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CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR
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ADVISORY BOARD ON RADIATION
AND WORKER HEALTH

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HANFORD WORK GROUP

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WEDNESDAY,
SEPTEMBER 12, 2012

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

JAMES M. MELIUS, Chairman
BRADLEY P. CLAWSON
PHILLIP SCHOFIELD
PAUL L. ZIEMER

ALSO PRESENT:

TED KATZ, Designated Federal Official
ISAF AL-NABULSI, DOE
ROBERT BISTLINE, SC&A
FRED DUNCAN, ORAU Team
SAM GLOVER, DCAS
JENNY LIN, HHS
ARJUN MAKHIJANI, SC&A
JIM NETON, DCAS
LaVON RUTHERFORD, DCAS
SCOTT SIEBERT, ORAU Team
JOHN STIVER, SC&A

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

(1:01 p.m.)

MR. KATZ: First of all, it's the Advisory Board on Radiation and Worker Health. It's the Hanford Work Group. Welcome, everybody.

Let's begin roll call. Since we're speaking about a specific site, please speak to conflict of interest as well for all Board Members and agency staff and related staff. And let's begin with the Board Members. Thank you.

(Roll call.)

MR. KATZ: So the agenda for this meeting is posted on the NIOSH website. And the document, which is the SC&A review of the petition and NIOSH's Evaluation Report on the petition, is up on the NIOSH website, as is the presentation by which people can follow along summarizing that review by SC&A, which Arjun will be doing.

So let me just remind everyone,

please, if you are not addressing the group, mute your phone. If you don't have a mute button, use *6 to mute your phone. And then you press *6 again to take your phone off of mute. Please nobody put their phone call on hold. Hang up and dial back in if you need to leave for a piece.

And, Jim, it's your agenda.

CHAIRMAN MELIUS: Okay. Yes. Thank you, Ted. And thank you for everybody to come on this call.

Today we are going to be focusing on Hanford, the Petition Number 155. And so that is going to be probably the major part of the discussions of this meeting. We will at least have as an agenda item a brief update on other Hanford activities at the end of the call, but, again, the major focus is the Petition 155. And we have recently received a very thorough evaluation of the NIOSH Evaluation Report on that SEC petition. And SC&A has done that.

And I am going to ask Arjun to present the SC&A review. And, as Ted mentioned, he has prepared a short presentation on that. So I'll turn it over to Arjun, and then we'll have questions and comments and further discussion on that.

So, Arjun, go ahead.

DR. MAKHIJANI: Thank you, Jim.

So I will just mostly follow the slides. I have a couple of other things I would like to mention along the way. But I will follow along with the slides so we have the record of what's being done. And, if you like, of course, you can interrupt me with questions on any slide or save it to the end.

The petition relates to the 1987-89 period to Hanford 200 area. And its basis is that the bioassay data are not trustworthy and should not be used for dose reconstruction.

Environmental Protection Agency had several problems with U.S. Testing in this

period that were detailed in various documents that are part of the petition. NIOSH evaluated this petition and found that any data mishandling and fraud had not affected the bioassay data. And so the bioassay data could be used for dose reconstruction.

And the Board asked SC&A to review, and we did. We focused on four questions, and they're not in the slide, but I should mention them. Of course, a large part of our investigation was, was that direct evidence of fraud or mishandling of data that affected the bioassay program? We looked hard for evidence.

Were there issues of concern that point to the potential for fraud or data mishandling? Were there other data integrity concerns? And how do the issues raised by the EPA relate to the usability of the bioassay data?

So these were the four broad questions. And we did a pretty wide-ranging

review. We reviewed the petition and Evaluation Report, a number of other documents from the EPA relating to the testing. We reviewed internal U.S. Testing and PNL audits of the bioassay program. We reviewed the external reviews in 1990 and '90-'91 that were done as part of this whole investigation of fraud and mishandling. And we reviewed documents supplied by the petitioner. And we also reviewed non-public documents. And Bob Bistline was our point person for doing that. And they were reviewed along with NIOSH and with Board Member Brad Clawson.

We also did a lot of other research. We interviewed the petitioner and the petitioner's representative. We reviewed external -- the external bioassay expert for the 1990 oversight. We interviewed two external experts who participated in the May 1990 oversight and had raised a specific concern. No. Sorry. We interviewed one of the two external experts who participated in

the May 1990 oversight for the DOE. And we interviewed two of the external experts who did the 1991 retrospective review.

And during these interviews, Board Member Brad Clawson and Sam Glover were present. And there was also a DOE classification officer. And all interviews which have been reported in the report itself were reviewed by DOE for classification and also by the interviewees.

And we reviewed data quality issues pretty extensively, including MDAs, minimum detectable activities. And we specifically reviewed bioassay data for plutonium, uranium, americium, strontium-90 and neptunium, and four completed dose reconstructions from just as specific kind of bioassay data used to address an issue raised by the petitioner.

MEMBER CLAWSON: Arjun?

DR. MAKHIJANI: Yes?

MEMBER CLAWSON: This is Brad. I

just wanted to let you know that I am on the phone. I have been on for a little while. But I hate to interrupt you. I just wanted to let you know I was on.

DR. MAKHIJANI: Well, and thank you, Brad, for all the effort you made during this process.

MEMBER CLAWSON: No problem.

