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PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes

WORKING GROUP

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

PROCEDURES REVIEW

The verbatim transcript of the Working Group
Meeting of the Advisory Board on Radiation and
Worker Health held telephonically, on April 2, 2008.

STEVEN RAY GREEN AND ASSOCIATES
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April 2, 2008

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TRANSCRIPT LEGEND

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-- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

-- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

-- "^" denotes telephonic interruption.

P A R T I C I P A N T S

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P R O C E E D I N G S

APRIL 2, 2008

(1:00 p.m.)

OPENING REMARKS

DR. BRANCHE: I'm Dr. Christine Branche, and I have the pleasure of being the Designated Federal Official, as well as the Principal Associate Director of NIOSH. I'm the Designated Federal Official for the Advisory Board on Radiation and Worker Health. And this is a meeting of the Procedures Working Group.

If the Advisory Board members could please announce their names, please.

MS. MUNN: This is Wanda Munn. I'll chair this meeting.

DR. ZIEMER: Paul Ziemer.

DR. BRANCHE: Are there any other Board members?

(no response)

DR. BRANCHE: Well, so far we don't have a quorum of the Board so we can continue. Would the NIOSH staff please identify themselves?

MR. ELLIOTT: This is Larry Elliott, Director of OCAS, NIOSH.

1 **DR. NETON:** Jim Neton from NIOSH.

2 **MS. ^:** ^ from NIOSH.

3 **MR. HINNEFELD:** Stu Hinnefeld from NIOSH.

4 **DR. ULSH:** Brant Ulsh from NIOSH.

5 **DR. BRANCHE:** Will the ORAU staff please
6 announce their names?

7 **MR. SIEBERT:** Scott Siebert, ORAU team.

8 **MS. THOMAS:** Elyse Thomas, ORAU team.

9 **DR. BRANCHE:** Would the SC&A staff please
10 announce their names?

11 **DR. BEHLING:** Hans Behling, SC&A.

12 **DR. MAURO:** John Mauro, SC&A.

13 **MR. MARSCHKE:** Steve Marschke, SC&A.

14 **DR. BRANCHE:** Would other federal agency
15 staff please announce their names?

16 **MS. HOWELL:** This is Emily Howell with HHS.

17 **DR. BRANCHE:** If there are any petitioners
18 or their representatives, would you please
19 mention your names?

20 (no response)

21 **DR. BRANCHE:** Any workers or their
22 representatives please?

23 (no response)

24 **DR. BRANCHE:** Any members of Congress or
25 their representatives please?

1 (no response)

2 **DR. BRANCHE:** Are there any others on the
3 line who would like to mention their names?

4 (no response)

5 **DR. BRANCHE:** If we could please acknowledge
6 telephone etiquette. We are all participating
7 by telephone so if you would please mute your
8 lines while our discussion goes on so that the
9 speaker can be heard by all parties especially
10 our court reporter. And when you're ready to
11 speak you can unmute your line. If you do not
12 have a mute button, then please use star six
13 to mute the line. And then when you're ready
14 to speak you can use star six again.

15 One more time for Mark Griffon?

16 (no response)

17 **DR. BRANCHE:** Michael Gibson?

18 (no response)

19 **DR. BRANCHE:** Robert Presley?

20 (no response)

21 **DR. BRANCHE:** Okay, Ms. Munn, it's all
22 yours.

23 **INTRODUCTION BY CHAIR**

24 **MS. MUNN:** Thank you. With the concurrence
25 of those of us who are online, I'd like to

1 propose one mild addition. I think it's not a
2 mild one; it's a big one. When I sent you a
3 reminder yesterday, I reminded you about the
4 primary document that we want to attack which
5 is SC&A's review of our procedures and
6 methods, PER number nine.

7 I also mentioned a quick run down of
8 the action list, whether we need to do
9 anything between now and next week. One item
10 I failed to put on, and that I do want us to
11 touch upon, I'd like that to be the second
12 item today, is the draft that Steve Marschke
13 has provided us of the overview of the summary
14 results of the first set of those 33 procedure
15 reviews.

16 We've seen that material before in a
17 slightly different format, and it does not
18 appear to me that there will be a very large
19 amount of discussion here other than I have a
20 number of comments to make with regard to
21 format and have not gotten those to either
22 Steve or to Paul. So I'd like to discuss that
23 after we've attacked PER-9 if that's agreeable
24 with everyone here. Am I taking us too far
25 afield from our primary objective or is that

1 okay?

2 **DR. ZIEMER:** Let's give it a try.

3 **MS. MUNN:** Very good.

4 **DR. ZIEMER:** That's Ziemer speaking.

5 **MS. MUNN:** Thank you, sir.

6 **DR. BRANCHE:** Ms. Munn, this is Christine.

7 Just one more item. I just want to let you
8 know that off line I am trying to get in touch
9 with the remaining Advisory Board members.

10 **MS. MUNN:** Excellent, appreciate that.

11 Thank you.

12 **PER-9**

13 Let's take a look at what Hans has
14 prepared for us as their review for PER-9.
15 This is a very heavily technical document
16 which requires a significant amount of
17 attention I think for more reasons than one.
18 I'm sure that NIOSH has had an opportunity to
19 take a look at this now.

20 And if it is amenable with you, Larry
21 and Jim, I'd very much like to get some
22 reaction from you before we begin our full-
23 scale discussion on the contents of this
24 document. I do hope that all of us have had
25 adequate time to absorb what's here because

1 it's going to impact quite obviously a number
2 of dose reconstructions.

3 Larry or Jim, do you have some
4 comments that you'd like to make before we go
5 further?

6 **MR. ELLIOTT:** Ms. Munn, this is Larry
7 Elliott. I'm going to start off here and turn
8 it over to Brant Ulsh who is going to carry
9 most of our water on comments regarding this
10 review. What I'd like to start with though is
11 that I want to set the record straight, the
12 history here a little bit straight.

13 I'm a little bit concerned that this
14 review that has been developed by SC&A
15 portrays or presents the issue of this change
16 and how we go about assigning a target organ
17 for lymphoma as being driven or initiated by a
18 prior SC&A dose reconstruction report review.

19 And that is, you know, I do appreciate
20 all the hard work and all the effort that SC&A
21 puts into their reviews, but the reality and
22 the facts are that we were well aware of how
23 we were handling lymphomas and other things
24 like this. And that started actually with a
25 NIOSH-sponsored meeting on CLL probably -- I

1 don't have the timeframe completely down in my
2 mind. But, okay, well, I do now.

3 **MS. MUNN:** It was a number of years ago.

4 **MR. ELLIOTT:** July 21st, 2004, there was a
5 meeting in D.C. on CLL, and that's where the
6 OCAS scientific staff started thinking about
7 are we assigning the correct organs for
8 lymphoma dose reconstructions. And so that's
9 where we started picking up this line of
10 inquiry. And certainly the review of the dose
11 reconstruction case confirmed our efforts and
12 reinforced our efforts to try to do a better
13 job for lymphoma claimants. But I just want
14 to take a little bit of exception here that it
15 was not SC&A's review that started us down
16 this scientific trail of making sure that
17 we're giving full advantage in our dose
18 reconstruction on lymphoma claims.

19 **MS. MUNN:** It's a point well taken. I
20 notice there was a reference very late in the
21 report about that early concern over CLL and
22 the meeting that was held. But --

23 **MR. ELLIOTT:** I don't mean any disrespect,
24 Hans, to you or to SC&A. But I just want to
25 make sure that we're all clear in our

1 understanding of how this all started off.

2 **DR. BEHLING:** And let me just point out if
3 there was any prior discussion, this was
4 something that we were not aware of --

5 **MR. ELLIOTT:** That's absolutely correct.

6 **DR. BEHLING:** -- at the time when we
7 reviewed the first set of cases, and one of
8 which was a Hodgkin's lymphoma, this was
9 something we weren't aware of. And as I
10 showed in my Exhibit 1 on page ten of the
11 report, I guess in 2005 the Board action
12 number three says SC&A for that particular
13 case stood fast on the issue of not
14 necessarily making a change to that.

15 **DR. NETON:** I think, Hans, by our current
16 methodology we probably would do that case the
17 same way because that's a Hodgkin's lymphoma.

18 **DR. BEHLING:** Well, it was among the 528
19 cases that was subject for review.

20 **DR. NETON:** That's what I'm saying. In that
21 particular response I think our response would
22 stay the same, that the Hodgkin's lymphoma
23 would be defined by the site of diagnosis for
24 our physician's examination of the facts.
25 It's not inconsistent with what we responded

1 there. But it's true. We did not go into any
2 length at the time to talk about our
3 activities behind the scenes --

4 **MR. ELLIOTT:** We were pre-decisional at that
5 time. We were doing our own research into
6 this. Doing our own scientific fact-finding
7 and trying to arrive at our position. And
8 you're correct, Hans. We had not shared that
9 on the outside, and so you were unaware of
10 that, and I appreciate that. I just want to
11 make it clear to folks on this phone call that
12 we were working this problem back in, late in
13 2004.

14 **MS. MUNN:** And I do remember the
15 discussions, some of the discussions that took
16 place. I'm not sure I was present at all of
17 them, but I recall that having been an issue
18 that we were well aware of on the Board.
19 Perhaps this can be resolved by the simple
20 insertion of a sentence somewhere in the
21 Executive Summary or near the beginning of the
22 report to indicate that all of the parties
23 involved had been concerned about this for a
24 significant period of time, and that although
25 SC&A had not been directed to do so and was

1 not aware of the information, NIOSH was
2 working on it.

3 **MR. ELLIOTT:** I think that's up to SC&A and
4 how they want to treat the report in that
5 regard. Let's put that aside now. I think
6 Brant and Jim have several other comments that
7 are more pertinent perhaps to our deliberation
8 and discussion today and moving us forward.
9 If we could return to that, I think that would
10 be beneficial for all.

11 **MS. MUNN:** The technical issues appear to be
12 the tough ones here, and I'm assuming that's
13 going to be Brant's bucket.

14 **DR. ULSH:** Yes, it will, Wanda. If it's the
15 Board's pleasure, I'll start going into the
16 technical issues here. First of all, let me
17 acknowledge that I am not a hematologist. I
18 don't think anyone on the call is. And for
19 that reason once those concerns were expressed
20 to NIOSH, and we started looking into this
21 issue, I did some preliminary research. And
22 it quickly became clear that we would need
23 some hematology expertise. And so we
24 contracted with Dr. Mark Crowther at McMaster
25 University.

1 Dr. Crowther's a very well qualified
2 hematologist. He has Board certification, a
3 master's degree in clinical epidemiology as
4 well as an M.D. in hematology. And we engaged
5 Dr. Crowther as a contractor to review our
6 selection of target organs for lymphoma and
7 for leukemia.

8 And we had several conversations with
9 Dr. Crowther throughout 2004, and it
10 culminated in his report which Hans has
11 attached as an attachment to the SC&A report.
12 At one point I sat down on a phone call with
13 Dr. Crowther and asked him to give me kind of
14 an educated layman's view of this whole issue.
15 And that might be helpful if I relate that to
16 you all.

17 Basically what we're talking about
18 when we're talking about lymphoma, or there's
19 a couple of broad categorizations. Mainly, if
20 you think of the lymphatic system as a system
21 of, well, a plumbing system, pipes that run
22 throughout the body.

