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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

THIRTY-THIRD MEETING

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

VOL. IV

DAY THREE

ABRWH BOARD MEETING

The verbatim transcript of the
Meeting of the Advisory Board on Radiation and
Worker Health held at the Knoxville Marriott,
Knoxville, Tennessee, on October 19, 2005.

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October 19, 2005

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P R O C E E D I N G S

(8:30 a.m.)

WELCOME AND OPENING COMMENTS

DR. ZIEMER: Well, good morning, everyone. We come to day three of the Knoxville meeting of the Advisory Board on Radiation and Worker Health. We welcome all who are visiting here. And if you haven't already done so, I need to remind you to register your attendance in the booklet out in the foyer.

This morning we're going to direct our attention to two Special Exposure Cohort petitions.

Before we get underway with those, Mr. Wade will -- Dr. Wade will make a couple of comments. Lew.

DR. WADE: Yeah, just as the mood strikes me, I'll speak. I'd like to just pause and reflect on what a positive meeting we've had to this point, and I think some thanks are in order. I think there are thanks due to the Board for its willingness to put in long hours of not only meeting time but preparation. I'd also like to thank NIOSH and SC&A for their willingness to engage in sometimes very difficult give and take on scientific issues. I think the level,

1 though, of professionalism that's been attained
2 speaks well to the parties involved. I think
3 it also serves the petitioners and the
4 claimants very well. So I think there's an
5 awful lot to feel good about, and I thank you
6 all for that and look forward to today.

7 **DR. ZIEMER:** Okay. Thank you very much, Lew,
8 for those comments.

9 **NBS SEC:**

10 As we get underway here we have two -- two SEC
11 petitions, one involving what was then the
12 National Bureau of Standards, an agency which
13 does not exist under that name any longer; and
14 then the other one is Linde Ceramics. And I
15 think to begin with we'll call on Mr. Elliott
16 from NIOSH to kind of kick off the discussion
17 here for us and then we'll go directly into the
18 petition.

19 **MR. ELLIOTT:** Thank you, Mr. Chairman. As a
20 way of introduction for these two SEC petition
21 evaluation reports, let me open with -- one of
22 these is labeled as an 8314. Well, they're
23 both 8314. In both cases, the National Bureau
24 of Standards and the early years at Linde,
25 we've identified that we could not do dose

1 reconstruction, and you'll hear that from Dr.
2 Neton and Mr. Hinnefeld as they present those
3 evaluation reports to you.

4 With regard to the National Bureau of
5 Standards, there are some deliberations going
6 on about this particular site and its listing
7 as a covered facility. So those deliberations
8 are going on as you take this up in your
9 deliberation in this forum. The Department of
10 Labor and the Department of Energy are
11 currently -- have evaluated whether it should
12 be presented as a covered site on the list of
13 covered facilities. It was inaccurately listed
14 as an AWE, atomic weapons employer, facility.
15 And as you can, I think, logically understand,
16 it's a -- it was part of the Department of
17 Commerce. It was a federal agency. It still
18 is a federal agency with a different name, and
19 the building that they worked in was a federal
20 building. So DOE and DOL are working through
21 trying to determine how this site either fits
22 in or does not fit in as a covered facility.
23 I was notified last week by the Department of
24 Labor that this issue existed. The site has
25 been listed from the very start as a covered

1 facility as an AWE. There's been an ongoing
2 review of the covered facility lists by the
3 Department of Energy in conjunction with
4 (unintelligible) supporting interpretation and
5 input by the Department of Labor for a number
6 of sites, like arsenals, that are under review
7 to either be de-listed or remain on the list.
8 I can't answer any questions more than that.
9 Mrs. Virginia Bond is here as the petitioner
10 for the National Bureau of Standards, and
11 you'll hear her presentation. Mr. Jeff Kotsch
12 is here from the Department of Labor and he is
13 here willing, I think and hope, to answer any
14 questions you might have on the current status.
15 There is a process of establishing this covered
16 facility list. That is the responsibility of
17 the Department of Energy. Department of Labor
18 has some -- some interest in that and they also
19 have some oversight and some responsibilities,
20 as well, as far as the time frame of the
21 covered periods. Right now it's my
22 understanding there is -- a *Federal Register*
23 notice has to be published by the Department of
24 Energy to de-list a site. I understand and
25 I've seen -- I understand that DOL has that

1 *Federal Register* notice draft from DOE and are
2 reviewing it and preparing comments on it.
3 It's not clear to me -- I do not have an
4 understanding of when that will be published --
5 that *Federal Register* notice will be published
6 and when the action -- and what the action will
7 be in the end. So I would just encourage you
8 to hear out the evaluation report, hear out the
9 petitioner, have your deliberation and make
10 your decision, and we'll take it from there.

11 **DR. ZIEMER:** Thank you, Larry, and I -- I think
12 what -- then what you're telling us is that the
13 status of this site we should in a sense not
14 pay attention to in our deliberations. Right
15 now it is a listed site and we can proceed on
16 that basis to make a determination, that our
17 determination probably should not be influenced
18 by whether or not we think it will or will not
19 remain on the list. Is that correct?

20 **MR. ELLIOTT:** That is correct. That's my
21 understanding. We have no formal notification
22 to provide you that this site has been de-
23 listed, so we --

24 **DR. ZIEMER:** Right, so (unintelligible) is on
25 the list, this is a valid petition --

1 on Saturday or such, but they are -- they are
2 here.

3 It's my pleasure to present to you NIOSH's
4 evaluation of an SEC petition we received from
5 the National Bureau of Standards. The Board
6 has seen a number of these petition evaluation
7 reports by now, so the format that you'll see
8 has become somewhat standard, and you should be
9 familiar with the flow of the information as I
10 present it.

11 This petition was submitted to NIOSH on behalf
12 of a class of employees. It was SEC petition
13 number 0034. It was received for evaluation by
14 NIOSH on May 9th of this year. The definition
15 of the proposed class was all physicists that
16 worked at the National Bureau of Standards
17 which, as Dr. Ziemer pointed out, is now known
18 as the National Institute of Standards and
19 Technology -- all physicists who worked in the
20 Radioactivity Lab in the East Building, and
21 specifically the East Building is located on
22 Van Ness Street in Washington, D.C. And the
23 proposed covered employment period was from
24 1943 through 1952.

25 As you know, once a petition meets certain

1 criteria that are defined in our regulation, it
2 has to be qualified. A petition, when it comes
3 in, has to meet certain qualification
4 parameters. And just in general, to remind
5 you, those are -- a couple of those key
6 parameters are the petitioner must be a member
7 of the proposed class or they must -- it must
8 be a labor organization representing that class
9 or must be -- a person's authorized to speak on
10 behalf of that class. And also the proposed
11 class definition needs to be provided, and the
12 basis for their belief that the records are
13 inadequate to estimate dose.

14 We looked at all those in the context of this
15 petition, and it was qualified by NIOSH on June
16 27th of this year. Again, in accordance with
17 the flow and the regulations, this is sort of a
18 process description of where we ended up, we're
19 required to notify the petitioner and publish a
20 notice in the *Federal Register*, which occurred
21 on July 14th.

22 NIOSH is required then to take that qualified
23 petition and evaluate it against the guidelines
24 in Part 83.13 and provide a summary report to
25 the Advisory Board of our findings. That

1 report was sent to the petitioners on the 14th
2 of September, and also provided to the Advisory
3 Board on that same date.

4 As part of the evaluation process, of course,
5 you're all familiar with this so-called two-
6 pronged test now. There's two -- two tests
7 that need to be passed for a petition to be
8 granted. One is, is it feasible to estimate
9 the level of radiation dose with sufficient
10 accuracy, and that's to individual members of
11 the class. And if we can't estimate with
12 sufficient accuracy any cancer in that group,
13 that says we can't do it with sufficient
14 accuracy. And secondly, if that's true, is
15 there a reasonable likelihood that the
16 radiation dose may have endangered the health
17 of the workers.

18 Let me talk a little bit about the evaluation
19 process, what did NIOSH look at when we were
20 trying to determine if we could reconstruct
21 dose with sufficient accuracy. We identified
22 and reviewed all data sources available to us
23 to look to see if we could come up with any
24 means of bounding -- that is, put an upper
25 limit on the dose received by any of these --

1 member of this proposed class. And in
2 particular we're looking for information such
3 as personnel monitoring data, air monitoring
4 data, radiation source material. That's
5 consistent with our hierarchical approach for
6 doing dose reconstructions. That is, we'll
7 first preferentially look for personnel data.
8 If we believe it to be valid monitoring data,
9 we'll assume that that is the best data we have
10 to reconstruct dose. But then -- our process
11 allows us to look at air monitoring data, area
12 monitoring, TLDs; and third, process; and then
13 source term -- I mean how much material was
14 there.

15 So we search for all of those types of pieces
16 of information in a number of various
17 resources. We looked at the NIOSH dose
18 reconstruction database. We looked at the ORAU
19 research database. We went to the National
20 Institute of Standards and Technology,
21 requested information from their library. Not
22 shown on this slide is we also went and
23 contacted the health physics department that
24 currently exists at the National Institute of
25 Standards and Technology requesting records.

1 We spoke to the chief health physicist of the
2 staff. And the bottom line is we could not
3 find any monitoring records for any of these
4 sources that would indicate the levels of --
5 potential levels of exposure to these workers.
6 I have to qualify that a little bit. I'm
7 getting ahead of myself a little bit. There --
8 there is some decontamination survey
9 information I'll speak to later.

10 I might say that the dose reconstruction
11 database -- normally what we would do is look
12 for individuals who have filed a claim, and
13 then we have in our possession where we're
14 attempting to do dose reconstruction. In this
15 particular instance we only have one claim that
16 fits this class definition. We've looked
17 through the data in that claim, and again we
18 could find no information that was informative
19 about the types of radiation exposures incurred
20 by members of this class.

21 The dose reconstruction database, again, I just
22 mentioned that. We looked for evidence of
23 internal/external records, any personal
24 monitoring data, and none were found, so that
25 was not useful to us.

1 Then we looked at a site research database.
2 Site research databases, as the Board knows, we
3 -- we travel -- ORAU and our -- we have travels
4 around the country searching repositories for
5 records -- known repositories of records for
6 DOE exposure information. And in that context,
7 we identified seven documents that were
8 relevant to the National Bureau of Standards.
9 But these documents were sparse. They had
10 histories of activities performed. In other
11 words, we could tell that there was an
12 analytical laboratory. They analyzed samples,
13 worked with radium, kind of got a feel for the
14 types of materials they worked with, but no
15 real evidence of any type of air samples or
16 personnel monitoring devices or even the
17 relative total magnitude of the source term
18 that these folks could have been exposed to.
19 Of note, though, and I just mentioned this
20 briefly before, is that there were two surveys
21 related to decontamination -- two documents
22 related to decontamination of this particular
23 facility. One was a 1952 document that spoke
24 to a decontamination that was performed of the
25 laboratory when the National Bureau of

1 Standards moved from Van Ness Street in
2 Washington to Gaithersburg, Maryland.
3 Unfortunately, there was no information related
4 to the types of -- the amount of contamination
5 found. It just alluded to the fact that there
6 was a decontamination performed, so that was
7 not informative other than the fact that there
8 was some contamination present there.
9 The facility was -- they moved out of that
10 facility and four of the rooms were locked, and
11 nothing happened at this facility that we could
12 tell until 1968 when it was being transferred
13 to the District of Columbia for another use.
14 And the District of Columbia and the National
15 Bureau of Standards combined to do a
16 decontamination of the laboratory at that
17 point, 1968. The surveys conducted at that
18 point found evidence of significant
19 contamination in these four rooms that were
20 locked. In addition the contamination was
21 found to have spread down the hallway. It was
22 in the air ducts and the vent fans, and in an
23 auditorium.
24 The levels were fairly significant, as I
25 mentioned. The data were not recorded in

1 disintegrations per minute, but counts per
2 minute. But even at that, I believe that they
3 were in the 100,000 to 200,000 counts per
4 minute -- very, very significant levels of
5 contamination. The exposure rates ranged as
6 high as 20 MR per hour in some of these rooms,
7 and radon levels were measured in the vicinity
8 of around 8 picocuries per liter.
9 Most of this -- although I don't think that the
10 contamination surveys spoke to the contaminant
11 itself, it's -- it can be inferred pretty
12 easily that most of this is probably related to
13 radium because of the high radon levels, the
14 gamma doses and the high levels of alpha
15 contamination. The National Bureau of
16 Standards, during this time period, was
17 responsible for handling medical sources of
18 radium and -- and calibrating them and working
19 with those sources.
20 Again, we contacted this library and this one
21 document that was found was applicable to the
22 class, but again, it had no -- no information
23 relative -- relevant to reconstructing doses or
24 putting upper bounds on them.
25 The petitioner supplied a number of documents

1 and affidavits -- one affidavit and a number of
2 documents, I believe. In total there were 55
3 documents provided; 40 of these documents were
4 mostly related to newspaper accounts,
5 descriptions of processes, were not really
6 necessarily informative about the site.
7 Fourteen of them, though, spoke to process --
8 you know, what happened there, what type of
9 materials. But again, nothing related to
10 exposure information, nothing that could be
11 used for -- nothing of exposure information
12 that could be used to reconstruct doses.
13 So based on the discussion we just had, the
14 evaluation report was revised, because we felt
15 that since this contamination was significant
16 and had spread outside the laboratories where
17 the physicists would be working, we revised the
18 class definition to say -- to cover all atomic
19 weapons employees who worked in the building
20 number two at the NBS facility on Van Ness
21 Street. We just felt that we couldn't parse
22 the information sufficiently to make -- to
23 determine whether it was physicists or anyone -
24 - because the hallway was contaminated, the
25 laboratory was contaminated, the exhaust fans

1 were contaminated.

2 This speaks a little more to the process

3 description of what -- what the National Bureau

4 of Standards worked with. A number of

5 radiological activities were performed there in

6 support of pilot studies for uranium

7 processing; many measurements related to

8 identifying, quantifying, purifying uranium.

9 They were developing techniques for the thermal

10 diffusion and separation of isotopes of

11 uranium. There's evidence of thorium handling.

12 We do have an indication that they were

13 authorized to possess around five pounds of

14 thorium, which is a significant source term of

15 thorium, if any of you are familiar with the

16 health physics practices of thorium.

17 They developed a number of analytical

18 procedures -- quality control measurements,

19 that sort of thing. I had mentioned that these

20 radium standards were probably responsible for

21 the widespread contamination of the facility.

22 These standards were shipped in ampules in the

23 early days of development of sealed sources.

24 There's an affidavit I think that discussed

25 these sources' actual rupturing, the buildup of

1 the gas pressures. These are very hot medical
2 type sources -- the sources' rupturing, and in
3 fact there is one account of the physicist
4 venting these sources outside the laboratory
5 window, which could account for it being
6 redistributed within the laboratory.

7 The other thing of note is these activities
8 were highly confidential and secret during
9 their early days of the pre-war. Workers were
10 not informed of the types of materials they
11 were working with. It was sort of on a need-
12 to-know basis. And in fact, the streets around
13 the NBS facility during this time period were
14 completely cordoned off and blocked from public
15 access.

16 So our conclusion is that we lack sufficient
17 monitoring, process or source information to
18 estimate internal or external doses to this
19 class of employees. We have no film badge
20 data.

21 I did mention -- I forgot to mention that there
22 was a potential source term for neutron
23 exposures. The NBS was involved in developing
24 -- ironically enough -- guidance for protection
25 against neutron exposures during this time

1 period. So if they're working with neutron
2 exposures, we have no information as to what
3 the levels may have been to these workers. So
4 again, we lack monitoring, process or source
5 information to do internal or external doses to
6 the class. And again, we find substantial
7 evidence that the contamination had spread
8 beyond the radiological laboratories.
9 Regarding health endangerment, again, we cannot
10 reconstruct dose. The key issue here then is
11 were these acute, high level exposures that
12 could have occurred such as in a nuclear
13 criticality accident, or were these indeed
14 chronic exposures to radiation over a period of
15 time. Based on our review of what processes
16 and what -- what the practices were with
17 handling these sources, we believe they
18 accumulated substantial chronic exposures to
19 episodic intakes so that in fact the 250-day
20 aggregate requirement for determining health
21 endangerment would apply in this case.
22 So again, the proposed class is all atomic
23 weapons employees working in building two at
24 the National Bureau of Standards on Van Ness
25 Street for the period 1943 to '52. And our

1 final slide is it's infeasible for us to
2 reconstruct doses at these facilities and health
3 was endangered.

4 And that's my -- end of my formal remarks.

5 **DR. ZIEMER:** Thank you, Jim. Larry, you have
6 additional comments on --

7 **MR. ELLIOTT:** I would, just before the Board
8 starts its -- any questions about this, I'd go
9 back to this last -- this slide on the proposed
10 class definition. We're going to have to
11 change our evaluation report, and I would
12 suggest that anything that comes forward from
13 the Board not use atomic weapons employee, use
14 National Bureau of Standards employee, because
15 this is obviously not an AWE, but we -- you
16 know, you want to I think correct your definition
17 correctly here.

18 **DR. ZIEMER:** So in that slide and in related
19 documentation, instead of the words "atomic
20 weapons employees who worked at building two"
21 it would be "NBS employees who worked at
22 building two" -- is that what you're --
23 everybody catch that one? Thank you.

24 Let me ask, Board members, do you have any
25 questions for Dr. Neton on this evaluation?

1 (No responses)

2 **PETITIONER PRESENTATION, MRS. VIRGINIA BOND**

3 Thank you. Next we will hear from the
4 petitioners. We're pleased to have Virginia
5 and John Bond here today -- welcome. And
6 Virginia, you may take the podium and make your
7 presentation.

8 **MS. BOND:** Good morning, Dr. Ziemer and members
9 of the Board. I want to thank you for allowing
10 me to appear before you personally to request
11 your approval of Special Exposure Cohort status
12 for the National Bureau of Standards site.

13 My name is Virginia Bond. My husband John and
14 I have traveled from our home in Mill Creek,
15 Washington so that I can speak as the personal
16 representative of my mom, Elizabeth L. Brown.
17 She is the surviving spouse of my dad, Burrell
18 W. Brown, Sr. My brother Burrell W. Brown, Jr.
19 would have joined us today, but since our
20 mother is 91 we make a point not to ever be out
21 of the area at the same time. He and my mother
22 are listening by telephone this morning, as are
23 many family members, friends and supporters.
24 Thank you for making that service available.
25 A little over a week ago I began drafting this

1 presentation. I understood that I needed to
2 explain to you the history of the site, what my
3 father did there, and why I felt NIOSH could
4 not reconstruct the dose. I dragged out the
5 many boxes I've collected over the years and
6 started sorting through the papers. Which
7 ones, I pondered, will convince the Board to
8 agree with NIOSH's assessment and to recommend
9 that the National Bureau of Standards become a
10 member of the Special Exposure Cohort.
11 I will get to that in a few minutes, but first
12 I must address what I consider to be a
13 completely despicable maneuver on the part of
14 the Department of Energy and the Department of
15 Labor. You've heard a little about this
16 already.
17 Last Wednesday Mr. Larry Elliott informed me
18 that DOL had requested that this petition be
19 taken off today's agenda. The reason they
20 wanted it removed was the Department of Energy
21 decided that the Bureau of Standards never
22 should have been approved as a covered facility
23 in the first place.
24 The National Bureau of Standards has been on
25 the list as a covered facility for over four

1 years. The Department of Labor accepted the
2 claims four years ago and forwarded them to
3 NIOSH for dose reconstruction. One week before
4 your deliberations on this petition these two
5 agencies decided to correct their mistake.
6 This appears to be similar to what the
7 Department of Energy did with the Iowa Army
8 Ammunition Plant (IAAP) petition.
9 Members of the Board, this action is cruel and
10 unconscionable. The reason the Department of
11 Energy has decided to de-list the Bureau of
12 Standards is because it is a U.S. government
13 agency, and the law exempts employees of
14 certain U.S. governm-- government agencies from
15 this compensation program. This does not seem
16 quite fair or just.
17 A compassionate Congress passed EEOICPA to
18 correct the past wrongs of nuclear weapons
19 production. My father, Burrell W. Brown, Sr.,
20 was involved in the development of the first
21 atomic bomb. He died a horrible death as a
22 result of working with radioactive materials
23 without protective gear, let alone health
24 monitoring.
25 My dad worked in the Radioactivity Lab of the

1 National Bureau of Standards from 1931 until
2 May of 1948. He was only 20 years old when he
3 started his career with the Bureau of
4 Standards. There are many records available
5 that identify the National Bureau of Standards
6 as being a crucial part of the Manhattan
7 Project. As the documents I have submitted and
8 the research done by NIOSH clearly proves,
9 there is no doubt that the Bureau of Standards
10 employees were exposed to high levels of AEC
11 and DOE radioactive materials relevant to
12 nuclear weapons production.

13 The documents listing the levels of radiation
14 found in the National Bureau of Standards
15 buildings are in the packets I supplied today.
16 I think you will be shocked at the levels. In
17 addition to those records, included in my SEC
18 petition is an affidavit from Dr. Rosalind
19 Mendell, who worked in the Radioactivity Lab
20 with my dad from 1944 until 1946. I quote Dr.
21 Mendell (Reading) I was hired by Leon Curtiss
22 of the National Bureau of Standards to do work
23 on the alpha spectroscopy of "W metal". Such
24 was the degree of secrecy or classification of
25 the Manhattan Project in our area. In

1 principle, I was not kept informed about the
2 nature of my research. I knew that I was
3 working on a project involving artificially-
4 induced fission of uranium only because I knew
5 the energy of alpha particles for U-235 and U-
6 238, because I could see the occasional huge
7 pulses from natural fission of uranium, and
8 because I was measuring the gradual enrichment
9 of U-235 alpha particles relative to those from
10 U-238.

11 You have a copy of her affidavit in her packet,
12 also.

13 I also have a document which I quote.

14 (Reading) Mr. Burrell W. Brown of this section
15 informs me that he holds a low number in the
16 selective service lists and may receive a
17 questionnaire at any time. Mr. Brown is
18 engaged in research on problems in
19 radioactivity concerned with national defense,
20 of a confidential nature, which would be
21 seriously delayed if he were called away for a
22 year. This work involves studies of nuclear
23 fission as a source of atomic energy, and
24 requires the use of highly specialized
25 equipment which he has developed and with which

1 he alone is familiar. It would be difficult to
2 replace him, and it would require at least a
3 year to train a man to attain the desired
4 proficiency in the conduct of these
5 investigations. It therefore appears that the
6 national defense is best served by retaining
7 him in his present work.

8 You also have a copy of this letter in your
9 packet.

10 At the onset of World War II my dad felt called
11 to join the Army. But he was told if he did so
12 he would be stationed right back at the
13 National Bureau of Standards, doing the exact
14 same job, but reduced in rank from his P3 to
15 PFC. Obviously he didn't join the Army.

16 My mother tells of trips with my father to the
17 Radioactivity Lab in the middle of the night to
18 check on experiments. She said at one time he
19 was checking on experiments being done with a
20 garbage can-like container filled with water
21 and positioned on -- there were several of
22 them, positioned on their sides. My dad's
23 responsibilities included being available 24
24 hours a day, seven days a week, to monitor
25 experiments being conducted in his lab.

1 Soon however the level of security was
2 increased, and not only was my mom not allowed
3 on these night trips, but even the streets
4 around the Bureau of Standards were blocked off
5 and traffic was no longer allowed into the
6 secure area. Information on this change is
7 readily available.

8 My father, Burrell W. Brown, Sr., meets the
9 requirements set forth in the EEOICPA statutes.
10 I believe I have proof, and the fact that NIOSH
11 is recommending approval of my SEC proves that
12 they believe, he worked on the Manhattan
13 Project. My dad was exposed to radioactive
14 materials during his work, developed
15 myelofibrosis with myeloid metaplasia, a cancer
16 verified by the Department of Labor as being an
17 approved cancer. NIOSH has now come to the
18 conclusion that they cannot do a dosage
19 reconstruction.

20 I've included many articles in your packet
21 showing that the National Bureau of Standards
22 was an important part of the Manhattan Project.
23 My father's work was seen as so sacred and he
24 was so valuable that he was not allowed to join
25 the Army when the United States entered World

1 War II. Among his treasured memorabilia is a
2 gold pin recognizing his distinguished service
3 to the Department of Energy, DOE. Dr. Leon
4 Curtiss, who was my dad's immediate supervisor
5 and a prominent Manhattan Project leader,
6 delivered the results of my father's work to
7 other scientists in Chicago and Oak Ridge.
8 Some things just don't add up here. It seems
9 to me that there is more to this story that has
10 been kept secret besides the development of the
11 world's first atomic bomb.
12 Additionally I received further information
13 this weekend on the role of the National Bureau
14 of Standards with the Manhattan Project.
15 President Roosevelt approved the formation of a
16 National Defense Research Committee in 1940.
17 This committee was made up of a group of
18 scientists responsible for researching nuclear
19 capabilities for bombs, and thus was a
20 predecessor agency of the Department of Energy.
21 The head of the Uranium Committee was Lyman
22 Briggs, Director of the National Bureau of
23 Standards. In December of 1930 the National
24 Defense Research Committee (NDRC) entered into
25 an agreement with the National Bureau of

1 Standards for the research and development of
2 proximity fuses and other related articles for
3 rockets, bombs, and mortar shells. At the
4 time, the National Bureau of Standards operated
5 one of the premier scientific research
6 facilities in the government on this campus in
7 the District of Columbia. It can be argued
8 that because of this contract the National
9 Bureau of Standards was also a predecessor of
10 the Department of Energy. I would like to
11 elaborate on my father's collaboration over
12 several years with Dr. Leon Curtiss and other
13 well-known scientists. Burrell W. Brown, Sr.
14 not only worked for Dr. Curtiss, he was also a
15 colleague in the publication of scientific
16 research articles related to radiation.
17 Included among them are the following:
18 Curtiss, L.F. and Brown, B.W. (1946). An
19 arrangement with small solid angle for
20 measurement of beta rays. *Journal of Research*
21 *of the National Bureau of Standards*, Volume 37,
22 August 1946.
23 Brown, B.W. and Curtiss, L.F. (1945). Thin-
24 walled aluminum beta-ray tube counters.
25 *Journal of Research of the National Bureau of*

1 *Standards*, Volume 35, August 1945.
2 Curtiss, L.F. and Brown, B.W. (1945).
3 Frequency meter for use with Geiger-Muller
4 Counter. *Journal of Research of the National*
5 *Bureau of Standards*, Volume 34, January 1945.
6 Curtiss, L.F., Astin, A.V., Stockmann, L.L. and
7 Brown, B.W. (1939). Cosmic-ray observations in
8 the stratosphere with high-speed encounters.
9 *Journal of the National Bureau of Standards*,
10 Volume 23, January 1939.
11 Curtiss, L.F., Astin, A.V., Stockmann, L.L. and
12 Brown, B.W. (1939). An improved radio
13 meteorographic (sic) on the Olland principle.
14 *Journal of the National Bureau of Standards*,
15 Volume 22, January 1939.
16 In addition there are pictures and newspaper
17 articles that document my dad's collaboration
18 with Dr. Curtiss. I am holding copies in my
19 hand. If Dr. Curtiss, Astin and Stockmann were
20 integral to the Department of Energy and the
21 Manhattan Project, so indeed was Burrell W.
22 Brown, Sr.
23 These articles and pictures are also included
24 in your packet.
25 It is fitting that I am speaking to you this

1 week. My mom turned 91 yesterday, October
2 18th. She has been a widow for the last 18 and
3 a half years. My dad would have celebrated his
4 95th birthday last Sunday, October 16th. His
5 sisters lived well into their nineties. He
6 should be here today to speak to you. He would
7 have been able to answer your questions. But
8 that is the reason we're here, isn't it? The
9 important role he played in the Manhattan
10 Project and the service he performed for our
11 country cost him his life. Which department
12 signed his paychecks should not be the focus.
13 You, as Board members, have an opportunity and
14 responsibility to help ensure that justice is
15 served in this case. If this claim is not paid
16 due to an oversight, it would be a glaring and
17 inexcusable statement of inequity.
18 I hadn't intended to ask you too many questions
19 today, but I do have a couple that have
20 surfaced because of the actions of the
21 Department of Energy and Department of Labor
22 employees this last week.
23 What happens to my petition and my claim if the
24 National Bureau of Standards is de-listed?
25 What appeal mechanism do I have if my claim is

1 denied due to de-listing of the National Bureau
2 of Standards?

3 How will the DOL adjudicate my claim if the
4 National Bureau of Standards is de-listed?

5 Members of the Board, I respectfully request
6 that you accept NIOSH's recommendation and
7 approve this petition and also recommend to the
8 Secretary of Health and Human Services that the
9 National Bureau of Standards become a member of
10 the Special Exposure Cohort. I also
11 respectfully request that you expedite your
12 decision. Please do not delay your decision
13 based on whether or not the National Bureau of
14 Standards is a covered facility. It was
15 covered four years ago. It was covered when
16 DOL accepted my claim. And it was covered when
17 NIOSH accepted and approved my petition. I ask
18 that you deliberate the merits of this
19 petition, not the eleventh-hour changes by the
20 Department of Energy and the Department of
21 Labor. Thank you.

22 **DR. ZIEMER:** Thank you very much, Virginia, for
23 that presentation.

24 Are there any others that are going to speak
25 for your petition? For example, John, are you

1 -- you're not. Okay, I just wanted to give you
2 that --

3 **MS. BOND:** Oh, no.

4 **DR. ZIEMER:** -- opportunity. Okay, putting him
5 on the spot. If you would remain there just a
6 moment --

7 **MS. BOND:** Oh, sure.

8 **BOARD DISCUSSION AND DECISION**

9 **DR. ZIEMER:** -- I want to ask if -- well, first
10 on the three questions you asked --

11 **MS. BOND:** Yes.

12 **DR. ZIEMER:** -- I don't think I know the answer
13 to those. I doubt if our Board members do, but
14 I'm wondering if either NIOSH or Department of
15 Labor representatives know the answers to what
16 happens to the petition if NBS is de-listed;
17 what appeal mechanism do they have and how
18 would DOE (sic) adjudicate the claim if it's
19 de-listed. I don't know if we know the answers
20 to those today. I think -- you'd certainly
21 hope we don't have to ever know the answers to
22 those, but do we know that information now?

23 **MR. ELLIOTT:** I think DOL has to answer those
24 questions. NIOSH is not responsible for
25 answering those questions in this regard, so I

1 don't --

2 **DR. ZIEMER:** Jeff, you probably don't at this
3 point know the answer, either, but... Jeff is
4 here from DOL.

5 **MR. KOTSCH:** Yeah, Jeff Kotsch, Department of
6 Labor. I -- first of all, I wouldn't know the
7 answer to the first question 'cause I'm not a
8 claims examiner for the case. There is an
9 appeal process for all claimants that allows,
10 at the recommended decision stage if it's
11 denied -- or the -- the claimant has the -- the
12 option to object, present additional evidence
13 that they feel could be used by then the Final
14 Adjudication Branch to review that and -- as
15 they render their final decision, so that's
16 the, you know, standard process for that.
17 And even beyond --

18 **DR. ZIEMER:** Would that apply in such a case as
19 she defined here where --

20 **MR. KOTSCH:** It would apply for all DOL
21 decisions.

22 **DR. ZIEMER:** Okay.

23 **MR. KOTSCH:** So does that -- that at least
24 answers the last two.

25 **DR. ZIEMER:** There is a formal appeal process,

1 though.

2 **MR. KOTSCH:** Yeah, even after the final
3 decision there is a -- there are additional
4 layers of what they call reconsideration or
5 even reopening requests if -- if the claimant
6 were to have additional evidence that they feel
7 still was not addressed. They could bring that
8 forward.

9 **DR. ZIEMER:** So in a sense, that answers two
10 and three here, they both -- there -- there is
11 a process then.

12 **MR. KOTSCH:** Yes.

13 **DR. ZIEMER:** Okay. Thank you. Now let me ask,
14 Board members, do you have any questions for
15 Virginia on this information that's been
16 presented? And you should have in your packet
17 all the documents that were referred to,
18 including the -- the various publications, the
19 newspaper articles and related materials are
20 all there. And we thank you for providing all
21 of that information. Thank you very much.

22 **DR. WADE:** I'd like to speak for the record
23 very briefly, if I could.

24 **DR. ZIEMER:** Yes.

25 **DR. WADE:** Again, I -- I am not authorized to

1 speak for the Department of Labor. I would
2 only offer the observation that, you know,
3 based upon the discussions I've been privy to,
4 I don't think there's any attempt to exclude
5 this claim. I think the agencies, DOL and DOE,
6 are just trying to get their procedures
7 correct, and I'd like that on the record. I
8 think we need to proceed according to the
9 information in front of us, but I wouldn't want
10 the record to -- to not contain at least my
11 belief that this is not an attempt to exclude
12 anyone. It's simply an attempt to make sure
13 the procedures are right and correctly
14 followed.

15 **DR. ZIEMER:** Okay. Thank you. Board members,
16 this petition now is open for discussion or for
17 action.

18 **MR. PRESLEY:** Mr. Chairman?

19 **DR. ZIEMER:** Yes.

20 **MR. PRESLEY:** I would like to take the action
21 that we accept the NBSB (sic) employees who
22 worked in Building 2 at the National Bureau of
23 Standards, Van Ness Street in Washington, D.C.
24 from 1942 through 1952 as an SEC site.

25 **DR. ZIEMER:** Okay --

1 **MS. MUNN:** I second that.

2 **DR. MELIUS:** Yeah, can --

3 **DR. ZIEMER:** Motion made and seconded that the
4 petition be recommended for approval.

