THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

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 Washington Court Hotel, Washington, D.C., on Wednesday, February 13, 2002.

NANCY LEE & ASSOCIATES
Certified Verbatim Reporters
P. O. Box 451196
Atlanta, Georgia 31145-9196
(404) 315-8305

C O N T E N T S

VOLUME I
February 13, 2002

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

(By Group, in Alphabetical Order)

ADVISORY BOARD MEMBERS

CHAIR
PAUL L. ZIEMER, Ph.D.
Professor Emeritus
School of Health Sciences
Purdue University
Lafayette, Indiana

EXECUTIVE SECRETARY
LARRY J. ELLIOTT
Director, Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health
Centers for Disease Control & Prevention
Cincinnati, Ohio

MEMBERSHIP

HENRY A. ANDERSON, M.D.
Chief Medical Officer
Occupational and Environmental Health
Wisconsin Division of Public Health
Madison, Wisconsin

ANTONIO ANDRADE, Ph.D. (Absent)
Group Leader, Radiation Protection Services Group
Los Alamos National Laboratory
Los Alamos, New Mexico

ROY LYNCH DeHART, M.D., M.P.H.
Director
The Vanderbilt Center for Occupational and Environmental Medicine
Professor of Medicine
Nashville, Tennessee

RICHARD LEE ESPINOSA
Sheet Metal Workers Union Local #49
Johnson Controls
Los Alamos National Laboratory
Espanola, New Mexico

SALLY L. GADOLA, M.S., R.N., COHN-S
Occupational Health Nurse Specialist
Oak Ridge Associated Universities
Occupational Health
Oak Ridge, Tennessee

JAMES MALCOM MELIUS, M.D., Ph.D.
Director
New York State Laborors' Health and Safety Trust Fund
Albany, New York

WANDA I. MUNN
Senior Nuclear Engineer (Retired)
Richland, Washington

ROBERT W. PRESLEY
Special Projects Engineer
BWXT Y-12 National Security Complex
Clinton, Tennessee

GENEVIEVE S. ROESSLER, Ph.D.
Professor Emeritus
University of Florida
Elysian, Minnesota

INVITED SPEAKERS

DAVID ALLEN
Health Physicist
Office of Compensation Analysis and Support
National Institute of Occupational Safety and Health

JAMES NETON, Ph.D., CHP
Office of Compensation Analysis and Support
National Institute of Occupational Safety and Health

TIMOTHY D. TAULBEE, MS, CHP
Health Physicist
Office of Compensation Analysis and Support
National Institute of Occupational Safety and Health

NIOSH STAFF/VENDORS

CHRIS ELLISON, NIOSH
RUSS HENSHAW, NIOSH
CORRINE HOMER, NIOSH
TED KATZ, NIOSH
MARIE MURRAY, Writer/Editor
KIM NEWSOM, Certified Court Reporter
TWILA SAITOW, NIOSH

AUDIENCE PARTICIPANTS

BOB ALVAREZ
NEIL BARSS
LYNNE FAIROBENT
MARK GRIFFON
JEFF HARPER
LIZ HOMOKI-TITUS
WILLIAM EARL JOHNSON
ALICE KELLEY
JEFFREY L. KOTSCH
SONYA LEVINE
MARTIN MATHAMEL
TIM McADAMS
RICHARD MILLER
FRANK MORALES
FRANK MORAN
LOUISE S. PRESLEY
JOSH SILVERMAN
CRISTAL THOMAS
WILLIAM D. ULICNY

P R O C E E D I N G S

8:31 a.m.

DR. ZIEMER: Good morning, everyone. I want to officially open the second meeting of the Advisory Board on Radiation and Worker Health. The Board members are here in the front at the table, and I'm not going to introduce them all. They were introduced last time. For members of the public, the names of the Board members and the support staff are on the tents, as they are called, just in front of each person.

Let the record show that all of the Board members are here, with the exception of Tony Andrade. And if I'm -- I'll ask the court reporter, I'm going to go off record just a moment.