DR. MAKHIJANI: So just to address directly the question, did fraud affect U.S. Testing bioassay data? So we looked extensively for evidence of fraud or mishandling of data. We asked the petitioner and the petitioner's representative for documentation of personal knowledge of fraud. And none of the information provided contained direct evidence of fraud in the bioassay program.

The interviews revealed two issues that could be potentially of concern, and I will talk about them in more detail. But those two issues also had reasonable

explanations and did not indicate fraud.

We didn't find any motive for fraud in the bioassay program. The reviews that were conducted could have detected crude levels of fraud, but they did not find. But it should be stressed -- and you will see this in the interviews as well as in the documentation of the reviews -- that these reviews as well as the audits that were done during the time by U.S. Testing, or by PNL, I should say, were not set up to find or detect sophisticated fraud.

So our conclusion is that, to all available evidence, U.S. Testing bioassay data are not affected by fraud or mishandling of data. But obviously since none of the internal or external audits were structured to detect sophisticated fraud, you know, we can't arrive at any complete and 100 percent definitive conclusion about this.

There are two views of data relating to the fraud. The petitioner in the

petitioner's interview, as well as the Department of Energy in 1990, PNL itself, and Environmental Protection Agency, indicated in various ways that if any part of the data generated by U.S. Testing was affected by knowing and willful manipulation of tests or data, that all of the data should be regarded as suspect. So in that case, if the data are suspect, then the implication is they should not be used.

And this was explained by the then-DOE site manager in a deposition. There was a lawsuit after the PNL contract was terminated. And PNL terminated the U.S. Testing subcontract, including for the bioassay program, for default in 1990, along the lines that are quite similar to the reasoning of the petitioner in the petitioner's interview as well as in the petition itself.

In contrast, there is another view expressed by the oversight and retrospective

reviews in 1990 and '91, that found the bioassay data to be acceptable because there was no direct evidence of fraud -- there were quality assurance and other issues, but overall these reviews found and the participants that we interviewed confirmed during the interviews that the data were useable.

One interviewee said he would give a qualified yes to the usability of the data for reasons that are explained in the interview. And I can go into it in more detail.

But the reviews did not conclude that bioassay data were unusable because of quality assurance issues or because of the fraud issues that had been raised on the chemical side of the U.S. Testing program.

And, finally, in the court proceeding regarding the termination of U.S. Testing's contract, the court said that termination of the contract for default was

not warranted, but termination for convenience essentially, as I read it anyway, that because so many concerns had been raised, that the contract had been terminated for convenience.

There were a number of quality assurance issues that stretched back to the 1960s. And this was some of the documentation provided by the petitioner and the petitioner's representatives.

There was also evidence that U.S. Testing and PNL made efforts to correct these problems, but they persisted from the 1980s until the period under review. Of course, the pre-1987 data quality issues don't have a direct bearing on the usability of the data.

We did review the quality assurance issues from the point of view of, do they affect the data sufficiently that they are unusable? Generally, the quality assurance problems related to minimum detectable activities in some cases, for example, for strontium-90, the minimum

detectable activities were more stringent than prevailing industry norms.

And we have a number of observations and recommendations about the use of the bioassay data. They would need to be adjusted to take into account these quality assurance problems, but we didn't think that problems such as those affecting minimum detectable activities rendered the data unusable.

The May 1990 oversight review found that a quality control file had been edited. I am now on slide 8. This edit appears to have a reasonable explanation. And this is based on a memory going back 20 years. There is no paper trail that can verify that only a minor change not involving the data was made. So this is memory from the person who participated in the review itself.

Also the quality, the change, the fact that the quality control data file had been changed was flagged in the file itself.

And this, according to SC&A, lent support to the hypothesis that a change was made to correct an error, rather than to manipulate data. Apparently, no data were changed, just the name of the person.

Were data withheld from the 1991 review? So the 1991 retrospective review contained, in more than one place, an observation that data were withheld. And so this, of course, raised a question in our minds. And we investigated it. We interviewed two of the participants.

There is, in our mind, some uncertainty regarding the completeness of the data in the possession of Pacific National Lab at the time of the review in 1991. But there is no evidence that records were actually withheld to hinder the review or affect it in any way. The unavailable records appear to have been the result of prior procedures for records transfer. And these procedures were basically set by PNL.

And the team, the review team itself, concluded that this matter did not affect the conclusions in any way. And they were able to conduct their review in the manner that they desired. And they got all the data that they actually requested for review. And they found no evidence of fraud or data manipulation.

So the bottom line in this review of fraud is really a policy question and not a technical question. Technically, we did not find fraud in the bioassay data. But there was the problem of fraud affecting the company and data mishandling in another side. So the bottom line, as it says on slide 10, is, should bioassay data, which to all available evidence are unaffected by fraud but generated by a company that was dismissed because of data manipulation and fraud in another technically unrelated area, chemicals, be trusted for use in dose reconstruction?

SC&A did not express a view

regarding -- because this is a policy question, we felt, for the Board.

There were some other observations we made and, in particular, failure to meet minimum detectable activity limits, a quite important observation and finding, actually, but fecal data had never been subjected to quality assurance sampling. NIOSH had also noted this in its Evaluation Report.

SC&A concluded that these problems did not invalidate the bioassay data but that appropriate adjustments would be necessary in some cases before their use.

We have two findings. There were a number of observations but two findings. Petitioner had raised the review of the proper use of fecal data. And SC&A reviewed four completed cases not in litigation and selected from the cases that NIOSH has completed.