5 Discussion? Jim.

6 **DR. MELIUS:** I'd like to offer a friendly
7 amendment --

8 **DR. ZIEMER:** Friendly --

9 **DR. MELIUS:** -- to be a complete -- a little
10 bit more complete motion in the form of a
11 letter in our usual style, if that's --

12 **DR. ZIEMER:** I think this will --

13 **DR. MELIUS:** Well, let me --

14 **DR. ZIEMER:** -- (unintelligible).

15 **DR. MELIUS:** Obviously we can do that, and I
16 was hoping to have copies made already. We had
17 a little technical difficulties getting it
18 transferred, but we should be able to shortly.
19 But let me read this and a lot of this language
20 will be familiar to the other members of the
21 Board who've heard this...

22 (Reading) The Board recommends that the
23 following letter be transmitted to the
24 Secretary of Health and Human Services within
25 21 days. Should the Chair become aware of any

1 issue that, in his judgment, would preclude the
2 transmittal of this letter within that time
3 period, the Board requests that he promptly
4 informs the Board of the delay and the reasons
5 for this delay, and that he immediately works
6 with NIOSH to schedule emergency meeting of the
7 Board to discuss this issue.

8 Letter. (Reading) The Advisory Board on
9 Radiation and Worker Health (the Board) has
10 evaluated SEC Petition 00034 concerning workers
11 in Building Number 2 at the National Bureau of
12 Standards in Washington, D.C. under the
13 statutory requirements established by EEOICPA
14 and incorporated into 42 CFR 83.13(c)(1) and 42
15 CFR Section 83.13(c)(3). The Board
16 respectfully recommends that a Special Exposure
17 Cohort be accorded to all National Bureau of
18 Standards employees who worked in Building
19 Number 2 at this facility from 1943 to 1952 and
20 who were employed for a number of work days
21 aggregating at least 250 work days occurring
22 under this employment or in combination with
23 work days of employment occurring within the
24 parameters, excluding aggregate work
25 requirements established for other classes of

1 employees included in the SEC.

2 This recommendation is based on the following
3 factors:

4 1. These workers were employed at a facility that
5 handled substantial amounts of radioactive
6 materials during the early time period for the
7 production of nuclear weapons.

8 2. NIOSH was unable to find any personal area
9 monitoring data or other data that would be
10 useful for individual dose reconstruction for
11 these workers. However, available data
12 indicate that these workers may have
13 accumulated substantial chronic exposures
14 through episodic intakes of radionuclides
15 (sic), combined with external exposures to
16 gamma, beta, and neutron radiation.
17 Furthermore, radiological contamination in the
18 building extended beyond the laboratories in
19 which the physicists worked.

20 3. NIOSH has determined that the health of
21 employees at this facility may have been
22 endangered by their radiation exposures. The
23 Board concurs.

24 Based on these considerations, the Board
25 recommends that this Special Exposure Cohort

1 (No responses)

2 The Chair senses that there is sentiment to
3 proceed. If so, all in favor of this motion
4 please raise your right hand.

5 (Affirmative responses)

6 Any opposed?

7 (No responses)

8 It appears to be unanimous. No abstentions?

9 (No responses)

10 The motion carries. Thank you very much.

11 Thank you, Virginia.

83.14 SEC:

12 **NIOSH PRESENTATION, MR. STUART HINNEFELD**

13 Next we have Linde Ceramics -- let's see, make
14 sure we -- are we due for a break?

15 **DR. WADE:** No. I would criticize the Board,
16 we're a minute off-schedule now, so work a
17 little harder.

18 **DR. ZIEMER:** Stu Hinnefeld from NIOSH will
19 present the petition evaluation for Linde
20 Ceramics. You should have a hand-out, as well
21 as the evaluation report.

22 **MR. HINNEFELD:** Good morning. At your last
23 meeting in St. Louis I discussed very briefly
24 and handed out a hand-out about procedures to
25 follow when we determine that it's not feasible

1 to do a dose reconstruction. And I said that
2 we hoped to bring a case like that to you at
3 the next meeting, and this is the case. It did
4 work out the way we had hoped, and so we have a
5 case where -- a situation where we have
6 determined that it's not feasible to do dose
7 reconstruction and we've proceeded down the
8 83.14 pathway for SEC determination.

9 The site involved is the Linde Ceramics Plant,
10 and it includes the Tonawanda laboratory. This
11 is the site in Tonawanda, New York -- several
12 buildings associated with that site.

13 I think all of our SEC presentations have to
14 have this two-pronged test slide in here, and I
15 couldn't think of a good place to put it so I
16 put it up front. Jim went through the two-
17 pronged test. We all -- I won't run back
18 through that. We all know what the two-pronged
19 test is.

20 Linde Ceramics Plant refers to several
21 buildings in Tonawanda, New York. They
22 produced uranium materials for Manhattan
23 Engineering District clearly from 1942 through
24 1946. There was a stand-by period that started
25 in the fall of 1946, and then production --

1 some portion of that production resumed in the
2 fall of 1947, around November of 1947. Clearly
3 one of the early uranium production sites that
4 assisted in the War effort.

5 There were actually -- the-- referred to a
6 three-step production process, so the
7 production process is referred to in three
8 steps. They're outlined on this slide. One
9 was to take ore and ore-like feed materials to
10 a U_3O_8 compound. Then to convert the U_3O_8
11 compound to UO_2 , they had to go through UO_3 to
12 get to UO_2 . And then once they had the UO_2 ,
13 then they converted that to UF_4 . All three of
14 these operations -- all three of these
15 processes were in operation from '42 to '46,
16 and research into these -- how to better do
17 these were done at the Tonawanda laboratory
18 during that period, as well. So this was a
19 very -- a varied uranium production facility,
20 and they did handle ore, including African ores
21 which are relatively high in radium -- actually
22 pretty high in radium.

23 Following the shut-down from '46 to '47, when
24 production resumed in 1947 in November, only
25 step three was resumed. So step three

1 continued from '47 to '49. There was a period
2 of time when the plants were essentially
3 cleaned and decontaminated -- that was a multi-
4 year period of time -- for them to be turned
5 over to Linde. These were actually MED-owned
6 plants when they were built. Linde took
7 ownership of them, because they were on their
8 property, in the early '50's. And then there
9 was future FUSRAP remediation in the '70's and
10 '80's. So that's the period of time for the
11 entire site, but we're really here to just talk
12 about the '42 to '47 period.

13 The information available for performing dose
14 reconstructions at Linde is we do have
15 urinalysis on -- we have several samples on a
16 number of workers. Those samples started in
17 November of 1947. Prior to that time we don't
18 find any radiological bioassay.

19 There was an air monitoring program
20 established. This is through HASL and the
21 Environmental Measurements Laboratory -- again,
22 in late 1947 -- where they do time motion
23 studies, time-weighted average, the typical air
24 -- air monitoring analysis that we see from
25 HASL, but that again started in 1947.

1 There are some isolated samples from the
2 earlier period that are -- they seem to be
3 total airborne mass samples. The results are
4 given in milligrams per cubic meter. They're
5 collected on glass tubes. We have a very
6 fragmentary description of the analytical
7 technique, nothing that we're particularly
8 familiar with, and there's not very many of
9 them. And we don't have a lot of confidence
10 that they reflect very well on what exposure
11 may have been during that early period.
12 The work activities that are described in the
13 documents we have available to us, we did the
14 typical document search in arriving at this
15 conclusion that Jim described in his, the data
16 that has been captured by our various data-
17 capture activities and provided by the
18 Department of Energy at the initiation. And
19 whatever we can find, we've -- we've actually
20 got a pretty decent store of information on
21 what they did. We have quite a number of
22 documents we reviewed.
23 We have a pretty good description of
24 activities. There are many, many manual
25 activities. Ore arrived in burlap bags and was

1 stored on-site in burlap bags. People moved
2 things by -- by hand, essentially -- hand-
3 shoveled or hand-troweled or scooped materials
4 into various vessels, hand-scooped materials
5 into oven trays to be heated and in the
6 fluorination furnaces, so there was a lot of
7 manual handling and potential for significant
8 internal exposure.

9 We do have radiation surveys from quite early
10 on, and we -- and they seem to be consistent
11 with a plant of this type and the materials
12 they had there. So we have radiation surveys
13 of external radiation from early on, and then
14 we have some film badge data that actually
15 started later, in the post-'47 period. So we
16 do have some information that we feel provides
17 us some information about potential external
18 exposures during this period.

19 And we actually do have a pretty good
20 description of the medical monitoring program
21 which defined the frequency of -- of exam --
22 medical exam and type of medical exam that
23 should be used to monitor the employees who are
24 going to be working at this plant during the
25 early period.

1 Our process on this was that we gathered this
2 information in our data capture information and
3 various sources in order to prepare a Linde
4 site profile. That profile was completed
5 earlier this year. And based upon the relative
6 lack of information for these 1942 to 1947
7 years, we marked as "reserved" the internal
8 dose portions -- you know, how do you do -- how
9 do you do an internal dose reconstruction for
10 Linde. Those sections are reserved in this
11 site profile, meaning that at the time of
12 publication we didn't have a method to do it.
13 And subsequently we've determined that we don't
14 think we're going to find a way to do that.
15 And so in our additional evaluation we've
16 decided that the information for -- available
17 to us in that period is insufficient to support
18 reconstruction of internal doses from the '42
19 to 1947 period, and the doses that result from
20 that.

21 So once we had reached that conclusion that it
22 was infeasible to do dose reconstructions
23 during this period, we -- we notified a
24 particular claimant from this population who
25 had worked in that period that we had

1 determined that dose reconstruction's
2 unfeasible. This puts us on the 83.14 path for
3 SEC.

4 We sent the individual that letter, and we
5 included a blank SEC petition Form A, which is
6 a short-form petition, which is essentially
7 sign here and send it back. And -- because
8 they -- you know, we had essentially already
9 arrived at the conclusion that it's infeasible
10 for us to do the dose reconstruction.

11 So that petition then was returned to us on
12 September 29th, and we prepared a petition
13 evaluation report, the basis for which we
14 already determined, and presented it to -- and
15 it was sent to the Board I believe about a week
16 ago, about like that.

17 Our conclusions on this is that we have
18 determined that we lack sufficient monitoring,
19 process or source information to provide -- to
20 estimate the internal radiation doses to Linde
21 Ceramic employees for the period of October
22 1942 to October 1947.

23 And we believe we do have sufficient
24 information to estimate external and medical
25 exposures during that period.

1 We did not identify a particular acute event,
2 such as criticality, that would -- that might
3 have occurred that would cause -- just presence
4 to lead to health endangerment, but we clearly
5 believe there is a potential for significant
6 chronic exposure, internal exposure, that does
7 lead to a potential health endangerment. So we
8 believe the health endangerment is present for
9 the site.

10 And so for the period 1942 to 1947, we estimate
11 that -- we find that it is not feasible for us
12 to do dose reconstruction (unintelligible) that
13 period, specifically the internal dose
14 reconstruction during that period and that the
15 health was endangered for the class of people
16 that worked there.

17 The class definition I neglected to bring up
18 with me. I believe it's all AWE employees who
19 worked at Linde Ceramics from October 1942
20 through October 1947.

21 **BOARD DISCUSSION AND DECISION**

22 **DR. ZIEMER:** Okay. Thank you very much, Stu.
23 Let me ask a couple of questions and we'll open
24 the floor to other Board members, as well.
25 Do I understand correctly that you were not

1 able to find any inventory information on
2 amounts of material being processed there? You
3 say there's no process or source information?

4 **MR. HINNEFELD:** Well, know what the mat-- we
5 know what the material was.

6 **DR. ZIEMER:** Right.

7 **MR. HINNEFELD:** I don't know that we know
8 definitively how much was there or --

9 **DR. ZIEMER:** How much.

10 **MR. HINNEFELD:** -- production numbers. Even
11 knowing the production numbers and having --
12 with the description of the processes that were
13 involved, the manual nature of the processes, I
14 think we'd be hard-pressed to provide a
15 bounding estimate on what the exposures might
16 have been.

17 **DR. ZIEMER:** And then my second question is, in
18 -- in some cases, and perhaps Bethlehem Steel
19 is an example, you have used another somewhat
20 similar facility to infer things like air
21 concentrations and so on, such as the Simonds
22 Saw data. Are there any other -- I assume
23 you've looked to see if there's other plants
24 that were sufficiently similar to Linde
25 Ceramics that might serve as a -- a substitute

1 or a model for -- for bounding the --

2 **MR. HINNEFELD:** One -- one that the Board's
3 fairly familiar with that would be fairly
4 similar would be Mallinckrodt St. Louis site,
5 'cause many of the same activities -- the
6 handling of the African ores and the conversion
7 of uranium compounds from one to another
8 occurred at that site, as well.

9 **DR. ZIEMER:** Uh-huh.

10 **MR. HINNEFELD:** And we also reached a
11 conclusion early on in response to a petition
12 from Mallinckrodt that from '42 to '47 it was
13 not feasible to do --

14 **DR. ZIEMER:** Right.

15 **MR. HINNEFELD:** -- dose reconstruction there,
16 as well.

17 **DR. ZIEMER:** So that is the one that is most
18 like this facility is --

19 **MR. HINNEFELD:** Certainly as far as the ones
20 that have been discussed in front of the Board,
21 that would be the one most like it.

22 **DR. ZIEMER:** Okay. Thank you. Other
23 questions, Board members? Yes, Dr. Melius.

24 **DR. MELIUS:** I have -- it's more to do with the
25 process. This would not -- this action would

1 not preclude the -- a petitioner from
2 submitting a petition regarding later time
3 periods. We're -- we're sort of focusing on
4 what, you know, can't be done, not really
5 coming to any sort of assessment of -- from '47
6 on.

7 **MR. HINNEFELD:** That is correct. Our
8 assessment at this date is that we -- we
9 concluded it's not feasible to do it up to '47.
10 There has not been a petition submitted from
11 this site other than the one that was submitted
12 in response to our letter that we can't do the
13 -- your dose reconstruction.

14 **DR. MELIUS:** I guess -- does the petitioner
15 understand that? I guess the -- and -- I
16 assume he does 'cause I know him and I know he
17 --

18 **MR. ELLIOTT:** I hope he does. We worked really
19 hard with this gentleman and his family, and I
20 think he understands this -- this set of
21 circumstances. And yes, the answer is -- to
22 your earlier question is, as Stu answered it,
23 this does not preclude a petition coming
24 forward for the remaining years beyond '47.

25 **DR. MELIUS:** I just think that's important to

1 have on the record so, should we have to --

2 **MR. ELLIOTT:** Right.

3 **DR. MELIUS:** -- encounter it, that's --

4 **DR. ZIEMER:** Other comments or questions?

5 Okay, then -- the -- for the petitioners, do we
6 have a presentation?

7 **MR. ELLIOTT:** I believe they're on the line,
8 but I don't believe they have anything they
9 want to offer.

10 **DR. ZIEMER:** Okay. We do have the -- Board
11 members I believe have the petition
12 information. Board members, are there -- you
13 have any questions on the material, as far as
14 the petition itself is concerned?
15 If not, this petition is open for discussion or
16 for action. Wanda Munn.

17 **MS. MUNN:** Since NIOSH is unable to make any
18 determination in this case, I move that we
19 accept this petition as an SEC and I'm sure Dr.
20 Melius has the appropriate words for that.

21 **DR. ZIEMER:** She's already ready for the
22 friendly amendment, but is there a second to
23 the motion?

24 **MR. PRESLEY:** I'll second.

25 **DR. ZIEMER:** And it's seconded. And Jim, are

1 you prepared to provide suitable wording for
2 this?

3 **DR. MELIUS:** Yes, I am. I was -- I was going
4 to hand my computer to Wanda and let her --

5 **DR. ZIEMER:** If you would read the official
6 motion then.

7 **DR. MELIUS:** Okay. And everyone will forgive
8 me for getting this lengthy document onto the
9 record again, which will sound repetitive.

10 (Reading) The Board recommends that the
11 following letter be transmitted to the
12 Secretary of Health and Human Services within
13 21 days. Should the Chair become aware of any
14 issue that, in his judgment, would preclude the
15 transmittal of this letter within that time
16 period, the Board requests that he promptly
17 informs the Board of the delay and the reasons
18 for this delay, and that he immediately works
19 with NIOSH to schedule an emergency meeting of
20 the Board to discuss this issue.

21 The letter. (Reading) The Advisory Board on
22 Radiation and Worker Health (the Board) has
23 evaluated SEC Petition 00044 concerning workers
24 at the Linde Ceramics Plant in Niagara Falls,
25 New York under the statutory requirements

1 established by EEOICPA and incorporated into 42
2 CFR Section 83.13(c)(1) and 42 CFR Section
3 83.13(c)(3). The Board respectfully recommends
4 that a Special Exposure Cohort be accorded to
5 all atomics weapons employees who worked at the
6 Linde Ceramics Plant from October 1st, 1942
7 through October 31st, 1947 and whom were
8 employed for a number of work days aggregating
9 at least 250 work days occurring under this
10 employment or in combination with work days of
11 employment occurring within the parameters
12 (excluding the aggregate work requirements)
13 established for other classes of employees
14 included in the SEC.

15 This recommendation is based on the following
16 factors:

- 17 1. These workers were employed at a facility that
18 processed substantial amounts of radioactive
19 materials during the early time period for the
20 production of nuclear weapons.
- 21 2. Monitoring for internal dosimetry was not
22 implemented at this facility until November,
23 1947. The other monitoring, process and source
24 information available for this facility is not
25 sufficient for estimating internal radiation

1 exposures in order to conduct individual dose
2 reconstructions for workers at this facility
3 during the earlier time period.

- 4 3. NIOSH has determined that the health of
5 employees at this facility may have been
6 endangered by their radiation exposures. The
7 Board concurs.

8 Based on these considerations, the Board
9 recommends that this Special Exposure Cohort
10 petition be granted. Enclosed is the
11 supporting documentation from the Advisory
12 Board meeting held October 19th, 2005 in
13 Knoxville, Tennessee. This documentation
14 includes transcripts of public comments on the
15 petition, copies of the petition and the NIOSH
16 review thereof, and related documents
17 distributed by NIOSH and the petitioners.
18 If any of these item-- we don't need to --
19 that's it.

20 **DR. ZIEMER:** Thank you. And the seconder
21 accepts that as the motion, I assume.

22 Let me ask for clarification on the one
23 statement about no monitoring being done until
24 whatever date you specified. Is that accurate
25 or do we need to modify that. I think I heard

1 you say there was some monitoring --

2 **MR. HINNEFELD:** There were -- there were some
3 isolated air samples, but there was no
4 monitoring. It started in November...

5 **DR. ZIEMER:** I want to make sure we have an
6 accurate statement on the monitoring.

7 **DR. MELIUS:** Yeah, I -- let me -- let me read
8 it back and just make sure we're -- what you
9 said is that monitoring for internal dosimetry
10 was not implemented at this facility until
11 November of 1947. The other monitoring,
12 process and source information available for
13 this facility is not sufficient. So I was
14 trying to capture that issue, that there was --

15 **MR. HINNEFELD:** I'm sure that's
16 (unintelligible) --

17 **DR. MELIUS:** I'm not saying there wasn't any
18 other monitoring, but that it wasn't suffi--
19 that other -- I think I'm accurate about the
20 internal dosimetry.

21 **DR. ZIEMER:** I wanted to make sure that date
22 was correct and that -- okay. Any other
23 comments on this motion?

24 **DR. MELIUS:** And I actually have also a legal
25 question for Liz. Do we need to site any other

1 -- we've used the usual citation, and I'm not
2 sure there isn't a separate part of the
3 regulations or -- yeah, yeah.

4 **DR. ZIEMER:** And also I'm not sure we had a
5 public comment on this petition. Did we have
6 any?

7 **MS. MUNN:** I did not hear any.

8 **DR. ZIEMER:** There's a reference made to
9 providing the public comment.

10 **DR. MELIUS:** Oh, okay, okay. We're --

11 **MS. MUNN:** Public comment. A question was --

12 **MR. GRIFFON:** (Unintelligible) a question. I
13 don't know in the past if we've included a
14 statement that indicates, as the recommendation
15 does from NIOSH, that external doses can be
16 calculated for this time period. Do we need to
17 -- I mean I know you said that internal cannot
18 be. Do -- we've -- we've remained silent on
19 that or --

20 **DR. MELIUS:** Yeah, my sense was that we would -
21 - you know...

22 **DR. ZIEMER:** It's kind of a moot point, I
23 guess, if you can't --

24 **DR. MELIUS:** Yeah, they still can't do internal
25 dose reconstruction. I think that's covered,

1 yeah.

2 **MR. GRIFFON:** And we say that we accept NIOSH's
3 recommendation, right, and so that -- that's
4 defined that way.

5 **DR. MELIUS:** Yeah.

6 **MR. GRIFFON:** Okay.

7 **DR. MELIUS:** Yeah.

8 **DR. ZIEMER:** We could, if you want to consider
9 including that, Mark, we could consider saying
10 something like although external doses --
11 although it may be possible to -- to
12 reconstruct external doses, the internal doses
13 cannot be, or something to that --

14 **DR. MELIUS:** Well, I thought I'd captured that
15 indirectly, and let me read the whole sentence.
16 (Reading) The other monitoring, process and
17 source information available for this facility
18 is not sufficient for estimating internal
19 radiation exposures in order to conduct
20 individual dose reconstructions.

21 **MR. GRIFFON:** Yeah, that's...

22 **DR. MELIUS:** So it brings it back to individual
23 --

24 **MR. GRIFFON:** Yeah, that's...

25 **DR. MELIUS:** It's just a little awkward to say

1 well, it is -- external's okay, you know --

2 **MR. GRIFFON:** I agree, yeah.

3 **DR. MELIUS:** Yeah.

4 **DR. ZIEMER:** Okay. I guess maybe -- I don't
5 know if counsel can help us. Do we need a
6 statement in there about the public comment,
7 since we had none on this --

8 **DR. MELIUS:** Or just say transcripts are --

9 **DR. ZIEMER:** -- or would you rather have it in
10 there anyway, or just transcripts of the
11 meeting would be sufficient. We don't have to
12 say anything about the public comment. If it's
13 agreeable, why don't we just delete that, since
14 there wasn't any.

15 Any other comments? Are you ready to vote on
16 this petition?

17 (No responses)

18 Okay. All in favor of recommending approval of
19 this SEC cohort, say aye?

20 (Affirmative responses)

21 Any opposed, no?

22 (No responses)

23 Any abstentions?

24 (No responses)

25 It is so ordered, and the motion carries.

1 Thank you. And thank you, Stu.

2 **DR. WADE:** I'd ask Stu -- could you stay up for
3 a minute, Stu?

4 **DR. ZIEMER:** Yeah.

5 **DR. WADE:** I mean while we have a few minutes,
6 I wouldn't mind just talking about what we
7 might expect to see relative to this process in
8 the future, and get the Board to have a bit of
9 a dialogue with you as to whether they'd like
10 to see this done in a different way than we've
11 done it or -- so Stu, I'd assume we will
12 continue to -- to look to identify these
13 targets of opportunity and bring them, as
14 appropriate, to the Board?

15 **MR. HINNEFELD:** Yes.

16 **DR. WADE:** Any speculation as to volume or
17 frequency or...

18 **MR. HINNEFELD:** Well, it would -- it would
19 certainly be speculation. I think easily half
20 -- half a dozen.

21 **DR. ZIEMER:** Of this type?

22 **MR. HINNEFELD:** Yeah.

23 **DR. ZIEMER:** Over the next year?

24 **MR. HINNEFELD:** It'll probably be a year or
25 more, maybe, to get through that many. Maybe

1 many --

2 **DR. WADE:** I'm not -- I'm not looking for --

3 **MR. HINNEFELD:** -- sites with very limited
4 information and a limited number of claims over
5 the next year --

6 **DR. WADE:** I just wanted to let the Board know
7 that --

8 **MR. HINNEFELD:** -- or about a year from now.

9 **DR. WADE:** -- this is a process. And again, I
10 think we would -- NIOSH would intend to
11 approach it the way we've done here. I don't
12 know if the Board has any suggestions for us or
13 -- it could become time-consuming, and yet I
14 think we just have to do this.

15 **DR. MELIUS:** Well, I guess my question would be
16 to what extent can we make it not time-consu--
17 as not time-consuming and is -- are we better
18 sort of bundling them -- (unintelligible) hold
19 up -- (unintelligible) keep it transparent. We
20 don't want to hold up, you know, settlement of
21 some of these claims. I mean would the Secre--
22 is it better to process these through in -- in
23 a -- sort of in a bunch, you know, to the
24 Secretary or --

25 **MR. HINNEFELD:** There is a potential for a

1 bundle --

2 **DR. MELIUS:** A bundle, okay.

3 **DR. ZIEMER:** On the other hand --

4 **MR. HINNEFELD:** -- (unintelligible).

5 **DR. ZIEMER:** -- you don't necessarily want to
6 delay some waiting for others. And frankly,
7 these types are not that time-consuming for us
8 as a Board, as I see it. I mean this is not
9 like Bethlehem or -- well, Bethlehem we didn't
10 have an SEC, but certainly not like
11 Mallinckrodt. The volume of paperwork for
12 these two was relatively low compared to most
13 things we get, and -- and certainly meeting
14 time was not excessive. Larry?

15 **MR. ELLIOTT:** I just want to speak to bundling.
16 We're certainly interested in that approach
17 where it makes sense. But I think you need to
18 recognize we -- we want to recognize, as you've
19 seen in these two examples that have been
20 before you today, they're different. And in
21 one we say we can't reconstruct any dose
22 whatsoever, and in this one we're saying we
23 hope we would be able to attempt reconstructing
24 external dose, perhaps for skin cancers. So
25 you know, the bundling approach may be fine and

1 may provide an efficiency, but we need to be
2 very careful in how we treat what we bundle. I
3 don't want to lose any opportunity here for --
4 for helping claimants with a non-presumptive
5 case.

6 **DR. MELIUS:** Yeah.

7 **DR. ZIEMER:** Roy?

8 **DR. DEHART:** I think, as well, it's important
9 for the record, and because of that we pretty
10 well have to cover some of this material. But
11 it's certainly an efficient way of doing it.
12 We -- we give the claimant an opportunity to
13 speak, we're hearing NIOSH's report, we've had
14 an opportunity to review the document and
15 events, and we move very quickly.

16 **DR. ZIEMER:** Wanda?

17 **MS. MUNN:** It's probably wise for us to be
18 extremely sensitive to the individual nature of
19 these claims, whether they are small and
20 relatively direct or not. It appears, if we
21 are to believe our own immediate past history,
22 that as long as NIOSH indicates that it's not
23 possible for them to do the dose
24 reconstruction, that there is no dissent on
25 the Board with accepting that. The only

1 dissention seems to appear when NIOSH says they
2 can do so and members of the Board do not
3 believe that's the case.

4 Bundling cannot be perceived, in light of what
5 we've seen today, as being an enormous time-
6 saver. On the other hand, there's some merit
7 to thinking about it. It just doesn't seem
8 wise to break down the process in such a way
9 that the individual case does not get at least
10 the amount of hearing that each one got here
11 today.

12 **DR. ZIEMER:** Thank you. Robert?

13 **MR. PRESLEY:** Stu, do we -- do you think are
14 going to have any -- the time we have our
15 telephone conference in December -- ready to
16 go?

17 **MR. HINNEFELD:** No, I don't believe we'll have
18 any more than these.

19 **MR. PRESLEY:** So we're looking at -- at the
20 January meeting somewhere?

21 **MR. HINNEFELD:** If then, I --

22 **DR. ZIEMER:** At the earliest.

23 **MR. PRESLEY:** At the earliest.

24 **MR. HINNEFELD:** The process -- you know, once
25 we determine that we have a class of cases, or

1 a case, that we can't do dose reconstruction,
2 that requires notification to the claimant --
3 you know, conversation with the claimant and a
4 letter exchange, having them sign the Form A
5 petition and send it back. So we're not at all
6 down that pathway I think on any other
7 population right now, so I don't think -- I
8 don't know that we'll have any more in January.

9 **MR. PRESLEY:** Okay.

10 **DR. ZIEMER:** Well, Stu, it seems to me that one
11 of the issues that NIOSH has had to deal with,
12 and maybe -- and with your contractor, and I
13 don't have a good feel for this, but one -- how
14 do you decide in a case like Linde that you
15 have come awfully close to exhausting the
16 record search? Or -- or are you able to
17 determine, from the records that exist, that in
18 fact there are not any records out there? In
19 other words, it's clear that they didn't do
20 monitoring or it's obvious -- we don't have to
21 search for monitoring records because we
22 already know from other things that they didn't
23 do in -- they didn't do urinalysis, for
24 example. And maybe you can give us -- use
25 Linde as an example. How did you decide that

1 for Linde and how would you decide it for other
2 cases --

3 **MR. HINNEFELD:** Well --

4 **DR. ZIEMER:** -- 'cause that's sort of the --
5 sort of one of the issues, have you in fact
6 exhausted the records search.

7 **MR. HINNEFELD:** I'll say this, with pretty good
8 confidence, is that the records capture people,
9 you know, that we have working for our
10 contractor have reconnoitered, at least, very
11 many -- very many repositories, and at least
12 have some idea about what they're liable to
13 find at various repositories, whether it's
14 actually been retrieved yet or not. So we are
15 -- we think that we are pretty well set in
16 terms of knowing what might be out there. And
17 if we have a site where we have no additional
18 leads and we have collected a lot of
19 information and no additional leads, and it
20 leaves us with this -- this gap in the data,
21 then we're pretty confident the -- you know, I
22 guess theoretically if you look long enough and
23 hard enough, you may actually find something
24 archived, but we're at a point where we feel
25 like it's time to stop and -- and do that.

1 There's a category -- you know, there's a
2 population of sites that we would expect
3 research to be done in a year, just because --
4 some contracting arrangements we have, we
5 expect research to be done in a year on a broad
6 category of sites with not very many claims
7 from them. So when I was saying there is an
8 opportunity for a bundle, that is I think the
9 best opportunity for a bundle of these cases
10 that -- research is done, you know, this --
11 based on this contractual arrangement, these --
12 research on these is done and we make the
13 decision now on a number of these, so that is a
14 good opportunity for a bundle, and that'll
15 happen about a year from now probably.

16 **DR. ZIEMER:** Uh-huh.

17 **DR. MELIUS:** I have one other -- I have another
18 question.

19 **DR. ZIEMER:** Fine, then we'll have -- Rich
20 Toohey has a comment. Go ahead, Jim.

21 **DR. MELIUS:** Well, if you're speaking to Stu's,
22 go ahead -- go ahead. I -- mine's sort of
23 separate.

24 **DR. TOOHEY:** Are we on?

25 **UNIDENTIFIED:** (Off microphone) Yeah.

1 **DR. TOOHEY:** Okay. Dick Toohey, ORAU. I just
2 want to mention one -- one of the key indexes
3 or indicators we use that data might be
4 available are actually the log books from
5 Health and Safety Lab where all the air
6 samples, many of the urine samples were
7 actually analyzed.

8 **DR. ZIEMER:** Right.

9 **DR. TOOHEY:** So -- and we have all those
10 records. So if, looking at that, we see
11 there's data available from a site --

12 **DR. ZIEMER:** Right.

13 **DR. TOOHEY:** -- we feel pretty good. If
14 there's no record in the HASL records of
15 measurements from the site, we haven't found it
16 in any search effort, so we figure well, that's
17 it.

18 **DR. ZIEMER:** Right. Okay, good.

19 **DR. MELIUS:** Yeah, I'd like to ask a sort of a
20 different type of question, and that's related
21 to how do you -- like, for example, with Linde
22 -- intend to publicize this decision? We're
23 pretty far away from Niagara Falls. There's
24 people from -- representing workers at that
25 facility have shown up at a number of our

1 public meetings on Bethlehem, actually, and --
2 and spoken, so there's some amount of interest.
3 And I think -- I think there's -- be some
4 benefit to some positive publicity on this to -
5 - for claimants that, you know, may be eligible
6 and are not aware of it. I mean there -- it is
7 also probably going to generate other claims
8 and other time periods, but -- and you know, so
9 be it, I think. I think it's good. But I
10 think it would be good for the program, where
11 you're being proactive, to go out and -- and
12 make sure that -- that people know about that.
13 Now the National Bureau of Standards I think is
14 a little bit different situation, but --
15 **MR. ELLIOTT:** Yeah, there weren't that many
16 people that worked at NBS, so --
17 **DR. MELIUS:** Right, right, Linde --
18 **MR. ELLIOTT:** Ten to 12, is our understanding,
19 and we only had one claim --
20 **DR. MELIUS:** Right.
21 **MR. ELLIOTT:** -- and that was Mrs. Bond's
22 father's. But I appreciate your question and I
23 agree wholeheartedly that we need to exert a
24 coordinated campaign here to notify people. We
25 will do that on an individual basis, of course,

1 as we do with all of the classes that are being
2 added. We notify each of the claimants, for
3 claims that we have in our hands, that their
4 claim fits into the class and is being returned
5 to the Department of Labor for a determination
6 of eligibility and adjudication under that
7 class definition. We will use our worker
8 outreach program because the site profile, as
9 you noticed, was developed back in -- earlier
10 this year.

11 We need to engage those folks and send them
12 back out into the field with that site profile
13 and use that opportunity to tell the -- tell
14 the audience that we have established a class
15 and our site profile covers the later years.
16 We want your input, we want your comment about
17 that. We want to hear your thoughts about our
18 ability to do dose reconstruction or your
19 thoughts about our inability to do dose
20 reconstruction.

21 We will notify the Congressional delegation, of
22 course, about this class being added. I think
23 -- I think we're going to have to work with
24 DOL, as well, if they have another town hall
25 meeting scheduled, or something like that. If

1 there's not, then we may need a town hall
2 meeting, as well, to go up into that part of
3 the country and -- and let people know that
4 this class exists now and what we're doing in
5 that regard.

6 **DR. MELIUS:** Okay, good.