23 And lymphomas can be broadly
24 categorized into two different types. One is
25 cancers, solid tumors, of the plumbing system

1 itself, the pipes, the cells that make up the
2 lymphatic system. And those are one category.
3 The other category is cancers that occur in
4 the lymphatic system as a result of what flows
5 through the pipes. Now we're talking about
6 circulating lymphocytes. They get trapped out
7 in particular lymph nodes and develop tumors
8 where they are trapped out.

9 Now as Jim mentioned earlier in the
10 discussion of the case that Hans cited,
11 Hodgkin's disease falls into the category of
12 cells or cancers where the cancer occurs in
13 the pipes, in the material that makes up the
14 piping system itself. And so on that basis
15 Hodgkin's disease and a couple of other types
16 of lymphomas, well, there's a couple of other,
17 yeah, lymphosarcoma, for instance, and a
18 couple of others.

19 Those can be, it can be inferred from
20 those that the site of original radiation
21 injury is the site where you see the tumor.
22 So, for instance, there is a mass of lymph
23 nodes in the groin area, and if you see a
24 tumor in the groin area, lymph nodes in the
25 groin area, you can assume that that's where

1 the radiation interacted with the cells to
2 later become a cancer.

3 Now contrast that with the other type
4 of lymphomas, and these are primarily non-
5 Hodgkin's lymphomas. These are cancers of the
6 material that flows through the pipes. And so
7 they're circulating all through the body, and
8 the radiation interaction could have occurred
9 anywhere in the body. And they get trapped
10 out in a particular lymph node. Now for those
11 the site where you find the tumor is not
12 informative about where the original radiation
13 injury occurred.

14 And so for those cases we decided,
15 with the advice of Dr. Crowther, to consider a
16 claimant favorable estimate. What could be
17 the highest plausible location that we could
18 give? And we had originally, I originally --
19 because I wrote the first TIB -- went with
20 LNET, the lymph nodes at the extrathoracic
21 region.

22 Now I want to make it clear that these
23 distinctions are internal dosimetry. They're
24 health physics distinctions. They're not
25 based on hematology. So when Dr. Crowther

1 reviewed the first version of the TIB, he
2 said, yes, this was, our report basically
3 reflected our discussion about these two
4 different types of lymphomas.

5 Subsequently, to get an expert health
6 physics review, we submitted our report to
7 Keith Eckerman, who is a very well known
8 internal dosimetrist. And Dr. Eckerman
9 suggested that we consider the thoracic lymph
10 nodes instead of the extrathoracic because
11 they gave a higher dose. And so we made those
12 changes. But that was not in contradiction to
13 the advice that Dr. Crowther gave us. Rather,
14 it was from a different perspective, a health
15 physics perspective.

16 But the bottom line is this report as
17 it exists now has been vetted by, well, I
18 would say one of the world's foremost experts
19 in hematology and also one of the world's
20 foremost experts in internal dosimetry. And
21 both of them have agreed with the way this
22 report currently stands.

23 Now I'll let Hans speak more about
24 SC&A's concerns. I don't want to paraphrase
25 and perhaps misstate what their concerns are.

1 But it does concern me that the references
2 that are cited in support of that are a 30
3 year old hematology textbook.

4 I mean, there's a lot of advances as I
5 think everyone will agree not only in
6 hematology but in medicine in general. And
7 the cases that we see today, the ICD codes are
8 assigned today by the Department of Labor
9 based on the medical records that come with
10 the case. And so they reflect, you know to
11 the best that we can, today's medical
12 knowledge.

13 And so while I certainly appreciate
14 the difficulty in making ICD diagnoses, that's
15 not something that NIOSH does. That's not our
16 role. That's the Department of Labor that
17 does that. And claimants always have the
18 option of questioning that and appealing that
19 to DOL if they feel that the ICD designation
20 is in error. And frequently, actually, when
21 we notice that an ICD code might be in error,
22 we raise it with the Department of Labor.

23 But in this case I just don't see that
24 we can actually agree to SC&A's
25 recommendations because they go against the

1 studies have examined Hodgkin's disease, and
2 there's simply not been observed any
3 relationship that would suggest that we should
4 pursue this course. So I'm concerned about
5 that.

6 **MR. ELLIOTT:** If I may, as I understand it
7 there's a recommendation from SC&A here to
8 revisit a large number of claims that they
9 feel is affected by their review comments.
10 And I think we need to, in Brant's comments
11 about that, I want to point out that we don't
12 think it's necessary to revisit those claims.
13 And we're worried here that this is going to
14 cause this report and this particular
15 comment/recommendation is going to cause
16 further and more frustration on behalf of
17 these claimants.

18 **DR. ULSH:** To sum it up I think we've
19 faithfully, well, I know that we have
20 faithfully reproduced or incorporated the
21 advice from the experts that we consulted in
22 our TIB. I think the program evaluation, that
23 report that we conducted in association with
24 this TIB, accurately reexamined the cases that
25 were affected, and the outcomes are accurate.

1 So I just don't see any need to, as Larry
2 said, go back and revisit these cases yet
3 again. I'd be happy to --

4 **MR. ELLIOTT:** That's just kind of the bottom
5 line of where we're at. We certainly can get
6 into the weeds on the technical issues
7 presented here, but I just want to make sure
8 that you Board members are aware of our
9 concern here.

10 **MS. MUNN:** Yes, my primary concern in going
11 through this once I overcame my resistance to
12 extremely technical language which is
13 necessary in a review of this kind, was the
14 suggestion that such a large number of cases
15 might need to be reviewed.

16 **DR. MAURO:** This is John. I'd like to offer
17 a perspective that may be a little different
18 than what I heard. And that is we actually
19 were not able to complete all the different
20 subtasks that made up this report. Because
21 the last step in our scope of services was to
22 select three cases and actually do a ground
23 truthing, so to speak, related to how, in
24 fact, the PER was implemented and in light of
25 the concerns that we raised regarding

1 diagnosis. What really came out of Hans'
2 report -- and certainly, Hans, you can step in
3 here and correct me --

4 **DR. BEHLING:** Yes, I'm waiting my turn here,
5 John.

6 **DR. MAURO:** Yeah, I know, but I just want to
7 say that I think that we really were looking
8 for some help in that we believe that if,
9 given the landscape of the problem, we felt
10 that there was a potential for incorrect
11 assignment of ICD codes to particular, for
12 some cases given the nature of this problem
13 and given the fact that many of these
14 diagnoses were performed many years ago.

15 So given that as a valid perspective
16 we felt that within the 400 or so cases that
17 were denied, it would be helpful for us to
18 complete our work to find a way to identify
19 those cases within the ones that were denied
20 to see if it's possible that some of these
21 potential missed diagnosis issues were, in
22 fact, real.

23 And so the way I understand it, we
24 were at a point where Hans didn't recommend
25 revisiting the cases but recommended a process

1 where perhaps we can select -- we proposed
2 three in our original work plan -- cases
3 amongst the ones that were denied that might
4 be the final proof of principle that, in fact,
5 the methods that were used to assign ICD codes
6 to those denied cases are ones that would be
7 good test cases to see, in fact, if the
8 potential problem that we identified was real
9 or perhaps wasn't for the very reasons that
10 you just gave, Brant.

11 So I think that that's how I saw, the
12 purpose of this call was to see first of all
13 if there was a general agreement that the
14 scope of our work would include doing some
15 cases, and also, seeking some help and given
16 the nature of the problem in identifying the
17 cases that we would look at.

18 **MS. MUNN:** And, John, I was under the
19 impression that this work group would indeed
20 identify some number of cases for you to
21 review again. However, my concern at this
22 juncture is with the process that was
23 suggested to provide us with a list from which
24 to make this choice. It's very difficult for
25 me to imagine the amount of work that would be

1 necessary for NIOSH to be able to provide a
2 list of the types that were suggested here.

3 **DR. ZIEMER:** Wanda, this is Ziemer. Could I
4 ask and maybe direct this to John Mauro.

5 John, are you talking about a
6 determination of whether the code was assigned
7 correctly?

8 **DR. MAURO:** It's really related to, as I
9 understand the problem, the assignment. In
10 other words in revisiting, in this PER, one of
11 the things that was done is say let's revisit
12 all of these denials. There were 500 or so as
13 a result of the PER. And in the process of
14 revisiting it there were assignments made as
15 to what cancer type each of those 500 or so
16 cases should be appropriately assigned. Some
17 of them were assigned to thoracic lymphomas,
18 cancer of the lymph nodes of the thoracic
19 region and some for other organs.

20 And what happens is there was a
21 sorting process. And as a result of that
22 sorting process, as I understand, there were a
23 number of cases where the dose was
24 reconstructed and there was, and people were
25 granted where formerly they were denied. Our

1 only concern was that amongst those that were
2 denied, our argument was that we think that in
3 making the determination of the proper
4 assignment --

5 **MS. MUNN:** I'm hearing serious telephone
6 break up. Is that John?

7 **DR. MAURO:** I will speak directly into my
8 headset. Is that better?

9 **DR. ZIEMER:** Yes.

10 **DR. MAURO:** Okay, I'm sorry for that.

11 **DR. ZIEMER:** There is some background noise
12 as well.

13 **DR. MAURO:** Oh, okay.

14 **MS. MUNN:** I'm hearing muddled conversation.
15 Is it my phone?

16 **DR. ZIEMER:** I'm not hearing that.

17 **DR. BRANCHE:** I'm not hearing that, Wanda.

18 **MS. MUNN:** Now, there's something going on.
19 Is it my phone?

20 **DR. BRANCHE:** Well, it wasn't your phone
21 before, but I just want to let you know that
22 Michael Gibson has joined the line and Mr.
23 Griffon will be joining soon.

24 Those of you who are on the line who
25 are not speaking if you could please mute your

1 phone, we would appreciate it. If you don't
2 have a mute button then please use star six.
3 And you can use star six again to unmute your
4 phone when you're ready to speak. Thank you.

5 **MS. MUNN:** I was getting --

6 **DR. BRANCHE:** I'm still hearing something,
7 but I think it's just background telephone
8 noise. I don't think it's conversation.

9 **MS. MUNN:** All right. I was hearing Larry
10 fading out badly for me and so was, I think,
11 Hans was trying to speak. I was getting
12 nothing but static from what I thought was
13 Hans. Was I the only person who was getting
14 that?

15 **DR. ZIEMER:** Apparently.

16 **DR. BRANCHE:** I heard Hans clearly.

17 **MS. MUNN:** Well, then it must be my hotel
18 phone here. I'll just try to get by.

19 **MR. GRIFFON:** Wanda, it's Mark Griffon. I
20 just joined, too, just to let you know.

21 **MS. MUNN:** Hi, Mark, good.

22 **MR. GRIFFON:** Sorry for being late.

23 **DR. ZIEMER:** Wanda, my question was, well,
24 maybe Larry can help on this, too. The coding
25 is done by DOL. Is that not correct?

1 **MR. ELLIOTT:** That is correct.

2 **DR. ZIEMER:** To what extent -- and you use
3 that code, but the dose reconstructor then, in
4 terms of this issue, if they decide that the -
5 - who decides whether the cancer is in -- I'll
6 use Brant's words -- the plumbing or the
7 circulating cells? Does the code tell you
8 that?

9 **DR. ULSH:** Dr. Ziemer, if I could answer
10 that perhaps. This is Brant. The ICD code is
11 set by the Department of Labor.