In three of those cases, we found that fecal data had been appropriately used in the dose reconstruction, but we found that in

one case, the procedure hadn't been followed and it resulted in a considerable underestimate of the plutonium intake.

And the second finding is that there is less confidence in the fecal sample results since no quality assurance samples were ever analyzed in the period under review. And this is what led one of the experts to say that QA samples are needed to assure that results are credible, but it does not necessarily mean that the results are not credible. But certainly was a weakness of the program that there were no fecal QA samples.

So there is some uncertainty arising from this problem. And that should be addressed when using the fecal data. Also, obviously, the procedure that had been set down for the use of fecal data should be followed more carefully since we found, in one of four cases, it was not followed. And I should caution four cases obviously does not constitute a statistically valid sample.

Thank you. That ends my presentation.

CHAIRMAN MELIUS: Thank you, Arjun.

Board Members on the Work Group have any questions for Arjun or comments?

MEMBER ZIEMER: This is Ziemer. I'll just make a general comment that I really appreciated the work that was done on this by SC&A. I know it was a very comprehensive and thorough look at the issues. So I appreciate their report.

DR. MAKHIJANI: Thank you, Dr. Ziemer.

CHAIRMAN MELIUS: Yes. I second that, Paul. I had told Arjun that I think it was a very good report technically and very helpful in terms of understanding this issue. And I think for this particular type of concern, whether it may have been fraud or other problems in a laboratory like this, a thorough report is really the -- the sort of

thorough technical report and going through the facts and what happened is really the best and only way we can address it. I thought he did a very good job with this and the others at SC&A.

DR. MAKHIJANI: Thank you. Of course, I should mention our team. Joyce Lipsztein was a very prominent member. And she did all of the QA review and the dose reconstruction reviews. And Bob Bistline was our document review point person and also participated in the review of the non-public documents. We had a lot of help from Lynn Ayers in terms of the logistics of arranging the interview.

CHAIRMAN MELIUS: Any other Board Member comments or questions?

MEMBER ZIEMER: This is Ziemer again. I'd maybe just ask NIOSH this question. In the use of this bioassay data for dose reconstruction, had we been using the minimum detectable limits that were stated to

be in the contract, which they apparently didn't need?

So I gather that the actual MDAs, or minimum detectable activities, were higher in actuality than the contract had called for. That's a matter of basically you would end up assigning a little more dose if there was a minimal value.

Do we know which was used in actual practice?

DR. GLOVER: This is Sam Glover. I believe that the TBD -- you know, at Hanford this has been going on for some time. So the TBD is part of the review.

And so we haven't changed it based on the things that we have found, but I believe the stated contractual limits I believe were what are in the TBD.

For a lot of people, coworker data, Paul, actually will be used in this time frame, though. And so that really won't be affected by the MDA so much. I believe I'm

stating that correctly.

MEMBER ZIEMER: Okay.

DR. MAKHIJANI: Could I ask Sam a question about that, if you don't mind?

CHAIRMAN MELIUS: Yes. Go ahead, Arjun.

DR. MAKHIJANI: Sam, doesn't the MDA kind of set the lower limit of how the coworker model is constructed?

DR. GLOVER: But it doesn't really affect below that. It really doesn't change the fit to the line. I think we basically use all of the data.

DR. MAKHIJANI: Oh, okay.

DR. GLOVER: And so I don't think it is going to have much material effect on how our coworker models are put together. We certainly will look at it.

DR. NETON: This is Jim Neton. I think the only way that it will affect the populations is if the 50th percentile of the distribution was at or below the MDA.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: Right.

MR. RUTHERFORD: This is LaVon. I think we need to look and see what the TBD actually calls out for the MDA. Me, I would be rather surprised if it actually took the contract limits. I would think it would have looked at other documentation for that. So I think we need to look at that.

DR. GLOVER: And this certainly isn't a question or an answer off the cuff. I don't recall. We looked at it. We discussed this. And I can't recall where we left it. And I apologize for that.

At the Board meeting, we can come up with an answer I think between now and then.

CHAIRMAN MELIUS: Yes. I think that would be helpful if you can do that.

DR. GLOVER: Yes.

CHAIRMAN MELIUS: Any other questions or comments on the SC&A report from

the Board Members?

MEMBER CLAWSON: Jim, this is just Brad. I would just like to make a comment. I know that Arjun has been through this, but if I could just have a minute, though, and part of my concern that I have with some of these things, if I could.

As you know, I was involved in most of the documentation that was pulled and so forth like this. And Arjun is right exactly in what he said, that we have seen no proof of manipulation and so forth like that.

There are some things that did bother me in going through the report. And the people we brought in to interview did a marvelous job. I think also, too, NIOSH, did a job. What this really comes down to, what I want to put out, especially to the Board Members, is this is going to come down to us. SC&A isn't going to say one way or another.

The thing that bothers me about this is that people were able to change

reports, that there was no documentation of it. Plus, we never knew what was changed. Now, they said that it was editorial or whatever else like that. Well, we could never know about that.

These are the caveats I just want you to think about as we go in and we're saying that, yes, we can use this data or, no, that we can't.

There was a comment that was made by one of the people that performed the audit about access to the files. And due to a PNL issue, they could take and request certain things within a category and then PNL would pull all of these documents out for them. They by no means had access to whatever they wanted. Whatever they requested they seemed to be able to get brought to them.