7 **DR. WADE:** If I could have one final comment.
8 I know this Board is painfully aware of the
9 criticism that's been brought to the program of
10 people waiting for years for their dose
11 reconstructions to be completed. I think this
12 is a very positive development, the mechanism
13 that is now available to try and deal with this
14 issue. So I applaud the NIOSH program bringing
15 this forward and I think it was worth the Board
16 spending some time talking about it and
17 developing a little bit of an understanding and
18 appreciation. But I think this is a very
19 positive development, and thank you.

20 **DR. ZIEMER:** We're now scheduled for a break,
21 so we'll recess till 10:30. Thank you very
22 much.

23 (Whereupon, a recess was taken from 10:00 a.m.
24 to 10:30 a.m.)

25 **DR. ZIEMER:** We're ready to call the session

1 back to order, if you'd please take your seats.
2 **MR. ELLIOTT:** Dr. Ziemer, if I -- if I might
3 interrupt right now, there was a blue folder
4 left on a chair here. It's got a BEIR VII
5 report in the front. I just wanted to know
6 hadn't claimed it for -- okay. Now I'm going
7 to ask -- Jim, will you get this lady behind
8 you a copy of this? Thank you. Sorry for
9 interrupting.

10 **PUBLIC COMMENT**

11 **DR. ZIEMER:** Okay. Thank you. You may have
12 noticed that we actually didn't schedule on
13 today's schedule a public comment session.
14 However, we have an individual who -- who drove
15 up from North Carolina for today's meeting,
16 anticipating participating in the public
17 comment session. So we do want to accommodate
18 that, and so without objection, I'd like to
19 have a brief public comment time and allow
20 Sherry Floyd from North Carolina to address the
21 Board. And Sherry, if you would approach the
22 mike, we'd be pleased to hear from you at this
23 time.

24 **MS. FLOYD:** Hello, Board. My name is Sherry
25 Floyd. I'm from Murphy, North Carolina, and

1 this is my daddy, Clyde Floyd. He worked at
2 Savannah River Plant for 35 years. He died of
3 melanoma in May of 2001. And my situation's
4 unique in that he was no longer married to the
5 woman he lived with for 25 years while working
6 there. He married a woman the last two years
7 of his life. This woman took all the money
8 that he had left for me in a trust fund. And I
9 filed a claim as a dependent under my father.
10 My claim was denied and (unintelligible). The
11 unique part of my situation is I was never sent
12 a letter with a final decision. It went to an
13 old address. I missed out on all the appeals
14 processes. And if it wasn't for Terry Berry, I
15 wouldn't have gotten a hearing that's coming up
16 next month. But I did want to thank y'all for
17 approving his claim and trying to help the
18 families. I know you have good intentions. But
19 you need to know this is not the '50's. The
20 men are not still married to the women for 20
21 or 30 years. There's several wives probably in
22 between. And one woman has ripped my heart
23 out. But losing my daddy was the worst, but I
24 did want to let y'all know. Thank you for
25 letting me speak.

1 just want to read some generic narrative out of
2 the letter that I think will demonstrate why
3 people are getting frustrated. And then after
4 I read that, if counsel wants to make sure it's
5 been redacted properly, we can make copies of
6 it. But it is a letter from the Department of
7 Labor and it says (Reading) This letter is to
8 inform you that your husband's (blank) claimed
9 under the Energy Employees Occupational Illness
10 Compensation Program Act, Part B, has been
11 forwarded to NIOSH. While we await the
12 completion of your dose reconstruction, we will
13 continue to develop your claim under E.
14 It says (Reading) We have asked the Department
15 of Energy to confirm the types of toxic
16 substances that (blank) may have been exposed
17 to at the facility. We ask that you provide
18 additional evidence so we can make a decision
19 on your claim.
20 Then it says (Reading) Please list by name the
21 toxic substances you believe caused or
22 contributed to the claimed conditions. Please
23 describe the nature, extent, frequency of
24 harmful work exposures. You may also submit
25 evidence to establish hazardous employment at

1 the exposures -- at the (blank) site. Please
2 specify the exact nature of the claimed
3 conditions, when the condition first was onset.
4 Please submit a detailed report from (blank's)
5 treating physician. The doctor should give an
6 opinion with medical justification on the
7 connection, if any, between the toxic
8 employment exposures to the claimed conditions.
9 The narrative medical report should contain a
10 complex history, social, family, work, medical,
11 exam findings, test results, diagnosis, date of
12 diagnosis, course of treatment and a well-
13 rationalized opinion as to whether, how and why
14 the employment exposures caused or contributed
15 to the claimed condition. The physician
16 should discuss the nature and extent of causal
17 relationship; i.e., direct causation, permanent
18 or temporary aggravation between the claimed
19 condition and the harmful work exposure you
20 reported.

21 Now I -- my question to the Department of
22 Labor, I guess, is how -- well, you know,
23 there's -- and then the last page, (Reading)
24 When we need the information. Please provide
25 the requested information within 30 days from

1 the date of this letter. As the claimant, it
2 is your responsibility to submit the evidence
3 needed to establish a claim under EEOICPA.
4 I just personally feel that that is just
5 unreasonable to -- to expect that of a survivor
6 when, just as the lady spoke before, the
7 survivor -- the surviving spouse may not even
8 been the -- the spouse that the person was
9 married to when they were employed there. And
10 number two, as most of you know, with a Q
11 clearance you shouldn't discuss what you've
12 been working with. So how is this claimant-
13 friendly? I think this shows why people get
14 frustrated and -- and give up on their
15 complaints. And I think this could really be
16 reworked to be a lot more friendly to the
17 claimants and/or survivors, and so if the
18 Department of Labor would like to comment on --
19 **DR. ZIEMER:** Is this a standard Part E letter?
20 I -- Jeff, do you know if that's a standard
21 letter that goes out under Part E?
22 **MR. KOTSCH:** Jeff Kotsch, Department of Labor.
23 I have to admit that I'm not that intimately
24 involved with Part E as I am with Part B as a
25 health physicist. But I assume that this is a

1 standard letter. I'll take it back to my
2 management that the -- I know that sometimes
3 our wording of letters -- it seems like we --
4 you know, much beyond the scope of what people
5 can provide, so I'll have to check with them
6 and, you know, (unintelligible) --

7 **DR. ZIEMER:** Yeah. In this case the issue of
8 burden of -- who -- who does the burden rest
9 on. Certainly in our part of the program we
10 expect -- we don't expect the -- the claimant
11 to come up with all that information. It
12 appears here that the burden is placed on --
13 clearly on the claimant to --

14 **MR. KOTSCH:** Well, even in Part B the burden
15 for medical and employment is -- it at least
16 starts initially with the claimant and then,
17 you know, we provide or we attempt to provide
18 assistance through the Resource Centers and
19 through other mechanisms, the centers to
20 protect workers rights and things like that.

21 **DR. ZIEMER:** Right, but certainly this listing
22 of all the compounds and related things seems
23 to go a bit beyond that --

24 **MR. KOTSCH:** That may be -- that may not quite
25 be reasonable for a survivor. Hopefully an

1 employee would have some recollection of what
2 things he might have been exposed to. Plus we
3 have a general feel for -- at the DOE 'cause
4 this -- Part E is just DOE sites. We have a
5 general feel for what toxic materials are at
6 the sites.

7 **MR. GIBSON:** This -- this letter was to a
8 survivor.

9 **MR. KOTSCH:** Yes, I mean it's probably -- it
10 may not quite be appropriate for the survivor
11 as persons, you know -- perhaps an employee
12 who's still alive.

13 **DR. ZIEMER:** I don't know the extent to which
14 this is directly in our purview, but certainly
15 there is, insofar as there's a relationship
16 between these programs, and we certainly end up
17 getting coupled with the Part E activities
18 frequently, it would seem that perhaps -- if --
19 if it's the sentiment of this Board, that it
20 would be appropriate to ask that that be
21 addressed in some way --

22 **MR. KOTSCH:** I will take the comment back.

23 **DR. ZIEMER:** -- and perhaps you could report
24 back to us --

25 **MR. KOTSCH:** Okay.

1 **DR. ZIEMER:** -- the nature of how this is
2 handled, what the -- what the real burden is on
3 the survivor to come up with information which,
4 as Mike indicated, is often classified at the
5 front end, anyway.

6 **MR. KOTSCH:** Right.

7 **DR. ZIEMER:** You know, I don't know if other
8 Board members have comments on this issue or --

9 **DR. MELIUS:** Yeah, I --

10 **DR. ZIEMER:** -- suggestions, and -- yes, Jim.

11 **DR. MELIUS:** Can I -- can I -- well, one is I
12 think it's important to realize that the
13 Subtitle E program is a very traditional
14 workers compensation program, and so it's sort
15 of modeled on what's expected of someone in a -
16 - filing any other sort of workers compensation
17 claim, and occupational disease claims have
18 always been difficult to assemble the
19 information for and so forth, for a variety of
20 reasons. The Department of Labor is -- has --
21 my understanding, it has taken some steps to
22 try to develop some of the background
23 documentation that will facilitate the handling
24 of claims and so forth and doing that. And I
25 participated in a workshop -- can't remember if

1 you -- were you there, Mark, or -- now I can't
2 remember -- with the Department of Energy, and
3 I think Jim Neton -- you were part of that,
4 also -- to try to develop sort of site profile
5 kinds of information and so forth that would --
6 would facilitate this and -- and so forth. So
7 I think recognize the problem.
8 On the other hand, it's also the -- what's
9 requested in the letter also goes back to
10 what's in their interim final regulations, and
11 (unintelligible) organization -- other
12 organizations I know have submitted comments on
13 those interim final regulations, pointing out
14 the difficulty of assembling a lot of that
15 information and the burden it'll put on both
16 survivors, as well as people who -- who worked
17 at these facilities to bring together all --
18 all -- be able to access and get -- get all
19 that information. And so where they -- where
20 the Department of Labor goes with this, I --
21 you know, where they draw the bounds, we'll
22 have to wait and see. But it -- it --
23 certainly the points Mike brings -- brings up
24 are -- are very appropriate, and I certainly do
25 worry for what -- particularly people that

1 won't have -- be able to sort of take advantage
2 of what's done under the OCAS part of the
3 program where there are the site profiles and
4 other information 'cause the site profiles
5 don't cover the chemical exposures and so
6 forth. And a lot of this will have to do --
7 and -- and again, what we talked about, you
8 know, how do you determine disability for
9 someone going back -- or an impairment going
10 back 20 years. And so it's a lot of
11 difficulties with this program.

12 **DR. ZIEMER:** And Roy, you've had some
13 experience with this kind of thing. You have
14 some comments for us?

15 **DR. DEHART:** When the original Part D was under
16 the Department of Energy, I did serve as a --
17 as a consultant and early on an evaluator of
18 the medical documentation. Jim's absolutely
19 right. This is a worker compensation claim
20 situation, and even in the best of
21 circumstances it is often very, very difficult.
22 We're not dealing, in this case, with a loss of
23 limb or musculoskeletal problems which tend to
24 be common worker compensation issues that are
25 more definitive and defining. We're dealing

1 with heart attack, stroke, metabolic diseases
2 such as diabetes, ulcer diseases, liver
3 diseases. These are the general complaints
4 that they're getting and they're trying to tie
5 that to the kinds of exposures or the work
6 stress that the worker sustained while
7 employed.

8 The more medical records that are available,
9 the easier it is for an evaluator -- or in this
10 case, generally not a physician, a claims
11 manager -- to make a recommendation. I totally
12 agree that it is beyond the capability of many
13 of the people making the claims to be able to
14 provide the information in detail. But I think
15 it needs to be requested, if available.

16 I would also suggest that possibly they would
17 be willing to consider -- and I don't know that
18 they do in Part E -- affidavits in lieu of
19 medical records. That would ease the burden if
20 that were possible, but I don't -- I don't know
21 if that is currently allowed in that -- in that
22 process.

23 I can tell you that I reviewed documents on
24 claims under Part D that would be 600 to 1,000
25 pages, with all the medical records from

1 hospitals, et cetera, and this is -- this is
2 what is happening. This is what they're
3 requesting. And the medical records can be
4 very comprehensive. But if a person died in
5 the '50's and there was a worker compensation
6 claim for someone who was in their fifties and
7 theoretically had 15 more years of work to do,
8 there could be substantial dollars involved,
9 but yet unable to acquire the medical records
10 because the records have been destroyed --
11 which is permissible after a period of time.
12 The practitioners are no longer available --
13 retired, moved, dead. And it -- it is really a
14 complicated situation and I -- I totally agree,
15 if there's a way of easing that burden on the -
16 - on the claimants who may not have access to
17 records, that would be helpful.

18 **DR. ZIEMER:** Yeah. Well, at least Department
19 of Labor's been made aware of these concerns
20 and perhaps Jeff will be able to come back with
21 some positive report for us on that. Thank you
22 very much, Mike.

23 **DR. WADE:** (Off microphone) Do you
24 (unintelligible)?

25 **DR. ZIEMER:** I think we'll hold that till the

1 work session.

2 **SCIENCE ISSUES, DR. JIM NETON, NIOSH:**

3 It's been a while since we've addressed our
4 list of what we've called "science issues,"
5 which are sort of the backbone of some of the
6 dose reconstruction work. But we have a number
7 of these back on the table for us today, and
8 Jim Neton is going to present some of the
9 breaking issues on -- on our science as far as
10 dose reconstruction is concerned, and some
11 possible upcoming changes to consider.

12 **DR. NETON:** Okay. Thank you, Dr. Ziemer.
13 You're absolutely correct, it's been a while
14 since we've had a discussion about science
15 issues, so I'm here to present to you a
16 discussion on four issues that have appeared on
17 the Board's priority listing in the past, and
18 there -- there are four areas where we -- we've
19 done some work, made some progress and, as Dr.
20 Ziemer pointed out, are going to make some
21 changes -- either proposed changes or in the
22 process of making those changes at the current
23 time.

24 I'd like to acknowledge that, although I'm the
25 spokesman standing up here, I certainly don't

1 purport to be the expert on all of these issues
2 in depth, and I have a great support staff back
3 there of the science team -- Russ Henshaw and
4 Brant Ulsh, as well as our friends at SENES Oak
5 Ridge who are responsible for some of this
6 work. And in addition, the Health-related
7 Energy Research Branch folks who are here who
8 are engaged in some of this work, as well.

9 **CLL ACTIVITIES**

10 The four issues that we're talking about are
11 chronic lymphocytic leukemia. As the Board is
12 aware, this is the only cancer that is
13 currently excluded from compensation. It's
14 assigned a probability of causation of zero,
15 and I'll get into the reasons for that and what
16 we're going -- where we're going with what
17 we've done so far in that area.

18 I'd also like to talk a little bit about dose
19 reconstructions for lymphomas -- not the risk
20 model, but really what is the relevant target
21 organ to reconstruct the dose -- where -- where
22 is the relevant target organ for the dose to be
23 reconstructed.

24 And so the two -- the first two bullets deal
25 with lymphocytes -- the lymph system in

1 general, and then the last two deal with the
2 cancer risk models. That is the cancer risk
3 adjustment for the age at exposure. There's
4 been some evidence in the literature, as the
5 Board is aware, that the age at which one is
6 exposed to radiation may have an effect on the
7 excess relative risk per Sievert, and also --
8 will finish up with the probability of
9 causation for lung cancers. And more
10 specifically, some adjustments that have been
11 made by the National Cancer Institute related
12 to smoking and -- and how we propose to
13 incorporate their model into the NIOSH-IREP
14 model.

15 That said, this go on for a while. I know I
16 tend to be long-winded, so we can stop at each
17 point maybe and have a discussion if that's --
18 that's preferable. I think that probably is,
19 so I'll proceed that way.

20 As I mentioned, chronic lymphocytic leukemia is
21 the only cancer that is excluded in 42 CFR 81
22 from compensation. That regulation was issued
23 in May of 2002. It was excluded for a number
24 of reasons. Primarily, there were no published
25 studies to support an association between

1 exposure and increased risk for chronic
2 lymphocytic leukemia. We couldn't identify any
3 at the time. It was also traditionally
4 regarded as non-radiogenic by outside expert
5 committees such as the BEIR committee and
6 ANSCEER*. And on top of that, there was no
7 risk model to apply. I mean no one -- no one
8 had come up with a relevant risk model to use
9 at that point.

10 However, we did note in our evaluation that at
11 a later time frame we would revisit this issue,
12 and that's what I'm here to report on, our
13 progress on where we are with this issue.

14 So what -- what has been done. There's been a
15 number of things going on that NIOSH has done
16 some research in this area, and at this point I
17 need to acknowledge the work of the Health-
18 related Energy Research Branch, which was
19 provided some money ear-marked by Congress for
20 research into this area specifically. To that
21 extent, HERB -- NIOSH/HERB convened a public
22 meeting in Washington, D.C. in July of last
23 year to have a panel discussion, a frank panel
24 discussion about data gaps in chronic
25 lymphocytic radio-- chronic lymphocytic

1 leukemia radiogenecity research -- that's a
2 mouthful to say.

3 This panel discussion was -- included six
4 invited experts. There was a public forum and
5 discussed a wide-ranging array of issues in
6 both molecular and epidemiologic CLL research.
7 There were several written products produced as
8 a result of that meeting. One was an annotated
9 bibliography of the research that had been done
10 in this area, and also the minutes -- or the --
11 a summary of that meeting has been published.
12 And in fact, as of a week or so ago, that's
13 been published as a NIOSH numbered document. I
14 believe the Board was e-mailed a copy of that.
15 There are also copies available at the back
16 table. It's a fairly extensive write-up -- I
17 think it's about 100 pages long -- that just
18 essentially paraphrases everything that was
19 said by all the participants in that meeting.
20 HERB -- based on the results of that meeting,
21 NIOSH prioritized the CLL efforts under -- how
22 they were going to approach -- you know, what
23 they were going to do with CLL research, and
24 one of the main thrusts of that research was to
25 incorporate, where possible, CLL research into

1 the ongoing epidemiologic studies that they had
2 already had in place. They have done that.
3 They've included that in two studies thus far
4 that are completed, and redone the analysis to
5 include CLL to see if any excess risk could be
6 teased out of those studies. Thus far they've
7 not been able to make any determin-- definitive
8 determination as to how CLL could be used in an
9 epidemiologic analysis. In fact, this is one
10 of the key issues with CLL is it's very
11 difficult. The number of cancers that are
12 reported in the literature are difficult.
13 Reporting is confusing over time, and it's --
14 it's just a difficult cancer to develop risk
15 models for from an epidemiologic perspective.
16 NIOSH has intended to produce, as a result of
17 this meeting, a structured review of the
18 literature that would be published in the peer
19 review literature. It's a much-expanded
20 version of the annotated bibliography that
21 would essentially be a critique on the studies
22 that have been done thus far and what the
23 status is at the current time.
24 We've also worked with the International Agency
25 for Research on Cancer to apply -- to do a

1 pooled analysis of the data that they had
2 available, I believe it was for the U.S.
3 cohorts, to look at CLL in their cohort to
4 determine if any definitive association between
5 CLL and radiation exposure could be determined,
6 and the results of that are not yet available.
7 So there's a number of areas that the Health-
8 related Energy Research Branch is
9 investigating, and those studies are ongoing.
10 NIOSH activities related to the compensation
11 program -- that is OCAS's mission on this --
12 have also been ongoing. We solicited opinions
13 from five outside experts in 2004, and we asked
14 them a question relevant in the context of a
15 compensation program only. This was not a
16 research question, but we asked them a specific
17 question, and I provided you a quotation of
18 what was in that packet that we mailed them,
19 and essentially it says (Reading) In your
20 expert evidence -- in your expert judgment, is
21 there evidence between radiation exposure and
22 the risk of developing CLL sufficient to
23 continue to regard CLL as a non-radiogenic
24 cancer and to continue to exclude it, a priori,
25 from eligibility for compensation.

1 It's a fairly loaded question, but we wanted to
2 get the question on the table and see -- see
3 what we could elicit from these experts. So
4 I'm just going to go through one by one -- and
5 keep in mind when I'm talking, this is just a
6 paraphrase, a snapshot, of what their -- their
7 opinion was. The first -- and these are in
8 alphabetical order so there's no significance
9 to the order that I'm presenting these.
10 The first opinion was Dr. John Boice, who is
11 the Scientific Director of the International
12 Epidemiologic Institute and a professor of
13 medicine at Vanderbilt University. And Dr.
14 Boice's opinion was that the body of scientific
15 evidence does indicate that CLL is not caused
16 by exposure to ionizing radiation. That was a
17 pretty definitive opinion from Dr. Boice.
18 If one -- the next opinion that we solicited
19 was from Dr. Mark Crowther, who is associate
20 professor of medicine at McMaster University,
21 and he is board certified in hematology and
22 internal medicine. In Dr. Crowther's opinion,
23 CLL is clearly not different from other forms
24 of cancer. And in his opinion available
25 evidence is insufficient to rule out an

1 association.

2 Next opinion, from Dr. David Ozonoff, who is a
3 physician, a professor of environmental health
4 at Boston University, states that the argument
5 for continued exclusions are weak and lacking
6 foundation. And he does support including CLL
7 as a radiogenic cancer and against continuing
8 to exclude it. Actually he believes the
9 practice to be an arbitrary exclusion.

10 And finally, the opinion -- or next opinion of
11 Dr. David Richardson, who many of you may be
12 familiar with. We've used Dr. Richardson in
13 the past for other -- other issues, such as the
14 lung cancer risk model that we're going to talk
15 about in a little bit. Dr. Richardson's
16 opinion is the available evidence does not
17 provide sufficient grounds for continuing to
18 regard CLL as non-radiogenic.

19 And finally, the fifth opinion, is from Dr.
20 Lydia Zablotska, who's assistant professor of
21 clinical epidemi-- did I go forward? I'm sorry
22 -- is Dr. Zablotska's opinion. Her opinion is
23 that from an epidemiologic perspective it is
24 not possible to prove that there is no risk.
25 It is only possible to say that we do not have

1 solid scientific evidence.

2 So that's sort of in the middle of the -- of
3 the opinions.

4 So essentially what we have here is three of
5 five outside experts recruited by OCAS argue
6 against excluding CLL and one is sort of in the
7 middle ground.

8 This is a preliminary report. While we've got
9 these expert opinions in-house, we've got the
10 HERB ongoing research activities. So right now
11 we're still in a pre-decisional status on this.
12 We have not made a determination, but I would
13 say that we are in parallel processing. We're
14 not pre-deciding whether it should or should
15 not be covered. But one also needs to have a
16 risk model to use, so we're in parallel trying
17 to develop a risk model, and that would have to
18 be in place if we were to decide that CLL was a
19 covered cancer. And we'd be happy to report
20 more fully when we've made a decision on this
21 issue.

22 I think at that point I'll open up the question
23 --

24 **DR. ZIEMER:** Okay, so before we go on to
25 lymphomas then, discussion on the CLL issue --

1 again indicating it's essentially still open as
2 far as the agency's concerned. Roy DeHart.

3 **DR. DEHART:** Jim, do you have any idea what the
4 number is of -- of current claimants that would
5 have chronic lymphocytic leukemia?

6 **DR. NETON:** No, those are not forwarded to us
7 by the Department of Labor. They're excluded
8 from -- from coming over to us, so I really
9 don't know. I --

10 **DR. DEHART:** You don't even see them then.

11 **DR. NETON:** No, we don't -- we did early on.
12 There was a -- they were coming over there
13 erroneously. I mean they were passing us on
14 and we sent some back, but you know, there were
15 -- there were not a large number at that point.
16 But I really couldn't speculate as to what the
17 total number is.

18 **DR. DEHART:** Is someone maintaining a log of
19 those claimants in case there is a reversal?

20 **DR. NETON:** I'm sure the Department of Labor
21 would know which cases have been denied based
22 on the fact that CLL is an uncovered condition.
23 And if there were a reversal, we would -- we
24 would be able to reconstruct that and notify
25 claimants, I'm sure.

1 **DR. MELIUS:** Yeah, I --

2 **DR. ZIEMER:** Jim.

3 **DR. MELIUS:** Yeah. This -- this situation's a
4 little bit different than some of the other
5 issues we're considering 'cause CLL's excluded
6 in the law, so it's not like a decision we can
7 make and -- or recommendation that we can make
8 and that it -- IREP gets changed. It would
9 have to -- require a legislative change.
10 However, having said that, I would urge you to
11 -- I think to take the same approach that you
12 did in the lung cancer case. I thought the
13 documentation that you sent us for that was
14 very -- was excellent. It was very useful to -
15 - to have because it sort of laid out the
16 options and what the implications were -- were
17 of those options.
18 I think in this case that whatever decision or
19 -- you know, you make or however you want to
20 frame that, I think it would be useful to have
21 the background saying well, what -- what really
22 would be the implication, what would be
23 involved in adding CLL to the IREP risk model
24 and what does it really mean, because I -- the
25 risk's going to be low. I mean that -- in --

1 no matter how you, you know, cut it and so, you
2 know, what is the -- really the meaningfulness
3 of that -- and it may not even be possible to
4 add it, I mean in sort of a scientifically-
5 defensible way given what's known. And then --
6 but I think laying that out and whether you
7 want the Board to endorse that in some way or
8 whatever is -- is fine, it's really up to you.
9 This is a little different situation, as I
10 said.

11 But secondly, I -- but I also urge you in doing
12 -- if you do do that is then also talk about --
13 lay out what you are doing to address the issue
14 in terms of, you know, research and so forth,
15 to the extent that's appropriate, really since
16 Congress has already asked you to give some
17 prior-- priority to that issue. But I think
18 having that kind of document available would
19 really be helpful 'cause claimants with CLL are
20 going to continue to, you know, be concerned
21 and -- and I think we really do need something
22 that's -- lays out what -- what is -- how much
23 -- what would it really mean, what effect would
24 it have even if you, you know, decide to
25 include it in the IREP model, or is it even

1 possible to do so. And then -- you know, and
2 it's -- you know, first or -- or lastly, you
3 know, is it really justifiable to do so and --
4 I also think that for the credibility of the
5 program, it's also important because there are
6 strong differences of opinion sort of expressed
7 there and sort of, you know, just an assumption
8 that it's not related and therefore you
9 shouldn't even consider it. Well, I think you
10 can lay out a good sound document, I think it
11 would be helpful.

12 **DR. NETON:** I definitely agree. The reason
13 we're taking such a measured approach here is
14 that this will require rule-making. It
15 wouldn't be a -- it's not a legislative issue.
16 It's in our rule. Liz maybe can speak -- speak
17 to that.

18 **DR. ZIEMER:** Yeah, Liz, you want to address
19 that? Is this legislative or rule --

20 **MS. HOMOKI-TITUS:** No, it's not in EEOICPA that
21 CLL is excluded. It's actually in the dose
22 reconstruction rule --

23 **DR. MELIUS:** The rule --

24 **MS. HOMOKI-TITUS:** -- so it wouldn't require a
25 change by Congress. It would require a rule-

1 making by HHS.

2 **DR. MELIUS:** Oh, okay.

3 **DR. NETON:** And certainly going through rule-
4 making we'll --

5 **DR. MELIUS:** Yes.

6 **DR. NETON:** -- this thing will be vetted very
7 thoroughly before we make any changes.

8 **DR. ZIEMER:** But aside from that issue, if --
9 if you did go to rule-making, basically that
10 allows consideration of it. But I think you
11 kind of put your finger on the issue, that even
12 so, the -- the risk value is going to be very
13 slow -- very low. If it wasn't, you wouldn't
14 have this issue to --

15 **DR. NETON:** Right.

16 **DR. ZIEMER:** -- start with. And the fact that
17 in a sense the experts are split on this
18 accentuates the fact that the risk is so low
19 you can't really -- really ascertain whether it
20 is there or not. So how would you go about
21 actually establishing a risk number that could
22 be used, for example, in IREP, if you took care
23 of the a priori exclusion to start with?

24 **MR. ELLIOTT:** Well, that is the challenge for
25 us right now, but -- and I appreciate the well-

1 made points from Dr. Melius on this. But I
2 would add this for your consideration. There
3 are other cancers that we included in our -- in
4 the IREP, like prostate, that's not recognized
5 as a radiogenic cancer. But yet we were able
6 to come up with a risk model, albeit it's --
7 the risk coefficients are very, very low there,
8 so I would just posit that, that -- you know,
9 if we can do that, there must be some way we
10 can come up with some sort of risk model for
11 CLL, and that's the challenge that I've placed
12 before the science team. So that's what we're
13 working on.

14 **DR. ZIEMER:** So they're -- even as we speak,
15 they're looking at -- are they looking at at
16 this point --

17 **DR. NETON:** Yes.

18 **DR. ZIEMER:** -- as to how -- how to construct
19 that risk model and --

20 **DR. NETON:** Right.

21 **DR. ZIEMER:** -- are we going to hear about that
22 at this point or --

23 **DR. NETON:** No.

24 **DR. ZIEMER:** -- no. There's not --

25 **DR. NETON:** We're not -- we're not far enough

1 down the line on that.

2 **DR. WADE:** Are you willing, Jim, to talk about
3 a time frame when the Board would likely hear
4 as to whether you're successful? I assume if
5 you can't develop a risk model, then the
6 question's moot. But if you can, then the
7 question's open.

8 **DR. NETON:** Right. I'm reluctant to give a
9 time frame at this point. It is very
10 preliminary. Chronic lymphocytic leukemia -- I
11 feel like Stu, it would be very speculative on
12 my part to -- to make a judgment there. CLL
13 has characteristics of both leukemia and
14 lymphoma, and the model is somehow going to
15 have to address that. We are working with
16 SENES/Oak Ridge, our friends over there, to
17 help us in this endeavor. But I really
18 couldn't speculate at this point.

19 **DR. MELIUS:** Yeah, but --

20 **DR. ZIEMER:** Another comment, Jim?

21 **DR. MELIUS:** I would just elaborate that -- not
22 to say not to take those steps or not to look
23 into what extent you can do it, but as compared
24 to prostate and some of the other cancers, I
25 mean there is a fair amount of scientific

1 scrutiny that more scientists (unintelligible)
2 put to the CLL issue in terms of studies
3 because other leukemias are so radiogenic and
4 just this one stands out. And so it's -- I
5 think it's a different type of -- of issue in
6 some ways and I think you have to be sensitive
7 to that and, again, to maintain sort of the
8 scientific credibility of what you do. Again,
9 I think laying out sort of the options and not
10 -- not to not pursue what you're doing, but I
11 think it has to be thought about, you know,
12 where's the scientific basis for that and is it
13 feasible to do and then, you know, what are the
14 -- what would be the implications of -- of
15 that.

16 **DR. NETON:** This would be -- a very good
17 comment. I agree with that. This would be
18 very precedent-setting. There -- to my
19 knowledge, there's no other compensation
20 program that considers CLL in a radiation
21 compensation arena.

22 **DR. ZIEMER:** Other comments on CLL?

23 **DR. WADE:** Just before Jim goes on, one of the
24 things that, you know, it would be good for the
25 Board to speak to NIOSH on on science issue --

1 science issues in general is priority. So I
2 think when we finish these, we -- we could have
3 a discussion giving some sense of priority to
4 NIOSH on these issues.

5 **DR. NETON:** Good point. I didn't bring with me
6 the --

7 **DR. ZIEMER:** There is an existing priority list
8 --

9 **DR. NETON:** Right.

10 **DR. ZIEMER:** -- on scientific issues. Of
11 course that could change as we learn more.

12 **DR. NETON:** I'm sorry, I probably should have
13 started off with that list, and I didn't. I
14 apologize for that. That would have been
15 instructive to do that.

16 **DR. ZIEMER:** Well, let's proceed then with
17 lymphoma, Jim.

18 **LYMPHOMA RISK MODEL**

19 **DR. NETON:** Okay. Lymphoma is not -- was not
20 really on the scientific issue radar screen.
21 It's something that NIOSH self-identified in
22 our continuing effort to use the best available
23 science to do these dose reconstructions. And
24 if I can get to the slide -- it has to do with
25 the target organ selection. It has nothing to

1 do with the lymphoma risk model, it has to do
2 with when one is presented with a case of
3 lymphoma and a health physicist receives the
4 packet, what is the relevant organ to
5 reconstruct the dose for. I mean where --
6 where is that dose relevant. And it turns out
7 that -- on the surface it seems like a very
8 simple issue, and it has turned out, as most
9 things in this program, to be much more complex
10 than one could imagine. And I've learned more
11 about lymphoma biology than I ever thought I
12 would in going through this. And I give Brant
13 Ulsh a lot of credit here. He is -- he has
14 been the main driver behind researching this
15 issue.

16 So like I said, we initiated a re-examination
17 of the internal and external dosimetry target
18 organs for lymphatic/hematopoietic cancers.
19 What -- what we had done in the past was if we
20 were presented with a lymphoma and it was --
21 there was a diagnosis that -- a biopsy was
22 taken, we would use that site of biopsy as the
23 organ in which the lymphoma occurred. It turns
24 out that's good in some cases, it's bad in
25 other cases, and let me just tell you the

1 story.

2 And our goal was to ensure target organ was
3 correctly reflecting the best science. So we
4 actually went out and obtained an expert
5 opinion from a board-certified clinical
6 hematologist on this, as well as an expert
7 opinion from a dosimetrist who's on the ICRP
8 committee, so we kind of have both issues
9 covered, is this the right organ, and then are
10 we doing the dosimetry right.

11 So it turns out that there's two types of
12 lymphomas. There is one that we call -- we
13 will call structural lymphoma, and that really
14 is a lymphoma that involves the cells that make
15 up the lymph nodes themselves. These are just
16 structural lymphocyte cells that make up the
17 lymph system that develop a cancer, and it turn
18 out that the site of occurrence of those organs
19 -- of those cancers is instructive as to when -
20 - where the -- where the relevant radiation
21 damage would have occurred. These types of
22 lymphomas would be Hodgkin's Disease, reticular
23 sarcoma and lymphosarcoma. So I have a listing
24 here of the ICD-9 codes, international
25 classification of disease, revision 9 codings

1 for these -- what we call structural lymphomas.
2 And they're all the 200 series, and so when we
3 have a diagnosis that said that this lymphoma
4 was diagnosed in the abdomen or the pelvic area
5 or the spleen, it gives us a clue as to where
6 we should be dose -- organ we should be
7 reconstructing.