12 **DR. ZIEMER:** Right.

13 **DR. ULSH:** NIOSH has nothing at all to do
14 with --

15 **DR. ZIEMER:** Right, that's why I was
16 concerned about an audit that was going to
17 look at the assignment of the code because
18 then we're auditing DOL.

19 **MR. ELLIOTT:** This is Larry Elliott. We do
20 go back -- when our folks here see something
21 of question, we go back to the claims examiner
22 and ask them to revisit that code. I don't
23 know how many times we do that. And it may
24 not be ^.

25 **UNIDENTIFIED SPEAKER:** ^

1 **MR. ELLIOTT:** No, we don't make a point of
2 checking it, but if it, Stu was saying we
3 don't make a point of checking that. But when
4 we do see something that seems untoward to us,
5 we go back to DOL and ask DOL's claims
6 examiner to revisit it with -- I don't know if
7 Jeff Kotsch is on the line or not -- but DOL
8 has a medical person on call or on retainer
9 that deals with these kind of questions for
10 them. They look at medical diagnosis or the
11 medical history information. And they're the
12 ones that help us find the ICD-9 codes.

13 **DR. ULSH:** But I do want to make it clear
14 though that this process where we revisited
15 this issue did not involve seeking changes in
16 any ICD codes. Rather, it involved what
17 happens after we get a case with the ICD code
18 assigned. What do we do? Well, we pick which
19 target organ is appropriate for that
20 particular ICD code. And that is what has
21 changed.

22 **UNIDENTIFIED SPEAKER:** As prescribed in TIB-
23 0012.

24 **DR. ULSH:** Right, as prescribed in TIB-0012.
25 And that was based on our updated

1 understanding of the latest scientific
2 evidence about what target organs would be
3 appropriate for which ICD codes.

4 **MS. MUNN:** Because those changes were the
5 ones that were made as a result of both Dr.
6 Crowther and Dr. Eckerman's reports, correct?

7 **DR. ULSH:** That is correct.

8 **DR. NETON:** This is Jim, and that kind of
9 confused me as to what John Mauro was talking
10 about in terms of looking at the ICD-9 codes.

11 **DR. MAURO:** And I may have been incorrect.
12 My only reason for stepping in at this point
13 was I felt that in order for us to finish our
14 job we did need to pick some cases out of the
15 400 or so that were denied in the PER process.
16 And one of the areas that we would
17 particularly look at would be for that
18 particular case if, in fact, the correct organ
19 was selected for dose reconstruction.

20 I think it's my understanding that the
21 protocol that you folks used is fine. The
22 question really was if the benefit of the
23 doubt, if there was some uncertainty, we were
24 going to be looking toward whether or not the
25 benefit of the doubt was, with regard to what

1 organ was in play, if there was some
2 uncertainty, I would say a legitimate
3 uncertainty from a medical perspective on
4 which organ you would pick.

5 We would be looking to see if, in
6 fact, you picked the organ that would give the
7 highest dose. And so we were going to try to
8 work with you folks to identify those three
9 cases, because that's all we really limited
10 ourselves to in our scope, that would test
11 that question.

12 And at that point I think I'd like to
13 back down a bit and let Hans speak because I
14 didn't want to go too far without, you know,
15 just let everyone understand I'm looking at it
16 from the point of view as being able to
17 complete an assignment. And we're looking for
18 some help regarding completion of that
19 assignment in light of the work that we have
20 completed so far.

21 **MS. MUNN:** Let's do by all means hear Hans'
22 comments here, but please very strongly Board
23 members keep in mind the comment that Dr.
24 Ziemer made earlier in case you weren't on
25 line yet. He expressed a concern that is a

1 strong concern of mine, if the code number is
2 assigned by Labor and not by us, then the
3 question arises whether or not we have any
4 legitimate reason to be questioning their
5 codes other than the kind of question that's
6 been returned to them in many cases by NIOSH
7 when they had some question arise. Whether
8 this particular audit should be addressing
9 that issue is a real concern, I think, in
10 terms of how the program's going to be
11 administered.

12 With that in mind, I'm sorry. Go
13 ahead, Hans.

14 **DR. BEHLING:** Yeah, let me back up and start
15 at the end where John started to point the
16 issue to the selection of cases. What we were
17 hoping to do is if we're going to audit any
18 dose reconstructions that have been completed,
19 it should be one, the selection probably
20 should be one that focuses on the best cases.
21 Obviously, at this point there are 348 cases
22 that have been denied as a result of the PER-
23 9. And some cases were, obviously, it's a no-
24 brainer for them to be rejected for any number
25 of reasons.

1 So what I had hoped to do is to
2 perhaps engage NIOSH in looking at the table
3 that I included at the end where we would have
4 some understanding of which, what these cases
5 really represent with respect to, for
6 instance, whether or not the original dose
7 reconstruction was based on a best estimate as
8 opposed to a maximized. The issue of what if
9 the original POC with the target organ that
10 was, in fact, now used to reassess it under
11 PER-9 specifically for the internal target
12 organ.

13 There were issues -- let's see here --
14 a number of other issues that are very
15 important in selecting those cases that may
16 very well prove to be the ones where we would
17 want to look at it very carefully in saying
18 was this reevaluation done properly including
19 the new POC. And also an issue we haven't
20 discussed -- I'll talk about it in a few
21 minutes -- the issue of smoking as a variable
22 that has not been addressed and so forth.

23 So we were hoping that perhaps NIOSH
24 without a whole lot of effort would be in a
25 position to provide us with that matrix of 348

1 cases that have been denied under PER-9 review
2 and provide us with certain parameters that
3 would give us a best chance of selecting only
4 those DRs -- and I think we're only talking
5 about three -- that might best be able to
6 answer whether or not the PER-9 did what it
7 was intended to do.

8 **MR. HINNEFELD:** This is Stu Hinnefeld, and I
9 don't think there'll be -- well, I'm a little
10 concerned that it will be a lot of work to
11 develop this table from all of the potential
12 cases. And the potential cases, in my view
13 it's going to be 260. And the reason I say
14 that, I say that is that a number of these
15 claims that we did the reanalysis indicated
16 the compensability is still below 50 percent.

17 A lot of those cases have been
18 returned to us by the Department of Labor
19 anyway. When they provided our analysis of
20 the, essentially, the new dose reconstruction
21 was entirely, dose reconstruction report, they
22 provided that to the claimants, and the
23 claimants raised some objection because now
24 they didn't have a dose reconstruction that
25 reflected their case. So the Department of

1 Labor returned those to us to do a dose
2 reconstruction. So in a sense it mirrors that
3 evaluation was done.

4 So I guess about eight of those have
5 been returned for that reason and would not
6 have been re-adjudicated yet. And since
7 they're not adjudicated, I believe what the
8 rules are, is we don't, the Board doesn't
9 review cases that are not completely
10 adjudicated. So the population's going to be
11 I think 260 rather than 348.

12 Now having said that, most of these
13 pieces of information are data based, and
14 therefore, can just be written onto a table
15 with very little effort, the ICD-9 code, and
16 because of that, the target organ can be
17 generated automatically. The POC, certainly,
18 the new one is available. The original one is
19 available. It just may take a second look
20 because application has a couple of versions
21 before the latest version. We'd have to make
22 sure we got the one we're interested in.

23 Cancer diagnosis here is data based.
24 Smoking history is data based if we have it.
25 On a lymphoma case we won't necessarily have

1 method, that you'd have to look at the dose
2 reconstruction to determine. And for the, so
3 that would be two dose reconstructions to look
4 at, both the one before the PER evaluation and
5 the one that was used in the PER evaluation.
6 And then the exposure to alpha emitters
7 similarly. You have to look at the dose
8 reconstruction report to know that.

9 So for that reason that's a lot of
10 work to do for 260 cases. And so I was
11 hopeful that we might be able to get by with a
12 selection of, if you're only going to two,
13 maybe 20 or 30 of these cases and prepare that
14 table for 20 or 30 of the cases to select
15 from.

16 **DR. BEHLING:** That would be fine. As I
17 said, I just don't want to have an audit of a
18 lymphoma case that within seconds of looking
19 at it you realize why it was rejected.

20 **MS. MUNN:** This is Wanda. I have already
21 expressed my concern about the amount of
22 effort that would be necessary to generate the
23 kind of table that was suggested here and the
24 kind of information. The other, one other
25 topic that's been touched on is the smoking

1 issue. And this is, I think, a thorny one and
2 an appropriate place for us to talk about it.

3 It's been understood, I think, by all
4 concerned that smoking or non-smoking is not
5 what we're looking at in this program. Only
6 recently has a lung issue been factored into
7 it. But there is a real question as to
8 whether or not we are appropriately expected
9 to go there. Am I incorrect in my
10 understanding that the smoking issue is a
11 problematic issue that Labor has to address
12 and not one that we, as the Radiation Advisory
13 Board is addressing?

14 **DR. ZIEMER:** This is Ziemer. I think -- and
15 Larry kind of referred to this already --
16 since that information is not generally
17 available for these cases, I mean, it could be
18 inadvertently in a sense, as Stu suggested,
19 but in most cases I don't think we have the
20 information. So I don't see how we would be
21 in a position to address that variable in this
22 particular case even though it may be, you
23 know, Hans has raised certain concerns there.
24 But it's sort of one of those issues not
25 unlike some chemical issues that as important

1 as they may be, actually fall outside of our,
2 either our jurisdiction or our authorization
3 to address.

4 **MS. MUNN:** It has always been my
5 understanding from the outset that our charter
6 was specifically radiation, and we are --

7 **DR. ZIEMER:** Smoking was considered for lung
8 cases.

9 **MS. MUNN:** -- yes. We all understand that,
10 of course, smoking affects what happens with
11 radiation. We recognize that. But it's
12 always been very clear to me that that's
13 outside our specific charter.

14 **MR. ELLIOTT:** This is Larry Elliott. I'd
15 really like to comment here. The only other
16 risk factors that we are asked to examine
17 under this law -- if you look at the law, this
18 is where it comes from -- is smoking with
19 regard to lung cancer and ^ with regard to
20 skin cancer. And we have not identified, nor
21 has the law identified, any other risk factors
22 that should come into play.

23 I think we need to have a discussion
24 about the comments, the review comments from
25 Hans, on smoking. I think Jim's prepared to

1 do that later. But I think the first order of
2 business here is to continue on. Stu was very
3 clear on our desire to accommodate SC&A's
4 review of specific cases and how we can go
5 about that. We certainly can do it.

6 But I think I'd like to turn it over
7 to Jim and have Jim speak about whether or not
8 he sees merit behind doing that because really
9 what we're talking about here I think from
10 SC&A's review is a question are we using the
11 right target organs.

12 **DR. BEHLING:** Well, no, it goes beyond that,
13 Larry. Let me finish, and I guess I feel like
14 I'm being cut off again. I just started
15 actually discussing things and talking about
16 the back end of the selection process for the
17 audits.

18 But the issue of smoking is very
19 different for lung cancer as opposed to the
20 lymph nodes. In the case of lung cancer the
21 issue of smoking only affects the POC
22 calculation in the denominator meaning that
23 people who smoke have a higher natural
24 incidence of lung cancer.

25 In this case the issue of the

1 disruption of the mucociliary escalator, which
2 normally clears, is being compensated by --
3 and if you read the very short, brief
4 discussion I enclosed in the last section,
5 six, the ICRP-66 publication notes that among
6 smokers versus non-smokers, you have 14-fold
7 increase in albumin macrophages, five billion
8 versus 70 billion.

