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

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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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WORK GROUP ON THE USE OF SURROGATE DATA

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MONDAY
JANUARY 11, 2010

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

PRESENT:

JAMES M. MELIUS, Chairman
JOSIE BEACH, Member
MARK GRIFFON, Member
JAMES E. LOCKEY, Member
WANDA I. MUNN, Member
PAUL L. ZIEMER, Member

ALSO PRESENT:

TED KATZ, Designated Federal Official
NANCY ADAMS, NIOSH Contractor
TERRIE BARRIE, ANWAG
HANS BEHLING, SC&A
TOM BOLIN
ANTOINETTE BONSIGNORE, Petitioner, Linde
NICOLE BRIGGS, SC&A
DENISE BROCK, NIOSH
JASON BROEHM, CDC
WILLIAM FRANKLIN
EMILY HOWELL, HHS
JENNY LIN, HHS
ARJUN MAKHIJANI, SC&A
JOHN MAURO, SC&A
ROBERT McGOLERICK, HHS
DAN McKEEL, Petitioner, Texas City
FREDDY MORGAN, JR.
JAMES NETON, NIOSH OCAS
ANITA PORTER, for Nelson Porter
JOHN STIVER, SC&A
BILL THURBER, SC&A

T-A-B-L-E O-F C-O-N-T-E-N-T-S

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

(1:03 p.m.)

MR. KATZ: This is the Advisory Board on Radiation Worker Health, the Surrogate Data Working Group. My name is Ted Katz and I am the Designated Federal Official of the Advisory Board.

And as always, we begin these meetings with a roll call. Jim, I'm correct, right, we're not really treating any individual site. Is that correct? We don't need a conflict of interest -- okay. Well, roll call beginning with Board members. Right. And before we do that --

MEMBER ZIEMER: Are these Board members signing in?

MR. KATZ: Yes. Everybody who is not speaking as a group at this time, would you please mute your phones. If you don't have a mute button, I know there is a member or two from the public on the phone, you use the *6 on your phone. That will mute your

phone if you don't have a mute button. And then when you want to speak to the group, you use *6 again and you can speak again.

And also let me say to everybody now please don't put your phone on hold at any point. Just disconnect and call back in if you need to go away for a bit.

Okay. So roll call beginning with Board members.

MEMBER MUNN: This is Wanda. I must say that the previous speaker expressed my feelings exactly.

MEMBER LOCKEY: Jim Lockey.

CHAIRMAN MELIUS: Jim Melius.

MEMBER ZIEMER: Paul Ziemer.

MEMBER GRIFFON: And Mark Griffon.

MR. KATZ: Okay. Josie Beach, are you on mute?

MEMBER BEACH: Can you hear me?

MR. KATZ: Now I can, yes.

MEMBER BEACH: Okay. This is Josie Beach. I'm here.

MR. KATZ: All right. Then moving on to NIOSH-ORAU team.

DR. NETON: Yes, this is Jim Neton in Cincinnati from NIOSH.

MR. KATZ: Okay. Anyone else from NIOSH ORAU team?

MS. BROCK: This is Denise in St. Louis.

MR. KATZ: Denise Brock.

MS. PORTER: Yes, this is Anita Porter for Nelson Porter from Texas City, Texas.

MR. KATZ: Wait, wait, now we're just getting people who are working for the program. But we'll come to the public soon.

MS. PORTER: Oh, okay.

MR. MORGAN: Okay. My name is Freddy Morgan, Jr.

MR. KATZ: No, we're just asking for roll call among people who are with the government right now.

MR. MORGAN: Oh, okay. So you'll

--

MR. KATZ: We'll get to you shortly.

So Denise Brock, that's it for NIOSH-ORAU team.

How about SC&A?

MR. MORGAN: Oh, okay. You are going to call me or do you want me to call you back?

DR. MAURO: This is John Mauro from SC&A.

MR. MORGAN: Oh, okay. Okay. All right, then. Thank you, sir.

MR. KATZ: Anyone else from SC&A?

MR. THURBER: Yes, Bill Thurber from SC&A.

DR. MAKHIJANI: Arjun Makhijani from SC&A.

DR. BEHLING: Hans Behling, SC&A.

MR. KATZ: I'm sorry, you're all talking -- stop, stop, you're all talking over each other and I can't make out one person

from another. I have John Mauro and Arjun Makhijani. Someone was in between?

MR. THURBER: Bill Thurber.

MR. KATZ: Bill Thurber.

MS. BRIGGS: And Nicole Briggs.

DR. BEHLING: Hans Behling.

MR. STIVER: John Stiver.

MR. KATZ: Okay. Is that it for SC&A?

(No response.)

MR. KATZ: Okay. Then other HHS or other government employees or contractors?

MS. HOWELL: Emily Howell, HHS.

MS. LIN: Jenny Lin, HHS.

MS. ADAMS: Nancy Adams, NIOSH contractor.

MR. McGOLERICK: Robert McGolerick, HHS.

MR. BROEHM: Jason Broehm, CDC.

MR. KATZ: Okay. And then how about any -- either members of the public or staff of Congressional offices who want to

identify themselves. You don't have to identify yourselves but if you want to.

DR. McKEEL: This is Dan McKeel. I'm the co-petitioner for Texas City.

MS. BARRIE: Terrie Barrie with ANWAG.

MR. FRANKLIN: This is William Franklin from Hitchcock, Texas.

MR. BOLIN: Tom Bolin, Columbia, South Carolina.

MS. BONSIGNORE: Antoinette Bonsignore for Linde Ceramics.

MR. KATZ: Okay, then. Let me just remind, again, everyone in the public. I can hear a lot of background noise which suggests to me a lot of people's phones are not on mute. Please mute your phones. If you don't have a mute button, use *6. And then use *6 again if you want to come back to actually address the group. Thank you.

MEMBER ZIEMER: Dr. Melius? This is Ziemer. Could I ask a question before you

get underway?

One of the questions Ted asked was whether or not any sites are being discussed in this meeting for purposes of us identifying conflicts of interest. I think you said no but we do have some materials that were sent by Dr. McKeel for -- regarding Texas City Chemical. Is that going to be on the agenda or not?

CHAIRMAN MELIUS: I was -- this is Jim Melius -- I was going to reference that. But since we got that late last week and my attempts to follow up on that and address some of the questions that Mr. McKeel -- Dr. McKeel raises, we don't have information back. And so I don't think we can really do justice to --

MEMBER ZIEMER: Yes, well, I just wanted to make sure in terms of the conflict question --

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: -- whether we

would be discussing Texas Chemical --

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: -- at all.

CHAIRMAN MELIUS: It's actually why I waited and didn't put out the agenda until -- ended up not putting out one because I was waiting to see if we would hear back and I've inquired of Ted and others trying to figure out what is going on. But we just don't -- I don't think I have enough information back --

MEMBER ZIEMER: Okay.

CHAIRMAN MELIUS: -- to do justice to it.

MEMBER ZIEMER: Thank you.

MR. KATZ: So, Jim, Dr. Melius, it's yours.

CHAIRMAN MELIUS: Okay.

Good afternoon or good morning, depending on where you are. And welcome to the fourth or fifth meeting of the Surrogate Data Work Group. And today we're going to

focus on surrogate data in a general sense. This is an issue -- as I said, we're not going to discuss any specific sites but, in essence, we end up discussing many different sites potentially when we have these discussions because of the use of surrogate data at many different sites in terms of dose reconstruction and SEC review. So we understand everyone's interest in the subject.

It's also a subject that is under the purview or review of a lot of different groups within the Board, a lot of different Work Groups. And so some of that is confusing at times in terms of keeping track of and we'll be referring to documents and comments that have come up in the context of other Work Groups and there is ongoing review in other Work Groups of this issue or of sites related where this issue is important of that.

