UNITED STATES OF AMERICA

CENTERS FOR DISEASE CONTROL

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NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH

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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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77th MEETING

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THURSDAY
MAY 26, 2011

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The meeting convened at 8:30 a.m., Central Daylight Time, in the Crowne Plaza St. Louis-Downtown, 200 North Fourth Street, St. Louis, MO, James M. Melius, Chairman, presiding.

PRESENT:

JAMES M. MELIUS, Chairman
HENRY ANDERSON, Member
JOSIE BEACH, Member
BRADLEY P. CLAWSON, Member*
R. WILLIAM FIELD, Member
RICHARD LEMEN, Member
JAMES E. LOCKEY
WANDA I. MUNN, Member

PRESENT: (continued)

ROBERT W. PRESLEY, Member
GENEVIEVE S. ROESSLER, Member
PHILLIP SCHOFIELD, Member
PAUL L. ZIEMER, Member*
TED KATZ, Designated Federal Official

REGISTERED AND/OR PUBLIC COMMENT PARTICIPANTS:

ADAMS, NANCY, NIOSH Contractor
AL-NABULSI, ISAF, DOE
DANIELS, DOUG, NIOSH
ELLISON, CHRIS, DCAS
GLOVER, SAM, DCAS
HINNEFELD, STU, DCAS
KOTSCH, JEFF, DOL
KINMAN, JOSH, DCAS
LEITON, RACHEL, DOE
LEWIS, GREG, DOE
LIN, JENNY, HHS
MAKHIJANI, ARJUN, SC&A
McFEE, MATT, ORAU Team
NETON, JIM, DCAS
RABINOWITZ, RANDY
RAFKY, MICHAEL, HHS
ROLFES, MARK, DCAS
RUTHERFORD, LAVON, DCAS
STEINBERG, GARY, DOL
STIVER, JOHN, SC&A
TAULBEE, TIM, DCAS
WADE, LEW, NIOSH Contractor

*Participating via telephone

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

CHAIRMAN MELIUS: Good morning everybody. We'll get started now. Relatively -- as I told you relatively short agenda for this morning.

MEMBER MUNN: We're here for the party.

CHAIRMAN MELIUS: Here for the party? Is there a party later? I was going to say we're all probably out at the airport. By the way, if any of you are interested, Mark Griffon did make it out of town last night, so he made it to Washington.

Few hours late, but he emailed me late and said that he -- he did make it. We had saved a place at dinner for him thinking that he would be coming back and join us. But he did make it to that.

This morning we have just one agenda item. But first, Ted, do your --

MR. KATZ: Right. We have a very short agenda here. We're just doing quality

of science review, the ten year program review. But let me check on the line and see if we have Board Members with us.

MEMBER ZIEMER: Paul Ziemer here.

MR. KATZ: Welcome, Paul.

MEMBER CLAWSON: Brad Clawson.

MR. KATZ: Welcome, Brad. Any other Board Members? Very good. Let's get going.

CHAIRMAN MELIUS: Okay, this morning we're going to talk about one -- one report that on the quality of science, part of the ten year review.

And Doug Daniels was good enough to change his itinerary and come into -- just that be able to come in and present to us today. I think it's a interesting report, and I thought it would be like helpful in some of the things we need to consider as well as give us a chance to ask questions and -- and understand it better.

So, Doug. Thank you. Welcome.

MR. DANIELS: Well, thank you. And I'd like to thank everyone for inviting me here. I had a wonderful day of travel last night. And that's the first time I've ever traveled 300 miles, at 1,400 miles. So it was great. Fantastic.

But I'm glad to be here this morning --

CHAIRMAN MELIUS: Where'd you come through?

MR. DANIELS: Well, I flew from Cincinnati to -- to St. Louis via Louisiana.

CHAIRMAN MELIUS: Well, thank you for taking -- taking the trouble. Lew came via Peoria.

MR. DANIELS: My name is Robert Daniels. I am a NIOSH employee. I'm not assigned to the Division of Compensation Analysis and Support. I work with a -- a colleague, Dr. Henry Spitz, University of Cincinnati professor of Nuclear Engineering, to do the quality of science element of the

ten year program review report.

Just briefly on this slide, Dr. Howard initiated this program review in February of last year as part of his -- our commitment to the highest quality science and NIOSH programs, and also to recognizing the importance of program transparency and the need to be responsive to stakeholders and members of the public and claimant.

So -- so it was an effort put in place to improve the program. The quality of science was a key element of this program review. There are several facets to the review.

The one we're talking about today is the review on the quality of science, which is a rather broad term. So the -- at the time, there were many questions on using exposure proxies and dose reconstruction. And so we thought that the best focus for our review was to also look at methods of indirect exposure assessment.

As you know, NIOSH is charged with providing reasonable estimates of dose to cover employees under the Act. So for us, reasonable, we determine to mean well based in science, obviously is an important tenet as well as timely and fair.

And that's the essence of NIOSH dose reconstruction. NIOSH is charged with evaluating the completeness of the individual monitoring data for -- for claimants and providing remedies when there are gaps in that information.