8 So for instance, in the -- if it was diagnosed
9 in the spleen, we would do an internal dose
10 reconstruction for the spleen. This HNMO
11 stands for highest non-metabolic organ, and
12 what that means is we have no idea that this
13 material concentrates anywhere in particular,
14 so we will assign it the dose of the highest
15 organ that doesn't concentrate this radioactive
16 material. In some locations, like the axilla,
17 this would be the thoracic lymph nodes that are
18 very near the axilla; thoracic lymph nodes
19 again; in the head the extra-thoracic lymph
20 nodes. So we have -- it gives us a clue as to
21 where we should be reconstructing the dose for
22 these structural lymph nodes -- structural
23 lymphomas.

24 In the external area it's the same thing. We
25 know in general the location of the origin of

1 the damage, and so we will assign an external
2 dose accordingly. It's a little confusing when
3 you see here why one would use -- let's say,
4 for instance, a stomach for the spleen, and
5 this actually happens to be a point of
6 confusion among many claimants. This has to do
7 with the fact that when we convert a badge
8 dose, a film badge dose to an organ dose, the
9 ICRP models do not give us the dose for every -
10 - the conversion factor for every single organ
11 in the body, so we pick what we would call a
12 surrogate organ that is the organ closest to
13 that -- to that particular organ. So for
14 instance, we would use the ICRP conversion
15 factor from film badge dose to stomach to
16 calculate the dose to the spleen. I hope I
17 haven't confused everybody, but that -- that's
18 been our practice and I -- and where -- where
19 the organs don't match up perfectly, we try to
20 pick one that would actually be a slight
21 overestimate of the dose.

22 Okay, the picture gets a little murkier when
23 you start talking about B and T cell
24 lymphocytes. These are lymphomas that involve
25 these actual circulating lymphocytes

1 themselves. These circulating lymphocytes can
2 become malignant and settle in the lymphatic
3 system, and essentially develop tumors
4 themselves. What'll happen oftentimes, as we
5 found out, is a physician will go take a biopsy
6 in a -- in a lymph node that is most
7 convenient. And when they take the biopsy
8 sample, they will use that to diagnose
9 lymphoma. That in no way is informative about
10 where the lymphoma started. Since these same -
11 - these lymphocytes are continually
12 circulating, we really have no a priori
13 knowledge as to where they were when the
14 radiation damage occurred. This is most
15 significant in the internal dose calculation,
16 'cause if you have no knowledge, then you --
17 you know, you -- you have to speculate as to
18 where -- where the damage may have occurred.
19 So what we've done is we said if we don't know
20 and one has a lymphoma that is a -- a cancer of
21 a -- that started with a cancer of a
22 circulating lymphocyte and we know that the
23 lymphocytes reside predominantly in the lymph
24 system -- I mean they are in peripheral blood,
25 but most of them are in the lymph system -- we

1 will pick the highest lymph node. Well, it
2 turns out we -- most -- in most cases,
3 inhalation exposure is the route of entry that
4 gives you the highest dose. And when you do
5 that, there are the thoracic lymph nodes that
6 drain the lung region, and those are the lymph
7 nodes that become most heavily irradiated.
8 So we are proposing a new procedure that I have
9 on my desk that I'm ready to sign any minute to
10 re-evaluate all lymphomas and use the thoracic
11 lymph node as the organ to be reconstructed for
12 internal dose. This will make a huge
13 difference. I think we have about 500
14 lymphomas that we've evaluated. As I indicated
15 earlier, almost all those were done using the
16 highest non-metabolic organ. The thoracic
17 lymph nodes are a very small mass of tissue,
18 maybe 30 grams of tissue, and they clear all of
19 the radioactivity that's inhaled in the lungs.
20 So the doses to these organs is -- is going to
21 be pretty large, so the -- it's -- it's the
22 first time I think that we're likely to change
23 a -- change a dose reconstruction concept that
24 will result in a large change in the number of
25 compensable claims that have heretofore been

1 denied.

2 In the external region we'll pick the highest
3 organ that is -- that -- the highest organ,
4 whether it's the lung or the thymus. It has a
5 difference between -- T cells and B cells stand
6 for bone and thymus lymphocytes. The site of
7 origin for those lymphocytes is relevant, so
8 we'll just pick the -- whether it's the thymus
9 or the lung. If it's a B cell -- let's see, if
10 it's a T cell lymphocyte, we'll pick the
11 thymus. If it's a bone lymphocyte we'll pick
12 the lung. If it's indeterminate, we'll pick
13 the thymus, which tends to give you the highest
14 external dose.

15 These are pretty trivial corrections compared
16 to what we're doing over here in the internal
17 arena. These -- these doses are going to go up
18 orders of magnitude. This -- this is likely to
19 change by percentage points.

20 There's a couple of odds and ends that just
21 didn't fit the model, and this is where the
22 devil's in the details and Brant has done a lot
23 of work in all these various ICD-9 codes.

24 There's a disease called mycosis fungoides -- I
25 hope I'm pronouncing that right, for our

1 medical folks that are here -- and it's
2 actually a -- involves the skin and it's a
3 lymphocytic and -- cancer that's associated
4 with the skin. So in this particular ICD-9
5 code we would use the skin dose from an
6 internal dose calculation perspective, and use
7 the external skin -- skin dose to the external
8 -- the external dose to the skin, as well.
9 While we were looking through this we decided
10 well, let's just take a look at leukemia and
11 multiple myeloma and make sure we're on the
12 right page with that, and -- and fortunately we
13 were. And the external and internal dose is
14 relevant. We calculated the bone marrow, which
15 has been our practice all along, and so we're
16 still comfortable with that. We're just going
17 to proceed that way.
18 The final note here, hairy cell leukemia is
19 listed as leukemia by nomenclature, but it is a
20 lymphoma under the ICD-9 code, so that's
21 another minor exception.
22 So I think with this analysis we've got the
23 waterfront covered now on lymphomas. We're
24 eager to go back and start re-reviewing these
25 cases. It becomes a little more complicated,

1 again, than you'd think because many of these
2 lymphomas were -- were evaluated under the
3 efficiency process. So we've given some very
4 large doses and demonstrated the PC is less
5 than 50 percent. So now it will require us to
6 go back to the drawing board and do a more
7 detailed dose reconstruction to determine what
8 -- what the relevant dose is. It may not be as
9 bad as we think, though, because of the -- it
10 doesn't take much inhalation dose to get those
11 30 grams of lymph tissue irradiated to a pretty
12 large extent, particularly when you're dealing
13 -- this is most relevant to alpha -- inhalation
14 of alpha-emitting radionuclides.

15 Okay. And -- and as I suggested, we're
16 currently re-examining our past lymphoma cases
17 and we'll be sending notices to the Department
18 of Labor as -- as we process them.

19 I've been a little long-winded on that, but I
20 think I've got the message. Are there any
21 questions?

22 **DR. ZIEMER:** Let's take some questions. Jim,
23 do -- have you in the past and do you still
24 distinguish between structural and B/T
25 lymphomas? So is this only applied to the B/Ts

1 **MS. MUNN:** Right.

2 **DR. NETON:** And we believe that the site of --
3 the site of diagnosis was relevant or the site
4 of diagnosis was informative about where the
5 lymphoma originated. And since the site of
6 diagnosis was in the general lymph system, we
7 just picked -- and the lymph system is not
8 specifically modeled by the ICRP, we assigned
9 it the dose -- the highest dose to what's
10 typically called "other soft tissue" and just
11 used that value in the calculation. Since --
12 since we believe that the site of diagnosis was
13 not the thoracic lymph nodes. See, if we had a
14 site of diagnosis that said that the lymphoma
15 was diagnosed in the thoracic lymph nodes, we
16 would have done that calculation.

17 **MS. MUNN:** Uh-huh.

18 **DR. NETON:** But typically what they do is
19 they'll take a biopsy punch of the axillary
20 lymph nodes or some -- someplace else and say
21 here's where we found the lymphoma. So we --
22 we believe that to be the site of origin. So
23 we did not know what the dose to those lymph
24 nodes were, but we knew that ICRP modeled all
25 soft tissue, so we would just pick the highest

1 other soft tissue that we could find to assign
2 that dose. Am I -- am I --

3 **MS. MUNN:** That sounds reasonable to me, but
4 what I think I hear you saying now is since the
5 lymph system is so pervasive that you have no
6 faith in which organ is the highest non-
7 metabolic organ, and therefore you're going to
8 choose the highest of all potential internal
9 organs; i.e., the lung.

10 **DR. NETON:** No, it's a little bit different
11 than that. What we're saying is that the --
12 the cancer of the circulating lymphocytes could
13 have occurred -- the lymphocytes circulate
14 throughout the body.

15 **MS. MUNN:** I understand.

16 **DR. NETON:** So the radiation damage to that
17 lymphocyte could have occurred anywhere where
18 it was circulating.

19 **MS. MUNN:** Uh-huh.

20 **DR. NETON:** Given that, we have no idea in what
21 organ the lymphocyte was when the radiation
22 damage happened. Given that, we will pick then
23 the highest lymph node exposure and assume that
24 that's where the damage occurred, which in --
25 in almost all cases will be the thoracic lymph

1 nodes.

2 **MS. MUNN:** Well, I can see that would certainly
3 be claimant-friendly. My concern is always
4 whether the claimant-friendly issue is
5 overriding the known science. And what you're
6 telling me is you -- the model that you're
7 working from doesn't really give you that
8 option. Right?

9 **DR. NETON:** Right, well, we --

10 **MS. MUNN:** Essentially.

11 **DR. NETON:** We looked at a few options. One
12 was to take a weighted average of where the
13 lymphocytes reside on a time-weighted basis. I
14 mean we had -- believe it or not, the ICRP
15 models get down to that level.

16 **MS. MUNN:** Uh-huh.

17 **DR. NETON:** But the values were so uncertain,
18 and by the time we would put uncertainties
19 about those, I thought it was much more
20 defensible just to pick the highest
21 (unintelligible) the highest lymph node value
22 itself.

23 **MS. MUNN:** When the bars get out there so far,
24 there's no point --

25 **DR. NETON:** That's exactly right.

1 **MS. MUNN:** -- in dealing with it, yeah.

2 **MR. ELLIOTT:** I'd like to provide maybe a point
3 of clarification that answers your question, if
4 I could, from a simple lay person's
5 interpretation here. What we're saying is that
6 the -- the organ of diagnosis does not lead to
7 -- to understanding of the organ of origin.

8 **MS. MUNN:** I understand that.

9 **MR. ELLIOTT:** Okay? And so we're picking what
10 we think is the highest organ of origin to use
11 in reconstructing the dose against that.

12 **DR. ZIEMER:** Since you can't otherwise
13 (unintelligible) --

14 **MR. ELLIOTT:** Since we can't otherwise, right.

15 **MS. MUNN:** Yeah.

16 **DR. NETON:** That's exactly right.

17 **DR. ZIEMER:** Jim.

18 **DR. MELIUS:** Yeah, that's a good point. I have
19 one caution and then a procedural question.
20 The caution would be that the nomenclature and
21 classification for lymphomas have changed over
22 time, as well as the way that they are
23 diagnosed -- the diagnostic information. And
24 you may have difficulty with older cases in
25 particular converting them to this scheme.

1 They -- they -- in terms of the available
2 information and -- and the way that they're --
3 they're classified in the medical records. And
4 you're going to have to give some thought to
5 that. I -- I'm trying -- I'm trying to think
6 in my mind, going back through the older
7 classification systems for lymphoma, how it --
8 whether -- to what extent it will impact. But
9 I think it will because I think some of the
10 systemic lymphomas that you're referring to
11 here are going to be classified anatomically in
12 some of the older nomenclatures. And that's
13 what you're -- you're going to see. And some
14 of the newer methods now to determine that they
15 are a certain systemic lymphoma just weren't --
16 the tests just weren't available 20 years ago
17 or even, some of them, ten years ago. So I --
18 Roy may have some additional comments on that.
19 My -- I don't think it's insurmountable, but
20 there will be some uncertainty on that.
21 Procedurally, I'm a little concerned that we're
22 making a -- you are, you know, offering up a
23 very significant change, it's going to have
24 significant impact, in terms of your dose
25 reconstruction methods. And that we're being

1 asked to approve that based on a small number
2 of slides -- presentation, without a document
3 to refer to. And I would even question -- and
4 this goes back since -- to our beginnings as a
5 advisory board -- as to whether this shouldn't
6 be federal -- noticed in the *Federal Register*.
7 I recall, and I don't recall specifically, but
8 we had talked about a -- that significant
9 changes would be noticed and public would have
10 an opportunity to -- to comment on them. I'm
11 personally in favor -- by doing it. I think it
12 is justified, but I am -- even I can say I'm
13 not quite sure what I'm approving of because I
14 don't -- you haven't even written out the
15 classi-- all the classifications here and --
16 and looked at some of these issues, so I'd like
17 some comment on the procedural issues.

18 **DR. NETON:** Well, I'd like to address your
19 first comment, which is that the uncertainty
20 about classification of lymphomas. We -- I'm
21 aware -- I've become aware of that, and it's
22 certainly a big issue. However, that -- the
23 responsibility for that codification lies with
24 the Department of Labor. We take whatever ICD-
25 9 code is delivered and we'll use it. I'm not

1 saying that makes it better, I'm just saying
2 that we need to make sure that the Department
3 of Labor is very aware of this and --

4 **DR. MELIUS:** Yeah, and I -- I think they may
5 need some documentation that helps them do
6 this, and I think you should have -- you have
7 some responsibility getting that to them,
8 parti-- particularly to these older cases,
9 which a lot of these will be, from survivors
10 and -- it's been significant change. I can't,
11 from the top of my head, sort of -- I don't
12 think it'll affect a lot of cases, but I think
13 it -- there'll be a significant number that
14 will be impacted -- there'll be some
15 uncertainty about and how to fit them into the
16 classification. I believe there are even
17 regional differences, particularly before
18 cancer registries became common, that you'll
19 find in older medical records in terms of when
20 -- like hematologists or whoever -- physicians
21 were trained and where they were trained in
22 terms of what -- what some of these tumors are
23 called.

24 **DR. ZIEMER:** Roy, can you speak to that point?
25 Roy DeHart, you want to speak to the point

1 there?

2 **DR. DEHART:** Jim, I was really surprised that
3 you're getting significant anatomical location.
4 In reviewing medical documentation over recent
5 years where lymphoma was the issue, the 200 or
6 the 202, usually the codings that I see are .00
7 -- in other words, non-specific. And to find
8 that we have them pretty well distributed body-
9 wise is a surprise, particularly when you've
10 got states that do not have cancer registries,
11 where they really don't hassle the doctors to
12 be very, very precise in their coding. Do you
13 recall whether the majority of these lymphomas
14 are in fact anatomically specified?

15 **DR. NETON:** I don't know that, and I'm sorry if
16 I meant -- I didn't mean to imply that we had
17 that level of knowledge. If we do know, you
18 know, beyond .00, we would apply it. But maybe
19 Russ Henshaw is -- is slightly more familiar
20 with what's been coded and he can help me out
21 here. Russ, please?

22 **MR. HENSHAW:** Yes, Russ Henshaw. I don't -- I
23 don't know the exact percentage, Dr. Melius,
24 but some time ago we asked the Department of
25 Labor to go back through all the lymphoma cases

1 and assign the fifth digits whenever possible.
2 And they actually spent several days doing that
3 for the coding, and so we have a fairly large
4 percentage of cases with that degree of
5 information. I don't know the percentage.

6 **DR. MELIUS:** I would be -- I'd be very cautious
7 on this. I don't know what information the
8 Department of Labor had, but this is not an
9 easy task to do, particularly for these older -
10 - older cases, and -- I mean I've reviewed
11 records also on -- series of lymphomas ranging
12 over a time period, and sometimes it -- it's --
13 you have to go pretty deep into the medical
14 records to -- to be able to understand what's
15 happening.

16 **DR. ZIEMER:** Russ, are these cases that might
17 originally have been specified as double-zeroes
18 and you've asked them to go back and --

19 **MR. HENSHAW:** Either --

20 **DR. ZIEMER:** -- differentiate and --

21 **MR. HENSHAW:** Yes, either double-zero or simply
22 no digits beyond the first three.

23 **DR. ZIEMER:** In which case the physician
24 involved wouldn't have made the
25 differentiation; it's someone else that has

1 looked at the --

2 **MR. HENSHAW:** Well, typically what -- the
3 process that was followed was to review all the
4 medical records, and in some cases that's
5 several hundred pages per claim. And first
6 look at the pathology report and see if the
7 information can be derived from that or just
8 really all the pages of medical information.
9 But -- but again, the digit assigned was the
10 site of the biopsy, not necessarily the site of
11 origin, the site of radiation injury.

12 **DR. NETON:** We tend to have a lot of medical
13 records on these folks. I mean a couple of
14 hundred pages, like Russ said, is not unusual.
15 And Labor has gone back and we've spent, as you
16 can tell, a lot of time looking through, trying
17 to refine this. But I totally understand what
18 you're saying --

19 **DR. MELIUS:** Yeah, again, I'm not criticizing
20 exactly what was done 'cause I don't know the
21 detail, but I'm just saying it's not an easy
22 task. And I'm sure if you have some cases from
23 the '50's or something, I'd be surprised how
24 much level of detail would be available. It's
25 an issue we've talked about in terms of missing

1 records. But the way it was diagnosed in those
2 days was very different.

3 **DR. ZIEMER:** But I'm confused then, if they are
4 simply using that -- for example, if the -- if
5 it's spleen, for example, do they still -- are
6 they able to distinguish whether it's a 200 or
7 a 202?

8 **DR. NETON:** That's the crux of the issue.
9 Really the site of diagnosis is not that
10 important because we will default to -- well,
11 for the circulating ones it's not important
12 because we're going to always assume the
13 thoracic lymph nodes, but for the non-Hodgkin's
14 -- or for the Hodgkin's type lymphomas, that's
15 going to be important and --

16 **DR. ZIEMER:** Well, let me back up and ask it in
17 a different way, maybe ask Roy, when you said
18 they tended to use the double-zero or, you
19 know, just generally unspecified, do they still
20 distinguish between the 200 and 202
21 classification or...

22 **DR. DEHART:** Normally they would, yes.

23 **DR. ZIEMER:** They would. So we -- if it's a
24 202, then it doesn't matter.

25 **MR. HENSHAW:** Right, I just (unintelligible) in

1 many cases also the information is conflicting
2 in these records, or just simply absent, so
3 many of the claims are coded as diffuse, which
4 is, you know, not helpful for this situation.

5 **DR. NETON:** And we would certainly adopt a
6 conservative default value in that case.

7 **DR. ZIEMER:** What is -- what -- is NIOSH asking
8 for action at this point, or are you just
9 reporting?

10 **DR. NETON:** Well, that's -- that speaks to Dr.
11 Melius's second point, which I was going to
12 address. I'm not sure this requires rule-
13 making. I think -- I think, Dr. Melius, you're
14 -- you're thinking about changes to the risk
15 models, which is where, you know, rule-making
16 may -- may be necessary. This is really a just
17 -- not just, but it is a change to a dose
18 reconstruction practice of selecting a target
19 organ.

20 **DR. MELIUS:** I'm not talking about rule-making
21 here. I'm talking about opportunity for public
22 comment, public notification --

23 **DR. NETON:** Right.

24 **DR. MELIUS:** -- and, you know, presentation.

25 That --

1 **DR. NETON:** Right.

2 **DR. MELIUS:** -- I believe we had another
3 option, short of rule-making, when we
4 originally approved the regulations and we were
5 concerned that the -- they were so general, and
6 given the time frame and so forth, the need to
7 get the program going, we -- I think we all
8 agreed to that. But as things needed to be
9 filled in, that if they would have a
10 significant effect either in the -- dealing
11 with the IREP model or in terms of the dose
12 reconstruction, that we would provide some sort
13 of public -- time for public comment, as well
14 as -- you know, in the notification for that.
15 Now my memory could be faulty. It's a number
16 of years ago, but it's come up periodically and
17 we have -- have discussed it here, and -- and -
18 -

19 **DR. ZIEMER:** I know we've had the discussion on
20 the IREP model itself. What we're hearing
21 here, though, is the IREP doesn't change. It's
22 just the -- you're using a different target
23 organ.

24 **DR. NETON:** Right.

25 **MR. ELLIOTT:** Well, we have to go back to our

1 rule-making effort in the early days and -- and
2 this goes to Dr. Melius's point. In that rule-
3 making, we -- and I asked Liz to check on this
4 -- what it says about -- my recollection in the
5 language is we are to bring substantive changes
6 to the Board for review and advice. Is this a
7 substantive change. You know, I guess I -- you
8 need to weigh in on that. We think it's a
9 substantive change. We think it's a change in
10 the right direction. We think it gives benefit
11 of doubt and it just feels right, it's doing
12 the right thing. Certainly if -- if you need
13 more information about this, we're -- we're
14 ready to do that. I'd hate to see us hold off
15 on, you know, treating 500 claims, and a
16 majority of those that have been denied, where
17 they may be found to be compensable under this
18 approach. So -- but appreciate your input.

19 **DR. MELIUS:** Yeah, it's not just a question of
20 what we need to see or whatever. We can talk
21 about that separately. But -- but as I recall,
22 there -- there was an agreement to notice the
23 public if, you know, substantial changes were
24 being -- going to be made, if something would
25 have a substantial effect on a num-- number of

1 claims, and so that then it would be on the
2 agenda for the next meeting and there'd be an
3 opportunity to talk about -- that was short of
4 rule-making, but I think we need to look back
5 at both what was in the rule and in the Board's
6 discussions of the rule at that point in time
7 and -- again, I'm not trying to -- I just think
8 we need to stick by what we said we would
9 originally do and -- and be consistent on that
10 and not an issue whether it's a good change or
11 a bad change or positive or negative that we --
12 we really need to follow that.

13 **MR. ELLIOTT:** And I agree, we do want to follow
14 that, but -- and this is what the lawyers back
15 in the office are checking on right now --

16 **DR. MELIUS:** Okay.

17 **MR. ELLIOTT:** -- what does the language of the
18 rule speak to. The POC rule, I'm pretty sure,
19 specifies that substantive changes in the POC
20 rule are to be brought before this -- this
21 Board. I don't -- we're trying to figure out
22 if this -- this is a dose reconstruction
23 methodology, and if that is couched a similar
24 and same way.

25 I would also offer that we did not agree -- or

1 I don't think we covered in our agreement that
2 we would put out a *Federal Register* notice.
3 This could serve as public notice that we are
4 interested in moving in this direction, but we
5 welcome your input again.

6 **DR. MELIUS:** Yeah, let's -- let's check and we
7 can --

8 **DR. ZIEMER:** Anything that's outside of the
9 rule-making issues, which are certainly
10 binding, and irrespective of what this Board
11 may or may not have done in the past, we can do
12 as we wish on -- we can take action today that
13 is even contrary to something we decided to do
14 before, if we so wish. In other words, we can
15 outline a procedure that we think should be
16 followed in this case in terms of public notice
17 and so on. I think those -- that prerogative
18 is open to us, because we are not necessarily
19 bound forever by any actions of the past. We
20 may not have anticipated exactly this kind of
21 thing in the past, or we had something else in
22 mind. But it seems to me we still are not
23 prevented from taking whatever action is
24 appropriate.

25 **DR. MELIUS:** Well, I would strongly disagree

1 with that, Paul. I think we -- we have made a
2 commitment -- if we did, and I'm not saying,
3 you know, we did. But if we did make a
4 commitment that if we were going to make
5 substantial changes in dose reconstruction
6 procedures or some other part of this program
7 and told people that we would publicly notify
8 them and so forth, then I think we do need to --
9 -- to follow that. Now if we want to change
10 that procedure and -- to what extent it was in
11 the rule-making and to what extent it was a
12 commitment that NIOSH made in terms of the
13 meeting, we -- I have no problems with
14 discussing that, but I -- I don't think we
15 should just arbitrarily decide that we're going
16 to change our approach or procedures because of
17 some such issue --

18 **DR. ZIEMER:** Well, actually we don't disagree.
19 I was looking at it from completely the
20 opposite point of view. It doesn't matter
21 whether -- if we didn't do that in the past, we
22 can still do it.

23 **DR. MELIUS:** Okay.

24 **DR. ZIEMER:** I was actually looking at it
25 completely the opposite way --

1 **DR. WADE:** All right, let me --

2 **DR. ZIEMER:** -- not dependent on whether we
3 made a policy in the past on this.

4 **DR. MELIUS:** Okay.

5 **DR. WADE:** Given the sentiment of the Board,
6 let me propose that we follow this course of
7 action. We can have a rules check and see what
8 the record shows, but I get the sense of this
9 Board that they would like more information on
10 this question, and they would like to see the
11 public noticed of the fact that at the next
12 meeting this item would be discussed. So I
13 think we can follow that path. We can see what
14 the lawyers produce in terms of what the record
15 shows, but other than Larry's caution about
16 wanting to do the right thing quickly, I see
17 nothing wrong with providing this Board with
18 the report that you said was on your desk, for
19 example, Jim. You've got those materials.
20 Provide them to the Board. When we put out the
21 agenda for the next meeting, make it clear that
22 this item's going to be discussed asking for
23 the Board's concurrence, and let the public
24 comment at that meeting if they would like.

25 **DR. ZIEMER:** And -- and indeed, we could also

1 identify previous commitments that we have --

2 **DR. WADE:** Sure.

3 **DR. ZIEMER:** -- made along --

4 **DR. MELIUS:** Yeah.

5 **DR. ZIEMER:** -- that line. That's certainly
6 appropriate.

7 Mark?

8 **MR. GRIFFON:** Just to -- just to follow on with
9 what Lew said, the -- I was thinking the same
10 thing. The procedure on your desk -- I don't
11 know if it's a procedure or policy, and I don't
12 know to what exten-- if you can describe that,
13 maybe, if it has --

14 **DR. NETON:** This is a --

15 **MR. GRIFFON:** -- enough background to help us -
16 - or is it just a --

17 **DR. NETON:** It's a procedure that really
18 changes the target organ selection based on our
19 input from our hematologist.

20 **MR. GRIFFON:** Does it include any of the basis
21 for the change, or that's really extern--

22 **DR. NETON:** I think there is some basis in
23 there about the discussions that took place,
24 but --

25 **MR. GRIFFON:** So that might be a -- a --

1 **DR. NETON:** -- again, I mean this is not a
2 giant rocket science sort of an issue. I mean
3 if you don't know the target organ, then one
4 has to default to something more conservative,
5 and that's about the extent of the scientific
6 debate, I think.

7 **MR. GRIFFON:** Yeah.

8 **DR. NETON:** I mean there may be other opinions.
9 Now maybe our one hematologist is not going to
10 be sufficient evidence, I don't know. But --

11 **DR. MELIUS:** But I -- I think there's some
12 issues in the -- excuse me for interrupting,
13 but in the details of it that -- about the
14 classification and -- or maybe those can be
15 dealt with on an individual basis, but I do get
16 concerned that -- I mean I would certainly like
17 to see the procedure and understand a little
18 bit more about how it's communicated to the
19 Department of Labor so that we --

20 **DR. NETON:** Sure.

21 **DR. MELIUS:** -- don't cause problems.

22 **DR. NETON:** Again, classification is out of our
23 hands. I mean we -- we have to assume we're
24 getting the appropriate classification from
25 them and they -- you know, that's their issue.

1 I'm a little concerned, though, because you
2 know, with SC&A's reviews we're making -- we're
3 in the process of -- there's numerous potential
4 changes that could be made and tweaks to dose
5 reconstruction. And if all these have to go
6 through public process, it's going to be --

7 **DR. MELIUS:** No, that --

8 **DR. NETON:** -- somewhat cumbersome.

9 **DR. MELIUS:** -- that was not the intent. This
10 had to do with basic procedures and so forth,
11 not individual dose reconstructions or site
12 pro-- profile reviews.

13 **DR. NETON:** Well, no, then there's other issues
14 related to rotations and --

15 **DR. MELIUS:** Well, then --

16 **DR. ZIEMER:** There's a concern about -- aside
17 from this particular situation, about setting a
18 precedent on how we actually deal with changes
19 of this type, and --

20 **DR. MELIUS:** And again, may-- maybe we have to
21 revisit the procedure or our procedure so that
22 we facilitate this. I'm not trying to hold it
23 up, but I do think we need to be, you know,
24 sort of consistent with what we had decided at
25 an earlier point in time.

1 **DR. NETON:** Okay.

2 **DR. MELIUS:** I also add that I think some of
3 this is the -- some of the reaction is because
4 -- we haven't talked about it yet, but what --
5 what an excellent job I thought you did with
6 the lung cancer model. That document I
7 thought, when you presented it to us, was
8 excellent and very useful. And I guess when --
9 then when we don't see it on something else,
10 then we're -- you know, it sort of raises
11 expectations.

12 **DR. NETON:** Appreciate that.

13 **DR. ZIEMER:** Okay, let's go ahead and -- we
14 don't have to take a particular action right at
15 this point. Let's go ahead with the rest of
16 the presentation, so after lymphoma we're up to
17 age at exposure.

18 **AGE AT TIME OF EXPOSURE**

19 **DR. NETON:** All right. This one is really just
20 for information only, and we're not asking for
21 any decision on the Board, although we
22 certainly would appreciate any input that the
23 Board might have -- we'll start with that --
24 on...

25 This issue was I believe a number two priority

1 on the Board's list of priority issues -- it
2 was in the second tier of priorities, let's put
3 it that way. It was not a first-tier priority.
4 And this has been an issue for some time, that
5 it's been in the literature that some
6 researchers have suggested that the
7 radiosensitivity to cancer increases with age.
8 There -- there are studies out there that one
9 can quote and cite that -- that demonstrate
10 that there's some statistical effect relative
11 to how old one is in the risk of developing
12 cancer.

13 We took a look at this and went back and
14 reviewed the relevant major studies that we're
15 aware of that we could find that demonstrated
16 this effect, and just -- just to see where the
17 science is falling on this issue at this
18 particular time. Again, I suggest it's a
19 priority research issue, but it was in the
20 second -- priority.

21 So what I have here really is sort of a summary
22 of the papers that have been published relative
23 to this, and there are a number of papers and
24 I've cited here on this slide the Hanford
25 study, Wing and Richardson, Gilbert et al,

1 Stewart and Kneale, the ORNL cohort and the
2 Rocketdyne cohorts. Each of those studies have
3 in some way made -- come to some conclusion
4 that there may be an effect related to age at
5 exposure. That is, older people when they're
6 exposed have a higher risk of developing cancer
7 per unit dose than -- than younger.
8 They -- they all -- the stan-- this is not a
9 standard analysis method, though, of how one
10 does this. They all -- one can group these age
11 bands differently and come to different
12 conclusions, and that's one of the issues I
13 think here is how one standardizes on this
14 analysis. I think one of the studies actually,
15 you know, picked a before-45 and after-45; one
16 grouped them by decades, that sort of thing.
17 So you can get different conclusions.
18 So those studies have reported associations,
19 and then on the bottom here we have studies for
20 the Rocky Flats, Atomic Energy of Canada, the
21 United Kingdom Atomic Energy Administration or
22 Agency, and the UK Atomic Weapons Establishment
23 and Sellafield. None of those studies, when
24 they looked for this age of -- at -- issue have
25 identified such an association. So again, you

1 have conflicting -- conflicting science on this
2 issue.
3 NIOSH -- HERB, that is, the Health-related
4 Energy Research Branch -- had engaged in some
5 research on this issue in collaboration with
6 Oak Ridge Associated Universities in the past.
7 And they looked at this effect in the ORNL --
8 the Oak Ridge National Laboratory cohort. And
9 the conclusion of this analysis was that the
10 observed trends may have been due to other
11 factors than age at exposure. This is an issue
12 of confounding within this -- this analysis,
13 and that is these birth-cohort effects. That
14 is, how you group these things from age at
15 exposure, you end up with people who were born
16 in different times. So then you may have
17 confounding due to the fact that these people
18 may have had different smoking habits, medical
19 screening may have been applied differently in
20 that time period. So there's -- there's other
21 plausible issues that come into play here that
22 tend to bring into question the robustness of
23 this analysis.
24 Richardson and Ashmore just recently looked at
25 this effect in Canadian workers, and their

1 conclusion was that there was an increase in
2 radiosensitivity with age for lung and leukemia
3 -- lung cancer and leukemia, but not for
4 others. But again, you know, a more detailed
5 analysis determined that this could have been
6 the differences in smoking behavior over time.
7 So again, not -- not conclusive. There's no
8 conclusive determination made here.

9 An interesting note here is, you know, NIOSH-
10 IREP actually has an age-at-exposure
11 adjustment, and that is -- it's sort of the
12 opposite of what we're talking about here. For
13 most cancers the radiosensitivity decreased
14 with age in the atomic bomb survivors, and that
15 -- those corrections or adjustments are applied
16 to a number of -- almost all of our cancer
17 models with the exception of female genitalia,
18 lung cancer and -- and leukemias and squamous
19 cell carcinoma. So you know, right now we're
20 doing something a little different than what --
21 if you hear age at exposure, this is different
22 than the age at exposure that I was just
23 talking about.