I thought a way of starting the discussion and sort of reminding us of this issue and where we've come and so forth to go

back to one of the early documents that SC&A put together, which was their sort of inventory of the use of surrogate data. It goes back to 2007 but I think it is still useful to sort of remind us of the scope of the use of surrogate data.

And, John Mauro, if you wouldn't mind sort of giving us a quick overview of that document and then any updates that you would have?

DR. MAURO: Sure. I'd be glad to.

Good afternoon, everyone. One of the first work products that SC&A was requested to prepare to sort of get the thinking started on surrogate data was what I call a compendium of information whereby there was a report prepared. I believe all the members of the Work Group have received a package of the various reports that SC&A has prepared, one of which is this compendium. It's 2007. I'm in the process of opening my file on this.

It's titled NIOSH Site Profile Surrogate Data Survey. It is a PDF file. And it is dated September 12th, 2007. And it was Privacy Act cleared on December 21st, 2007. So it is a document that can be distributed if it has not already been distributed.

What was done at that time was to review the Site Profile reviews and the dose reconstruction audits that SC&A had completed to that date and try to capture places where surrogate data was used in its various forms. And one of the things, in brief, we found that it is possible to sort different ways in which you could talk about surrogate data. And I called them Type 1 versus Type 2.

And what we basically did is we prepared a series of tables, which identified those sites or those dose reconstructions where Type 1 surrogate data was used. By Type 1, I mean places where bioassay or film badge data or air sampling data were used from one facility to supplement the data for another

facility for the purpose of dose reconstruction.

We called it Type 1 because that is really the primary place. That is the kind of data that is most directly relevant. And, of course, it is of primary interest to the Work Group. It is when you may take bioassay data from one facility, air sampling data from a facility and then use that data somehow to reconstruct doses for workers at a different facility.

So -- and there's a whole -- I won't go into them but there is a long list in these tables that we provided of where we found such use of surrogate data in Site Profiles and dose reconstructions.

In the very same table, I have another column called Type 2. These are places where it is less direct, where, for example, there may be certain information that is of more of a generic nature that is being applied. It is not bioassay data. It's not

air sampling data. But it might be other types of information that is taken from the open literature or taken from a site which is not bioassay, it's not air sampling, it's not film badge data, but it is other data related to experience at another site that is of use in performing dose reconstructions.

And I'm looking at the table now. And it was somewhat of a judgmental call of what to drop into Type 1 versus Type 2. But, in general, if there is an assumption made and a calculation that is more of a neutron to photon ratio, I think that would be a perfect example of what I call a Type 2 data where there is widespread information from the weapons complex on neutron to photon ratios for reactors versus plutonium handling facilities versus various types of facilities where there is some experience.

And there are occasions when you could say okay, from the experience at this facility on neutron to photon ratios, it might

be useful in helping to reconstruct doses at another facility. There are a number of parameters like that -- minimally detectable levels of neutron exposure, MDLs.

Medical X-ray default assumptions regarding exposures to occupational medical X-ray, these are all what I would call Type 2. So in effect -- and I'll cut this off at this point -- this table is a compendium of examples of where, at that point in time, SC&A had observed Type 1 and Type 2 uses of surrogate data.

And it was a starting point to start to get a feel of the extent and the nature that surrogate data is being used on the program.

CHAIRMAN MELIUS: Thanks, John.

I'll just sort of point out two things there. One is that -- strikes me is really where we have, I think, what we are reviewing and have been discussing and probably what is controversial, we've had

disagreements among Board members and so forth of how to apply it has been in the area of Type 1 --

DR. MAURO: Yes.

CHAIRMAN MELIUS: -- not Type 2. And I don't think that is always clear in some of our discussions on this. And I think it is sort of an important point to keep in mind.

Secondly, I think although a lot of our discussions and focus have been on two areas of the use of surrogate data, one has been use of radon data, the other is in the uranium processing facilities, there are a number of other areas where it has been or is being used within the OCAS program.

So we are talking about areas that go beyond just radon, go beyond just the uranium processing facilities. So I think we need to keep in mind that it is a broader use of it. And I think how we approach it, at least to some extent, needs to keep in mind that there are these other areas where it is

utilized.

Does anybody else have any additional comments on the Board?

MEMBER ZIEMER: Yes. Are you going to get to the other SC&A document as well --

CHAIRMAN MELIUS: Yes, I am.

MEMBER ZIEMER: -- Dr. Melius -- yes. This one is more of a compilation rather than dealing with the issues per se, I think, isn't it?

DR. MAURO: That is correct.

MEMBER ZIEMER: I mean you've identified how it is being used pretty much in this first document.

DR. MAURO: Yes, Paul, this is John. Yes, that was, at the time, which was back in 2007, just to get a feel of how --

MEMBER ZIEMER: Right.

DR. MAURO: -- surrogate data is being used and the extent to which it is being used.

By the way, of course, a lot has happened since 2007. And there are many, many more examples that could be laid into the table. But it was the experience we had as of that date.

CHAIRMAN MELIUS: Any other comments or questions from the Board?

MEMBER MUNN: I guess -- this is Wanda -- Jim, I would just question whether you are making any implication with respect to these Type 2 uses. Are we just simply saying they exist?

CHAIRMAN MELIUS: I think we're just saying that they exist. I suspect that many of those uses as you are glancing through it have been reviewed or are being reviewed by your Work Group or the Subcommittee on Procedures. It seems that that is where they would fall.

But just, I think, reminding us that, I think, where we focused and feel that there is, you know, we needed to develop some

criteria then in the Type 1 area.

MEMBER ZIEMER: And this is Ziemer again. And I agree with that. I think that, for example, on the medical dose reconstructions, I don't think there's typically been much question about those other than sometimes the question as to whether or not it's fluoroscopy or radiography that was used.

But in general, if you say that, for example, that radiography was used and you have the information on the milliamp seconds that were used typically in a certain time period and, you know, the size of the chest X-rays, those are fairly straightforward use of surrogate data that I don't think that -- the Board hasn't really been that concerned about it because it is a pretty straightforward, you know, medical X-ray within those parameters is pretty much the same wherever it is done.

And they have been using, you know, the worst case kinds of the -- I mean

obviously you get different chest X-ray outputs from different places but you can take worst cases and use those.

CHAIRMAN MELIUS: Right. And I also think there that assumptions about the frequency of the surveillance X-rays probably are as important as assumptions about --

MEMBER ZIEMER: Right, right.

CHAIRMAN MELIUS: -- those exposures from a single X-ray --

DR. MAURO: Jim, this is John Mauro. I would like to add one point, something that was not captured in the compendium, is that there have been a number of very important procedures that have been issued subsequent to this that go toward this question.

I can think of two. One is OTIB-0054, I believe it is, which is a generic approach for reconstructing doses at reactor facilities when you only have gross beta gamma in urine. In other words, very often the only

information you have is a very simple gross beta gamma measurement of a urine sample. And you have to allocate radionuclides. So what the distribution of radionuclides might be that the person inhaled.

And I would consider this to be a type of surrogate data because, in effect, generic approaches come up whereby if you know the type of reactor a person may have worked at and you have some gross beta gamma information, there is a look-up table in OTIB-0054 that will help you navigate you way through doing dose reconstruction.

And similarly, TBD-6000 and 6001, which deals with uranium and thorium metal handling and processing facilities, provides a great deal of compendium of information on what are air dust loadings to assume if you are confronted with a real uranium handling or processing facility where you don't have sufficient data.

And so these are two very

important, I would say, procedures and TBDs that we did not capture in our compendium but very much go toward the question of surrogate data.