And that therein lies the use of indirect methods to fill these data gaps. So the scope and conduct of the review, quality of science, as I said, is a very -- is very broad.

We narrowed it to indirect exposure assessment methods, and more specifically, looking at -- at coworker and surrogate data use. Now, the dose reconstruction program makes a distinction

between those where surrogate data is referring the information from facilities other than the covered facility of the covered worker.

And coworker data, as you would expect, it's -- it's exposure data from similar workers within the facility. There were two of us working on it, myself and Dr. Spitz.

I focused on issues related to coworker models, and Dr. Spitz, working independently, was looking more into the issues of surrogate data. So you could imagine if you read the report, there -- there certainly is a lot of redundancy where we -- we talk about the same -- the same things a number of times throughout the report.

That's to be expected given the fact that we were actually working independent for most of the time on the report until we brought it together in a single document.

It has been reviewed. It's still

draft. I consider it still draft anyway, because the public -- the docket's still open for public comment. So -- so as we get public comment, I've been making revisions.

I think the latest revision has been posted on the -- on the docket for -- for continued review. And however, it's -- it's not finalized yet. It was reviewed by my management team as the internal review.

We did have some scientific peer review on it. We did not have any review or comment from members of Office of Compensation Analysis and Support. So it's -- it's independent of that office.

And of course, public comment is ongoing. So the structure of the report is -- is -- there are three key elements. The first is the general program where we discuss our findings regarding the scientific basis of -- of the dose reconstruction program's use of indirect exposure assessment methods, the quality of the documentation that's used in

conducting those reconstruction, and the review process that is part of that system.

The second part was -- was specifically looking at external radiation coworker analysis. So again, I'm parsing things down to look very narrowly at a single component of the dose reconstruction program, which is external radiation coworker analysis.

We looked at the scientific methods that were used as well as we replicated a model that was used by the NIOSH dose reconstruction program for -- for the Oak Ridge gaseous diffusion plant.

The third element was public comment. We reviewed a number of comments that were received in regard to the -- the program review. This is prior to the first publication of the draft report we have now. And I summarized those comments in the -- in the back portion of the -- of the report to give you an idea of stakeholder concerns.

And then there is a summary of the

findings and recommendations. And then finally, there is an appendix on surrogate data use in the end of the report.

So, general findings, first it's noteworthy that the dose reconstruction program has made a number of accomplishments since its beginnings. There have been over 24,000 dose reconstructions at the time of the report.

The report is -- is getting close to a year old now. So certainly that number has increased since. The group itself has made several advancements in exposure assessment methods.

And they've made these methods available to other researchers outside of dose reconstruction. So they have contributed to the scientific literature in a number of ways. And many of the methods that were developed essentially in support of the compensation program are now being used in other sciences.

So that's a key accomplishment.

They gathered an enormous amount of information on the U.S. Atomic Weapons Workers program. I do believe there's hundreds of thousands of images.

I think the last count was 300,000 images on the Department of Energy documents that have been collected in support of this program as well as other key sources of information.

That will be useful for science as well as compensation. And they've developed and published over 100 technical documents on dose reconstruction, and made these documents available to the public and other researchers.

General findings on authority, it was obvious that epidemiologic studies also rarely benefit from complete exposure information. So it wasn't a stretch to see that many of the methods that are used under dose reconstruction were developed during epidemiologic studies.

And they basically have started

with those methods and enhanced them specifically to support individual dose reconstruction for compensation purposes. So there's a lot of similarities in the science with regard to methods of indirect exposure assessment.

There's a firm foundation within the Act for using the supplement data for indirect exposure assessment. The use of information from coworkers is clearly authorized.

And although it's not specifically stated in the Act, the use of data from other facilities, it -- it seems to be referred to such that you can provide data to complement, but not supplant to plan information from -- from preferred sources.

So there's a hiearchical tree of data used. And where there are gaps it seems perfectly acceptable, at least from a scientific perspective, to use data from other facilities and other workers to fill these

gaps in our information.

General findings and documentation of the -- the program itself uses a -- a process that's similar to standing -- standard operating procedures that you would see in a high functioning industrial setting.

There's a very layered structure of policies, plans and procedures. They have systems in place to standardize the use of terms and the format of the documents. The documents are internally reviewed prior to issuance.

There are sign offs. There are -- they are controlled. Nevertheless, given the vast number of documents and the vast number of document authors, there were some inconsistencies between documents.

And the content of documents, in some cases, varied markedly, even though they had similar uses. So -there could be room for improvement in future revisions to maybe clean some of that up.

One other noteworthy component of this was we noted that even those these are controlled documents that are -- and industry settings, standard operating procedures are routinely reviewed and revised, given the dynamics of a system.

We would expect that those reconstruction could be dynamic as well. And so we -- we thought that perhaps revisions, in some cases, were infrequent and there could be improvements made there.

Methods, it's very clear that in dose reconstruction, there's a graded approach applied that attempts to balance precision and accuracy with fairness and efficiency. So there's a give and take with respect to the scientific rigor that's done for dose reconstruction.

