THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

CENTERS FOR DISEASE CONTROL AND PREVENTION

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

MEETING BETWEEN REPRESENTATIVES OF NIOSH AND SC&A

JANUARY 12 AND 13, 2005

The verbatim transcript of the above-mentioned meeting held at SC&A, McLean, VA, on January 12, 13, 2005.

CONTENTS

TRANSCRIPT LEGEND

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PARTICIPANTS

ABRWH:

MIKE GIBSON

MARK GRIFFON

WANDA MUNN

NIOSH:

STUART HINNEFELD

TOM TOMES

SC&A:

HANS BEHLING

KATHY BEHLING

JOE FITZGERALD

P R O C E E D I N G S

(11:35 a.m.)

THE COURT REPORTER: Dr. Behling, is everybody connected now?

DR. H. BEHLING: We're still waiting on Wanda Munn and we had a problem with her because she's calling out of Canada and she couldn't (unintelligible) on the line that we had reserved for conference call, so she had to call and that may very well have been the problem that we faced early on when you had all the static. We don't know.

THE OPERATOR: Pardon me, Wanda Munn joins.

DR. H. BEHLING: Okay. Wanda, are you on?

MS. MUNN: I am.

DR. H. BEHLING: Okay, we're all here.

MS. MUNN: Are we static-free?

DR. H. BEHLING: Yes.

MS. MUNN: How wonderful.

DR. H. BEHLING: It's great.

THE COURT REPORTER: Dr. Behling --

DR. H. BEHLING: Although we're a little -- I guess we're running a little late here, but let's perhaps then -- then briefly identify the participants. And I guess for speed, let me

just give you all the names for the benefit of the transcriptor. For NIOSH we have Stuart Hinnefeld and Tom Tomes -- is that right, how --

MR. TOMES: Tomes.

DR. H. BEHLING: Tomes?

MR. TOMES: Uh-huh.

DR. H. BEHLING: Tomes, okay. I'm sorry, Tom Tomes.

THE COURT REPORTER: I'm sorry, what was that last name?

MR. TOMES: Tomes, spelled T-o-m-e-s.

THE COURT REPORTER: Thank you.

DR. H. BEHLING: From the Advisory Board we have Mark Griffon, Mike Gibson and Wanda Munn on the telephone.

THE COURT REPORTER: And do we not have Rich Espinosa?

DR. H. BEHLING: No, we do not.

THE COURT REPORTER: Okay.

DR. H. BEHLING: And from S. Cohen & Associates is my -- myself, Hans Behling; Kathy Behling, and Joe Fitzgerald.

THE COURT REPORTER: All right.

DR. H. BEHLING: Okay.

THE COURT REPORTER: Dr. Behling --
DR. H. BEHLING: Behling, B-e-h-l-i-n-g.
THE COURT REPORTER: Right. This is Ray, the court reporter, can I just say one thing before you get started, please?
DR. H. BEHLING: Sure.
THE COURT REPORTER: I just wanted to tell everybody, I think I know everyone's voices pretty well, but if we could just start with the format that if I say "Please I.D.", that means I'm not sure who's speaking.
DR. H. BEHLING: We've already discussed that and we have made an agreement amongst us that any person who speaks will first identify himself by name to you.
THE COURT REPORTER: Okay, great. Thank you.
DR. H. BEHLING: Okay. Well, let me just briefly go over a few things that I think is really more for your benefit, Ray, than anybody else's.
THE COURT REPORTER: All right.
DR. H. BEHLING: These will be in the opening remarks that we had initially scheduled for 10:00 o'clock but is obviously a little late now. We lost an hour and a half. So let me

just briefly go through a number of things that perhaps are important to people who may read your transcription later on, and they basically go to an understanding of why we're here today. And let me start out by saying that under task four S. Cohen & Associates is to assist the Advisory Board in the review of about 2.5 percent of all dose reconstructions completed by NIOSH and provide the Board with a final report of its findings for each of the set of cases that have been given to us. Currently we are reviewing case number one through 20, and -- and those are the cases that we'll be discussing here today.

The first 20 cases that we were given to review fall under the category of basic review, and there are guidelines that define what a basic review must look at. Among the cases that we have looked at for the 20 basic reviews are five Atomic Worker Employer facility cases and 15 DOE facility cases. And let me give you just a brief background.