24 So you know, just a brief summary on an arm's
25 length view of this issue and -- and I

1 certainly have more experts here to help me,
2 who can discuss this issue and flesh out the
3 scientific details, but -- but the balance of
4 the evidence right now is not conclusive as to
5 whether or not, you know, we should engage in
6 applying, you know, unilaterally an age-at-
7 exposure adjustment for occupational cohorts.
8 There's certainly evidence out there. More
9 research needs to be done, and we're going to
10 continue to accrue these studies as they come
11 out and -- and, you know, analyze them, keep
12 our ear to the ground as to what the Health-
13 related Energy Research Branch may be doing and
14 see what happens in the future. Right now
15 we're not -- we're not proposing to make any
16 change based on that -- that effect.

17 **DR. ZIEMER:** Okay. Now let's open the floor
18 for discussion on the age of -- age at exposure
19 issue. Any questions or comments -- Dr.
20 Melius.

21 **DR. MELIUS:** Yeah, would anybody -- Jim or you
22 or any of the other staff here -- be aware of
23 what other studies are currently underway that
24 are likely to be completed shortly in terms of
25 addressing this issue? And also I'd be curious

1 -- I don't recall what the current -- current
2 BEIR report, most recent one, to what extent it
3 tried to address this issue and what their
4 conclusions were.

5 **DR. NETON:** Right, I'm familiar with what --
6 the BEIR report had a very brief -- several
7 sentences, and maybe Brant can speak to this;
8 he's more familiar with the literature than I
9 am.

10 **DR. ULSH:** The first part of your question
11 about what major studies are underway right
12 now, I think the biggest one on the horizon is
13 probably the IARC 15-country study.
14 Preliminary results of that study have been
15 published, but we're still waiting for detailed
16 results to come out and I think that's
17 underway.

18 **DR. MELIUS:** Okay.

19 **DR. ULSH:** With regard to BEIR VII, it really
20 didn't have a lot to say about this. As Jim
21 indicated, there were a few paragraphs and
22 basically they summarized what we said here in
23 the slides, that some cohorts have some
24 evidence of it and others have not, but they
25 really didn't delve into it in much more detail

1 than that.

2 **DR. MELIUS:** Okay. Thank you, Brant.

3 **DR. ZIEMER:** Okay. Other comments or questions
4 on that?

5 Okay, if not, let's proceed then, Jim.

6 **DR. NETON:** I think (unintelligible) more
7 smoothly when we're not making major changes to
8 models.

9 **DR. ZIEMER:** Counsel has an issue.

10 **DR. WADE:** There goes smooth.

11 **MS. HOMOKI-TITUS:** No, I think this'll actually
12 help smooth the last issue. 82.33, which is
13 part of the dose reconstruction rule, how will
14 NIOSH inform the public of changes to the
15 scientific elements underlying the dose
16 reconstruction process. NIOSH will publish a
17 notice in the *Federal Register* informing the
18 public of changes and the rationale for the
19 changes. This notice will also provide a
20 summary of the recommendations of comments
21 received from the Advisory Board and the
22 public, as well as responses to the comments.
23 So therefore, we need to receive y'all's
24 information before we put a *Federal Register*
25 notice out.

1 **DR. NETON:** I guess, Liz, I'm not --

2 **MS. HOMOKI-TITUS:** Obviously, however you all
3 decide to do that, whether it's hey, we need
4 more information --

5 **DR. ZIEMER:** And Liz, I don't know if you can
6 help us on this, but I suppose one of the
7 issues -- Jim kind of said, you know, we're --
8 we're always massaging the -- the things, it's
9 -- it's, again, this threshold issue of at what
10 point does a change become significant. Do we
11 have any test of that internally, or is it the
12 Board's judgment on these things? I mean this
13 one looks significant insofar as it may cause
14 re-examination and changes in a number of -- of
15 what are now closed cases. Is that the test of
16 significance, or -- I -- I'm -- that's sort of
17 --

18 **MS. HOMOKI-TITUS:** I think I would have to --

19 **DR. ZIEMER:** -- that's sort of a rhetorical
20 question.

21 **MS. HOMOKI-TITUS:** I was going to say, I don't
22 think that we have a standard (unintelligible)

23 --

24 **DR. ZIEMER:** Don't have --

25 **MS. HOMOKI-TITUS:** -- that.

1 **DR. ZIEMER:** -- a standard, it's a judgment
2 call I think, perhaps both on the part of the
3 agency -- in a sense, you've said it's
4 significant because you brought it to us to --
5 to look at. That's sort of -- implies that you
6 think it's -- has some level of significance.

7 **DR. WADE:** You know, I think there'd be two
8 tests. One you just mentioned. If NI-- if the
9 agency brings something to you and says it's
10 significant, then I think we -- we live under
11 this provision. The agency will also be making
12 you aware of all the things that it's doing,
13 and I think at any point the Board can say I
14 consider that significant and would like to
15 follow the procedures that Liz just read to us.

16 **DR. ZIEMER:** This could include changes that
17 come about that we become aware of as part of
18 the interaction with the contractor, for
19 example. If something they do causes NIOSH to
20 change a process or a methodology, one might
21 identify that. Dr. Melius?

22 **DR. MELIUS:** Yeah, and I think if one would
23 want to go back through the transcripts of all
24 our previous meetings, I -- this actually --
25 issue has come up before and where we I think

1 have actually had discussions and decided that
2 the proposed changes really weren't that
3 significant and -- do that, and -- I mean the
4 threshold is fairly -- I think this one does --
5 is significant, does meet that, you know, sort
6 of arbitrary threshold we -- we've talked
7 about. But we have discussed this before and
8 have decided that it wasn't warranted so...

9 **DR. ZIEMER:** Okay, and it does appear that the
10 rule itself is a governing thing over and above
11 anything we might have done in our Board then,
12 in terms of this notification process.

13 **DR. WADE:** Could I also ask the agency a
14 question there? Given the fact that now we
15 have significance defined in this term, do you
16 bring this issue to the Board as a significant
17 issue?

18 **DR. NETON:** I -- I think I -- I certainly
19 (unintelligible) call this a significant issue,
20 I could not. But I think -- my take on this is
21 this is a fundamental change to dose
22 reconstruction, I don't know. It's a target
23 selection. It's a lower-tier procedure that's
24 being modified, not an implementation guide or
25 an ICRP model. But it is significant, I will

1 grant you.

2 **MR. ELLIOTT:** Is the word "significant" or
3 "substantial"? We don't know, but I would say
4 it's a substantial change.

5 **DR. WADE:** So you're bringing it to the Board -
6 -

7 **MR. ELLIOTT:** Yes.

8 **DR. WADE:** Well, the Board has every right to
9 say in order for us to comment, we need certain
10 information and we can proceed down that --

11 **DR. MELIUS:** Yeah, and -- I mean I would also
12 say, 'cause it -- something has to be commu--
13 Department of Labor has to -- I won't say
14 endorse this, but implement this and -- in
15 change and so forth, and -- and since it will -
16 - it does involve the recalculation of a number
17 of completed dose reconstructions, I really
18 think it's better to do it as -- a little bit
19 more formally than we would do, you know, other
20 -- deal with other issues.

21 **DR. NETON:** No problem doing that.

22 **DR. WADE:** Let's also all pause to realize that
23 we're doing the right thing. There is general
24 agreement about it. We just want to make sure
25 we do it the right way, so --

1 **DR. ZIEMER:** Mr. Presley I think has a comment,
2 too.

3 **MR. PRESLEY:** Jim, I believe you said this
4 could impact as many as 500 cases?

5 **DR. NETON:** That's correct.

6 **MR. PRESLEY:** I believe that's a pretty
7 significant number.

8 **DR. NETON:** Well, I agree.

9 **DR. ZIEMER:** Mark.

10 **MR. GRIFFON:** I just wanted to go back one
11 second for the age at exposure, just -- just to
12 follow up on that. I mean the last slide you
13 said evidence does not suggest modifying the
14 NIOSH-IREP model. I guess -- I guess my only
15 concern is the time frame on this because it
16 seems the current model, as -- as you
17 indicated, decreases the ER per sievert over
18 time and some of these studies at least suggest
19 an increase and yet, you know, you wonder if --
20 if the models should be made to say must at
21 least be neutral over -- for age at exposure.
22 And I guess you're saying there's just not
23 enough evidence yet. I'm just wondering, you
24 know -- 'cause that could significantly change
25 models and results on the IREP outputs, and I

1 don't know if there's any kind of time frame
2 expectation on resolving this.

3 **DR. MELIUS:** Well, that -- can I jump in --
4 'cause that was my really sort of my question I
5 was trying to get at and -- and maybe to
6 specify this a little bit more for your
7 question, Mark, is to ask NIOSH to come back to
8 us once this IARC analysis is done 'cause
9 that's the sort of next big thing coming -- at
10 least to inform us of -- of where that stands
11 and then I think we can decide do we need to do
12 a formal -- you know, more complete evaluation
13 of this, given the conclusions of BEIR VII and
14 then given the -- you know, what we -- what we
15 see is coming. I think we -- I'm satisfied
16 with waiting. I would like to know when that
17 IARC report comes out and then when we can
18 decide for --

19 **DR. ZIEMER:** Did we -- did we hear that was on
20 the street in a draft form or --

21 **DR. MELIUS:** No, the early report of the -- I
22 don't think they've done this kind of analysis
23 yet, at least I'm -- I haven't heard of it.
24 Now people more informed than I may have.

25 **DR. ZIEMER:** Okay, the good, the bad and the

1 ugly. Which one's the good and which one's the
2 bad?

3 **DR. MELIUS:** Who's Clint Eastwood today?

4 **MR. HENSHAW:** I just want to make one
5 clarification on the age at exposure issue.
6 Dr. Melius, you raised this issue. In IREP a
7 list of cancer decreases from ages 15 to 30,
8 but then it remains constant from age 30 on, so
9 it's not -- you know, after age 30 this would
10 not be (unintelligible) with the current
11 adjustments.

12 **DR. MELIUS:** Okay.

13 **DR. NETON:** Thanks, Russ.

14 **DR. ZIEMER:** Do we have some SENES input on
15 this or is that --

16 **DR. NETON:** I think that was the input.

17 **DR. ZIEMER:** All right.

18 **DR. MELIUS:** Can we go back to -- we're all
19 over the place here -- can we just sort of get
20 some closure on what we're doing with the
21 lymphomas?

22 **DR. ZIEMER:** Actually I want to get the closure
23 -- this topic's going to continue after lunch.
24 We have some more to cover --

25 **DR. MELIUS:** Oh, okay.

1 **DR. ZIEMER:** -- and then we can sort of wrap up
2 the whole thing.

3 **DR. MELIUS:** Okay, fine.

4 **DR. ZIEMER:** I think we'll go ahead -- it's --
5 it's 12:00, let's get our lunch break --

6 **DR. WADE:** Could I impose upon --

7 **DR. ZIEMER:** -- and continue after lunch.

8 **DR. WADE:** I'd like to impose upon my friend
9 Jim -- Jim, would it be possible after lunch
10 when we do the wrap-up for you to put up the
11 list of priorities that the Board had had
12 before? Can we get our hands on that and let's
13 --

14 **DR. NETON:** I think I can.

15 **DR. WADE:** If we could just have that as
16 background.

17 **DR. ZIEMER:** Okay, we'll recess till 1:30.
18 (Whereupon, a recess was taken from 12:00 p.m.
19 to 1:30 p.m.)

20 **SMOKING RISK ADJUSTMENT**

21 **DR. ZIEMER:** Okay, we're ready to resume our
22 deliberations. We're still on the topic of
23 scientific issues, and I think we're ready to
24 discuss the lung model aspect here, Jim, so
25 let's proceed with that and then we'll have a

1 chance to discuss related things. And we also
2 I think have the priority list that was
3 requested prior to lunch so we'll have a chance
4 to look at that.

5 **DR. NETON:** Thank you, Dr. Ziemer. You should
6 have a copy of our document labeled status of
7 research topics as of June 2005. It's a
8 summary of the Board's priority one and two
9 issues that were identified by the Board.

10 There may be some confusion, there is another
11 longer, three-page -- two or three-page list
12 that Dr. Melius I believe put together, so --
13 but I think this (unintelligible) reflects --

14 **DR. MELIUS:** Yeah, that -- actually this does
15 reflect that. I think we had a discussion and
16 agreement of the Board that -- so from that
17 longer list we culled it down to this shorter
18 list.

19 **DR. ZIEMER:** The longer list was everything
20 that we wanted to have before us, from which we
21 selected the priority ones and twos.

22 **DR. MELIUS:** Correct, yeah.

23 **DR. ZIEMER:** So these are the important ones.

24 **DR. NETON:** These are the ones that ended up
25 being, you know, listed --

1 **DR. MELIUS:** And I also believe you convinced
2 us to add some priorities of yours to our list
3 so that it worked out.

4 **DR. NETON:** Yeah, in fact target organ for
5 lymphoma claims is there right on the bottom,
6 isn't it?

7 **DR. ZIEMER:** And also CLL.

8 **DR. NETON:** Right, so it's a little bit of a
9 medley, but I think this does accurately
10 reflect the current issues. And if we're going
11 to have a discussion about those, we could use
12 that as a sounding board.

13 Okay, I want to move on with the final topic,
14 which is the NIOSH-IREP lung cancer model. And
15 in this case we're asking for advice from the
16 Board, and as Dr. Melius pointed out -- input
17 from the Board. As Dr. Melius pointed out, a
18 fairly lengthy package was sent to the Board
19 outlining all of the relevant documents that
20 were reviewed and used in coming to this
21 decision.

22 I'll get right to the chase on this one, and
23 the first bullet says this, that NIOSH proposes
24 to modify the NIOSH-IREP lung cancer risk
25 model. There are -- right now there are two

1 competing models out -- not competing, two
2 distinct models. One that's owned by the
3 National Cancer Institute, they developed it --
4 was developed by the National Cancer Institute
5 and that is NIOSH-IREP. We are proposing, and
6 I'll get into the details why we believe this -
7 - we're proposing to do lung cancer probability
8 of causation calculations through a program,
9 NIOSH-IREP, to run both our model and the
10 National Cancer Institute's NIH-IREP model, and
11 select the higher PC of the two runs and that
12 we would use that to determine claim outcome.
13 The decision is based on this NCI revision
14 that's out there, and I'll talk a little bit
15 about that, and solicitation from expert
16 opinions -- and I'd like to acknowledge the
17 fine assistance we had in reviewing this with
18 our friends at the SENES/Oak Ridge, Owen
19 Hoffman, John Trabalka and Iulian Apostoaei.
20 I'm never sure if I quite pronounce that right,
21 but I think that's a close approximation.
22 I left my notes on my chair, so if you'll bear
23 with me one second...

24 (Pause)

25 Okay. If we think back to the original Board

1 meetings that we had, NIOSH was required to
2 come up with risk models for all cancers, and
3 we worked very closely with the National Cancer
4 Institute and have adopted much of what they
5 put together in NIH-IREP, which was created to
6 help adjudicate claims for radiogenic cancers
7 in the Veterans Administration program that's
8 administered by Defense Threat Reduction
9 Agency.

10 Initially when we adopted the NCI model, they
11 were identical. We had no differences between
12 the two. But in late 2003 the National Cancer
13 Institute modified their risk model based on a
14 re-analysis of the Hiroshima/Nagasaki survivor
15 data. There was a study put out by Pierce et
16 al in *Radiation Research* in 2003 that included
17 four years of additional follow-up of the
18 Japanese cohort. So there was more data and
19 there was also -- they incorporated a new
20 interpretation between smoking and exposure to
21 low level radiation. This new interpretation
22 of smoking and low level radiation puts more
23 weight on the additive interaction between
24 smoking and cancer than in the multiplicative
25 interaction. That is, both models acknowledge

1 that the interaction could be additive or
2 multiplicative. But the new NCI interpretation
3 using the Pierce data gave some more weight to
4 the additive interaction. That is, these two
5 agents acting independently, the synergism
6 between the two is not as great as had previous
7 been thought.

8 So because of that, we end up with a different
9 model out there that, you know, produces
10 different PC results, given the same inputs.
11 So you know, we're uncomfortable with that.
12 These are both calculating the same type of
13 parameters. So we undertook an analysis of
14 this model to see (a), could we use it in toto.
15 Was it just appropriate to adopt wholeheartedly
16 into our program, or should we not adopt it
17 because there are differences in our cohorts
18 from the veterans; or should we do some
19 combination of the two.

20 Another factor that I forgot to mention is the
21 new NIH model does factor in dependence upon
22 age at exposure in the risk calculation, and
23 it's -- it's similar to the other -- the other
24 models we talked about. The risk -- risk
25 changes up to about 30 years of age and then

1 it's a constant risk. So the dependency stops
2 -- the dependency correction stops at around
3 age 30.

4 Okay, let me make sure I got all my points in
5 here.

6 Okay. We began evaluating this in -- in 2004
7 we were looking at it. And during this
8 evaluation the NCI actually changed their model
9 again twice. They felt there was a need to
10 change a couple of things. One was they
11 recognized that the transfer factor that was
12 used to go between the Hiroshima/Nagasaki
13 survivors and the U.S. population was not
14 applied in accordance with the actual document
15 that they produced. It was a -- I wouldn't
16 necessarily call it an error, but it was not
17 consistent with what they thought was
18 happening. The other factor had to do with --
19 I forget -- it was alpha particle-- weights
20 given to alpha particles. So we had this issue
21 of a -- of a changing model in the middle of
22 when we were trying to evaluate whether the
23 original NIOSH -- NCI change was appropriate.
24 We did go out and to evaluate this model we had
25 SENES do an analysis to see what -- what the

1 major differences were compared to the NIOSH-
2 IREP model and the NIH model. And the
3 differences, we found out, could be
4 significant. For instance, the NIH -- the
5 NIOSH-IREP model would produce a -- these are
6 generalities, nothing is -- nothing is cast in
7 stone because there's so many parameters that
8 are changing. But the NIOSH-IREP model would
9 produce a greater probability of causation in
10 general for non-smokers, whereas the NIH-IREP
11 model would produce a greater probability of
12 causation for smokers. And also the NIH-IREP
13 model would have a greater probability of
14 causation for females exposed at younger ages.
15 There's other effects that are more difficult
16 to generalize, but a lot of that has to do with
17 this age at exposure adjustment that was added.
18 So with that knowledge we went and solicited
19 some expert opinions in late 2004 and received
20 these comments in 2005. The outside experts
21 are shown on this slide. They were each asked
22 to independently evaluate the model -- in the
23 context, again, of an OCAS compensation
24 decision. Our goal was to recruit nationally-
25 recognized experts with as diverse a background

1 as possible, given that this is a fairly narrow
2 -- narrow-focused field. So here we have the
3 list of folks -- David Brenner, for those of
4 you who have been around the risk analysis
5 epidemiology business in radiation have, I'm
6 sure, heard of Dr. Brenner at Columbia
7 University; Faith Davis from the University of
8 Illinois at Chicago; again, David Richardson,
9 who we also used for the age at exposure -- the
10 CLL, I'm sorry, I have been talking too much
11 this week -- the CLL analysis; and Jonathan
12 Samet at Johns Hopkins University.

13 But we posed the same question to each of them,
14 and that was: In your expert scientific
15 judgment, should NIOSH adopt the NIH-IREP lung
16 cancer risk model for exposures other than
17 radon?

18 That's an important point; if you recall, we
19 have a separate lung cancer/radon model, and
20 this is not being called into question at all
21 at this time.

22 And if so, should the model be adopted intact
23 or should we do something different? Should we
24 modify it or should it be programmed to run
25 both models?

1 So we left a wide-open issue here. We didn't -
2 - we didn't try to prejudge anybody to one side
3 or the other. And we asked them to provide
4 their rationale.

5 Much like the chronic lymphocytic leukemia
6 issue, we received a number of comments and I'm
7 going to just mention these alphabetically
8 again, and again paraphrase very succinctly
9 here what we believe to be the main message we
10 received from each of the reviewers.

11 Brenner suggested that we do a mixed model
12 where we capture risk estimates from
13 alternative distributions. Since he -- he
14 didn't say run them both, he just said use a
15 mixed model imbedded in the program, which
16 effectively ends up being the same thing. He
17 further went on to say that the overall weight
18 of the evidence suggests an interaction between
19 smoking and radiation is intermediate between
20 these additive and multiplicative.

21 It's actually not really the same thing. This
22 would be our own hybrid distribution of
23 effects.

24 Okay. Davis suggested that we adopt the NIH-
25 IREP model as the sole model, and primarily

1 because there was a new study that -- you know,
2 for the reasons I mentioned; there's four more
3 years of follow-up, there's age-specific
4 effects; it seemed to her to be well-reasoned
5 biologically and statistically and, you know,
6 we're supposed to use the best available
7 science, so -- so why not. She firmly believed
8 that overall it was a substantial improvement
9 over our -- our current model.

10 Okay. David Richardson suggested that we
11 program both models and used the higher
12 probability of causation. And again, it was
13 the current science provides an inadequate
14 basis for determining which model is more
15 appropriate.

16 And Samet suggested that we, again, program
17 both models and use the higher probability of
18 causation. And he actually went on to say use
19 of the NIH model alone would be a mistake, and
20 he had some rationale for that about the
21 possibly flawed understanding of the smoking
22 adjustment profiles that were used, and
23 specification may be inadequate.

24 So we sort of received a mixed bag on this
25 issue of comments, but -- but at the end of the

1 day not a single reviewer said just stay with
2 NIOSH-IREP. I mean they all suggested one --
3 one side or the other, which led us to be-- led
4 us to this position that we've been in a number
5 of instances, particularly in the dose
6 reconstruction business, where if you have a
7 couple of equally plausible scientific
8 explanations for something, and you can't pick
9 one or the other and the science is not
10 informative to allow you to do that, then we
11 would pick the one that was more claimant
12 favorable. And in this case, neither one was
13 clearly claimant favorable over the other in
14 all cases. So we have made a decision that we
15 would just run both and use them that way.
16 This would in no way reduce any PCs for any
17 claims that have been processed thus far. We
18 are proposing that we would go back and re-
19 evaluate lung cancers that have been -- been
20 denied thus far with this new model, and then
21 use it for future cases as they come available.
22 The effect of this on our program we expect to
23 be pretty small. If you recall our
24 conversation yesterday, a large percentage of
25 the lung cancers are already over 50 percent by

1 nature of our dose reconstruction efficiency
2 process for inhalation of actinide elements.
3 So the ones that have been denied, you know,
4 we'll look at. And it certainly could change
5 some, but it's nowhere near going to be the
6 dramatic effect that we have seen with maybe
7 the lymphoma -- the lymphoma change.

8 So I think -- I think that's a brief synopsis
9 of where we are with this, and I'm ready to
10 entertain any questions.

11 **DR. ZIEMER:** Okay, this is open for discussion.

12 **DR. MELIUS:** Yeah, I have some --

13 **DR. ZIEMER:** Jim.

14 **DR. MELIUS:** -- questions and -- and points. I
15 would just go a little bit further than you did
16 in sort of describing what your experts said,
17 'cause I thought what was especially important
18 wasn't just, you know, counting up the votes,
19 so to speak. There were good reason not to use
20 the NCI model, and -- and it's the fact that
21 smoking patterns are different in Japan and
22 they took up heavy smoking later than we did in
23 the United States, so it's just hard to judge
24 since there's really a single time of exposure
25 there to -- it just does -- isn't provide an

1 adequate basis, so I think it give you, you
2 know, sound justification for not just adopting
3 their -- their model by itself and do that,
4 even though it has some advantages over -- so
5 to speak, over the -- the NIOSH model. So --
6 so I thought that was good.

7 I have two questions. One is, I missed the --
8 what the September 2005 update was of the NCI
9 IREP. I didn't see that referenced in there.
10 I might have missed it 'cause I wasn't looking
11 for it, but it just --

12 **DR. NETON:** Russ, can you help me out with
13 that?

14 **DR. MELIUS:** I mean especially since your --
15 all your analysis preceded that. That's --

16 **DR. NETON:** That's a good point.

17 **DR. MELIUS:** Yeah.

18 **MR. HENSHAW:** Yes, the September 2005 --

19 **DR. NETON:** It's off, Russ; I think you --

20 **MR. HENSHAW:** -- (unintelligible) NIH-IREP was
21 --

22 **THE COURT REPORTER:** Russ --

23 **MR. HENSHAW:** -- (unintelligible) correction --

24 **DR. ZIEMER:** Turn your mike on, Russ.

25 **MR. HENSHAW:** Thanks. The September 2005

1 change was a modification of the computer code
2 to make the -- to make NIH-IREP consistent with
3 the documentation published in fall of 2003.
4 It affected the -- the change affected the --
5 the transport function from the Japanese
6 population to the U.S.

7 **DR. MELIUS:** Okay.

8 **DR. ZIEMER:** I think that was the discrepancy
9 that --

10 **DR. NETON:** Right.

11 **DR. ZIEMER:** -- Jim referred to where the --
12 the program didn't follow what their actual --

13 **DR. NETON:** Right.

14 **DR. ZIEMER:** -- process said it was supposed to
15 be doing.

16 **DR. MELIUS:** Right, and I just didn't see a
17 reference to the Sep-- I was trying to make
18 understood that was what the September 2005
19 change was. That was the -- the content of it
20 was referenced, not the date -- at least I
21 missed it.

22 My second question was that Brenner recommended
23 a -- sort of a hybrid model. I don't know if
24 that's the term he used. But he had actually
25 made a very specific recommendation on how that

1 should be accomplished, and I think there was a
2 -- you have a rationale for not adopting that,
3 though it has some (unintelligible) advantages.
4 You know, you just have to run two models and
5 it's sort of -- you know, gives this a unified
6 approach and so forth. I -- you know, I'm not
7 sure we want to be in a position of adopting
8 multiple model runs for every type of cancer
9 and just pick out what's best. Not that I
10 disagree with what you're recommending, but --
11 but if someone could sort of explain the
12 rationale for not adopting his approach, I
13 think that's -- I think it was in some of the
14 comments where the -- I think it was in
15 actually the -- the SENES review, but I want to
16 make sure I understood it and (unintelligible)
17 --

18 **DR. NETON:** I'm going to ask Russ to help me
19 out again with that. I think I could explain
20 it, but it would be better than -- than getting
21 corrected.

22 **DR. ZIEMER:** And also as you comment on that,
23 does his approach always give kind of an
24 intermediate value, or is that -- I got the
25 idea that it -- being a mixed model, it -- it

1 would end up somewhere between what you would
2 get with the other two individual ones.

3 **MR. HENSHAW:** I think that's probably a fair
4 characterization, but we asked SENES to
5 evaluate the effect of Dr. Brenner's proposal.
6 It actually turns out at the 99th percentile it
7 was not that terribly different from what --
8 from some mixture of the NIH model and what
9 we're actually proposing here.

10 I might add that we received an e-mail from Dr.
11 Brenner after making this decision, and he
12 stated that he thinks we've made is extremely
13 sensible.

14 But the reason I think -- the rationale for not
15 going with Dr. Brenner's suggestion would be
16 that we're already -- we're already two years
17 past the adoption of the NIH lung model. If we
18 created a brand new hybrid model or mixed
19 model, we would then need to vet that and
20 obtain peer review on the model. We had no
21 real consensus on -- on this proposal. Our --
22 our feeling was that if we went down that road
23 it would be another year to two years and we'd
24 be back essentially to where we started, back
25 to square one. We felt it wouldn't be fair to

1 claimants to just basically postpone this whole
2 process another couple of years.

3 **DR. MELIUS:** Yeah, but one could equally well
4 argue that you could adopt the approach you're
5 suggesting as an interim approach, and then,
6 you know, adopt his suggestion -- you know,
7 given that it takes two years to implement.
8 I'm not -- at least as I read some of this
9 documentation, I wasn't convinced that -- that
10 his suggestion was necessarily the -- was
11 feasible and appropriate to do, and I was just
12 trying to make sure that was also other
13 people's understanding, I wasn't reading too
14 much in it, 'cause he had sort of -- he had
15 different recommendations at sort of different
16 points in time and I --

17 **DR. NETON:** You raise a very good point, Dr.
18 Melius. I was concerned when we first looked
19 at this that -- and -- and I was -- actually
20 thought that the Brenner suggestion made a lot
21 of sense to me. And for the reasons that Russ
22 mentioned, he convincingly portrayed that, you
23 know, that doesn't make sense from a time
24 perspective. But then again, as you mentioned
25 earlier, going with two models every time we

1 run up against a change is -- is a precedent
2 sort of setting thing, and I didn't want to
3 necessarily go there. But I think -- we've at
4 least convinced ourselves that, what you
5 suggested, is this is maybe an interim, and
6 when the science is more informative and we can
7 figure it out and make a better determination,
8 we would be prepared then to go with one -- one
9 universal model.

10 **DR. MELIUS:** Okay.

11 **DR. NETON:** So that's -- that's sort of what --
12 how we ended up there.

13 **DR. ZIEMER:** Is the dual model approach -- will
14 that cause you to have to review a number of
15 closed cases --

16 **DR. NETON:** That's --

17 **DR. ZIEMER:** -- and give us some idea of what
18 the impact there is going to be.

19 **DR. NETON:** Well, as I -- as I mentioned, it
20 would -- many of the lung cancers are already
21 compensable so we wouldn't have to look at
22 those. So for the ones that are less than 50
23 percent, we'll go back and look at every single
24 one. The number shouldn't be that large.
25 Russ, do you have a feel again? I don't -- I

1 don't know that we -- we don't feel it's a
2 major effect and we don't feel that it is
3 necessarily going to be a wholesale reversal in
4 lung cancer compensation cases.

5 **MR. HENSHAW:** But bear in mind that we have a
6 large number of lung claims, and the majority
7 have been compensated. But that still leaves
8 somewhere around 500 lung cancer claims that
9 were not compensated, give or take 25 to 50.

10 **DR. ZIEMER:** Okay, that order of magnitude.

11 **DR. NETON:** But the magnitude of the change is
12 nowhere near what we were discussing with the
13 lymphoma model. These are -- we've labeled
14 them as significant changes, but they are --
15 they're percentage changes, you know. I think
16 it's hard to predict exactly, but it's not an
17 order of magnitude.

18 **DR. ZIEMER:** Gen -- Gen Roessler.

19 **DR. ROESSLER:** I agree with Dr. Brenner in his
20 most recent conclusion that this is a sensible
21 way to go. For one thing, we don't have to
22 discuss whether it's claimant friendly or not.
23 I think this is kind of an obvious thing to do.
24 It's claimant friendly and it ought to be
25 looked into.

1 What I think we should expect, though, is down
2 the road -- maybe six months or a year -- is a
3 report back on what transpired using both
4 models, going back in time, and then for any of
5 the cases that -- that have come up up to that
6 point, just out of scientific interest, if
7 nothing else.

8 **DR. NETON:** We'd be very happy to do that and
9 maybe report if we still stand with this model,
10 if the science is any better or not at that
11 time.

12 **DR. ZIEMER:** Rich.

13 **MR. ESPINOSA:** When running the two models
14 together for a smoker, about what's -- what's
15 the difference on the percentage and in running
16 it for a non-smoker what's the difference on
17 the percentage?

18 **DR. NETON:** I hate to keep going to Russ here,
19 but he's -- he's really the expert. It's --
20 it's percentage points. Again, I don't think
21 it's --

22 **MR. HENSHAW:** Richard, it's really -- I don't
23 know that I can characterize that simply. It
24 can range from a few percentage points to 20
25 plus percentage points, depending upon the

1 exact claim scenario.

2 **DR. NETON:** There's so many variables in these
3 models that it -- you know, it's not easy to, a
4 priori, come up and bracket what the magnitude
5 of the change is, which is in fact one of the
6 reasons that we've proposed both.

7 **DR. ZIEMER:** Jim, another comment?

8 **DR. MELIUS:** Yeah, can I ask what NCI's
9 reaction was to this...

10 **DR. NETON:** I think they -- they are supportive
11 of what we're doing. I don't think there's any
12 (unintelligible) --

13 **DR. MELIUS:** Yeah, it seems to me there's also
14 implications -- that there are deficiencies in
15 their approach. I mean I think that's --

16 **DR. NETON:** Yeah, we -- we --

17 **DR. MELIUS:** -- documented. I mean I'm sure,
18 you know, you can argue which one's best, but
19 it sort of depends who you are from the
20 claimant's point of view. But also
21 scientifically it's hard to -- to
22 (unintelligible).

23 **DR. NETON:** We've informed NCI where we're at
24 and what we're doing with this, and we've
25 received no negative feedback.

1 **DR. ZIEMER:** -- and seconded. Now -- so the
2 motion -- and that motion deals specifically
3 with the lung model.

4 **DR. MELIUS:** Lung model, yeah.

5 **DR. ZIEMER:** And let me ask for discussion on
6 that motion. If there is none, we'll -- did
7 you have a comment, Rich, or not?

8 **MR. ESPINOSA:** No.

9 **DR. ZIEMER:** Okay. Then let's proceed to vote
10 on that motion. Do we -- everybody understand
11 what the motion is? Can anyone help the Chair
12 remember what it is?

13 **DR. MELIUS:** Yeah, the Board supports NIOSH's
14 proposal to adopt this dual -- dual model
15 approach to evaluating lung cancer cases, with
16 the proviso that in approximately one year's
17 time they sort of review what any new
18 literature and sort of reconsider whether a
19 unitarian model approach may be more
20 appropriate.

21 **DR. ZIEMER:** Okay.

22 **MS. MUNN:** Is that a capital U?

23 **DR. MELIUS:** That's unitarian with a small u,
24 not a large U.

25 **DR. ZIEMER:** Yeah, we're going to have a

1 Presbyterian approach on...

2 Okay, all in favor of the motion, say aye?

3 (Affirmative responses)

4 Any opposed?

5 (No responses)

6 Any abstentions?

7 (No responses)

8 And for the record, Dr. Anderson is not here.

9 Let's -- now I'm going to ask that we return
10 and ask if there's any actions the Board wishes
11 to take on the CLL portion of the report. That
12 was the chronic lymphocytic leukemia.