It's also clear that when in doubt there's always attempts made for claimant favorability and decisions and assumptions that are made. However, even though claimant

favorability, in most cases, could be intuitive, it has rarely been quantified in NIOSH dose reconstruction.

So we feel that there is room for improvement in this area to where they could start looking at trying to quantify a margin of claimant favorability in certain circumstances.

Better assessment of bias may greatly improve the competence of the program and reinforce assertions of claimant favorability. What I'm speaking of here is it's recognized in the case of NIOSH dose reconstruction in contrast to epidemiologic research.

We're interested in risk to individual. So small biases could play a large role in adjudication. So I think it's important to -- to give more emphasis in trying to quantify these biases.

So in the -- in the end of the report there was series of specific findings

and recommendations. We had two on documentation. There were two on peer and stakeholder review. And there were seven on methods validation.

I'm briefly going to go over these methods a little bit now. They're quite detailed in the report. So in documentation, we found that the system provided documents that were clear and concise and relevant to the points of views.

However, we did note several, or not several, there were errors and inconsistencies among some of the documents. One of the key findings, at least with regard to documents, is the fact that they use a hiearchical system of records where they have a parent Technical Basis Document.

And then in turn, they derive more site specific information from that. And they will refer back to the parent, which is a good approach to -- to eliminate redundancy in documentation.

However, it's also -- there are pitfalls there to where you can carry on inconsistencies in children documents, or perhaps you revise the parent and not revise the documents that are referring the parent. And so you have inconsistencies.

So we thought they could improve upon that by developing a system to monitor layered documents and effectively revise documents. Have a way to trip which documents are affected by revision of another.

Revisions lack timeliness, and in some instances appeared unresponsive to concerns raised in previous reviews. Again, this goes back to the revision process.

One of the things we found was as in any scientific process, there's a very deliberate manner in which certain science issues are resolved between the Board and the Division of Compensation Analysis and Support staff, as well as the Board's contractor, which is great.

That process itself has really benefitted the quality of certain documents. But it does slow the revision process down. Another problem that appeared during our review is there was a concern that certain revisions could trigger more work, even if that revision really didn't play a key role in dose reconstruction or the dose estimates that are provided under that document.

So what I'm saying here is that it's recognized that if we make changes to our methods that we have to evaluate the impact on the program from those changes.

And there's a very deliberate process in doing that, which if the worse substantive changes, which would require reopening a claimant's file, then there is a process in place to do that.

But on the other hand, when there are revisions that are necessary, which are minor technical inaccuracies, let's say, that are well known, that have been identified by

stakeholders or other members of the public, there's a reluctance to make those changes early on, waiting for more substantive changes later because it invokes this process of reevaluating the claims.

So that doesn't seem to be an efficient way of handling certain non-substantive revision. It would seem prudent, especially given the fact that these documents are available and these inconsistencies have been identified by claimants and other members of the public that we could better revise those in a more timely manner without, you know, waiting for the final substantive revision.

And of course, another -- another finding was that many of these documents have not been reviewed since they've been first issued. Some of these documents have gone five or six years and haven't been revised or, to our knowledge, reviewed for revision.

So although several documents,

well over 130, let's say, documents have been reviewed by the Board, and well over 500 findings have come as a result of those reviews, and a lot of those documents have been revised, there still are a great number that are left to be reviewed and revised.

So our key recommendations were to put in place some sort of process to recognize interrelationships between documents and avoid these transfers of technical inaccuracies that we found on our review.

We suggest including periodic reviews by subject matter experts to uncover inconsistent and erroneous text. And we suggest avoiding delays in correcting technical inaccuracies, especially if they really clearly have no impact on the claimant's dose estimates.

The review process -- the current review process for dose reconstruction documentation is internal only, although the documents are all available for review by the

Board. And the Board has reviewed many of them.

So there is no requirement for external scientific or stakeholder review. We noted that many of the documents have benefitted from the Board's review, although, as I mentioned before several have not been reviewed.

Information is inconsistently sought from stakeholders and only after publications. So we were a little bit concerned in the instance where we -- it seemed in the sake of expediency.

We published a number of documents to get the process going. And then after the documents were available there were comments received by former workers and other members of the public, which suggested that we could have done a better job.

So at this point it seems like there was advantages, at least from a scientific perspective, to get more feedback

prior to publication. Now that we have a working body of documents, it would seem the emphasis should be placed on getting that feedback and organizing that feedback to where we can effect revision as needed.

Right now there's a weekly define process for comment resolution. When I say that that's mostly in regard to public comment. We'll receive several comments from the public and former workers.

And they're handled individually, usually by a letter. It would be better to track these, if possible, in a more efficient means, and to see if it's necessary to effect changes to these documents based on the new information that's provided.

This was a problem with another dose reconstruction program from DETRA. They also had a number of comments about weekly taking advantage of worker input.

So here's an opportunity to improve the signs by improving the use of

worker input in the -- in the current documentation. We recommend that you seek external peer review on science documents that have not been reviewed by the Board.