CHAIRMAN MELIUS: Yes, John, one question I have. And that's OTIB-0054, I'm not familiar with at all -- 6000 and the appendices to 6000, I'm more familiar with -- but with 0054, would you consider a Type 1 or a Type 2? In hearing you describe it, I almost thought it was more of a Type 2.

DR. MAURO: That's a judgment call.

CHAIRMAN MELIUS: Yes.

DR. MAURO: In my judgment, I would call it Type 1 because what it does is it allows you to reconstruct bioassay basically. My breakpoint is if the methodology directly goes toward bioassay results, external dosimetry results, or air sampling results.

In a way, I guess the OTIB-0054 is

a way for you to sort out your bioassay information. You know it's sort of -- it is a difficult one to split whether you -- and it's a judgment call whether you would drop that as a Type 1 or a Type 2.

MEMBER ZIEMER: But -- this is Ziemer again -- could I just ask the question there, John, you are talking about cases where they have actual bioassay data for that reactor.

DR. MAURO: Yes.

MEMBER ZIEMER: But so that wouldn't be surrogate data then.

DR. MAURO: Well, they have bioassay data but it is in a gross beta gamma form. And you have to figure out a way to assign what the radionuclide distribution is.

MEMBER ZIEMER: Yes, I understand that. And you are saying it is surrogate data in the sense that you use the experience of other reactors where they have had a similar distribution --

DR. MAURO: Yes.

MEMBER ZIEMER: -- of the nuclides.

DR. MAURO: Yes.

MEMBER ZIEMER: Yes.

DR. MAURO: It's completely, you know, a judgment call on whether you would consider that something within the Type 1 or Type 2. But I thought it was important to bring it up because it was one of those areas that form that gray area. And we should be aware of these distinctions.

MEMBER MUNN: But it is using known science just as we use known science every day. Making biscuits or making medical diagnosis or doing dose reconstructions, we're using known science.

CHAIRMAN MELIUS: But I think we're talking about what is the criteria for what known science will we use and when will we apply it. I think that's the issue to that. But I actually think the distinction

between the Type 1 and Type 2 is important. And I guess, again, the same reaction with Dr. Ziemer that it seemed that OTIB-0054 -- which again, I'm not familiar with -- it sounded more like a Type 2 situation.

DR. MAKHIJANI: Jim, this is Arjun.

CHAIRMAN MELIUS: Yes?

DR. MAKHIJANI: I think, you know, we recently had a look at this same issue in the Nevada Test Site because NIOSH said it is hard to interpret fission product and beta data for NPF workers. And partly the time of sample relative to the time of exposure was not known and there are so many short-lived fission products.

And some of that reasoning may apply here in that you need to know the time at which the sample was collected. And then presumably you could run a computer model for that reactor. But you couldn't find the mix of fission products for the bioassay sample

unless you knew the times. So maybe you would resort to something more generic if you don't know that.

DR. MAURO: Yes. Well, that's one of the challenges of surrogate data, certainly.

CHAIRMAN MELIUS: Yes. And, Arjun, I guess like in thinking about it that way and it's not just thinking about it in terms of TBD-6000 appendices, is there are differences among the sites in terms of what data is available to use --

DR. MAKHIJANI: Yes, I think --

CHAIRMAN MELIUS: -- from the site. And then how much -- sort of the extent to which surrogate data needs to be used at that site. And these are all, I think, very dependent on what kind of dose you are trying to model, the situation where, you know -- because obviously they can range over a wide range in terms of the complexity of the situation and how much information is

available to be able to extrapolate from.

DR. MAURO: Jim, if you really want to make a -- one of the problems you have is if you really want to make a really clean break between Type 1 and Type 2, and we can do that, and interpret Type 1 in its narrowest sense -- in other words it's just a way to kick the discussion so that it doesn't blur lines -- if you are directly using bioassay data or directly using air sampling data or directly using film badge data from one site to sort of supplement the data or use those measurements and interpret that as Type 1, then I would say 0054 -- OTIB-0054 is clearly then Type 2 because, you know, it is one step removed from that.

So I mean it may be easier for the sake of this discussion in order to create a nice, strong, clean boundary between Type 1 and Type 2, and certainly that doesn't mean we're not interested in OTIB-0054 -- but I mean perhaps the greatest interest right now

is when you take air sampling data from one site and you use it at another site. That would be the classic radon question, for example.

Maybe just for the sake of this discussion, it is easier to make a bright line. And that bright line can be drawn.

CHAIRMAN MELIUS: Yes, I know, I think in a lot of our discussions, we're assuming that that -- what you say, that that bright line -- and I think trying to keep the focus here on the -- should I say the purer Type 1 situation though given the complexity of these situations, it can be hard to figure out where the line is and so forth.

Any other comments or questions?

(No response.)

CHAIRMAN MELIUS: Okay. What I thought would be useful is the other document, given how much paper there is out there on this, is to then go ahead and John, if you would like to talk about your review of the

NIOSH surrogate data document?

DR. MAURO: I'll be very brief. We delivered to the Board -- this was not a Work Group product but it was a full review of OCAS-IG-004. This is the procedure that was issued by NIOSH entitled The Use of Data from Other Facilities in the Dose Reconstruction Under EEOICPA.

It is a formalization of NIOSH's position regarding under what conditions can you use surrogate data in the strict sense that we just provide. And SC&A was tasked with reviewing that. Our deliverable, the date of delivery was March 30th, 2009. And I believe the document was cleared for -- was PA cleared.

Well, let me make sure -- no, I'm not 100 percent certain of that because I'm looking at the document right now on my page. And I don't see a place where it says PA cleared.

MR. KATZ: John, that's correct.

It is PA cleared.

DR. MAURO: It has or has not?

MR. KATZ: It has been cleared, yes.

DR. MAURO: Oh, very good. Thank you.

See, without getting into the details of it but in effect what the most important thing, I guess, we did was look at the criteria that NIOSH set forth. And they had a number of criteria for how to -- when and where, under what conditions surrogate data can be used.

And we reviewed it -- and we performed a review of that document. And we reviewed it. This is a subtlety that is important to follow. We reviewed it purely from the point of view of Part 82. In other words, Part 82 provides direction in the regulations for dose reconstruction and how to go about doing dose reconstruction.

And we reviewed OCAS-IG-004 from

the point of view of compatibility of these protocols with the provisions of Part 82 as opposed to Part 83 where there is some specific language regarding surrogate data. So this is what I would call strictly a review of the degree to which we felt technically NIOSH has identified all of the salient issues that we think are very important when you are going to use surrogate data within the context of -- you know, to do dose reconstructions in accordance with Part 82.

And we had a number of findings. Hans Behling did all of the heavy lifting and hard work on this. And there are a list of seven findings that are right there in the Executive Summary. I believe everyone has that. But, you know, I guess -- and we also made a comparison between the criteria that NIOSH has set forth in this OCAS-IG-004 and the draft criteria that the Surrogate Work Group prepared.

And in many regards, they are very

similar. That is there is a lot of overlap between this document and the draft criteria by the Working Group.

There is one criterion that is in OCAS-IG-004 that is not in the criteria for the Work Group and that has to do with plausibility. And I know that everyone is aware of that issue.

And the other aspect that is an important difference between the Working Group is the issue of the -- I guess at the time -- the time period. The Work Group -- Surrogate Data Work Group had some very specific language that you really have to -- the data you are using as surrogate data has to come from the same time period that you are applying it to.

While NIOSH's criteria says that well, you know, it is desirable to do that but you certainly can use data from another time period to apply but, of course, you have to be very careful. And they lay out the

conditions under which, you know, perhaps, you know, you could do that.

So I would say to boil things down, those are the two areas where there is a -- I would say a substantive difference between the two documents.