But then one of the other things that came out that struck me into this, and this is the weak program. The process that they did, even in the auditors' eyes, was a

weak program. There were no checks and balances. There was nothing like this.

All these things put together, I'm sitting here. I'm looking at a Board Member, at the other Board Members, and how they think about this. And I want us to just keep this in the back of our minds.

All this information is questionable anyway because of what happened at U.S. Testing. We have gone through this report. And I can truthfully tell you that I could not really see any kind of outstanding -- that there was any kind of fraud or anything else like that. But there were many things that didn't pass the smell test, they just didn't smell right, but the processes were very weak. There are a lot of little things that I didn't like into this.

So this, in my eyes, is going to come down to us as Board Members to be able to discuss this process and be able to understand it. And we've already heard that they have

lost these contracts because of convenience, because it didn't look right, it didn't smell right, and so this is why their process came to an end.

And this is mainly for you, Jim, and also as we bring this forth to other Board Members. I just want to make sure that they understand the SC&A did a marvelous job. NIOSH has done a marvelous job.

I would like personally to compliment Sam because he has really dug into this and really worked on this. I have been involved in many, many of the interviews with this process. And I have not seen any fraudulent things, but I have sure seen some things that didn't sit right with me. And I just wanted to make sure that I say this up front of what my personal -- and this is just my personal feelings on what I have seen.

That's it.

CHAIRMAN MELIUS: Okay. Thank you, Brad.

Just one comment or question. I believe that Arjun certainly addressed the PNL issue in the report or is that a discussion?

DR. MAKHIJANI: Yes, it is in the report, Dr. Melius.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: PNL did conduct audits, but they weren't really --

CHAIRMAN MELIUS: Audits.

DR. MAKHIJANI: You know, they weren't so independent from the bottom-up audits. They were more like double checks of what U.S. Testing was doing.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: And this is in the review reports that were done, I believe either one or both of them, in 1990 and 1991. For example, when they submitted blind samples, it was often known. So the blind samples weren't really blind.

And what Brad just said is right, that there wasn't a check on whether third

parties could change the data or not. So one of the very strong recommendations in the May 1990 report was that some control should be put in place as to when and how data were changed, and that there should be a paper trail of the old data as well as the new data and who changed the data and all of that. So that there was a verifiable trail of why data were changed and so fraud could be ruled out in cases. But none of the audits actually covered this issue. They couldn't. There isn't a paper trial to go back.

And the other thing regarding availability of data that I should have mentioned but didn't, is that the retrospective review team in 1991, to the best of my memory now, requested data from a PNL log. So they requested data from what PNL already had. So it was natural that they were able to get whatever they requested, but we don't know what data remained with U.S. Testing. It didn't remain with U.S. Testing

because U.S. Testing withheld it for some nefarious reason, to the best that we can tell, or the PNL policy. But I do think that probably some data remained with U.S. Testing at the time, or possibly some data remained with U.S. Testing at the time of the review.

CHAIRMAN MELIUS: Okay. Thanks for that clarification.

MEMBER CLAWSON: Jim, this is also Brad. There is something else I wanted to just throw out. I apologize, but just to keep in the back of your mind, too, that these audits that came in were like a one-time audit.

They never followed up. If I remember this correctly, they never followed up down the road to be able to see the changes. These people came in. They did a one-time audit, and basically they were gone. And so, you know, to me that is just another weakness that I was looking at.

And I know why that they did the

audits and so forth like that, but it doesn't even -- you know, if the information was taken "Okay, we'll look into that" or anything else or any follow-up that we could see that the programs were or the suggestions were even taken.

DR. NETON: Yes. They were outside groups.

MEMBER CLAWSON: Yes.

DR. NETON: And, as I recall, I mean, some pretty prominent people were involved.

MEMBER CLAWSON: These auditors were all quite renowned, and they did a very good job. They had some -- I think I guess the thing that kind of got to me a little bit is here we're looking at this. We're looking at this program here. And they come in. And as they do this audit for certain reasons, they also offer up suggestions to be able to control the process, et cetera.

CHAIRMAN MELIUS: Yes.

MEMBER CLAWSON: And then, you know, we don't even know if anything was followed up on or if changes were made or so forth.

CHAIRMAN MELIUS: Yes.

MEMBER CLAWSON: And so --

CHAIRMAN MELIUS: And I understand that.

MEMBER CLAWSON: Okay.

CHAIRMAN MELIUS: Any other Board Member questions?

MEMBER ZIEMER: This is Ziemer. I have another question. I think I just asked Arjun this. This has to do with the inter-comparison issue. I think contractually they were required to do this every so often, maybe every six months or something like that.

Was the issue that they didn't do that on the frequency that they were supposed to. Were some inter-comparison standards run on these bioassay samples? They're fecal samples or not?

DR. MAKHIJANI: There was no quality assurance done on the fecal samples. There were some inter-comparisons done with the environmental measurements lab, but there were gaps in that inter-comparison program.

MEMBER ZIEMER: Right.

DR. MAKHIJANI: And they are identified in the report. I actually don't recall the specific areas that were called out as a deficiency in inter-comparisons, but I can do a search of the document.

MEMBER ZIEMER: I think they wouldn't do it as frequently as they were supposed to. Is that --

DR. MAKHIJANI: There is actually a gap in the inter-comparison program. And there were also gaps in the internal audits. But, you know, U.S. Testing and the EPA actually called this out as a problem in 1990, when they were discussing the whole question of the status of U.S. Testing.