So as I said before, there a number of documents that haven't been reviewed. It would seem to be wise to look for independent scientific peer review on those documents as a means to sort of catching up and cleaning shop, with respect to external science review.

Expand reviews to systematically solicit input from peers and stakeholders on important scientific individuals prior to publication. Again, better use of -- of information from former workers and other members of the public.

And develop a more formal process to handle comment resolution. That would readily document the resolution that has been made, the actual comment, the source of the comment and what changes have been made.

Methods. Dose estimates from independent modeling were comparable, but on average less than the dose reconstruction results. So what I'm talking about here, we did a replication model of the K-25 coworker study, and using the methods that are outlined by the Division of Compensation Analysis and Support, but using other data sources and other means to complete that replication.

And in essence, we got the same answers. We got the same estimates that DCAS came to in their models, although on average they were less than. So the conclusion is that their coworker models are reproducible, and supported their claim of claimant favorability.

However, we did note that there is room for improvement in these models. Some models lack information on source data assumptions, statistical methods and limitations.

These types of things, I think,

would be readily identified in scientific peer review. Validation was inconsistent or absent from some models.

So I think from a take-home message, if I really wanted to stress any facet of this report, the most important finding was that a great number of things have been done in support of the program in expeditious manner and keeping with timely and efficient dose estimates for covered workers.

However, the time might be now to focus more on validating these methods. There has been limited work done in the -- in the indirect exposure assessment methods that have been used in trying to validate the margin of safety, if you will, for claimant favorability.

I think that's the key here. How bounding is bounding? So if I were -- on this slide if I were to just emphasize one point, it would be the validation was inconsistent or absent and where there is room for improvement

in this area.

So of course that goes back to recommendations as I just said. We think you could -- we could do a lot more in assessing the validity of these estimates. And there were some wonderful comments raised by Dr. Richardson on this area, suggesting using some of the modeling that has been done in epidemiologic research as a gold standard, if you will, and making comparisons.

And that's somewhat what was done in this report. But it gives an idea of how much the bias is away from the null, assuming that we do have claimant favorability in our dose estimates.

So we think that we could do more in quantifying the coverage anomalies and limitations in the data that are selected, you know. In any model, the model is only as good as the data that's going in it.

So there should be some more discussion in these coworker models and some

more review -- some more critical review on the data that are being used.

Examine between and within worker variance components of the coworker models. What I'm speaking of here is a lot of the coworker models are based on standard statistical models, which rely on dose distributions.

And what isn't really clear is the fact that those distributions within a worker group, let's say millwrights compared to an office worker, are going to differ.

So there's opportunities to improve the estimates based on looking at different strata. And so we're suggesting to look at those between worker strata as well as looking at within worker, because the statistical models may assume there's no correlation from year to year for a worker.

And in fact that's not the case. In some cases it has been identified that some workers are dose-prone. So you really need to

consider correlations.

I think intuitively when we look at the external coworker model, which the premise is you take the 95th percentile of each year. And if you were to sum those up over all years, that would be a conservative estimate.

But there are ways that you can judge the amount of conservatism in that estimate, based on looking at these different strata. Use well defined gold standards.

Again, this goes back to the issue of using epidemiologic information as sort of a gold standard to do your comparisons and to judge validity. And it goes back to what I said very early on in the discussion, quantify the degree at which claimant favorability is achieved.

You know, we talk about it all the time. It's inferred. Some of the estimates are clearly claimant-favorable estimates, yet we haven't really spent enough time, I

believe, in trying to quantify that claimant favorability.

At the very end of the report -- oh, sorry. Excuse me. Okay. At the very end of the report I tried to summarize the stakeholder comments that were on the docket at the time that I did the report.

And in essence, and these certainly aren't surprising, but it was recognized that dose reconstruction is a lengthy and complicated process. And we know that. We know that it's very difficult to do individual dose reconstruction in a way that's simple to understand.

So I'm not quite certain how much we can work to improve upon that. But it is recognized that that, of course, is an issue with the claimants. And then the second one is comments were wary of differences and facility and jobs that may be inadequately addressed in current models, using coworker or surrogate data.

So this goes back to really two issues. One issue is the use of input from the workforce in the models that have been developed. Have we assessed all the scenarios? Are there other scenarios that are put out by the workforce that may not be covered under the current model?

Those types of things, a systematic approach to that, and weeding out those things would improve this bullet, I believe. And the second thing is a judgement on claimant favorability.

If we're going to assert that we are claimant-favorable, then some efforts to validate these dose estimates in a means to quantifying that claimant favorability would go a long way in doing that.

So with that I believe that was the end of my slide. And thank you.

CHAIRMAN MELIUS: Thank you. And Wanda, then Jim.

MEMBER MUNN: Mr. Daniels, I want

to thank you for the obvious effort that you and Dr. Spitz have put into this. I have so much to say about it that I would delay the departure of about 90 percent of this Board if I were to actually launch into it.

And I hesitate to do that, specifically because I have not given the original document the amount of study that I need to do. But the tension that is frequently spoken of here, with respect to timeliness as opposed to completed science, is more than amply demonstrated by your notes here.