I don't know, Hans, is there anything -- Hans, are you on the line?

DR. BEHLING: Yes, I am.

DR. MAURO: Yes, is there anything that you may want to add to that? And I just tried to capture the sense of your report.

DR. BEHLING: Yes. I would just like to say that the initial issue that you discussed was really a legal issue. And we were asked to refrain from further comment because I guess we were considered non-lawyer types and, therefore, perhaps not entitled.

But on the other hand, it seems in our write up we did ask the Board to look into it and specifically in context with Paragraph 82.17. And I guess it really comes down to

the simple thing. When we talk about surrogate data, we cannot talk about a single type of surrogate data because what we are really talking about are degrees of separation for the various types of surrogate data.

And I guess the surrogate data that are being addressed in Implementation Guide 004 is really defined in footnote number three on page four of that particular document which basically provides you with the following.

It says in footnote three, traditionally the term surrogate data refers to the use of any data that is not a direct measure of the individual worker's exposure conditions, e.g., general air samples of coworker models. In this document, however, the surrogate data is only considered in the context of the use of data from another facility.

So here we are basically looking at a very unique definition of surrogate data

which says from another facility, which means separation in space and time. And, of course, that is probably the furthest of degree of separation in use of surrogate data.

For instance, if we were to say a person worked at Facility A and he was not monitored but we have coworkers who were monitored at the same facility during the same time period, we would say well, it is surrogate data but it is very close in time and space.

On the other hand, I think what we were questioning in our initial assessment of Implementation Guide 004 was this high degree of separation in time and space. And for that we referenced 82 CFR 17 and there is the definition that we were looking at or I was looking at was that there were three types of data that can be used.

But in two of the three types, the statement in the regulations state that the monitoring data taken from coworker data has

to be considered. In other words, we have to really look at the environment in which the individual for whom there is no direct monitoring data was actually exposed. And, of course, that is the question.

It's a highly subjective issue when you say okay, the surrogate data is not the facility in which he worked both in location and in time. And to what extent do the current regulations support the use of such data? And I think this is something that the Board has yet to really discuss.

CHAIRMAN MELIUS: Anything further, John?

DR. MAURO: I just -- yes, one of the things that we neglected to point out, we're defining surrogate data -- I presume everyone agrees -- as using data from one site for another site. And it has become a term of trade amongst ourselves.

Whenever we're talking about data on a given site for the same site, that goes

toward the building of a coworker model. So I guess it is important that everyone recognize -- I assume everyone was familiar with -- when we refer to surrogate data, we're referring to data collected from one site and them somehow applying it to workers at another site. We want to keep that in mind.

CHAIRMAN MELIUS: Okay. Anything further?

MEMBER MUNN: Yes, with respect to this particular group of items, Jim, I'm sure that you are aware that we have looked at all of these findings in the Procedures Work Group. And the decision was made to transfer the two outstanding items, which is Item 3 and Item 7 from Procedures to you.

You have not yet received that email from me with that information. But I -- it was the expectation of Procedures that those two items would be transferred to this Work Group for a solution.

CHAIRMAN MELIUS: Wanda, are you

saying the check is in the mail?

MEMBER MUNN: The check is in the mail. It's on my list of Work Group items to be completed.

CHAIRMAN MELIUS: I understand.

MEMBER MUNN: It's on my action list, my personal action list.

CHAIRMAN MELIUS: Which is one of the reasons I wanted to focus on this document because I think it is probably the most -- the one we've all reviewed and there is written comments on. And I believe the specific areas are the ones that we would be focusing on anyway.

But there is one other issue I guess to go back to which I find sort of puzzling. And this is a question for NIOSH. It came up -- the NIOSH surrogate data document, the document that SC&A is reviewing, you present sort of a -- what I originally took to be sort of a scientific justification for using surrogate data by referencing other

situations where surrogate data is used, either other programs or epidemiological studies or models in the area.

But in your response to the SC&A critique of those, sort of NIOSH seems to walk away from that. And I guess I'm having trouble understanding your response on that.

DR. NETON: This is Jim Neton. I think SC&A's observation was correct in the sense that the -- some of the examples that we offered as precedents for the use of surrogate data are not directly applicable to a compensation program. And, in fact, this is a fairly unique compensation program.

As I indicated -- as we indicate in our response, we are merely trying to point out that, you know, we did not sort of invent this technique. Surrogate data has been used scientifically in a number of different applications, including epidemiologic studies but also I think we reference one previous compensation program.

Even in that case, however, one can argue that, you know, it was a different type of compensation program and methodology and such.

So the point really wasn't that it justified the use of surrogate data under EEOICPA but the fact that it is a valid scientific technique that can be used when you have to fill in, as the law requires, for missing data. By that definition, any missing data is surrogate data. And we've developed techniques and one of which is to use data from one facility to another.

So I'm not saying -- I don't know as we necessarily backed away from it but we definitely didn't want to leave the misconception that SC&A seemed to have that we offered that as positive proof that it was valid for use under EEOICPA. I'm not sure I have much more to say.

CHAIRMAN MELIUS: No, no, that's putting it well. That's like -- I thought you

were saying and it wasn't in your response -- the SC&A review of IG-004. However, it has not been sort of what, I think, has been presented verbally at least at a number of our previous discussions of this issue.

And so I was just, I guess, wanting to reaffirm that because I mean I actually agree with SC&A and I guess with NIOSH that these other uses are significantly different. And, for example, the use of surrogate data for epidemiological studies is sort of far different than using surrogate data for individual dose reconstruction.

In fact, one would expect a higher degree of accuracy or precision in using it for individual dose reconstructions than one would for using it in epidemiological data where in a sense you are looking at big groups of people and trying to categorize them in some way.

And albeit more accurate to do that, the better, but it still -- you're not

trying to predict what an individual's dose was.

DR. NETON: I agree with you on that point except for the fact that in this program, we do have the opportunity to produce what we would believe to be a plausible upper bound so that they are not necessarily exact representations of the person's dose. We're not constrained to that.

We can demonstrate that as a plausible upper bound, we believe that it is a significantly accurate technique.

MEMBER LOCKEY: This is Jim Lockey. In some of the studies that we do here at the university, and they are epidemiology studies, we actually will go back where the data is good data, we'll use surrogate data where we can actually come up with a worker-specific cumulative exposure based on -- and, again, it's really based on how good the data is from the company we're looking at or the industry we're looking at

and productivity changes and equipment changes and ventilation changes. And how you can apply it across industries.

But it is a scientific methodology that is accepted if you have good quality data and you can really keep a log as to your justification as to why it is applicable to another industry across the street that is essentially doing the same job.

And so I would say there is literature out there that says -- and, again, it is based on the quality of the data and how high you set your confidence intervals on that data -- but there is literature out there that supports using surrogate data from an epidemiology perspective, looking at dose response relationship, particularly your dose, not duration, not job task, but true dose.

DR. MAKHIJANI: This is Arjun. Just the difference between what the two Jims said. You would not put an upper bound dose in an epi study because it would distort it.

CHAIRMAN MELIUS: I'm sorry. I can't hear you.

DR. MAKHIJANI: This is Arjun.

CHAIRMAN MELIUS: Yes?

DR. MAKHIJANI: You would not put an upper bound dose in an epi study because it would distort your dose response relationship. But in this program, you sometimes want to put an upper bound.

CHAIRMAN MELIUS: Well, what we do is we can put a -- we can say this is what we think the mean is and this is what the upper bounds can be based on how good or not good the quality of the data is.

So you present it all so the reader can read it all. But you can do that like, you know, for refractory summary fibers, which we've been looking at for 20 years.

