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

convenes the

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

VOLUME I

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Hyatt Regency Denver, Denver, Colorado, on Monday, July 1, 2002.

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C O N T E N T S

VOLUME I
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(By Group, in Alphabetical Order)

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District Director
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P R O C E E D I N G S

8:30 a.m.

DR. ZIEMER: Good morning, everyone. I'd like to call the meeting to order.

This is the fifth meeting of the Advisory Board on Radiation and Worker Health. Three of our meetings were face-to-face in Washington, D.C. One was a conference call, and now we have our fifth meeting here in Denver. We're pleased to be here and to have some of the local folks here with us today, as well.

I'm Paul Ziemer, Chairman of the Board. All of the Board -- the record will show that all of the Board members are present. And if some of you who are visitors have not had a chance to meet the Board, we're not going to have introductions this morning of the Board, but you can introduce yourself during the break or at some other time.

I would like to particularly indicate to members of the public, if you have not already registered your attendance with us there is a book in the back. Please do that. Also, if you wish to make a comment, a public comment later on in the meeting, please sign up so that we can

schedule that. There's a book back on the table for you to sign up for public comments.

Also on the table there are copies of today's agenda, as well as other informational items, some items from past meetings, the minutes of our past meetings, the recommendations of this Board from previous meetings, and other related hand-out materials including some of the materials that will be used today.

Since the last meeting there has been a working group that has been considering approaches that the Board could use in carrying out its responsibilities relative to the dose reconstruction activities, and we're going to hear from that subcommittee yet this morning, and have at least an initial look at what they are thinking and what they are going to recommend to this Board.

We have a number of other presenters today and tomorrow, as you see on your agenda. And by the way, the agendas are available on the table, too, if you did not get one. So we have a busy schedule before us for the next two days.

One of the important items is a proposed rule-making on special cohorts that we will be

considering today and tomorrow, if necessary. Particularly be thinking in terms of possible comments that the Board may wish to make on that rule-making.

I've indicated that we do have a full complement of the Board members here. As a matter of information I might tell you that it's my understanding that the White House Office of Personnel is considering making additional -- at least one, maybe two, additional appointments to the Board. I'm not quite sure where they are in that process, but it's my understanding that that is in process, and we may by next meeting have one or two additional members in place.

So we have a full schedule before us. We'll adjust the agenda if needed, based on how things go and how much time is actually needed for the different items on the agenda. In general we'll try to follow that agenda as closely as we're able to, but recognize that there is some flexibility, if necessary, to adjust the times of various activities.

We're going to move directly to the minutes of our last meeting, and I'm going to move myself back to my seat for that purpose, so if you'll

bear with me just a moment.

The draft minutes of the meeting of May 2nd and 3rd, 2002, are in your packet. I believe they were also on-line in advance so that even though the Board members didn't get their packets till last night, and I know many of you stayed up till long into the morning hours reading the materials, but you did have an opportunity to look at these earlier, about a week ago or so, on-line. I had the opportunity of going through these in detail myself prior to this version, and there were a few editorial changes. But now is the time to ask for any additions or corrections to the minutes.

Wanda.

MS. MUNN: I had no significant additions or changes, and I know it's word engineering, but on the very first page of the minutes --

DR. ZIEMER: Which page is it?

MS. MUNN: The very first page.

DR. ZIEMER: Very first page?

MS. MUNN: Uh-huh, next to the last sentence.

DR. ZIEMER: This is the executive summary or the minutes themselves?

MS. MUNN: This is the --

DR. ZIEMER: 1-5 or 1/5?

MS. MUNN: This is 1/5.

DR. ZIEMER: Okay.

MS. MUNN: The next to the last sentence, every time I read that sentence I get to the word "hazard" and it stops me. There are -- it seems to me that "jeopardize" is a better word, possibly "compromise," but in my mind "jeopardize" is much more straightforward and easily understood on first reading.

DR. ZIEMER: Any objection to substituting the word "jeopardize"? Probably grammatically that might be better anyway, even though someone might have said it this way.

(No responses)

DR. ZIEMER: Other corrections or additions? Yes, Dr. Roessler.

DR. ROESSLER: I'd just like to comment that somebody put in a lot of work on these minutes. They're very easy to read. They're very concise. They're just really good, good minutes. I think it's due to our people here, and perhaps, Paul, your going over them.

DR. ZIEMER: I would say it's mostly the staff effort. We thank them for that.

MS. MUNN: They need a gold star.

DR. ZIEMER: So you're not suggesting any changes to anything, thank you.

Again, corrections, additions, modifications?

(No responses)

DR. ZIEMER: Motion to approve with the minor correction given?

MR. PRESLEY: So moved.

DR. ZIEMER: Second?

DR. DEHART: Second.

DR. ZIEMER: All those who approve the minutes, say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed?

(No responses)

DR. ZIEMER: Motion carries. The minutes stand approved.

We are already ahead of schedule. You were supposed to take longer on these minutes than you did.

If the staff is ready, we can move on to the NIOSH program status report. And Larry, would you introduce the staff members who participate here?

MR. ELLIOTT: Thank you.

We will start off this morning with your NIOSH program progress report or program report, which we've done in the past. I'll ask my Deputy, David Sundin, to present that to you today. I've had a number of things occupy my mind and my time since we last met, and he was gracious enough to take this role on.

And then he'll be followed by Bob Mansanares from the Department of Labor's District Office here in Denver to give you a report on DOL's piece of the program and the status in that regard. This was an action item that I took from our last minute -- or last meeting, that somebody expressed an interest to have that kind of a presentation as well.

So, Dave Sundin.

MR. SUNDIN: Good morning. I'm pleased to be with you here in Denver for your fifth meeting, and I've planned to give you a brief overview of program status. I'll be following the model that has been used in previous Board meetings.

June 30th marked the end of our third quarter of our fiscal year, so for many of these indicators I'll be able to give you statistics which show trends over three quarters, three full

quarters, and these are the three quarters that we've basically been receiving claims for dose reconstruction.

It's our understanding that the Department of Labor has received approximately 15,000 non-SEC cancer claims for which they're verifying employment and diagnosis, and they have transferred as of last week over 5,000 claims to NIOSH for dose reconstruction. You may recall that we began receiving claims from the Department of Labor on October 11th, 2001, and as you can see the number of claims referred to NIOSH has increased each quarter of this fiscal year.

You may also recall that each of DOL's four district offices sends us one batch of claims each week. We then send a letter to each claimant to let them know we've received their claim for dose reconstruction, and in that letter we also inform them of the steps their claim will go through and how they can contact us to monitor progress. We log each case into our computerized claims tracking system. We electronically scan all documents in each case file and also create and maintain a paper file system, which is

growing by leaps and bounds, as you might imagine.

We then identify, using the DOL referral summary sheet which accompanies each case file, the covered sites where the energy employee worked and the various jobs he or she held. We identify any NIOSH-held information that's pertinent to the claim, and this all permits us to focus our requests for radiation exposure information on specific locations and time periods, and to direct our requests to the appropriate DOE points of contact.

We're working very closely with DOE and the designated points of contact at the sites to ensure that we get the kind of exposure information needed to conduct the dose reconstructions in a timely manner. We continue to explore ways to expedite the fulfillment of our information requests, build site-specific profiles, establish efficient ways to access and evaluate sensitive information, and verify that no further information exists.

We're continuing our discussions with DOE on the terms of the Memorandum of Understanding between HHS and DOE on all of these points. The

purpose of this MOU, of course, is to set forth the guidelines for collaboration between HHS and DOE in carrying out our respective responsibilities under EEOICPA and the Executive Order. And I believe we're very close to having a document which both Departments can sign on to.

Within the last quarter we've seen an improved response to our requests for information from most of the DOE sites, and we expect continued improvement as each site becomes more familiar with our information needs and develops the capacity to respond.

We evaluate the information provided by DOE for accuracy and completeness in light of what we need for dose reconstruction. And where we determine that the information is incomplete or inadequate we follow up with DOE with additional information requests, and to date there have been 51 such follow-up requests for additional information.

In some cases we've asked DOE to continue searching for information where none was provided in response to our initial request. Atomic weapons employer facilities are an example of this situation, and we have worked with DOE to

identify repositories of data which we can capture for our use in reconstructing doses for AWE claims in particular.

In other cases we're seeking site-specific information on historical dosimetry and bioassay practices and methods. And of course, this general information is valuable in that it could be used for the benefit of all claims relevant to that site and time period.

Once we've assembled and reviewed all relevant information from NIOSH records and received and examined the information from DOE, we schedule the interview with the claimant. As of today we've conducted 105 claimant interviews with employees and survivors. We currently actually have 127 dose reconstructions underway. This means that we've received, assembled, evaluated, and reviewed readily available information pertinent to the claim, and for 13 claims we have completed the draft dose reconstruction report which is called for under our Rule 42 CFR 82. We've actually mailed out four draft dose reconstruction reports to claimants, including one claimant from Rocky Flats here.

This is followed up by a phone call from the dose reconstructionist who did the dose reconstruction. The purpose is to explain the report process and the findings of the dose reconstruction. We also seek the claimant's approval on an OCAS-1 form so that we can close the dose reconstruction process and move the claim on to the Department of Labor for determination of probability of causation.

At this point a comprehensive administrative record is also created for transmittal to DOL. This includes all documents in the case file, all information used in the dose reconstruction, all correspondence and phone calls with the claimant, and the input file for the NIOSH-IREP. One completed dose reconstruction and administrative record has been transmitted to DOL to date, and several others will be sent soon. Obviously we all want this number to begin to increase rapidly.

From the outset, a key element of our plan to conduct a large volume of dose reconstructions in a careful but timely manner, and return these cases to DOL in a form appropriate for final adjudication, has involved awarding a substantial

contract for support across the entire range of activities required to complete work on a claim. The success of this contract partnership is essential to the success of all of our efforts on behalf of claimants, so we're proceeding carefully and thoughtfully to ensure that we select a contractor that has the resources, skills, and experience to handle a large number of claims in a timely and scientifically rigorous manner. We intend to establish and manage this contract such that OCAS, our claimants, and the public can be confident in the fair and timely treatment of all claims.

We're nearing the end of this competitive procurement process, and I believe I speak for everyone at OCAS when I say we're very eager for the arrival of this much-needed contract support. Actually, just as an update, we expect the best of the final offers from the technically acceptable proposers on the 18th of July.

As you probably know, we make it very easy for claimants to contact us, and they do so. The number of phone calls received at OCAS has increased substantially each quarter as we receive more and more claims. We are currently

receiving an average of 40 phone calls per day, which really keeps us connected with the claimant concerns and issues, and motivates us to continue our efforts on their behalf.

Our web site, as I hope you'll agree, is an unusually rich source of information on this program, and it also serves as a channel through which claimants can contact us. We've received nearly 300 claim-related e-mails, and responded to every one of them within 24 hours.

So with that, I thank you for your attention, and I'll try to answer any questions you might have.

DR. DEHART: Roy DeHart. The question I have regards the telephone interviews. Those are rather extensive, and you've had a rich period here this third quarter to conduct those. Is there anyone here that can talk to the response of the individuals you've been calling on those interviews, survivors as well as the individuals?

MR. SUNDIN: Well, I've not actually conducted an interview myself. You're right, it is an extensive interview. I think we are getting reasonably good information from Energy employees, less detailed information, as you

might expect, from survivors. But of course, the questionnaire is designed to be less demanding for those survivors.

Jim, I don't know if you wanted to add to that?

DR. NETON: Yeah. This is Jim Neton.

It's been a fairly encouraging process thus far. We've been getting good feedback. Claimants are very responsive. We do mail out in advance of the interview a template of the questionnaire that the people will be responding to, so it gives them a heads-up, a week or so to review and refresh their memory about some things that happened in the distant past.

Dave's right, survivor knowledge is much less complete than the workers', but we do take names of coworkers at that point and will follow up, if necessary, with coworkers of that person to fill in the details.

In many cases we don't really flesh out the record much greater, but there's been some really good surprises in there where people will bring forth some information that will make a difference in the dose reconstruction. So by and large, I think it's been a worthwhile process.

We have not taken as long as -- well, they've taken about what we thought it would take. The average interview is running about an hour, although I think our record right now is well over four hours, so it varies. But it's been a very encouraging process thus far.

Larry just reminded me that we have run into some issues with classified interviews, and we've dealt with that in an appropriate manner. A number of these workers have in the past had security clearance, Q-cleared classifications. We make arrangements on those cases to conduct the interview in accordance with the rules and requirements surrounding that, and that is we actually will do the interview in a Department of Energy facility that is cleared for classification. A (inaudible) classification officer reviews the interview notes after the interview is complete, and we use that process.

So we've done two in that manner thus far, and it's worked really well. We're trying to keep the number of classified interviews down. We feel by and large most of these people do not need to share classified information for us to complete an adequate dose reconstruction, but at

least in two instances thus far -- we have a third one coming up, I believe -- they believed there was sufficient classified information that was needed to be brought forth to complete the interview.

DR. MELIUS: As I understand it, you're going to award -- you hope to award the contract for dose reconstruction later this month, and there'll be some time period getting the contractor then up and working. Have you got any projections as to how this will affect your ability to complete dose reconstructions, and what the time table will be to deal with the long backlog of dose reconstructions that will need to be done?

MR. SUNDIN: Well, first of all, I'm not absolutely sure that, given the best and final by the 18th, that we'll have a contract award on the 30th, because there's a negotiation process. But having said that, I think we're close to getting the award. We'll continue to do dose reconstructions using our in-house staff until the contractor comes on board, obviously. But you're well aware that that -- what our capacity is using in-house staff.

The scope of work for this contract calls for a very ambitious start-up period. And that's going to be one of our very high priorities, is that there's not a long learning curve, to the extent that we can continue to remind this contractor that this contract calls for certain deliverables within 30 days of start-up. We intend to get them pointed on the task and going just as soon as possible. So it'll be a quick start-up, and hopefully making a lot of good progress against a considerable backlog.

DR. MELIUS: I guess my question is have you made any projections as to when you would catch up with the backlog? Say you have the contractor going September 1st -- whatever, some arbitrary date in the next few months -- then where does that put you in terms of dealing with the backlog of cases as well as, what, the 15,000 sitting over at DOL waiting to come over? I guess that's one question, and then I have a follow-up to that.

DR. NETON: I think I can answer that. The contract is written so that the contractor will have sufficient surge capacity to handle backlog volume. We have a requirement in the contract

that they bid to performing 8,000 dose reconstructions in the first year of operation. So at this point, it looks like that was a pretty good guesstimate going in, that there may be around 8,000 claims to process in the first year, maybe even slightly less than that. And so as best I can tell you is that within the first year of the contract all this backlog should be completed.

DR. ZIEMER: Follow-up question?

DR. MELIUS: Then -- actually two separate questions. One is that -- if I make sure I understand this right -- is that then that's 8,000 a year plus whatever you can do in-house, we're talking about a two-year time period, roughly, if all those 15,000 or so over at Labor come over to NIOSH?

DR. NETON: Well, all the 15,000 haven't arrived at NIOSH yet. All I can say is -- well, it's 8,000 in the first year, although the contractor does have -- we do have -- we can request that they increase their capacity to handle whatever volume comes our way. Now whether they can handle 15,000 in a very short time period, I don't know. But it's certainly in

the scope of the contract to add dose reconstructions essentially as the volume increases. I really don't know what percent of those 15,000 that are out there are going to end up here.

DR. MELIUS: Then my other related question is what do you see as being the sort of rate-limiting step in trying to deal with that large backlog, whatever the number may be? We don't know obviously what that is. Is it going to be completing the dose reconstructions, or is it going to be getting information, the dose information from DOE? Because there's got to be some limitation on the capacity for the individual sites to respond.

DR. NETON: That's correct. Right now obtaining the information from DOE is a limiting step, but it really depends upon the case. We have a number of cases that we have sufficient information, they can go through very quickly. There are always going to be those difficult cases that are out there that are going to take much longer than we would like. But right now, obtaining adequate information on each claimant to complete the dose reconstructions is going to

be the limiting step.

DR. ZIEMER: Sally.

MS. GADOLA: My question has to do with basics. And I am sure that you've learned a lot while you've been doing the dose reconstruction, but I haven't seen it recorded anywhere. And I'd like if someone could address such basic questions as who actually recorded dosimeter readings, how were they kept, how were they transferred when employees transferred from plant to plant? If an employee thought that they were sick from radiation and they questioned this, were they able to obtain dose records? And if those records are kept the same in all the DOE plants, and have you noticed a big difference in the subcontractors and the various DOE plants?

I know those are a lot of questions, but I feel like we need to somehow record the actual basis before we get into the more complicated reconstruction.

MR. SUNDIN: If I understand, we don't have a large number of completed dose reconstructions, obviously. We've got several underway. But I think you're point's a good one, at some point, when we've done a few of these and gotten to the

end, to look back and see what we can take from that and learn, and apply it to those that still remain to be done.

Is that sort of the sense of your --

MS. GADOLA: I want to know who is really responsible for recording them, and who was taking a look way back when to make sure that the employees were not receiving too much radiation.

DR. NETON: Well, NIOSH is doing that. We are developing what we call the site profiles for each of the sites. We requested monitoring -- not only do we request the monitoring information for the individual, but we've made a separate request for general information going back from the beginning of the site to document the radiation monitoring programs, what type of samples were taken, what the capabilities of their external monitoring devices were, and those type things.

We are assembling them and developing a database. All these things are electronically scanned, and then we derive secondary databases from them and profile these sites. We're working on that. I think we have about information on eight or ten sites right now. It's put on our

intranet. We don't have it out there for the public on our web site, although I suspect that that could happen if it was desired.

The other answer to your question, I think, is much of this is documented when we perform a dose reconstruction. It's an individual -- much an individual basis type thing, depending on when the person worked, basically, as you would think. And each dose reconstruction we take and we discuss which records were available, and why we used or did not use those records, and what the adequacy of them were for performing the dose reconstruction. That would be hard to get your handle on because they're individuals, but possibly when the Board undertakes its review of our dose reconstructions that may come out from that process.

MS. GADOLA: Thank you.

DR. ZIEMER: Sally, I might add a comment to that. In the early days of the AEC, and actually to some extent now, the individual laboratories have, perhaps intentionally, been made to develop a “not invented here” syndrome, where each one does its own thing. And so you see very different dosimetry schemes, it's not one scheme

for the DOE or for the old AEC. Oak Ridge had its own film badge system, Hanford had its, Savannah River had its. There are similarities, of course, and there was exchange of information. But if you look through those old records -- I have -- and there are differences in each case.

So you have to look at it certainly site by site. In many cases there are pretty good records as far as from a health physics point of view. But how far back you have to go before you would say they're pretty fuzzy, I think that'll come out as things develop. But even today you don't see that consistency from one lab to another, because the labs like to do their own thing. And to some extent they were encouraged in the past to do that. There was kind of a -- almost a competition encouraged between the labs, and certainly in the early days, and that has carried forth.

Other questions or comments?

Yes, Sally.

MS. GADOLA: I appreciate all that you've done, and I appreciate from working some with NIOSH and with OSHA in the past and understanding their desire to give accurate, honest

information, and also realizing the difficulty -- I'm talking about my experience in working in other plants, not DOE plants, and also working with people that were very well-meaning that worked in safety, but also did not have adequate training. Therefore, I appreciate the magnitude of this task of trying to be accurate, trying to give good information, and also realizing that when employees in other plants have questioned levels -- like for chemicals -- that often those records were lost, those records had been altered, and from my own personal knowledge knowing that some of the people that were responsible had lapses of memory.

And that's why I think it's important that as a Board that we just question it and document it, and appreciate the difficulty of really obtaining scientific, accurate, very basic information. And I appreciate all that you have been doing, and I think NIOSH understands the difficulty of that. Thank you.

MR. GRIFFON: Mark Griffon. Just to follow up on this line of questioning, saying the limiting factor was getting information from DOE, I think last meeting we asked about a Memorandum

of Understanding between NIOSH and DOE. Do you have a status on that? Did I miss that maybe?

MR. SUNDIN: I did speak to that. We have had a number of exchanges with our counterparts in DOE, have arrived at some shared understanding on certain issues, and identified others that we may want to table. But I believe we're close to having a document which both Departments can sign on to. The discussion process itself really has value, I think, in negotiating MOUs, which are of course not legally-enforceable documents. In that respect I think there's been a lot of good interchange and exchange of views between HHS and DOE. I can't give you an exact date when we might have a signed agreement.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah, to follow up on that question, it would seem to me that in the MOU there would be at least two sort of deadlines or schedules that would be important.

One is sort of for routine responses, where it's straightforward and getting records that are available, and it's just a question of sort of the time at the facility to find the records, get them in a form that they can be sent to NIOSH.

And you still want that to occur within a certain time period or it'll back up the entire process.

The second one would be that if -- for harder to find records, or where there's questions whether records are available at all, or whether even monitoring was done on an individual. And that may take longer, but if you don't have some sort of a deadline or schedule to deal with that it would seem to me it would back up the whole process, and you have people that would be waiting for months or years to get even into the dose reconstruction phase.

Is there consideration in the Memorandum of Understanding for dealing with both of those issues?

MR. SUNDIN: There is, Jim. I share your basic observation. That has been a major point of discussion during our negotiations -- if that's the right word -- around this MOU. So I don't know exactly how we will come out on that, but we want to make it clear that both agencies share a commitment to timely satisfaction of information requests, with acknowledgement that there are certain requests which will require more time. So that is a central discussion point

in the MOU.

Any other questions?

DR. ZIEMER: Additional questions?

(No responses)

DR. ZIEMER: There appear to be no additional questions at this time. Dave, you'll be here -- will you be here throughout the meeting, or just today?

MR. SUNDIN: Yes, I'll be here both days.

DR. ZIEMER: Good. So if additional questions arise, then -- or other staff members could also address some of these things.

Might I ask, just before our next speaker, Larry, would you just take a moment and introduce all of the other staff members who are with us today just for the record? Many of them we've met before, but I'd like to ask that they be introduced.

MR. ELLIOTT: Surely. We have with us today -- from OCAS we have Jim Neton, who you've heard earlier this morning, is the health science administrator; and my staff, Russ Henshaw, who has been presented to the Board before, an epidemiologist on OCAS; Ted Katz, who's a policy analyst within NIOSH; Dave Sundin, you just met

and heard from; and Cori Homer, who's probably dealing with some issue administratively right now. And we have Mary Armstrong, who's Office of General Counsel assigned to NIOSH; Liz, Elizabeth Homoki-Titus, who I don't see in the room right now, another attorney assigned to us from the Office of General Counsel. I think that's all the staff members from NIOSH.

DR. ZIEMER: Thank you.

And then before we hear from the representative from Department of Labor, I would like to also take this opportunity to have members of the public or other guests introduce themselves. We generally do this sometime during the morning, not only for the record, but just so that we have an awareness of who is with us this morning. So I'm just going to take a minute now, and if you're not one of the staff members that's been introduced but are an observer of member of the public, just if you would please introduce yourself and indicate who you represent, or whether it's yourself or a group. We can start in the back there.

MS. KIEDING: I'm Sylvia Kieding, and I'm with Pace International Union.

MS. ARMSTRONG: I'm Mary Armstrong, OGC.

MR. TINNEY: Joe Tinney with SAIC, and a former DOE employee and union contractor. Spent two and a half years with (inaudible).

MR. TABOR: I'm Bob Tabor. I've been here before. I'm from Cincinnati, the Fernald site, Fernald Atomic Trades & Labor Council.

MR. SCHOFIELD: I'm Phillip Schofield. I spent 21 years at LANL as a radiation worker. I'm here to represent Los Alamos POWs. I was put out on (inaudible) in '96.

MR. MANSANARES: I'm Bob Mansanares. I'm with the Department of Labor.

MR. MALITO: I'm Ray Malito, the manager of the Energy Resource Center here in Denver.

DR. BISTLINE: Bob Bistline. I'm with the Rocky Flats Field Office in Department of Energy. I've been at Rocky Flats for 36 years, on a contractor site with DOE.

MS. PRESLEY: Louise Presley, observer, wife of Board member Robert Presley.

MR. KOTSCH: Good morning. My name is Jeff Kotsch. I'm a health physicist with the Energy Compensation Group, Department of Labor, back in Washington.

MS. LEVINE: I'm Sonya Levine from the Department of Labor, Office of the Solicitor, from Washington.