SC&A completed a preliminary review of the 20 cases and -- on November 9 and 10. At that time we had met at McLean right here in this

office for a preliminary review of those cases, and at that point -- let me just briefly try to under-- well, I won't go through the number of specific people we had. All -- all I will say is in attendance were the -- at the meeting that was taking place on November 9 and 10, in attendance were all the SC&A auditors who had themselves participated in the review of those individual dose reconstructions. There were also SC&A members representing task one and task three. And of course task one involves the review of site profiles and task three involves the review of NIOSH procedures and ORAU procedures. Also at that meeting were representatives of NIOSH that included Jim Neton and Stuart Hinnefeld.

During that particular meeting -- again, I'm referring to the November 9 and 10 meeting with SC&A -- we essentially discussed every one of those 20 cases amongst ourselves, but also in -- - in -- in discussing this, we did this with the attendance of -- not attendance, but awareness of the Advisory Board members. For each case there were two Advisory Board members who were monitoring this discussion via the

telephone conference line.
Following the November 9 and 10 meeting in McLean, SC&A within a few days forwarded a draft report of our evaluation by mail to each of the Board members. That involved the week of November 15th that we forwarded by mail a hard copy of SC&A's review of the 20 cases. And along with the forwarding of that report, SC&A requested that each member of the Board review the cases that he was to monitor and provide SC&A with any comments that they may have and return those comments to us.
Following the receipt of the draft reports, the Board requested that SC&A give an oral presentation to the Board via a closed session during a scheduled Advisory Board meeting that was held in Livermore, California on December 13, 14 and 15. At that time SC&A was prepared to give a overview of those 20 cases, but unfortunately the closed session that was scheduled wouldn't really allow us to discuss each individual case as we had hoped, and as a result we were only able to present about three or four select cases during that closed session meeting.

The Board at that time was also informed that NIOSH, who had also received a copy of the original preliminary draft report, had a number of issues and concerns regarding SC&A's report. And in response to concerns raised by NIOSH, the Board concluded that on I believe December 14th, the second day of the Livermore meeting, that these issues and concerns that NIOSH raised with respect to our draft report would be best resolved in a face-to-face meeting between technical persons representing SC&A and NIOSH, and that that meeting should be monitored by a working group representing the Advisory Board. And of course we have today two in attendance and Wanda Munn on the telephone conference. So we have three Board members monitoring and they represent this working group that was appointed at the time of the Livermore meeting.

The preliminary issues of concern raised originally by NIOSH at the time of the Advisory Board meeting in Livermore, California in December, however, has been amended. And SC&A received a final list of specific issues from NIOSH at 3:50 p.m. this past Friday, January

7th, 2005. So we've had a couple of days to look at the amended list of issues that NIOSH has raised. And as I said, we received that late on Friday afternoon.

What we plan to do today here is to -- to -- just to give you an overview. It's not a very formal presentation, but hopefully at least we will try to follow through a specific format which will involve going over each and every one of the cases that have been identified as having issues of concern.

And we will give NIOSH -- and it's likely that Stu or Tom will introduce the issues that they feel have to be resolved at this meeting, or should be addressed in this meeting. And for each of the issues that will be introduced by NIOSH, I will also follow it up as to perhaps why we agree with that issue now or perhaps why we will not agree. So the format will be that NIOSH will introduce, on behalf of each of the cases, the issue in sequence as they appear in the handout, and then allow me a chance to address what potential issues I can either agree with or disagree with in behalf of each issue.

And there'll be an attempt to perhaps resolve some of these issues, if we can, on the spot. We need to -- if we -- if one or the other side agrees that perhaps this issue can be resolved, we will at this point in time try to make that resolution and (unintelligible) about it as a -- an issue that has been resolved, or it may not be resolved.

I do want to caution everybody because -- especially -- we already had a full plate to begin with, but we've got obviously an hour and a half delay here, but we do want to stick as close as we can to the timetable question because there are an awful lot of issues and many of these issues are quite complex and, if allowed, would potentially delay the completion or fail to complete all the issues that we hope to at least address as best as we can in the next day or so.

With that, I'll turn it over to Stu if he has any specific issues or statements to make at this point. Stu?

MR. HINNEFELD: I'll just comment that NIOSH appreciates the opportunity to participate in meetings like this and we envision future

meetings like this, and we're confident that we'll have a product that we can both either agree to or, on occasion, we will politely agree to disagree on some items for the Board's further discussion.

