestimating.

A lot of overestimating is, you know, we've always agreed is usually a little unrealistic but I think --

(Simultaneous speaking.)

Dr. Mauro: I think, yes --

Mr. Katz: Paul, this is Ted. I'm sorry.

Dr. Mauro: I'm sorry, Ted.

Mr. Katz: It's okay and you can follow me, but I was just going to say I think there's a difference between saying the surrogate data criteria were met and saying that the surrogate data are not an issue here with this dose reconstruction approach. But go ahead, John.

Dr. Mauro: Oh, you used up the wind out of my sails.

Mr. Katz: I'm sorry.

Dr. Mauro: I think that, that this is, when you're in the place where you're not, if you're trying to do a realistic dose reconstruction, certainly surrogate data becomes essential.

In this mode whereby we're trying to place a bounding, all of a sudden surrogate data -- and you certainly need to say something intelligent about it, hopefully we did.

But you're right, you really, the surrogate data criteria may not be explicitly met when you're in this mode of placing an upper bound on an exposure -- and you demonstrate that there's still no compensation. If there was compensation here, we'd be having a whole different conversation.

Mr. Katz: Let me just add, I mean, so thank you John, let me just add, the other thing just for the board members to keep in mind, well everybody, I guess, is it's somewhat comparable to what we've already said with co-worker modeling as well, which is when we're talking about levels of dose that are exceptionally low and inconsequential, it's a different matter and we're not applying criteria the way we would when we have substantial doses and we're trying to estimate reasonably. So, and that's a position the board took related to co-worker modeling as well.

Chair Ziemer: So the wording that we would need to agree on would be along the lines of, well, I'm trying to recall the wording you said, Ted, not that the criteria were met but that what?

Mr. Katz: That surrogate data, it's not really a matter of surrogate data being applicable in this case because this is a bounding estimate and because

these are not consequential levels of exposure.

Chair Ziemer: The surrogate data issue is dealt with? That's different than saying it's met. Is that, I'm trying to find the --

(Simultaneous speaking.)

Chair Ziemer: What?

Mr. Katz: I was saying they're not really applicable in this circumstance but --

Dr. Taulbee: Hey, can I offer a word here, this is Tim. How about that there is no surrogate data issue with the approach that's used for this dose reconstruction?

Chair Ziemer: That's the wording. That's the wording. Yes. Data issue.

Ms. Beach: Well, the surrogate data issue actually came up with the 2015, what we were doing early on, right? So this new --

Chair Ziemer: Right. Right. And it was raised by SC&A originally, was it not?

Dr. Mauro: Yes. Yes. Yes.

Mr. Katz: But, I mean, the subcommittee actually came to the same conclusion earlier on before Dr. Melius wanted to have more examination of the questions. So it's actually pretty consistent with where the subcommittee went with this.

Chair Ziemer: Okay. Well, let me ask if individual members of the work group are comfortable or satisfied with that as our position. Let me ask you individually. Josie, are okay with that?

Ms. Beach: Yes. Yes, I am.

Member Lockey: Yes, Jim Lockey, I'm okay with that.

Member Valerio: Loretta Valerio, I'm okay with that. And I also have one quick comment on John Mauro's --

Chair Ziemer: Oh sure, yes.

Member Valerio: -- regarding what John Mauro said. My question was on the open versus closed buildings. And when he explained it and how it was resolved, that made it much clearer for me so thank you, John, for that.

Chair Ziemer: Yes.

Dr. Mauro: You're welcome.

Chair Ziemer: And you're okay then going ahead, Loretta?

Member Valerio: Yes, sir.

Chair Ziemer: Okay. And I'm agreeable and so, Ted, I think we have the final conclusion.

Mr. Katz: Right.

Future Follow-Up

Chair Ziemer: And we'll have SC&A back their comments up at the appropriate time when they get the transcripts. Is that good?

Mr. Katz: Yes, so that's good. And then, Paul, but then, and the final act would just be for you to send the memo to the DR subcommittee and you can just attend to it in the SC&A report.

(Simultaneous speaking.)

Chair Ziemer: Yes. Very good.

Mr. Katz: And that would be a nice way to wrap this up.

Adjourn

Chair Ziemer: Okay. Thank you very much, everybody. I appreciate everybody's work on this and that concludes our meeting. We'll see everybody in a couple of weeks or a week and a half or whenever it is, coming soon.

Mr. Katz: Bye-bye. A week from now, yes.

Member Valerio: Thank you.

Ms. Beach: A week from today.

Chair Ziemer: We are adjourned now.

(Whereupon, the above-entitled matter went off the record at 2:39 p.m.)