9 What that really translates to is a
10 much higher transfer of radioactivity into the
11 regional lymph nodes meaning that you can
12 certainly be sure that this affects the
13 radiation dose as opposed to the incidence of
14 cancer that results from smoking. The two are
15 very, very different mechanisms. One only
16 affects the POC equation. The other one has a
17 direct impact on the amount of radioactivity
18 that's being transferred from the lung into
19 the thoracic or extrathoracic lymph nodes and
20 thereby increases the actual radiation dose to
21 those tissues.

22 So we have to be very careful about
23 understanding the difference in terms of
24 assessing the smoking issue for cases
25 involving lymphomas versus lung cancer. And

1 it's very important to make that distinction.

2 **MS. MUNN:** That was very interesting
3 information, Hans, frankly, rather shocking to
4 a lay person.

5 **DR. BEHLING:** I would like to continue if I
6 could.

7 **DR. NETON:** I would like to address that a
8 little bit though, Hans. This is Jim. I
9 think what you raised is a scientific fact,
10 but there is no model that could be applied to
11 make this adjustment even if it were true.

12 **DR. BEHLING:** Well, you can look at the
13 mathematics, Jim, one or five micron particles
14 are removed expeditiously by way of other
15 mechanisms such as absorption, but if it's an
16 enzyme material that goes out. And if you
17 have an impaired mucociliary transport
18 mechanism that ultimately clears it into the
19 EP-2 region and then from there into the
20 gastrointestinal, you can look at it
21 mathematically and say what is the potential
22 impact if this is now cleared by the way of --

23 **DR. NETON:** I think we're committed to using
24 the best science available, and I'm not aware
25 of any good science that's peer reviewed out

1 there that we could use to make this
2 correction. But let me add to that. I think
3 that you need to look at the total picture
4 here involving the lymph nodes as well. It is
5 well known that cigarette smoking also causes
6 an increased inhalation of natural
7 radioactivity.

8 I have personally measured this in the
9 laboratory for Thorium-230, -232 and -228.
10 There is a considerable amount of additional
11 intake that occurs there. So I would
12 challenge your assertion that smoking does not
13 affect the denominator in the calculation. It
14 does. And, in fact, Polonium-210 is even more
15 widely known as a natural constituent of
16 cigarette smoke. So you have a natural
17 increase of radioactivity that should
18 contribute to the denominator where we're
19 going to look at the scientific picture in
20 total.

21 Secondly, if you've done like I have
22 done and looked at lymph nodes of cigarette
23 smokers versus non-smokers, they are much
24 larger because of the collection of the inner
25 mass of the material that's in the cigarette

1 smoke. That mass by making the lymph nodes
2 larger tends to diminish the dose and the dose
3 to the organ from the amount of radioactivity
4 in there goes down considerably. So you have
5 to look at that whole picture. It's not just
6 a one-sided analysis. And I'm not sure any of
7 those factors could be modeled appropriately
8 to be sufficiently accurate.

9 **DR. BEHLING:** Not to belabor this issue, but
10 when you increase the lymph nodes in size, you
11 also increase the number of cells at risk so
12 they cancel each other out.

13 **DR. NETON:** No, it's mass, it's
14 transformations per unit mass, Hans. Energy
15 per unit mass deposit in --

16 **DR. BEHLING:** I realize that, but when you
17 have three times the number of cells, you have
18 three times the number of cells at risk. And
19 I know the dose would --

20 **DR. NETON:** Well, this brings me to another
21 issue, Hans. Let's talking (sic) about the
22 lymph node model itself. We are assigning a
23 dose to the lymph nodes as if it was entirely,
24 the entire lymph system. As you well know,
25 the radiation risk model developed from the

1 Hiroshima-Nagasaki survivors is based on a
2 uniform whole-body exposure.

3 We are treating our intakes as if that
4 same amount of material in the
5 tracheobronchial lymph nodes irradiates the
6 entire lymph system. That by its very nature
7 is an extreme over-exaggeration of the dose to
8 the lymph system. So we feel this is an
9 extremely claimant favorable analysis to begin
10 with. To do it properly one should take and
11 take the weighted dose to the lymph system
12 over the entire lymph system and not just that
13 one little piece.

14 **DR. BEHLING:** That's another issue for
15 discussion --

16 **DR. NETON:** Well, again, one has to look at
17 the total picture, Hans, not just a one-sided,
18 scientific review.

19 **DR. MAURO:** Jim, I think that what I'm
20 hearing is that we're dealing with a
21 multifaceted problem, scientific problem, in
22 terms of how do you come to grips with this
23 situation. And the only reason why I would
24 say that it requires the attention is we're
25 talking about differences in -- for example,

1 in the simpler sense depending on the organ --
2 let's just put the smoking issue on the bench
3 for a second.

4 Depending on the organ that was
5 selected for doing the dose calculations, my
6 understanding is that the difference in the
7 dose, that reasonable people may come to
8 different conclusions regarding what was the
9 organ of concern in this diagnosis. And one
10 choice would result in a dose that is several
11 orders of magnitude, maybe three orders of
12 magnitude as I understand, higher than the
13 other organ. So if there is, so we're talking
14 about a scale of things.

15 So if, in fact, Hans' concerns that
16 there might be some ambiguity in selection of
17 the proper organ and that reasonable people
18 could differ on what the correct one is, and
19 if judgments have been made in the process you
20 just went through which perhaps did not always
21 give the benefit of the doubt, we are talking
22 about difference in doses to the organ of
23 concern that could be on the order of a
24 thousand or more.

25 **DR. NETON:** John, let me stop you right

1 there because I've got a question. We're kind
2 of talking about two separate things here.
3 One is the organ of concern. And the organ
4 that is reconstructed is clearly tied in our
5 TIB-0012 to the ICD-9 code provided by the
6 Department of Labor. So we have no choice in
7 that number. With the ICD-9 codes provided to
8 us is what we use, and we have a look-up
9 table.

10 There is no room for judgment on the
11 part of the health physicist. If he sees an
12 ICD-9 code of something-something-something-
13 dot-X, he'll go to the table and apply the
14 dose reconstruction to that organ. So there's
15 no judgment involved here at all on the part
16 of NIOSH.

17 Now, Hans has raised a bigger issue I
18 think --

19 **DR. BEHLING:** Well, I would like to be able
20 to make some comments here, and I'm constantly
21 being cut off. And I'm not sure there's any
22 point in my continuing on this if I'm not
23 given a chance to even comment.

24 **DR. MAURO:** Hans, please go forward because
25 I've been jumping in --

1 **DR. BEHLING:** I've been told to get quiet.

2 **DR. MAURO:** Please, go ahead, continue,
3 please.

4 **MS. MUNN:** We definitely need to hear what
5 you have to say, Hans.

6 **DR. BEHLING:** I'm trying very hard here.

7 Anyway, let me go back to a few things
8 that were mentioned earlier. When we talk
9 about Hodgkin's disease I concur with some of
10 the original statements that were made.
11 Hodgkin's disease is a very easily definable
12 form of lymphoma, and it's something that can
13 be done with an ordinary light microscope
14 because the histopathologist who looks at a
15 biopsy will look at it and identify what's
16 called the Reed-Sternberg cell.

17 It's a very large cell. It has a
18 morphology that is readily recognized by even
19 a very novice-type person; and therefore, the
20 diagnosis is one that is without question one
21 that you can rely on. On the other hand the
22 issue that even involved Hodgkin's disease is
23 one of which lymph node was identified for
24 biopsy.

25 And now we're talking about what is

1 the stage. If you have a Stage I Hodgkin's
2 lymphoma, then that means there's only one
3 tissue or one location by which that neoplasm
4 exists. And so if you biopsy that, then it's
5 true, then the tissue where you biopsy the
6 tumor is also the location at which the
7 transformation, the original transformation,
8 took place.

9 On the other hand we all know that
10 when you have most incidences lymphomas, if
11 you read through the medical text, it usually
12 is not something that is diagnosed at a Stage
13 I level meaning that you will have Stage II,
14 III and IV. At which point the biopsy may
15 very well represent a location that is not the
16 primary neoplasm but a secondary neoplasm.
17 And therefore, the biopsy, the anatomical
18 location for that biopsy has very little in
19 telling you where that original transformation
20 takes place. That's for Hodgkin's.

21 When we talk about non-Hodgkin's
22 lymphoma the issue becomes even murkier
23 because now we're talking about a host of
24 different cell lines from which that neoplasm
25 was derived. And therein lies the problem in

1 making a very definitive diagnosis. And what
2 I tried to tell you is in my review, is that
3 the ability to identify the cell line of
4 origin has been a problem throughout the
5 history of treating lymphomas. And it's due
6 to the fact that when you talk about non-
7 Hodgkin's lymphoma, the cell lines are
8 extremely difficult, and they change with
9 time.

10 If you read the statements that I
11 extracted directly from my medical text --
12 it's true. It's 1979 -- but I also want to
13 point out to you that many of these lymphomas
14 I'm sure among the 500 and some odd were
15 probably diagnosed prior to the introduction
16 of the ICD-9 codes which now leaves you with a
17 big open-ended question is how do you
18 translate those particular medical records
19 into a contemporary ICD-9 code.

20 And if you look even at Dr. Crowther's
21 comments, there's a very brief, one-and-a-half
22 page consultant report. He had some serious
23 questions about that ability, and how do we go
24 about making a diagnosis at this late in the
25 day or in the year 2007 and assign an ICD-9

1 code from records that may be 30, 40 years old
2 and at a time when many of these definitive
3 methods that are currently in use, and most of
4 these are immunological.

5 They look at cell receptors for the SC
6 component that was set formation and other
7 things that didn't exist until, in some
8 instances, only very recently. So you have a
9 very difficult time in looking at medical
10 records, especially older ones, and somehow or
11 other pigeonholing that particular cancer and
12 saying we can assign with a reasonable degree
13 of certainty an ICD-9 code. And on the basis
14 of which we then assign an internal and
15 external target organ. And that is the sum
16 total of this whole report.

17 **DR. ZIEMER:** Could I comment?

18 **DR. BEHLING:** Yes.

19 (no response)

20 **DR. BRANCHE:** Hello?

21 **DR. ZIEMER:** This is Ziemer. I couldn't
22 tell whether my mute is on or off.

23 I appreciate those comments. I just,
24 it seems to me that, Hans, you're addressing
25 an issue that's a DOL issue it seems to me.

1 Am I --

2 **DR. BEHLING:** Well, if it is, Paul, then I
3 guess this whole discussion has very little
4 purpose. I just brought it up from a purely
5 scientific --

6 **DR. ZIEMER:** Yeah, I understand the point
7 that you made, Hans. The concern I have is
8 that assignment is made prior to us getting
9 any, getting the case as far as I know. And I
10 don't think we're in the position, unless
11 Larry says that as they look at a case if
12 something looks fishy, they can send it back,
13 but maybe Larry would comment further. But my
14 understanding is that we're not assigning
15 those codes and are not typically auditing
16 them.

17 **MR. ELLIOTT:** You are correct in everything
18 you said there, Dr. Ziemer. It is a DOL
19 issue.

20 **DR. ZIEMER:** The concern is a valid concern
21 but not one that we're in a position to
22 address I think.