It raises an enormous number of questions, not the least of which from some perspectives would be how would you propose to do some of the things that you are suggesting be done here?

For example, the quantification of how favorable is favorable, boggles the mind when one begins to imagine how one would address that question. I have a very simple

question to begin with. This is an easy one.

Over on your general findings authority you said epi studies rarely benefit from complete exposure information. Are you saying they rarely enjoy complete exposure information?

Am I misreading the word benefit? I cannot imagine how one would not benefit from complete exposure information if one could only get it.

MR. DANIELS: Well, I agree with your statement at the end there. Yes, what I meant to say was that --

MEMBER MUNN: The last one.

MR. DANIELS: Right. An epidemiologic study, especially an occupational epidemiologic study, we very rarely have complete monitoring information on any individual.

MEMBER MUNN: That's all I needed to hear. The use of the word benefit was what raised the question in my mind. Why would it

not benefit. You're saying you seldom enjoy that --

MR. DANIELS: That's correct.

MEMBER MUNN: That plethora of information that we would all like to have. Did either of the preparers go so far as to suggest some metric by which this assessment of quantity of bias could be addressed?

MR. DANIELS: Right. That's a very good question. And I do understand the difficulties that I raise by suggesting improved validation of these methods.

It's impossible to truly validate because we don't have true dose. However, putting that aside, if you really look at what was done through the report, I took a very crude approach to validating the K-25 external coworker model.

What I did was I replicated the model with another data source and compared those results to measured value. And then by looking at that, I can judge whether or not

you would expect, in the case of the coworker model that is based on a claimant favorability that the values would be biased high from the coworker model compared to my model.

And they were. So that was a very crude approach. What I'm suggesting could be done is more detail -- is given the fact that in epidemiologic analysis, let's say the Savannah River cohort for example.

There was a cohort study. And there was great efforts made in doing dose assessment and constructing exposure estimates for every individual at Savannah River, based on their measured data as well as missed dose from non-measured doses.

That could be a gold standard, which could be used as a basis for comparison to estimates derived from a coworker model. That would be one way of determining, you know, if there is claimant favorability in the estimates, and to what degree.

Now, certainly there is

uncertainty in that estimate of claimant favorability. But at least you get an idea. Are we talking about a factor of two or are we talking about a factor of three?

It would be, I think, important to at least try to get our arms around that to some extent. So there are a number of methods that could be used to independently -- and I would suggest that this would be done independent of -- not within DCAS, but perhaps look at other persons to take a crack at validating their models.

And I think that would go a long way in assurances of claimant favorability. So that's just one example. I think, you know, that was the reason why we replicated the K-25 coworker model, was first off, wasn't reproducible.

And I get the same numbers. And second off, are the estimates accurate? And when I say accurate, in the context of biased high, biased away from the null. So that's

kind of what were trying to do with that part of the analysis.

CHAIRMAN MELIUS: Okay, Gen?

MEMBER MUNN: Oh, I haven't anywhere near stopped. However, as I -- as I said to begin with, this could go on from this chair for a long, long time. And I don't want to do that. There were several more questions that I have -- if we run out of time. Go ahead.

CHAIRMAN MELIUS: We had said we'd go to 10:30.

MEMBER MUNN: Go ahead.

CHAIRMAN MELIUS: But I wanted -- I assumed you were just going to do one question.

MEMBER MUNN: No. I have about eight. But that's --

CHAIRMAN MELIUS: You can submit more to the record.

MEMBER MUNN: We won't attempt to do that. I=ll provide written comments.

CHAIRMAN MELIUS: Gen?

MEMBER ROESSLER: I think one of the really high points in this whole program has been in the advances in science that have come about through this, particularly in retrospective dose assessment.

I think you call it exposure assessment. But I'm going to -- I'm going to call it dose assessment. And in fact, I think we should recognize the peer review publications that have come about as a result of some of the science.

And I'm familiar with the ones that have appeared in Health Physics. My question is have there been publications in other peer reviewed journals?

MR. DANIELS: Yes. Of course you are referring to the one special series that was published in the Health Physics B

MEMBER ROESSLER: Well, I'm -- in particular. But there have been other ones too.

MR. DANIELS: Certainly. And as well, the recent report by the NCRP on dose reconstruction has a large section devoted to dose reconstruction for compensation purposes, which is largely a result of the work that the Division of Compensation Analysis and Support has done.

CHAIRMAN MELIUS: Henry?

MEMBER ANDERSON: My question was most of your slides here in presentation focused on coworker models. And I'm more interested in the surrogate data use. And if you could give us some examples of other surrogate data use.

NIOSH has industry-wide studies that, you know, have studied across all sorts of industries. I'm just not that familiar with that surrogate data -- using data at one, you know, chemical factory has been assigned to do epi studies at another chemical factory manufacturing the same products and things like that.

So what were your comments regarding surrogate? Coworker is pretty well recognized and has been used. But going afield for surrogate data is somewhat unique, I think, to this program.