DR. GLOVER: Dr. Ziemer, this is

Sam Glover. I just want to mention, the fecal sampling didn't exist unto itself. I mean, usually that's a complimentary technique. And these people also had urinalysis.

MEMBER ZIEMER: Okay. In dose reconstruction, what was used or what would have been used?

DR. GLOVER: I believe what happened on one, they treated the fecal sampling as if it was a positive data point, is why it was low, rather than use like MDA and multiplying it. There's a Super S correction factor that wasn't put properly. But there is a procedure, and it is spelled out in one of the appendices of OTIB-49. It can walk you through how the data should be applied.

MEMBER ZIEMER: Okay.

DR. MAKHIJANI: Dr. Ziemer, I can now answer your earlier question more precisely. They did do inter-comparisons of the uranium with the environmental

measurements lab, but they were required, as you said, to do them every six months. And inter-comparing also shall be performed with EPA.

Now, environmental radiochemistry section of UST participates in these QA programs. The bioassay section does not. And this, I was just reading a direct quote from a DOE reviewer, one of the auditors in 1990.

So there was a lack of external checks because, as I said, the PNL reviews were not what one would really call external audit. And that was observed at the time. There was more in the nature of a double check.

MEMBER ZIEMER: Okay. Thanks.

DR. MAKHIJANI: Sure.

CHAIRMAN MELIUS: Any other questions or comments?

(No response.)

CHAIRMAN MELIUS: Are the petitioner or the petitioner's representatives

on the line and wish to make comments?

(No response.)

CHAIRMAN MELIUS: Apparently not. Then do we have a recommendation as a Work Group to give to the Board, or how do we want to handle that?

MEMBER ZIEMER: This is Ziemer. What are our options here? What actions are needed?

CHAIRMAN MELIUS: A possibility is the -- I mean, I think the major possibility would be that we have the SEC Evaluation Report from NIOSH recommending that the petition be denied. And we have a report from SC&A that basically confirms that recommendation. And I think the question would be, do we recommend to the Board that the petition be denied, that the NIOSH Evaluation Report be accepted?

DR. MAKHIJANI: Dr. Melius, just one sort of point is we didn't actually go into the area whether the NIOSH recommendation

should be accepted or not.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: We posed the policy question to you.

CHAIRMAN MELIUS: Yes. Well, I think certainly on technical grounds, NIOSH did not find -- SC&A's findings were basically confirming the NIOSH findings on a technical level.

DR. MAKHIJANI: That's correct, Dr. Melius.

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: We did agree with NIOSH that we did not find evidence of fraud in the bioassay program.

CHAIRMAN MELIUS: Yes. All right, which is the basis for the petition.

MEMBER ZIEMER: So let me sort of ask this question. This is Ziemer again. It seems to me there are two parts of this. One is the policy issue on whether or not, even if there is no evidence of fraud, because this

company had some questionable practices on the chemical tests in a separate program, whether that should carry over to this, even in the absence of evidence of fraud.

And then a separate issue is, well, suppose we say, if there is no evidence of fraud, then the data can be accepted. You still have the issue of the quality of the data or the related issue.

So I don't know if we -- let me ask it this way. If we were to recommend to the Board that they agree that the fraud issue is not sort of a showstopper in itself, I believe NIOSH is saying, in spite these other sort of shortcomings on the minimum detectable levels and quality assurance and so on, they can still reconstruct dose. And it's not clear to me whether SC&A agreed with that part of it or not.

CHAIRMAN MELIUS: Yes. We --

MEMBER ZIEMER: I think they haven't taken a position on that part of it.

CHAIRMAN MELIUS: Yes. I think we have basically charged SC&A with evaluating the fraud question/concern --

MEMBER ZIEMER: Okay.

CHAIRMAN MELIUS: -- and to evaluate what reports have been done to, you know, evaluate that in the past with the two outside reports and then to go into that for us. So I think that was the main focus of their charge and of their report.

I think certainly -- I certainly, in reading the report and reviewing the NIOSH report before, I didn't see any findings in the SC&A report that would support a finding that -- you know, that contradicts the NIOSH Evaluation Report. I mean, I think that I didn't see any findings that say that NIOSH cannot do dose reconstruction with sufficient accuracy, despite the shortcomings in the data.

Now, I mean, another option we have, we could, you know, ask SC&A to evaluate

some of those technical issues, if that's what people would like.

MS. LIN: Dr. Ziemer and Dr. Melius, this is Jenny with OGC. I think the Board is definitely in a position to make policy decisions with respect to the air quality and the use in this program, but I just want to caution the Board that, even though you could make a policy decision, that decision needs to be sustained by some technical basis. So I'm just putting it out there --

CHAIRMAN MELIUS: Yes. No, I understand.

DR. MAKHIJANI: Dr. Melius, maybe I just --

CHAIRMAN MELIUS: Yes.

DR. MAKHIJANI: -- point the Working Group to a couple of things? As you know, we did look into the quality assurance issues to some extent, specifically with regard to some radionuclide. As you observed,

this report was mainly focused on the fraud and data manipulation question.

The petitioner raised the question of quality assurance. And so we have looked at it also. It's not a full review of the quality assurance question.

The one issue, I think, the one finding we had in that regard relates to the lack of quality assurance on fecal samples. And, you know, when it comes to minimum detectable activities, you can make adjustments for that. We have not investigated whether or not adjustments can be made, given that there are no quality assurance samples in the fecal program and that fecal data are being used for dose reconstruction.