DR. ZIEMER: Thank you very much.

Let's proceed with the Department of Labor program status report, Robert.

MR. MANSANARES: Good morning. My name is Bob Mansanares. I'm District Director for the Department of Labor's Energy Compensation District Office here in Denver.

I want to thank you, Mr. Ziemer and Mr. Elliott, for having me, for asking me to come here and speak to you and give you a progress report for -- I do not say EEOICPA; I say Energy Compensation. The EEOICP is long enough in itself, and I feel that Energy Comp is understood.

First of all, let me say that I'm here, and I'm very happy to note there are two DOL colleagues here. I was feeling somewhat overwhelmed this morning, and then I realized I'd seen those faces before, but I wasn't quite sure where. And it really is nice to know there are colleagues here. So if I misstate a legal point of view, just raise your hand and advise me, and

I will retract and we will correct.

And the other thing is, as I understand it this is the Advisory Board's first meeting in Denver, and of course, welcome to Denver. You're going to find Denver is a very inviting place. We have a tax structure that says to us, if we're smart Coloradians, welcome, visitors, and do spend your evenings profitably on behalf of Colorado by shopping and taking in the sights.

I think that most of you know the program provides compensation for persons who have become ill as a result of working at DOE facilities and certain vendors and subcontractors. Again, uniformity in the development and the payment of benefits is the protocol that I'm sure the Congress had in mind when they started thinking about Energy Comp and the Department of Labor delivering benefits in terms of administration.

These are the benefits that are payable: Covered medical costs; lump sum is $150,000 to the employee or the eligible survivor; Radiation Exposure Compensation, or RECA benefits, Section 5 recipients receive an additional $50,000. Of course, that's in addition to the $100,000 that they receive from the Radiation Exposure

Compensation Act.

And in Denver that's what we handle principally, is the Radiation Exposure Compensation Act claims. We'll be showing you a pie chart here, and a significant part of the claims or benefits paid through that pie chart are the RECA claimants. These are claimants that were established for this entitlement under Section 5, then we would provide $50,000 to the employee or the survivor; and if it's the employee, then they also have the entitlement for the covered condition that this provision or this Act provides for.

The four conditions that are covered are cancer, chronic beryllium disease, beryllium sensitivity, silicosis, nd the illnesses under Section 5 of the RECA.

Program highlights are that it was enacted October 30th, 2000. It went effective July 31st,and Secretary Chao presented the first payment on August 9th. Amendments were enacted to the provisions on December 28th, 2001.

This is the overall organization chart, if you wish, or description of how services are delivered across the United States. We have four

District Offices. Federal staff number 122 -- this slide is somewhat dated; that number is a little bit larger, but not by much. Contractor staff are 26, and then there's a break-out. National office staff, 25 federal staff, including the director; contractor staff, nine. And then groups that fall within the administration are Director, Automated Data Processing, Policy and Procedure, Outreach and Training, and Final Adjudication Branch.

So the Director's Office is basically Turcic and Roberta Mosier and their staffs. Automated Data Processing are Jerry Delo, and the ADP staffs that work with him to set up systems. Policy and Procedure are Rachel Leiton, who is the branch chief there. Outreach and Training are generally headed up by Carol Bronowicz, and many of you know Larry Hoss, and their staffs that provide outreach. Final Adjudication Branch is Luann Kressley, is headed up by Luann Kressley. Each one of these Final Adjudication or the National Office FAB, in fact, also has a presence in the regions. The local FAB is headed up by Joyce Terry.

This will give you a jurisdictional idea,

Colorado in blue, the 15 states that we provide services for. And then you have Cleveland up in green, Jacksonville depicted in red, and Seattle in yellow.

These are the participants in the claims process. These are our constituents: NIOSH; medical providers; Social Security Administration for verification of employment; claimants who are filing, both the survivors and as employees; corporate entities who provide us with information as to employment and if they have health records or health information, we're provided that; the Department of Energy; and the Department of Justice, all feed into the claims process that is handled by the Department of Labor.

This is probably a number -- these are numbers that you probably will be interested in. Effective June 13th, total number of claims received is just under 30,000. Total cancer claims numbered 19,000. Total beryllium sensitivity are at about 1,019. CBD claims are 1,010. Silicosis, 534. RECA claims are 3,512, and other claims are about 4,496.

This is the program statistic as of June

13th. Claims processed with final decision -- that's a decision by the Final Adjudication Branch -- approvals, 3,531; denials, 1,277. Claims processed with recommended decisions -- these are decisions by the Energy Comp District Offices which have not become final, but are sent to the FAB for review as a final decision -- the approvals were 4,176, denials were 3,262. Cases awaiting employment verification number about 5,300. Cases sent to the NIOSH are 4,914. Payments issued are 3,170, and if you recall, I said that the RECA comprises the biggest majority of this payment, at about 1,200. And amount of compensation paid, well, that's a big number, $237 million. And of course, again, that was as of June 13th.

This is just -- this is a break-out of the same figures you saw in the previous slide, to give you a visual and an idea as to where the number of claims are outstanding, listed at 10,903.

This is the last slide. As of June 13th, the yellow indicates overall acceptance of claims. These are final decisions, not proposed. You can see there's 73 percent acceptance, 27 percent

denial. And again, of the accepted cases, more than likely the majority of these are Radiation Exposure Compensation Act cases, which total payment of $50,000. It can be broken up by survivorship. As the District Director in Denver I authorize payment on these, and it's not uncommon for me to authorize payments of about $4,000 to $6,000 for anywhere from four to eight siblings of survivors when there is no surviving spouse.

So that is the status of our program at the present time, and I'm willing to take questions. I'm sure some of these slides may need clarification.

DR. ZIEMER: Thank you, Bob.

Let's open it for questions then.

Roy DeHart.

DR. DEHART: Just a comment on how you're doing the job validation. There have been complaints that people who have been employed in the environment for 20 to 30 years are having to go through their files personally, their own files, to send information -- I'm from Tennessee, so it would be Jacksonville?

MR. MANSANARES: That's correct.

DR. DEHART: Could you tell me why that's necessary, why there isn't records available on these people who have been employed in the nuclear business?

MR. MANSANARES: I think that the experience as to -- this, for us, as a claims manager, would be factual evidence. And for anyone who's involved in claims development for factual evidence, which would be comprised of employment records or marriage certificates, children's birth certificates, and things of that nature, I do not personally understand why some of these records are not available, other than the explanations that are given me by the Department of Energy and others that are involved in the record retention process. I think that the experience of the claimant depends and varies as to where in the country they're worked and for whom they worked.

We use alternative procedures for establishing employment verification. If that primary evidence is not available from the employer, there are secondary and tertiary pieces of evidence that we can use to establish the person's presence or employment at those sites.

And they can vary from -- oftentimes birth certificates will indicate the occupation of a parent. Many times there are clippings or newspaper notices that individuals retain because they were involved in a process or in a success that a particular facility experienced. So these are other types of evidence that we will use.

Also, if you noticed in the constituents to a claim slide here, we had the SSA, the Social Security Administration, from 1938 to the present time, oftentimes with a list of the individuals working for a contractor or vendor at a specific location, and we would use that information. And of course, we will also go to the affidavit. As long as the affidavit has a value that can be established and it is supported by other evidence in the file, then we will make a finding of employment and proceed as is necessary.

But yes, we are experiencing at some sites -- some of the District Offices are experiencing difficulty in obtaining records. Although the initiative and the efforts of the NIOSH, for instance, they're finding records that previously we were told were not there. But as a result of their on-site inspections and their interactions

with the records keepers, they've turned up records that we're able to use in Jacksonville, Denver, Cleveland, and Seattle.

Did I answer your question, or did I just waltz all the way around it?

DR. DEHART: No, I think you answered it.

MR. MANSANARES: Somewhere, okay.

Yes, sir.

DR. MELIUS: What is the rate of claims coming in now?

MR. MANSANARES: It varies by District Office. Initially in Denver -- and I can talk to Denver -- I think we have about 4,400 claims in-house at the present time. We have a staff of about 15 claims examiners at the present time, and many of those are recent hires. But I would say that prior to March we were running -- it varied 300 to 400 claims. Last week we had 89 claims. It's been running less than 100 claims per week at the present time for Denver.

DR. ZIEMER: No further questions?

(No responses)

DR. ZIEMER: Okay, thank you very much.

MR. MANSANARES: Thank you, sir.

DR. ZIEMER: The next item on our agenda is

the report of the dose reconstruction workgroup, and that was -- the workgroup was headed by Mark Griffon.

And Mark, if you would, before you get into your slides, go ahead and introduce the members of the workgroup, then proceed.

MR. GRIFFON: Thank you. Yeah, I was going to -- I didn't have a slide on the members of the group, but the members of the group, going around the table, Genevieve Roessler, Roy DeHart, Bob Presley, Rich Espinosa, and Jim Neton as our NIOSH representative on the working group.

After I introduced the members, I also wanted to say it was a process. We ended up having two conference calls as a working group. The first conference call we had, we did generate minutes from that and we sent them around to the Board, and I believe they got posted on the web site. I haven't checked that.

The second meeting of the working group was actually last week, so rather than generate minutes we took the time to generate this presentation. And we ended up having pretty good discussions on some issues. I think we ended up with some recommendations. I think we need to

flesh out some other issues to end up in the form of a recommendation actually, and we'll get to that as we go through the slides.

The charge was to develop options to review the scientific validity and the quality of the NIOSH dose estimation and dose reconstruction efforts, and this comes right from the statute. The four main issues that we ended up, or I consolidated these into four main topics that we discussed, was who would conduct the review, how the selection of cases -- how would we select the cases, the protocols that we would use for the review and sort of the scope of work for the Board to review the cases, and then the reporting out of the reviews that the Board does to the public and elsewhere.

Who will conduct the review: We talked about some different options, either with independent experts along with Board representation, and this was probably something that we agreed the most on as a recommendation. We felt pretty strongly that we needed an independent panel with independent experts, but we also needed Board representation and Board oversight. I think we noted that the Board is ultimately responsible

for these reviews, so the Board would certainly have to maintain oversight on this process.

As we were developing that option we talked about several issues: Whether these should be -- whether we should have individual experts, contractors, or a consortium, and it might be a consortium of several contractors; the size of the panel, what was a workable size; the availability of independent experts. The issues that came out here was that as NIOSH is in the process of hiring a contractor to do the dose reconstruction, we all know that there's a limited pool of experts in this area. So we just thought that may really be an issue here. And then the selection, which was more of who and how do we do the selection process. And the nature of the panel meetings, should the independent expert panel meet, should they have public meetings? They obviously have to get their work done, but there also has to be a level of transparency of what that panel's doing.

So along the lines of the expertise, individual experts, contractor or consortium, we talked about the issue of they had to have a wide variety of expertise to review the cases.

Sometimes there's individual experts out there that really their strength lies in internal dosimetry, and they're less skilled in reviewing external radiation dose cases. Or they may have worked in certain sectors of the nuclear industry and not be familiar with reactor exposures and things like that. So we thought that was one criteria we needed to discuss further.

Also, the second one, important to have credibility to do objective work. And this again was our attention to the concern that the public has to have faith in this Board as doing an independent review. And along with transparency, we thought it was important to have maybe -- the panel have representation that maybe was outside the box a little bit. If it was the same -- if it was perceived as being the same -- this overlaps a little bit with the next item, which is the conflict of interest -- but it was if there was a perception that the same people were reviewing that have always reviewed the cases and always done the dose work at these sites, then the claimants on the other side, especially the rejected claimants, may say, of course, we certainly saw that one coming. So we think that

-- we thought that there might be a use in having expertise that was sort of outside the box that could be critical of the model assumptions, et cetera. And if after all that the cases stood up, then they have more credibility actually.

The size of the panel and the availability of the experts: One model we turned to in our review -- and Jim Neton provided us some documentation, a GAO report which I think was sent around to the whole committee. And I followed up on the NAS folks, and there's actually on their web site they have some documentation of their scope. They are required to do a review. They have a NAS subcommittee headed, chaired by John Till, and I think currently they have nine experts on this panel. That was one model we looked at. We're not sure that's the right number. That's the model they're using. Some folks thought that was a little large and may be unwieldy, actually, but it was something we turned to. And then again, I mentioned the small pool of experts that may be left available for this.

The selection, the Board felt pretty strongly that -- or the working group felt pretty strongly

that the Board should be responsible for the selection of who. And Jim Neton, before I overstep my legal bounds here, I'm going to ask -- I think NIOSH would actually have to do the contracting process. I don't want to get this wrong, but we felt pretty strongly that the Board should make the determination and decisions on who, whether it be individuals, contractors, or a consortium. The Board should have the input on that, and NIOSH can work out how to do the contracting on that.

As far as meetings, we felt first that the panel should report to the Board. Again, this goes back to the Board being responsible for these reviews. And again, we emphasized again and again, this has to be a transparent process. So somewhere -- and that's, again, those reports back to the Board would be public meetings, and the public would be able to see what's going on.

Another recommendation was the workgroup felt that the Board should select the cases for review, and we felt also that we needed to have a stratified sampling of cases. I believe in the case of the VA it's more of just a random sampling. I'm not sure of that, but the way they

describe it on their web site it's a random sampling. But due to the nature of the DOE sites, we felt it behooved a stratified sampling strategy. And we talked about some parameters. These may not cover all, and I think this is an area where we may need to be -- give a more specific recommendation. But the site, the exposure type, cancer type, time period are some possible parameters that we may stratify on.

The number of cases, overall case load greater than 2.5 percent. We came on that number because we turned to this VA model. The VA has selected about 100 cases out of an overall of about 4,000, which is about 2.5 percent. And we thought -- we tried to hone in on a number, but we said, well, at least we think that it should be greater than 2.5 percent, the rationale being that we've got to have a stratified sampling, and that's going to create more cases that have to be reviewed. It seemed to be a reasonable answer to that. So we don't know the upper bound of that, but we think that it's probably going to be something greater than 2.5 percent of the cases.

Again, the workgroup agreed that the Board should establish the protocol for the panel. And

protocol and -- scope of work/protocol, I might say -- scope of work for the NAS review, we looked at the scope of work that was described for the NAS panel, and we discussed potential tasks for the scope of work and the type of review. I'll go into those a little bit here.

These are the -- some of these overlap pretty well with what was done on the -- what is -- I guess what was Congressionally mandated to the NAS as the scope for their review of the VA cases. I hope I got that right. The panel should determine whether or not the reconstruction of the dose is accurate. And the parenthetical point is important. I'm doing this for Jim Neton. He reminded me several times that accurate to the extent that it's good enough to determine eligibility. And I think that's an important point of this, because sometimes, as NIOSH has said, they may not have to be very accurate. If someone has really high doses they don't need to fine tune it that much. They trigger, they're in; it doesn't matter. And if they're very low, on the other side, they may not have to fine tune as much. So the panel should determine whether or not the assumptions,

individual case assumptions or assumptions that are applicable to groups of people, are credible. So that's the accuracy of dose estimate, the credibility of the assumptions.

The panel should determine whether or not the data from DOE or other sources is accurate. And the panel should determine whether or not the estimate of the dose is a reasonable estimate, and “reasonable estimate” being a term that was in the statute.

Now, the panel should determine whether or not data from DOE or other sources is accurate, that item generated a lot of discussion. We felt pretty strongly -- and this, I think, goes to Sally's points earlier, that in order to maintain transparency of this process and to give credibility to our review, we need to in some ways check that to make sure that NIOSH went back, and the data they got was good quality and was useful for -- was good enough for determining whether people were eligible. So now how we get there is another question, but we think that is a very important aspect.

And that sort of leads to this, too, which is this tiered review idea. The three methods of

review here are simplest to most complex or most extensive. And the initial review of the cases and the calculations, that will be just sort of looking at NIOSH's or the contractor's work and checking all the assumptions, checking the calculations, that sort of thing.

The next step is to check a little further, and on a certain number of cases you might look at quality of the data and how NIOSH decided, if there was inconsistencies, for instance, between personal interviews and the records, how did NIOSH rectify that, and how did NIOSH handle that in their reconstruction.

And then the third is even more extensive, where we actually want to see what was requested, what did NIOSH request from DOE, were all the records -- and I put “all” in parentheses, too -- were all the records provided from DOE. And the question that was chased around by the working group was, well, how do you -- as it is by many researchers at the DOE sites, how do you know if all the data was reviewed if you don't know what all the data is? So it's a -- but we thought that is, again, an important point because of some people's concern about the DOE either

destroying records, destroying data, et cetera. We think that the Board should have some level to look into what kind of data is coming from the DOE, not just the secondary steps. So we felt that was an important point.

The review panel reports, the workgroup agreed that the panel must first report back to the Board, and then the panel reviews and the reports of panel activities, policies, and procedures should all be made available to the public in de-identified form, obviously. But that, again, is for the transparency for that. So that's the report out by -- I think that's it.

I just wanted to say the last thing -- I think the three areas that -- and we discussed this -- that we may, after discussion with the full Board here, we may want to go out tonight and fine tune three areas for more specific recommendations. One of them is the makeup of the panel, flesh that out a little better; also the selection of cases; and then the scope of work for this independent review panel. So I think we agreed that the panel would meet tonight if we needed to.

Did we agree, panel, or working group, I

mean?

(Affirmative nods)

MR. GRIFFON: Roy says as long as he gets ice cream.

DR. ZIEMER: Thank you very much, Mark. I believe, based on those comments and what you've just now suggested, probably it would be worthwhile if we got the initial feedback from the full Board and reactions, comments, suggestions that the committee could use to -- as they huddle tonight and refine this. And then we can revisit it tomorrow in perhaps in what we might call more final form, and see if the Board is ready to take formal action tomorrow or if further refinement is needed.

I think we're not under tremendous pressure to necessarily finalize it at this meeting, because we know that there's going to be a little time lag before cases are -- until there's a body of cases to be looked at. So we can be fairly deliberate, if necessary; but we want to move ahead, on the other hand, and be ready to hit the ground running.

So let's open it up at this point for questions, comments, and other reactions. I

think the subcommittee has done a very good job of thinking about the issues that have to be addressed, and we appreciate the input that you've given us here.

Okay, Tony.

DR. ANDRADE: Mark does a good presentation. I appreciate all of the work and the thoughts that you and the panel put together with respect to the -- the questions are very important questions that will face this panel, group, team, whatever you want to call it.

Let me start from the back end of my though process, and then I'll get into what might be considered a very quick straw man on the recommendations.

What would happen if this team were to somehow find a shortcoming, a potential shortcoming, a disagreement with a dose reconstruction activity, even if it was for a single individual, or perhaps the way those dose reconstructions were being conducted? Perhaps the answer's not available right now, but it's certainly one that's going to have to be addressed at some time.

My next statement is in the form of a

comment, and it's more along the lines of a recommendation that might be considered as a straw man for further discussion this evening. For the John Till group, my own personal experience has been a group that -- how shall I say -- it seeks to keep the maximum number of contractors employed. I would strongly recommend the following criteria for a team.

Number one, that we should consider no more than two relevant and independent experts. What I mean by relevant is, as you pointed out, experts that are familiar with the particular type of dosimetry that was conducted at a particular site. If it happened to be Washington, for example, you might want to have reactor experts, reactor health physicists.

Number two is that I think it would be beneficial to have at least one, and perhaps even two, Board members be members of that team, so long as they have no conflict with the operations of the site that is being reviewed. For example, I would recuse myself from any work that was done in review of work at Los Alamos.

And number three is that I would recommend that whatever panel is put together, that they be

allowed to conduct at least two reviews at two separate sites for that minimum number of reviews that you're talking about, for the following reasons: One is that a working team develops a relationship and a rapport, perhaps during the first experience they have, and they start to learn about what is important, what sort of records need to be considered and kept -- alluding back to what Sally was talking about this morning. And it would be a tragedy to lose that experience if that panel is disempaneled without going back and approaching a different site with a whole different way doing -- that had a whole different way of doing business without this same type of approach, so that they can do an apples-to-apples comparison of the state of affairs at the two different sites.

So those are my comments for now.

DR. ZIEMER: Thank you.

Other comments?

Yes, Jim.

DR. MELIUS: Yeah, a number of comments.

I would agree with Tony. I guess number one is I think we need to get this review going as soon as feasible. It's not something we should

put off until we get enough numbers to sample from or whatever, whatever kind of plan we -- tiered plan we develop. Because I think sort of the credibility of the process is important, the overall process is important, and we don't want to be in a position where we have to redo a bunch of dose reconstructions or whatever. And the credibility's particularly important at an early point in time in this process. So I think we ought to try to get as far as we can today, and then push NIOSH to get whatever we recommend implemented, doing that.

Secondly, I like the idea of sort of small, smaller teams making up a panel that reviews cases, and that they also review cases for more than one site so it's not just a site-specific panel. They may draw -- well, let me get to that in a second. But I think that might be a way of sort of keeping the process moving quickly, efficiently, and at the same time building some confidence and expertise. So I think that way of developing a panel may work, but any way we do it it's logistically complicated because of conflicts and availability of the appropriate experts.

Third, I think it is important, and Mark's comments, this whole issue is is all the data, available data or information or appropriate data and information, being considered in the dose reconstruction? I think that's going to be probably the major concern the claimants have, that, oh, I know there's other information that's being hidden that wasn't available, whatever. I think when we get to the special exposure cohort proposal from NIOSH, I think that is even -- emphasizes and makes that even more important. Is all the data really being considered?

So I think we need some way as part of this process of getting that information. And whether that'd be some way of accessing some people with long-term knowledge of the site, just to make sure that they -- NIOSH has considered all of the available information, or all the available or appropriate information is made available to them, I think is key. And I think whatever we can do to get that would really help with the credibility of the overall process. And that may have to be done a little bit separately than the group of experts who would do the dose reconstruction. At the same time it's got to be

tied to that, because I think you want to be looking for appropriate information, not just every piece of information that's not relevant to what is being done for this dose reconstruction.

DR. ZIEMER: Thank you.

Yes, Henry.

DR. ANDERSON: I guess I would agree that we probably need to get started fairly quickly. It would seem to me that as we move into meeting eight, nine, and ten or whatever, the activity of the Board will focus more and more on these reviews.

It would seem to me what we may want to do is rather than have a few Board members be on the panel, establish panels so that all Board members would either rotate on the panel or would be part of a separate panel. So we may -- I also agree that smaller numbers is probably more than adequate. So I would think in terms of setting it up so that a few Board members would not bear all of the work brunt, and that everybody would in fact be part of these panels so we'd have the experience of, when it comes back to the panel or the Board for final approval, that we'd all have worked through some of these individually but not

have to work through all of them. So that would be one.

The other is it would be interesting to see or maybe hear from the VA panel what's their protocol, maybe have them come at a meeting and just say what's been their experience, how do they do it. It seems to me we'll need a number of things. Being an epidemiologist, I would look in terms of wanting to analyze data, looking at perhaps case-control things to look at, what are the parameters, perhaps even datasets, that might well predict who is accepted and who isn't accepted, over and above what the actual exposures were. It may well be the quality of the data may become very obvious in one side or the other.

So I would think we're going to have to have some check sheets of what's there, and then the validation process. That may be something contractors could do. But I would think we need to have a protocol. We need to have a data collection system so that as we get these we'll be able to see, and you may identify that in this one, gee, look, they had that data; and this one is missing that data, and is that because they

couldn't find it, or what is the issue, so we kind of have all-encompassing, all possible sources that you'll get through all of the systems, and then we'd want to check to see does this particular case have those. And that would lead us to the question, if they don't, was it not collected, or was it -- is it missing? And that might be one way to look at some of that.

So I think, again, everybody needs to be involved, not on one big panel, but on multiple panels. And if we want to look at where people have conflicts so that you'd then be assigned to an overlapping two sites, that might be the way we could break it up, and people would then become expert in those particular two comparison sites.

DR. ZIEMER: Thank you.

Wanda.

MS. MUNN: Yes, I'd like to agree especially with one thing that Henry said. With respect to data that we're looking at, I was really bothered during Mark's presentation by the word "accuracy" of data. I can see no way that anyone can look at 50-year-old data and determine whether it is accurate. We might be able to have a shot at

making some assessment of the quality of the data. But accurate? I don't know how you'd do that. I just don't know how to do that. And if we start off saying one of the things we're going to do is try to identify the accuracy of the data, it seems to me we're setting ourselves up for an impossible task. The quality, the quantity, the source can be determined. But how do we say, even if the data is complete, that it was accurate from 50 years ago?