MR. DANIELS: Yes. It's very interesting you say that, because in the exposure assessment sciences they really don't distinguish between surrogate and coworker data. It's all forms of indirect exposure assessment.

Exposure proxies. And in some cases, the proxies are coming from, you know, other buildings, other facilities within the industry. One key example is in the petroleum industry looking at benzene.

A lot of the exposure matrices that were developed in support of the health effect studies for that industry are based on maybe one facility that actually had some monitoring data.

And then they would just as we've

done in dose reconstruction, apply those in similar work locations across the industry. And so it's more common than you would expect.

I do list in the report, in the section discussing epidemiologic methods, several studies that have been done using both nearby methods, coworker methods and surrogate data use.

So there's a number of examples in there.

CHAIRMAN MELIUS: Dr. Lemen?

MEMBER LEMEN: To follow up on Dr. Anderson's comments of which go along the same lines that I have, first of all I'd like to say you've put in a lot of work on this. And I appreciate that.

And it's a very useful document for the Board to have. As far as surrogate data though, when you state -- I think on page A-12 is just an example that the use of surrogate data to estimate occupational radon exposure for workers who were unmonitored or

inadequately monitored is a conventional practice that is successfully used by governmental agencies in epidemiological studies to determine risk to humans.

I wouldn't totally disagree with that. But I would say is that I still think that NIOSH has not understood, in this program, that we're not doing epidemiological studies.

What we're doing is compensating people. It may fine to use the surrogate data for an epidemiological study with all the caveats that are connected with that so that the reader can do it.

But when we're dealing with compensating individuals in individual facilities, to me I still have a major problem with the surrogate data usage. And I think that it may be a welcome tool to epidemiological studies.

But I don't think it's a welcome tool to those that are going to be

compensated. And I'd really like to see this report focus more on the pitfalls of surrogate data than it has. Thank you.

CHAIRMAN MELIUS: I mean, another way I thought about that is, because I share some of Dick's concerns, is that I wouldn't necessarily view what's been going on in the exposure assessment in epidemiological studies translate into dose assessment, and for this program, is necessarily the gold standard.

But I think the methods that -- I think it may be the silver standard or it's -- it ought to be at least as good as that. And the way I thought what your recommendations were very helpful were helping to think about the kind of validation and the kind of evaluation that needs to go on at least achieve that.

It ought to include that, because when we have disagreements within the Board or our contractor and DCAS over, it's usually questions of whether it's uncertainty or lack

of information and we're trying to apply a new method or a different approach.

And we really haven't undergone the kind of review and validation in a broad sense that would be helpful for that. And I thought that your comments were -- some of the analysis that you were very helpful in that regard.

You know, thinking of the example you used on benzene. And actually, in epidemiology you have the same sort of problem we face. It's limited data in a lot of facilities.

And if you look at, at least, the criteria the Board came up with, and I believe somewhere with NIOSH came up with for evaluating surrogate data, those criteria for evaluating are similar.

You know, how similar are the facilities? Were they built the same time, same kind of industry. I think it's -- may be more variabilities or pretty special

facilities.

You know, the DOE facilities, if you're familiar with. But, you know, there are similarities to what may be found in industry. There are other studies. I can think of where, you know, you may be doing epidemiologic study at multiple facilities. You may have good exposure information for three or four. You apply that to the two that don't, you know, that have weaker data.

Or you may do it on the basis of who have done a better assessment of a certain part of the workforce or something. And it's clearly a gradation.

It's not, you know, yes or no or black and white in terms of evaluating that. But -- but I think some of that thinking transferred over, I think, would be very helpful.

MR. DANIELS: I agree. You know, and I do understand your concern about using surrogate data for individual risk assessment,

you know. The slides -- I tried to keep the slides short.

But there is a section on the report talking about differences between epidemiologic approaches and individual risk assessment. I think key to this is the fact that, you know, small biases and individual exposure assignments in support of an epidemiologic study really won't play a large role in the outcome of the risk that you get from that health effect study.

But that's not true in the case of individual exposure assessment. Small biases could certainly have an effect on adjudication. So when you're working in the tail end of an exposure distribution, as you are in the case of trying to determine bounding doses, you know, a lot of the assumptions that you make in modeling fall apart.

And so we got to be wary of that. And that's why, I think, the validation

component is so important, because we aren't working with means and medians anymore. We're working at the tail of distribution. And we need to be sure that what we say is bounding is indeed bounding.

CHAIRMAN MELIUS: No, I thought that was a very good way of looking at -- looking at that. The other part of your report that I thought was -- was helpful, and I don't know if there's others have reaction to, was sort of the document updating issue and then science and so forth, because I think due, you know, largely to how busy and how much work there is in this program, we've not kept up with that.

And I think, frankly, the Board is at fault also. You know, we've -- we've tended to divide up our reviews. We do dose reconstructions reviews. We look at certain issues. We do Site Profiles. We look at certain issues.

We do procedures. We look at

certain issues. We don't always pull those altogether. And we often do those reviews in isolation. And we struggle with the issue of continually updating and -- and so forth.