We can actually go back and extrapolate what the most likely individual dose is in another company who made that material based on the time frame they were

producing it, the machine that they were using, the ventilation equipment they were using, and their particular job tasks.

So we can assign an individual dose to that worker even though we don't have industrial hygiene data.

MEMBER LOCKEY: And, Jim, I think really it depends on the quality of the data and how much of the information you have available. If you don't have the production data, you don't have the machinery, you don't have the ventilation data, you don't have the source material, et cetera, et cetera, it becomes much more difficult.

CHAIRMAN MELIUS: I think we have two conversations going on here, Jim. But I heard most of what you said on that.

DR. BEHLING: Dr. Melius? Let me just make a comment since I was the one who wrote most of the stuff that you are referring to here.

I didn't say that epidemiologic

data would suffer from very accurate data. What I intended to say here is that accurate data, while it is most important if you do have a dose response relationship that you need to define.

On the other hand, many epidemiology studies can survive in the absence of dose-particular, highly detailed information and still provide the epidemiologist with a tool to say that there is a positive correlation even if the individual numbers are far from accurate.

And in the case of the compensation program, we do look for accuracy. And for that reason, we do have -- if there is an absence of data, the SEC option. And this is the point that I was trying to make here. I didn't want to imply that, as Dr. Lockey said, when there is good data available, of course you use it.

But there are plenty of epidemiology studies that are not necessarily

in a position to make use of those highly definitive information, including some of the earlier BEIR studies that defined the dose relationship between Hiroshima and Nagasaki survivors to that of cancer induction.

And that was the whole point of my statement here is that an epidemiologic study, unlike the compensation program, may survive in the absence of definitive data. But in the case of a compensation program that looks at a 50 percent probability causation as a cut-off point, then I think you have to be a little more discriminating as to what is acceptable and what is not acceptable. And that's the point of that discussion.

MEMBER LOCKEY: Hans, I agree with your statement. I just think there are studies -- there are epi studies available that do precisely that. That can come up with a very precise individual dosimetry on person.

DR. BEHLING: Absolutely. And I fully agree. And as I said, that's not the

point of what I stated here.

When that data is available, of course you would make use of it. There's no question that there are some epidemiologic studies that have as a basis in terms of defining a dose response relationship, first class data. On the other hand, there may be many epidemiologic studies whose data would not suffice to do a compensation program. And that's the point of my discussion.

MEMBER LOCKEY: No, I don't disagree. I think your write-up though didn't give fair to the former, that there are -- actually there are some studies out there that do have very precise dose response relationships on a worker by worker basis.

MEMBER ZIEMER: This is Ziemer. I would just comment that I think we're only talking here about the principle that if data is used in scientific applications, not just epidemiology, but multiple, you always have to show that it applies in the case that you are

using it for. So --

DR. BEHLING: Absolutely.

MEMBER ZIEMER: -- that's what I think leads you to the criteria which, you know, we will get to I suppose and at some point we need to formalize. But what it leads you to is the criteria which you can operate and say this is a valid use or not.

I don't think anybody is arguing that we're using this for epidemiological studies. I think the question Hans is raising is can you use this sort of methodology in a different application.

I think the general statement, as I understood it in the NIOSH document, was simply that the principle of using surrogate data is one that cuts across a number of scientific disciplines. It's not a new method by focus but it is used in a variety of different scientific applications in appropriate ways. So that's just a comment.

CHAIRMAN MELIUS: Yes, this is Jim

Melius. But I think the way it has been discussed, though it is not, I don't think, written in this document, but discussed in the past is that sort of the use of surrogate data in epidemiological studies therefore means that it has sufficient accuracy to be used in dose reconstruction.

And I think that doesn't necessarily follow. And I think that is sort of what we had heard before. And similarly the use of surrogate data in individual exposure protection means that it is sufficiently accurate. And I think that that also, you know, doesn't necessarily follow.

And as we continue to go through this program over the years, what we continue to wrestle with what is sufficient accuracy and also what is plausibility. And I'm afraid that is what this issue also tends to come down to. And I guess we will continue to wrestle with those.

And I guess we don't -- we can't

rely on outside uses of surrogate data or anything else, the applications as a way around having to wrestle ourselves with what is sufficient accuracy and what is plausibility.

Anybody else have any comments on that?

(No response.)

CHAIRMAN MELIUS: Okay. In the interest of the third -- if you are referring to the Executive Summary that -- SC&A's report which starts on page four and goes through -- number one is the legal issue -- regulatory issue. I'm not going to -- I'm going to ignore that.

Secondly was the precedent, the discussion we just had.

The third issue that is raised is the issue of -- which I think NIOSH agrees with, if I understand correctly, that basically -- and what John stated earlier -- is that the -- that while the criteria that

are laid out in 004 may be sound, I mean the real issue is the application. And if I understand NIOSH's response to the SC&A comments is basically NIOSH agrees. It's sort of a question of application.

DR. NETON: Yes, that's right. I mean we don't disagree that there may be some difficulties in countering the application of the data -- or surrogate data. But, you know, the proof is in the -- we believe that it is incumbent upon us when we do use it to demonstrate through the application of these tests that they are, indeed, scientifically sound. So it will be -- the proof is in the pudding, I guess.

CHAIRMAN MELIUS: I think we've been using biscuit analogies.

DR. NETON: Okay.

CHAIRMAN MELIUS: The proof is in the biscuit dough.

DR. NETON: Yes. And there may be some applications where, you know, we run up

against the wall and say yes, we can't use it in this particular situation. That remains to be seen.

CHAIRMAN MELIUS: Well, I think Blockson is an example, right?

DR. NETON: Well, Blockson, I was going to mention that previously -- well, there's two issues with Blockson.

One is the radon issue, which I don't really believe is a Type 1 surrogate data application. That is a model, a probabilistic model that was based on essentially first principles of air turnovers and such. So it did not -- I'm speaking of the second generation radon level.

CHAIRMAN MELIUS: Oh, okay. I was talking about the first generation.

DR. NETON: The first generation model, I would agree --

CHAIRMAN MELIUS: Yes, okay.

DR. NETON: -- withdrew that because it didn't pass the test in our paper.

CHAIRMAN MELIUS: Yes.

DR. NETON: Okay, if we're talking about the first model, I would agree with you.

CHAIRMAN MELIUS: Yes, okay.

DR. NETON: At least for that particular facility.

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: Dr. Melius?

CHAIRMAN MELIUS: Yes?

MEMBER ZIEMER: Ziemer here. We're still on the third item in the --

CHAIRMAN MELIUS: Yes, we are.

MEMBER ZIEMER: Yes, it looked to me like -- is the focus on this the time period issue? Or maybe I should ask SC&A that. It basically ends saying such use would be in conflict with the draft criteria, which restricts the use of surrogate data to the same time period.

DR. MAURO: This is John. To answer your question, it's both. Item number three is a broad sweep. It identifies the

different parameters that you have to be careful about when you are applying surrogate data. And it talks about lots of things.

MEMBER ZIEMER: Yes.

DR. MAURO: But one -- and we brought up in this particular finding under number three specifically, that we do have a difference between the draft Work Group criteria and the OCAS-004.

MEMBER ZIEMER: Yes.

DR. MAURO: That has to do with time. So yes, I think we do have an issue here that needs to be dealt with.

MEMBER ZIEMER: Yes.

DR. MAURO: That is right now I think that, you know, the NIOSH position is notwithstanding the fact that they may be from different time periods, you still can use it if you are careful.

MEMBER ZIEMER: Yes. Well, my comment on that was -- and I had a comment in the draft comments that we made -- I'm getting

a lot of noise here. Is that just my phone?

CHAIRMAN MELIUS: No.