DR. ZIEMER: Let me insert at this point, and I think this is an issue that the NIOSH people are trying to address as they look at the various sites, because with each system there is calibration information that in fact allows you to establish some level of accuracy with some degree of error or uncertainty. So in principle, you can do it if they have enough information on the calibration processes.

MS. MUNN: Degree of confidence I can understand, but I'm concerned about our obsession with accuracy.

I certainly agree with everything that's been said here relative to the desirability of small groups as opposed to large groups.

I'm concerned with the comment about stratification. I understand and agree that some significant amount of it is necessary, but that's one of those areas where you can get yourself into a real quagmire trying to get too specific in identifying too many different strata.

And the number, the percentage of cases, is one of those things that perhaps we should look at a little more carefully. I don't know that we achieve an awful lot by identifying a specific percentage. Perhaps there might be some other type randomness that would serve as well.

This is a question that I don't know the answer to. I recognize the real problem vis-a-vis identifying well-qualified people to do this. Is there some possibility that one of the things which might also add one more degree of objectivity is the consideration of individuals from outside the United States who are qualified to do this type of thing? I can think there are maybe individuals in Britain, for example, who would have the same general broad experience that we would want, also maybe France. Don't know whether that's even possible for us to do, but it's worth thinking about.

DR. ZIEMER: Thank you.

Henry, again.

DR. ANDERSON: Yeah, on the two and a half percent, I think, one, we have to ask ourselves, we could do a power calculation on our likelihood to be able to detect the degree of problem that if we're just checking to see were errors made, we can look at what NIOSH is going to be doing for their QA/QC activity and see whether we need to do something similar.

The other thing we may want to think about if we do a relatively small percentage is do we want to have an appeal process where individuals could request to have their records reviewed, and we then have a process for selecting a certain percentage of those so that it -- while that's not part of a random or a stratified sample, there may be issues that in a random process wouldn't be identified when an individual may say, gee, you know, they totally ignored this, and it wouldn't get into a –- the review process. So we may want to think in terms of having a capacity for individuals to say, gee, I'd like to have this reviewed by a panel. We'd have to put some restraints on how many of those we could

handle, but that might be another way to allow individuals who will be the ones that may be concerned about it to have their records reviewed, and then you would have some process like that.

DR. ZIEMER: Maybe we can ask the staff at this point if there is a type of appeal process already for those, particularly in the middle of the scale, I think. But I'm not sure if you're talking about that, or the Board acts as appeal --

DR. ANDERSON: No, no, no, not -- only as to what the panel will be doing as the reviewer of the records and the other activities. If we set as our goal here what is this review going to accomplish, and if the review is to determine the completeness and the systematized or systematic approach that's been used to be sure that things are not missing or whatever, individuals who believe their data is more missing than somebody else's, we might have that as opposed to the decision process that was made.

DR. ZIEMER: Perhaps this parallels the point that Tony made originally, and let me -- and I'll ask Tony this question, because you were sort of

saying bottom line, what happens if the panel says a mistake was made or that the database is inadequate, or there's some flaw in the process of the dose reconstruction? And I believe you were suggesting that perhaps as part of this process we think about how do you handle that. What happens when that occurs?

And that might be something, Mark, that the group should also address. What happens if in fact there is a concern raised? Does it bounce back to staff to redo something, or just what happens? I don't think we have to answer that right now, but certainly that's an important –

Was that the nature, Mark -- Tony, of what you were asking?

DR. ANDRADE: That was precisely what I was asking about. I know that it's already law insofar as what the appeals process will be for those people who would like to have their cases reviewed. However, as an advisory body -- again, not an expert body -- if we do find something lacking in terms of the quality of reviews or a review, the open question is what do we do? How do we feed back into the process? And I think that's really the route that we should take.

DR. ZIEMER: Additional input?

DR. NETON: This is Jim Neton. I think that's been addressed, in the sense that if the case has been through final adjudication and then the person has appealed, and essentially he had lost or been turned down at that point and the Board has reviewed the case, I think what would happen is the recommendation would be referred back to NIOSH. We would evaluate that, and then with our capability to turn back to the Department of Labor and say reopen that case, we feel there's new information that's come to light that would warrant reopening that case at that time. So I think that the way the mechanism works is it would all come back through NIOSH to be able to -- we would recommend the case be reopened at that point. That has been addressed.

DR. ZIEMER: Jim, is that -- do we know for certain that that process is already well codified in the --

DR. NETON: Well, I think Ted could probably answer this better than me, but I think the last rev allowed NIOSH to --

DR. ZIEMER: For a variety of --

DR. NETON: For a variety of reasons, one of

which would be the Board's review. That's essentially, I think, the only mechanism that's open to reopen a case that's been through final adjudication.

Is that correct, Ted?

MR. KATZ: Yeah, it's -- Ted Katz. The specifics are not in the reg. They're in the implementation. But it's broad enough as it's written in the reg to accommodate that perfectly.

And just the other thing I would just mention is obviously, for dose reconstructions that are recently completed, there may be an opportunity to -- if those go before the Board for people who are unhappy with those before the claim is finally adjudicated, then that sort of shortcuts the process in terms of how do you remedy a problem if you find one.

DR. ZIEMER: Thank you.

Roy.

DR. DEHART: I would like to thank you all for joining us on the frustration of the amount of material that we're going to have to consider here.

I find it difficult to perceive in my own mind just what we're talking about. I haven't

seen a case, so I have no idea what the data is, what the datasets consist of, what the interview information happens to be, whether or not there's classified data in there that would require Q clearance of those of us who are participating in the reviews. There is a lot of information that -- I would like to ask NIOSH if they could put together for us some dummy files so that we can begin to see what the mass of information is going to be that we're going to be responsible for reviewing.

DR. ZIEMER: I think I heard a sort of a nod or a yea?

MR. ELLIOTT: Larry Elliott. Yes, we can certainly do that. We can prepare some -- I think what you should start with is the de-identified administrative record for the file. That contains everything that was used to support the file -- the case.

DR. NETON: That may be very difficult to accomplish. These cases have 4- or 500 pages of information, in many cases, that we would have to go and redact virtually every single page, if we could do that.

MR. ELLIOTT: But I think we will do that.

DR. ZIEMER: I think Roy is requesting -- we need to get a feel for what we're talking about. It's not a simple matter of having a few pages and a quick calculation, saying everything looks good.

DR. NETON: Well, I just wonder if the Board couldn't -- the small working group in particular, just looking at an actual case rather than redacting one. It would be simpler to just turn over a case or two to the working group, rather than to start redacting thousands of pages of information. Just a practical suggestion.

DR. ZIEMER: That might be a way for -- the working group could then develop a feel and report back to the whole, full Board on the magnitude of the effort.

MR. ELLIOTT: We'll provide the Board something, the administrative record, and we'll take into consideration what needs to happen to provide that to you. It'll be done.

DR. ZIEMER: Wanda.

MS. MUNN: Or alternatively, it may be simpler and less work in the long run to just simply have our working group go visit NIOSH and talk to the staff, take a look at some of the

files. That might be the simplest way to get a feel for what has to be done.

DR. ZIEMER: Again, I don't know that we have to decide that at this moment.

But maybe, Mark, as your group addresses this later today and talk with the staff, and you can develop a strategy on how that might best be accomplished. Is it a visit to Cincinnati, or to a site, or what --

MR. ELLIOTT: It would have to be in Cincinnati, but we could accommodate that kind of a visit, too. Maybe it's a combination of both those things that needs to happen.

DR. ZIEMER: Mark, let me ask if you have additional questions for the full group here now before -- do you have enough sort of feedback and ideas and stimulating comments that will be helpful to your group as you proceed?

MR. GRIFFON: Yeah, I hope so. And Roy pointed out well that that was part of our frustration in this, was sort of talking in the -- without being able to see case files and know the process, and know how many cases from what areas, we were kind of -- so I think it's all -- a lot of the points that came up, although there

were certainly some new ones that we appreciate, a lot of them we have jumbled around within our conference calls, and where we couldn't quite come to some conclusions. So that was very helpful.

I should point out also that we also noted the -- I think most of us agreed that the nine-member panel wasn't a construct that we were really looking at. We were looking at less members. And what we did want, we did talk of one to three Board members. And we threw around the notion of rotating Board members, too, so --

DR. ZIEMER: I'd like to get a, in fact, a kind of a straw poll feel for how the Board reacts to -- I guess it was, Henry, your suggestion that there be perhaps multiple groups, allowing each of the Board members to participate in some way in this. How many like that idea and would be willing to be involved in such a group?

(Show of hands)

DR. ZIEMER: We're not holding you to this. I just want to get a feel for whether -- is Henry the only one that likes this idea?

(Laughter)

DR. ANDERSON: You won't get volunteers

otherwise.

DR. ZIEMER: Mark.

MR. GRIFFON: I'm sorry, one point of clarification on that. Henry, in your model are you talking about multiple panels?

DR. ANDERSON: I was just assuming that we would kind of spread the work around. Now whether it could be rotating people but a fixed number of experts, that, I think, has some benefit versus multiple panels. I think it depends on how long it takes to do a case review if we're going to do this. That's why I would ask the VA or whatever, if we're going to have 20 files to review and it takes several hours per or a day per, the group is going to get bogged down unless you have multiple groups. But rotating certainly would be a way to do it.

DR. ZIEMER: And if you do it that way, sometimes what you do is you give a common file to several of the groups to sort of cross-calibrate them, to see if they --

DR. ANDERSON: Right, yeah. You'd have to kind of set up a study design, as it were.

DR. ZIEMER: Right. In other words, is the outcome on the panel or did you reach the same

conclusion if you have a different set of reviewers?

DR. ANDERSON: Right.

DR. ZIEMER: Bob.

MR. PRESLEY: I agree. I agree with Roy and with Henry, because the way our schedules are at times, a lot of people are not going to be able to be there, or are going to have a conflict of interest. And if you had maybe two panels that could swap back and forth with your experts, I believe that would be a lot better.

DR. ZIEMER: You have additional questions you want --

MR. GRIFFON: I think we have something to go on tonight, so thanks for the input.

DR. ZIEMER: Larry.

MR. ELLIOTT: One of the ideas that I heard expressed -- I'm not sure as to who expressed it -- but was to hear from the VA about their experience and their protocol. And I'd ask you to kind of think through that a little bit. Do you want that as a presentation to the Board? Do you want to have just the working group interact with the VA and report back to the Board? How would you -- think about how you would like to

effect that so that we could put it into play for you.

DR. ZIEMER: Well, let's get it -- let's find out right here.

MR. GRIFFON: Well, just a question on that, because I did some follow-up phone calls. And the NAS -- I never did get a hold of John Till, as I mentioned -- but the NAS sort of stopped -- they weren't very specific with protocols. They said they couldn't get specific with me with protocols. I don't -- is that something they can share now? Do people know? Or are they still working on their protocols, and -- because the most I got was on a web site from NAS, where it described the scope of work. And we did look at that, and those last slides sort of overlap with some of that. But as far as specific protocols, they said they couldn't share at this point.

DR. NETON: I think I may be able to address that a little bit. The NAS review is really a one-shot review that was commissioned as a result of (inaudible) investigations, so it has a somewhat different focus than what you guys are all trying to set up, which is an ongoing review process. So I suspect that they don't want to

review -- to release their protocols because it's an ongoing study that's not been completed. So I don't think that they're probably willing to share at that time, but once the study's released I think they can share with all.

DR. ZIEMER: So it's a different --

DR. NETON: It's a different focus than what we're trying, or what you all are trying to do here. So it's relevant to look at what they're looking at, to examine what they're looking at. But their process and protocols, I think, are somewhat different. It's reviewing 20 years worth of work, or something like that.

DR. ZIEMER: It appears, then, that that wouldn't be so useful. Is that correct? Is it the VA, or the -- the VA staff versus the NAS review panel.

MR. ELLIOTT: Right. I think what Jim's characterizing is the NAS review of the VA --

DR. ZIEMER: Well, then that may not be so helpful.

MR. ELLIOTT: If you want to hear -- yeah, right. If you want to hear about the VA model and their approach in reviewing dose reconstructions, that's what I -- or any other

models that you might identify for us, and how we might bring them to your awareness.

MR. PRESLEY: Would there be a possibility, if we did go to Cincinnati to review cases, to have the VA at that point talk to us, kill two birds with one stone?

MR. ELLIOTT: Well, again, that's something to be considered as an approach, yes. But again, I would take it back to do you want the whole Board engaged, or do you just want the working group engaged? I think it could go different ways. And so all I'm asking is to think through this, and then place something in front of me that I can effect for you.

DR. ZIEMER: Let's not -- let's hold that till tomorrow.

Maybe -- Mark, maybe your group can address that question as well.

Certainly we can't -- I shouldn't put it that way. We probably don't want the whole Advisory Board to be going to review the sample cases because this becomes an official meeting at that point, and this is something, because of the confidentiality of the files, we can’t really do in public. So that's got to be the smaller

group. If the whole Board wishes to hear from the VA, then we can schedule that as part of a regular meeting.

DR. NETON: I'd just like to offer one point, a minor correction. It really is the Defense Threat Reduction Agency that is responsible for conducting the dose reconstructions that is turned over to the Veterans Affairs, so it would be -- or their contractor.

DR. ZIEMER: For the record, that's what we need, then.

Okay, I think we're at a point where we're ready to take our morning break, so let's do that at this point. We'll reconvene at 10:45.

(Whereupon, a break was taken at 10:20 a.m.)

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DR. ZIEMER: Okay, we're back in session.

The next item on our agenda is Special Exposure Cohort petitioning. You recall that the *Federal Register* notice 42 CFR part 83 appeared just this past week, June 25th to be exact, the proposed rule. That rule is open for public comment actually till August 25th or -6th, a 60-day period. Ted Katz is going to lead us through the document, then we'll have an opportunity to

discuss.

So Ted, if you would, please.

MR. KATZ: Thank you.

Okay, so I'm going to give an overview, a little bit of background. I realize the Board -- for the Board, this background's a bit redundant at this point, but there may be people in the audience who don't have your experience already with this. And then I'm going to talk about the rule. I'm not going to run through the rule in a section-by-section forum, which I think would drive you crazy at this point. And I realize the Board may want to later, actually, as they've done with the previous two rules, review the rule in that process. But I'm going to try to get some essential points up before you. So some background here about the cohort.

Congress, in enacting, and the President, in enacting EEOICPA, established an initial cohort from four facilities, three gaseous diffusion plants and a nuclear test site in Amchitka, Alaska. And the Board has had a presentation about that process of establishing the initial cohort from Dr. David Michaels, who explained a little bit about the background and how that

worked for Congress to make the decisions they made. But in addition, it was realized that the cohort may need expanding, and let me explain this.

The cohort, for people who are in the Special Exposure Cohort, they are not required to have their doses reconstructed individually and to have a probability of causation determination to determine whether it's at least as likely as not that their radiation dose has caused their cancer. In their cases there is a presumptive finding that because they were employed at the sites and meet certain minimal criteria that are specified in EEOICPA and addressed in the DOL regulations, they will be compensated if they incur one of 22 specified cancers.

And the one other point I should just make about this is they are compensated under the cohort provisions only for these 22 specified cancers. And as we discussed with the dose reconstruction rule and probability of causation rule in the past, some of these individuals, if they don't have one of these 22 specified cancers, they can seek a dose reconstruction from NIOSH, and we will attempt to do a dose

reconstruction. This will be an important point as we go forward in talking about this rule.

Adding to the cohort, I think I've covered this basically. Congress assigned this responsibility to the President, who delegated the responsibility for adding to the cohort to the Secretary of Health and Human Services. So that's where the buck stops. That's the person who makes the decision ultimately whether to add or to deny adding a class of employees to the cohort.

Now Congress did give some broad statutory requirements to guide the President and Secretary of HHS as to how it was to go about this process of considering and adding classes to the cohort. Two criteria were identified: One, that it's not feasible to estimate radiation doses with sufficient accuracy; and the second criteria, reasonable likelihood that these radiation doses endangered the health of the class.

And then there were also some specifications with respect to the process. One, that HHS was to consider petitions by classes of employees to be added to the Special Exposure Cohort. This is how we come to consider a class. And secondly,

that after giving consideration to a petition as appropriate, we would get the advice of the Board on whether or not to add that class. And there's more -- it's worded more specifically in the Act, but this is the meaning.

Congress also allowed itself, as it was said to me from a Congressional staffer, a sort of escape hatch, a Congressional review period. So for affirmative decisions, if the Secretary of HHS decides that a class should be added to the Special Exposure Cohort, that decision and its basis go to Congress, and Congress has 180 days to consider that decision. And I'll be more specific in how we interpret that.

Now I've separated the presentation into two pieces, really. The front end, I want to talk about sort of the substantive work of evaluating whether a class should be added or not to the cohort. And then on the second half of this presentation I'll talk about then the process for doing those evaluations, for considering petitions and doing those evaluations.

So key technical issues, these are what we just identified in the Act. They come from the Act. We need to be able to determine for a class

when it's not feasible to estimate radiation doses with sufficient accuracy, and when is there a reasonable likelihood that the radiation endangered the health of members of the class. What I'm going to do now is just sort of drill down into these concepts as to how HHS has interpreted this.

The sufficient accuracy first. There is, first of all, there was a discussion earlier about the difference between -- well, about accuracy. And I recognize there's a difference between accuracy and precision from a statistician's or a scientist's point of view, and you discussed some of the problems with dealing with the issue of accuracy. But I think in this case really the issue is precision, and there is no gold standard for precision. It's an entirely utilitarian concept. It depends what you're doing how precise you need to be.

And our practical answer to this was we need to be able to estimate doses to enable the sufficient -- to enable fair adjudication of claims. This is our answer. And it sounds on the front of it, I think, a little bit circular. If we can do a dose reconstruction, what we're

saying, then they will be sufficiently accurate. And the reason we say that is because the way we've designed the dose reconstruction process is to first and foremost ensure the fair adjudication of claims. And what that means with respect to precision is that we'll either be able to estimate the doses with uncertainty properly, in which case we're all right. Or -- I'm sorry, I'm losing my place here. Let me move to the next three sub-questions here.

Can we reasonably estimate -- this is what we've said before -- can we estimate the doses? It means can we do, give you essential estimate and a dose distribution around that? If not, can we reasonably estimate the upper limit of the dose? These next two provisions are if so, and if so is it below or above a compensable level? This is what we've talked about before. In some cases we may not be able to produce a proper dose estimate with uncertainty limits, but we can cap the dose estimate. We can give a worst case of what that dose might be. With very low doses, that would be sufficient to produce a dose reconstruction. We would be giving them, in effect, then a worst-case dose reconstruction

versus a dose estimate with uncertainty parameters. But nonetheless, fairness would be assured here, we believe.

When is dose reconstruction infeasible? And this was discussed again with the dose reconstruction rule, I think. Substantially, again, it's a case-by-case determination only, and there are limitations just to really explicate that that could prevent a dose reconstruction, which we talked about in the dose reconstruction rule.

Really these three parameters all, when we fall short on all three, we have a problem doing dose reconstruction. And that's lacking personal or area monitoring records for radiation exposure -- and here, just to clarify, I'm talking about not the fact that there are some personal exposure monitoring or area monitoring, but the issue is where are we lacking such records. And secondly, where we don't have sufficient information on the radiation source to estimate doses. And this goes hand-in-hand with the third, where we don't know enough about the work processes involving the radiation sources, or where they could result in a hazardous dose. And

here I'm talking about a compensable dose. And in effect if we can't get a handle on this, how high the dose might be, and we can't put uncertainty parameters on it, we can't do a dose reconstruction.

I should mention, we've had a presentation for a small stakeholder group about this rule, and one of the issues that was raised in that meeting was this whole question of feasibility again. When is it feasible for NIOSH to do a dose reconstruction? And our response in that discussion with the stakeholders is really that feasibility is a knotty issue when it comes to regulations, when it comes to getting a specific standard in place. And it's a problem in other areas of public policy as well, and people probably in this group understand how it's a problem when it comes to OSHA law. Feasibility is a big issue there. It gets determined on a case-by-case basis. There's really no better -- it's like trying to define joy. It doesn't accommodate itself well to a regulatory process.

But it is something to point out that we'll be addressing on a case-by-case basis, and an issue which then will be coming before the Board

under those circumstances. The Board will be reviewing dose reconstructions and seeing those instances where we're not. If you're stratifying across all sort of possibilities, you'll be looking at instances where we couldn't do a dose reconstruction. And when we are considering classes, of course, every time we consider a class for a Special Exposure Cohort you'll be looking at the logic behind our finding that we couldn't do a dose reconstruction. So there is a public process for reviewing that.

The next term I'd like to define, “endangered the health.” That's very broad. HHS interpreted this to mean potentially caused a specified cancer. The reason we did that is because there is no benefit to being part of the Special Exposure Cohort for any other end point, health end point. Only if you have a specified cancer can you be compensated.

And then “reasonable likelihood” is another term that has no standard definition, but we had a lot to work with, we thought, in terms of using this definition or defining this further. We have NIOSH-IREP, which is designed to address the whole issue of likelihood under EEOICPA. And we

thought to the extent we can be consistent we should be consistent between claimant groups, so using NIOSH-IREP was the preferred approach. And again, similarly, the 99th percentile credibility limit that's being applied in using NIOSH-IREP for people who can have dose reconstructions, we wanted to apply it here. The big difference is -- comes in the specifics of NIOSH-IREP, the variables that you use. Because as you all understand, in this case we're not talking about an individual, we're talking about a class. And that raises obviously a whole different situation with respect to the particulars that you put in NIOSH-IREP.

And these are the variables where this is relevant. Cancer type/site; radiation type, doses and dose parameters; radiation source I should add to that, too; cancer latency; age at exposure and cancer diagnosis; other demographic variables; and smoking history, which is relevant only for lung cancer. For all these variables what the rule says is in effect what we'll do for a class, since we're not talking about an individual, is choose these parameters to give the benefit of the doubt to that class because in

many cases, in most cases, perhaps, none of these parameters will be known. But the rule also says that where we do have a handle on the profile of the class, we'll be certainly attending to that profile in making these assignments. We're not going to make assignments that completely sort of disregard the actual facts of the class.

Let me -- let me -- wait, I can't go back, can I? There's no going back. Maybe I'll leave this up here and talk about it instead of trying to change it, but let me -- I'm going to talk about two of those variables. If we need to go back and you want to look at the other variables, we can. The two variables I'm going to talk about is selecting the cancer type and latency, which are two clearly very important variables in what probability of causation you determine. And what the rule says is that we will -- and it depends on the radiation exposure -- we will choose the most radiogenic cancer, which means the cancer that's caused by the lowest dose, in effect, at the 50 percent level. We will use that as our parameter in NIOSH-IREP.

And there's sort of a different situation you have when you're dealing with radiation exposures

that are from internal dose versus external dose. If there's external dose, then leukemia is going to be the most radiogenic, in most cases, most radiogenic cancer. And the problem addressed in the rule in that situation is that leukemia can have, depending on the specifics, a phenomenally low dose threshold, one and a half rem, perhaps. And in that case you're basically saying everybody qualifies. At practically no radiation dose you would add the class to the cohort.

And the problem with that is that there's a balance to be struck between individuals who may come forward in the class and the class as a whole. And we're having to make a judgment about what threshold is appropriate for the class as a whole. If it's an extremely rare cancer and you have 50 people who are part of that class, the chances are you'll have no leukemia cases in that class, or 100 or 200. And the problem is should that be then your measure if in all likelihood those people will be presenting solid tumors for which probability of causation is substantially higher? So we propose splitting the difference in these cases, splitting the difference, taking an average between what applies for leukemia,

what radiation dose level would be the threshold, and the radiation dose level that would be the threshold for solid tissue tumors.

And then it gets more complicated, as you see, because latency is a big issue, and latency works in opposite directions with respect to leukemia and solid tissue cancers. In other words, low latency -- if a cancer occurs very soon, with leukemia it's more likely that the leukemia's caused by radiation exposure; whereas with solid tissue tumor cancers, generally speaking, a much longer latency increases the probability that that cancer was caused by radiation exposure.