(Off the record)

DR. ZIEMER: Now back on the record, there are sign-up sheets at the entry. If you have not already signed in, please do that. For members of the public, there is also a sign-up sheet if you wish to make public comments during that portion of the agenda. We ask that you sign up simply so we have an idea of how many plan to comment and we can apportion the time

accordingly.

One instruction for the Board members on the use of the mikes this time. Your mikes have a push-button in the front, and when you speak you'll need to flip that button to the on position and then turn it back off when you're not speaking so that we eliminate feedback.

I'd also like to point out to everyone, particularly members of the public, there are handouts on the table over in the far corner, and those handouts represent some -- both background material as well as material that may be used by presenters during the program today and tomorrow.

Although I'm not introducing the Board members individually this morning, we do, for the record, want to have our guests -- that is, the members of the public -- introduce themselves, and if you're representing an organization, to identify who that is. This information will likewise be in the public record. So if we could start on the far side and have each person there stand. If you speak loud enough, you may not have to use the mike, but the court reporter will try to get that information. Please identify. Thank you.

MR. ULICNY: Bill Ulicny with ATL International.

MR. MORALES: I'm Frank Morales with the Government Accountability Project.

MS. FAIROBENT: Lynne Fairobent with the American College of Radiology.

MR. BARSS: Neil Barss, SAIC.

MR. KOTSCH: Jeff Kotsch. I'm a health physicist with the energy group at Labor.

MR. JOHNSON: Earl Johnson, representing the ATLC, Atomic Trades and Labor Council, at Oak Ridge.

MS. SAITOW: I'm Twila Saitow, I'm with NIOSH.

MS. PRESLEY: Louise Presley, spouse of Bob Presley.

MS. HOMER: Cori Homer, NIOSH.

DR. ZIEMER: Okay, and there are some staff members. Maybe the other staff members sitting in the back could go ahead and identify for us also.

MS. HOMOKI-TITUS: Liz Homoki-Titus, Health and Human Services, General Counsel's Office.

MR. HENSHAW: Hi, I'm Russ Henshaw, NIOSH, Office of Compensation Analysis and Support.

MR. KATZ: Ted Katz, NIOSH.

MS. ELLISON: Chris Ellison, NIOSH.

MR. TAULBEE: Tim Taulbee, health physicist at NIOSH.

DR. ZIEMER: Thank you very much. So consider yourselves all introduced at this point. We're glad to have all of you here this morning.

You'll note -- oh, make sure you have an agenda. If you haven't already picked one up, I believe there are copies on the back table as well.

The first item on our agenda is the approval of the draft minutes of the last meeting. We've set aside a full 30 minutes to do this. I don't think it'll take that long since we don't have the draft minutes. We can debate about them, but due to the fact that there has been such a brief time since our last meeting, it's simply not been feasible for those minutes to be prepared and distributed. So the only comment I will make, and I will -- without objection, we will delay or defer the action on those minutes until our next meeting.

The only comment to make is, for members of the public, if you wish to have copies of the

minutes, they will be available to you as well. But there is a sign-up book for you on the table so that if you wish to have copies of those draft minutes, please sign up and those will be distributed to you as well, when -- once they are ready.

I'm going to ask the staff -- maybe I lost Cori there -- but are there any other announcements that need to be made at this moment? I think not. If others arise, we'll make them as we learn of them.

The first item on today's agenda, then, is a program report by Larry Elliott of the NIOSH staff. And Larry, I don't know if you want to come up here and make your report, that'll be fine.

MR. ELLIOTT: Well, good morning again, and it's a pleasure to be with you all again on such a short turnaround and short response time between meetings. I'm very pleased to be able to meet with you again and to take on the additional business of the Board.

Dr. Ziemer and I, in preparation of your agenda, had talked about what's called -- what we're calling a program report, just to let you

know a little bit of information about what goes on within the Office of Compensation Analysis and Support at NIOSH. I think I tried to tailor this presentation to give you that understanding, but in the context of where you fit in and what has been going on since the Act was passed, what's been happening at NIOSH in support of implementing our responsibilities. And this information, I hope, will give you a sense of what's forthcoming both for not only for the program but for the Board as well in its work in reviewing dose reconstructions.