MEMBER ZIEMER: In any event, about a year ago, I forget the exact date, I made some comments which were distributed to the Work Group on our draft. And on that particular one, I made a note that said we need it to be clarified the meaning of the same general time period in terms of what that means.

Now the time period might be the time where the technology is the same or different, where the legal requirements are the same or different, the work practices were the same or different. A time period might be less than a year or it might be a decade, depending on what the particular parameters are.

So it seems to me that in any event under temporal, we would have to clarify -- and I think the intent here on time period is that you have to compare situations where

the working conditions and processes and monitoring methods were the same or similar. And, in some cases, even the legal requirements because people are working where there are different dose constraints.

But -- so what is the intent, I think, of the time period issue, as I would understand it, is that you can't compare a period where there are completely different work practices, safety measures, and all of those things, and make a valid case for using that as surrogate data.

CHAIRMAN MELIUS: Any comments on that? I think that would be the intent. I actually have your document in front of me, Dr. Ziemer, your comments on the document.

DR. MAKHIJANI: Jim, this is Arjun.

CHAIRMAN MELIUS: Yes?

DR. MAKHIJANI: Sorry.

MEMBER ZIEMER: Yes. And at some point, I even have some wording to propose for

that. But that will come at an appropriate time.

CHAIRMAN MELIUS: Okay.

DR. MAKHIJANI: Jim, this is Arjun. One of the things to consider is, you know, as John was saying, the surrogate data we're seeing as applied from one -- data taken from one site and applied to another site.

But we have also considered this an issue of data within a site, you know, when you take data from one period and try to apply it to another period. This has turned out to be a problem type of, you know, use of data, even within the site. And we're not calling it surrogate data but I think to some extent, at least, it is the same issue.

DR. MAURO: That is exactly what happened at Blockson where there were radon measurements collected in the `80s and we all agreed that listen -- well, I don't know if we all agreed but there was a general consensus that it is very difficult to use the radon

data measured in the 1980s to dose reconstructions that occurred before the 1950s. So that's, I would say, a good example.

DR. NETON: This is Jim. I would agree with what has been said.

But I would also go back to what Dr. Ziemer suggested which is the intent really is the similarity of operations. And I think to just make a blanket statement that it has to be exactly the same time period is problematic for us.

I mean there are situations where forward in time might be more appropriate where they use exactly the same grinding machine for 15 years and the example I can think of is the grinding operation and there were process samples taken that were right there at the generation of the aerosol at the same machine.

It really doesn't make a lot of difference about the general area patterns of

air ventilation and such under those unique situations what we would be able to take advantage of. That's somewhat what I had in mind here when we drafted that section.

CHAIRMAN MELIUS: Any other comments on that?

DR. MAKHIJANI: Well, Jim, the only other comment I would have is, you know, in partial agreement with what Jim Neton just said, is that data from one building to another building or one facility to another facility within the same site has also been the same kind of issue.

So I think broadly yes, the environmental and dosimetric comparison needs to be established. And I think how that is to be elaborated is kind of complicated.

CHAIRMAN MELIUS: Yes, no, I agree with you Arjun that we're looking at -- we focused on sort of one specific type of surrogate data or data that is being, you know, where we're either extrapolating time

periods or locations. And this is, you know, where we're taking something outside of an area but outside of the facility.

But that is sort of an artificial distinction. And the same kinds of considerations would apply to the area that you mentioned, really the two, one building to another, one part of a facility to another, or one time period to another.

And we have often found those kinds of application of information to be problematic for some of the same reasons that are set out in either the NIOSH criteria or the staff criteria that the Work Group had originally developed.

MEMBER MUNN: This is Wanda. There are commonsense considerations that certainly override any of our concerns with respect to definitions of terms, especially with respect to bounding issues. If one knows that only a certain type of material is handled and it is handled consistently and it

is handled over a long period of time, common sense tells us that the highest measurements that one gets, no matter what period of time is involved, is the highest measurement one gets.

And it -- to lean upon a statement that is involved in a general definition as being a reason to disregard good basic information that you have is not a reasonable thing to do. And we have had considerable discussion about reasonableness and plausibility.

CHAIRMAN MELIUS: Yes, I don't disagree with some of that. But we also don't have certainly criteria for plausibility. It's something that when we get into difficulty, we disagree on and wrestle with. And similarly with sufficient accuracy.

And I think that as a general statement of either moving from one facility to another or moving from one time period to another, the farther one gets, the more

differences that are unknown because of the lack of documentation, you know, different parts of the site or time periods of the site, or because of limitations on monitoring methods in the past and so forth, so I think we've run across a lot of situations where we just don't know enough about it.

So not having sufficient, you know, a building or operation or other factors like that, make the extrapolation or use of surrogate data more difficult.

MEMBER ZIEMER: Jim, this is Ziemer. I agree with that. And I think it would be helpful at some point, and I know you intend to do this, would be to actually deal with the plausibility issue. I think we can discuss it as we have some of the other parameters.

And say what does it mean for something to be plausible. And what are, you know, at what -- we can't necessarily define when something becomes implausible. But we

could at least put some parameters down or some approaches to how you establish plausibility.

And it seems to me you can talk about plausibility in terms of workplace, for example how well do things match up or maybe the grinding machine, you got workplace plausibility issues.

I think you have scientific plausibility issues with regard to like bioassay models, radon models, those kinds of things. There are different kinds of plausibility that would have to come together in a way that would give people confidence in use of surrogate data.

Or if it doesn't come together, you don't do it. But it seems to me we do need to grapple a bit with what constitutes or how we would go about establishing plausibility.

MR. KATZ: I'm sorry to interrupt. This is Ted.

Jim, let me just make another attempt. Maybe there are some people on the phone who were not on the front end of the call. Everybody on the call who is not participating, please mute your phones. It is very hard to hear with all the background noise.

And even if you don't have a mute button, there is a * and a 6. You can press *6 together and that will mute your phone and make it much easier for the participants to hear each other as well as the court reporter who has to transcribe all of this. Thank you.

MEMBER LOCKEY: Paul, Jim Lockey. Were you talking about their plausibility in relationship to how two work sites meet criteria that is plausible that they were similar? Is that what you were referring to?

MEMBER ZIEMER: What I was referring to?

MEMBER LOCKEY: Yes. Are you talking about work site plausibility?

MEMBER ZIEMER: Well, I was talking about the overall concept of plausibility as some component. One is how well the workplaces compare. Another is the scientific parts. I mean --

MEMBER LOCKEY: But in relationship to --

MEMBER ZIEMER: -- you have to use models that are scientifically plausible --

MEMBER LOCKEY: Right.

MEMBER ZIEMER: -- as well as -- and we've had these kinds of discussions in other venues for other Work Groups where we talk about what is scientifically plausible in certain cases. But I was thinking in terms of our criteria document, that we need some discussion on how one goes about establishing plausibility.

It is more than a gut feeling. I think --

MEMBER LOCKEY: I think so, too. I think -- but I hear you talk about workplace

situations where it is plausible that Work Site A is similar to Work Site B even though ten years separate them in time.

MEMBER ZIEMER: Well, I don't even know at this point, I'm just thinking conceptually that if it is not plausible that the workplace in question is well represented by some other workplace who is the surrogate, then, you know, how do you decide that?

MEMBER LOCKEY: Yes. I think -- I agree with both of you, I think there should be work site plausibility criteria. You know why are they similar? It's based on these following blah things.

MEMBER ZIEMER: Or if they are not, what would allow the data to be used.

MEMBER LOCKEY: That's correct. I agree.

MEMBER ZIEMER: And there may be -- I just thought of workplace and scientific, both of those things. There may be some other issues but --

MEMBER LOCKEY: Yes.