MS. K. BEHLING: Okay. This is Kathy Behling, and I'm representing at this meeting John Mauro, who is unable to attend. And John Mauro was the reviewer for the five AWE cases from the 20 initial cases that SC&A received. However, today we will talk about only two of those cases because three represent the Bethlehem Steel (unintelligible), and as you know, SC&A is currently -- has currently submitted their report on the Bethlehem Steel site profile. And since all of the issues or many of the issues that were discussed under the three claims of Bethlehem Steel cases are tied to that site profile, and we will not discuss those today since SC&A and NIOSH are separately discussing those issues.

So if Stu -- if Stuart is in agreement with this, I thought -- I made a summary slide of the first case, and I thought I would just briefly discuss the issues -- just a brief

overview of what this case entails and then I'll let Stuart talk about the issues and we can respond.

MR. HINNEFELD: Sure.

PRESENTATION/DISCUSSION OF ISSUES FOR CASE #1

MS. K. BEHLING: Okay, case #1 is Blockson -- is from the Blockson facility and a claimant worked from the period of to . He was a : and . He had prostate cancer and worked at various locations throughout the plant. And so at this point I'll let Stu bring up our -- our issues of concern.

MR. HINNEFELD: Okay. I think following through the handout on case #1, the first categorized issue describes a critique of airborne calculation techniques that weren't actually utilized in the Technical Basis Document anyway, but they were essentially included for demonstration of reasonableness. And whether they're convincing or unconvincing I think really doesn't matter because they weren't utilized in the Technical Basis Document. So I would propose we move on to the second -- what we've enumerated as the second

issue, which relates to the actual method by which the internal exposure was estimated or reconstructed at Blockson.

Our belief is that the approach that was used to estimate intake at Blockson is -- is appropriate, and if it errs, it errs on -- in the favor of the claimant. I want to make sure that everybody understands clearly the process that we use to estimate intake and intake rates for Blockson.

There were -- there were some 20-odd personnel at Blockson that we have records of bioassay results for. The dates of these bioassay data go from 1954 to 1958. These people -- it's about 25 people. Almost all of them have multiple samples. There are some -- one or two who only have one sample, but the bulk of them have multiple samples. And it's our conclusion from this that Blockson, for at least a period of time, conducted a bioassay monitoring program for the personnel involved in the uranium separation process at Blockson. So we believe this -- this population of people is representative of the highly-exposed population at Blockson, and they were working directly

with the uranium separation operation.
As I said, most of these people have multiple bioassay points over this four-year period. In order to determine an estimate or to develop a model for intake at Blockson, we took each individual's data and fit that, using IMBA, to an intake rate, after first ignoring any zeroes. Many of these bioassay results were recorded as zero, which we would interpret to be less than some minimum detectable level, but we didn't include those in the IMBA fit at all. So any sample that was below detection, we didn't even worry about. We only worried about the detectable samples. So from the start we are estimating an intake -- our -- our calculation will estimate an intake that is higher than what the actual data presented to us would have supported, had we included those less than -- less than detectable numbers.
We fit this data and presumed that the employee was chronically exposed from either the start of the work at Blockson, the AEC work, or from the person's first day of employment, whichever date would have been (unintelligible). So the appropriate -- whichever the appropriate date

is. And we plotted the datapoint on the particular database -- or did a chronic intake and then presumed that that chronic intake rate continued onward past 1958 till the termination of the uranium recovery operation, which I believe was in 1962.

So based on those bioassay -- using the bioassay data and the manner in which we used it to fit those excretion patterns, we feel like we have a good representation of the -- of the intake rates that were experienced by the exposed population of Blockson. And so that's why we feel that the -- the internal exposure avenue that we -- or method that we chose appropriately and favorably estimates the intake rate for the people involved in the work.

We can also, if we want to, get into an ingestion comment which the author has also commented about potential for ingestion pathway, which is issue number four on case #1. The ingestion pathway would be integrated in the bioassay that was used to generate the intake. So if in fact -- you know, our -- our model presumes that all of that daily ingestion

calculated from the bioassay is an inhalation exposure. We do, I think, account for some modest ingestion in a bit different fashion, which essentially occurs independently of the bioassay data. And the comment from the SC&A reviewer was that our estimate of ingestion may have been too small. And our response -- or our view is that since we utilized bioassay data to model the intake, we accounted for any intake, whether it had been through ingestion or through inhalation. All of those would have contributed to the bioassay results. And by apportioning it 100 percent to an inhalation exposure we have arrived at a higher dose for virtually all organs --

UNIDENTIFIED: Yeah.