23 **MR. ELLIOTT:** You say you're not in the
24 position to address. We can only address it
25 when we think there's something that DOL

1 should re-look at. And we don't look at, we
2 don't examine them to that level of detail
3 because we accept the, what's called the --
4 what do they call this now? The statement of
5 facts, the statement of accepted facts
6 associated with the claim. And it is not our
7 responsibility. It's DOL's responsibility to
8 provide those to us.

9 **DR. ZIEMER:** But then the issue is given
10 that we have a code, is the follow-on question
11 then are we using the right target organ?
12 What is the next issue either Hans or John?
13 What's the follow-on point?

14 Let's assume for the moment that the
15 code was correct. I mean, certainly some of
16 them are, but what's the follow-on issue from
17 our end?

18 **DR. BEHLING:** It has repeatedly been told by
19 both Jim Neton and Larry and Brant, we don't,
20 NIOSH does not select the ICD-9 code. That's
21 handed to us. And the ICD-9 code is very
22 specific if you look at it. It identifies an
23 internal target organ and external. And if at
24 this point we have no authority over DOL, this
25 whole discussion as it is basically an

1 exercise, an academic exercise that has little
2 or no value if they can't change the DOL.

3 **DR. MAURO:** Except, would you agree, the
4 smoking issue then? In other words it sounds
5 like we're talking about two different issues.
6 One dealing with is the right diagnosis to the
7 organ of concern. And this sounds like it
8 might be outside the purview of the Board.
9 And the second part is if it was properly
10 diagnosed, if, Hans, in your opinion is the
11 smoking issue an issue in terms of can you,
12 the numbers you threw at us, the effect that
13 smoking might have on the biokinetics.

14 **DR. BEHLING:** Yeah, it truly will. As I
15 said, if you have 14-fold increased in
16 alveolar macrophages whose principal objective
17 is to transport and clean the lung of
18 particulate matter into regional lymph nodes,
19 it's clear that you're going to increase the
20 dose. Again, on the other hand there is no
21 documented -- I looked at ICRP-0066, and while
22 they made reference to it -- you can read it
23 yourself -- there's no quantitative data that
24 would allow you to make an adjustment.

25 **DR. ZIEMER:** Going back to the point Jim

1 Neton was making. We could certainly regard
2 this as a long-term, scientific issue that
3 hopefully down the road, I think that question
4 would be of interest to the scientific
5 community outside of even of this program
6 because there are other factors for the
7 smokers that come into play.

8 There are clearances, the lung
9 clearance into the lymph nodes but the
10 coughing and all of that affects the clearance
11 and the GI tract doses. And then Jim raised
12 the issue for the smokers of the added
13 internal burden of natural nuclides that
14 affects part of those equations. So it's very
15 complex it appears to me.

16 **DR. BEHLING:** Yeah, and I'm not suggesting
17 that this become a scientific investigation --

18 **DR. ZIEMER:** No, not for us, but it could be
19 an issue that we tag as one of scientific
20 interest in the future. For example, if NCI
21 or some other group is looking at this, we
22 would want to keep abreast of what's
23 happening.

24 **DR. BEHLING:** But we did make, for instance,
25 an adjustment when we encountered the Super S

1 plutonium and with limited scientific data, we
2 essentially defaulted to an approach that
3 acknowledges the difference between S and
4 Super S, and therefore, the dose involving the
5 lung. And so is it appropriate for us to
6 perhaps in a very questionable, not
7 questionable, but in a less than 100 percent
8 scientific method approach this issue as sort
9 of default to a value that gives the claimant
10 perhaps an elevated dose if he's a documented
11 smoker.

12 **DR. ZIEMER:** Well, if you could identify all
13 of the variables. I think the Super S was a
14 little more straightforward than this.

15 **DR. NETON:** I agree with Dr. Ziemer on that.
16 It's not exactly a fair comparison.

17 **DR. MAURO:** I like where we are in this
18 conversation. I think that we've really
19 crystallized the issues. I don't think
20 there's any ambiguity; I think we all see the
21 same picture. Namely, there is perhaps a
22 legitimate question regarding the selection of
23 the organ of concern. But what I'm hearing is
24 it's really outside the purview, at least
25 right now, for investigation of the Board and

1 for its contractor.

2 In regard to the issue of clearance
3 and the effects of smoking and how it might
4 affect the loading up of the thoracic lymph
5 nodes are actually extrathoracic lymph nodes,
6 that is a scientific question that is
7 certainly of interest. But what I'm hearing
8 is something that really cannot be taken on at
9 least at this time for this particular PER
10 review. I say all this because if what I just
11 said is in general agreement, it means that
12 our job is completed on this particular PER
13 review, and we really need not go into the
14 last step, subtask, which is reviewing
15 particular cases.

16 I'm trying to find a way to achieve
17 closure on fulfilling our obligations to the
18 Board. And I think that if what I just
19 described accurately characterizes the state
20 of affairs, you know, I think some very
21 important things came out of this
22 conversation, but perhaps they're not items
23 that are appropriately addressed by the Board
24 and its contractor at this time.

25 **MS. MUNN:** Well, they are certainly

1 important. There's no question about that.
2 One of my questions is whether we even have
3 any knowledge relative to Labor's
4 consideration of the questions that have been
5 raised here. I have no way of knowing whether
6 these questions have been kicked around by the
7 medical folks over at Labor, whether they have
8 taken some of these or all of these questions
9 that Hans has raised so thoroughly into
10 consideration as they make some of their code
11 assignments even.

12 **DR. ZIEMER:** Well, this is Ziemer again.
13 Let me make a couple of comments, and I'll
14 play off of what John said a little bit. We
15 have this report. I would like to see a
16 couple revisions. One is to take care of that
17 early issue that Larry raised and recognize
18 the work that NIOSH had been doing and also
19 point out that unbeknownst to you, they were
20 doing that and that you had also reached the
21 same conclusion in your early review. So to
22 be fair to both sides, you both identified the
23 problem. So let's make that known.

24 Number two, the information is in
25 there, a good discussion by Hans. I see no

1 reason why that can't still, it still will be
2 out there in a sense. You might add a comment
3 that in a revision that it appears that this
4 is the purview of DOL so the Board will not
5 need to address this further. And I think we
6 have to leave it there.

7 In a sense the information that you
8 have would be at DOL's prerogative to use or
9 not use. We're not going to force it on them,
10 send it to them or whatever I don't think. I
11 think it's in the public record at that point
12 and they can see it and use it as they see
13 fit.

14 Let's see, was there a third --

15 **DR. BEHLING:** Smoking.

16 **DR. ZIEMER:** And the smoking issue seems to
17 me, again, you could point that out as you
18 have and indicate as well that there may be
19 other aspects of this that you haven't, that
20 would have to be considered including the
21 impact of natural activity on the smoker and
22 perhaps other clearance mechanisms besides the
23 lymph node clearance. Hans, I think you
24 probably mentioned the GI clearance would
25 probably change with --

1 **MS. MUNN:** It was in --

2 **DR. ZIEMER:** Anyway, I'm just saying the
3 information is in a sense useful to have for
4 whatever we can use in the future. And you
5 might mention that although we can't make that
6 correction now, it's something that might, as
7 we move forward, might reach a point where
8 perhaps NCI or some other group will come out
9 with a model.

10 I'm just trying to make, say we have
11 the report. Let's get it in a form that
12 identifies, recognizes everybody's concerns
13 and then we can't do any more at this point I
14 don't think as far as procedurally.

15 **DR. BEHLING:** If there is one
16 recommendation, and again, I don't want to
17 speak disparagingly of Dr. Crowther, but being
18 a hematologist is obviously related subject
19 matter that would perhaps give this person
20 insight. But the person I would really
21 consult is a clinical histopathologist and one
22 who has a very, very working knowledge about
23 the issue of identifying the cell type that
24 would ultimately then give an understanding of
25 the modality for treating that lymphoma which

1 is very critical.

2 And for that I looked at Dr.
3 Crowther's background. He's really not a
4 clinical person in that sense where he has a
5 lot of experience in this particular area.
6 You would probably want to look at somebody
7 who worked in a hospital environment or a
8 research environment that deals with this
9 issue on a daily basis in looking at tissue
10 biopsies and running various tests whether
11 they're immunological tests, serological tests
12 to make that ultimate diagnosis.

13 And those are the people that I would
14 sort of look at and sort of say they're the
15 best people to provide us with an
16 understanding of whether or not the current
17 ICD-9 codes are, with regard to the
18 internal/external target organ, are they
19 really correct.

20 **DR. ZIEMER:** Well, again, I think we're
21 getting into that other territory. I don't
22 know -- you don't want to put that in your
23 report.

24 **DR. BEHLING:** No, I'm not.

25 **DR. ULSH:** I've got to take exception to

1 that. Dr. Crowther is the head of the
2 largest, well, one of the largest hematology
3 departments in the world. He has, I think, 30
4 or 40 interns under him. Hans, what might be
5 tripping you up is that in the United States
6 there really isn't a separate sub-discipline
7 of hematology. Everybody is an oncologist.

8 That is not the case in Canada where
9 Dr. Crowther is from. Hematology is a
10 separately recognized sub-discipline. Dr.
11 Crowther has over 125 peer reviewed
12 publications. He's coming out with a textbook
13 this summer, Evidence-Based Hematology. He
14 has both clinical and research experience. He
15 works at a research and teaching hospital at
16 McMaster University.

17 He is eminently qualified. He is also
18 internationally recognized. So to imply that
19 he doesn't have the right qualifications to
20 review this, I think, it's not accurate.
21 There's no one more qualified to review this.

22 **DR. BEHLING:** Well, okay, as I said, I don't
23 know him personally, and maybe that's what's
24 lacking here. But if you read his consultant
25 report, it does leave an awful lot of

1 questions open to interpretation which he
2 himself acknowledges. There's very little
3 hard evidence, scientific evidence, in the
4 classification of certain lymphomas. I think
5 that comes through loud and clear. So if you
6 recognize him as your expert, he certainly has
7 raised a few questions about the ability to
8 assign ICD-9 codes in his very brief
9 consultant report.

10 **DR. ULSH:** Actually, I'm looking at his
11 report right now, and he did not ever address
12 the issue of the adequacy of historical
13 records in assigning contemporary ICD-9 codes.
14 Like any prudent scientist he acknowledges
15 where there's uncertainty, but he was
16 specifically tasked by us to address where
17 there are areas of uncertainty and to point
18 those out.

19 But we go with the best available
20 science and the weight of the evidence. Dr.
21 Crowther went through a very detailed review
22 of the ICD codes that we asked him to and did
23 exactly what we asked him to. He went through
24 them one by one and told us what his
25 recommendations are. Now I don't see a whole

1 lot of uncertainty there at all. It's very
2 clear what he recommended.

3 **DR. BEHLING:** Well, it's a difference of
4 opinion. I'm looking even the very first
5 paragraph and it certainly raises a few
6 questions in my mind. But again, this is an
7 academic issue.

8 **DR. MAURO:** Yeah, I think that as I said
9 before, we're at the right place on this.
10 That is, we've expressed some concerns that
11 obviously are really not, the last step in our
12 scope of services in looking at cases, we
13 walked away -- as I understand it,
14 notwithstanding the issues we raised regarding
15 smoking and regarding identification of the
16 organ concerned, we found that the PER was a
17 very good PER and was being implemented in a
18 scientifically sound way.