So this is an issue for the Board to dig into if it supports the concept here of doing this, splitting the difference, is how do we go about addressing latency versus the cancer type? As you can see here -- and one thought that we would put forward is that we would be claimant-friendly to the extent that we lack information on the class in both directions, so we wouldn't be choosing the same latency for leukemia as we would for the solid tissue, solid tumor cancer. So we'd use, in other words, a low latency for

leukemia, a long latency for the solid tissue cancer, and be averaging those doses. But this is something that certainly deserves discussion by the Board.

Now where we have clear specifics on the class -- it was a very small class, we know all the individuals, we know when they incurred cancer and so on -- then we would abide by the facts that describe the class.

Now I'm going to move from then substantive issues to the process we'll go through, what we're proposing to go through for evaluating claims. And these are our goals: To establish an evaluation process that is public, thorough, and fair -- underline thorough; achieve timely consideration of petitions -- you'll see why this is an important issue; and invite maximum petitioner involvement -- just as under the dose reconstruction, we try to involve claimants to the maximum extent possible.

Who can petition? The Act requires that classes of employees petition, so we've interpreted this as broadly as we saw appropriate to mean covered employees and/or their survivors, as well as unions representing or having

represented employees, since in some cases it may be past tense for the unions. But they would all be qualified to petition.

And the basis for the petition: There really are sort of two tracks, in a sense, for petitioning. And the one is one that this Board understands, I think, already. It's the case where we've already attempted to do a dose reconstruction and were unsuccessful, found there are not sufficient records to do a dose reconstruction. And in that situation, in effect the petitioner would have to do no more. The petitioner would bring that to us, that finding to us, and at that point we would go on with defining the class initially and evaluating the two criteria that we just discussed as to -- and the first criteria is, of course, met for the individual already, and the question is is how many other individuals are in that petitioner's shoes in terms of it not being feasible to do a dose reconstruction?

Now if there hasn't been a dose reconstruction attempted for anyone in the class, then we require substantial grounds on behalf of the petitioner for believing that the class may

have met the requirements of being added to the cohort. And let me just say we're not requiring for them to do our evaluation for us, which I'll get into, our evaluation of those two factors, but simply to show that they've made a substantial effort to determine whether or not -- within their means to determine whether or not dose reconstruction is an unlikely possibility for them.

And if you want me to run through those, they're written out in the rule, but in effect we're asking them to define who is the class they're talking about initially. And that's an initial definition, which will be addressed and possibly changed as we go through the evaluation process, and I'll get back to that later. We're also asking them to determine what records are available, if there are records available concerning exposures they believe there are uncovered by DOE records, and for us to show some reason to believe that they were exposed to radiation. So it's fairly minimal, I think, and we will be providing them with a petition form that draws out as much information that could be useful to us as possible, and we'll be working

with them then, as they may have problems in responding to that form, to help them complete that form.

The next step is that there'll be an evaluation made by HHS as to whether or not they meet the basic criteria for having their petition evaluated, and they'll be informed of that. The next point, if they don't, the question is is what recourse do they have. And all of these petitions that HHS is considering evaluating will come before this Board with -- and where we have made a recommendation, HHS has made a recommendation that there's not a basis for considering this petition, the Board will have a chance to review that recommended finding and dispute it, dig into it more, whatever. But HHS will not make final decisions until this Board has had a chance to consider those decisions.

Now what happens once we've selected a petition to evaluate? NIOSH will evaluate the petition and report the results to the petitioners. We will be evaluating the two factors that I discussed, the substantive key technical issues. So the burden will be on NIOSH to go to DOE, to go to AWEs, to go to the other

resources that are available to it, including the petitioners, of course, to dig up as much as possible information to make these decisions.

It will then report to the Board. It will report, providing its initial definition of the class based on that evaluation. The class may be different at that point, having evaluated it, than the class was proposed. For example, a class may have been proposed that in fact represents several classes with different circumstances, different exposure experiences, different record availability, and so on. If that's the case, at that point NIOSH will be recommending in fact there are two classes here for which decisions need to be made, and those will receive separate decisions. On the other hand, NIOSH could receive several petitions that in fact should all be bundled into one because they really represent the same class of workers.

In any event, we'll produce this report that will define the class or classes, and it will address the substantive issues that I've discussed before and provide the basis for a recommendation. The petitioner at that point -- this will be presented to the Board, and the

petitioner will have an opportunity to come before the Board and make a case if the petitioner disagrees with the NIOSH evaluation, and the Board will have an opportunity to advise NIOSH on whether it needs to do further work in evaluating the petition. After this process with the Board, HHS will recommend a decision and the basis to the petitioners, who may contest that. That's a contestable decision, and there will be an administrative review when there are contests. After those contests they have 30 days to bring contests in those cases.

After that's resolved, HHS will publish and report final decisions. Now that's sort of a different -- a staggered approach here. Denials of petitions we will publish in the *Federal Register* and report immediately. We will report all decisions immediately, but if HHS has made an affirmative decision we actually will report our decision and its basis to Congress first, as I mentioned earlier, and Congress has 180 days to act on that decision. And HHS interprets that role of Congress as to either expedite the decision -- Congress would have to pass a law to do anything, we believe, but to say that the

class, instead of waiting 180 days, will be effective at whatever point, immediately. Or vice versa, Congress could decide that it's going to in effect deny the petition after HHS has affirmed it, that it will not become effective, reject it.

And this is just to make clear the point I made earlier, that whatever the class definition is going into this process, at the end of the evaluation process the class definition may differ, and you may have more than one class you're actually talking about, or less than several classes you're talking about in the output here.

And then finally, there's a provision in the rule to cancel a cohort addition. And this relates to the sort of basic premise there isn't sufficient information to do dose reconstructions. There've been some experiences in the history of DOE where information comes to light, no one knew, no one was aware of, comes to light, it provides sufficient information to estimate doses. So in that case, if we received information and were able to, at that point HHS would cancel, after a due process of evaluating

that new information, which again would come before the Board and so on in the same sort of process that a petition comes before the Board, but HHS could decide ultimately to cancel a class at that point.

And that, I believe, concludes my slide presentation.

DR. ZIEMER: Okay, thank you, Ted.

Let's open the floor for discussion. Now let me pose a question here to kick this off. Is it my understanding that this requirement of sort of canceling a cohort would only apply to ones that had been added sort of from this point on? It would not apply to those original four?

MR. KATZ: No, there's no authority to address the cohorts that were established by the law.

DR. ZIEMER: By the law itself.

MR. KATZ: Right.

DR. ZIEMER: Thank you.

MR. KATZ: That's correct.

DR. ZIEMER: Let's ask for other questions.

Okay, Roy.

DR. DEHART: If I or a group had had their estimate of exposure reviewed by individual

submission, you deny it, I come back then and petition as a special cohort, which I expect would be common. Is that correct, I could do that?

MR. KATZ: You could -- you could come back --

DR. DEHART: Saying that you didn't really have sufficient data of my exposure?

MR. KATZ: Let me clarify, though. There's nothing barring you from petitioning. The issue is that you will have already, I assume, then appealed your dose reconstruction since you differ with its results or its feasibility, in effect, what you're saying. You will already have appealed that to the Department of Labor, and if there were substantial grounds we would have already reconsidered that dose reconstruction under the dose reconstruction rule. Those provisions are provided.

So you're saying after you've done all that and then you're denied, your claim is still denied by DOL, then you would come back and petition, and yes, you could. But lacking -- unless you can provide information that wasn't provided before to make your case, it seems like

that would be an open-and-shut case, in effect. We've done your dose reconstruction. We can do it. And if you provide no reason for us to believe that information wasn't available, then --

DR. DEHART: If I read the *Federal Record* (sic) correctly, there was a statement that a petitioner's statement now becomes a matter of fact, which it would not have been earlier.

MR. KATZ: I'm not following you. I'm not following you.

DR. DEHART: If I had said I had been exposed to a situation where I'm stating I had 15 R exposure, you could not validate that earlier on in the process so that there's no evidence that I had sufficient exposure to qualify. Now I could come back as a petitioner under this system, and as I read this the implication was if I simply state that I had had an exposure, that becomes sufficient evidence for consideration.

MR. KATZ: Well, there would have to be records to support that.

DR. DEHART: I wasn't sure that that was stated in the -- I'll see if I can find that specific statement.

DR. ZIEMER: You're asking whether simply asserting that you were exposed is sufficient --

DR. DEHART: Yes.

DR. ZIEMER: -- grounds.

And Ted, as I understand it, there would have to be -- even if you couldn't reconstruct the dose there would have to be, for example, some evidence that there were sources around or something like that.

MR. KATZ: We would have to, with certain specificity, identify what those sources were, what occurred, and so on.

DR. DEHART: Yes, I understand that.

MR. KATZ: And you're saying that someone could do that, then?

DR. DEHART: Correct.

MR. KATZ: And specify those, and they would make the first hurdle. And that's true, I think.

DR. ZIEMER: Jim.

DR. MELIUS: Ted and Larry have heard this already, at least parts of it, but my major concern about this approach is -- and it goes back to when we were doing the dose reconstruction rule also, and the guidelines for that -- is that we have not established any

guidelines for when a dose reconstruction is not of sufficient quality to sort of pass muster, whatever you want to call that, and that there are no criteria for that that have been established nor any real guidelines. And if I remember correctly -- it goes back a couple of meetings -- I think Jim Neton said they were going to eventually develop some sort of guidelines or consideration. But we don't have those yet. We've based a whole rule on this sort of nebulous case-by-case approach that we will -- there'll be a determination that there's not sufficient information, whatever, in order to be able to do a quality dose reconstruction.

However, at the same time we're saying that there ought to be enough information that we can do this reasonable likelihood dose reconstruction in order to make sure whether the class would fit. So it meets some criteria, but it doesn't meet the criteria for individual dose reconstruction. And I believe that without any sort of guidelines or parameters on this that we're getting into a very murky area. One could see situations, depending on who in the class applied, how we could come up with very different

decisions that we really -- that the scientific quality of what's being done in terms of the dose reconstructions would be quite variable because we'd be at the edges of where there's adequate information to do that.

I'm not sure that as we've talked about a review process by the Board that we've even set up a scheme that would capture those where a bad dose -- a poor quality dose reconstruction's been done for a person, how -- we're going to sort of pick those up randomly. And rather, as opposed to a situation where we -- because of the absence of criteria, we really don't know when the criteria is between a bad dose reconstruction -- where's the line between a bad dose reconstruction and an admission that there is not enough quality information to do a dose reconstruction?

And then in between that we set up this third parameter, this reasonable likelihood calculation that's going to be done that somehow fits in between those two, and we're doing all of that without any really established criteria for doing that. It's all case-by-case basis. And I find that very troubling to this whole process, that

until we've established some criteria for when there's not adequate information to do a quality dose reconstruction that this whole process becomes very arbitrary and very unfair to the applicants, and very hard to have it transparent for people on the outside to know what to do.

Carry that over another step to the petitioning process: How do you know when you have -- when there's poor enough information that you would qualify under the petitioning process? And again, we've not established the criteria or the guidelines for doing that. I think that's a major hole in this whole process as it's being proposed here.

DR. ZIEMER: Let me comment in part on that. It seems to me we have to be careful when we talk about sort of quality dose reconstruction. Actually, the methodology has built into it the issue of uncertainty. And so under the scheme that's proposed, you could do something that I might call a quality dose reconstruction that has a lot of uncertainty because there's uncertainty in the data, there's missing data, and there are provisions for handling this.

So in fact, what someone might call a poor

quality -- in terms of getting the right number -- I think we find out in many cases actually favors the claimant, because the uncertainty gets larger, and that almost in every case that I've looked at helps the claimant as the uncertainty gets larger. If there is dosimetry data available -- and you can say what you will about its quality, but presumably the quality of that gets reflected, in a sense, in that uncertainty information, which includes the calibration methods, the limits of detection, and all that sort of thing.

It seems to me what you're talking about here is a case where there's virtually no dose information. You have some knowledge that there were certain kinds of sources around. And I can think of cases where if someone said I know that we had this ten microcurie carbon 14 source and nobody was wearing film badges, and therefore I'm going to make a claim, and a reasonable person could do a calculation and show that it doesn't matter what you did with that, there's no way you're going to get a dose above some value, even if you ate it all. So you can do those upper boundaries with no dosimetry and no monitoring

data and do that.

So I think in principle you can do the things you're talking about. What turns out is that we don't know all those cases, and that makes us very leery. Do we really have the tools to address all these, and we haven't defined all the parameters.

DR. MELIUS: That's my point, is that we haven't made -- defined the parameters --

DR. ZIEMER: And can you, without knowing what they are, can you do that in advance, yeah.

DR. MELIUS: Well, I think you can. I think you can do some of it, and quality, I'm trying to use it in a broad sense because it includes availability of information.

DR. ZIEMER: Right.

DR. MELIUS: And the other issue that comes raised is feasibility. How feasible is it to go down and track down all -- how much time and effort will it take to track down and obtain all this information, and how do we judge the effort that NIOSH has made and that the people holding the records have made to --

DR. ZIEMER: Right. And I think that's where most of us have a little more apprehension. Do

we really have the information that we need --

DR. MELIUS: Yeah, and so --

DR. ZIEMER: -- to make the judgment.

DR. MELIUS: Yeah. But somehow we're setting up this scheme that will do a -- say we can't do a dose reconstruction, yet we can do enough of a dose reconstruction to do this reasonable likelihood estimate; and then in other cases we can do a dose reconstruction. And where are the parameters that will determine how those do -- and I understand it's complicated and so forth, and we can say it's case-by-case. But I think there has to be some rules and some guidelines on how this is going to be -- both to make the program, as I say, work, and not arbitrarily make these decisions.

MR. KATZ: Can I just respond a little bit to part of that? Part of that is there to the extent that it can be there, is the reasonable likelihood is -- it's fairly clearly stated how you would use NIOSH-IREP. And then in terms of how you make a determination as to whether radiation doses could have exceeded that threshold is, as it's discussed in the rule, is a subjective decision. It's a subjective judgment.

But it is a judgment that is made openly and presented to the Board, and considered by the Board as to whether it's reasonable to consider that these radiation sources could have caused such a high level and so on, given what's not known about the process and so on.

So I think it's the best you can do in this circumstances of lack of information, is have a subjective decision that is open to scrutiny because there's no decision logic you could drive this by that would simply be a sort of factual open-and-shut case. Or that we have been unable to imagine it, is what I should say, and if the public presents with us a better solution for addressing this sort of murky area we will lunge at it, I'm sure.

DR. ZIEMER: Henry.

DR. ANDERSON: Yeah, I got kind of a -- two different issues. It seems to me that most of the focus of the rule is on people coming in via the filed claims mechanism, and I think that's where we're having some of this trouble, that we don't know -- you file a claim, where exactly will the claim -- what are the parameters that'll say we can't reconstruct it? And then based on

that lack of ability to reconstruct, will we be able to meet the likelihood issue? Because if you had the likelihood issue, your parameters would be such that you probably could estimate.

So coming in through a claim, then to me the issue would be, okay, if you get that, then is this person a accurate reflection of the class of people? Because I could see -- at least I don't see anywhere that it says that to be a class, everybody in that class can't have their dose -- the ability to be reconstructed. So it seems to me you could begin to get a sense of some classes where some of the individuals are borderline and others would not be. And so it's one of a streamlining process coming in through that system.

Now I could see -- my question is, so let's take a look at what would you anticipate as a hypothetical class that isn't currently a part of the system to not have to go through this? And then can we define those kind of people so that you now have a definition of a class, and then when somebody comes in you see whether they fit that class rather than having to go through the dose reconstruction. It would seem to me the

kind of -- and I'd ask, so what classes do you think are reasonably out there that might fit this kind of parameter?

And it would seem to me you might have accidents or unanticipated events that were not monitored and measured that could have delivered a significant dose, so you could then define here are the kind of parameters that this class would fit. And your measurement would be not can they be dose-reconstructed, but -- as is now -- if you meet the class, you're in the class for the selected 22 cancers. And again, the averaging and all of this kind of thing, what I think you have to look at, what are the hypothetical classes out there?

And it seems that's a process that's a little easier than -- to do than wait for an individual to then say, well, is this a sentinel event for a class, rather than trying to define those classes up front, and are there circumstances where you wouldn't expect there to have been anybody monitoring because you're into an emergency response kind of activity? Are there -- can NIOSH think of any classes, hypothetically, that might be out there? And it might be easier to

come at it from defining those classes, getting those petitions going before you've got a potential person coming in. Because to me then the process would be does the person meet the class, rather than can we reconstruct the dose for this person; and then secondarily, are they in a class?

Now if they came in with a cancer that isn't part of the special cohort, then obviously you would go through the -- they could get compensated based on exposure. So to come in every time through we can't do your dose, so therefore you would then be looked at to see if you're part of the class, I would turn that around and say can we or are there things that we ought to be looking at, establishing those classes, before we have any claims filed of individuals.

MR. KATZ: A just partial response to that. If we thought we could define the classes up front, we'd be in great shape. We don't think we can. And just to take an example you outlined, exposure incidents, special exposure incidents, in some cases there is monitoring and you do have records, and you can reconstruct the doses from

those incidents; and in other cases you can't. You can't -- there's no happy category, unfortunately, of class that stands on its own, which is why we're left with case-by-case.

Now there are situations -- I think there are some situations we know about which we think hold real potential as classes, and Jim could talk about one of those if you want to hear an example. But it is a problem because we can't define the classes up front.

DR. ANDERSON: See, I -- then what you're doing is you're now defining classes of one, is really what it is. As individuals file claims that can't be reconstructed, they then become a class of one because somebody else who meets the same parameters might well be able to be dose-reconstructed. And that I see as the potential problem in the thing.

MR. KATZ: Can I respond?

DR. ANDERSON: Because you can't -- does everybody in the class have to not be able to have their doses reconstructed?

MR. KATZ: And the answer, I think, to that is yes, because you can reconstruct a person's dose by their co-workers' experience if they have

the same exposure experience. That's a standard approach in dose reconstruction to use. So in that case, where you have the same exposure conditions, the same circumstances, the co-workers' data would be good enough to reconstruct the dose for that individual.

But as far as establishing classes of one, again, as you said, it's a sentinel there. We don't stop with the one individual who we couldn't reconstruct their dose. That's a starting point for us to determine how many others are in the same situation as that individual and thus should be added to that class definition, which is why I explained that the initial definition going forward from the petition isn't necessarily the definition that comes out the other end.

DR. ANDERSON: A last question. The current special cohorts, are you saying that in those special cohorts nobody can have their dose reconstructed?

MR. KATZ: Absolutely not. And actually it was very explicit in our dose reconstruction rule that we would be considering those cases when they don't have one of the 22 specified cancers,

because in their cases, if they can't have a dose reconstruction, they're out of luck. They have no remedy. So we will be attempting dose reconstructions, we're sure. I don't know if we've received any yet. I think we -- yes, we have; Larry's indicating we have. We've received requests for dose reconstructions from individuals who are part of that established Congressional Special Exposure Cohort.

DR. ZIEMER: And keep in mind, those were identified by Congress --

MR. KATZ: Right.

DR. ZIEMER: -- regardless of --

DR. ANDERSON: I know, but what I'm getting at is on a fairness issue one might want to look at is there going to be a same level -- can we use those groups as a comparison to say, okay, they were put in that way, we have some understanding of exposures there, and why they were considered. And then do we -- can we apply those kind -- use that to generate criteria for the other, or are we setting a different hurdle for the hypothetical group?

DR. ZIEMER: My evaluation is that the law has already set a different hurdle the way it is

written. The fact of the matter is because there are people at other plants that say, why wasn't I included because what we do is similar to what they did or worse. So I'm not sure that fairness in itself is the criteria that's -- one can argue how is the law fair the way it's written.

DR. MELIUS: Let me just understand another approach on this. If these are all classes of one, then aren't you really just saying -- one approach would be that if a person -- you can't reconstruct their dose. You would then do the reasonable likelihood calculation for them, and then if they pass that then they're --

UNIDENTIFIED: They're compensated.

DR. MELIUS: -- they're compensated, if they have one of the appropriate cancers. And then they have to go through the process up through the Secretary, et cetera, et cetera. But it's -- we go through the different scenarios. That's going to be one scenario.

Another scenario is how fine tuning do you get in terms of within what's the class? Because if you can't do it for person A, but person B who worked beside them, there was enough information but you didn't have that information at the time

you were doing person A, then you're going to have -- person B gets dose reconstructed, person A doesn't. Well, is person A and B, are they different classes, or how do you do that? It seems to me this gets awfully complicated. And again, my concern is either it takes an awfully long time to sort this all out, people aren't going to get compensated for many years, or it's going to become very arbitrary as to who within a group will get compensated and who won't.

DR. ZIEMER: Ted has the answer to that.

MR. KATZ: Just a partial answer there. Person A, we've done it, we've said we couldn't do a dose reconstruction and then we attempt to do Special Exposure Cohort, and now you're saying we look at person B and determine we can do a dose reconstruction. When we're doing the dose reconstructions, one of the things we'll be doing is looking at co-workers in the first place, because that would be an avenue for being able to do the dose reconstruction. So we'll have done a lot of work in determining, in effect, the parameters of the class when we attempted to do that individual dose reconstruction, which is part of the reason it'll be more efficient once

we have done that work to go forward.

But if we were in circumstances -- I guess this is the other thing you might have been raising -- is as we go forward with the Special Exposure Cohort petition, we do a lot of work, something turns up and we find out we can do dose reconstructions for person A, who kicked this off in effect -- we told him we couldn't do a dose reconstruction -- at that point we would be going back and then doing a dose reconstruction for person A. Again, it's not about establishing classes of one. It's about, as Dr. Anderson said, they in effect work as sentinels for us to know we have a problem in a group of workers for whom there's a likelihood that they should be added to the Special Exposure Cohort.

DR. MELIUS: I have one other related issue, and it goes back to our review process on these dose reconstructions. It would seem to me that if this approach were the approach that's followed, that people that can't have a dose reconstructed or close to not having their dose reconstructed become the ones we really become very concerned about. And that it behooves us to have a review process that captures many, if not

all, of those where there's real uncertainty or -- I don't know what the right term, uncertainty isn't the right word here because it -- but say there's real difficulty, and the persons on a borderline between having their dose reconstructed and not, that it would behoove us as this Board to be very careful reviewing those because those are going to have some major implications in terms of decisions for that individual as well as for -- potentially for a large class of people where the information is marginal.

And how are we going to have a process of -- are we going to be willing to first review all that number -- and again, at this point it's hard to tell what that number will be, but certainly a sizeable number of people out of the 5-, 10-, 20,000, whatever claims are out there right now. And how do we have a system that identifies those, because it's going to be hard to identify without criteria set up or guidelines set up that will sort of guide this process in some way.

DR. ZIEMER: I'd like to comment on that part, too, at this point. Just one of the concerns that I have as I read through the

proposed rule is the future role of this Board in terms of time commitments. I don't think we have a feel yet for numbers of cases. It looks like many of these could come before this Board, and we could be spending a lot of time as a Board adjudicating cases.

Do we have any feel at this point for what this is going to look like? Let's say that a year from now that we have our other things in place and we're monitoring the dose reconstructions and so on, and some of this kicks in. Does anybody have a feel for what we're talking about here? It may be too early to even know, but this rule-making has a lot of involvement of this Board in the process, and --

DR. ANDERSON: And we don't know how many.

DR. ZIEMER: Well, we can come back to this. But I don't know if the staff even -- do you have any sort of early thoughts on that, what that's going to mean?

MR. KATZ: I'll be glad to address that, but it's not very helpful because it's entirely speculative. And in some respects the design of the ultimate final rule will have a bearing on how many petitions there are as well. But for

the purposes of this notice of proposed rule-making, we estimated I believe around -- that there would be 90 petitions a year we would be, on average, addressing. And that was predominantly then petitions that are coming as a result of not being able to do complete dose reconstructions, and then others that are brought on initiative without that being a parameter.

DR. ZIEMER: It might be helpful -- and take a number, say it's 90. You may be off one way or the other by a great deal. But if there were 90, for example, what are the implications of that in terms of sort of the caseload of this group? We need to think about that.

MR. ELLIOTT: You're going to see every one of them.

MR. KATZ: Yeah, the way this is written.

DR. ANDERSON: At an hour apiece, that's a lot.

MR. KATZ: And that's a requirement of the law that you see these.

MR. ELLIOTT: Ted's certainly correct in his statement that until we see what the final rule looks like and what the process is stated to be in the final rule, it's hard for us to predict.