MEMBER ZIEMER: I mean by workplace, I'm talking not only about the physical facilities but the working procedures, maybe even the types of personnel present and probably even some legal issues in terms of what safety processes were mandated or required under certain time periods and so on.

MEMBER LOCKEY: No, I think that's a good point. And I agree with that. And that's what we do when we do dose reconstructions.

DR. MAURO: Yes, Paul, this is John. I often, when I'm looking at these dose reconstructions and the construction of coworker models and, of course, the use of surrogate data and the issue of plausibility emerges in my mind. It usually is not the issue of plausibility. It's implausibility.

MEMBER ZIEMER: All right. Well, and that may be a good way to look at it.

DR. MAURO: Yes, because -- yes, I have another example. You know in addition to, for example, if you are about to use a model or use data from one site to another, or make certain assumptions from one location in the building to another location in the building, I very often ask myself well, we find ourselves often in a situation where the exposures that you are going to assign to an individual in your coworker model are of such a nature that very often I'll say that doesn't sound plausible.

And the reason I would say -- that comes to mind often is if that were to occur -- well, an example would be the person couldn't stay in the room and continue to breathe the air. Or --

MEMBER ZIEMER: Yes.

DR. MAURO: -- the dose the person would experience would result in acute radiation syndrome, you know local damage to the respiratory tract.

In other words, though, very often the test I put it to, in addition to the types that you have been discussing by way of facility operations, it is not within the range of what would have been the operating parameters of a given facility, I also sometimes think in terms of just -- almost like biological endpoints.

They've got a person actually working in an environment like that without there being some record of there being some acute radiation effects at such levels. I've run into circumstances where we find ourselves in that realm. And then I start to ask myself plausibility questions.

DR. NETON: Jim, that's exactly Section 3.6 says in the IG-004.

CHAIRMAN MELIUS: Yes, I was going to point that out. It's on the bottom of page eight into page nine on that. But I mean I guess I find that sort of lacking -- not to fault NIOSH but it sort of addresses the

obvious issues. It doesn't address -- I think a lot of times we're tying plausibility to sufficient accuracy. And so the question may be -- and I think in other factors. And I think it would behoove us to I think give more thought to what we mean by plausibility and how we would consider it separate from these other factors.

At first I was resistant to adding it as a criteria because I think it is hard to define. And secondly, to some extent, it is taken care of by the other criteria. It may be an overriding factor that, you know, would override. Yes, you're not going to come up with something that is so high that, you know, people wouldn't be able to breathe or whatever.

But I think that usually the situation we're having trouble with, it is more complicated than that. But it is hard to get at aside from an example. But we continue to wrestle with it in lots of different

situations as we're doing now with the Blockson model, too.

MEMBER ZIEMER: Jim, this is Ziemer. I think you may be right that in a sense, you handle the first four criteria, that kind of overall kind of deals with plausibility issues perhaps although I'm not sure that we have dealt with -- specifically with scientific plausibility in those. Maybe indirectly we have.

CHAIRMAN MELIUS: Yes, as I say, in some ways it is overriding. It is one of the factors you are considering when you deal with temporal situations.

MEMBER ZIEMER: Yes, right. You would say it is not plausible because temporally this has occurred.

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: Or it is not plausible because these processes are under Criteria Two, the slider processes are sufficiently similar or something like that.

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: Yes. So maybe it gets inherently covered in the other criteria.

CHAIRMAN MELIUS: Yes, I mean I think if you sort of take the absurd example that we had a facility we knew nothing about. You know it was a unique operation, a unique type of exposure. I don't think we would consider it plausible for NIOSH to just sort of pluck the number out of the air and say that's the upper bound.

DR. NETON: Yes, this is Jim. I think the idea here was that when we do these -- when we apply surrogate data and port it from one facility to another, there are typically uncertainties involved. And more often than not, we would end up using the 95th percentile of some empirically-derived distribution from that other facility.

And the idea was that if the uncertainty was so great -- the GSD was so large that the 95th percentile got you into

one of those situations where, you know, it was just physically impossible to occur, then, you know, we certainly wouldn't want to use that. So I think it is sort of tied up in the uncertainty of the model more than anything.

CHAIRMAN MELIUS: Yes.

MEMBER MUNN: But that's no longer a plausibility issue. That's a possibility issue. When it continues reaching the impossible, then that is outside of plausibility.

DR. NETON: Right. And another -- the next paragraph under 3.6 I believe talks about a situation such as we had at I believe it was the Iowa Army Ammunition Plant where we had developed a model time period that was monitored for external that ended up being so large that when you compared it to the previous year, it was an order of magnitude higher. And it certainly didn't pass the plausibility test in that situation. So that's, again, what we had in mind in this

section.

DR. BEHLING: This is Hans Behling. I just want to make a comment regarding the issue of plausibility and using extreme high end numbers. And what I'm looking at here is under the regulation paragraph 82.10(k). There is obviously a limitation when you use such extreme numbers because under the regulations, those values can never be compensated.

And I can read you the specific section where it talks about worst case assumptions can never be used to compensate a claim but only to deny a claim if the PoC under the worst case assumption still doesn't match the 50th percentile value. So --

DR. NETON: Well, I think that is a slight misinterpretation of that section. That section was for worst case assumptions without conducting additional research.

In other words, NIOSH would have stopped short their research and used a worst

case assumption and decided that the case was still under 50 percent. You can't use that to start compensating people. I would agree with that.

But if, at the end of the day, all your worst case assumptions end up being your best estimate and it is plausible, I would suggest that it could be used.

DR. BEHLING: Okay. It is a very fine definition and I just wanted to bring that up because sometimes we tend to get reckless in assigning a worst case assumption, realizing however that it is still going to end up with a PoC of less than 50 percent when, in fact, if we were to realize that it was greater than 50 percent under those conditions, we would be in violation of the regulations.

DR. NETON: Right. I agree. And I think there was one episode in the past where that occurred. But I think that was an isolated incident. And that's the only one

that I can think of.

CHAIRMAN MELIUS: What was that? What was that -- this is Jim Melius -- that determined?

DR. NETON: Well, I think at one point, there were a few dose reconstructions where we actually -- they ended up going out the door using worst case assumptions.

CHAIRMAN MELIUS: Oh, okay.

DR. NETON: And, you know, we certainly reversed our thinking on that.

CHAIRMAN MELIUS: Yes, okay.

DR. NETON: And to my knowledge, nothing like that has been done since.

CHAIRMAN MELIUS: Okay, no, I recall that. I was trying to think if it was something I missed.

DR. MAURO: Interestingly enough -- this is John -- when we encountered those circumstances, it was during our dose reconstructions audits where a bounding assumption that was written up into a

procedure was developed mainly for the purpose of efficiency -- oh, let's just assign this -- which, of course, is, you know, off-the-charts conservative, and it was still not compensating.

But we really never encountered this situation when we were reviewing in an SEC or site profile perspective when, for example, let's say NIOSH was building a coworker model and they were collecting data and making running models and making assumptions in order to build a coworker model.

In the end, that's what we're talking about, whether we're using a site-specific data to build the coworker model or data from one site to apply to another site. Ultimately, what we're talking about is building a coworker model. And we're talking about that aspect of building a coworker model where NIOSH may need to draw upon data from another site.

And within that, we are talking about, you know, at what point does the data from one site, as applied to another site, become implausible? In other words, just not plausible -- it could not apply to that site? And, therefore, you wouldn't need the plausibility.

And it is almost just like you would know it when you see it. But to talk about it in generalities, is difficult to say when would we be at a point that, you know, you really can't use that data, that situation. It just wouldn't make sense.

But it is so hard to define that. I mean there may be a way to explain it. It sounds like there is some language in the write up. I don't have your write up near but, Jim, so you have some language that sort of set the framework of plausibility? I just don't have it in front of me.