DR. GLOVER: Dr. Melius, this is Sam Glover.

CHAIRMAN MELIUS: Yes.

DR. GLOVER: I just want to briefly mention that this is a -- you know, we

are seeing this data only because we are getting nearer to the '90s and seeing the advent of DOELAP and these issues. You know, this is a process that has taken decades to come here. This quality assurance is something that was developed over time. Many of the old samples from HASL, they're the best available science and technology that was implemented.

I just want to throw that out and remind you that we used that QC data to -- did we see anything? They were testing it. Did that give us evidence that something bad was happening? I wasn't trying to put them and hold this program into another standard when we hadn't tried to subject the same data previously when no QC, no EML existed. I just wanted to throw that out.

CHAIRMAN MELIUS: Yes.

MEMBER SCHOFIELD: This is Phil. I've got a little bit of worrying just on the fecal samples. How large of an impact that

would have on the reliability of the dose reconstruction.

DR. MAKHIJANI: So I think that's a question maybe that NIOSH should address because we reviewed for dose reconstruction. We didn't address the specific question that you are asking.

MEMBER SCHOFIELD: Okay.

CHAIRMAN MELIUS: Sam, do you want to address that or --

DR. GLOVER: I hate to do it totally off the cuff.

CHAIRMAN MELIUS: I mean, if you are not comfortable --

DR. GLOVER: I just want to make -- you know, they are complementary tools. I mean, we have data from lung counts, urinalysis, and fecal sampling. So it's part of a complementary -- basically, Hanford was looking at trying to assess -- they brought a special program into play, to see was there a very low-level intake happening below which

the urinalysis program might be missing it?

They're assigning missed dose for that anyway. So they're trying to go down even further and use this fecal sampling program to look at really low doses. So that's why it was done.

And it also complements what you can understand from the particle sizes. And so it can be useful from an accident scenario.

Lack of a fecal sampling program does not prevent us from doing, even if we throw out the fecal data, from doing dose reconstruction. I hope that's -- we could address it technically and show you in a presentation, but, really, they had a very broad-scope bioassay program. It was multi-tracking, multi-pronged.

CHAIRMAN MELIUS: Yes. I guess I'm just having problems, Sam. I know you are speaking off the cuff on this and so forth, but I guess I have a little bit of problem with an argument that, well, just because this

is a newer and at least theoretically better technique, the fact that there was no quality assurance doesn't mean that it couldn't have been, you know, misused or misapplied or that there couldn't be some problem with certain individuals as this technique was -- you know, other dose reconstruction would be more dependent on this and so forth.

DR. GLOVER: Would it be fair to ask maybe if we looked at it if we had bioassay data from the fecal program or any other and then we were to remove that, what would the impact be? Would that be helpful to the Board? I guess what I am asking --

CHAIRMAN MELIUS: Yes. I'm trying to think off the cuff also on what would be appropriate steps to take and who should do them, and how that would be done in the most sort of efficient way to address this.

I guess, first of all, I would just like to back up a little bit on this issue to get some input from the other Work

Group Members as to whether they would like this avenue to be pursued before we go to make a recommendation to the Board.

MEMBER CLAWSON: Hey, Jim, this is Brad. Can I speak for just a minute? I'm going to speak just from my personal opinion on this. So take it for what this is worth.

I know that we were looking at this from the fraud standpoint of it. And we got into this. And, you know, it's not inconclusive that -- we didn't find any blatant fraud. To tell you the truth, I wouldn't use this data with a ten-foot pole because there are too many questions over it. And this is where SC&A put out to the Board that this is actually a policy question.

I saw the audit reports. I talked with the people that got involved with it. My personal opinion is that I don't like the looks of the data. And it doesn't look and smell very good to me.

I just want the other Board

Members to realize that because of my involvement in this -- this is just my opinion now. I know that Dr. Ziemer is going to look at this from a different standpoint as, well, "We can change this and go to that." But also, too, from the standpoint of a petitioner who has brought question into this, the company has been under question. I myself would not really like to use this information, period.

CHAIRMAN MELIUS: But, Brad, I mean, I think the problem with that approach is that, as Jenny said, then we have to have a technical basis for --

MEMBER CLAWSON: Not using.

CHAIRMAN MELIUS: -- not using the data that was fraudulent or there is some other technical problem with the data that renders it not --

MEMBER CLAWSON: It's not useable.

CHAIRMAN MELIUS: -- useable for the purposes of dose reconstruction in a way

that, you know, precludes or does not support dose reconstruction with sufficient accuracy. So I think we have to have more than, you know, than that, than what your sort of personal view would be on this.

And I think that I personally looking at reviewing the report from SC&A don't see a technical basis for doing that based on the fraud issue. And that was the issue that we asked them to do.

MEMBER CLAWSON: Right.

CHAIRMAN MELIUS: I guess the question I am asking is would other Work Group Members feel that it was more helpful before we make a recommendation to the full Board to look in further detail at the use of this data in relationship to the quality assurance issue, which was not addressed in the SC&A report because we didn't ask them to do that. Maybe this step, because I think if it hadn't --

MEMBER ZIEMER: This is Ziemer.

Let me comment on that, Jim. As I understand it, the fecal data really only becomes important at the lower end of the intakes where the known samples, or the in vivo counts are insufficient could detect something. Is that what you were saying, Sam? It sounds like this was a tool for the very low end of the intake spectrum. Did I understand that correctly?