It's speculative now. But perhaps this will inform, to a certain extent, your question.

We have heard from various entities that they have an interest in filing a petition, an interest on behalf of construction workers, construction workers across the complex, construction workers at a given site; interest here in Rocky Flats, for what -- on behalf of what class, I'm not sure; interest in Los Alamos on behalf of the folks who worked in -- I forget the technical area, but the dump area.

MR. ESPINOSA: Area G.

MR. ELLIOTT: Area G, okay. Army ammunition plant at Iowa, there's a huge interest out there because of the complex situation where Department of Defense and Department of Energy shared space, et cetera. There's a large amount of confusion about, in that particular instance, about where we think we can do dose reconstruction and where they're not so sure we can. We have heard of interest in Oak Ridge. I believe that's pretty much the extent of the interest that's been expressed.

Now what fruit comes from those expressed interests, I can't predict at this point in time.

We'll have to wait and see what the final rule looks like, what the process stipulates, before we can actually see how many petitions come forward.

DR. ANDERSON: Just one thought that some of us had is, is it possible to go with an interim rule? Since we really don't have a good -- I mean, it's all speculative at this point and we can go 'round and 'round. But one way, when you're uncertain as to the workload here, would be to have this be an interim rule that sunsets or has to be finalized in three years, so we have some track record to take a look at it rather than having it be final, and then kind of the hurdle to have to go back to reopen it becomes much more difficult than it if it's --

MR. ELLIOTT: There's more -- I'll let Ted speak to this as well -- but there's more problems with going forward with an interim final rule where you can actually do work, as we did on the dose reconstruction rule. Because if we work on a petition, and let's say we come out with -- the Secretary makes a decision, and then once the rule becomes final and how it looks and what the process is established in the final rule, we may

end up revisiting those petitions that were worked on in that process. So I think there's an interest within the Department and the Secretary's Office of this approach of a notice of proposed rule-making to get all of the -- thrash out the public comment and the interests and the concerns that are being identified.

Ted, you want to add to that?

MR. KATZ: Well, I just -- I'm sorry. I'm just trying to understand what Dr. Anderson's saying better. But are you talking about then the next step being -- we've made a notice of proposed rule-making, the next step being issuing an interim rule, interim final rule as opposed to a final rule? Is that what you were asking?

DR. ANDERSON: Yeah, and then you have --

MR. KATZ: Yes. No, I understand. I understand. And that's certainly a --

DR. ANDERSON: Because you may want to revisit them. The whole point of it is we don't have experience. It's all speculative at this point, so we don't know how many or whatever, how well this -- and if you get a lot of public comment that, gee, this is all very subjective, a way to approach that is, well, let's get some

experience. I'm just raising that as one --

DR. ZIEMER: Jim, you have another comment?

DR. MELIUS: I have two points. I don't know when you're planning on announcing it, but in terms of public comment, I believe there is a plan for some stakeholders, additional stakeholder meetings? Is that --

MR. KATZ: Yes, that's correct.

DR. MELIUS: Can you sort of tell us about those?

MR. KATZ: Yeah. I can tell you --

DR. MELIUS: And then I have a follow-up question.

MR. KATZ: I can tell you that the details aren't settled, but we are planning -- well, for good reason, the whole issue of doing stakeholder meetings just arose recently. But we are planning to have four meetings, local meetings at sites where we expect there would be people would have an interest in petitions. And we haven't settled the details as to which sites they would be. We've had a general discussion of that, and we've raised sites as possibilities.

Larry, do you want me to run through those possibilities?

The possibilities that we're considering -- and we're open to input on these, most certainly -- are Hanford in Washington State, and Los Alamos area, and thirdly, the New York/Pennsylvania area. The Department of Labor did this in Buffalo because there are a lot of sites around Buffalo. So whether that is the right location exactly, there are a lot of AWEs in that area, which is the reason why that might be appealing, because they also may have lots of records problems. And the fourth site -- there were several discussed -- and I believe the Savannah River site was one that was discussed, because there are a lot of claims under the EEOICPA right now that are coming from Savannah River site.

And the other one, Larry, is either Rocky Flats or Fernald, I believe?

MR. ELLIOTT: We talked earlier about Oak Ridge.

MR. KATZ: Oak Ridge, I'm sorry.

DR. MELIUS: Your plan is to do these --

MR. KATZ: Our plan is to do these within 45 days of the comment period, to include these within 45 days of the comment period, which means

that in effect we would have to set these up to be able to do these at the end of July and the very beginning of August. Which is soon.

DR. MELIUS: Anyway, the Board -- we should take that into consideration developing our comments.

My question actually goes back to the last Board meeting. I believe at that time these were guidelines, not formalized rule-making procedure. It was going to be a set of policy or guidelines coming from the Secretary, and I believe you mentioned at that meeting that there was some differences of opinion, or you're trying to make up your mind to do that. But I was just wondering if someone could sort of tell us a little bit more about the difference, and particularly in relationship to Henry's question about interim rule, and do these need to be -- does this need to be done by rule-making as formal regulation? Why is that? What changed in the process that --

MR. KATZ: I'll be glad to address that to the extent I'm able. And if the HHS lawyers want to clarify they might, but I think I understand this well enough.

This does not have to be done by rule-making, that is correct. The law, EEOICPA, does not require us to do this by rule-making. The problem lies in producing procedures that are binding on HHS. In effect, you end up producing something that walks and talks like a rule, and if it walks and talks like a rule there's legal history to support that it needs to be a rule, and that ends up being part of the issue.

HHS intended to go down the guideline route as opposed to issuing a rule because -- precisely because of the issue that you're all wrestling with right now, because there's a whole lot of uncertainty about what's going to be coming in and how and so on. And all that uncertainty, I think, HHS wanted more flexibility to address that than they have when they issue a rule, which is binding. But in reality, the procedures we've produced walk and talk like a rule, and hence we needed to issue a rule.

Now the difference between interim final rule and a final rule, in effect -- there's no difference in terms of the way they bind the Agency and so on. They're treated the same under the law. But the issue is simply you save a step

when you issue an interim final rule if you're going to go about changing it down the road, because if you issue a final rule then you would after that have to issue a notice of proposed rule-making again before you go issue a change in that final rule. Whereas if you issue an interim final rule and have comments on that again, so that would be a second period of comments, then you could immediately afterwards, so long as you stayed within sort of the scope of what you asked for comments for and the information that was available to the public, you could then issue a final rule immediately without having to go through an extra step.

I'm sorry this is long-winded, but --

DR. MELIUS: That's helpful. The lawyers didn't jump up and down, so that's a good sign.

(Laughter)

DR. ZIEMER: We're going to have more time after lunch to address this further, so I'm going to call for a recess here in just a moment.

I do want to tell you that again we don't have group lunch or plans for a group lunch. There are many restaurants in this area. There's a list of --

Cori, where are you?

MS. HOMER: I'm back here.

DR. ZIEMER: Okay. You have copies of all these downtown Denver restaurants. I don't see addresses on this, but there are names and indication of whether they take big bucks or little bucks to eat there. I guess the concierge desk has information on how to get to some of these, but there's probably two dozen restaurants around here close by.

Our experience has been that when we do go outside the hotel, which many may wish to do, it's a little hard to get served and back within an hour. So I'm going to suggest that we reconvene at 1:15; 1:15 will be our target for reconvening. And if the Chairman gets back from lunch by then, then we'll reconvene.

Are there any other housekeeping announcements we need to make before we recess?

MS. HOMER: I would suggest everybody take anything that's worth anything to you. Take it with you or lock it up, because the room cannot be secured while we're gone.

DR. ZIEMER: And that means what, like laptops?

MS. HOMER: Laptops. We can shut the doors and secure these downstairs, but I can't guarantee anything.

DR. ZIEMER: Thank you.

(Whereupon, a lunch break was taken from 11:57 a.m. until 1:25 p.m.)

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DR. ZIEMER: We're going to go ahead and reconvene. Tony didn't make it back yet, but there were some problems with the elevators -- well, I don't know if they were problems. There was some drill going on and some got stuck, but hopefully he'll be back shortly.

We're going to continue with discussion on 42 CFR 83. Let me ask first if there are any additional sort of general comments or questions that anyone has to direct to Ted or the staff based on the discussion this morning.

(No responses)

DR. ZIEMER: If there are none at this time, let me then suggest a couple of things. One of the items that we need to accomplish is to prepare some Board comments on this proposed rule-making. Unlike the previous rule-makings, this one does not pose specific questions that it

asks people to comment on. You recall the other two rule-makings, there were some very specific questions they asked commenters to address. That is not the case here. So as we think about what form our comments might take, let me start by implanting some seeds of ideas.

We might think about whether or not there are technical issues that we wish to address, technical or scientific issues. Are there procedural issues that we wish to address? Are there questions that we want to identify that we think should be answered, sort of parallel to the general questions that were asked of the other rule-making items? And then I would ask whether or not at some point this Board feels that it can make an overarching statement about the rule-making, that if the following issues are addressed, then this rule-making would be considered to be, for example, acceptable or something like that.

Now I don't want to lay out a format at this point as to how this ought to be or should be addressed. I think -- I want to be completely open on this. So let's think about whether or not we can identify issues that we think need to

be addressed in some way or another, without doing any -- just identify sort of categorically what needs to be addressed in here in some way that would help with your comfort level.

DR. ROESSLER: Before we get there, I don't seem to find that. Is that in the packet?

DR. ZIEMER: This I downloaded from the web site.

DR. ROESSLER: Ah.

DR. ZIEMER: You have this in your packet in the form in which it was submitted to the -- oh, is it in there?

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: Yeah, but it's in the typewritten form rather than the *Federal Register* form.

DR. ROESSLER: I downloaded half of it and my printer quit.

DR. ZIEMER: The nice thing about the *Federal Register* version is that rather than 64 pages it's more like -- yeah, not so many pages. But otherwise, as far as I know, it's the same stuff.

So is anyone ready to start thinking about issues that we need to talk about?

Jim, kick us off.

DR. MELIUS: I think there are two general questions. They are somewhat related, but one is that this rule-making puts an emphasis -- the approach is the emphasis on individual dose reconstruction as a way of generating Special Exposure Cohort members, as opposed to an approach that relies on group petitions. And I think there's some pluses and minuses to those approaches, and to some extent they're complementary. But I think we ought to discuss is that the proper approach.

The second issue, general issue, is one I raised earlier, is this whole issue of the lack of any definition or guidance on or parameters covering when can a dose not be reconstructed with sufficient quality, et cetera, for the purposes of this program. And I think that just raises a whole host of scientific and procedural issues within this rule-making, but should that be addressed, it would really change the whole approach.

DR. ZIEMER: Thank you.

Other -- let's just get items out on the floor here.

Sally.

MS. GADOLA: I have some questions as to some of their definitions and why things are stated the way they are stated. One of my particular ones was about ill effects -- not quoting it exactly -- but it just has to do with radiation and cancer, and at the beginning it also talks about silicosis and beryllium. And my direct question was some areas appear to have more cases of silicosis, and why are they not considered a special cohort?

Which leads me back to another question that I think we should ask, is how did they determine special cohorts to start with? Why are certain people at K-25 with bladder cancer in a special cohort?

DR. ZIEMER: Does anyone wish to actually answer that question, other than the fact that that's what Congress decided?

MS. GADOLA: It helps us to establish new ones if we know how they did the old ones.

DR. ZIEMER: Well --

MS. GADOLA: I think NIOSH would be in the best position to determine if it was done by what I sort of suspect, is if you have a large

percentage of workers that worked in a particular area that developed a particular type of cancer. So if you're getting a lot of claims for a certain type of cancer from a certain area or during a certain time period, then that would indicate that there's definitely a problem there. And it would seem that that might be one of the criteria to say this should be a special cohort. Any comments?

DR. ZIEMER: Maybe the staff can help on this, but it's my understanding that the way the law is written now, if you can do dose reconstruction on those that would preclude the special cohort.

Is that correct?

UNIDENTIFIED: Yes.

DR. ZIEMER: Yes. Even -- right.

MS. GADOLA: But if you get a bunch of claims and you can't prove it, you can't reconstruct the dosage but you're still getting a lot of claims from that area for that type of cancer, then it would give you a clue that something happened there.

That brings up another question that I have on this specific rule because it states who can

bring this to our attention, and one of the groups that was recognized was the unions. And I was wondering if there were not other groups that should be included. And I was trying to think, well, who might these other groups be? And I thought perhaps health care providers might notice that they had a certain type of high rate of cancer from workers in a particular area that worked at a particular plant during a certain time.

MR. PRESLEY: We have retiree organizations, too, that ought to be able to come out and -- but I have a question --

DR. ZIEMER: Before you ask your question, is there anything that would exclude the other groups? This doesn't preclude other groups, does it?

MR. KATZ: From petitioning?

DR. ZIEMER: Yeah.

MR. KATZ: I'm sorry, it's Ted Katz. Yes, it does. The rule limits petitions to be submitted by either employees, survivors of employees, or unions. It does preclude other groups from submitting the petition. But it does discuss this to some extent in saying that because the

petitions are supposed to be by employees, and that's what we're trying to define, but it does go on to express that there are other parties that may have expertise in those cases. They need to get together with people who might be petitioners and simply assist them in petitioning, but they would not be the name on the petition in effect.

DR. ZIEMER: They could not petition on behalf of an employee group since they don't represent them per se, is what you're saying? Other than the union groups?

MR. KATZ: That is what I'm saying.

DR. DEHART: But could they not then get the signature of a single employee --

MR. KATZ: Yes.

DR. DEHART: -- and serve then as an expert in that individual's --

MR. KATZ: Yes. And that's mentioned in the preamble, is that that may arise, that sort of situation.

DR. ZIEMER: Henry.

DR. ANDERSON: I guess one thing that we don't have is what the petition form and application will look like. And my question

would be is, depending on what that form looks like, it may be unreasonable to expect that an individual would have the wherewithal to complete that form.

So we're basically setting up a system whereby somebody has their individual case reviewed, and now they're sent back saying we can't reconstruct your dose; you may want to consider filing a petition for special cohort status. And is it reasonable that a next of kin or an individual would in fact have the hurdle low enough that they could in fact do that? Or would it be better in the rule to say you may be eligible, you should contact -- or set up some kind of a system for that person to be more of an active participant -- or passive participant than active?

It just seems to me it may -- it's tough enough for people to deal with the exposure issues of themselves. And until we know what's in that form, it may be totally unrealistic to send somebody something they can't possibly do, or they would have to hire and spend considerable money to hire somebody to do it on their behalf.

DR. ZIEMER: The content of the petition is

set forth --

DR. ANDERSON: Is it?

DR. ZIEMER: -- in 83.9.

But Ted, perhaps you --

MR. KATZ: I just was going to -- that's true. It's sort of the -- the framework is laid out there. The petitioner form will be more useful than that framework for petitioners. But in the case that you were mentioning of someone for whom we haven't been able to do dose reconstruction, a survivor, they basically don't have to -- there is no hurdle for them, other than giving sort of identifying information and the finding that we couldn't do a dose reconstruction. There is no other burden on them in terms of making the petition go forward to be accepted by HHS for evaluation.

DR. ANDERSON: Okay, because I thought the -- it would go forward, and then what would be your evaluation? If all they have to do is turn around and say here's why I think it may be, what does your evaluation do but rely on what they submit, I guess, is the question.

MR. KATZ: So our evaluation fleshes out how many other employees fit their circumstances and

would comprise the class that they represent, that being a class of individuals for whom, in the first place, dose reconstructions can't be done. So that would be the first step. And the second issue is whether they incurred a dose that could cause specified cancers. But this is all done by NIOSH, not by the petitioner.

DR. ANDERSON: So if you then went back through the list that's been reviewed and found somebody who you could do a dose reconstruction on, say it's somebody with a prostate cancer, and then their claim is denied, how would that go into the class --

MR. KATZ: In this case we just found that we couldn't do a dose reconstruction for the individual, so we would have -- again, we would have looked at co-workers of this individual as well.

DR. ANDERSON: So you may be looking at classes --

MR. KATZ: In making that original determination that we can't do a dose reconstruction, one of the avenues that you will search when you do that is if we don't have data to reconstruct the dose for this individual, do

we have it to reconstruct it for other individuals who were similarly exposed? So --

DR. ANDERSON: So you would have determined -- I guess my concern, I don't see how you get to a class if you've done it on -- if you look to see does this person belong to a class -- everybody's going to belong to some kind of a class. So you're going to say, okay, how -- see what I'm saying?

MR. KATZ: Our job is to define that class. When an individual is denied because we couldn't do a dose reconstruction, at that point we will have done considerable work looking at co-workers and so on and know a considerable amount about the situation, not just the individual's case. But we have to go on from there and define the parameters of that class beyond that individual as a first step, and that would be a class of individuals for whom dose reconstruction can't be done. And then there's the second question as to whether they were exposed at a level that would -- that could cause specified cancers.

MR. PRESLEY: I may open a can of worms -- Bob Presley. Can we, as a Board, look at a group of people and make a recommendation that they be

added to the special cohort?

MR. KATZ: Not under this rule, no. You can't independently, in other words, identify a class of employees.

Let me just clarify, first of all. You are empowered to make recommendations to the Secretary of HHS on everything that's covered in your charter. But in terms of the procedures for the Special Exposure Cohort, under the proposal your recommendations come in after NIOSH has already done an initial evaluation of a petition.

DR. ZIEMER: Tony.

DR. ANDRADE: It seems like even after the presentation this morning, which I tried to parallel process as I was once again going through the *Federal Register*, the proposed legislation -- let's not forget that -- but even after that, I found myself very ill at ease with what has been written into the proposed legislation. It certainly did not have the clarity nor the specificity with which -- or which was included in your presentation. It does not say, for example, that one might be considered for a Special Exposure Cohort if there is new documentation, there is new information

about an individual or a group of individuals brought to light. That should be in here. That should be clarified. That is the comment I have about what's in the *Federal Register*.

Number two is that I find the table of using, say, leukemia versus solid tumor and then latent periods as a comparison for finding the lowest dose rather arbitrary, especially given a case in which perhaps a dose reconstruction couldn't be done because there was a huge uncertainty or perhaps not even any very good knowledge about doses involved at all. So I find that arbitrary, period. And it's very -- and it's disturbing, again, that we're not using science but rather something that's contrived to try to go forth with setting a level at which one would consider putting together a Special Exposure Cohort.

I would say that I think the probability is going to be very small that we do run into situations in which we're going to have a group of workers that we just know so very little about that we're going to have to define one. However, let's say one does exist or a couple do exist. Then let's make this legislation very clear that one can go forth with a proposal, but there has

to be a commonality of lack of data or lack of understanding of data for this group of people from, I would suppose, a site, a site where it would be most common that you would have a group of people for which -- that were doing some kind of work that no records were kept for, something happened along the way, and that reconstruction became an impossibility. It just has to be clearer in the proposed legislation as to what those trip points are going to be.

I think you did a good job in your presentation. I think the *Register* should reflect it.

DR. ZIEMER: Jim, just one moment.

The question was raised earlier about what this Board can do with respect to special cohorts. The charter says:

(Reading) upon request by the Secretary, advise the Secretary on whether there is a class of employees at any DOE facility who were exposed to radiation, but for whom it is not feasible to estimate the radiation dose or whether there is reasonable likelihood that such radiation doses may have endangered the health of members of the class.

It does not appear to restrict the Board as to how they go about establishing that, whether it be through this proposed rule-making or outside the rule-making. I don't see, at least in the charter, that it necessarily restricts the Board on that issue. Just an observation.

Jim, did you raise your hand?

DR. MELIUS: Make sure we have on our list -- I think they both have been mentioned specifically, but in terms of specific parts of it -- that one of the issues we should discuss, and the Board may want to comment on, is how classes of employees will be determined for the purposes of the Special Exposure Cohort. And secondly, is this endangerment criteria that Tony was just really talking about, both that issue with the latency, type of tumor, et cetera, as well as the general approach for that.

DR. ZIEMER: Others?

Yes, Henry.

DR. ANDERSON: Yeah, I want to just raise again the issue of how do we, if we want to, comment on should it be a rule, should it be an interim rule, should it be guidelines. And I think we heard that because it seemed to be or

NIOSH felt it was prescriptive, it therefore made more sense than a rule. And what I've gathered is there's enough kind of uncertainty in how this will be applied that it would seem to me it may well fit better guidelines.

If the idea is to hold the Agency accountable it seems to me there's enough uncertainty in how the process is going to be applied that it's going to be a best judgment, many situations defended with the justification behind it, that unlike the other, it -- I'm not sure it really is -- that we gain anything by having it be a rule versus the others. And I guess I'd like to hear more about why you feel this fits better with a rule than a guideline for how one approaches this, when it seems to me there's a fair amount of inner-decision logic rather than science in your process that you're proposing.

MR. KATZ: Sure, let me -- this is Ted Katz again. Just to clarify, this was not NIOSH wanting to produce a rule versus guidelines. That's not what this is about. This is lawyers and the government looking at this and saying based on legal precedent this needs to be a rule. And I think you'll actually -- it wouldn't be a

good use of your time to be arguing that this should be guidelines instead of a rule, because it's being made on the basis of law and not on the basis of a preference, I should say. And as you know, HHS actually preferred to produce guidelines and found itself with difficulty, finding that in fact it needed to produce this as a rule.

DR. MELIUS: Could we take maybe five minutes and have an HHS lawyer explain that to us? Since they're all the way here in Denver --

MR. KATZ: There's really no more for them to tell you than what I've told you, which is specifically that there is case precedent that when you have a certain degree of specificity in requirements, in effect, when you have requirements that are binding on an Agency, that in effect operates like a regulation, and hence is supposed to be a regulation, and in fact can result in then a challenge if it's not issued as a regulation. So it needs to be issued as a regulation, and just -- the lawyers from HHS looked at this issue. Lawyers from the *Federal Register* looked at this issue. This was a well-vetted issue that they came to this conclusion

on.

DR. ZIEMER: Ted, is it also the case that by going through rule-making you also assure the public process that might otherwise be bypassed with a guideline, or not?

MR. KATZ: Well, it's absolutely true. You're not bound by the Administrative Procedure Act if you don't produce a regulation. You're not bound by that. You don't have to have public notice and comment and so on.

In reality, with our guidelines we were always planning to have public notice and comment, so we were almost -- we were doing almost all of what it would require to have a regulation anyway. And in a sense, this is a formality that it was decided that it would then be produced as a regulation instead of as voluntary guidelines.

DR. ZIEMER: It would appear to me also that even though there's right now in our minds a great deal of uncertainty, in fact the Agency would like there to be more specificity so that we do know, going in, what the rules of engagement are for this approach.

Tony, you have a comment?

DR. ANDRADE: Yeah, one more comment. Again, I truly believe that this is going to be used less often than not. But nevertheless, I had no objection to it being turned into or codified.

However, I really believe that the criteria, the criteria or guidelines, if you will, that are entered into the Code itself have to be extremely clear. And I think that one of the criteria that I'm feeling is bothering us here is that -- or criteria that does not exist and is bothering us here -- is that we don't want this to be an automatic third step in the petitioning process. We want this to kick in if there are very clear guidelines: Lack of information, a group of individuals for whom that lack of information is common, perhaps site commonality, perhaps work of those individuals, et cetera, et cetera.

I think that the proposed rule, as it is written, is incomplete. It leaves us with a bad flavor, and I just don't think it's anywhere near ready for finalization without, I think, some extensive mark-up that can come from this committee, from this Board. And I know that this Board is free to do so, at least to make recommendations.

DR. ZIEMER: Thank you.

I have a question, and maybe, Ted, I'll direct it to you again. I notice that in Section 83.14 it says as a matter of -- item (e):

(Reading) As a matter of discretion, the Secretary may consider other factors or employ other procedures not set forth in this part when he deems necessary to do so to address the circumstances in a particular petition.

It seems to me that that opens the door for almost anything to override what's already in the rest of the rule. Could you help me understand -- and that same sort of thing is repeated near the very end. It's 83.16, item (3), recommendation by the Board to the Secretary as to whether or not Secretary should cancel or modify, and so on. It says any -- or it's actually number four:

(Reading) Any additional procedure the Secretary may deem appropriate, as specified in the notification.