13 (Pause)

14 Roy.

15 **DR. DEHART:** Yes, we have discussed in part the
16 possibility of getting additional information,
17 and if so, would that be available in December
18 when we have a phone conference?

19 **DR. NETON:** Additional information on chronic
20 lymphocytic leukemia?

21 **DR. DEHART:** On the -- on the proposal there.

22 **DR. NETON:** Yes. Yeah, we can certainly update
23 you on the status of where we are with it at
24 that point --

25 **DR. ZIEMER:** Yeah, and --

1 **DR. NETON:** -- and if we've made any additional
2 progress.

3 **DR. ZIEMER:** -- keep in mind on this one NIOSH
4 is not recommending any change at this time, so
5 we're looking for just update or --

6 **DR. NETON:** If we've made any progress on the
7 risk model, I think that's what you're
8 referring to.

9 **DR. DEHART:** Yes, that's correct.

10 **DR. ZIEMER:** Are you making a specific motion
11 or just -- is this just a general --

12 **DR. DEHART:** I was just clarifying information
13 that we could get that information.

14 **DR. ZIEMER:** No action is otherwise required.
15 Okay.

16 Then on age at -- age at exposure.

17 **DR. NETON:** Skip the lymphoma issue, possibly?

18 **DR. ZIEMER:** I'm sorry. I didn't intend to do
19 that, but lymphoma.

20 **DR. MELIUS:** Yeah, on lymphoma can I -- I just
21 want to understand -- I don't know what counsel
22 or anybody's had -- change -- has the rules
23 changed, first of all. I'm taking that meaning
24 it hasn't. We didn't -- so my question would
25 be sort of a logistical question, sort of how

1 to -- what's the best way of accomplishing this
2 without, you know, unduly holding this up and
3 so forth. And I think the consensus of the
4 Board is we'd like to see a little bit more
5 information. I think -- I think we could
6 accomplish that with -- at the phone call
7 meeting in November and -- and that would then
8 fit, and then a Board action and then a *Federal*
9 *Register* notice, is that the -- this question's
10 for Larry or for Liz, is that the --

11 **DR. ZIEMER:** I believe -- and Liz, you may want
12 to help us again on this. I believe the
13 *Federal Register* notice was to include
14 something relating to Board's recommendation.
15 Was that --

16 **DR. MELIUS:** Yeah.

17 **DR. ZIEMER:** -- this, so we --

18 **DR. MELIUS:** We need --

19 **DR. ZIEMER:** -- need formal --

20 **MR. ELLIOTT:** We need Board input on a -- on
21 any substantive change of this sort
22 (unintelligible) --

23 **DR. ZIEMER:** Does that input appear in the
24 notice itself or -- that was really the
25 question I have.

1 **DR. MELIUS:** Yeah.

2 **MS. HOMOKI-TITUS:** For the Federal -- the
3 *Federal Register* notice will include any
4 comments that the Board makes, but you're not
5 under a legal requirement to make comments if
6 you don't want to.

7 **DR. ZIEMER:** Yes, okay.

8 **DR. WADE:** So the way this will happen, we'll
9 put out an agenda for the meeting. We'll
10 mention in that agenda we're going to discuss
11 it. We'll come to that phone call and make a
12 presentation to you. You'll react. We'll
13 capture your comments, and then issue a *Federal*
14 *Register* notice of the change and your
15 comments.

16 **DR. NETON:** I might add, though, prior to that
17 meeting we'll provide the Board with some more
18 documentation --

19 **DR. MELIUS:** Yeah, now --

20 **DR. NETON:** -- (unintelligible) to this issue.

21 **DR. MELIUS:** -- what I think the documentation
22 should include would be your new procedure. I
23 think --

24 **DR. NETON:** We can do that and we'll --

25 **DR. MELIUS:** And some -- some of the background

1 -- to the extent that background's not covered
2 on lymphomas and sort of the science behind
3 this, I think to the extent you could attach
4 some of that, either a review article or
5 whatever background documentation you have. I
6 don't think it needs to be, you know, an
7 extensive report, but something that would be -
8 - be helpful for us to understand that would be
9 useful.

10 **DR. NETON:** That won't be a problem.

11 **DR. ZIEMER:** And let me ask, any of the other
12 Board members have particular items you feel
13 should be included in that report? I think to
14 some extent we'll leave it to your judgment as
15 to what that contains, but at least some
16 background material so that we have a basis for
17 making informed comments for the *Federal*
18 *Register*. I -- I assume that the Board will at
19 least want to have something on record in that
20 -- in that *Federal Register* report.

21 I don't -- since the procedure in the *Federal*
22 *Register* is defined and we have conveyed the
23 information desired, I don't think a formal
24 motion is required here unless someone believes
25 that you'd like to formalize it in some way.

1 But I believe we understand how to proceed
2 here, so without objection, we'll proceed on
3 that basis.

4 Then age at exposure --

5 **DR. MELIUS:** Yeah, I...

6 **DR. ZIEMER:** Jim, do you have a comment there?

7 **DR. MELIUS:** Yeah, I think we had discussed
8 briefly that -- again, the issue was for NIOSH
9 to come back to us and -- particularly when the
10 large IARC study has been analyzed and -- as to
11 whether that sheds any further light on -- on
12 this -- on the age at exposure issue and where
13 there may be other -- other science at -- at
14 the time and I think then make a decision if
15 appropriate after that point in time on what
16 way to go forward. But I think we generally
17 agree that we need more science here.

18 **DR. ZIEMER:** Well, and keep in mind now that
19 NIOSH is not recommending a change in this
20 particular thing at this time. They have
21 committed themselves to continue to monitor the
22 research literature and keep us informed. So
23 with that background and the comments you made,
24 we --

25 **DR. MELIUS:** Yeah, yeah, and the action may be

1 very well as sort of more formal evaluation of
2 this in relationship to the IARC -- and to --
3 excuse me, to the IREP model.

4 **DR. NETON:** It's been a long day.

5 **DR. MELIUS:** Whatever those are, one of those
6 I-Rs.

7 **DR. ZIEMER:** Now in -- so thank you, Jim, on
8 that. Why don't you stay put for just another
9 moment. I'd like to make sure on the -- I have
10 too many pieces of paper here, but on the list
11 of priorities -- thank you, to the rescue -- on
12 the risk -- or on the list of priorities to
13 make sure that we have, number one, still
14 retained the same priorities, or changed them;
15 and are there other items that should be on
16 this list now, as time has passed since the
17 list was first generated.

18 Gen Roessler, Jim Melius.

19 **DR. ROESSLER:** I think it's referred to on this
20 list, but under DDREF it mentions the imminent
21 release of BEIR VII, and I'm wondering how that
22 will impact on this particular topic and
23 whether there are any other topics identified.
24 I haven't read BEIR VII, maybe nobody else here
25 has really read the whole thing, either, but --

1 **DR. ZIEMER:** Well --

2 **DR. ROESSLER:** -- I'm wondering if there's
3 anything that --

4 **DR. ZIEMER:** -- Owen claims to have read BEIR
5 VII, and -- and since he's here from SENES and
6 they're one of the key players here -- but
7 please don't summarize BEIR VII for us, Owen.

8 **DR. HOFFMAN:** Well, I think the question has to
9 do with the low dose, low dose rate
10 effectiveness factor --

11 **DR. ZIEMER:** Yeah, this is the dose rate
12 effectiveness factor.

13 **DR. HOFFMAN:** -- and at the time that issue was
14 discussed here, BEIR VII was not yet out.

15 **DR. ZIEMER:** Correct.

16 **DR. HOFFMAN:** It has since come out, and what
17 you'll be interested to know is that what's in
18 BEIR VII effectively is not much different than
19 what's in IREP. The biggest difference is that
20 they've chosen a continuous distribution to
21 represent uncertainty, and that distribution
22 conforms to a lognormal distribution instead of
23 it being discrete -- a discrete distribution
24 where weights are given at different points.
25 The center of the distribution is at 1.5. They

1 did an evaluation just based on Japanese
2 survivors' data at very low doses and came up
3 with a geometric standard deviation at about
4 1.24, but in committee said this intuitively is
5 too tight of a distribution and inflated that
6 to the equivalent of a geometric standard
7 deviation of 1.35. And so when you look at a
8 95 percent credibility interval on the DDREF
9 itself, it's not markedly different from what's
10 in IREP at present time.

11 Now just to give you some insights, we have
12 been tasked by NIOSH to look into the whole
13 question of DDREF, and we're not ready to
14 report to you on our results, but just to give
15 you some preliminary insights as we still think
16 there are some open questions having to do not
17 so much with low dose acute exposure, but the
18 whole question of chronic long-term exposures
19 and whether or not the distribution adopted by
20 BEIR VII is wide enough to account for our --
21 the uncertainty in our state of knowledge.

22 **DR. ZIEMER:** You're puzzled as to whether that
23 answered your question or not, so --

24 **DR. ROESSLER:** I think what you are saying, at
25 this time there is nothing from BEIR VII that

1 suggests that there's anything inconsistent
2 with IREP.

3 **DR. ZIEMER:** There's no (unintelligible) --

4 **DR. HOFFMAN:** No, no -- no, in terms of BEIR
5 VII there is nothing that stands out. What
6 stands out to us, there is some inconsistencies
7 with the general literature.

8 **DR. ZIEMER:** Thank you. Jim.

9 **DR. MELIUS:** Just to follow up on that, maybe
10 what's appropriate and -- is when you finish
11 your report and there's sort of closure on it
12 within NIOSH, maybe we could have a
13 presentation, discussion of this issue then and
14 sort of cover everything at that point in time.
15 The other issue that I'd like to raise that's
16 on there that's sort of listed as there's no
17 action is the -- the issue of the interaction
18 with chemical and other exposures in these
19 facilities, which is something that, if I
20 remember the law -- it's been a while -- it's
21 sort of that NIOSH is tasked with evaluating in
22 some way if -- at some point is -- you know,
23 should worker populations be treated
24 differently because of the worker populations
25 and other issues. And I believe we discussed

1 this probably two years ago, may have been --
2 maybe longer, and at the time decided there
3 just wasn't enough information to be able to
4 adjust the IREP model to take that into
5 account. I would think it's worth it at some
6 point to sort of reopen that discussion, just
7 to get updated. You know, what's new, what's -
8 - what's changed with that. And I think
9 particularly because the Subtitle E program
10 really raises that question again. Department
11 of Labor's going to be going through and
12 evaluating sort of mixed exposures --
13 radiation, chemical, asbestos, and so forth.
14 And I think as we heard in the public comment
15 period, it's -- and it's going to bring that
16 more to the forefront in terms of people
17 thinking about this program. And again, I'm
18 not sure the science is ready to change the way
19 we approach things, but -- but I think we do
20 need to revisit the issue and at least get
21 updated on -- on where we are 'cause I think
22 it's still -- it still should be open at some
23 point as to whether we -- we couldn't have a
24 better approach that would take into account
25 the other exposures at these facilities, at

1 least to the extent it interacts with the
2 radiation exposure.

3 **DR. ZIEMER:** Is there someone in NIOSH that's
4 currently tracking the literature on this? I -
5 - frankly, this is a vast, vast topic, I mean
6 when you think of all the possible interacting
7 agents and toxic agents that could be
8 considered. Is anybody focusing on any
9 particular subsets within the whole realm of
10 toxic chemicals? And who's tracking the
11 literature on this?

12 **DR. NETON:** Thank you, Larry.

13 **MR. ELLIOTT:** Well, I would love to say that --

14 **DR. ZIEMER:** I mean it's a --

15 **MR. ELLIOTT:** It is a vast --

16 **DR. ZIEMER:** Mind-boggling.

17 **MR. ELLIOTT:** -- vast, complex subject area,
18 and I would like to say that somebody is
19 tracking it with regard to radiation and
20 effects associated with other exposures and
21 radiation. We have a NORA committee on mixed
22 exposures. They are probably the sole entity
23 monitoring research and progress on determining
24 synergistic, additive, multiplicative effects,
25 interactions and these kind of things. But I

1 don't believe that they've included a specific
2 focus on radiation and other chemicals in those
3 interactions.

4 **DR. ZIEMER:** Are they -- are they looking at
5 that as one of the things, though? Do they --
6 do they look at it at all, do you know?

7 **MR. ELLIOTT:** I don't -- I'll have to check
8 into that, and it merits some follow-up, to see
9 if -- if they have an interest in that and if
10 they're following it. If not, I can express
11 the concern that we want them to and see where
12 that'll take us. There may be individual
13 researchers, of course, at NIOSH who have, you
14 know, a special interest in this and are doing
15 what they can, but they're working at -- in
16 their own vacuum in that regard and they need
17 to seek those out, as well, so --

18 **DR. MELIUS:** Who did the presentation two years
19 ago? I -- 'cause we did have a presentation on
20 this and decided -- I thought it was somebody
21 from HERB that updated us as part of --

22 **DR. NETON:** I think that might have been Mary
23 Schubauer-Berrigan, if I'm not mistaken --
24 who's in the audience right now, actually.

25 **DR. ZIEMER:** Was it?

1 **DR. MELIUS:** (Unintelligible) that, and again,
2 I don't want to say that we're ready to make
3 changes or underestimate sort of the complexity
4 of this. But at the same time, I think it is
5 something that's going to be a recurrent issue
6 among the claimants and I'd much rather have us
7 take an -- affirmative steps to say -- at least
8 stay on top of this issue. I really think
9 Congress has charged you to -- to be at least,
10 you know, monitoring what's going on. And
11 again, it's not something that has to be at the
12 next meeting, but at some point in the -- you
13 know, next year or two, we need to be, you
14 know, just updated on where this is. And if
15 you -- the update is there's no new literature,
16 nothing that's really helpful, then fine. At
17 least we've -- we've said we've -- we've looked
18 at it to that --

19 **DR. ZIEMER:** I think it's a good suggestion,
20 and let's make it -- two years is a little far
21 out, I think, on the horizon. I'd like to
22 suggest that we try to get this on the agenda
23 this year, if we can -- simply a status report.
24 It may be that there's someone else in the
25 agency, maybe the NORA group has someone who

1 can at least give us a status report, if only
2 to say nobody's funding such research. I'm
3 also wondering if -- if there is any funding in
4 either NIH or DOE, 'cause it's really these
5 interactive or synergistic effects that often
6 are synergistic, actually, and would be at
7 least useful to identify what's going on in --
8 in that field.

9 **DR. MELIUS:** Just I would be happy to have Mary
10 welcomed back or -- she did a good job last
11 time.

12 **DR. ZIEMER:** That would be fine. However, if
13 the agency has someone who's actively working
14 on that --

15 **DR. MELIUS:** I understand, I'm not -- that was
16 just...

17 **DR. ZIEMER:** We'll have both. We'll have a
18 synergistic presentation.
19 Yes, Roy?

20 **DR. DEHART:** As I recall, in the last several
21 years there have been a number of publications
22 coming out of Scandinavia and Europe regarding
23 solvents and radiation exposure. One specific
24 one is benzene.

25 **DR. ZIEMER:** Yes.

1 locations. We're also -- have maybe -- maybe
2 one item can precede this pretty rapidly, but I
3 want to point out to the Board that although we
4 have desi-- or are recommending designating
5 Linde Ceramics as a Special Exposure Cohort,
6 our contractor also is, as we speak, in the
7 process of reviewing the site profile for Linde
8 Ceramics. And John Mauro has asked for some
9 guidance from the Board as to how they proceed.
10 In other words, does designating the early
11 group as part of this Special Exposure Cohort
12 affect how they review the site profile.
13 Let me add to that, it would seem to me that
14 for the early years where there still is a
15 possibility for reconstructing external doses
16 because there is monitoring data, and since
17 there is the possibility that one could have
18 skin cancer claims made in the -- outside the
19 exposure cohort, that reviewing the site
20 profile for the full scan of years may still be
21 important, that we shouldn't necessarily
22 exclude the early years simply because there's
23 a Special Exposure Cohort.
24 I'd like to get some feedback from the Board as
25 -- so that we can give guidance to the

1 contractor on that issue. Jim?

2 **DR. MELIUS:** Yeah, another parameter that would
3 be of use, 'cause I don't think we can predict
4 whether we'll have another SEC petition
5 relevant to other years, but this latest action
6 may increase it -- that chances, but it -- it's
7 hard to say. But -- but it would also be
8 helpful to know where NIOSH is in terms of
9 addressing -- obtaining the documentation, to
10 what extent it's available, for later years and
11 being able to have a comprehensive -- I don't
12 know what the right term is -- site profile
13 there, because -- you know, the question would
14 be, as I looked at the site profile when we --
15 when I got the Linde evaluation, saw there was
16 nothing there to review for -- for -- very
17 little for '47 -- there wasn't much there in
18 general. I mean it's a pretty sparse document,
19 and I'd hate to have our contractor spend a lot
20 of time rushing to get that done when there's
21 really not much to review. And even if we got
22 an SEC request there, we would end up having to
23 spend --

24 **DR. ZIEMER:** Yeah.

25 **DR. MELIUS:** -- you know, going back to it in

1 some way. I mean -- and some of the
2 inefficiencies we've had are the fact that in
3 addressing SEC petitions we end up then
4 expanding or updating a site profile and it
5 turns out our review wasn't really, you know --

6 **DR. ZIEMER:** Wasn't needed.

7 **DR. MELIUS:** -- it goes -- isn't complete
8 enough to address all the issues that have then
9 come up, and I think it does tend to prolong
10 the process, so it's -- I mean I think what
11 we've been doing is appropriate in terms of
12 action. So I guess my question be is -- you
13 know, are there plans to fill in that more or
14 is that -- are we -- all we have with Linde is
15 what we've got now and that's it. So to the
16 extent you can answer that in 30 seconds or...

17 **DR. NETON:** I think that what we have right now
18 is our best shot. It's unlikely to change
19 substantially.

20 **DR. MELIUS:** Okay. Thanks.

21 **DR. ZIEMER:** Okay. And which means that what
22 SC&A would review is what's there, which is
23 sort of a minimal amount, but nonetheless, it
24 is on their list. It's not -- it's -- they
25 have some other priorities, but it is in the

1 list. And I think you've actually gotten
2 underway. It's -- or at least somebody's
3 started to review it, from what I understood
4 from John.

5 **MR. FITZGERALD:** Yeah, we -- we have started
6 reading and going through -- again, it's just -
7 - not too far, but just beginning to get into
8 it. But certainly the same thought crosses our
9 mind as far as the material to review. It
10 might not be certainly as much on that
11 particular one.

12 **DR. ZIEMER:** Okay.

13 **DR. NETON:** I'd just like to add, I think in a
14 case like Linde it's not exactly -- sort of
15 like Bethlehem Steel. But where you have a
16 paucity of data, we have constructed models to
17 fill in the blanks, so to speak, and those are
18 technical issues. You know, we certainly would
19 welcome review comment by SC&A, you know, just
20 because of the fact that we don't have a lot of
21 -- of volumes of data, so it would be relevant
22 I think to get some feedback on those
23 approaches.

24 **DR. ZIEMER:** Now no particular action is
25 required unless this Board wishes SC&A to

1 somehow modify what they are doing. Is -- I
2 just simply wanted to make you aware that they
3 have raised the question, does the action that
4 we took affect them in terms of their review of
5 Linde. Wanda?

6 **MS. MUNN:** No.

7 **DR. ZIEMER:** Okay.

8 **DR. WADE:** Could you be more specific?

9 **DR. ZIEMER:** Okay. Any other comments?

10 **DR. MELIUS:** Don't equivocate.

11 **DR. ZIEMER:** Okay. Thank you very much. We
12 are going to talk about scheduling things, and
13 then there are a couple of Board members who
14 have some -- a variety of motions to make on
15 dealing with a variety of issues, one having to
16 do with -- there's been some consideration as
17 to what we might do to define the parameters
18 for quality of data for dose reconstructions,
19 and perhaps a workgroup along that line, and
20 we'll entertain a motion dealing with that.
21 Also, some desire to make a formal response to
22 the New York delegation, since they have
23 written us some letters that were put on the
24 record, and to reply to those, as well. But --
25 so we have several items there in addition to

1 the future meetings, future activities and so
2 on.

3 **DR. WADE:** And the last item on the agenda,
4 we'll just have a bit of a discussion of
5 conflict of interest and get your sense -- the
6 Board's sense as to the things they would like
7 us and the Office of General Counsel to
8 consider in any future analysis or review.

9 **FUTURE MEETINGS**

10 But let me try and tackle the topic of
11 scheduling, and I'm going to do it in three
12 pieces.

13 **DR. ZIEMER:** And everybody should have a copy
14 of Lew's proposed schedule, I think.

15 **DR. WADE:** First I'm going to ask you to try
16 and hold some dates for Board meetings. Then I
17 would like to look at a proposed sort of
18 future-looking agenda for Board activities.
19 And then I'd like to take you back to some
20 things you've been binning as potential topics
21 for workgroups.

22 So first the dates, and let me be very
23 prescriptive, if I might, and then you can stop
24 me, shout me silent, when it's appropriate.
25 Right now we have a Board call scheduled for

1 November 28th. I would like you to mark on
2 your calendars for a potential Board call on
3 January 9th.

4 **DR. ZIEMER:** As well.

5 **DR. WADE:** As well. Again, I'm just trying to
6 build some potential into the system for issues
7 that might come up.

8 **DR. ZIEMER:** Do we have a time on the 28th
9 Board call?

10 **DR. WADE:** Well, I think in deference to our
11 friends on the west coast, I would say --

12 **DR. MELIUS:** 7:00 a.m.

13 **DR. WADE:** -- 7:00 a.m. west coast time, which
14 would be --

15 **MR. ESPINOSA:** 7:00 a.m. west coast time.

16 **DR. ZIEMER:** 10:00.

17 **DR. WADE:** -- 10:00 a.m. on the 28th, 10:00
18 a.m. on the 9th. The 28th I think is a go.
19 The 9th remains to be seen, but I'd like to get
20 it on your calendar.

21 We have a Board meeting scheduled for the 24th,
22 25th and 26th. I'd like to come back and
23 revisit that in a moment.

24 I would like you to hold March 14th at 10:00
25 a.m. for a Board call. And then I would like

1 you to hold April 25th, 26th and 27th for a
2 Board face-to-face meeting.

3 **MS. MUNN:** April.

4 **DR. ZIEMER:** Give us the March date again.

5 **DR. WADE:** March 14th. And these are all open
6 dates on all of your calendars.

7 **MS. MUNN:** The March 14th was...

8 **DR. WADE:** A call.

9 **MS. MUNN:** A call.

10 **DR. WADE:** And again, we might not need it.
11 But I'm guessing -- the way we're doing
12 business, I think there'd likely be a Board
13 call between each face-to-face meeting to sort
14 through some of these issues.

15 **MR. GRIFFON:** And the April date for...

16 **DR. WADE:** The April dates are the 25th, 26th
17 and 27th.

18 **DR. DEHART:** And December again for the phone
19 call?

20 **DR. WADE:** The phone call is November 28th.

21 **DR. DEHART:** Oh, I thought there was a phone
22 call in December.

23 **DR. WADE:** December's phone call is November
24 28th.

25 **DR. ZIEMER:** It was -- it was changed --

1 **DR. WADE:** We changed it yesterday.

2 **DR. ZIEMER:** It was on the 1st.

3 **DR. DEHART:** Okay.

4 **DR. ZIEMER:** It was originally on the 1st.

5 **DR. WADE:** We changed it to accommodate some
6 schedules, so now I think everyone can
7 participate in those dates.

8 Okay, deep breath --

9 **DR. MELIUS:** April date's 25th --

10 **DR. WADE:** 25th, 26th and 27th, full Board
11 meeting, likely Colorado.

12 **DR. MELIUS:** I'd better to play the lottery, it
13 just fit my calendar perfectly.

14 **DR. WADE:** I understand. Now let me go to the
15 knotty issue of -- we have long scheduled a
16 face-to-face Board meeting for January 24th,
17 25th and 26th. It has come to my attention
18 that that is a conflict for some people, given
19 the Health Physics Society meeting. There is
20 an open period with one small exception. If we
21 were to go to January 30th, 31st and February
22 1st, that's open on everyone's calendar except
23 Paul's on the 1st. I wonder, Paul, if there's
24 any flexibility in that?

25 **DR. ZIEMER:** Yes, I can -- I can skip my other

1 meeting.

2 **DR. ROESSLER:** I might be the only one with the
3 conflict with the health physics meeting, and
4 if that's the case it's not a problem because I
5 think I can send a representative to the health
6 physics meeting and be here. I don't want to
7 throw everybody off, because that date has been
8 there and I've thought about it and thought
9 that that would work for me.

10 **MR. ESPINOSA:** Where is your meeting at, Gen?

11 **DR. ROESSLER:** Scottsdale. You want to switch?

12 **DR. WADE:** Paul, are you -- Paul, would you
13 prefer to keep the dates originally or to
14 switch one week?

15 **DR. MELIUS:** Let's switch our location.

16 **MR. ESPINOSA:** (Off microphone) Let's switch
17 our location, yeah. Let's piggyback on Gen's
18 (unintelligible).

19 **DR. MELIUS:** We have an SEC petition from
20 Scottsdale.

21 **MR. ESPINOSA:** Yeah.

22 **DR. ZIEMER:** Yeah, my preference would be to
23 keep it where it is, but I can switch my date,
24 as well.

25 **DR. ROESSLER:** No, I -- I think it'll work.

1 **DR. WADE:** So let's keep it where it is,
2 January 24th, 25th, 26th. I think it's going
3 to be here in Oak Ridge. Not here in
4 Knoxville, in Oak Ridge. And I think, LaShawn,
5 we already have the hotel in Oak Ridge? Okay.
6 So those are the dates. One more time, Board
7 call at 10:00 a.m. Eastern Daylight Time on
8 November 28th; a face-to-face Board meeting in
9 Oak Ridge on January 24th, 25th, 26th; a
10 tentative Board call at 10:00 a.m. on January
11 9th; a tentative Board call at 10:00 a.m. on
12 March 14th; and a face-to-face Board meeting on
13 April 25th, 26th, and 27th, likely in Denver.
14 Okay? That was okay.
15 Next is this piece of paper that you've got
16 that looks at starting to cobble together
17 agendas for the Board meetings. For the
18 November 28th call, we are likely to be looking
19 at a Pacific Proving Grounds SEC that will
20 likely be a recommendation to add the class.
21 If that is the case, rather than to wait
22 another month and a half, I would propose,
23 again, if it's a simple recommendation we would
24 do it on the November 28th call. Okay?
25 We do want to deal with the Bethlehem Steel

1 Technical Basis Document, and we'll talk more
2 about that in a moment as to what the issues
3 are, but you asked that that be considered on
4 the November 28th call. And we have the Y-12
5 TBD that I think will be very important to
6 address on the November 28th call. And you've
7 asked that update on science issues CLL and
8 lymphoma be on the November 28th call.
9 That's starting to make a busy call, but those
10 are the tentative agenda items for the November
11 28th call. Okay?

12 For the January meeting --

13 **DR. ZIEMER:** Don't we have January 9th in
14 between there?

15 **DR. WADE:** Well, we don't know what we'll do at
16 that. That's, to me, held as a potential.

17 **DR. ZIEMER:** So we --

18 **MR. GRIFFON:** Lew --

19 **DR. ZIEMER:** -- if we can't cover all these, we
20 would carry them over? Is that what you're
21 suggesting?

22 **DR. WADE:** Possibly, and some of these other
23 items that we're going to discuss I think might
24 take some agreement before the Board meeting.

25 **MR. GRIFFON:** I -- I don't know if I'm getting

1 ahead of things here, but do we have some
2 workgroup dates in between these, too, and --

3 **DR. ZIEMER:** Right, yeah, we'll set those next.

4 **MR. GRIFFON:** Okay. The only reason I raise
5 that is I'm wondering if -- on this conference
6 all if -- if we would be ready and -- and it's
7 probably not good to present this in a
8 conference call format, anyway, but the
9 procedures review of the internal dose. I'm
10 not sure if -- that might want to wait until
11 the face-to-face, but --

12 **DR. WADE:** Okay. Jim?

13 **DR. MELIUS:** Yeah, I would just add that I get
14 a little worried if we have a long agenda that
15 involves a lot of public participation in a
16 conference call. Just the sheer numbers of
17 people on just cause problems. We've had
18 problems with highway noise and other problems
19 there, and I just think that -- we may just
20 have to think through to the extent, again, if
21 Pacific Proving Grounds is straightforward,
22 that -- that may be okay. But some of these
23 other -- both Bethlehem and Y-12 -- I don't
24 know to what extent there'll be more people.
25 And at the same time I think we have to be

1 available for the public so I don't want to say
2 curtail it, but --

3 **DR. WADE:** Yeah, I think -- I think we'll
4 refine this as we go through the discussion.

5 **DR. ZIEMER:** Just --

6 **DR. MELIUS:** Okay.

7 **DR. ZIEMER:** -- voiced a concern. Okay.

8 **FUTURE ACTIVITIES**

9 **DR. WADE:** Now in January we have a number of
10 things that have been asked to be put on the
11 agenda. Right now we're imagining that the Y-
12 12 SEC petition for '48 to '57 will be on the -
13 - and it'll be the centerpiece of the January
14 face-to-face meeting agenda.

15 We hold open the possibility, although it might
16 not be great, that there'll be other 83.14
17 NIOSH-identified SEC classes, although Stu
18 indicated not likely. But I would like to hold
19 that potential on the agenda.

20 You asked very specifically yesterday that the
21 working group would report out on Bethlehem
22 Steel, particularly the interview with Mr.
23 Breslin and then the other issues. I put that
24 on there. We'll talk about that in terms of a
25 working group item.

1 I think we'll need to look at the Rocky Flats
2 Technical Basis Document, the Savannah River
3 Technical Basis Document, Hanford Technical
4 Basis Document. We have the Mike Wright letter
5 that was referred to last night that I think we
6 need to put on the agenda of the next Board
7 meeting. I'm open to the possibility of trying
8 to do that in a telephone call but, again, that
9 might be difficult. But I think we owe Mr.
10 Wright an answer.

11 We are looking at a re-write of the SEC rule
12 that could well be through our department and
13 ready for discussion with you in January.

14 We owe a report on adding to the list of the 22
15 covered cancers. We think tentatively we might
16 be ready in January; we might not.

17 Depending upon what flows from the conflict of
18 interest, we have the DR reviews that are
19 continuing to -- to flow.

20 And I imagine there'll be updates on science
21 issues.

22 Liz?

23 **MS. HOMOKI-TITUS:** I'm not sure if that report
24 that you just referred to regarding the
25 updating of the SEC cancers list is something

1 that NIOSH is doing on their own, but as far as
2 we know it has not been signed by the
3 President. It's not a requirement yet.

4 **DR. WADE:** We understand. I'm just trying to
5 make potential space available.

6 **MS. HOMOKI-TITUS:** Okay.

7 **MR. GRIFFON:** It -- it seems to me that -- that
8 this meeting may require a few more days. I
9 also -- I also think procedures review belongs
10 on there --

11 **DR. MELIUS:** Yeah.

12 **MR. GRIFFON:** -- and -- and you know, this is
13 getting full. I don't know that we're going to
14 get to Savannah River or Hanford TBD,
15 realistically.

16 **DR. MELIUS:** And I -- let me just add to that
17 so -- I mean I'd much rather have us make
18 significant progress on one of them than a
19 little bit of progress on all three 'cause then
20 we're -- you know, it just sort of prolongs it,
21 at the same time recognizing that it may not be
22 possible to have complete closure on one within
23 a time period. So there may need to be some
24 judgment on that based on some of the working
25 groups.

1 I'm also a little confused, and it's probably
2 my own fault 'cause I wasn't here when you were
3 discussing Bethlehem, but -- but if Bethlehem's
4 on both November and January, is -- I don't
5 understand why it's on both. The idea, I
6 thought, was to bring closure, and do we need
7 to discuss it -- I think one or the other. I'm
8 not sure --

9 **DR. WADE:** Right, I'm not sure we do, either.
10 When we talk about the working group --

11 **DR. MELIUS:** Okay.

12 **DR. WADE:** -- I think that'll sort --

13 **DR. MELIUS:** Okay.

14 **DR. WADE:** But what about this wonderful
15 suggestion of meeting four days in Oak Ridge --
16 24, 25, 26 and 27? You've made the trip.

17 **DR. MELIUS:** How about a half a day on the
18 (unintelligible) --

19 **DR. ZIEMER:** It seems to me that that's really
20 almost too long to be productive, both for us
21 and for NIOSH staff, but that's my own feeling.
22 These are -- I know we've made the trip, but
23 there's a point of diminishing returns on these
24 kind of activities.

25 **DR. WADE:** Okay, I understand.

1 **DR. ZIEMER:** I don't know how the rest of you
2 feel, but I think three days pushes --
3 certainly for me it does, but speak for
4 yourselves.

5 **DR. WADE:** I understand.

6 **DR. MELIUS:** How about a half-day on Friday?
7 Will we get anything done or --

8 **DR. ZIEMER:** I don't know.

9 **DR. WADE:** Okay, let's keep the three days.
10 I'll be shifting things -- things will -- the
11 weight of this agenda will naturally cause it
12 to flow down, but again, I wanted to get -- let
13 you know the breadth of the kinds of things
14 we're considering.

15 Then when you get into the April meeting, we're
16 likely looking at the Rocky Flats SEC petition.
17 We're likely to be looking at the Ames
18 University of Iowa -- or is it Iowa State?

19 **DR. ZIEMER:** It's Iowa State, Ames.

20 **MR. ESPINOSA:** Would there be any possibility
21 of having a face-to-face maybe for a day and a
22 half to -- for the Oak Ridge SEC, late
23 November, early December?

24 **DR. WADE:** I honestly don't think we'll be
25 finished with the work on the --

1 **MR. GRIFFON:** No.

2 **DR. WADE:** -- the site profile.

3 **MR. GRIFFON:** Right.