Frankly, we're running on the ragged edge. Our products that we're now providing to you are preliminary in draft, but in order to achieve our goals, a goal of promulgating two rules by the first -- or by April; I hope it'll be the first of April and not the last part of April. We find ourselves in this dilemma where even our program books for today -- I'm glad nobody showed up yesterday -- we're short-staffed, and we're extremely tasked right now to keep ahead of the curve. And I think that's where the Board's at. I've really put a lot on your shoulders to read through all of the material that we provided and

get an understanding of the direction that we're trying to take this program, and make sure that we bring along your understanding of that direction and hear what your thoughts and comments are.

So that's the intent and the purpose of this program report, just to kind of set the stage and give you a little bit broader context of understanding about what's going on with this program and NIOSH's responsibilities, and your role in assisting us in those responsibilities.

So I'm going to go through a very brief time line here. The Act was passed in October of 2000. There were several people that were tasked immediately after its passage to start thinking about NIOSH's responsibilities as they might be delegated through the Department to us. In March of 2001 six people were detailed on special assignment to craft the implementation policy and guidelines and development of the rules.

We had a reorganization of NIOSH that was approved in July of last year that established this new Office of Compensation Analysis and Support within NIOSH. That reorganization plan that was approved included 22 full-time

equivalent positions, and I'll talk about those in a moment, but just to give you a sense of how few people are working to do such great things on this whole program.

We prepared the charter for this Advisory Board and got it through concurrence, and it was signed in August, shortly after OCAS was established. Then we come forward and published our notice of proposed rule-making for guidelines on determining probability of causation, the 42 CFR 81 that you reviewed and commented upon last meeting and during your teleconference. We also published an interim final rule on dose reconstruction methodology, and that was presented as 42 CFR 82.

And there's a reason why we went in different tracks with these two rules. The notice of proposed rule-making on probability of causation required you, by statute, to review and comment on it. It was open for 30 days for public comment period. We reopened that comment period to coincide with the last Board meeting, retained the docket open for your comments up until February 6th.

The rule on dose reconstruction was an

interim final, and that regulatory process track allowed us to start working on dose reconstructions immediately while the rule was being finalized, during public comment and to the point of finalization.

In October, October 11th, we received the first batch of claims from the Department of Labor. For us to receive a claim from the Department of Labor, what has to happen is two criteria are met: The claim has to have had the employment for the energy employee verified by DOL turning to Department of Energy and seeking that verification that the individual actually worked at the site or sites they claim. Second criteria test is medical diagnosis. The claim has to present a confirmed diagnosis, either a death certificate or a clinical diagnosis of the cancer. Then the claim is verified as eligible and sent to us.

On October 19th the President made announcement about your appointments to this Advisory Board. So a lot has happened in a short amount of time up to this point. Now a lot more has happened.

The first batch of acknowledgment letters -

and I'll talk about the steps in our process in a moment -- but this is significant and remarkable in that we're trying to -- we're working with batches of claims, and we're trying to turn batches through steps in the process as expeditiously as possible. So the first step is get the claim from DOL, the second step is to send a letter to the claimant letting them know that we have their claim in our hands, and they can contact us at this point to verify status of the claim.

As I mentioned, the public comment period for the dose reconstruction rule closed on November 5th. We reopened it again during your last meeting, and it is now open again for public comments on the dose reconstruction rule. That will close on March the 1st.

The first batch of requests for personal monitoring information data that were sent to the Department of Energy on November 27th. This is on individual claims seeking dose information, badge results and bioassay information from the Department of Energy to start our initial evaluation of the dose reconstruction process for that claim.

The public comment period for guidelines on determining probability of causation were again closed on December -- and as I mentioned, they reopened. We've reopened them to coincide with your meeting.

On December 20th we conducted the first claimant interview as an expedited interview. Well, expedited the interview because the claimant was wanting to share their work history with us before they passed, and we thought it was beneficial to get that and accommodate that situation.

On December 27th of 2001 the first batch of letters informing claimants that we had gone to DOE seeking information regarding their claim were sent out. Again, we reopened the public comment period. That's throughout this.