I realize the Secretary needs some latitude and discretion in making the decision, but it looks like all kinds of other factors could be brought in. As a minimum I would think that we'd

have to say any other procedure that does not conflict with the established procedures, because otherwise you can override everything. I'm having a little trouble understanding the intent there. I know it's sort of a catch-all, if all else fails let the Secretary make the decision or something. But --

MR. KATZ: Well, in fact it is an open, vague opportunity for discussion on the part of the Secretary, and it is there because of not being -- because of the situation we have, which is we have considerable -- I can't use the word uncertainty, but I don't know which term to use -- about exactly how things will work down the road. And this was simply a parameter left in there for the Secretary in case there are situations we don't envision that require other procedures.

Should such measures be taken, it certainly would be taken in full public view and with the involvement of the Board, but there's not more to explain about it. That's exactly what it is. It's an open door, and it was put there with the intention of having unknowns out there in terms of how this world is going to evolve in terms of

Special Exposure Cohort petitions, what those circumstances are going to be.

DR. ZIEMER: Okay. Other comments?

(No responses)

DR. ZIEMER: I call attention to the fact that in the document probably the first almost half or more -- I didn't count up pages -- but the actual rule-making itself is probably less than half of the document. It's sort of -- for general purposes I'll call it the last half. I think it's a little less than that. The first section is really sort of background information and discussion of why they're doing the document and so on. The rule-making itself is the rest of this, this back half.

And let me ask, because I've asked this specific question, are there specific things in the body of the rule itself that you would like clarified at the moment before we go any further? Do you have questions on the meaning or something like that?

DR. ANDERSON: Paul?

DR. ZIEMER: Yes, Henry.

DR. ANDERSON: We can go through some of this now, but I'm just wondering, since there does

seem in this case to be some time and we haven't had a lot of time to review this, if there's going to be public meetings for additional input. It would seem to me before we finalize something it would be nice to hear what those other comments are.

So I'm wondering if there is going to be these meetings, whether we might want to have a subgroup that might work along the lines that you were saying, to try to -- we could even break up into a workgroup tomorrow or something to try to start drafting something, that we could then come back together at our next meeting, hopefully either in conjunction with one of the public comment -- say the last comment session or right after that to finalize our comments, rather than draft comments, send them in now, and then potentially have other comments that we haven't thought of that workers would bring at the public meetings.

So I don't know when our next meeting or what -- I would only want to do it here if it's impossible for us to get together for discussion of suggested comments. I think we've had a fair amount of uncertainty feeling here. Translating

that into specific language, I think, is somewhat difficult.

DR. ZIEMER: Well, there basically are almost two month till the comment deadline.

DR. ANDERSON: Yeah.

DR. ZIEMER: I think the target that we heard was that these public things would be in the next six or seven weeks, the last one of which would occur maybe a couple of weeks before the August 26th deadline. How --

DR. ANDERSON: But I'd like to hear what --

DR. ZIEMER: What is the process for compiling that information and promulgating it? Is that done in a sort of a timely fashion? In other words, how easily would it -- how easily could the Board have access to the Q and A stuff that comes out of that meeting, those meetings?

MR. KATZ: So the public comments, I'm sure we will handle it as we did in the past. We will put those public comments in our docket. It's going to be open on the web, as it was with the other two rules, and you'll have access to those public comments, written comments that are submitted that way.

In terms of the comments that are made at the

four town hall meetings, all those meetings will be recorded, and that material will all be put on the docket, too. And in the process going forward we will want the Board's recommendations before we -- obviously before we finish our work. But the process is to consider all those comments, address them all, and -- are you asking about our questions and answers in response to those, seeing those? Or are you asking for --

DR. ZIEMER: Well, as a minimum, what the questions are and the comments that are presented in the public meeting, I think is what Henry was referring to.

DR. ANDERSON: Yeah, it gives us some additional input. We may say, well, that isn't relevant, but at least we will have had an opportunity to consider, though.

We were the last commenters, I would say, on the first two rules. So now we have it fairly early on, we've got some time. Let's be near the end again so we can hear those. The written public comments, if they come in in time for us to look at them, fine. But their deadline's going to be the same as ours, so they may not come in in a timely fashion for us to read them;

where the town meetings, those you could be able to capture what the sense -- are they all over the map, are they different in different regions? And that might help us in then taking individual comments to focus them into a Board set of comments as well.

That's my only suggestion, that if that could be done, that would seem to me to be -- at least to me it would be helpful to hear. I don't know enough about the nuances of a lot of this that I'm sure people who are out there in the field or workers are perhaps going to have a better handle on, and get a sense of how -- how many of these are there going to be? If it's 90, is it -- what that means for the Board. We'll get a better sense from the public comments, I think. Or maybe, I'm hoping.

DR. ZIEMER: Ted, that 90 number, in your mind what did that represent? Ninety individuals or 90 groups?

MR. KATZ: That was 90 petitions, but the vast majority being generated as a result of us not being able to complete dose reconstructions; so the vast majority being generated as a result of us not being able to do individual dose

reconstructions coming from individuals.

DR. ZIEMER: But a number of those could commonly -- or be common to one site or location where --

MR. KATZ: That's possible, right.

DR. ANDERSON: The difficulty is it will become much more robust as you get more and more submissions. The first person or the first ten people who you can't do their dose reconstruction and you look for are there others like them out there, you aren't going to know because there aren't any others that have been submitted that have been turned down yet or have not been reconstructed. So you're more then into more speculative -- well, there may be a lot of these people out there, but we don't know.

And so it's kind of how robust does it have to be, or will you look at it and say, well, this one individual seems to have -- potentially meet some of your criteria, though you can't do the dose reconstruction. So you might -- would you see recommending certifying a single individual and then wait to see if there's others in the class that come up? I just have a hard time that as the -- when you first look there's nobody else

like them there, so would they possibly get turned down as a class because we can't identify a class?

MR. KATZ: We don't think there will be -- we think that would be an extremely rare circumstance where there is an individual whose situation is unique, and hence would comprise a class alone. So we're really thinking with these individual dose reconstructions, again, that those are a sentinel for an entire class that has yet to be recognized.

So it's not a matter of 90 individuals in 90 separate classes, but really when the individuals come forward and we can't do a dose reconstruction, then it's a question of how many individuals are in the boat with them and defining that class. And it probably will, in effect, short-circuit the concern I think that you could have that, well, you'll get a lot of individual requests from one site, and you won't be able to do each of them; but once you fail on one, the word's going to go -- the person can petition, and then you'll start looking at who's in the boat with them. And if there are other individual dose reconstructions in the pipeline

you would still carry forward on them, but as soon as it became clear that they're part of that class you'd be cutting to the chase there and defining your class.

DR. ANDERSON: If it's just when do you close it out -- the data will -- as you continue to review, some may come in, and --

MR. KATZ: Well, it's not reviewing on an individual basis. It's going back based on an individual not having a dose reconstruction. It's looking at the data that speaks to all the workers in that individual situation. So it's not sort of boundless, I think -- I'm not sure I understand you -- but it's not boundless at all. It's determining, well, how -- what's the scope of this class.

DR. MELIUS: How much work -- what's the workload involved and timetable involved in looking at those 90 petitions?

MR. KATZ: What's the workload involved in --

DR. MELIUS: How long is it going to take to complete the average evaluation for a class petition?

MR. KATZ: I can't recall what we estimated in terms of hours of work to address one of those

petitions.

DR. MELIUS: Or time, do you have no --

MR. KATZ: No, it wasn't -- we didn't have to address it in terms of a time line. We would have addressed it in terms of hours of work, but I don't -- I just don't recall. I couldn't tell you, off the top of my head, what sort of labor we had guessed at in terms of addressing one of those petitions.

DR. DEHART: I've read an awfully lot in the last couple of weeks on this topic, and I may be confused as to where this sits, but wasn't a provision made for an individual who would not qualify as a claimant because there is no cancer, but would qualify to enter as a petitionary to this program because he may have cancer?

MR. KATZ: That's exactly right, and that's why --

DR. DEHART: So that opens it up to every employee, basically, who has been an atomic worker?

MR. KATZ: That's exactly right. It is not limited to -- you do not have to have incurred a cancer to petition to be part of the cohort.

DR. ZIEMER: But you do have to have the

cancer to get the --

MR. KATZ: To get compensated.

DR. ZIEMER: -- compensation, yes, eventually, right.

DR. MELIUS: And if you don't -- if you don't have the cancer, you're not a claimant, you haven't been turned down, you have to meet a higher level of proof in your application. Your petition has to -- excuse me, your petition has to meet a higher degree of --

MR. KATZ: Really, to clarify, it's not a higher -- in a sense, the person who's had a dose reconstruction turned down has met a higher burden of proof, but -- and probably will have put more labor into it, being involved with us in the dose reconstructions, but in any event there are requirements. There is sort of a threshold of effort they have to put in to petition, that's true.

DR. ZIEMER: Jim has a comment.

DR. NETON: I just sense that there may be some confusion; maybe it's just me. But when the SEC petition is evaluated, we're evaluating not individual workers but a particular work activity. So you don't qualify like 20

individuals and say those 20 individuals are in this class. There's a particular work function that may have occurred.

And I'm reluctant to give examples, but someone working in a facility changing out some kind of filtration mechanism or something, there was no monitoring but we recognize that that filtration mechanism had a large potential amount of some actinide material that is -- since there's no urinalysis, no TLD information, we can't put any estimate on that exposure at all, but we recognize that it is potentially sufficient to have caused cancer in that class of workers.

But once that class is established, then anyone who did that particular function is eligible to apply for that class. And we would evaluate them at that time -- did they really work during the constraints of the time frame that we specified and at that particular facility, those type of criteria. So it's not really qualifying an individual. It's a group of -- a work function, essentially, or even a whole facility, as Tony had mentioned.

MR. KATZ: I'm sorry, it's Ted again. But

just to clarify for the record, that evaluation, then, once the class is established, the Department of Labor is responsible for saying do you fit in this class. So they are the ones who make that judgment, not HHS.

DR. ANDRADE: No, I don't think that there's any misunderstanding about that here around the table. As a matter of fact, if what you said was written into the *Register,* I think the point would be moot. We're looking for commonality to establish a cohort. We cannot do this for individuals. And that commonality can be just about any sort of thing.

DR. NETON: I don't think that it's possible to define those particular job functions. I hope that's not what you're suggesting.

DR. ZIEMER: No. No, no.

DR. ANDRADE: No, I'm saying commonality.

DR. NETON: Commonality.

DR. ZIEMER: And that perhaps would go a long way to clarifying the intent here.

UNIDENTIFIED: Exactly.

DR. MELIUS: And I think if that were carried over to the question of the individual application, because it’s really going to be some

of those same criteria, whatever we want to call them, that would apply to a group and define a class in terms of what information's available and so forth that would apply in an individual case, which is why you couldn't complete their dose reconstruction. And it would seem to me that if NIOSH is not capable or doesn't want to, whatever -- I don't understand -- come up with these criteria, that one of the recommendations that the Board should make is either those criteria be developed or that we develop some criteria ourselves as recommendations. In fact, I think in order to deal with the issue of reviewing dose reconstructions we're going to have to wrestle with that issue at some point anyway as a Board.

DR. ZIEMER: Some of these individual ones, it appears -- and I think the word you used, Ted, was they're sort of sentinels -- they trigger you to begin thinking, is there this class of individuals for whom this person perhaps is a surrogate or a representative? And it may be that that point simply is not clearly stated here.

DR. ANDERSON: I think what's more clear when

you say a specific activity, that's different when you say acting as a sentinel. To me, when you say sentinel, that's the whole person, and it would be his lifetime exposure and all as opposed to an incident, event, or a period of -- a three-year period of time when everything was lost or whatever. I think that kind of detail probably needs to be in there.

DR. ZIEMER: Possibly could be either.

DR. ANDERSON: But rather than if you can't do a dose reconstruction, you're really saying the person's whole lifetime of employment you couldn't do a dose reconstruction, or are you just saying this component in your dose reconstruction we can't do? That, to me, isn't clear. It seemed to me that denial is to get back to the person, say we can't reconstruct your dose, not your dose in 1953 or your dose in February of '64. It's rather we can't do your dose reconstruction for your period of employment. And that, I think, is the confusion here. At least to me --

DR. ZIEMER: Well, maybe --

DR. ANDERSON: -- if you're maybe looking at a specific segment of time where you say we --

there's a critical period in your work history where we have no exposure information; therefore, we can't do a reconstruction.

DR. ZIEMER: Could you clarify that, Ted, because it may very well be that you can reconstruct everything except what occurred with regard to a particular incident.

Is that what you're –

DR. ANDERSON: Yeah.

MR. KATZ: We've talked about that. I talked about that in my presentation, too. It's absolutely true. We're not concerned with the periods when we can reconstruct the dose. We're concerned, in effect, with is there a period when you can't reconstruct a dose? That's sufficient. It doesn't have to -- they can have perfect records for three-quarters of their career. What's important is a period for which there aren't records or adequate records. So that's the issue.

But I want to clarify also what Jim was saying with activity. Activity -- and you, then, in effect, Dr. Anderson, you started to rattle off the reason why we're saying we can't be more specific. Jim said that an activity, for

example, and he gave you this example. Well, that is just one example of a situation where you'd have basis for a cohort. But there are other situations, too. They could be in the same area doing completely different tasks, and have incurred radiation doses that can't be measured. So that's not it. That's just an example that Jim was giving of a circumstance.

DR. ZIEMER: Wanda.

MS. MUNN: Thank you.

I'm wondering if we're kind of getting out in front of ourselves here and trying to do what many of our jobs have taught us to do, which is look at the minutiae instead of the big picture. Because I have a hard time seeing that there is likely to fall upon this Board any large amount of material that is not already covered in what's here, perhaps with some additional specifics, as Tony has indicated.

But on page 50 there is -- of the material that we have here -- there is a table identifying what the petitioner needs to identify or not identify in terms of becoming a special cohort. And almost everything that I've heard talked about around this table involves some class or

some incident that is either specified or referred to here on this table.

Further, anything that we would see would already have gone through this process, and as I read page 51, would come to us for review primarily of what the Secretary's decision was, not as to what the contents of the file were. Am I incorrect in that? I believe what I'm reading here is there's a very defined process. If the Secretary does not find that this petition meets the requirements, then and only then would this Board become involved. And the Board, as I read this, will have an opportunity to review the Secretary's recommendation as to why that finding was made. And really that's all we're being asked to do, I think.

Am I incorrect, Ted?

MR. KATZ: Yeah, you are.

MS. MUNN: I'm wrong. Okay.

MR. KATZ: I'm sorry. But there are two phases, in effect.

There's the first phase, which is deciding whether HHS is going to evaluate the petition in full, and that's what I think you're talking about there. There the Board would only make

recommendations if we were saying -- HHS were saying this petition doesn't warrant being evaluated. In that case, it would come before you before it was decided not to evaluate that petition, and you would in effect be sort of a review element of that decision, and you would make recommendations to us as to whether or not we should in fact be evaluating that petition. So I think that's what you're addressing on those pages.

But you are fully involved as a Board, once we evaluate a petition, in overseeing our evaluation and making recommendations to us with respect to our evaluation.

DR. ZIEMER: Sally.

MS. GADOLA: Ted, this sort of gets back to what I first was talking about, and I just wanted to ask you the question and it's to clarify it in my own mind. And I liked your illustration when you were talking about putting people in a boat. I am assuming that with the IREP that there is a way that you can capture some of this information that shows that you're not able to do the dose reconstruction, but there are some similarities that would put these employees in a boat. Are

there?

MR. KATZ: Yes. This is -- again, this not IREP, but our task will be to lay out very clearly which individuals we can't do dose reconstruction for and why. So the parameters of the class -- in the case of doing a dose reconstruction you have to lay it out very clearly for that case, that dose reconstruction. When you go on to a Special Exposure Cohort petition, we're going to have to lay out very clearly what information exists, what doesn't, and why that prevents us from being able to do a dose reconstruction. And that would then come before you, that whole logic, the data behind it and so on, for your evaluation.

MS. GADOLA: Thank you. I think that's why I was first saying I assumed that NIOSH would be the first ones to often recognize this group, which I would call a cohort rather than individuals, being able to say, well, I'm sure that this must have happened at work because I remember so-and-so, but I don't have -- I just wanted to hear you reiterate how that is possible to capture some of this data.

And I think all of that helps us to clarify

whether or not there really are going to be individuals to put in the boat, because some people think, well, it'll just be a very, very few, and that might be true. But you need some type of data to go by and some type of standards to go by. And if you have two or three people at Oak Ridge and two people in Paducah and so forth, how are they going to know about each other?

MR. KATZ: Well, let me just -- that's an important point to clarify. The petitioners have to be actually from the same facility to be in the same class, to be in a single class. So you can have separate classes that can have very similar circumstances at different facilities, but they would be separate petitions.

MS. GADOLA: Okay. So one of the ways that they get in the boat is if they worked at the same site. What I was thinking was if they did -- also if they did the same type of job at different sites, but that could vary what they were exposed to by a large amount of radiation dose.

MR. KATZ: And as the Board was discussing earlier, I think Dr. Ziemer was saying that practices were fairly different at different

sites, too. So at one site you may have had good record-keeping, good information available, and another site not, too.

MS. GADOLA: Okay. And that sort of goes back to my first comment, too, is about the way that the first cohorts were established by Congress was according to where they worked. It was site-specific.

MR. KATZ: That's correct.

MS. GADOLA: And that's something that we might be seeing in the future, that certain sites, certain departments may end up being a special cohort.

MR. KATZ: Or parts of a site, not necessarily the whole site.

MS. GADOLA: It also seems like that would simplify things a lot for everyone, once that was established. Thank you.

DR. ZIEMER: Ted, does the -- maybe I missed that. I think that's a point that perhaps is worth stating somewhere -- maybe it is and I missed it -- that any special cohort will, as a starting point, have the commonality of site-specificity. Is that correct?

MR. KATZ: That's correct.

DR. ZIEMER: Is that stated?

MR. KATZ: It is stated.

DR. ANDRADE: It's 83.5 in subsection (c). I completely skipped over that myself. But that's what I mean about the clarity of the rule. If all of these --

DR. ZIEMER: I got it. I see it.

DR. ANDRADE: If all of these criteria were listed up front somewhere, where everybody understood precisely what needed to get -- what had to be done in order to be considered for an SEC, I think this would be a much more valuable document. It seems to be scattered throughout.

MS. MUNN: Maybe it would help to include the form, which I haven't pulled down and looked at.

DR. ZIEMER: I'm sorry, could you -- I missed that, Wanda. What are you saying?

MS. MUNN: I said it might even help to include the form, which is available on the home page, but I haven't pulled it down and looked at it -- the application form.

DR. ZIEMER: No, I don't think it exists yet, does it?

MR. KATZ: No, it doesn't exist yet. And that's written as it would be in a final rule,

where it would be available. But it's not there yet.

DR. ZIEMER: Incidentally, just as an aside, you'll notice in section 83.13 it talks about the consensus of this Board. And it has a footnote about that, so I think it's okay.

DR. ANDERSON: And if we wanted to be sure. If one person supports it.

DR. ZIEMER: No, we have -- it says it may -- it's --

DR. ANDERSON: Yeah, it does not require you --

DR. ZIEMER: Right.

Okay, additional comments?

Yeah, Mark.

MR. GRIFFON: If we had a little time here, I'm just going on what Tony was talking about with the clear triggers. I completely agree. Part of my frustration with it was the lack of clear triggers.

And we've had discussions with NIOSH, and I guess what I wanted to explore maybe, if we had a few minutes now, was what was your thought process in defining things like reasonable estimate? It's defined as you can complete a

dose reconstruction. And I know that you turned it back and said, well, if you have a better way to do this, fine, give us a proposal. And I agree. I don't know that I have the perfect answer right now. But I can think of some quantitative -- potential quantitative triggers to be used to assist in determining that reasonable estimate idea. And I'm just wondering if it might be helpful to the Board if we heard some of -- I'm sure you went through a lot of the same thoughts that we're going through, on how can we possibly quantify this, and was there other -- can you share some of that logic with us?

MR. KATZ: Well, we went through the issue of -- because it was -- it's been mentioned before, the issue of whether it's a question of the size of the standard error, for example. Is that what you're referring to, in effect, as a way of clearly defining that? And the way we veered from there or felt that was really inappropriate is because the size of the standard error is not harming the claimant in this case, as Dr. Ziemer expressed over there when we were discussing this provision before. If increased standard error

means more benefit of the doubt to the claimant, in effect, we're not harming the claimant that way, then that doesn't seem to us a good measure in this circumstance, which is, I grant it, it's sort of unique to what we've set up here in terms of how we're doing dose reconstructions. But it fits, I think, more or less like a glove with what we've proposed for doing dose reconstructions and what we're doing now there.

So again, our logic led us back to saying if we can do the dose reconstructions we are treating these claimants fairly. And our concern is about claimants who don't have this as a remedy, and those claimants are people for whom we can't do dose reconstructions. There's really -- there's no more logic to present to you than that, for whatever limits it has.

DR. NETON: I think I could just add a couple of things to that.

One thing I think is important is it's unbounded, reasonably unbounded at the upper end, where you can't necessarily put a handle on what the upper end of the dose of that cohort or that group or class of workers would be. Your other alternative would be to assign everyone some

extremely large exposure, which in effect qualifies them as a Special Exposure Cohort to begin with. That's the only alternative, is to say I know it's less than a million rem, something crazy like that.

And one could do that, but I think that's when you get into this reasonableness test. Well, that's probably not reasonable, but we don't really know. And that's part of that logic process, is this unbounded -- sufficiently high to have caused cancer, but unbounded at a very high end where you'd never be able to establish it with any certainty. All the other ones that we could do, we feel that we could bound it within some reasonable scientific certainty. There I go, use the word “reasonable” again.

But it's hard -- I'd be interested to hear whatever quantitative numbers you might have.

MR. GRIFFON: Well, yeah, I've been playing around with that, but it's not ready for sharing publicly yet.

But I guess the other concern I have, really, is from the standpoint of the potential claimants, that if we don't have some clear triggers, then I think there might be the

reaction that, oh, once again I just missed the hurdle; boy, surprise, surprise, my -- even on that maximum likelihood where you give them the worst case dose estimate, they may say, surprise, surprise, once again we missed the trigger for compensation. And I think that -- I guess I was just trying -- if there were clear triggers, clear triggers for you would be helpful, clear triggers for the Board when we reviewed things would be helpful, because we're going to have to put our opinion out on these things as well. And it would be helpful to the petitioners so they knew what they were up against, maybe.

And like I said, I don't have any clear answer to that. I'm just kind of exploring that. And that's my concern on that side, is that we're going to get a potential backlash of people that really believe their records were destroyed and information wasn't correct, and they go through this process again and -- your worst case scenario, they just don't believe that it was really a worst case scenario. So I think the review process is good, but I think the triggers would be helpful for everybody involved, is all I'm saying.

DR. ZIEMER: Mark, could you -- when you use the term “triggers” here, give me an example of a hypothetical trigger in your mind. What are you meaning by it?

MR. GRIFFON: I guess part of what I was talking about is how do you determine for the reasonable estimate. And it could be tied -- I think it could be tied to the uncertainty combined with the mean in a way that's end-cancer-specific, so that you look at your sigma values on either side and compare it against your IREP model and see what that does to probability of causation. And I don't know, maybe you've looked at this. I'm not saying -- that's just one notion of a --

DR. ZIEMER: Isn't that what you're doing, in essence?

DR. NETON: -– dose reconstruction.

DR. ZIEMER: You're doing a type of dose reconstruction in the absence of any data. You're saying this group might have gotten a dose this high, and that would --

DR. NETON: Right, that's exactly it. I don't want to get into too much --

MR. GRIFFON: Well, that's not quite how you

do a dose reconstruction. But like I said, I'm not really ready to put a model out there, but a dose reconstruction, you put the whole distribution into your calculations.

DR. NETON: Right. But these triggers are extremely -- if you run the IREP model, cancer-specific, age at exposure, it's specific to every individual, and I don't know that you could actually establish a single trigger value. It would not be possible, given the infinitely variable nature of the calculation, at least in my opinion.

MR. KATZ: Can I just --

MR. GRIFFON: I was proposing that more for the other side, with the individual where you want to determine if you can do a reasonable estimate. If that estimate is reasonable, then -- I'll leave it at that.