And I think some more systematic approach that would involve, you know, you said not only -- so the current structure of the Board, the Board's contract. But additional, you know, external peer review, I think, would be very helpful to this program.

Dr. Ziemer, Brad Clawson you're on the phone? I don't know if you have questions. I'll give you the opportunity then. Got a couple more.

MEMBER ZIEMER: Paul Ziemer here. And I just have a couple I'll at least have, you know, one question and make a comment if that's all right.

CHAIRMAN MELIUS: Go ahead.

MEMBER ZIEMER: Well, first I wanted to thank Dr. Daniels for an excellent presentation. My sort of question right now

is I like the question you raised, how bounding is bounding.

In your mind, is that the same issue as the quantitation of claimant favorability? Is that another way of stating it or are you thinking of two different things here?

MR. DANIELS: No. That was the same. That's the same.

MEMBER ZIEMER: Okay. That's -- that's what I thought, but I wanted to make sure that that was just another way of talking about quantitating claimant favorability.

The other -- if I can just have one other minor question right now. And this relates to slide 14 and the -- the discussion on -- on what you call the weakly defined process comment resolution.

I did notice that you were focusing a lot there on public comment resolution, which we're starting to do a little better, I think, with our matrix of

tracking these.

But is -- were your comments here today mainly focused on that sort of thing or what -- what was the -- what was your conclusion in terms of comment resolution as it's formerly done with our contractors and the agencies and the Board?

We have a rather elaborate -- it's not necessarily well-defined. It may be weakly defined. But it operates much like peer review in science where you have a -- a give and take and try to resolve specific issues and questions.

Did you have any particular comment on that part of the -- of the methodology that is used to resolve scientific issues?

MR. DANIELS: Yes. We did look into that, and we noted that the Board tends to resolve -- have scientific debate in resolve issues in a Work Group format. And not all Work Groups are equal. Not all Work

Groups manage themselves the same way.

So what happens in some cases is -- - is there have been instances where comments have -- have come about, which may have been transferred to another Work Group or may be sitting in a Work Group or may be or not as well documented in that Work Group, the process of resolving them as another Work Group.

So there's a lot of, you know, personal -- the Work Groups themselves, there's a lot of individuality in the Work Groups. So what we're suggesting is a better way, maybe would be at least reporting to a centralized place to where you could track these comments and track the resolutions accordingly, and -- and show some, you know, expediency in getting things revised.

So -- so that's what we saw in that part B

MEMBER ZIEMER: Right. It seems to me that that may be every bit as important

as the process for handling the public comments, many of which in the public arena have to do with how the program operates rather than necessarily scientific issues.

But certainly some consistency from Work Group to Work Group in terms of identifying those issues and having a more of a structured process for resolving them. And thank you.

CHAIRMAN MELIUS: Brad, do you have questions?

MEMBER CLAWSON: Well, yes. I would also like to thank him for bringing his report, because, you know, it's given us all food for thought on this and while we were just talking about of the Work Groups being individual differences.

You know, we can always see that and we can always improve. I'd like to echo what Dr. Lemen said that I have an awful lot of issues. I know that we have to be able to use coworker data and so forth like that.

But one of the other ones that bothers me is the coworker data. When a lot of these plants were looking back, 40, 50 years, the names have changed and so forth like that.

And working in the industry myself, I've seen so many times that you may call somebody a chemical operator or a fuel handling operator or whatever. But their name has changed and their tasks have changed over time of what -- what they actually did and where they went.

They sometimes feel that because they can put this name on them and put them into these buildings. But these, you know, we need to spend a little bit more time. And I feel to check out where they've been.

I know that we've got to use coworker data. But sometimes we generalize them too much, and I don't think that we really capture what really goes on in there. But I -- I think as -- as what you said, the

Board takes a little bit of criticism on this too.

I know this was a NIOSH review. But also two of those areas we can improve. And I appreciate what was brought to us instead. That's it.

CHAIRMAN MELIUS: Phil?

MEMBER SCHOFIELD: I'd like to think coworker data particularly gives me a lot of -- I'm a little suspect at times on that. But surrogate date, in particular though, because you have the issues of time, distance and shielding.

And from one facility to another, even with similar materials there's a good chance of large variabilities, particularly when you're looking back 20, 30 years or more. This becomes a real factor and what people are exposed to, in particular when it comes to their compensation.

CHAIRMAN MELIUS: Wanda, would you like the last -- no? Bill?

MEMBER MUNN: I think not. Futile. Thank you.

CHAIRMAN MELIUS: I knew you'd never forgive me.

MEMBER FIELD: Dr. Daniels, I thank you. I think this is -- this is very helpful to have a fresh look. Someone coming from of sort of the outside and giving it a fresh look and sort of a different perspective.

I have a question on slide number seven. I just -- probably just more of a clarification. But at the bottom it says the use of surrogate data is an acceptable scientific approach provided that the data complement but not supplant information from preferred sources.

And I'm just wondering for the word supplant, do you mean take the place of?

MR. DANIELS: Yes.