MR. HINNEFELD: -- that if we had apportioned it partially inhalation and partially ingestion. So that's why we feel like our ingestion -- the internal exposure model at Blockson Chemical is appropriate for the data we have.

I guess there's one more relevant comment or --

DR. H. BEHLING: I was hoping to take issues one at a time --

MR. HINNEFELD: Okay.

DR. H. BEHLING: -- so that we can address -- it's going to be more confusing --

MR. HINNEFELD: Right.

DR. H. BEHLING: We have issues for each case and (unintelligible) each other.

MR. HINNEFELD: Okay. Well, you're right.

DR. H. BEHLING: I don't care to get --

MR. HINNEFELD: Well, let's go back -- let's go back to issue two, then --

MS. K. BEHLING: Okay, let me --

MR. HINNEFELD: Let's go back to issue two, then, about the actual calculation of the intake rates.

MS. K. BEHLING: Okay, fine. If I may also just give one comment regarding issue one, and the reviewer and SC&A feels that although the -- - that they did not use as -- the dust (unintelligible) data is not actually used for the inhalation and for the calculation for the internal, it's just the approach which was used which assumed that the dust loading was proportional to the uranium (unintelligible), SC&A still feels that's not very (unintelligible) and maybe it would be best if

that wasn't even included in the TBD because it's not (unintelligible).

With regard to the second issue, which is the critical (unintelligible) group, (unintelligible) answers the question. Now we do -- we do have -- we took the definition of what the critical (unintelligible) concept of the ICRP publications of 26 and 43 --

THE COURT REPORTER: Excuse me, this is the reporter.

MS. K. BEHLING: Yes?

THE COURT REPORTER: I'm having just a little trouble hearing you, Dr. Behling.

MS. K. BEHLING: Okay, I'll speak up.

THE COURT REPORTER: That's great right there.

MS. K. BEHLING: All right.

THE COURT REPORTER: Thank you.

MS. K. BEHLING: To repeat, we looked at the definition of the critical group and the critical population group from ICRP, and that definition looks at the size of the group and it -- specifically be small in number and how homogenous that group is with regard to the highest and lowest doses. And I believe that Stuart just said something that may have

clarified some of the questions that we did have on the critical group population. We were under the impression that zero doses were used in -- in your assessment for the range of people, and you're telling me that's not the case.

MR. HINNEFELD: Well, none of -- none of the monitored personnel were assumed to have a zero intake. And the -- all of the zero -- individual zero bioassay results were disregarded in the fitting calculation in order to determine the intake that corresponds to those -- to the bioassay data. So we disregarded zero results in that point and so, you know, from the purely scientific standpoint, we overestimated the intake for anyone who had a zero result, as well, so that zero result would have pulled down the estimated intake had we included it in the fit.

DR. H. BEHLING: Yeah, also -- this is Hans Behling. I guess issue one really centers around more the people who were monitored in behalf of this particular group of exposed people, and Stuart had mentioned they tried to focus on the people that they thought might

have been the maximally exposed individual group of workers, mainly the critical group. And yet if you look at the definition of critical group, you realize that it is the upper end portion of an exposed population. And the ICRP definition really states that this group of people should represent the top ten percent. And in fact, one of the definition is that -- for modeling purposes, that the range of values between the lowest member of the critical group and the highest member of the critical group should not be more -- by a factor of ten. In other words, if you take the critical group and divide it and say where's my median value, the lower end and the upper end should not be more than a factor of about three different from the median. And when we looked at the data and we realized that the actual -- medians were average values, that was the finding, on behalf of this group was 24 and the upper was 240, then we realized that that didn't in itself fit the definition of a critical group, meaning that we were perhaps not dealing with bioassay data that defined a critical group, but more that the whole

population of exposed workers, which would then therefore dilute the intakes that we are estimating our -- our -- our doses on. So it's a question of defining who the critical group is. I'm not sure we can at this point. But the fact that we -- among the bioassay data that was observed included a large number of zero values raises the question as to whether or not the bioassay data, in itself, do in fact represent a maximal or upper end group of individuals defined by ICRP as a critical group. And I think this is where the issue is, do we have bioassay data that defines the critical group; and if not, are we underestimating the potential exposures that define the high end worker.