MR. KATZ: Well, I was just going to point out, too, that if you're -- but then I think he just canceled my comment in a sentence. If you're not talking about Special Exposure Cohort procedures, but where you apply this whatever kind of arbitrary or whatever trigger like this, the result of that is if it results in your

creating a class where you could have done dose reconstructions for those individuals, some of those individuals will have cancers that are not on the specified cancer list. And there you've basically taken away any remedy from them that --

MR. GRIFFON: I understand. I also think -- and another -- I'm sorry, Wanda.

I think another definition that might play into this is -- and Ted did present on this a little today in the presentation -- was feasibility. And I think I disagree a little bit with Ted that the description, I think it can be defined to some extent, at least in terms of -- we threw around examples of, well, you can always reconstruct a dose, given enough time and effort and -- but I think part of that plays into feasibility. How much time, effort, et cetera is going to be involved for one small class, possibly, to define a source term if you have to go back and characterize a dump site, for instance? I think that might be unfeasible, as an example. Maybe it's not. But I think that's something that might be able to be defined to some extent based on time and allocation of resources.

DR. ZIEMER: As a practical issue, if you have to spend $50 million to decide whether 25 people are a special cohort.

MR. GRIFFON: Yeah, right.

DR. ZIEMER: Wanda has a comment.

MS. MUNN: It's my observation that no matter what threshold of either dose or event is chosen, there will be people who didn't quite make that and who will continue to feel that they have been mistreated. I believe the only thing that people who are involved in this kind of activity can do is to do the best job they can based on the best science that's available to them, and not be swayed by the fact that there will be people who will be unhappy with whatever decision is made. You just have to use the best science that's available.

DR. ZIEMER: Thank you.

Okay, it's time for a break, unless there's -- does somebody have another comment?

UNIDENTIFIED: I think yeah was the comment over there.

(Laughter)

DR. ZIEMER: Okay, let's take a 15-minute break.

(Whereupon, a break was taken at 2:40 p.m.)

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DR. ZIEMER: Our agenda actually calls for us to go back to dose reconstruction review process, but I think we agreed this morning, with the input to the working group -- and that group is going to meet sometime tonight, or after this session --

MR. PRESLEY: After this meeting.

DR. ZIEMER: So if it's agreeable, we'll defer discussion on dose reconstruction until tomorrow, then.

Mark, where are you? Is that agreeable? I guess it is. Mark, if that's not agreeable, say so.

(Mr. Griffon is not present.)

DR. ZIEMER: So let's go back to Special Exposure Cohort. We were kind of catching our breaths there, but you've had a chance to mull over things further. Do we have any additional comments at this time?

Oh, yeah, just a reminder to members of the public who wish to make comments to sign up. There are several already signed up, so we do have you on the schedule, at least three people

I'm aware of. Okay.

MS. HOMER: (inaudible)

DR. ZIEMER: Now up to four? Okay.

Okay, I've called for additional comments on the Special Exposure Cohort petitioning process, rule-making.

(No responses)

DR. ZIEMER: Do you feel like we've identified all the issues we need to address? There's a cross-section of them.

Okay, Roy.

DR. DEHART: You mentioned earlier the possibility of trying to have comments that could be placed on the docket for review. Is that still the intent, or as was suggested to let the course run its full outing and then put our comments in?

DR. ZIEMER: Well, I think it's up to this Board, number one, what it wishes to say and when it wishes to say it, so I'm not certainly dictating that. The comment period closes August 25th or so, doesn't it?

MR. ELLIOTT: Yes.

DR. ZIEMER: And I think Henry suggested that we might wish to be made aware of the public

comments on this before finalizing anything that we do. Not that we are -- we certainly aren't going to do the staff's job, which is to respond to the public comments, but we would use those mainly to see if there are other issues that we think we should also be addressing, something that might be triggered by public input.

So Roy, and then Henry. Or Henry and then Roy.

DR. ANDERSON: Yeah, I was only thinking that as far as clarifying language or recommendations that we could make, there may be comments where the public is confused or has some questions that in fact, in honing in on our own comments, we could help address some of those.

DR. ZIEMER: Right. I would certainly suggest that we need to be pretty far along and maybe have a semi-final draft ready that we could say, okay, in light of the public comments, we might make some additional minor changes or massage it a bit. But we need to be ready to go by mid-August or so in any event.

DR. ANDERSON: Right.

MR. ELLIOTT: Just for clarity's sake, let me make sure everybody understands that when we

receive public comment on this notice of proposed rule-making, as soon as we receive that it'll be entered into the docket and available on the web site. That's a fairly innovative, very new practice in rule-making. We're the first to have done it with the two rules we've already completed. It's been our experience, though -- and limited experience that it is -- that people wait till the last few days to provide their comments. And so I'd just caution you in that regard.

Secondly, with regard to the stakeholder meetings that we're proposing to conduct, we're going to attempt to get a transcript of those and put that on the web site as soon as it's available from the court recorder. So that would be to your avail as well.

DR. ANDERSON: It seems to me, though, that depending where you hold them it's likely to be that there'll be one Board member that actually may be in the town where your town meetings are being held, and we could maybe task that individual to go to the meeting to take some notes to give us that feedback. That was my only suggestion on it, is there may be something that

would be helpful that would help us make our comments more --

DR. ZIEMER: There will be a transcript, but probably you --

DR. ANDERSON: Yeah, that may be too late.

DR. ZIEMER: -- don't need the detailed transcript. You --

DR. ANDERSON: Yeah, and the published comments, I agree, I'm not --

DR. ZIEMER: You want more the flavor of the comments, and maybe a synopsis of what the issues were that were raised.

DR. ANDERSON: Right, right. And if those are ones that we could address, that would be helpful to NIOSH to have us do that, and then they can reference that.

DR. ZIEMER: Roy, did you have another comment? No. Gen.

DR. ROESSLER: What is the next planned meeting of the Board? I'm assuming that this discussion centers about maybe a teleconference if we had to get back together and make some decisions?

DR. ZIEMER: We don't actually have an additional meeting scheduled at this time.

That's one of the items of business before we leave, is to talk about the time for the next meeting. But if necessary, we can always have a teleconference. Keep in mind, though -- teleconference, a telephone conference -- keep in mind, though, even that requires notice in the *Federal Register,* and it's not a minor matter.

DR. ROESSLER: So how would -- whatever we develop today and tomorrow, how would we refine that before the end of the comment period?

DR. ZIEMER: We would either have to have a telephone conference or a real, face-to-face meeting, yes.

Tony.

DR. ANDRADE: Paul, I think it would be in our best interests to try to, as you said, draft something in terms of recommendations for wordsmithing this proposed rule, perhaps adding some clarification -- clarification of philosophy, what it's intended to accomplish, the whole idea of commonality that people are looking for, those sorts of things -- sooner than later. And then we can address the issue of finalization -- that is via teleconference or another meeting -- later on.

DR. ZIEMER: Yes, thank you.

I'm glancing here at our schedule to see whether or not there will be time to actually do some of that while we are here. There is, tomorrow afternoon, a fair block of time that could be devoted to this. It would require probably some preliminary work between now and tomorrow by one or two people to organize and categorize the comments that we had, and to come up with a scheme for how to approach that. It would probably preclude the Mark Griffon subgroup, which has its own task before it. But if there were one or two others that would be willing to spend a little time maybe after dinner, I'd certainly be glad to participate if we had one or two others, just so we can sort of organize the comments.

Any volunteers for that? Okay, Tony. Any others? Wanda. I've jotted down, I think, a good portion of them. Maybe you've made notes. Maybe we can -- you haven't made notes. Okay. Anyone want to replace Wanda on the committee?

(Laughter)

MS. MURRAY: Wanda, you can have my notes.

DR. ZIEMER: No, no, no, you -- she has it

all in her head.

DR. ANDERSON: Where are you going to meet? Depending on how much --

DR. ZIEMER: Well, I don't know. Where would you like to meet? We can meet in my room, I think. It's -- I think I've got three chairs and a bed. Okay. Let's do that after dinner and do some preliminary -- sort of lay out a scheme that might help the committee work together tomorrow.

But I don't want to preclude additional discussion on that right now, so again let me ask this question. Do you feel, with the clarifications you've heard today -- and I think some of you said, well, if that were said in the rule-making that would help, some of the things that were said -- and perhaps some -- I don't know, reformatting or reorganizing of some things that are in there to bring out certain points, and maybe some -- well, identifying those issues that need additional clarification, maybe that'll give us a start. And we can then work on that tomorrow and see where we end up, whether we are far enough along that we feel we'll be able to get a draft before mid-August.

But I want to make sure that we've identified

all the issues that people wish to raise. Not to say that you can't raise more later, but --

(No responses)

DR. ZIEMER: Okay. I'm going to, if it's agreeable with our members of the public who were originally scheduled for 4:30, if they're all here, I'd like to ask them if they would be agreeable to beginning this part a little early.

Richard Miller -- Rich, are you still here?

MR. MILLER: Yeah.

DR. ZIEMER: Robert Tabor?

MR. TABOR: Here.

DR. ZIEMER: Phillip -- Schofield, is it?

UNIDENTIFIED: He stepped out.

DR. ZIEMER: Okay. And Robert Bistline.

DR. BISTLINE: Yes.

DR. ZIEMER: Let's proceed, then.

Richard, would you go first? And why don't you come up to the podium. There's a lavaliere mike there. You just need to snap it on.

MR. MILLER: I promised Phil he could go ahead of me. I think he’s actually --

DR. ZIEMER: Do you prefer to have Phil go before you?

MR. MILLER: Well, I would, but I -- just to

avoid redundancy, also. Maybe we can do that. Why don't we --

DR. ZIEMER: That's fine. No problem.

Phil?

MR. MILLER: Yeah, let's do that, and if he's not back in time I'll --

DR. ZIEMER: Oh, Phil's not in the room.

Well, Robert Tabor, we'll let you go first. Is that all right?

MR. TABOR: Yeah. You want me to speak here or up there?

DR. ZIEMER: Go up there, that would be good.

MR. TABOR: I don't know if I'm totally prepared for this, but since I've been here a few times and we all put our pants on the same way, except for the ladies, I guess I'm comfortable enough with talking to you.

DR. ZIEMER: Robert, just for the record, tell who you're representing here.

MR. TABOR: Okay. I'm Bob Tabor, Robert G. for the record, whatever you want to put down -- T-A-B-O-R. That's Tabor, like labor; a little pun there.

There's some things that I'd like to basically discuss. Maybe I can categorize the

issues. One is somewhat the issue of integrity. I've kind of picked up on this this morning, the integrity overall of the review process. I'd like to emphasize that I think a great deal of importance and attention needs to be paid to that. And let me give you an example.

For years the site that I work at, the Fernald site, and the people that I guess would be -- I would call my constituency, the Fernald Atomic Trades and Labor Council and those workers at the site, I remember when we first come there there was comments made -- well, there's no way you can get injured out here or anything to worry about out here. The only way you can get hurt is if a piece of uranium dropped on your head, that was about it. And there was even comments to that nature that were made in certain testimony during the lawsuits.

But obviously that's not the case in this industry, and it's not the case with the materials that we dealt with out there. But most of the people were, I think -- or at least myself, and I know a lot of folks that I could say this would be true of -- were told that there basically wasn't a whole lot of risk in this

business, and that you didn't have to worry about exposure. Well, that didn't end up being the case, as later on litigation and various types of studies that were done by maybe individuals like Arjun Makhijani did some things for, I think, some of the case suits that were filed against the company that ran the operation out there at the DOE. And the same was true, I think, with some of the workers in that case suit. And the Till study, I think, showed evidence contrary to what we were told were the risks and the potential exposures at our site.

And when you take that in consideration, maybe it indicates that our processes for accumulating the data could be -- I don't know if I want to say tainted -- but certainly sheds maybe some doubt on how we accumulated information and data for exposure information. And when you take that into consideration, and you look at the fact that -- I'm not a scientist, but a lot of these things like risks, you got a lot of statistics involved in projecting probabilities when it comes to exposure data. You're dealing with a lot of other ways that in my mind, in doing estimates, that really -- I

guess if I was some type of a legislative type of a person on top, I would look at this as being a very mushy type of business. And that's not saying anything against the scientists that do this, it's just -- I think it's the nature of things, that sometimes you can't be just really, really exact.

So now we have this process for trying to make things right out here and do something for those who paid the price during the Cold War for our freedom and what have you, and we have the situation of how we're going to go about this. And obviously there's still some questions that are unanswered. And some of these things, I think, that the Board will be playing a very valuable role in because now we're talking about hiring, what, some subcontractors to assist in the processing of the information or processing of things that a small group of people are not going to be able to do by themselves at NIOSH.

And I guess on a personal note I probably know some of those individuals that are going to be -- that these -- in these contractors that are looking at winning that bid. But on a note of integrity, I'm not so sure that as a labor

person, and I'm not so sure that other folks like me around the country in labor would say that maybe we trust any of those folks, because most of them -- that's my understanding currently -- we're still talking about people who are paid by the government. And you know what that story means. There's going to be still a lot of distrust there. So now we're back to this situation on integrity.

If we're going to do right by these folks, I think that the processes really, really need to have a certain flavor integrity. And I think on that note, in my mind, that the role of this Advisory Board here is very, very important, that you people need to be in that process somehow. And I'm not getting necessarily the indication where there's some assurance that your role into the process of assuring that we can have that integrity across the board there.

And I think also it reminds me of a conversation not too long ago about some of the things that went on out at -- let me see, was that --

Your site. Where are you from again?

MR. ESPINOSA: Los Alamos.

MR. TABOR: Oh, Los Alamos. And some of the stuff out there, I think that it dealt with tritium. And there was a lot of question, as I believe, and I can't -- I'm no authority on that because I'm from Fernald. But you hear things elsewhere. But there was some issues concerning whether or not -- compliance issues relative to dealing with those materials and what have you.

And I guess my point is not until certain people got involved, some folks like maybe Till and Arjun got involved in some of that, was there any confirmation as to whether you are in compliance or whether you aren't, and whether the public trusted what was said or what wasn't. And the integrity in these processes, as far as I'm concerned, is really going to be important.

So the type of things that you've been talking about here today and the issues it seemed to like -- to allow to have a lot of black holes in this process. Those things really need to be looked at very, very thoroughly. When I listen to you I can understand what you're talking about, but it's very, very hard to, I guess I would say, reiterate or -- what that -- you know, what I mean by that.

One of the other areas that I wanted to bring up was like our Fernald situation there and the Special Exposure Cohort issues, and some of this most recent proposed rule-making. Fernald was not included in those special cohort group. I don't know how they managed to get left out of that because when I look at the fact that, well, what did we do there? Well, let's see, we received Paducah's material and we dealt with the same thing they did down there, and we received material from Portsmouth and we dealt with the same thing that they had there. Even though maybe some of our processes might have been a little bit different than those, some of the things that you were exposed to be identically the same.

And we'll have people there who are going to come up ill, come up with cancers, and by the nature of the Act they won't qualify there because it isn't this particular cancer or that particular cancer as defined in the Act. But if you look over at some of the things that would qualify individuals at Paducah or qualify folks at Portsmouth, they would certainly be comparable to. And yet I'm not certain how they would

explore their cases. I guess through the petitioning of -- saying that we believe we qualify for a particular class.

Things that come to my mind today as I was listening, I don't know if I can really explain, but we were talking a lot about -- somebody brought up this number, well, if we had 90 people and they didn't -- let's see, what was said -- they couldn't do a dose reconstruction on them, and we put them over here in this pool and a certain period of time went on, and eventually we would look and see if there was some kind of commonality or something there and maybe take a relook at those things later. I'm thinking, why wouldn't you want to take a look at it from a group perspective on the front end rather than look at it from an individual perspective on the back side and wait a long period of time? Because sometimes these long period of times, folks, people are dead by the time they would ever be able to get reconsidered or get considered for these claims. And that was one of the issues.

I'm not sure that I believe that the proposed rule-making takes into consideration or doesn't

have some black holes there that allow some things to slide in the cracks. And I did hear some discussion from the Board members here about some proposals that possibly would plug those holes, so I would encourage you folks to do what you can to maybe shore up the ship there.

The last time I was here I brought up an issue concerning -- it was after a gentleman spoke from the National Cancer Institute, and still what comes to my mind -- and I would like to use the analogy of apples and oranges -- we may have bad data out here that we've accumulated over the years relative to exposures on people, and I just want to say data that we accumulated that we know applies to apples. And we say, well, I guess if this data applies to apples, I guess I can apply it to other fruit. But the truth of the matter is you can't apply what you know about apples to oranges. Simply because oranges are fruit doesn't mean you can apply it.

And I'm still not convinced that the kind of data that we've accumulated from the atom bombs -- Nagasaki, Hiroshima -- that the studies on the survivors, that that particular data really is applicable to what workers have been exposed to

in the nuclear network, and I still have some questions about that. There are a lot of other worker studies out there. I don't know exactly whether -- how we're looking at those things or if we are looking at those things. But we certainly should assure ourselves that we need to compare apples to apples and oranges to oranges.

There was one other thing that I had and I don't -- I'm trying to think here; I didn't get it jotted down.

Well, those were the three particular things that I had in mind. If I think of the other one I'll mention it. But with that, I guess those would be my comments.

DR. ZIEMER: Thank you very much. If you'd remain there just a moment, let me ask if any of the Board members have questions or items they want clarified here.

(No responses)

DR. ZIEMER: Okay. Thank you.

Did Phillip come back in?

UNIDENTIFIED: No, still not back yet.

DR. ZIEMER: Let's see, Dr. Bistline? You can go next.

DR. BISTLINE: I'm Dr. Bob Bistline with the

Department of Energy, Rocky Flats Field Office. And I just wanted to make a few comments to the Board here this afternoon, and I appreciate the opportunity, Dr. Ziemer and Board members.

My background is I've been at Rocky Flats for about 36 years, a little over 36 years, and worked on the contractor side in their internal dosimetry, lung counting and so forth, and started a study back in 1980 bringing back old retired workers from the plant that had known depositions of plutonium or had exposures greater than 20 rem dose, overall external dose, and recognized some of the problems with the dosimetry of the program at Rocky Flats. And so started that program in 1980. I had about 900 individuals that I was bringing back to the site every three years for physical exams.

I presently work for the Department of Energy, have been there with the Department of Energy for about a little over seven years now heading up the internal dosimetry oversight, occupational medicine oversight, and the beryllium program oversight.

But I want to concentrate, and appreciate any helpfulness that can be given by the Board, in

terms of clarification of the SEC part of it. I know Henry and Jim and Tony have addressed some of those issues as it stands, and I bring out the point that we are seriously considering at Rocky Flats looking at Special Exposure Cohorts in a couple of areas.

One particularly that stands out -- and if this is not the intent of it, we certainly would like to hear, because I'm struggling with that clarification myself -- things like the fact that before 1964 we had no lung-counting capability. And we know now from our experiences with plutonium and the insolubility of the material that if you didn't have lung-counting capabilities, we're now finding some of these old-timers that worked back in the fifties and sixties showed no indication of bioassay, positive bioassays, and had very little external exposure recorded for them; that now, lo and behold, we brought in a 92-year-old gentleman here a while back, and he's got quite an extensive lung deposition of plutonium. And so there's a whole cohort of population before 1964 that we have no internal dosimetry in terms of lung counting.

Prior to 1957 there were only 18 people out of the entire population at the plant that had ever been given neutron dosimeters. There is a neutron dose reconstruction project, and I know Larry -- Mr. Elliott and the crew are looking at that. Some of that data is -- we're making progress on re-reading some of the films, but there isn't even data available on some of these people.

And so there are very specific types of cohorts here that I'm concerned, we're concerned about. And I think that those kinds of nuances probably occur throughout the nuclear industry, the Department of Energy, with different sites. And I would hope that -- and I don't know how extensive that's going as far as capturing the unique information that is lacking at the various sites, the historical information that some of us know about.

And I know the NIOSH people are trying to explore that, and I certainly would encourage any information that they can gain by various sources. And maybe through the public comment at stakeholder meetings and so forth they could capture some of that through some of the old-

timers that could provide additional information along the dosimetry lines, because there is a lot of information that's lacking in, I think, all the sites. Probably we're not unique at Rocky Flats. I know other sites are struggling with some of the same things that -- to try to go back and capture the exposures of individuals back in the 1950's and sixties is next to impossible.

And on internal dosimetry of plutonium, with the insolubility and the various differences that you find, just going to a fellow worker and looking at a fellow worker, it doesn't necessarily give you anything in terms of internal deposition. We've found at Rocky Flats where we're doing a lot of hands-on work, and I think this is a unique population at Rocky Flats because these guys have been doing hands-on work with plutonium for years. In fact, we still have over 12 tons of plutonium out there right now. And these are the guys that made almost all the nuclear weapons in the Defense Department over the years. And we know that some of these guys, two guys standing side by side, one guy can be pumping the gloves and be pumping, and a hole in the glove, and that guy gets an intake; and the

guy next to him, standing shoulder to shoulder with him, comes up with nothing. And so you can't really rely on fellow workers as an indicator of internal uptakes in a lot of cases.

So I just bring those points out to the Board, that there's a lot of uniqueness with working around a facility like that. And I certainly hope that all the information possible can be captured in terms of historical knowledge of the dosimetry. And I know Larry and people are anxious to capture as much of that as possible, but unfortunately at a place like Rocky there aren't very many of us old-timers around anymore that have the historical knowledge of the site and the dosimetry. Most of the guys that work out there now in closure, most of the old-timers are gone. And it's guys that have worked there less than five years, or five to ten years is the lifespan of most of those guys.

So I just encourage you, that the Board work on trying to get a little more clarification in some of these areas that would certainly be helpful to some of us in considering whether Special Exposure Cohorts would be appropriate to pursue. Thank you.

DR. ZIEMER: Thank you very much.

Again, let me ask if there are questions or clarifications? I might ask one question. I assume now on these ones where you're going back and doing the lung counts, assuming some kind of a clearance model, you can reconstruct doses then on them?

DR. BISTLINE: It's -- yeah, you can do a pretty good job of it if you capture those. But unfortunately, like in this particular individual, it just so happens that he's 92 years old. He left the plant site before we ever got a lung counter. So we are able to go back on that individual. But there's a lot of people that are no longer living, and a lot of people that worked at the site that aren't a part of this particular recall cohort. And so many of those people have never been lung-counted, historically never have been lung-counted. But yeah, Dr. Ziemer, we have been able to go back and get a fairly good range of dose that this -- the internal uptake from the dosimetry models on this individual.

DR. ZIEMER: Yes, Tony.

DR. ANDRADE: I'm curious, sir. In your follow-up bioassay, is it only lung counting that

you are performing, or are you doing any special, say, urinalysis or --

DR. BISTLINE: Yeah, we're doing urinalysis and the lung counting both. The reason why that's particularly important, because at Rocky Flats we have quite a cohort of population that has been exposed to what you would call high-fired plutonium oxide.

And just to give you a good example, one of the individuals that I did an autopsy on back a number of years ago -- I've done autopsies on about 120 people from Rocky Flats, former workers -- and one of these individuals was involved in a fire in 1965 with high-fired plutonium oxide, and there were a number of people -- in fact, there's quite a few people -- that have been exposed to this type of material. At the time of this autopsy, 20 years post-exposure, almost 20 years post-exposure, at the time I did the autopsy he had 222 nanocuries of plutonium, 48 nanocuries of americium still in his lungs and lymph nodes; and in all the rest of the body -- the soft tissues, the bones, et cetera -- less than 10 nanocuries after 20 years. So the models that exist out there for transport of plutonium in the case of

high-fired oxides have absolutely no relevance whatsoever.

DR. ANDRADE: Right. I completely agree in that particular case. And, furthermore I wanted to ask you if you had tried any of the ultra-sensitive techniques with some of the folks -- for example, mass spectrometry, whether it be thermal or inductively-coupled plasma?

DR. BISTLINE: We haven't done that with any of the folks at Rocky that I'm aware of. I don't think anybody has tried that with any of those. Back in 1967 I started up with the -- converting over to germanium, hyper-pure germanium detectors for lung counting. But as far as looking at the bioassay with some of these newer techniques, no, we haven't. Only just on a few people, isolated people.

DR. ANDRADE: The last point I'd like to make is just simply a comment. I think that this is precisely the type of case that I think one would, in my opinion, would be considered for a special cohort status, because new information has come to light about an activity that was common to many, many people for many, many years that we perhaps never kept any formal records on.

So I wish you the best.

DR. BISTLINE: Yes, Wanda.