19 That's what I walked away with when I
20 read this. And the main concerns we have had
21 to do with this, number one, appropriate
22 diagnosis and to smoking. And the only reason
23 we wanted to go on to the last step in the
24 process was to look into those two particular
25 issues to determine the degree to which they

1 may represent a challenge to a way in which
2 the PER is currently being implemented.
3 Without that I don't know if there really is a
4 need for us to go on and do any of the three
5 case reviews.

6 **DR. ZIEMER:** I agree. I think it's
7 complete. In my mind it is. I don't know how
8 the other Board members feel.

9 **MR. ELLIOTT:** John, this is Larry Elliott.
10 You said something there that raised my
11 eyebrows. You said that your report finds the
12 PER to be well done and the work to be
13 appropriate. But I don't read those words in
14 this review.

15 **DR. MAURO:** Well, I'll let Hans speak to
16 that.

17 **DR. BEHLING:** Well, as we just heard from
18 Paul, he wants us to amend the report at three
19 levels.

20 **DR. ZIEMER:** Well, I was expressing my
21 opinion. I think it's -- and I want to hear
22 from the others. I don't want to make
23 decisions for the Board.

24 **MS. MUNN:** Well, you certainly expressed my
25 opinion appropriately. My concern from the

1 outset was that the issues that were being
2 raised were extremely valid issues, but I was
3 not at all sure that they were within our
4 purview. That was my concern.

5 **DR. MAURO:** And, Hans, please speak to --

6 **DR. BEHLING:** Well, John, basically, I still
7 have some reservations, and I think everyone
8 who understands the issue of lymphomas and
9 their diagnosis, especially as we go back in
10 time 20, 30 years, there's a big open-ended
11 question. How accurately were these medical
12 records reflected through a type of lymphoma
13 and the source or the primary neoplasm and its
14 anatomical location et cetera, et cetera.

15 **DR. ZIEMER:** And I'm saying that I'm not
16 asking you to revise any of that. I think
17 that's fine. I'm just saying we can't impose
18 that on --

19 **DR. BEHLING:** No.

20 **DR. ZIEMER:** -- on DOL.

21 **DR. MAURO:** Yeah, and I want to go back to
22 Larry's point because I want to make sure that
23 I'm correctly representing my understanding.
24 Except for the two issues that we just
25 discussed which are outside the purview of our

1 mission so to speak, it's my understanding
2 that the process that NIOSH went through and
3 that given that there was not a smoking issue
4 that we're concerned with, and given that we
5 did not happen to encounter a PER where the
6 ICD-9 or diagnostic issue came into the play,
7 the process that they went through and how
8 they implemented it, and how they selected the
9 cases and did their dose reconstructions, it
10 is my understanding that every part of that
11 seemed to -- when we spoke last, Hans -- that
12 seemed to be very well done until we ran into
13 these two what I would call major issues.

14 **DR. BEHLING:** No, John, the ICD-9 code is
15 not selected by NIOSH as you've been
16 repeatedly told. So they followed the
17 instructions of DOL. And if there is to be a
18 change in how we assign ICD-9 codes, it cannot
19 come through NIOSH. It has to be at the level
20 of DOL. And so therefore, that issue goes by
21 the wayside.

22 **DR. MAURO:** I'm not sure whether you're
23 agreeing with what I just said. We happened
24 to run into a PER, I mean, what we really have
25 before us is the very first PER we were asked

1 to review is this one where the issues that
2 emerged that we have concerns with really are
3 outside the purview of the Board.

4 Other than that, if those issues were
5 not there, and we were dealing with some other
6 PER where those issues that emerged, I guess I
7 would say that if those were unfair with by
8 and large the process that was used to get to,
9 the way in which the cases were -- for
10 example, the way I've always looked at this is
11 that there's a multi-step process where once
12 the issue is raised, however it comes about,
13 then NIOSH goes through a process of selecting
14 the cases that could possibly have been
15 affected by that issue. And then
16 systematically go through a triage to identify
17 the ones that will need to be reconsidered and
18 then reconsider them. And then, of course,
19 the compensation process goes forward. It's
20 my understanding that that process, the front
21 end of the process, was done well. And I
22 think that was my understanding --

23 **MR. ELLIOTT:** John, this is Larry. Can I
24 jump in here?

25 **DR. MAURO:** Sure.

1 **MR. ELLIOTT:** Because I want to hearken back
2 to what I said at the start of this conference
3 call. That I'm very concerned that this
4 report will lead to claimants being further
5 frustrated. And on page five of the Executive
6 Summary at the last paragraph of the page,
7 this phrase, the first sentence ends in a
8 phrase, "nevertheless this contains
9 significant deficiencies," does not match up
10 with what I heard you say just now or a moment
11 ago.

12 **DR. MAURO:** Well, of course, this is in
13 light of what we've just learned about what's
14 within -- what I'm hearing is there's a need
15 to re-issue our report.

16 **MR. ELLIOTT:** I would appreciate that
17 because the folks out there in the claimant
18 world are going to hold this up and ask DOL to
19 send claims back to us, and we're going to
20 turn right around and say we have applied the
21 best science possible.

22 **DR. MAURO:** But we do have a dilemma. And
23 the dilemma being that, I mean, in a funny
24 sort of way, hey, we think NIOSH did a great
25 job with this PER; however, the Department of

1 Labor, we wonder whether or not that we have
2 some concerns about, you know, the fundamental
3 biokinetic models as applied to this class of
4 problem which goes toward ICRP.

5 And, two, we have some concerns
6 regarding the process that was used to
7 identify the organs of concern, both of which
8 are outside the purview of NIOSH, at least at
9 this point in time perhaps, and the Board. So
10 I don't know what we do at this point. I
11 think we have something very important to say,
12 but I'm not too sure how to go about saying
13 it.

14 **MS. MUNN:** It appears to me that you've at
15 least cast the outline of what has to
16 transpire here. Clearly, the report needs to
17 be reissued. Clearly, the issues that you
18 have brought up are valid issues. They simply
19 cannot be addressed here. I see no problem in
20 identifying the issues. Does anyone else see
21 any problem with that? It appears to me that
22 it's only fair to identify the issues. It's
23 just they're not, the issues are not
24 applicable to this PER and --

25 **DR. ZIEMER:** Yeah, I think one of the

1 problems, for example, on the statement Larry
2 just referred to on page five, it says the
3 deficiency is in the PER. Well, actually, the
4 deficiencies that you identified are really
5 outside, they're not only outside the PER,
6 they are outside the NIOSH fence.

7 So I think, John, you may need to
8 think of some creative ways to indicate that
9 there are these kinds of concerns, but under
10 the current framework of this law, NIOSH is
11 not in a position to address them. You could
12 speculate -- well, I don't know if you could.

13 Part of this where you identify the
14 coding issue I suppose you could point out
15 that this is a concern that has to be handled
16 by Labor. You don't know at this point, you
17 don't know that Labor has not --

18 **DR. MAURO:** Yes, yes.

19 **DR. ZIEMER:** -- and so you have to be very
20 careful and say this is a concern and that --

21 **DR. MAURO:** Could we say that? Maybe we
22 could just say that.

23 **DR. BRANCHE:** This is Dr. Branche. May I
24 make a suggestion? I think to be able to say,
25 I think that Dr. Ziemer was leading along a

1 very wise path. But I think you could simply
2 end by saying but this is outside the purview
3 of NIOSH. You don't have -- and since we
4 don't know or we can't ascertain explicitly in
5 whose purview it is. And I wouldn't risk
6 saying it's Labor only to find out it's
7 somebody else.

8 **DR. MAURO:** I would go a step further. I
9 wouldn't even be judgmental. I would say that
10 based on what we reviewed, we see that there's
11 a potential for a certain class of problem
12 emerging in terms of diagnosis. Now, we're
13 not saying that problem exists. We're not
14 saying that it needs to be fixed. But at
15 least from what we've seen, we see the very
16 real possibility that that kind of problem
17 could emerge on a particular case.

18 **DR. ZIEMER:** You need to make it clear that
19 it's not something that NIOSH can handle. It
20 sounds like --

21 **MR. ELLIOTT:** And I would offer that it's
22 not, you know, lymphoma is probably the poster
23 child for this problem.

24 **MS. MUNN:** No question.

25 **MR. ELLIOTT:** But it's not the only ICD-9

1 code that would have problem being assigned
2 based upon rough, I mean --

3 **DR. NETON:** Fifty year old medical records.

4 **DR. MAURO:** Yeah, yeah, we've got to work --
5 I accept this challenge to try to craft words
6 carefully to communicate something that might
7 be very important, but do it in a way without
8 being presumptuous regarding what Labor's
9 doing and not doing, and not even point toward
10 Labor. Just make the statement as Christine
11 wisely suggested, this is outside the purview,
12 but nevertheless it is a question that has
13 come up that may require further
14 investigation, that sort of thing. And then
15 stop at that point.

16 **DR. BRANCHE:** This is Christine again, and
17 the other thing that you have on your side is
18 that the Departments of Labor and Energy do
19 participate -- I don't know if they're
20 participating in this call. I don't know if
21 they've joined yet, but then the staff at
22 NIOSH as well as SC&A would have a point of
23 reference if this should come up later on.
24 And you'd have documentation where you made
25 certain that it wasn't pointing to NIOSH, but

1 there was an issue, a deficiency, that you
2 uncovered.

3 **DR. MAURO:** Right, and we leave it that way.
4 And I think it serves everyone's purpose this
5 way. And at some point in the process the
6 degree to which it's picked up by those
7 organizations and individuals that feel it's
8 something that needs to be picked up, great.
9 If not, that's certainly their choice.

10 I feel as if that we've done something
11 important here, but at the same time we have
12 to function within the structure of the way
13 business is done here. And we have to go
14 gently, but nevertheless get the information
15 out. We'll do that. And we certainly will
16 put out another draft for consideration by all
17 concerned to make sure that we strike that
18 delicate balance that we're looking for.

19 **MS. MUNN:** I know you can do that, John.

20 **MR. ELLIOTT:** This is Larry Elliott. I
21 think that is a very good thing that you have
22 proposed to do there, John. And I encourage
23 you, and I would offer my help if I can in any
24 word-smithing that you would like help on.
25 For the working group, I just want the working

1 group to hear my thoughts about review of
2 PERs.

3 I was very excited that the Procedures
4 working group was going to pick up an
5 examination of PERs. And I was further
6 excited by the fact that the working group
7 assigned this particular PER for a first
8 examination. And what I hoped to have seen
9 out of that was how well we identified the
10 scientific issues surrounding the change, and
11 how well we implemented that.

12 And quite frankly, I have to say, you
13 know, I'm not real comforted by on either one
14 of those points here. I don't see that in
15 this review, and I hope the revised review
16 will speak to both the scientific basis for
17 the change and how well the change was
18 implemented. And any way we can help you in
19 that review I certainly will stand up and do
20 that.

21 **DR. BEHLING:** Larry, not to belabor the
22 issue, but I think one of my concluding
23 statements was that NIOSH fully understood the
24 technical basis for this PER and accommodated,
25 as I said, with the two things that I

1 identified here as potential problems are now
2 not considered your problem.

3 And so as far as I'm concerned I was
4 not harsh or hypercritical of anything that
5 NIOSH did. Now that we're all of the
6 understanding that this whole issue of ICD-9
7 codes is strictly something that is outside of
8 NIOSH's purview, those two issues go by the
9 wayside.