MR. HINNEFELD: This is Stu Hinnefeld again. The difference between 24 and 240, that factor of ten, that is the difference between the median bioassay datapoint and the maximum bioassay datapoint, not the difference between the lowest intake rate and the highest intake rate, which would be the analog to the exposure. And in fact, the Blockson Chemical model is a lognormal distribution -- it calls

for a lognormal distribution of intake with a standard deviation somewhat less than two, I think. So if you do the math, we're probably well within that. But also within the factor of ten in terms of the actual intake -- not the individual bioassay numbers but the intake numbers, which was what we used to generate the model, and -- (unintelligible) and then the second point I wanted to make was the use of the term "critical group" and a definition (unintelligible) of the critical group. I'd have to go look and see the use of it in that ICRP documentation to make sure I really understand what -- what the point of the critical group there is.

What we in-- what we feel like we have is the monitoring data for the exposed people, people in the uranium purification part of this (unintelligible). If we have built a distribution based on the monitored population, the exposed population, we feel like use of the distribution is appropriate. Not like -- we didn't take a monitoring distribution for the entire team of Blockson Chemical work force. We don't think we have that. We think we have

the exposed people and their -- and their exposure and the distribution of their exposure.

And again, comparing the 24 median to the 240 maximum I don't think is a -- is the correct comparison because that individual bioassay datapoint not intake value, which is what we developed based on all the bioassay points for (unintelligible).

MR. GRIFFON: This is Mark Griffon. I'm just cur-- I mean looking at this issue, I'm just wondering (unintelligible) back to the air sampling if there's any other way that you attempted to validate whether these 20 people were -- were the -- you know, a represent-- representative -- more so than using the term "critical group", were they representative of the --

MR. HINNEFELD: We've not found --

MR. GRIFFON: -- the highest exposures or --

MR. HINNEFELD: We've not found a roster for building 55. We've not found a roster of the people who worked there, so --

MR. GRIFFON: Did you make any attempt -- aside from the dust loading question, did you make

any attempt to calculate intakes based on the air monitoring data and compare them to intakes you calculated from the urine data?

MR. HINNEFELD: I don't think we have any air monitoring data at Blockson.

MR. GRIFFON: Oh, you don't have any. Okay. I saw something about dust loading, but that's -- that wasn't --

MR. HINNEFELD: There was some -- there were some calculation manipulations that really I'm not prepared to defend. They're manipulations that --

MR. GRIFFON: They don't have any --

MR. HINNEFELD: -- (unintelligible) to discuss it, but we don't -- I don't believe have any air sampling data.

MR. GRIFFON: But what's hanging out there is the assumption that the people who were monitored are the representative group of -- of exposed workers.

MR. HINNEFELD: I guess that would be the -- that would be the key question, and then -- because that essentially is our -- drives the (unintelligible) distribution in its entirety represent the intake rate for the people.

MR. GRIFFON: If all those zero urine -- I mean if all those zeroes were dropped, does that approach more closely your definition of a critical group? That's the other question that was running through my mind.

DR. H. BEHLING: Hans Behling. Perhaps one way to resolve this issue is not to -- and I concur with your statement that we shouldn't compare one urine sample against another, but perhaps the 20 people who were monitored, so that if person number one had five urinalyses done, take the average of -- do the same thing that -- two, three, four, five, then look at the distribution and see how far or if the lowest end -- apart from the median and the high end, and that would perhaps agree with the context of the critical group if in fact you're now closing the gap between the extreme individual samples.

MR. HINNEFELD: But I suspect it would because the person who had the highest sample also had mul-- several other samples --

DR. H. BEHLING: (Unintelligible)

MR. HINNEFELD: -- (unintelligible) his sample would have to be lower.

DR. H. BEHLING: Yes.

MR. HINNEFELD: So I suspect it would, although we felt like we had done essentially the analog of that approach by (unintelligible) all those datapoints to an intake rate. I mean it's sort of an analogous approach, whether you average the bioassay or whether you (unintelligible) intake rates. The arithmetic's different, but analogous. If you essentially determine a person's experience, one person's experience, how does it compare to everyone else's experience.

DR. H. BEHLING: I think in order to -- this is Hans Behling. In order to resolve this, maybe we can come to a quick agreement if we look at the original data, identify the 20 individuals who were monitored, get an average of each of those individual urinalyses for each person and then see how that appears in terms of distribution. And if the numbers come -- start to get bunched a lot closer, the idea of a critical group and an upper end worker group that was monitored that will satisfy this issue.

MR. HINNEFELD: Well, we can certainly do that.