MEMBER FIELD: Okay. And what --

what happens in the case from your reviews if you don't have data to complement, that there's just a lack of data?

MR. DANIELS: Well, I think there's a process in place. If you don't have data to do dose reconstruction then that -- that process is Special Exposure Cohort. So I think that's what's laid out in the Act. And that would be the direction to go.

CHAIRMAN MELIUS: I believe Dr. Wade wants the last comment.

DR. WADE: I'd like to just very quickly. Four things. I'd like to Doug personally for his efforts in coming here and being with us. Doug did end his opening speak to the fact that he was focusing on indirect exposure assessments.

But I think if you read the report he was commenting upon the quality of science in the program overall. And the lastly, with regard to comments, the external review of the document is open.

So if anyone would like to make a comment or a suggestion, I'm sure that Doug would take that to heart and modify his report based upon what you would say. So I think you have the ability to impact the substance of Doug's report.

We then have the ability to impact what John Howard would do relative to the recommendations that Doug makes by commenting upon those as well. So there's opportunity for this process to continue to improve in ways that Board Members might like to see it.

And I would ask you to take advantage of that. And thank you again.

CHAIRMAN MELIUS: Yes. Yes. Thanks very much. I told Lew that I and maybe others had questions about sort of using internal people to do some of these -- these reviews. And I thought that your report, and in fact, some of the others also sort of showed that someone withing NIOSH could do a fair and, you know, I thought very good

assessment of the program.

So in the spirit of peer review, which I think we're used to, but it's not always done in other settings as well. But it was a very good -- good report that you and Dr. Spitz did.

And I thought some very good recommendation, very perceptive about -- about the program. And we do appreciate that.

MR. DANIELS: Thank you.

CHAIRMAN MELIUS: We have anything else? Okay. Yes, Josie?

MEMBER BEACH: I just wanted to make sure that we had tasked SC&A for Sandia National Labs. It wasn't really clear to do a -- the Site Profile Review and prepare a matrix.

CHAIRMAN MELIUS: Yes, we did it yesterday.

MEMBER BEACH: Okay. I just wanted to make sure.

CHAIRMAN MELIUS: We set up the

Work Group.

MEMBER BEACH: Well, the Work Group was going to be set up at the next meeting.

CHAIRMAN MELIUS: Meanwhile we tasked SC&A. Yes.

MEMBER BEACH: Just wanted to be clear. Thank you.

CHAIRMAN MELIUS: SC&A has already done the Site Profile.

MEMBER BEACH: The review would be just do the matrix?

CHAIRMAN MELIUS: The matrix, correct. Yes.

MEMBER BEACH: Okay. Thanks.

CHAIRMAN MELIUS: Good. Anyway, thanks, everybody. And hope everyone makes it out of here fine. And we will see you all in -- for an extended -- possibly extended visit to, hopefully not extended by the weather, but extended by the agenda in the Tri-Cities.

MEMBER MUNN: In the Tri-Cities.

And I will make every effort to see that the day prior to our meeting is a tour day. Something quick. Which I think we all should take into consideration in planning our -- I'll try to get back to you on that as quickly as possible. But you should keep it in mind.

MR. KATZ: I mean DOE is working on setting up a tour --

MEMBER MUNN: Yes.

MR. KATZ: -- for the day before. So that's -- that's a fact. And folks that are interested in having that tour on the Board, please let me know, as well as folks from SC&A who would like to join that and folks from DCAS.

It would probably be good to get a head count of how many people are interested.

MEMBER CLAWSON: Hanford has asked me that as soon as we can get a head count they'd appreciate it so they would be able to accommodate how many people want to be able to go.

MEMBER MUNN: Brad, if you're doing this, I'm not.

MEMBER CLAWSON: Well, I started this a couple of months ago for the tour. And I've been in contact with our point out there, and she -- we've already got it set up for the day before, but she just wanted to get a head count the closer we got to this so she could make sure if she needs big bus or just a van.

So I would really encourage, especially the new Board Members that haven't been there. This is an excellent tour that they do. And Hanford's marvelous site, and they've accomplished a lot of things in their in their life up there. I highly recommend it to anybody.

MEMBER MUNN: Brad, why don't you send an email and tell me what you have planned, because I would like to coordinate your plan with what I had anticipated for the rest of the day. Thank you.

MEMBER CLAWSON: Okay. I'll be in

contact with you.

MR. KATZ: I'd like to be the loop too, please. So let's all get coordinated here on this. Thanks.

MEMBER MELIUS: I can just envision the three tour buses crashing into each other meeting at the -- the B

MEMBER CLAWSON: We just had a -- we just had comments on this about how we're suppose to get together. So I'll let you know when I've got, I believe her name is Spills -- Spells or something like that, that I've been dealing with up there.

And she basically set up B

CHAIRMAN MELIUS: Brad, why don't you do this offline with everybody okay?

MEMBER CLAWSON: Okay.

CHAIRMAN MELIUS: Get coordinated with them. Thank you. Bye. Meeting is adjourned.

(Whereupon, the above-entitled matter was adjourned at 9:35 a.m.)