10 **DR. MAURO:** And I would --

11 **MR. GRIFFON:** John, this is Mark Griffon.
12 Can I ask one thing?

13 **DR. MAURO:** Yeah.

14 **MR. GRIFFON:** Two issues, I agree with that
15 one. That's obviously in DOL's camp. But the
16 question of the biokinetic model I think is
17 certainly a NIOSH issue even if it's a long-
18 term science issue. I mean, and I agree with
19 everything Jim Neton said that it's not only
20 one side that you have to look at. But I
21 think we should examine that. The ICRP-66
22 does have a section on that, but they're
23 basically, from what I can tell -- Jim
24 probably has looked at this certainly more
25 than I have -- but it looks a little

1 inconclusive, the research, at this point.

2 But I don't --

3 **DR. ZIEMER:** Not that there's as an issue,
4 but they don't have a solution at this point.

5 **MR. GRIFFON:** Right, right, but I think --

6 **DR. ZIEMER:** That's what I was saying --

7 **MR. GRIFFON:** -- it is in NIOSH's --

8 **DR. ZIEMER:** -- ^ table maybe.

9 **MR. GRIFFON:** Yeah.

10 **MS. MUNN:** That can be said and at the same
11 time maintain that NIOSH has appropriately
12 handled these issues with the best science
13 available which has done so. It's an
14 outstanding question, but it's not a question
15 to be resolved in this program.

16 **DR. ZIEMER:** Right.

17 **MR. GRIFFON:** Right. I'd have to look at
18 the exact language, but I mean, I think that -
19 -

20 **MS. MUNN:** I don't think that the law gives
21 us that prerogative, Mark. I really don't.

22 **MR. GRIFFON:** The law doesn't give us what
23 prerogative?

24 **MS. MUNN:** The prerogative to weight these
25 kinds of issues that go outside the standards

1 that currently exist.

2 **MR. GRIFFON:** What standards? This is ICRP.
3 I mean, it's raised in ICRP --

4 **DR. ZIEMER:** But we --

5 **MR. GRIFFON:** -- papers in here that do make
6 some conclusions. NIOSH is determining that
7 all the literature basically is, there's no
8 trend or there's no, you know, I think that's
9 what the conclusion is. But I don't know that
10 we've examined that or talked about that. I
11 mean, I'm looking at the most recent one I
12 could find was a '93 Kathryn paper which is
13 referenced in there which is sort of
14 suggesting some modifications to the
15 biokinetic model. I'm reading while we're on
16 the phone here.

17 So I don't know why we can't at least
18 put that as a, you know, it seems like we're
19 consistent, you know, ICRP is saying that
20 there could be an effect here, a concern with
21 smoking and lymph nodes, but currently they
22 have no suggestion, but we're going to put it
23 in the long term, you know, we're going to
24 further look at that in long term science
25 issues.

1 **DR. NETON:** Mark, this is Jim. I have no
2 problem saying that this is a long-term issue
3 that we should keep aware of.

4 **MR. GRIFFON:** Okay, maybe we're saying the
5 same thing.

6 **DR. MAURO:** Yeah, I think we're in agreement
7 on this.

8 **DR. NETON:** I would not argue that we
9 shouldn't be concerned about it. I was just
10 trying to make the point that at this point in
11 time we have no consensus scientific opinion
12 on this issue that we can hang our hat on.

13 **MR. GRIFFON:** I guess the one question I
14 had, Jim, was do we have anything that says
15 that your current approach where you didn't do
16 any weighting sort of will bound any of the --

17 **DR. NETON:** Oh, absolutely.

18 **MR. GRIFFON:** -- most conservative factors
19 being found in some of these studies such as
20 Kathryn. I mean, --

21 **DR. NETON:** I think that's probably, that's
22 something that's going to likely happen. This
23 weighting thing all started when we tried to
24 develop a model for CLL. And we actually are
25 working on this weighted model right now. And

1 once that's done, it'd be easy to make that
2 comparison.

3 **MR. GRIFFON:** I think that would be
4 worthwhile just to have on paper. It
5 certainly shows that you're aware of the
6 current literature. You've considered it, and
7 you still believe your calculations are
8 bounding. I mean, I think that's good for all
9 of us to have.

10 **DR. NETON:** ^ any of that right now. I
11 guess we were here prepared to discuss this in
12 light of the current PER and the scientific
13 validity of what we've done here.

14 **MR. GRIFFON:** Yeah, that's fine.

15 **DR. NETON:** I do agree. We need to track
16 and keep abreast of all the best science. And
17 if we have to put it on a list, and I get
18 reminded every three months as to my
19 delinquency, that's fine.

20 **MS. MUNN:** Hans and John, will there be any
21 problem in your issuing your revised report
22 well in advance of the Procedures work group
23 next face-to-face meeting toward the end of
24 May?

25 **DR. BEHLING:** Yeah, I mean, there shouldn't

1 be any problem. However, I guess I'm still
2 wondering if, in fact, the audit of at least
3 two or three cases is still something that
4 should be done in light of or in spite of this
5 issue that we resolved this saying we won't
6 question the ICD-9 code or even address the
7 smoking as a variable, but strictly review the
8 assigned doses that in the science based on
9 bioassay data.

10 That is still an independent variable
11 that goes outside the scope of these two
12 issues, smoking or ICD-9 codes. I mean, this
13 could be just another routine dose
14 reconstruction audit that skirts the two
15 issues that we've been discussing for the last
16 hour, but it's nevertheless an audit that may
17 have some potential value especially for POC
18 cases where we're talking about revised POC of
19 let's say between 45 and 50.

20 And now the focus will be on, well,
21 how did the bioassay data contribute to this
22 new assessment. This is going to be just like
23 any other dose reconstruction except we're now
24 dealing with lymphoma. I mean, you could look
25 at this as two dose reconstruction audits or

1 three dose reconstruction audits that are
2 very, very similar to the other ones that we
3 do under Task Four.

4 **DR. MAURO:** And those can be picked, I
5 guess, without this, see, the trouble we ran
6 into is that we were trying to pick ones that
7 would test the two issues that we were
8 concerned with. Since those issues are off
9 the table, we simply now have to, I guess,
10 demonstrate that this process was, in fact,
11 implemented on these three cases. I don't
12 know how we would pick it, maybe just
13 randomly.

14 **DR. BEHLING:** Yeah --

15 **MS. MUNN:** That was the first big word that
16 I wrote on my notepad here when we were
17 discussing it an hour ago, random, question
18 mark, and why not.

19 **MR. HINNEFELD:** This is Stu Hinnefeld. If
20 you're interested in cases where the new POC
21 approaches 50 percent, why don't we just run
22 the top ten, the ten cases that are still not
23 compensable after rework that are available
24 for review by the Board, sets ten of 250, and
25 take the ten that have the highest new POC,

1 and you can select the three you want.

2 **DR. MAURO:** Send them over.

3 **DR. BEHLING:** The point here would be
4 strictly to assess the assigned dose to the
5 either thoracic or extrathoracic lymph nodes
6 but evaluate the use of bioassay data that
7 gave rise to that number.

8 **MR. GRIFFON:** Sounds good, yes.

9 **DR. MAURO:** Yeah, straightforward, it's a
10 standard dose reconstruction audit. That's
11 what it comes down to without these other
12 issues at play.

13 **DR. BEHLING:** Yes, we will assert the issue
14 of smoking and ICD-9.

15 **DR. MAURO:** Of course, you know we're going
16 to be tempted to slip that in, but we won't do
17 that. Please send us those ten cases, and
18 we'll go ahead. And is it okay with the
19 working group for us to just go ahead and pick
20 the three we like, or would you like to pick
21 those?

22 **DR. ZIEMER:** It seems to me we should pick
23 them like we do the others if we're going to
24 do it.

25 **DR. MAURO:** That's fine.

1 **MS. MUNN:** I think this is good.

2 **MR. ELLIOTT:** We will issue the top ten
3 cases as Stu has described. I think this is
4 appropriate. This goes to the implementation
5 aspect that I spoke about a moment ago.

6 **DR. BEHLING:** And the reason I brought it up
7 --

8 **DR. ZIEMER:** And once you do that then you
9 can issue your revised report that will
10 include what you did there.

11 **DR. MAURO:** Yes, we'll revise the report --

12 **DR. BRANCHE:** Excuse me. Excuse me. Ladies
13 and gentlemen, I know how excited you are, but
14 this is like the third time you all are
15 talking over each other. It makes for a
16 really bad transcript. Thanks.

17 **MR. ELLIOTT:** Do you want us to send the ten
18 cases to the working group and let them select
19 or do you want us to send it to everybody and
20 you guys decide who you want to select?

21 **MS. MUNN:** Send it to the working group.
22 We'll set up a very quick teleconference, and
23 we'll choose three.

24 **MR. ELLIOTT:** Thank you.

25 **MS. MUNN:** And we'll get those three to Hans

1 and to John.

2 **DR. BEHLING:** And just to answer your
3 question which precipitated this discussion in
4 the last few minutes, the timing. If we were
5 to exclude any dose reconstruction audits, May
6 would be, obviously, I'd do it within a matter
7 of days. On the other hand if there are, if
8 this revised draft is to also address the
9 issue of audits, then I think the time scale
10 may have to be expanded a bit depending on
11 when we get those cases and how soon we will
12 be in a position to review those.

13 **MS. MUNN:** Then, Stu, what do you see as the
14 timeframe for your pulling those ten and
15 getting them to us?

16 **MR. HINNEFELD:** We'll probably ask ORAU for
17 the pieces of information that are not data
18 based. And it's going to take a custom query
19 to build the table for the cases, for the
20 information that is data based. So I think it
21 might be a couple weeks or so, maybe --

22 **DR. MAURO:** How about a two-step process,
23 Wanda? We could put out a revised report that
24 gets to the delicate issues that we've been
25 talking about. You'll have it in your hands,

1 and my guess is it may take a couple of
2 iterations to get that down.

3 **MS. MUNN:** I would imagine so.

4 **DR. MAURO:** Yeah, and I'd like to get that
5 right because of its sensitivity for the
6 reasons that Larry clearly articulated. It is
7 important that we get this language correct.
8 And once we have that in place, that's going
9 to be the important document that -- and right
10 behind that some place along the line, of
11 course, we'll get started on -- I would not
12 want to hold that up because we want to work
13 on the three cases. We'll supplement the
14 report expeditiously as soon as the three
15 cases are completed. But I think getting that
16 first one out is going to be important.

17 **MS. MUNN:** That's a wise observation.

18 **DR. BEHLING:** So we're on for May to get the
19 revision to this draft. And then however soon
20 we can get to complete the dose reconstruction
21 audits, we'll add those to the report.

22 **MS. MUNN:** Yes, we're set for, I believe,
23 May 20th for our next face-to-face in
24 Cincinnati.

25 **DR. BRANCHE:** That is correct.

1 **MS. MUNN:** Which would be a good time to
2 address this. I'm hoping to be able to be
3 there. I'm going to be having some surgery
4 right after this Tampa meeting, and they're
5 giving me another shoulder. I don't know
6 whether they're going to let my shoulder
7 travel by then or not, but May 20 is the day
8 we set. So if it's going to be possible for
9 you to get a revision to us ten days or so
10 before that, John, it would be very helpful.