DR. GLOVER: I think one of the reasons we had the discussion about the two to three times multiplier, that's so we don't underestimate the dose. We're supposed to multiply it and raise that up, because there's a ratio of --

MEMBER ZIEMER: Yes, yes, but --

DR. GLOVER: And you're right. It's going to be a complementary technique that you would look at all of the data packages together.

DR. MAKHIJANI: Dr. Ziemer, there's a procedure -- is it 49, Sam?

DR. GLOVER: That is correct.

DR. MAKHIJANI: -- in which it is stated that if the fecal sample is more than two months after the incident, then there is -- then it should be used as a urine -- I mean, be misstating it, so correct me if I am wrong. Then it should be interpreted as a urine sample and multiplied by three. And that is the specific thing that we actually reviewed as to whether that procedure would be applied.

So it isn't exactly, in my reading, that these correspond to where there are very low intakes that are being interpreted with this dose reconstruction procedure. That was actually the review that was done at the time to try to detect whether they were missing something as part of the fecal program. So I think that's correct, but I don't think that's exactly the way it is being applied.

Unfortunately, Joyce could not be

on the call. And she is the one that did all of the detailed review of these cases. But that's the best of my understanding. I could certainly stand to be corrected by Sam or Jim.

MEMBER ZIEMER: Well, this is Ziemer again. I would just like to know if maybe I would recommend sort of a two-part motion, the first part being that, recommending that the Board accept the data as being useful with respect to the issue of data fraud, since there is no evidence of fraud, that we proceed on the basis that we have a usable database and then ask SC&A and NIOSH, to the extent that they need to provide additional information, to give us an assessment of the impact of the way the fecal sample calculations and corrections are made.

CHAIRMAN MELIUS: Yes.

MEMBER ZIEMER: Something along that line.

CHAIRMAN MELIUS: Yes. I sort of agree with --

MEMBER ZIEMER: And maybe it would be two motions. I don't know.

CHAIRMAN MELIUS: Well, I'm thinking even to sort of step back from motions but think about the way of moving forward.

DR. NETON: Dr. Melius?

CHAIRMAN MELIUS: Yes?

DR. NETON: This is Jim Neton.

CHAIRMAN MELIUS: Yes.

DR. NETON: I would like to just say something first before this goes too far down the path. It seems to me that -- and Sam can correct me if I am wrong, but the fecal samples, as Sam indicated, are really used to estimate a lower bound than what would be predicted by the urine samples. In other words, the fecal samples always have a much better lower limit of detection of an intake than a urine sample.

So it seems to me that if the fecal samples are invalid, then one can always

rely on the urine samples to calculate the intake. At that point it becomes effectively a Site Profile issue, in my mind, not can dose reconstructions be completed.

Fecal samples aren't absolutely necessary to complete dose reconstructions. They're helpful. They're useful to help bound, to count at a lower bound, but they are not in and of themselves a whole new way one can do a dose reconstruction. So I just thought I would offer that.

CHAIRMAN MELIUS: No, I think in theory, I agree with you. I'm not sure that we've presented it to the Work Group and we're all familiar enough with it to sort of reach conclusion on it in this meeting is my concern.

What I was about to suggest was that, rather than ask for an additional report, though that is a possibility, is that we ask that we hold another Work Group meeting, that we ask NIOSH to present in more

detail the method that's used and how these are used, and that we also schedule it at a time when both Arjun and Joyce would be available and that we have a discussion and we try to reach, you know, conclusion then.

So we wouldn't require another report necessarily, I don't think. Now, you tell me if a report would be helpful. But that way it would inform us on it and I think we could reach either closure on this or certainly can determine if further work is necessary.

Paul, does that --

MEMBER ZIEMER: Sure. I'm comfortable with that. I was just wondering if we would want to put the fraud issue behind us as far as the Board is concerned.

CHAIRMAN MELIUS: I just think that my concern about that is that the Board deals with things better if they come with a package, at a single time. And the second issue is so major, it would require further

work on that.

And I think to some extent a part of this issue is so it would bind with this fecal sampling issue that I'm afraid other Board members would have some of the same questions we're having. And we need to be ready to address those at the same time.

MEMBER ZIEMER: That's fine with me.

CHAIRMAN MELIUS: Brad and Phil, is that --

MEMBER SCHOFIELD: I agree with that approach because, like Paul said, I'm still uncomfortable with using that data at this point until it's a little more qualified.

CHAIRMAN MELIUS: Yes. I think then we would all know better how the data is being used and what some of the primers are and some of the, I guess, potential problems with that.

MEMBER CLAWSON: This is Brad again. I agree with you, Jim.

CHAIRMAN MELIUS: Yes.

MEMBER CLAWSON: I think this would be a lot better approach to it, and personally it would make myself feel better and I think the other Board members coming in, too.

CHAIRMAN MELIUS: Good. Okay.

DR. MAKHIJANI: Dr. Melius, could I request one specific thing --

CHAIRMAN MELIUS: Sure.

DR. MAKHIJANI: -- that might kind of smooth the way a little bit? Since the question of MDAs is fairly prominent in our report, maybe as NIOSH prepares their presentation, they might address the MDA and other QA issues that aren't specifically related to fecal sampling but do concern urine sampling as to how they are actually used, what they are actually using in the current dose reconstructions, as you discussed earlier with Sam.