4 **DR. WADE:** I think it's a good idea, Richard,

5 but I don't think we'll be ready to have

6 completed the site profile or...

7 And you can see we've got the Nevada Test Site

8 coming up.

9 **MS. MUNN:** Oh, yeah.

10 **DR. WADE:** You've -- I have an arrow up on the

11 NIOSH status report on Task III external dose

12 actions. Again, we've done -- no, we've done

13 the external; this would be internal. Right?

14 We've done the external?

15 **MR. GRIFFON:** Yeah.

16 **DR. WADE:** The internal is yet to be done.

17 **MR. GRIFFON:** It's procedures review, I think

18 you can call that, yeah.

19 **DR. WADE:** Yeah, the Task III procedures review

20 on the internal. It'd be nice to do that in

21 January, but again, January is so full.

22 So again, enough said on it. This gives you a

23 sense of the kinds of things that we're

24 juggling and we've -- we've identified some

25 dates.

1 Now to the last issue, which is the working
2 groups. I made notes and I've put it up on the
3 screen of things that you said you wanted to
4 deal with in working groups. And I know it's
5 not a complete list, but on Bethlehem Steel
6 there are the two issues. They are the
7 discussions with Breslin relative to the GA
8 versus BZ samples. And then there were trying
9 to reach resolution on all the other issues
10 that have been identified in Bethlehem Steel.
11 Those are two separate things. I think we need
12 to do them. Dr. Melius is correct, maybe we
13 don't do them on the call. Maybe we do them
14 when we sit down face to face in January. But
15 again, there needs to be working group action
16 taking us up to resolution on those two issues.
17 We need the development and population of what
18 I call the resolution matrices -- that's the
19 start of the six-step process -- for Savannah
20 River, Y-12 and for Rocky Flats. And I
21 highlight Y-12 as the most important.
22 We have the Task III, which again is the
23 internal dose matrix and the CATI interview
24 matrix. That needs to be done in working
25 group.

1 And then I know there are other proposals going
2 to be made to deal with working groups, so I'll
3 end my comments to say once you hear the other
4 motions, then we need to start to schedule
5 these things.

6 **MR. GRIFFON:** I think -- I think there's the
7 ongoing six-step process for the DR reviews,
8 too, that we need to --

9 **DR. WADE:** Okay.

10 **MR. GRIFFON:** -- need to add to that list.
11 We've got the second set of 20 and the third
12 set of 20 --

13 **DR. ZIEMER:** We have DR calls coming up next
14 week on the third set.

15 **MR. GRIFFON:** But we haven't resolved the
16 second set, either.

17 **DR. ZIEMER:** And second set comments haven't
18 been resolved yet.

19 **MR. GRIFFON:** Right.

20 **DR. WADE:** So you're correct, Mark. Thank you.
21 Okay. Just to set the stage for your very
22 productive discussions.

23 **DR. ZIEMER:** Any comments on these or any items
24 that have been overlooked in terms of at least
25 being out there before us so we know what's

1 coming down the pike?

2 **DR. MELIUS:** Yeah, I actually -- I'm --

3 **DR. ZIEMER:** Yes, go ahead, Jim.

4 **DR. MELIUS:** Just also think about populating
5 these January 9th calls and March 14th calls,
6 'cause I -- I think it is possible to do a call
7 with significant public participation, but it's
8 a lot easier when it's public participation on
9 one issue.

10 **DR. WADE:** Right.

11 **DR. MELIUS:** And so that way people can pay
12 attention to that issue and they're not
13 confused by discussing multiple things.

14 **DR. ZIEMER:** Well, actually multiple calls may
15 be a better approach.

16 **DR. MELIUS:** A better -- yes, what I was
17 thinking, and so we have those scheduled, but
18 utilize them in that way and -- you know, maybe
19 --

20 **DR. ZIEMER:** In fact, it might be possible to -
21 - even on a given day -- to break it into two
22 calls or three calls or something like that.

23 **DR. MELIUS:** Yeah.

24 **DR. ZIEMER:** And so if you're interested in the
25 discussion on say Pacific Proving Grounds --

1 **DR. MELIUS:** Yeah.

2 **DR. ZIEMER:** -- that's when it's going to be
3 discussed. We may even have a different call-
4 in number so we can --

5 **DR. MELIUS:** Yeah.

6 **DR. ZIEMER:** -- keep those groups separate.
7 But could we look into that --

8 **DR. WADE:** Yes, we can --

9 **DR. ZIEMER:** -- as a possibility.

10 **DR. WADE:** We need a quorum to --

11 **DR. ZIEMER:** 'Cause that background noise issue
12 and multiple people issue is very, very
13 difficult to conduct business.

14 **MS. MUNN:** We could do from 10:00 to 12:00 and
15 then --

16 **DR. ZIEMER:** Roy?

17 **DR. MELIUS:** Yeah.

18 **MS. MUNN:** -- 2:00 to 4:00 or something.

19 **DR. ZIEMER:** Good suggestion, Wanda.

20 **DR. DEHART:** I don't want to overplay the
21 obvious, but I'd just remind everyone that
22 there's an enormous amount of paperwork --
23 reading reports, et cetera -- as part of our
24 homework for each and every one of these calls
25 and attendance at meetings, so...

1 **DR. MELIUS:** Well, and the corollary to that is
2 a plea to NIOSH to get them to us early -- fast
3 and well and give us adequate time to review
4 them.

5 **DR. WADE:** Certainly.

6 **DR. ZIEMER:** Well, this will serve as a kind of
7 road map, but it may take some detours as we
8 proceed. But certainly the idea of considering
9 multiple calls, even -- all in one day or in
10 successive days might be a possible way to
11 handle some of these.

12 Okay, the Chair's going to recognize Roy DeHart
13 for purposes of a motion. This -- this motion
14 would deal with responding to the letters from
15 the New York delegation.

16 **DR. DEHART:** I want to apologize for the group
17 -- to the group for not having written the
18 letter. It wasn't the intent of the motion to
19 do that, but to indicate a need for the letter.
20 The motion basically is it is moved that the
21 Board prepare a letter addressed to the -- to
22 Senator Shreimer, to Congressman Higgins and to
23 Congressman Slaughter, with the following:
24 One, express our appreciation for their
25 interest in the Board's deliberation regarding

1 Bethlehem Steel;

2 Two, provide current information on the status
3 of Bethlehem Steel claimants, to include the
4 number of claimants, the number not qualified
5 or disqualified, the number for whom dose
6 reconstruction has been completed, the number
7 who have a POC greater than -- equal to or
8 greater than 50 percent, the number who failed
9 to achieve 50 percent, the number awaiting dose
10 reconstruction;

11 Part three, address other information of value
12 to the discussion; for example, payments made
13 to the Bethlehem claimants.

14 **DR. ZIEMER:** That is your motion?

15 **DR. DEHART:** That is the motion.

16 **DR. ZIEMER:** And if it passed, the Chair would
17 be instructed to prepare such a letter with
18 that content.

19 **DR. DEHART:** I would hope so, (unintelligible)
20 motion.

21 **DR. ZIEMER:** Seconded?

22 **MR. PRESLEY:** (Off microphone) (Unintelligible)

23 **DR. ZIEMER:** Okay. Discussion on this motion?
24 I assume if it passed that NIOSH would provide
25 the necessary statistical data and information

1 for the Chair.

2 **MR. ELLIOTT:** We would be happy to do so except
3 for the one point on those cases that weren't
4 qualified. We don't have that information and
5 we'll try to get that from Department of Labor,
6 but...

7 **DR. ZIEMER:** Okay. Comment, Jim?

8 **DR. MELIUS:** Yeah, again, I wasn't here for the
9 discussion so I'm -- don't quite understand the
10 context of -- complete context for this letter,
11 but I think I would object to the letter as
12 proposed, but would approve a letter than
13 included then some description of what our
14 follow-up actions would, you know, be -- what
15 the process has been and where the process was
16 going; i.e., what we plan --

17 **DR. ZIEMER:** On the site profile.

18 **DR. MELIUS:** -- on the site profile that we
19 plan to resolve, you know, 'cause I think
20 that's some of the -- the questions. And I --
21 to some extent I'm -- I think talking about
22 that in the context of what's already happened
23 at the site which you lay out. I just thought
24 your letter stopped a little bit short, and I'd
25 like to not just respond and say this is the

1 situation there, but this is what the Board
2 plans to do to, you know, sort of complete our
3 part of the -- our responsibilities at that --
4 at that site. And that by whatever the date is
5 that we intend to complete the review of the
6 site profile and -- and so forth, and that it's
7 gone -- undergone an extensive and very
8 complete and comprehensive review.

9 **DR. DEHART:** My letter was intended to be brief
10 and informative. The -- all three letters
11 implied that nothing was being done for the
12 workers, and that is incorrect.

13 **DR. MELIUS:** Yeah.

14 **DR. DEHART:** It was a misinformation. And my
15 letter intends to simply provide that
16 information.

17 **DR. ZIEMER:** Jim, I don't know if you're
18 proposing an -- a friendly or semi-friendly
19 amendment that there be point four to the
20 letter to sort of give them a status report of
21 where we are on the site profile. Is that what
22 you were suggesting?

23 **DR. MELIUS:** That was what I was suggesting.
24 And I was trying to suggest it as a friendly
25 amendment, so --

1 **DR. DEHART:** As a friendly amendment I would
2 accept that, but I would not want to see a date
3 to hold us to it. And if you put a date in
4 there, I'll guarantee you the Congress will
5 hold us to it.

6 **DR. MELIUS:** Well, I -- I think we have to --
7 I'm comfortable with fudging or estimating a
8 date that -- where we are and that we hope in
9 the next few months to complete that
10 (unintelligible) --

11 **DR. DEHART:** I have an area in number three
12 which -- for other information that's
13 appropriate to the letter and so I can -- I
14 would accept that.

15 **DR. MELIUS:** And I'm sure Paul can craft an
16 appropriate...

17 **DR. ZIEMER:** I was hoping you guys would draft
18 a (unintelligible) -- Wanda, you have a
19 comment. Are you speaking for the motion or --

20 **MS. MUNN:** Yes, I am, and I'm speaking --

21 **DR. ZIEMER:** -- against the motion?

22 **MS. MUNN:** I am speaking for the abbreviated
23 motion. It -- one -- of course I can count the
24 votes now and see what the opportunity is for
25 my passing that, but I know this won't go.

1 Nevertheless, that doesn't change the fact that
2 the purpose of this letter, it seems, should be
3 to correct the misinformation and obvious lack
4 of knowledge that our lawmakers have with
5 respect to where this particular claim is right
6 now. They need to understand that there are
7 not gross errors in what NIOSH has done, that
8 no one is dragging their feet, that Bethlehem
9 Steel has not been ignored and is not being
10 unfairly treated, but that 45 percent of the
11 claims that have been received so far from
12 Bethlehem Steel have been paid and that most of
13 them have actually been handled already. They
14 don't -- they clearly do not know that.
15 If we incorporate into this letter everything
16 that we have done or plan to do, then it does
17 not have either the impact nor does it meet the
18 real purpose of responding to the issues that
19 were raised in the letters to this Board.

20 **DR. ZIEMER:** Thank you. Now, other comments?
21 It appears to the Chair that you were speaking
22 against expanding -- adding the semi-friendly
23 amendment.

24 **DR. MELIUS:** The friendly amendment --

25 **MS. MUNN:** You are correct.

1 **DR. MELIUS:** -- Roy had accepted where we are
2 and (unintelligible).

3 **DR. ZIEMER:** That's all right. Okay, other
4 comments pro or con?

5 **DR. DEHART:** To try to make room for everyone,
6 let me suggest we leave this to our Chairman to
7 prepare. He -- he has heard the comments from
8 those of us around the table with regard to
9 such a letter.

10 **DR. ZIEMER:** I think Bob has a comment.

11 **MR. PRESLEY:** As -- as second to the motion, I
12 -- I agree to both parts. I think we do need
13 to make it short and sweet as to what we plan
14 on doing, but I do think that we need to
15 address very strongly the three points that
16 were made in that letter. Letters.

17 **DR. ZIEMER:** Letters, yes. Okay. Leon?

18 **MR. OWENS:** Dr. Ziemer, I think that the Board
19 has, over the past several months, responded in
20 kind when we've had Congressional inquiries.
21 We've also allowed our contractor to respond in
22 kind to Congressional inquiries, and I would
23 agree with Roy's motion. I'll speak in favor
24 of it, but with the friendly amendment that Dr.
25 Melius has suggested. I don't think the Board

1 in any way wants to chastise any member of the
2 Congressional delegation. I think that what we
3 would like to do, though, is to provide
4 information and provide a status update when
5 they have received information that was
6 incorrect. I think that NIOSH, Mr. Elliott,
7 provided us information yesterday in regard to
8 the status of Bethlehem Steel, and I think it
9 would be wise for the Board to include that
10 information and also an update on the site
11 profile, along with the points that Roy had
12 made in his motion.

13 **DR. ZIEMER:** Okay, thank you. Other comments?
14 Jim?

15 **DR. MELIUS:** Yeah, I was not necessarily trying
16 to weaken what Roy was intending as much as
17 just saying we need to add a fourth strong
18 point and to -- to the letter. And I -- I just
19 think it would both read better and I think it
20 also conveys our efforts involved in that.

21 **DR. ZIEMER:** And the mover and seconder
22 actually accepted that, so it does become part
23 of the motion. The Chair will rule that the
24 motion that's before us does include some brief
25 -- brief comments about the status of -- of our

1 review of the site profile and is coming to
2 closure on that.

3 Further, if the Board so wishes, we could
4 certainly distribute copies of a draft in
5 advance to make sure there aren't levels of
6 heartache, although I'm -- we can't really take
7 any votes by mail, so -- and we can't do
8 business by e-mail, so what -- what could
9 happen is that if it took me long enough to
10 draft this, it may almost take to the November
11 28th conference call.

12 **DR. WADE:** Well, the other approach could be
13 you could draft it and send it out, and if you
14 heard from -- you pick the number, three Board
15 members --

16 **DR. ZIEMER:** We could call a meeting.

17 **DR. WADE:** -- concerned, then we --

18 **DR. ZIEMER:** Right.

19 **DR. WADE:** -- could do it at --

20 **DR. ZIEMER:** Right.

21 **DR. WADE:** -- the meeting. If not, we can send
22 it out.

23 **DR. ZIEMER:** Right. Are you ready to vote on
24 this motion?

25 Okay. Then all in favor, say aye?

1 (Affirmative responses)

2 Those opposed, say no?

3 (No responses)

4 And any abstentions?

5 **DR. WADE:** Henry Anderson's not here.

6 **DR. ZIEMER:** And Henry is not here. Motion
7 carries, thank you very much.

8 **DR. WADE:** Just so -- for my understanding, you
9 will draft a letter, send it out. If you hear
10 from three Board members with a concern, you'll
11 wait until the Board is next formally convened.

12 **DR. ZIEMER:** Right.

13 **DR. WADE:** If not, you'll send it on.

14 **DR. ZIEMER:** Right.

15 **DR. WADE:** Okay.

16 **DR. ZIEMER:** Now the Chair recognizes Jim
17 Melius for purposes of making a motion relating
18 to a potential workgroup for --

19 **DR. MELIUS:** Yeah.

20 **DR. ZIEMER:** -- developing -- well, the motion
21 will -- will --

22 **DR. MELIUS:** Yeah.

23 **DR. ZIEMER:** -- I won't give your motion as
24 part of the --

25 **DR. MELIUS:** Yeah, let -- let me discuss the

1 context of this thing. It's certainly going to
2 be popular in suggesting another workgroup and
3 another meeting, but I -- I think this would be
4 very helpful to the process.

5 I think all of us have been frustrated by the
6 difficulties we've had in addressing some of
7 the -- both the SEC petitions, particularly the
8 Mallinckrodt one and to a lesser extent the
9 Iowa SEC petitions, and also in dealing with
10 the site profiles, particularly the Bethlehem
11 one where we have spent a long time wrestling
12 with these issues. And part of the reasons for
13 this are just sort of procedurally and us sort
14 of learning how to deal with SEC petitions and
15 so forth. But I also think that some of the
16 problem is that -- that we really haven't
17 defined the criteria for determining, you know,
18 when has a SEC petition been adequately
19 evaluated, what's a dose reconstruction that's
20 been completed with sufficient accuracy, how do
21 we -- what does it mean by sort of, you know,
22 maximal feasible dose reconstructions and
23 things like that that, while they may be
24 difficult to define those precisely and
25 mathematically in a regulation or whatever, I

1 do think that we could -- we need to try to
2 come to grips with those issues and try to
3 develop some guidance that NIOSH could follow
4 in terms of dealing with SEC petitions, in
5 terms of dealing with the evaluation of these
6 site profiles, that the Board could utilize in
7 having to make some assessment of those
8 petitions and of the NIOSH evaluation reports,
9 that it would also better instruct our
10 contractor in terms of how to do some of these
11 evaluations so that we focus on what is
12 important to the process, not get sidetracked
13 quite as often on -- on other issues which I
14 think is sort of a -- in some ways it's just a
15 natural result of a -- of how complicated these
16 issues are and -- and the nature of the
17 available -- available science. And I think
18 we've -- could accomplish something by trying
19 to develop -- and I think we could actually
20 complete a set of guidelines that would help to
21 inform the process and inform our work and
22 NIOSH's work. I've had some discussions with
23 NIOSH staff, including running into them in
24 airports and so forth as we've traveled around
25 the country, who I also think that they believe

1 this would be helpful also. So I would propose
2 that we set up a small working group, that we
3 hold, you know, sort of a one-day meeting with
4 some of the NIOSH staff to discuss this and --
5 hopefully sometime in November in Cincinnati,
6 that we try to, to some extent, meld this with
7 what we're doing on the Y-12, but also go back
8 and -- with a review of the site -- of the Y-12
9 site profile, but also go back and sort of look
10 at what happened with Mallinckrodt and Iowa and
11 Bethlehem, and really see if we can come to
12 grips with what our guidelines that would make
13 this process work better for -- both for NIOSH,
14 NIOSH staff, their contractor, ourselves as a
15 Board having to make rulings on these and
16 recommendations and also for our contractor --
17 do that. So that's my proposal, is another
18 working group to look at this issue and I --
19 I'm optimistic that we could be successful with
20 this, though. You know, we're never going to
21 have all the answers. This is a complicated
22 area and not a lot of external guidance for us
23 to rely on.

24 **DR. ZIEMER:** For lack of a better term, the
25 Chair will call this the workgroup on

1 sufficient accuracy and --

2 **DR. MELIUS:** That is the motion then.

3 **DR. ROESSLER:** I second.

4 **DR. ZIEMER:** -- it's not clear to me that that
5 was a motion as a -- but I think, Jim, the
6 motion is to establish a small working group to
7 -- to evaluate possible criteria for sufficient
8 accuracy. That's a concise way of saying it.
9 Some of us have had some conversations about
10 the makeup of the working group, and let me
11 suggest -- well, first of all, the Chair would
12 like to ask Dr. Melius to chair the working
13 group. The Chair himself has agreed to
14 participate in the group. I understand Mark is
15 available to participate. We do want to keep
16 the group small. I don't necessarily want to
17 exclude others and -- but I think we -- we may
18 want -- if there's say another person that
19 would want to volunteer, that would be fine.
20 But at least Mark and Jim and I would be
21 willing to take a stab at this. Anyone else
22 want to -- have an urgency -- and Roy would
23 like to participate, so that -- that would give
24 us a start.

25 **DR. MELIUS:** Yeah, we would hope that we could

1 report back by the November 28th -- we --
2 conference call for where things stand and then
3 maybe --

4 **DR. ZIEMER:** Well, as a minimum we could give a
5 status report. And of course this may indeed
6 not be something that can be resolved, but at
7 least we could have a status report on where
8 we're headed, whether we're making decent
9 progress or not. It's a thorny issue, really,
10 to say what are -- what are the criteria for
11 really saying something is sufficiently -- I
12 know that we tend to do this in an intuitive
13 manner. We all do.

14 **DR. MELIUS:** Uh-huh.

15 **DR. ZIEMER:** You look at the Mallinckrodt data
16 and we sort of all have our own internal
17 criteria as to does it feel right, does it look
18 right, do I trust the data. There's a whole
19 gamut of issues. I think each of us approaches
20 it somewhat differently.

21 We may not be able to come up with criteria
22 that are completely objective. One would like
23 that. I don't think we'll ever completely
24 remove some subjectivity -- and indeed, it
25 would be the Board -- Board members' individual

1 rights to say, even beyond whatever criteria, I
2 still don't like this dataset, or I do, for
3 whatever reason it might be. We're not going
4 to be able to cover every possible criteria,
5 but we're hoping to have some guidelines that
6 we can use as a -- kind of a measuring stick
7 for sufficient accuracy and related issues,
8 that we have some sort of guide as to how to go
9 about evaluating.

10 And Arjun, maybe you have some input.

11 **DR. MELIUS:** Well, can I just -- before Arjun,
12 just to elaborate that a little bit. I mean it
13 disturbed me that our vote on Mallinckrodt,
14 that we were as split as we were. Not that it
15 wasn't a difficult situation to evaluate and
16 given the pressures and so forth, but it seems
17 we've operated, up until then, pretty much on
18 consensus. We've been able to craft some
19 agreement on how to approach things. And
20 again, it may not always be possible, and we've
21 had other sort of close votes, but usually on
22 more minor issues.

23 And I also think that if you look back at the
24 process and what NIOSH went through, what SC&A
25 went through in terms of process, and the

1 amount of time we spent wrestling with some of
2 these issues, and I don't think that's sort of
3 fair to the whole process -- nor to the
4 claimants to try to understand -- goes on, and
5 it just reaches a point where everybody sort of
6 -- sort of stops and then says well, let's just
7 vote, let's just do it, and that's not a --

8 **DR. ZIEMER:** Plus -- plus many issues are time-
9 consuming and yet have very little impact --

10 **DR. MELIUS:** Yes.

11 **DR. ZIEMER:** -- on the bottom line, so that's
12 another related thing. Arjun?

13 **DR. MAKHIJANI:** Dr. Ziemer, just as a reminder,
14 at the last meeting you did ask SC&A to prepare
15 two reports under Task V, one of which is an
16 evaluation of the NIOSH procedures on SEC
17 petitions. And the second report has two
18 parts. One is suggested draft procedures for
19 the Board itself to take up SEC evaluation --
20 petition evaluations, and the second part of
21 that would be the SC&A procedures when you do
22 ask us to evaluate an SEC petition evaluation.

23 **DR. ZIEMER:** Right.

24 **DR. MAKHIJANI:** And as you know, I'm tasked
25 with -- with -- I'm the task manager for those

1 reports, and we have started work on that and
2 expect to have, in about a month, by mid-
3 November or so, so before -- before -- the
4 second part, the SC&A procedures, as well as
5 the -- perhaps to a lesser extent, the Board
6 procedures will be more of a checklist, but the
7 SC&A procedures will correspond to some extent
8 with the list that Dr. Melius was talking about
9 --

10 **DR. ZIEMER:** Well --

11 **DR. MELIUS:** -- and may be helpful to you.

12 **DR. ZIEMER:** Right, and in fact to the extent
13 that your procedures would include criteria,
14 obviously this would be very important input to
15 that. We certainly don't want you to have to
16 operate in a vacuum on that, so perhaps this
17 will -- will inform that part of it, to some
18 extent.

19 **DR. WADE:** I'll talk to you and John. Anything
20 that would be available I think that could
21 inform this process would be accepted and
22 welcome.

23 **DR. MAKHIJANI:** Yeah, I --

24 **DR. ZIEMER:** And I think the -- our procedures
25 for evalua-- or our Board procedures that you

1 were going to help develop, as you say, are
2 more along the lines of -- I think a little
3 more mechanical than what we're talking about
4 here, which is the -- sort of the underlying --
5 I don't want to call it philosophical so much,
6 but the underlying criteria by which we make
7 decisions. But that very well could end up --
8 and as you evaluate you've got to be looking --
9 or using such criteria, in any event.

10 **DR. MAKHIJANI:** Yeah, Dr. Ziemer, the second
11 part of the report on procedures, which would
12 be the SC&A procedures, for evaluation --
13 evaluating the NIOSH --

14 **DR. ZIEMER:** Yeah.

15 **DR. MAKHIJANI:** -- petition evaluations, that
16 would seem at least largely to overlap with
17 what you're talking about. And I was -- if the
18 working group members had some input to provide
19 SC&A as they proceed --

20 **DR. ZIEMER:** Oh, yes --

21 **DR. MAKHIJANI:** -- and vice versa, so -- for --
22 I think it would be useful.

23 **DR. ZIEMER:** Oh, we would certainly keep you
24 informed and -- and I think it's a two-way
25 street because the Board doesn't have a corner

1 on ideas. We often like to think we do, but we
2 realize that you guys occasionally have a good
3 idea, too.

4 **DR. WADE:** Thank you, Arjun.

5 **DR. ZIEMER:** Thank you, Doctor.

6 **DR. WADE:** Let's -- Larry, you should be on the
7 record as to reacting to this. Your reaction?

8 **MR. ELLIOTT:** I'm pleased that we're going to
9 take this step. I think that we've heard loud
10 and clear over the course of the last three
11 face-to-face Board meetings concern among
12 select Board members as to their understanding
13 of what we mean by sufficient accuracy. It
14 goes to what Dr. Ziemer was talking about
15 earlier, we all bring something a little bit
16 different to that, I think, on what level of
17 subjective interpretation and trust we apply to
18 this -- this bounding criteria for maximum
19 plausible dose for the SEC evaluation reports
20 and what we provide with regard to sufficient
21 accuracy on dose reconstructions. These are
22 both spoken about in our rules. You can find
23 it in the preamble. You all worked with us on
24 that. But it's still I think a somewhat
25 confusing if not nebulous concept, and anything

1 that we can do to -- to bring clarity to that I
2 think is only -- is welcome from my perspective
3 and is going to aid us all in lowering the
4 frustration levels and lowering the amount of
5 effort and work we have to all go through to
6 try to get to the -- the end posts, the goal
7 posts here on these things. So I'll
8 appreciate this. I'm supportive of it, and I'm
9 looking forward to the day in Cincinnati when
10 we sit down with the working group.

11 **DR. WADE:** How about November 2nd?

12 **DR. ZIEMER:** Okay, let's --

13 **MR. ELLIOTT:** Did you say November 7th?

14 **DR. WADE:** 2nd.

15 **MR. ELLIOTT:** 2nd.

16 **DR. ZIEMER:** Let's -- have we voted yet on
17 establishing this? We basically have a motion
18 to establish the working group with membership
19 as described. And I think it's been seconded
20 or it's now seconded by Rich.

21 **MR. ESPINOSA:** Gen seconded it.

22 **DR. ZIEMER:** Gen seconded it.

23 **MR. ELLIOTT:** We'll have to set a date later.

24 **DR. ZIEMER:** Okay. All in favor, say aye?

25 (Affirmative responses)

1 And any opposed?

2 (No responses)

3 Any abstentions?

4 (No responses)

5 Thank you. The motion carries. Now while
6 we're talking about working groups, we still
7 have some carryover activities relating to dose
8 reconstruction and Task III matrix review --

9 **DR. WADE:** Bethlehem.

10 **DR. ZIEMER:** -- and some Bethlehem things. We
11 have a working group that has gotten underway
12 on that, and I would hope that working group
13 could continue that activity. We -- we know
14 that working groups aren't supposed to go on
15 indefinitely, but they were not able to finish
16 that task. This was Mark and Wanda and Robert
17 and -- and Mike, and then Rich was an alternate
18 if someone couldn't come. And so we would ask
19 them to continue those activities and have to
20 make sure that they're on the schedule, too, to
21 deal with those items.

22 **DR. WADE:** And I would ask again that Y-12 be
23 prominent in those discussions.

24 **DR. ZIEMER:** So Mark, in that workgroup you
25 have the internal dose par-- or the -- yes, the

1 internal dose part of the procedures matrix.
2 You have the dose reconstruction matrix for the
3 second round to work on, the Bethlehem Steel --
4 closure of Bethlehem Steel issues, and --

5 **DR. WADE:** Y-12.

6 **MS. MUNN:** Y-12.

7 **DR. WADE:** Y-12 site profile.

8 **DR. ZIEMER:** -- Y-12 site profile.

9 **DR. WADE:** The resolution matrix.

10 **DR. ZIEMER:** Resolution matrix, so those four
11 issues. Okay.

12 **MS. MUNN:** That's a lot.

13 **DR. ZIEMER:** Okay. Do we have other --

14 **DR. WADE:** No. I don't know if you want to do
15 anything with scheduling. You can work with
16 LaShawn and I, both chairs, and we'll --

17 **DR. ZIEMER:** I think the working groups can
18 work out their schedules individually 'cause
19 they're small groups. We don't have to do that
20 as a -- as a whole.

21 **DR. WADE:** Now I assume that the -- that the
22 Board would like us to follow the procedure
23 that we would notice -- *Federal Register* notice
24 about the working groups. We'll post a notice
25 on the OCAS web site. Do you want us to make

1 these meetings available publicly or not? They
2 don't have to be.

3 **DR. ZIEMER:** You're talking about open them up
4 for the public to be physically at the
5 meetings? Well, certainly we're committed on
6 Bethlehem --

7 **MR. GRIFFON:** (Off microphone) (Unintelligible)
8 --

9 **DR. ZIEMER:** -- but at least keep Ed Walker in
10 the loop.

11 **MR. GRIFFON:** -- (unintelligible) for
12 Bethlehem, so...

13 **DR. ZIEMER:** I don't know on the others if
14 we're really going to be productive to do that.
15 Jim, on yours I don't see any reason there, and
16 as long as you have --

17 **MR. GRIFFON:** I actually --

18 **DR. ZIEMER:** -- Ed in the loop on the Bethlehem
19 --

20 **MR. GRIFFON:** On the non-Bethlehem stuff, I --
21 I -- I think we could actually be more
22 productive if -- if we didn't have them open to
23 the public, as long as they're transcribed. I
24 --

25 **DR. WADE:** We'll transcribe them --

1 **MR. GRIFFON:** Yeah.

2 **DR. WADE:** -- we'll let people know that the
3 meetings are going on. We'll promise then to
4 deliver the transcripts on the web site, but we
5 will not open the working groups to the public,
6 except Ed Walker invited to Bethlehem.

7 **DR. ZIEMER:** Is that agreeable? It appears to
8 be.

9 Okay, we're ready to move on to conflict of --

10 **MR. PRESLEY:** (Off microphone) Paul --

11 **DR. ZIEMER:** Oh, I'm sorry, Bob, I missed you
12 there.

13 **MR. PRESLEY:** Before we -- before we get into
14 the conflict of interest, (unintelligible) been
15 asked to come back to Washington two or three
16 times. I was -- I was asked not too long ago
17 by one of our representatives in the state of
18 Tennessee as to when the Board was going to
19 come back to Washington, and I think it's been
20 what, four years since we've been up there
21 again -- or since we've been up there. We
22 might want to think about that down the road as
23 to when the executive branches are going to be
24 in session and schedule a meeting. I know it
25 takes a long time to schedule rooms and meeting

1 places and things like that when they're in
2 session, so you might want to start thinking
3 about that down the road, if -- if the Board
4 would like to go back to Washington. And with
5 all the stuff that we've gotten here lately, it
6 might be a good idea if we did hold a meeting
7 up there where we can have some input.

8 **DR. MELIUS:** Yeah, I just -- point -- I mean I
9 think I was one of the ones that suggested it,
10 but -- but the other -- I mean we're always
11 torn 'cause I also think it's important that we
12 try to hold meetings near the sites and -- and
13 now it seems we have more than -- that's even
14 become impossible to address all of the sites
15 that we need to, you know, address at a given
16 meeting. We can't accommodate everybody, and I
17 just worry that we go up to Washington, then
18 we're just one less -- we're going to make a
19 decision on something that's without the
20 opportunity for the public to participate from
21 at least one of the sites. Now some of it's
22 unavoidable and I'm not sure what the solution
23 is and...

24 **DR. ZIEMER:** Well, your -- your suggestion is
25 so noted, and we'll look for an opportunity to

1 do that, certainly.

2 **CONFLICT OF INTEREST, HHS REPRESENTATIVE**

3 Lew, conflict of interest --

4 **DR. WADE:** Yeah, let me --

5 **DR. ZIEMER:** -- lead us in that discussion.

6 **DR. WADE:** Yes, it will be just a discussion.

7 Let me introduce the -- the concept to you.

8 There's been an awful lot of talk about

9 conflict of interest. There's a lot of

10 agitation over conflict of interest when it

11 comes up here, and we've asked the Office of

12 General Counsel to start to give sort of some

13 holistic thought to this issue of conflict of

14 interest. We -- we have many people involved

15 in the program -- NIOSH employees, contractors

16 of various types, this Board. The Office of

17 General Counsel has been giving thought to it.

18 We've also asked the Office of General Counsel

19 possibly, when a plan emerges, to -- to be the

20 implementer of that plan because it clearly

21 can't be NIOSH.

22 As that process is going on, I thought it would

23 be worthwhile just to spend some time hearing

24 from the Board things that it would want us to

25 take into consideration as we imagine putting

1 together such a holistic plan. So I thought
2 this was just an opportunity to talk a little
3 bit. I know that there is some concern on the
4 part of Board members, and I thought this might
5 be an opportunity to get it out in the presence
6 of the Office of General Counsel and NIOSH so
7 we could hear these things and be sensitive to
8 them as we move forward with putting together a
9 plan of action.

10 **DR. ZIEMER:** Okay. So what we're looking for
11 now is just comments relating to that that
12 would provide input to your thinking. Jim.