DR. NETON: Are you talking to me, John?

DR. MAURO: Yes. I guess --

DR. NETON: Yes, there is a very brief section 3.6 in IG-004 that tries to set the stage plausibility although Dr. Melius is right, it's short on specifics although it is that way by nature because we couldn't come up with some very specific guidance other than these generalized tests.

We're certainly open to hearing suggestions as to how to make that better.

CHAIRMAN MELIUS: Somehow a criteria of we'll know it when we see it, would be helpful to -- but you said it, not me, Jim.

Any other comments on that?

(No response.)

CHAIRMAN MELIUS: Any other comments in general on surrogate data?

(No response.)

CHAIRMAN MELIUS: Then I have a suggestion for how to move forward.

(No response.)

CHAIRMAN MELIUS: No comments?

MEMBER MUNN: We're breathlessly waiting.

CHAIRMAN MELIUS: Oh, okay. I thought Dr. Ziemer had something he wanted to bring up. That's why --

MEMBER ZIEMER: Oh, well, no, I thought if we were going to discuss the criteria documents, I would propose some things. Otherwise not. I have some words on the temporal consideration thing for that document.

But if you'd like, I could just --

CHAIRMAN MELIUS: Oh, okay. Well, actually what I was going to propose was that -- to update the -- our criteria document and include a section on plausibility, and circulate that to the Work Group between now and our meeting in February. And then we would have a discussion at the Board meeting.

But I'd like to get input, particularly on plausibility beforehand as

well as anything else that people want to comment on.

MEMBER ZIEMER: Well, I'll be glad to share some words both on temporal and I had already, on my own document here at home, put in some words on plausibility. And I can provide that as a straw man so that --

CHAIRMAN MELIUS: Okay.

MEMBER ZIEMER: -- that can at least get some people thinking. I'd be glad to have these things shot down completely. We can grapple with them. We might decide on plausibility that the other four criteria inherently cover it if you meet those.

But I agree, Jim, I think it makes sense at least to grapple with it. There may be something that emerges that is sort of outside the other criteria that we would need to consider. I don't know at this point.

But I'll be glad to offer up some words to at least people think about. And I don't ascribe to them any level of

profoundness. But sometimes it helps to have something to take a shot at.

CHAIRMAN MELIUS: Yes. I think that the examples offered by NIOSH are part of plausibility so that they're -- but I think it's -- how we think beyond that is -- I mean and I'll try something independently then maybe merge it with what you write, Paul.

MEMBER ZIEMER: Yes. I think that would be good. And probably other Work Group members, too.

CHAIRMAN MELIUS: Yes. Do that.

MEMBER MUNN: Well, you would assume that this would be, if I understood you correctly, in addition to our current document with regard to what constitutes surrogate data?

CHAIRMAN MELIUS: It would be part of our current document, correct.

MEMBER MUNN: Right. Thank you.

CHAIRMAN MELIUS: This Work Group's current document. I guess the other

issue I have is sort of -- well, I think in terms of the Procedures Work Group, I think we're okay. I just don't know how this ties in with the TBD-6000 Work Group and where that Work Group is.

MEMBER ZIEMER: Well, two things on TBD-6000 Work Group, we're dealing with the main document. And then we're dealing with some of the appendices.

The big focus, of course, now is on the Appendix A, which is General Steel Industries. But then we have a couple of others that have emerged after our last meeting. So there are some other sites. One is a 6001 site. And there is another 6000 site. So there are some site-specific things we're dealing with.

But I think it's either -- and, of course, I think that the Texas City case was more of a surrogate. General Steel Industries, we're dealing with GSI's own data and its usability and some related issues.

But I think Texas City came to the Surrogate Data Work Group because it is more clearly a surrogate data issue.

DR. MAURO: This is John. When we look at TBD-6000 without the appendices for a moment, one of the most important things we were doing is to make sure that the different -- it is basically a look-up table for different types of work activities that a person may be engaged in. For example, at a metal-working facility.

And there is a range of airborne dust loadings of a grain. And the main thing we looked at are the categories that were created and the range of concentrations of the dust loadings assigned and default values. Do we believe that they represent or properly capture the range of operating experience that is out there? And there's lots and lots of experience.

So we really looked at it from the point of view of when you are saying that a

machinist working at a metal-working facility will be assigned this concentration distribution in terms of dpm per cubic meter dust loading let's say of uranium, is that distribution a good distribution? Does it reflect the real experience that has occurred in the past?

So we really, when we looked at it, we just looked at it from the point of view of did it capture everything. That's a very different question than whether you think it is appropriate to apply that distribution to a given case. So I think it is important to make a distinction between -- TBD-6000 is a document that, in a claimant-favorable way, captures the range of exposures people might have experienced doing different kinds of jobs.

And then the big question always is okay, given that you get to the point where you agree, yes, this is a very good representation of the range of exposures, then

it becomes a matter of okay, you know, under what circumstances can you use this and use it in a way that you feel is plausible and claimant favorable.

I have to say that our experience is that when TBD-6000 is used, they usually draw upon the categories that are, by far, the most claimant favorable. In other words, if you had a real site and you are trying to assign some dust loading, they would go into TBD-6000 and usually pick that case, that job category that is the worst one, not giving any other information.

So we have gone a long way, I believe, in coming to closure on a lot of TBD-6000 issues. What is the issue that really is in play is okay, how do you apply it? And how do you know you are applying it in a claimant-favorable and plausible manner? And I think we are yet to engage that issue.

MEMBER ZIEMER: John, this is Ziemer. I agree with what you said because

that is, in a sense, a generic document. And you still have to show in a specific case that the parameters in there are applicable in terms of, you know, is there something about a particular site, either in terms of process -- well, all of the things we talked about -- that would take it outside of those parameters or that somehow it wouldn't apply.

So I think in principle, we still need the surrogate data criteria if you want to say yes, we're using TBD-6000. But do we still have a facility that matches up?

DR. MAURO: Yes, in fact, more than ever.

MEMBER ZIEMER: It's got be done on a case-by-case basis. You always have to make the case that it applies.

DR. MAURO: Yes. I would argue that the surrogate data criteria that eventually emerge from the process we're in is going to be extremely helpful when we are confronted with the use of TBD-6000.

MEMBER ZIEMER: Exactly.

DR. MAURO: Yes.

CHAIRMAN MELIUS: But I would just add that I think that is the plausibility issue that we wrestle with the most is that balance between -- so sufficient accuracy on one hand, claimant friendliness on the other, and then are what we're doing, you know, is it plausible? And I think it is where we need to have some -- or at least attempt to develop some criteria as to how to address that.

Any other comments?

(No response.)

CHAIRMAN MELIUS: I will -- today is Monday -- try to circulate something by the end of next week at the latest so that there is time for input from the Work Group.

MEMBER ZIEMER: Okay. So you want something this week probably?

CHAIRMAN MELIUS: Yes, this week, yes. Or early next week.

MEMBER ZIEMER: Good.

MEMBER LOCKEY: Paul, are you going to send something out as a straw man? Is that what you are going to do?

CHAIRMAN MELIUS: Yes. So if people could get any comments to me by say Tuesday of next week, then I'll circulate something by Friday.

MEMBER ZIEMER: Okay. I'm just going to send my stuff to you, Dr. Melius.

CHAIRMAN MELIUS: Okay, yes.

MEMBER ZIEMER: Okay.

CHAIRMAN MELIUS: Great. Any other comments? Ted, do you have anything?

MR. KATZ: No, I don't. Thank you.

CHAIRMAN MELIUS: Okay. Good. Take care everybody.

(Whereupon, the above-entitled matter went off the record at 2:35 p.m.)