CHAIRMAN MELIUS: Yes. Thanks.

That makes sense. Sam, Jim, do you meet with that?

DR. NETON: Yes. That's fine by me.

CHAIRMAN MELIUS: Yes.

DR. GLOVER: Seems perfectly fine. Many of the Board members haven't heard the Super S stuff. This might be a time for them to.

CHAIRMAN MELIUS: Good. Okay. What I'll do at the Board meeting is just report on our review, you know, discussions, and that we will be having another Work Group meeting and share our recommendation with the Board we hope after that meeting.

Sam or Arjun, do you want to have an update on other Hanford activities?

MR. KATZ: Jim, before we do that, can I just clarification for preparation at least for Denver? So Arjun's presentation and so on, that won't, then, need to be presented at the Board level in Denver. Is that

correct?

CHAIRMAN MELIUS: That is a good question.

MR. KATZ: Well, either way. I mean, I was meaning that as a leading question, actually. I just am uncertain.

CHAIRMAN MELIUS: Well, I was actually thinking it would be helpful to do that.

MR. KATZ: Okay. Okay, good. Then, actually, if other Board members have other questions or whatever --

CHAIRMAN MELIUS: Right. Exactly. That's what I'm also thinking. And then we sort of declare up front that we're not ready to make a recommendation yet, that we have further work with this schedule. We go and Arjun's ready. So --

DR. MAKHIJANI: Is this scheduled for the 18th, Ted? Because I am only going to be there on the 18th.

CHAIRMAN MELIUS: It's on the

18th.

MR. KATZ: Yes, it is. So, Arjun, I don't think you need to make any changes to your presentation. We can just send that out for that, right?

DR. MAKHIJANI: Okay. No, no changes are needed.

CHAIRMAN MELIUS: Eleven a.m. on the 18th.

DR. MAKHIJANI: Yes. I'll be there. I'm coming on the 17th.

CHAIRMAN MELIUS: Okay.

MR. KATZ: Okay. Thank you.

CHAIRMAN MELIUS: Good.

DR. GLOVER: I wanted to just be absolutely confirmatory. NIOSH will develop a presentation for the future Work Group meeting.

CHAIRMAN MELIUS: Right.

DR. GLOVER: We will not try to develop a presentation between now and next week?

CHAIRMAN MELIUS: Yes.

DR. GLOVER: Very good.

CHAIRMAN MELIUS: Yes. Good. Sam or Arjun, do you have updates on other Hanford-related activities that you can share with us or want to share with us?

DR. MAKHIJANI: Sure, I can give you an update. I think that ball is in SC&A's court after NIOSH presented the last Evaluation Report to you. So you asked us to investigate the remaining outstanding period, 1984 to 1990, for the Hanford SEC 57-2. And we are doing that. You know, Hanford is such a complicated site. So, unfortunately, it is taking a fair amount of digging.

We have scheduled with NIOSH a cooperative sort of data capture visit. I prepared a memorandum for Joe Fitzgerald and Bob Bistline, who are going out there on SC&A's behalf. So there are some very specific requests.

Just to give you a little

vignette, you know, there were highly enriched uranium inventories into the 1990s, just to make sure that, were they handled, were they repackaged. And there are uranium data that can be used, but to try to see whether the workers who handled the highly enriched uranium were the ones who were monitored appropriately. So we're kind of really trying to get down into the fine print.

And there will be at least one data capture visit. It is scheduled for September 30th. In the meantime, I am working in parallel to review the available documentation and prepare, you know, initial notes for a report.

But I think it is going to be February before you see a report. I hope to give you a report that can be presented at the February Board meeting, but I am not sure that I will be able to do that because I don't know when the documentation we requested will be available. The first visit is September 30th.

Sam might want to amplify. We have been corresponding a little bit about these data capture visits.

DR. GLOVER: Very briefly. Arjun has some very specific things that he has listed. We, as you know, Bob Bistline and SC&A have participated in this. But we went through an extensive data capture.

And so some of this is to make sure that Joe Fitzgerald and Bob are fully aware of what we have already put hands on, where that is, and make sure that we use the data that we have already touched because some of that certainly had an extensive classified review.

So they will come to grips with that and then determine what else they need to pull. And then they will be working with Gail Splett to resolve budgetary issues so that they can get this done in a timely fashion.

DR. MAKHIJANI: Yes. Just to complement what Sam just said, you know, it is

important for us to have unclassified notes from these classified reviews so we can actually put them in reports that then petitioners can see and the Board can discuss and evaluate. So part of the effort here is to go for this classified review but also to make a set of notes that can go through the declassification review process and be made available for a public report.

DR. BISTLINE: This is Bob Bistline. Just for clarification, that session at Hanford is going to be on the week of the 24th, Arjun.

DR. MAKHIJANI: Oh, I see. I wasn't aware that the dates had been shifted. Thank you.

CHAIRMAN MELIUS: Any Work Group Members have questions for Sam or Arjun on that?

(No response.)

CHAIRMAN MELIUS: If not, then I don't believe we have any more Work Group

business for today. And I believe we can adjourn. Ted, do you have any final words?

MR. KATZ: No final words. In fact, I look forward to seeing all of you out in Denver.

CHAIRMAN MELIUS: Denver next week. That's right. Thanks, everybody.

(Whereupon, the above-entitled matter was concluded at 2:08 p.m.)