13 **DR. MELIUS:** Yeah, first, I think it would be
14 useful for the Board to have an update from
15 someone knowledgeable and have some discussion
16 of how our individual -- not our specific
17 individual, but sort of the context and the
18 criteria for how our individual conflicts of
19 interest or potential conflicts are evaluated.
20 You know, what is the -- the general rules for
21 this and so forth, 'cause it's -- to me it's
22 always been confusing, and I think -- we've had
23 presentations before and I don't think they've
24 really -- I've never understood. And I know
25 when I think of what's in my letters and so

1 forth, it doesn't always fit with what I'm
2 hearing and I then go out -- get individual
3 explanation and it's helpful. But -- but I
4 think having that sort of a background might be
5 helpful, and also as it applies to -- in the
6 general sense, to contracts 'cause some of the
7 issues we've wrestled with is how to apply
8 conflict of interest to contractors and -- I
9 think it's a little bit different, at least
10 operationally, and even going back to our own
11 is -- is sort of -- it's always been confusing
12 to me how we operation-wise -- dealing with our
13 own, do we wait for Lew or do I -- does the
14 Chair enforce that? Is somebody from Counsel's
15 office informing us? Are we supposed to sort
16 of self-identify when there is -- how -- how do
17 we do that and particularly in these cases,
18 'cause nearly all of us have some dealings with
19 some of the sites in the past and -- or ongoing
20 and we really need to understand this and this
21 question of appearances. And at the same time,
22 in order to function there's a lot of very
23 general topics that we deal with that cover
24 multiple sites, and what's appropriate there?
25 And maybe there's a list of questions that we -

1 - we want to put together to ask somebody and -
2 - to be addressed, but it -- I would certainly
3 like to have a better understanding of what
4 we're doing before we sort of offer too many
5 opinions on what's good or -- or bad 'cause I
6 don't quite understand the rules completely
7 myself.

8 **DR. ZIEMER:** Right. And actually it's often
9 difficult to ascertain the logic that is used.
10 For example, if you worked at a site, are you -
11 - you end up being sort of banned from dealing
12 with any of the years, even though -- for
13 example, if -- let's take early years of Oak
14 Ridge, maybe be-- before you were ever there,
15 Bob, what vested interest would you have, pro
16 or con, on what happened in the site when you
17 weren't there? You couldn't be putting
18 yourself into a cohort or something like that
19 on the early years, so why would that matter?
20 That sort of thing. And I'll take my own case
21 where I'm excluded from Y-12 because I worked
22 there a week as a student, not an employee, and
23 yet actually probably had more direct dealings
24 with sites when I worked for DOE when -- I mean
25 when we were doing tiger teams and our group

1 was having more impact on what went on on sites
2 than I ever had working at Oak Ridge or Y-12,
3 but those aren't excluded, and if they were, it
4 would be every site, I guess.

5 **MR. PRESLEY:** (Off microphone) (Unintelligible)

6 **DR. ZIEMER:** So it's those kind of -- there's a
7 certain illogic to what goes on. Yeah. Who's
8 next?

9 **DR. MELIUS:** I think Wanda was next.

10 **DR. ZIEMER:** Wanda.

11 **MS. MUNN:** Bob was going to say something.

12 **MR. PRESLEY:** Since -- since you -- since you
13 mentioned me, that's one thing I want to -- had
14 a problem with. You know, I've been out there
15 at Y-12 for 40 years, and I can see where I
16 shouldn't vote on something. But I am
17 considered a site expert and think that I ought
18 to be able to have some input to some of this
19 stuff. I agree -- I agree about the voting,
20 but it -- it really bothers me that I can't
21 have input to some of the questions asked or --
22 or some of the things.

23 **DR. ZIEMER:** While sitting at the table.

24 **MR. PRESLEY:** That's correct.

25 **DR. ZIEMER:** Yeah. Okay.

1 **MR. PRESLEY:** As a -- as a site expert.

2 **DR. ZIEMER:** Wanda.

3 **MS. MUNN:** Can we get the people who actually
4 make these determinations -- that is to say the
5 Ethics Office -- can we get a presentation from
6 them? A 15-minute presentation, not a two-hour
7 workshop, making it clear to us how those
8 decisions are made so that we can ask our
9 questions of the people who make those
10 decisions. It seems difficult for us to have
11 to place these questions, time and time again,
12 in the hands of staff, who must interpret what
13 they've been told from the Ethics Office. And
14 so --

15 **DR. ZIEMER:** Well, I don't know --

16 **MS. MUNN:** -- why not --

17 **DR. ZIEMER:** -- the answer to that, but --

18 **MS. MUNN:** Why not go to the source?

19 **DR. ZIEMER:** -- right now we'll put that on the
20 list of questions. Okay. Jim?

21 **DR. MELIUS:** Yeah, I would agree with that,
22 that -- I think what we're looking for is a
23 better understanding of the criteria and then
24 how they apply sort of overall, and -- and how
25 do we sort of operationalize tho-- I mean does

1 -- in Bob's example, should he -- when he is an
2 expert on that site, some knowledgeable on that
3 site, should he identify himself at the -- at
4 the table's that -- should there be some -- or
5 should he be -- have to go to the back
6 microphone or, you know, what's re-- reality of
7 the difference I think is there's some value to
8 -- so that the people in the audience know how
9 he's acknowledged some of the -- that he'll be
10 speaking, but not, you know, voting on this
11 situation and -- and so forth, and I think we
12 need to know how that -- that works. And there
13 are other situations for -- you said, Paul, and
14 I think my own situation where there've been
15 some sites I've been involved in on particular
16 issues that -- you know, I think that if
17 someone knew the details of those issues, then
18 I -- that -- that it's very -- I should be
19 conflicted, I should -- should avoid being
20 involved in those issues. But you know, I --
21 understand what I'm saying, nobody here's going
22 to know -- have the knowledge or very few
23 people would ever have the knowledge of what I
24 was involved in, so you sort of try to self-
25 identify those and maybe when, you know, you

1 were working for DOE there were certain things
2 you're so vested in you really shouldn't be,
3 you know, involved in if it comes before --
4 before the Board. Yet you know, I don't know
5 everything you did at DOE or couldn't expect to
6 and, you know -- so but does that mean every
7 DOE issue and then, you know, to me what's
8 ridiculous is if you spent a week as a student
9 there at Y-12, I mean that makes -- you know,
10 any sense at -- sense at all in that.

11 **DR. ZIEMER:** Other comment? Yes, Michael.

12 **MR. GIBSON:** There's also the issue that, you
13 know, when NIOSH or our contractor goes out to
14 the sites, they look for site experts to get
15 their information, which obviously they have
16 to. Those site experts could be just as much
17 conflicted. They could hide their dirty
18 laundry in one instance, or they might have a
19 vested interest in -- in the future
20 establishing a cohort for the site. So you
21 know, I think that's why we were chosen,
22 because of our vast backgrounds and in -- the
23 expertise at different areas, so what's the
24 difference in going to a site expert at the
25 site as opposed to, you know, us being

1 conflicted?

2 **DR. ZIEMER:** Okay, good question. Others?

3 Yeah, Jim.

4 **DR. MELIUS:** Just -- just along those -- those
5 lines, and I think it also comes up even with
6 the Board occasionally, is sort of the
7 transparency of -- of that process and to the --
8 -- to the public in -- in how that's -- that's
9 dealt with, so that -- you know, to what extent
10 is that expert consulted or does that expert
11 control the process, did -- is there sort of a
12 public process to it so it's happening in the
13 open like our Board meetings, which are, you
14 know -- most part all open and so forth, other
15 than our working groups. Or is it happening,
16 you know, out in the field someplace where no
17 one's going to know what's going on until
18 something's completed, and I -- and I think
19 that's different. So again, we're -- we -- we
20 have a situation where we've been involved in a
21 site and are offering sort of our knowledge.
22 That's happening in front of an audience and in
23 public. There's a public record of that --
24 again, as opposed to something where there's --
25 you know, we do an off -- you know, writing a

1 report or doing something sort of behind closed
2 doors. And I just don't understand how they're
3 applying that and those criteria -- or even
4 what they are all the time.

5 **DR. WADE:** Could I --

6 **DR. ZIEMER:** Yeah, let me make one other
7 comment. I think typically -- and maybe Liz
8 can correct me if I'm wrong. Typically the
9 test for conflict of interest sort of -- in all
10 cases, not just the Board, but -- is whether or
11 not you somehow would stand to gain from a
12 decision that you make in terms of the
13 relationship you've had or have -- an ongoing
14 or a past relationship. For example, would you
15 be in a position to put yourself on a -- in a
16 Special Exposure Cohort or, you know, do you
17 somehow enhance -- in many -- many kinds of
18 boards it's do you gain -- will you profit
19 personally from the action you take because of
20 either your previous association or you have
21 some insight or knowledge of some sort, and
22 that often is the test of conflict of interest
23 --

24 **DR. WADE:** Yeah, but --

25 **DR. ZIEMER:** -- where -- where your decision is

1 really colored by the fact that you are either
2 going to personally gain from this or you have
3 friends that are going to gain from this or
4 whatever it may be.

5 **DR. MELIUS:** Yeah, but -- but it -- it's
6 actually a little -- usually a little bit more
7 -- would it appear --

8 **DR. ZIEMER:** Or does it appear --

9 **DR. MELIUS:** It's not just the actual conflict,
10 it's would it appear, and it's a little more
11 liberal --

12 **DR. ZIEMER:** Yeah, it's a little more --

13 **DR. MELIUS:** -- situation, though it doesn't
14 always make it any easier.

15 **DR. ZIEMER:** Right. Roy.

16 **DR. DEHART:** There's also the other side, that
17 -- the fact that you have worked at that plant
18 and now sit on a decision process, are you
19 protecting yourself or your decisions that you
20 made while you were employed there, and I sense
21 that is a very strong --

22 **DR. ZIEMER:** Yeah.

23 **DR. DEHART:** -- part of the conflict.

24 **DR. ZIEMER:** Yeah, and that's why I say if it's
25 a set of years that you weren't there and

1 weren't in either a decision-making process or
2 any -- any part of that -- for example, earlier
3 years, let's say in Presley's case. Suppose a
4 cohort came before us that was -- long preceded
5 him, unless it was his dad or something that
6 worked there, how -- how does it -- why does it
7 matter? That's what I'm having a little
8 trouble with here.

9 **DR. MELIUS:** Yeah, while you were a student
10 there for that one week, you've controlled
11 everything that's ever happened or ever will
12 happen at Y-12, Paul. We know that.

13 **DR. ZIEMER:** Well, unfortunately, the week I
14 worked there at Y-12 was the week they had the
15 criticality (unintelligible) --

16 **DR. MELIUS:** See?

17 **DR. ZIEMER:** -- I don't want to take any credit
18 for that.

19 **MS. MUNN:** Mystery solved.

20 **DR. WADE:** Not to -- not to bring this to
21 closure or even to end the discussion, but let
22 me sort of -- there are three issues that have
23 emerged, and let's talk a little bit about
24 them, each in turn.

25 The first is the agency's rules for dealing

1 with issues like individual dose
2 reconstruction, site profiles and SEC petition.
3 And I can articulate those again and you can
4 react to them and -- and we can hear your
5 reaction and then possibly modify or -- or
6 continue with them.

7 There is this issue of transparency, who should
8 know if there is a conflict; should we begin
9 each discussion on a particular topic by
10 identifying those people that have a conflict.
11 I think we need to talk a little bit about
12 that.

13 And then the third and most vexing, as I listen
14 to you, is by what logic were these conflicts
15 identified. On the third, you know, I will use
16 Liz's good offices to see what we might be able
17 to do to get someone from the Ethics Office
18 here to talk to you. That is easier said than
19 done, but we think that's a reasonable
20 suggestion and we would attempt to honor that.
21 Liz has twice now during this week articulated
22 what is the operative policy of the agency
23 right now, and that is that for a discussion of
24 a site profile someone with a conflict can be
25 at the table and fully participate in the

1 discussion, completely participate in the
2 discussion, but would not vote on a Board
3 action relative to that site profile.

4 **MS. HOMOKI-TITUS:** (Off microphone) Can I --

5 **DR. WADE:** Okay?

6 **MS. HOMOKI-TITUS:** And not make a motion.

7 **DR. WADE:** Not make a motion about the -- on
8 issues of individual dose reconstruction
9 reviews or SEC petitions, someone who's
10 conflicted would not participate in the
11 discussion at the table, but would be free to
12 participate in the discussion as a site expert
13 from the microphone -- that microphone -- but
14 would again not make a motion and not vote.
15 So those are the rules we're operating under.
16 Again, we've heard some concerns about that.
17 We'll consider those concerns. If you wish to
18 speak to Liz or I after this meeting and
19 articulate your concerns again, we'd be glad to
20 hear them. But those are the positions we're
21 operating from now. Liz?

22 **MS. HOMOKI-TITUS:** I just wanted to let you
23 know that I have heard from a number of members
24 that they do have concerns with that policy,
25 especially regarding the site profiles, so

1 we've made arrangements to have further
2 discussions with the Ethics Office again and
3 look forward to letting you know what we hear
4 about that.

5 **DR. WADE:** Yes. And we -- we have heard your
6 discussions and we are aware of your concerns.
7 To the issue of transparency, intellectually I
8 don't have my mind around that. I mean I could
9 see some logic that would say if we were to
10 dis-- start a discussion of Y-12 via a site
11 profile or an SEC petition that we would
12 identify all those people who were conflicted -
13 - for the record, for the public. On the other
14 hand, I could see saying everyone knows of
15 their conflicts and we ask them to self-police
16 on those issues. Again, we have not taken the
17 position of identifying at the start of every
18 discussion. Again, if you have thoughts on
19 that, you could let us know. We've heard some
20 comment around the table now.

21 And then the third one is, again, making the
22 logic clear to you by which the decisions are
23 made, and that we'll push to have someone from
24 the Ethics Office come and speak to you about.

25 **DR. ZIEMER:** Thank you very much. You have an

1 additional comment, Mark?

2 **MR. GRIFFON:** Yeah, just -- just to follow up
3 on Liz's comment and Lew, your last item, the
4 logic for identifying. I guess that's where --
5 especially -- I think -- I don't know if
6 there's any generic sort of way in which it was
7 determined whether there was -- there was a
8 conflict on participation in the site profile
9 review process. I think it's probably specific
10 to individuals around, depending on -- on our --
11 -- our work histories or whatever. But I think
12 that -- that's one item I think that I was kind
13 of surprised the other day on and I would like
14 some clarification on that, as Wanda stated.

15 **DR. WADE:** Thank you.

16 **DR. MELIUS:** Yeah --

17 **DR. ZIEMER:** Jim.

18 **DR. MELIUS:** -- I'd like to maybe -- sort of go
19 -- a little different issue, but one that's --
20 that's related. I think all of us received in
21 the mail a report or -- I believe it was a
22 draft report from Larry concerning the issue of
23 the possible conflict or evaluation of possible
24 conflict for some of the people involved at the
25 Paducah site and -- and that thing. And the

1 only reason I wanted to -- my understanding is
2 that that's getting further review and some
3 input from the person that asked for the
4 report. I don't think we need to discuss that
5 portion of it, but -- but it struck me when
6 reading through it -- 'cause I thought we were
7 going to discuss it at this meeting, I was
8 getting prepared -- was that, at least for the
9 second part of that report which dealt with the
10 site profile itself and some of the scientific
11 issues that -- that -- one way of addressing
12 that, if we feel it needs to be addressed, is
13 having our contractor evaluate the site
14 profile. My -- my recollection is that Paducah
15 site profile is not on the list to be reviewed.
16 And if we're going to take that step or -- and
17 maybe we don't need to take it now, but to
18 consider it, we -- it just -- there's a time
19 frame involved and -- and at least like to get
20 that out as something to -- to think about and
21 -- as to whether we discuss that again. But
22 maybe it's something NIOSH comes back to us as
23 saying that yeah, that's what they also think
24 is something -- makes sense to do, but -- but I
25 at least wanted to mention that.

1 **DR. ZIEMER:** Yeah. Larry, you have a --

2 **MR. ELLIOTT:** I would like to react to that
3 point, and I think it does make sense to -- to
4 have the site profile reviewed. But I would
5 suggest it makes more common sense to me to
6 review it after it's revised, based upon the
7 corrective action that has been identified in
8 that -- that assessment report that you're
9 speaking of. It wouldn't do any good, I don't
10 think, at this juncture to review that rev. of
11 that site profile. You need to review what's
12 modified after this assessment is done.

13 **DR. MELIUS:** Okay. That makes sense.

14 **DR. WADE:** Thank you.

15 **DR. ZIEMER:** Thank you.

16 **DR. WADE:** I think we're done with this point.

17 **APPROVAL OF MINUTES**

18 **DR. ZIEMER:** Okay. We have one final item I
19 believe on our agenda. This is a carryover
20 from earlier in the meeting. We have the
21 minutes for our July meeting to -- to act on,
22 so I'm going to call now for any corrections or
23 additions to the minutes.

24 Wanda, I know you have some.

25 **MS. MUNN:** Just a couple. They're minor.

1 Would you like me to go through them one by
2 one?

3 **DR. ZIEMER:** Yes. Give us a page number and
4 paragraph.

5 **MS. MUNN:** Page 13.

6 **DR. ZIEMER:** Page 13, paragraph?

7 **MS. MUNN:** The next to the last paragraph.

8 **DR. ZIEMER:** Uh-huh, in bold type?

9 **MS. MUNN:** Yes, uh-huh. Seems to me that it
10 should tell us what provisions -- what those
11 provisions were. If one's just simply reading
12 through this quickly, we know that provisions
13 were adopted governing communications and
14 program direction, but it doesn't say what
15 those --

16 **DR. ZIEMER:** Now what we may need to do -- in
17 the Executive Summary from which you're
18 reading, many of these motions were abbreviated
19 --

20 **MS. MUNN:** Very much so, and I had no problem
21 with any of the others and I agree with the
22 idea of abbreviating.

23 **DR. ZIEMER:** I was looking to see whether --

24 **MS. MUNN:** It just seemed to me this doesn't
25 tell me anything.

1 **DR. ZIEMER:** -- the motion, as it's discussed
2 in the main minutes, covers that.

3 **MS. MUNN:** Well, I have rewording for the main
4 minutes, but --

5 **DR. ZIEMER:** For that same motion?

6 **MS. MUNN:** -- not for the motion itself. Not
7 for the motion itself.

8 **DR. ZIEMER:** Oh. I believe this is a result of
9 the condensation process there.

10 **MS. MUNN:** I think it is, too. The two
11 preceding motions right on -- on that same
12 page, on page 13, tell you what happened.

13 **DR. ZIEMER:** Uh-huh, and this one does not.

14 **MS. MUNN:** And this one really doesn't. It
15 just says it had to do with this, but it
16 doesn't tell us what happened. I think minor
17 wording revision is in order and it doesn't
18 have to be extensive.

19 **DR. ZIEMER:** Maybe we can -- Ray, did you
20 prepare the Executive Summary or did NIOSH
21 staff -- Ray Green?

22 **THE COURT REPORTER:** I do.

23 **DR. ZIEMER:** Ray?

24 **DR. WADE:** Ray does the minutes.

25 **DR. ZIEMER:** Perhaps we can find a condensed

1 version of the provisions for that motion.

2 **MS. MUNN:** That would help a little.

3 **DR. ZIEMER:** Would that be agreeable.

4 **MS. MUNN:** That would be fine with me, yeah.

5 **DR. ZIEMER:** Okay.

6 **MS. MUNN:** On page 14, paragraph five that
7 starts "Dr. John Mauro," perhaps I --

8 **DR. ZIEMER:** What page is that?

9 **MS. MUNN:** Page 14 --

10 **DR. ZIEMER:** Fourteen?

11 **MS. MUNN:** -- the next page.

12 **DR. ZIEMER:** Uh-huh.

13 **MS. MUNN:** Perhaps I'm just not reading that
14 paragraph correctly, but the planned procedures
15 did not seem to fit in there.

16 **DR. ZIEMER:** John Mauro commented that their
17 conflict of interest planned procedures --

18 **MS. MUNN:** And forms have been completed.

19 **DR. ZIEMER:** The procedures and forms, I -- I
20 think the thrust is that the procedures and
21 forms -- the conflict of interest procedures
22 and forms that they plan to use, I believe is
23 the thrust of it, so maybe the -- maybe the
24 wording is awkward here.

25 **MS. MUNN:** Wasn't clear to me.

1 **DR. ZIEMER:** I think you could leave out the
2 words "planned" -- the word "planned" and it
3 will read correctly -- their conflict of
4 interest procedures and forms have been
5 completed. It was -- it was forms that they
6 planned to do. They now have been completed --

7 **MS. MUNN:** Yes.

8 **DR. ZIEMER:** -- so --

9 **MS. MUNN:** Yes, that's --

10 **DR. ZIEMER:** -- take out the word "planned".

11 **MS. MUNN:** That's what I thought it meant, but
12 I wasn't sure.

13 **DR. ZIEMER:** Okay.

14 **MS. MUNN:** There are many places in the -- in
15 these minutes where there's a typo, which I'm
16 assuming may just be --

17 **DR. ZIEMER:** If you'll pass those on to Ray,
18 we'll get --

19 **MS. MUNN:** No, it's the same typo.

20 **DR. ZIEMER:** Oh, okay.

21 **MS. MUNN:** An equal mark appears instead of an
22 apostrophe.

23 **DR. ZIEMER:** And actually I think it's probably
24 the printout process. Many of the bullets
25 showed up as -- in other forms, so --

1 **DR. MELIUS:** I think Ray did it.

2 **DR. ZIEMER:** -- Ray can take care of that.

3 **MR. GRIFFON:** I question that silver medal now.

4 **MS. MUNN:** I literally meant typo. I meant
5 that the printing process itself had done
6 something strange there.

7 **DR. ZIEMER:** Thank you.

8 **MS. MUNN:** On page 26, the last of the marked -
9 - bulleted items there that have Ps in front of
10 them, I was -- I think it's just language that
11 doesn't read well. There seems to be a
12 systematic overestimation error of the Barnes
13 data due to the standard precipitating --
14 standard precipitating? -- which artificially
15 jacked up the calibration curve.

16 **DR. ZIEMER:** Okay, I think their chemical
17 standard precipitated out of the solution is
18 what --

19 **MS. MUNN:** That would have been precipitation.
20 Right? Not precipitating.

21 **DR. ZIEMER:** Well --

22 **MS. MUNN:** The standard having precipitated,
23 which --

24 **DR. ZIEMER:** I think that's the thrust of it.
25 Maybe we can --

1 **MS. MUNN:** Which artificially jacked up the
2 calibration curve back up to expectation.
3 That's -- if that's clear to everyone else
4 here, then I'll shut up.

5 **DR. ZIEMER:** It's a little bit awkward, but the
6 thrust of it is there was a chemical
7 precipitation --

8 **MS. MUNN:** That's fine. That's fine with me.

9 **DR. MELIUS:** Just to shut you up.

10 **MS. MUNN:** Yeah, I know. The only other one --

11 **DR. ZIEMER:** If you -- if you could say due to
12 the fact that the standard precipitated out of
13 solution or something like that. How is that?
14 Is that better?

15 **MS. MUNN:** Sounds fine to me.

16 **DR. ZIEMER:** Due to the fact that the standard
17 precipitated out of solution, which
18 artificially jacked up the calibration curve.

19 **MS. MUNN:** Uh-huh.

20 **DR. WADE:** Due to the fact that...

21 **DR. ZIEMER:** Well, then it still is awkward --
22 calibration curve back up to expectation.

23 **MS. MUNN:** Back to the expected level?

24 **DR. ZIEMER:** Yes.

25 **MS. MUNN:** Back to the expected level.

1 **DR. WADE:** Page 26.

2 **DR. ZIEMER:** And Ray, I'll give you my marked
3 up copy. Back to the expected level I think
4 would handle that. Thank you.

5 Others, Wanda?

6 **MS. MUNN:** The last one, which I have written
7 out, is page 43, line three, where it starts
8 talking about my rant, and I have re-written it
9 to say (Reading) Ms. Munn strongly protested
10 the unexpected presentation of such a process-
11 changing motion, previously unannounced in the
12 agenda, at a time when several Board members
13 could not be present. She indicated that in
14 these circumstances she would not vote on the
15 motion unless it was a vote to table. She then
16 put forth a vote to table the motion.
17 And then the last sentence would continue on as
18 it was. Just replace the two sentences.

19 **DR. ZIEMER:** Can you provide that wording for
20 Ray?

21 **MS. MUNN:** Yes.

22 **DR. ZIEMER:** Is that agreeable to everyone?
23 Thank you.

24 **DR. ROESSLER:** That's okay, but that's
25 (unintelligible), we got --

1 **MS. MUNN:** (Off microphone) (Unintelligible)
2 left out a great deal.

3 **DR. ROESSLER:** -- we got the sense of it.

4 **MS. MUNN:** I left out a great deal.

5 **DR. ZIEMER:** Okay. Wanda, do you have
6 additional ones?

7 **MS. MUNN:** No, that's the last --

8 **DR. ZIEMER:** Okay. I'd like to call attention
9 of the Board to page 4 in the middle of the
10 page, the highlighted paragraph on the motion.
11 It says the Board passed a motion granting an
12 SEC petition. The Board does not grant SEC
13 petitions. It should read -- we may have
14 thought we did -- had really done that, but it
15 should the Board passed a motion recommending
16 the granting of an SEC petition.
17 Also on page 2 under privacy issues, I'm going
18 to suggest -- this talks about Board -- a Board
19 member being required to recluse (sic) himself.
20 I wasn't sure what we would do if the Board
21 member was either Gen or Wanda since this only
22 talks about reclusing (sic) himself.

23 **DR. ROESSLER:** We're fellows.

24 **DR. ZIEMER:** You're fellows?

25 **MS. MUNN:** Both of us.

1 **DR. ZIEMER:** My solution here would be under
2 which Board members might be required to
3 recluse (sic) themselves -- becomes -- just
4 pluralize it and make it -- is that agreeable?
5 And leave out the word "a" -- condition under
6 which Board members might be required to
7 recluse (sic) themselves.

8 **MS. MUNN:** Fine with me.

9 **DR. ZIEMER:** It just makes it neutral
10 genetically -- genetically, generically. It's
11 getting late in the day.
12 I don't know what the Board's preference is on
13 the use of data. My preference is to consider
14 it plural.

15 **MS. MUNN:** Yes.

16 **DR. ZIEMER:** So in --

17 **MS. MUNN:** It is.

18 **DR. ZIEMER:** -- on page 5 throughout the
19 discussion of data -- and Ray, I'll mark this
20 up -- we'll pluralize the use of the word
21 "data" where it appears -- a number of places.
22 If you have other minor changes -- are there
23 any other major changes where there's incorrect
24 information or incorrect concepts? If not, a
25 motion to approve the minutes with these

1 suggested changes is in order.

2 **MR. GIBSON:** (Off microphone) (Unintelligible)

3 **DR. ZIEMER:** So moved?

4 **MS. MUNN:** Second.

5 **MR. ESPINOSA:** Second.

6 **DR. ZIEMER:** Motion by Gibson, second by Rich,
7 and any discussion? All in favor, aye?

8 (Affirmative responses)

9 Any opposed, no?

10 (No responses)

11 Motion carries, thank you. Any other business
12 to come before us? Yes, Mark.

13 **MR. GRIFFON:** I know that Lew indicated that we
14 can take care of workgroup dates outside of the
15 Board. However, with -- with -- with our
16 workgroup for -- covering Bethlehem, et cetera,
17 I know we impact on NIOSH and SC&A, and I
18 thought maybe while we have the key
19 representatives here, we might --

20 **DR. ZIEMER:** Check calendars?

21 **MR. GRIFFON:** -- check calendars. And -- and
22 also I want to try to think out loud about if
23 it's reasonable to expect certain things to be
24 done by certain dates, otherwise we would push
25 it back a little. I'm looking tentatively at

1 November 15th or 16th --

2 **DR. ZIEMER:** So --

3 **MR. GRIFFON:** -- November 15th or 16th, and
4 hopefully by then having --

5 **DR. ZIEMER:** This would be in Cincinnati.
6 Correct?

7 **MR. GRIFFON:** Yes.

8 **DR. ZIEMER:** And how is that, Arjun, for you
9 and --

10 **UNIDENTIFIED:** (Off microphone) What workgroup
11 (unintelligible) --

12 **MR. GRIFFON:** This will be the workgroup
13 covering Bethlehem, procedures review, case
14 review of Y-12, but I think we can decide which
15 or all items -- I think it'll be -- at least
16 Bethlehem I'd like to --

17 **DR. NETON:** This is separate apart -- separate
18 and apart from the discussion with Breslin and
19 (unintelligible).

20 **MR. GRIFFON:** Right, I'm assuming by then you
21 would have the conversation with Breslin and --

22 **DR. NETON:** That's fine.

23 **MR. GRIFFON:** -- can report to our workgroup on
24 that --

25 **DR. NETON:** Yes, that's okay with us.

1 **MR. GRIFFON:** -- and then we can resolve the
2 other findings. Okay.

3 **DR. MAKHIJANI:** (Off microphone)
4 (Unintelligible)

5 **MR. GRIFFON:** Let's say the 15th. Is that --

6 **DR. MAKHIJANI:** The 15th would be all right. I
7 just have a little bit of a conflict in the
8 first part of November, so essentially John --
9 John and Jim and I would have to figure out a
10 schedule with Mr. Breslin and then Mr. Breslin
11 has to be available, so there's a -- otherwise
12 the --

13 **DR. ZIEMER:** If that doesn't work, then they'll
14 have to find (unintelligible) --

15 **DR. MAKHIJANI:** Yeah, the 15th otherwise is all
16 right.

17 **MR. GRIFFON:** But tentatively it's -- it's an
18 okay --

19 **DR. MAKHIJANI:** Yes. Yes.

20 **MR. GRIFFON:** -- date to hold it? And I would
21 say that at least Bethlehem -- I don't know if
22 there's any chance that we might have the
23 internal dose responses to the procedures
24 review by then?

25 **DR. NETON:** I'd have to rely on my colleague,

1 Stu, to --

2 **MR. GRIFFON:** Yeah -- yeah, I'm asking Stu to -
3 -

4 **DR. NETON:** -- speak to that.

5 **MR. GRIFFON:** -- and/or the -- any -- any -- if
6 it's too soon to work on Y-12 issues there,
7 too, but --

8 **DR. WADE:** It'd be nice to have the matrix on
9 Y-12 put together with the SC&A comment and the
10 NIOSH response.

11 **MR. HINNEFELD:** Okay. The matrix based on
12 procedures --

13 **MR. GRIFFON:** Procedures review.

14 **MR. HINNEFELD:** -- let's see, the internal
15 procedures review, we can certainly be at the
16 point on the internal and the CATI procedures
17 on the 15th that we were on the 6th on the
18 external.

19 **MR. GRIFFON:** That'd be great.

20 **MR. HINNEFELD:** We can have our initial
21 responses --

22 **DR. WADE:** Right, what about Y-12?

23 **MR. HINNEFELD:** -- (unintelligible) by that
24 time.

25 **MR. GRIFFON:** And Y-12?

1 **DR. NETON:** First let me verify, that's the
2 15th and 16th, Tuesday and Wednesday.

3 **MR. GRIFFON:** Or just the 15th, I'm saying.

4 **DR. NETON:** Or -- well, just the 15th --

5 **DR. WADE:** Jim has a conflict on the 15th. The
6 16th?

7 **DR. NETON:** No, I don't.

8 **DR. MELIUS:** Well, I was going to throw out
9 let's further complicate this -- either the
10 15th or the 17th would work for me for the --
11 the new workgroup if you're going to be out
12 there and --

13 **DR. NETON:** I do have a conflict on --

14 **DR. WADE:** I understand. What about the 16th
15 for Mark's workgroup and the 17th for Dr.
16 Melius's workgroup?

17 **DR. NETON:** That seems okay.

18 **DR. WADE:** With the wisdom of Solomon.

19 **DR. ZIEMER:** Okay.

20 **MR. GRIFFON:** Okay.

21 **DR. ZIEMER:** Okay, Mark?

22 **MR. GRIFFON:** Yeah.

23 **DR. MELIUS:** The 17th?

24 **DR. DEHART:** The 17th?

25 **DR. MELIUS:** Yeah.

1 **DR. DEHART:** Okay.

2 **DR. WADE:** The 16th for Mark's, the 17th for
3 Jim's. I would really ask NIOSH if we can have
4 the matrix on Y-12 put together by then. I
5 think that would be very important, given the
6 fact that we're likely to see a discussion of
7 the SEC petition at the end of January.

8 **DR. NETON:** We'll -- we'll try.

9 **DR. WADE:** Thank you.

10 **DR. MAKHIJANI:** Just a question, Dr. Melius,
11 did you want any SC&A representative to be
12 present at the 17th --

13 **DR. MELIUS:** No.

14 **DR. MAKHIJANI:** -- just for planning purposes?

15 **DR. MELIUS:** No, not at this point.

16 **DR. ZIEMER:** I don't think we to on the initial
17 meeting.

18 Okay. Any other business to come before us?

19 **MS. MUNN:** We're talking the 16th?

20 **DR. WADE:** 16th for Mark, 17th for Jim.

21 **DR. ZIEMER:** Motion to adjourn?

22 **MR. PRESLEY:** So moved.

23 **DR. ZIEMER:** Second?

24 **MR. ESPINOSA:** Second.

25 **DR. ZIEMER:** All in favor, leave.

1
2
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DR. WADE: Well done.

(Whereupon, the meeting was adjourned at 3:50
p.m.)

1

C E R T I F I C A T E O F C O U R T R E P O R T E R**STATE OF GEORGIA****COUNTY OF FULTON**

I, Steven Ray Green, Certified Merit Court Reporter, do hereby certify that I reported the above and foregoing on the day of October 19, 2005; 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 4th day of December, 2005.

STEVEN RAY GREEN, CCR
CERTIFIED MERIT COURT REPORTER
CERTIFICATE NUMBER: A-2102