11 **DR. ZIEMER:** And remember, I won't be at
12 that meeting in Cincinnati, but I would be
13 there by phone.

14 **MS. MUNN:** Good, okay.

15 **DR. BEHLING:** So May 10th should be my target
16 date.

17 **MS. MUNN:** If that's possible. If that's
18 not --

19 **DR. ZIEMER:** Is it the tenth or 20th? Oh,
20 ten days before. Okay.

21 **DR. MAURO:** May 10th, so that's our marching
22 orders. May 10th, now, May 10th would be, what
23 I'm getting at is though it sounds like that
24 this document though is going to go through
25 some type of process. And is it the May 10th

1 version that you would like to see having gone
2 through the process whereby I would say us,
3 with Larry and perhaps the working group
4 having a chance to work it through? In other
5 words right now we're talking, today's what,
6 April 2nd? That's five weeks from now.

7 Hans, is this something we could put
8 out within two weeks, get it into Larry's
9 hands, get it into the working group's hands,
10 Christine's hands so that they can see the
11 language, the tone? And then we can maybe
12 even go through an iteration before we
13 actually have what I would call our official
14 May 10th deliverable.

15 **DR. BEHLING:** Well, from my point of view
16 it's a matter of spending a few hours of
17 wordsmithing, but it's a question of how, you
18 know, how diplomatic is my rewrite that will
19 be acceptable to Larry and whoever else would
20 be in line for the review. We may argue a bit
21 here and there.

22 **DR. MAURO:** That's why I'm saying, I don't
23 this is going to be a difficult thing to do in
24 terms of us putting together the next straw
25 man.

1 **DR. BEHLING:** No, and we spent an ample
2 amount of time discussing why NIOSH is not
3 responsible for the assignment of ICD-9 codes,
4 and that smoking is an issue that is complex
5 but without the documentation and scientific
6 literature. I mean, this is not going to take
7 me very long.

8 **DR. MAURO:** Wanda, how about we get it to
9 you in a week, and we get it to Larry in a
10 week?

11 **MS. MUNN:** That would be wonderful.

12 **DR. MAURO:** We'll get it to you in a week.
13 We'll all have a chance to chew on it a little
14 bit and do it again, and maybe even do it
15 again. And by the time the tenth comes --

16 **DR. ZIEMER:** We'll be in Tampa in a week so
17 --

18 **DR. MAURO:** -- oh, yeah, that's right. I
19 forgot, two weeks. How about we get it to you
20 within two weeks? That would give us two more
21 weeks to fool with it and make sure we get it
22 polished up so that on the tenth we've got
23 ourselves a draft that we're feeling pretty
24 good about.

25 **MS. MUNN:** That would be terrific.

1 **DR. MAURO:** Very good, very good.

2 **MS. MUNN:** That would be great. We'll look
3 forward to that.

4 So we're all on that page? We're all
5 happy with what we're doing with the PER-9
6 issue?

7 **DR. ZIEMER:** Right.

8 **MS. MUNN:** All right, very good.

9 **OVERVIEW OF THE FIRST SET OF 33 PROCEDURES**

10 Next topic, the rework that Steve
11 Marschke got to us on the overview of the
12 first set of 33 procedures. Steve, you're
13 still on?

14 **MR. MARSCHKE:** I'm here, yes.

15 **MS. MUNN:** Good. My apologies for not
16 getting my comments back to you and to Paul
17 and Kathy. I think you've covered just about
18 the waterfront here. It's what you sent is
19 not in the format that I would prefer to see
20 it. I still would prefer to see a very brief
21 text, all of which you have here, but with
22 most of the tables not as a part of the text.

23 If we can all stand the time element
24 involved, I would like to have an opportunity
25 to do a little cut and paste job of my own and

1 send it to you and Paul and Kathy for your
2 sort of overview as to whether or not you
3 think that's closer to what I had in mind --
4 it'll be closer to what I had in my mind. I
5 don't know whether it'll be closer to what
6 Paul had in mind or not. But if you would
7 allow me to do that, I would certainly
8 appreciate it.

9 For one thing, for example, I'd like
10 to remove the review criteria and findings up
11 into the part of your text that ends the first
12 two paragraphs on page three. I'd like the
13 criteria and findings to be up front. And
14 then the contractor findings and status of
15 findings that follow that can be, can easily
16 encompass all of the material that needed to
17 be done which removes a lot of the overview
18 material back under paragraph four because
19 we've already done it up front in the other
20 table.

21 I think it will work just fine with a
22 slight change in table or back at the back the
23 one that we discussed in our e-mails earlier.
24 We talked about how many columns should be
25 added. At least Kathy and I, I assume you

1 were privy to that, about how many went under
2 Table 4. And I think if we expand Table 4
3 just a little bit, put it in landscape format
4 instead of portrait format, we can include the
5 titles of the procedures reviewed.

6 And that would be everything everybody
7 ever wanted to know right there in those two
8 tables. They cover almost everything that's
9 been done in this first set I think. I'll let
10 you take a look at that after I put it
11 together and will try to get that to you as
12 soon as I can. I'm traveling right now and
13 don't have access to the kind of equipment
14 that I really need, but I think perhaps I can
15 do that.

16 Is that all right with you, Paul?

17 **DR. ZIEMER:** Yeah, that'll be fine.

18 **MS. MUNN:** Is that all right with the rest
19 of the group?

20 **MS. BEHLING:** Wanda, this is Kathy Behling.
21 I just wanted to, excuse me just a minute
22 because Steve was unable to be on the last
23 conference call so I tried to incorporate the
24 changes and apologize if I didn't capture
25 everyone's suggestions. So Steve is not to

1 blame for any of the changes that were made,
2 and I'm sure he's certainly in agreement with
3 seeing any changes that you would like to
4 incorporate.

5 **MS. MUNN:** Well, if it's not going to hold
6 up the wagon too much, I'll do that.

7 **DR. MAURO:** This is John. I really
8 appreciate that. That really helps. We can
9 really get your direct perspective. That will
10 be very helpful to us in finalizing this.

11 **MS. BEHLING:** And actually, the other thing
12 I want to make mention of is because this was
13 a report that we're sending to you, I
14 obviously realize you would not probably want
15 this format with the disclaimers and that kind
16 of thing. Because currently it's a discussion
17 piece that we're having between SC&A and the
18 work group and NIOSH, but obviously this will
19 be a report from the Board to the Secretary of
20 HHS. And so it won't have the look and the
21 format that is typical for SC&A. I just
22 included that for this working piece during
23 our discussions here.

24 **MS. MUNN:** I understand that, and I
25 appreciate it. As I said, I think everything

1 we need is here. It's just a preference with
2 respect to how it's presented I think.

3 Mark?

4 **MR. GRIFFON:** Yeah, I'm still on. I'm not
5 too worried about format, Wanda, so that's
6 fine.

7 **MS. MUNN:** Okay, that's fine.

8 Mike, any problems?

9 **MR. GIBSON:** No, that's fine.

10 **MS. MUNN:** Okay, very good. I'll try to get
11 that to you hopefully before we go to Tampa,
12 but I'm not at all sure.

13 **DR. ZIEMER:** There's not much time left.
14 You can bring it with you if you want.

15 **MS. MUNN:** Yeah, that's one of the things we
16 probably will end up doing.

17 **DR. ZIEMER:** I won't have a chance to do
18 more on it before I leave anyway.

19 **MS. MUNN:** All right, then we won't feel
20 like that's a big pressure thing, but I will
21 try to get it to you.

22 I do not have on my list of action
23 items that I have from our last meeting, I
24 don't believe that I have anything that we
25 were required to touch on before our PER-9

1 discussion --

2 **DR. BRANCHE:** Wanda, do you hear the music?

3 **DR. ZIEMER:** Yeah, I hear it.

4 **MS. MUNN:** I do hear the music. Somebody's
5 put us on hold.

6 **DR. BRANCHE:** Yes, they have.

7 **MS. MUNN:** So we're hearing the symphony.

8 But is any other member of the work
9 group aware of outstanding information that we
10 had indicated we needed before the Tampa
11 meeting?

12 **DR. ZIEMER:** I don't believe so.

13 **MS. MUNN:** I don't think so, and I didn't
14 have any list unless someone else has some
15 action item that I failed to record.

16 (no response)

17 **MS. MUNN:** That's fine. Then --

18 **MR. GRIFFON:** Wanda, one question. Where do
19 we stand on the discussion of the CATI
20 procedure review? I think it's 90, 92, one of
21 those.

22 **MS. MUNN:** Ninety-two. We're going to use
23 the new matrix to report on it at the next
24 meeting which is, I'm not sure whether I meant
25 Tampa. I don't think we did.

1 Kathy can you help me remember what we
2 were, what I meant when I said we were going
3 to use PROC-0092, the new matrix, to report
4 where we are at the next meeting?

5 **MS. BEHLING:** Yeah --

6 **DR. ZIEMER:** You were going to report on the
7 nature of the matrix for the full Board.

8 **MS. MUNN:** Yes, I know. That's one of the
9 things I want to, when we finish here, want to
10 very quickly ask Kathy to stay on for a minute
11 and Christine to stay on for a minute while we
12 talk about that for just a minute.

13 But, Kathy, were you planning on using
14 PROC-0092 then as part of your presentation?

15 **MS. BEHLING:** No, I wasn't. I was simply
16 going to give an overview of the matrix, what
17 we're capturing, trying to show to the other
18 Board members just so they have an
19 understanding of. If they also want to have a
20 similar matrix database put together for a
21 matrix for their work group, I think it's
22 probably a good idea, and it's as we discussed
23 --

24 **MR. GRIFFON:** So, Wanda --

25 **MS. MUNN:** So when I said at next meeting,

1 in my mind I was saying at our next meeting in
2 May. But I just wanted to make sure that from
3 what Mark had just asked that I was not
4 misinterpreting that.

5 **MS. BEHLING:** That's correct. In fact --

6 **MS. MUNN:** Do you have something else, Mark?

7 **MR. GRIFFON:** No, no, no, I just, you were
8 asking about outstanding actions related to
9 the tracking matrix and stuff more than the
10 individual findings in the resolution of
11 individual findings, correct?

12 **MS. MUNN:** Yes.

13 **MR. GRIFFON:** Okay, then I'll retract my
14 question.

15 **MS. MUNN:** I thought one of the notes that I
16 had underneath it was include three and five
17 as being in abeyance. But I think it's a May
18 item. That's what I'm thinking.

19 **MR. GRIFFON:** All right, thank you.

20 **MS. MUNN:** All right, then I have nothing
21 else other than a conversation I wanted to
22 have with Christine and Kathy. Does anyone
23 else have anything we need to touch on before
24 Tampa?

25 **DR. ZIEMER:** No.

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MS. MUNN: Otherwise I will let everybody go back to work with the exception of Kathy and Christine if you'll two hang on for a moment, then I'll see you all in Tampa next Monday.

DR. BRANCHE: Everyone travel safely.

(Whereupon, the working group meeting was adjourned at 3:00 p.m.)

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I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of April 2, 2008; and it is a true and accurate transcript of the testimony captioned herein.

I further certify that I am neither kin nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 7th day of Dec., 2008.

STEVEN RAY GREEN, CCR, CVR-CM, PNSC**CERTIFIED MERIT COURT REPORTER****CERTIFICATE NUMBER: A-2102**