MS. MUNN: I haven't looked at the data myself. Do you have a significant number of excess lung cancers or other related cancers that you've been able to identify with exposure?

DR. BISTLINE: Not really. I was talking to Dr. Ziemer, I think, earlier, and Dr. George Voelz at Los Alamos and I went back a couple of -- well, about two years ago went back and looked at a lot of the old-timers that were exposed back in the fifties and the sixties at Rocky Flats and some of the workers at Los Alamos that had been published, and no real follow-up had ever been done. And when we went back, well, it turns out a good many of these people are still living, and turns out that the guy that got the second most -- I talked about the 222 nanocuries and 48 nanocuries. Well, the other guy -- there were 25 that had greater than maximum permissible lung burdens, which was the old terminology that was used. The second-highest guy just passed away about a year and a half ago, and he was 87 years old and died of complications of surgery.

MS. MUNN: Which is sort of confirmation of

the original PU club --

DR. BISTLINE: Yeah.

MS. MUNN: Figures. Thank you.

DR. BISTLINE: Very much so, Wanda.

Yes.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah. Just to follow up on Tony's comment, I also would think this would -- description would suggest a parameter that could be used to describe a type of cohort that would be considered, type of class group that would be considered for a Special Exposure Cohort, and could give some guidance to other groups out there in this way.

The other question actually is more for Larry, if I word this carefully, but I'll use your terminology. Has NIOSH developed any sort of process to gather a group of old-timer experts to help, assist at each site with understanding the availability of data and so forth? Because I think that would certainly be obviously very useful at a site that would be -- where you were doing dose reconstruction, and also valuable in terms of even where you're fairly certain about your access to information in terms of the

Board's review of those dose reconstructions, that yes, all the relevant information was obtained, nothing was missed. And if we could have a roster of that group of people, I think it would be worth the investment to try to put that together now and for use later. Obviously with -- not at every site, but certainly at many of the major sites it would be useful, because we are losing those people, particularly at sites closed down and so forth.

MR. ELLIOTT: I'm very familiar with the loss of the people, having served ten years in the research program and wanting to talk with many people. Louise Presley's father was one I wanted to talk to before he passed away. He was very integral to a lot of industrial hygiene work that went on in Oak Ridge and K-25, and we missed the opportunity.

No, we have not put a roster together. In our statement of work for the contractor this is a research effort that they will take on for us, and it's building site profiles for a given site. And again, I apologize for the excuse, but I don't have enough staff to do dose reconstructions at hand and build site profiles

and interview the people that we need to interview. So we are -- I think it's important to note, though, that as we conduct these interviews of the claimants we are finding that they direct us to other individuals who knew about particular dosimetry program, historical changes in those, and we're pursuing that along with the case as we proceed with the case development.

DR. ZIEMER: Any other questions?

(No responses)

DR. ZIEMER: Thank you very much.

Phil Schofield, you want to address us?

MR. SCHOFIELD: Yeah, I have a couple of things, comments I'd like to make on --

DR. ZIEMER: Phil, for the recorder here, just tell where you're from and --

MR. SCHOFIELD: Okay. I'm Phillip Schofield. I used to work at LANL for 21 years. I'm with the project, Los Alamos project on worker safety.

Particularly I'd like to address some concerns I have about the special cohort. One of them is that it says that the petitioner must have and include positive evidence the records required to do dose reconstruction do not exist.

I would like -- I think if the petitioners have done everything they can, they have requested the records in a timely fashion, if they have tried to access records and have either been denied or the contractor or DOE, whoever it is who owns those records, has not delivered them in a timely fashion, then by default they should be allowed into the special cohort.

And a reasonable time effort, I think, would be -- because a number of people we have run into have had this problem. I, myself, I've been after my exposure records for almost six months now, and I still do not have them. At some point there has to be some teeth that the contractor has to either deliver or pay some kind of penalty. And if they don't deliver -- because you're asking someone to prove a negative, saying, well, these records don't exist. Well, they may exist. But if you can't get those records, then you can't prove it. The other thing is that when these records are missing or they have not been brought forth, the burden of proof would then shift from petitioner to NIOSH and Department of Labor rather than the petitioner about these facts.

The other problem I have is when we get into the thing about the cancer, you can have two people working side by side and one may develop liver cancer, one may develop lung cancer. This has been my experience working in the field, is that we've had people I've worked with, some of them died of one cancer, some died the other. Yet we all worked in the same areas. In many of these areas it's going to take a concentrated effort by whoever does this dose reconstruction to do what is a fairly accurate job. And we need to have a legal point at which people can say, okay, I can meet this criteria or I cannot meet this criteria. But if you have a moving target they can say, well, you didn't get enough exposure here, you didn't get enough exposure there.

But just using dosimeter badges is flawed, from my personal work history. I can tell you there are people who are running around there who have badges that are biased towards gamma, and yet had a lot of neutron exposure. But you will not see that. Same, very same thing, we have various -- we have processes where you had a high neutron flux, like HF reduction, on the same --

and you had people over there doing direct oxide reduction. That's basically gamma. And then you had people working with americium. They're getting both of it. But if you look at their exposure records, it does not reflect these matters.

And the other thing is we have some special classes, I think, that need to be looked at, because you take a lot of the crafts, a lot of the guards, what they call laboratory services inspectors. They would go through an area, and in one shift they could get exposed to plutonium, americium, uranium, and who knows what all -- 238, 239, 243, 241, americium -- all in one eight-hour shift. So how do you reconstruct these doses that are accurate enough to reflect what these people have been exposed to?

That's my comments. Thanks.

DR. ZIEMER: Thank you very much.

Let's see if anyone has questions or items you want clarified.

Yeah, Tony.

DR. ANDRADE: Phil, when you requested your own exposure records, did you request them for the purpose of this program alone, and/or did you

request a copy of your records for yourself?

MR. SCHOFIELD: Both for this program and for myself, because -- let me give you another example. There is very strong distrust of LANL/DOE there among the workers. I have a document by the nurse, Jan Crosdale, at TA-55 -- she was our site nurse -- talking about when I was getting radiation poisoning, as Dr. Williams referred to it. My hair was falling out. I was having skin problems. It was turning red. Little blood vessels were breaking down. So I saw her. I have that document. But when I went to see him a week or two later, he put all -- he was putting this stuff in my file. You won't find that file anymore. Now doesn't it seem a little bizarre that I've got the one from the nurse, but the one from the LANL medical doctors no longer exist? Tell me who I trust.

DR. ZIEMER: Okay. Thank you, Phil.

And then Richard Miller is going to come back to the podium now.

Richard? The first shall be last.

MR. MILLER: Good afternoon. I'm Richard Miller, here today. I work for the Government Accountability Project in Washington, D.C., and I

would like to run through several questions, first regarding the Special Exposure Cohort rule.

I wanted to first thank the NIOSH staff. They were kind enough, as alluded to earlier today, to convene at least a small group of us in Washington last week to try to gauge reaction, I guess, to the draft rule. There has certainly been a lot of interest and anticipation, because this aspect of the legislation is really at the heart of whether this law is going to work or not.

It's at the heart of it for this reason. When I had the pleasure, I guess, and the honor of representing a number of nuclear weapons production workers and their survivors during the legislative process, and when the debate came about about whether this bill should look like RECA and the benefit of the doubt -- rather, the presumption should just go to the claimant for the list of cancers or illnesses across the board, whether it -- and the answer that came back was, well, where it's clear-cut now we'll put people in the special cohort, but we want this to be a science-based program.

And so then the question was, okay, and what

happens if the data isn't there to do the science? And given that the hearing after hearing after hearing had demonstrated the absence of quality data, the absence of adequate monitoring information, the intent in some cases consciously not to monitor, in other cases records were missing. There was the wonderful story that was told about what happened to some of the data from Amchitka Island that I think wound up in one of those really cold, cold oceans off of -- between Alaska and the mainland.

But the core of this program is in the Special Exposure Cohort, because that's the only people -- only way people are going to ever feel as though, at the end of the day, if the data isn't there to reconstruct the dose -- and it's because the government failed to fulfill, or through its contractors, certain obligations -- that they aren't at the end of the day left holding the bag, and it's their fault because the data isn't there to make the case affirmatively. That means that broad presumptions and people are going to be compensated, right, for whom one could statistically say they may not have actually been harmed.

But there's a very powerful equity issue at work here. This isn't just a science question. It's a question of equity at the end of the day. And that's why the special cohort process exists, and that was the grand compromise, in a sense, not only about how much did this program cost, but about what are you going to do for those people who would fall through an awful lot of cracks that exist out there.

With that in mind, I want to just express some concerns with several aspects of the SEC process or proposed rule. And the first has to do with, as Ted and Larry have heard, what do we -- why is it that the threshold for endangerment is set at the level for 50 percent of the way between leukemia and the next most radiosensitive tumor?

And what comes to mind is a colleague of Phil Schofield's, Joe Garcia -- and I don't have the transcript today, but I want to try to get the transcript to you all, of a hearing that was held in Los Alamos on May 11th of this year. And Mr. Garcia worked in the hot dump in Area G, and he had leukemia, came down with leukemia after beginning employment a significant number of

years later. He had a bone marrow transplant. He's obviously incapacitated and can't work, but he's alive. And as he's described it, at least, there's very little data to support his exposures from having worked in Area G.

Now if the hot dump turns out to be -- and I'm not saying it is or it isn't today -- but if the hot dump turns out to be a good candidate for a Special Exposure Cohort group because it's not feasible to really estimate the dose, and Mr. Garcia is your lead petitioner and Mr. Garcia has leukemia, and it's not -- and in the process of coming up with what is your sort of maximum possible estimate of radiation dose you don't come up with a radiation dose -- if you come up with a radiation dose that's well above what he may -- for what you could estimate he may have had at its worst case potential, I guess (inaudible) when you use the word “worst case” it's sort of this maximum estimate process -- then he as a petitioner is going to find himself locked out of the cohort.

Now when we challenged, why set leukemia, and the answer is, well, it could be as low as one and a half rem of exposure -- and that seems

absurdly low; the charts that I have do vary anywhere for chronic myeloid leukemia from 1.2 rem to 19 for certain kinds of other types of leukemia at age 40, when that was your exposure. But at the other hand there's an equity question. Does the statute say in its two-pronged test where it's not feasible to estimate dose and people may have been endangered, does it say they may have been endangered except if you have leukemia? Are they carved out of the process by statute? I think not. I think there's nothing in the legislative intent that says you carve those people out.

Now the response we get back from NIOSH, in all fairness to staff, is, well, it's not a very popular cancer, and statistically it doesn't turn up all that often. And so, geez, it's -- so a few people fall through the cracks. And you can really take that attitude pretty easily until you're face to face with people who've been through it. And then it's different. And then all of a sudden that statistical explanation doesn't make any sense.

So when you go to Los Alamos -- I hope you'll have the opportunity to meet with Mr. Garcia and

hear him face to face, and see whether or not it makes sense to him to carve him out of a Special Exposure Cohort if he doesn't fall through this algorithm. But he's got leukemia. He's got one of these rare cancers. But you all have to sort of put your hands on the scale, it looks like, to say that number's too low, can't go there. That number's just too low. We've got to come up with something a little bit more plausible. And so you've come up with this algorithm of 50 percent of the difference between the next radiosensitive tumor. Well, I hope his potential exposure falls above that threshold, but all I can say is I don't see any legal authority for you to do what you did. I think you made it up, and it doesn't look right when you view it through the lens of potential -- people who have leukemia.

I also wanted to raise sort of a point about a suggestion that Dr. Anderson raised, which was this idea of claimants who have concerns about how the dose reconstruction process is going. And I -- by the way, this is not to say that I don't think it's going to go well. But let's just assume, for the sake of argument, people are in it, and they've been going back and forth with

NIOSH, and lo and behold, they just don't feel like the right quality of work is being done by the contractor, and they don't feel like the data that they know should exist is being chased down. Why not give them an opportunity to come to this Board through some formal process?

This is not to circumvent the adjudicative process with the Labor Department in any respect. The Labor Department's adjudicative process is very, very clear. What it says is after you sign OCAS-1 you go over there and you're turned down, you can file an appeal. The only thing the administrative hearing officer's going to deal with is was or wasn't this reasonably based, and then they'll remand it back if they determine that it was not reasonable. Well, they will not get involved in the Labor Department in any substantive analysis or assessment of the quality of the dose reconstruction. They will not get involved in the substantive what should the number have been as opposed to the number that NIOSH and its contractors came up with.

So I like that idea. I heard sort of murmurings of how much work did you expect this Board to do at certain points in terms of 90

petitions, and now we're going to be reviewing all this dose reconstruction and we're going to have a major undertaking in terms of review. But I think that's a really great safety valve. And I don't know what the lawyers are going to say about it, but in terms of the role of the Board, I think that would be a really valuable way to give people a sense that they're not boxed in without a place to come when they think things are off-track. And I don't know what the criteria is to let them in, because you could be inundated with those things on the other side.

In addition, I wanted to just point out one suggestion which I mentioned to Mark Griffon, but I want to offer to you all. There's one statutory criteria that was excluded from the proposal in the review, in terms of the Board's job in reviewing dose reconstruction. Under section 36.23 subpart (d)(2), it says:

(Reading) The President shall establish an independent review process using the Advisory Board on Radiation and Worker Health, one, to assess the methods established under paragraph one, which are your guidelines, and two, to verify a reasonable sample of the doses

established under paragraph one.

And this notion of having a feedback mechanism into your dose reconstruction rule-making and guidelines is very much contemplated in the statute. It wasn't necessarily presented today, and I understand why. But I just wanted to make sure it was on the record that that part ought not get left out when you finalize your report to the Board.

I had some suggestions with respect to the definition of feasibility. One of the concerns that we have, at least, is that the statute says that you have to not only determine whether it's feasible to estimate dose with sufficient accuracy -- there's a lot of emphasis that's been put on the sufficiency of accuracy. “Feasibility” is its own weasel word, kind of like the “reasonable likelihood” weasel word, and there's all these fuzzy terms in the statute which Congress charged you with trying to figure out. And we think feasibility ought to account for some reasonable notion that at some point too long has transpired in getting enough information to make a decision.

Now Phil Schofield touched on this a bit, and

I had some sort of very specific suggestions in this area. What happens if NIOSH requests from our friends at the Energy Department records on groups of workers, and the data is not forthcoming after three months, after four months, after five months? Or the data that comes in is so incomplete that you can't really work with it. At what point does NIOSH say it's not -- we can't come up with a reasonable estimate because we don't have data?

Now there could be any number of reasons why it's not forthcoming. But that's not -- it's not a question of second-guessing people's good faith here. The question is, from a claimant perspective, how long is too long for NIOSH to wait? Is a year too long for it to wait? Is two years long for it to wait? At some point it gets to the ridiculous, right? I don't know where the point of the ridiculous is, but I think there needs to be an outer bound at which NIOSH says we can't do the dose reconstruction because the information hasn't come across the transom to our contractors. And otherwise, claimants are left holding the bag, and they're -- they may call your 800 number, but there's got to be more than

that. There's got to be a cutoff point.

Shifting gears, I'd like to just spend a minute on a process issue that arose out of the last meeting, and I want to commend Larry for his good efforts at trying to get some key information that got into our hands at the end of last meeting which had to do with the CIRRPC, comparison between the CIRRPC or the 1988 screening dose information -– I think the copy of that report was circulated -- and the IREP model. I don't know if any of you have had a chance to compare the two, but I thought I would just put it up on the viewgraph here for a moment.

Now this is from Charles Land's report. Now this particular chart, I assume it's the same as in the final report -- I didn't double-check it -- that we were given dated June 11th. But this comes from the January 24th report prepared by NCI. And I just wanted to do some comparisons here for a moment and then raise a question.

In the first column is the 1988 CIRRPC report, as it's known. And this is what is used by the Veterans Administration for both screening and compensating people under the atomic veterans program for certain cancers and under certain

circumstances.

The middle column is -- and this number here, adjusted for a particular factor that was introduced, the center column there, and that factor has to do with reducing the baseline risks of the U.S. population. And in this case CIRRPC reduced it to, I think -- when they set the probability of causation they reduced it to ten percent of the baseline risk for all counties for each particular type of cancer.

And over here is IREP, which is -- and I assume these numbers are fairly close to what NIOSH used. And you can see by looking at the numbers, both in leukemias in solid tumors, that there was a significant increase between the CIRRPC numbers. Let's just take esophagus. Atomic veterans would be compensated at about 3.9 if they were exposed at age 20 at the 99 percent confidence interval, and you compare it with the IREP model, which I believe is 45. And so you see a jump here of, I don't know, maybe a 12-fold increase. And you can sort of get a feel for what my point is, which is that this is this interesting increase in eligibility criteria for the amount of radiation you have to get to get

compensated under two different programs involving radiation compensation.

This obviously left us with a lot of unanswered questions, and we went back to Larry to ask if we -- and to Kathy Rest -- if we could get a copy of what explains this particular differential. And we just received that by e-mail. I guess last Thursday I got a copy. Others had requested it from Congress as well. And there was a second set of data that we've been asking to get, which is the baseline risk data that was originally in IREP 2.1 and which was not available on-line, at least in the on-line version, of the risk coefficients of the excess relative risk per sievert for the various cancers. And so we're looking forward to getting that information; hopefully that will be in the pipeline soon. That will allow us, I think, to potentially cross-walk what's going on here exactly.

Now Dr. Land had laid out in the report that you all received a set of explanations for why there's this significant jump, and I think it would be worthwhile for the Board to spend some time with a diversity of perspectives debating

that. But I'm just going to raise a slightly different issue, because I'm really not qualified to get into the debate, which is the equity question. And I think it's a question of should this Board even look at the equity question.

Is it appropriate for an individual, say, at the Nevada test site who happened to be an atomic veteran who was there for a particular blast to be compensated at one level of excess relative risk per, say, sievert, compared with anywhere from three to 20 times higher amount of radiation required for an individual who happened to be working at the Nevada test site going in after the blast, or anybody who worked at Hanford or Idaho or anywhere else for that matter? I find it inexplicable how to deal with this. I don't have a suggestion.

But I, for one, am going to have a really hard time trying to explain to somebody who's got lung cancer, since that's the most common form of cancer leading to fatality, how you can wind up with a jump anywhere from 15 to 51; or given two very important factors, which are that most of the cancers, not all, but most of the cancers from the most updated atomic bomb survivor data

would favor the claimant because they're based on cancer incidence as opposed to cancer mortality, and because of the way that doses were estimated using the more recent DS-86 estimation for the atomic bomb survivors.

I think the Board ought to take a look at this question, and I think the Board ought to be pondering how it can be blessing a system for compensation where the outcomes are so radically different for potentially similarly-situated individuals. Because there's nothing in the statute that specified that you wound up with the results you wind up with under the NIOSH-IREP today. But this is -- it lays out here as a backdrop. It is applied as we speak today by the atomic veterans program for their compensation system. And when they were questioned about it, they clearly see they've got serious equity problems on their hands. So I just thought I would add that for discussion purposes.

DR. ZIEMER: Richard, could you show -- what does the top of that slide say? Could you just slide it down?

MR. MILLER: Yeah, and I'll tell you, they Xeroxed it wrong. They put the top of the paper

--

DR. ZIEMER: Oh, I see.

MR. MILLER: I apologize. It's the very last table in the report dated June 11th, and it is Appendix -- I think it's table E-4. Is that right?

UNIDENTIFIED: E-4.

MR. MILLER: Yeah, I think they Xeroxed the title off, unfortunately.

UNIDENTIFIED: Page 110.

MR. MILLER: And this is on the June 11th draft that you received.

DR. ZIEMER: I've got it.

MR. MILLER: My last -- do you want me to take a moment, Dr. Ziemer, to -- should I stop here?

DR. ZIEMER: No, I found it.

MR. MILLER: Last, I just want to underscore the last issue which is from the outside, at least, as we've mentioned, I think, on several occasions in earlier meetings, concerns about -- our concerns, at least, about the potential for conflict of interest in the selection of contractors.

And I know that NIOSH is working hard on

trying to get this contract awarded, and I know they've had some bumps on the road. But at the end of the day we're going to wind up with somebody who's dependent on the Energy Department for their income doing the dose reconstruction in some significant -- to some significant degree. And whether it's Battelle or whether it's SAIC or whether it's Oak Ridge Associated Universities, these folks get their bread and butter there.

And I really think it's very important that when you think about selecting somebody to do the work of assisting this committee in its independent review process, that the word "independent" means they have no contractual relationships with the Energy Department. The word "independent" has to mean something in the statute, and I would hope it would mean at least that. The statute made it clear the DOE wasn't supposed to do the dose reconstruction, but now DOE contractors are doing it. Maybe that's unavoidable.

But in terms of integrity, which Bob Tabor harped on, there are only a handful of people out there, at least in the United States that I know of -- and I can't speak to people overseas --

that fall into that category. And John Till's name has been kicked around. Dr. Makhijani's name has been kicked around. They've made friends and enemies out there. But the one thing that an awful lot of people, I think, believe is that people of that caliber, their integrity's unimpeachable.

And I would certainly hope that if this committee makes a recommendation, they get somebody who advises and assists you in your dose reconstruction reviews who is completely beyond reproach so that there's nobody can say at the end of the day that there's any aspect of the dose reconstruction process that ultimately doesn't speak to the credit of NIOSH. NIOSH is much stronger and in a much stronger position when it denies claims if the likes of Dr. Makhijani or Mr. Till come in and say this was a credible process. At that point it's really hard to bark at it, and I know that was certainly the intent in how they were used in other circumstances. And I hope you'll consider -- it doesn't have to be them, but it's an awfully small pool to fish from out there, and we all know who everybody is.

So I would just offer you, it's got -- they've got to be completely beyond reproach, and in my sense they also have to be critics of the system. If they're not a critic, if they're seen as part of it, then people will come back to them later on and use them, and say why didn't you, why didn't you, why didn't you, and why didn't you. So why not bring them in to begin with, and then when you've got them in the tent you're going to have the benefit of their advice instead of their spears at a later date.

Those are my thoughts.

DR. ZIEMER: Thank you.

Again, let me ask if anyone on the Board has questions or items for clarification of Mr. Miller.

(No responses)

DR. ZIEMER: Apparently not. Thank you very much.

Are there any other members of the public that wish to make comments?

MR. TABOR: I remembered the comment that I didn't make before, if you'll let me make that.

DR. ZIEMER: Okay. We'll count that as --

MR. TABOR: I'll make it quickly, and I can

make it right from here.

DR. ZIEMER: That's fine.

MR. TABOR: At the last meeting I reminded the Board about record-keeping. I'd like to remind us again about record-keeping. We have a lot of sites out there that are closure sites, and records are going to be going away.

I was hoping that there was a way that the Board could possibly influence whatever other agencies or departments there are in government to possibly suggest to some of these sites to go back into a mode of record retention, because recently I believe there's been some -- what's the word I'm looking for -- release or legislation that says that record retention is -- that's been lifted. I don't know if that's the exact words, but looking at not just the data you're going to be looking at but looking at some of the processes and the records on hand, the historical records of the operations of these sites, as well as the information from some of the old-timers, that's going to be very, very important in my mind.

And I really believe that, if there's a way that the Board has any influence to say to

whatever other agencies there are, that it might be beneficial to suggest that we not lose these records. Some of these sites are still going to be here for a long time, but Fernald is not. I just wanted to remind you about that, folks.

That was my fourth item that I didn't think of up there. Thank you.

DR. ZIEMER: Thank you.

We actually have at our disposal approximately an hour, and I'm wondering if the committee has enough -- the committee, the Board has enough stamina to use that hour as -- to do some of the evening work that's before you. We can leave it at your option.

But for example, Mark, if your group would rather do some work now rather than wait till after dinner, and likewise for our other group. So I'm going to suggest that we just recess from the formal meeting, allow the little subcommittees that need to work to stay and do their work. Others can take a break. But I think we can stay here and use the room. Is that agreeable to everyone? It might be a little more efficient if you do that work now rather than wait until after a big dinner and a few drinks

and what all.

(Affirmative responses)

DR. ZIEMER: In that case we'll recess from our formal meeting and go to our working groups.

(Whereupon, the meeting was adjourned at 4:19 p.m.)

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C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 270 pages, was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this 22nd day of July, 2002.

_____
KIM S. NEWSOM, CCR-CVR
CCR No. B-1642

[SEAL]