You all met in January, on the 22nd and 23rd, and I know that was a hectic two days with a lot of information provided. Again, the public comment period closed on those rules, and we've again reopened them.

Let me talk a little bit about the staff. I mentioned 22 FTEs approved. Not all 22 are filled. I'm blessed by having a very competent,

exemplary staff. You met Dave Sundin last meeting. You know Jim Neton from last meeting; he'll be here shortly. Martha DiMuzio, you checked in last meeting, she was here. Nichole Herbert was also here as my secretary. They're not here today. They're back tending to business in Cincinnati. Jim will be here shortly, as I mentioned.

And our technical support team, you met Russ Henshaw last time. David Allen, who will be here shortly this morning to present to you later. Grady Calhoun you met last time; he's back in the office for this meeting. Tim Taulbee's here today. He'll be presenting to you, another health physicist on staff. We have a couple of vacancies in guise of a statistician and an office automation assistant for this team.

Then we have a records management team comprised of these individuals. You met Trudy Zimmerman last time, I believe. And we have Paula McCreary, who's an office automation assistant or a secretary to this team; computer specialist Nancy Kuo. Chris Ellison's here today, who's a health communications specialist, and a very vital job she performs for us. She's

responsible for our web site, and if you haven't -- if the public hasn't been there yet, I'd encourage you to get on there. We have a lot of good information there for you, and I think it's only going to get better. And we have a number of vacancies shown here as well.

We've augmented gaps where we need assistance in technical support by bringing contractors in, and I've listed those as well. I just want to give you -- share this level of information with you to give you a sense of how few people are doing the great things that are going on.

I'm going to talk about the steps in this process now so that you get a sense of this, and I'm also going to give you a sense of what we're facing. What you don't see at these meetings, what a lot of people don't see, is the face on this program, the claimants. And my folks have to deal with those folks every day, and it's tough.

Right now we understand that there's more than 12,000 non-Special Exposure Cohort cancer claims staged in some point of verification of eligibility for the claim, ready to come to us.

That number may decrease. It may increase, depending upon whether verification is achieved or not on an individual claim.

In step one, as I mentioned, the claims come to us once they're verified. This kind of portrays how we saw those claims coming to us during these months, and gives you a sense of the increase by months that we're seeing. These numbers -- all the numbers I'm presenting to you are as of last Friday.

Step number two involves sending a letter to the claimant letting them know that we have their claim in our hands, and we're beginning the process of dose reconstruction. The letter tells them that this point in the process they do not have to give us information. We'll be seeking them out to find information.

The first thing we're doing is we're evaluating our own records for information relevant to their claim, making an informed decision about what we need in addition to that, and then we're taking the next step to go to DOE to get the dose information. And so that's shown in step three, and this is where we're at as far as sending information requests to Department of

Energy, only for badge-related data and bioassay data.

In step four we also follow back up with the claimant to let them know what we're doing, that we've approached DOE for the personal dose information that we think they should have and we need to start the dose reconstruction with.

In step five, this represents the number of claims that DOE has responded to us with information, and these keep trickling in all the time.

In step six, this is where we do the initial review of that information provided to us by DOE, in conjunction with whatever we had in our hands, and make a decision do we have enough, given what we've been provided and what we have from our own holdings, or do we need to go back to the DOE site and request specific information that'll fill a gap or an information need in pursuing a dose reconstruction to completion?

We've conducted, as I said, only one phone interview, so you see the numbers are decreasing. We're now getting to the apical point, top of the pyramid, if you will, of where we're at with all of this.

We've gone back to DOE at this point in time with 21 additional requests for information, and we're going to have to work with DOE to pursue that additional information that we want.

How many dose reconstructions have we completed to date? None. That's relying upon us finalizing the rule, getting your assistance in doing that.

So as we proceed through today's business, I want you to keep in mind what we are asking of you. We need your review and comment on the dose reconstruction rule. I call your attention again to the three questions at the start of that rule. I've tried to help, through this presentation, frame what I think we're doing with regard to those questions, that we are being interactive with claimants, we are seeking information from DOE. The presentations you're going to get shortly from Jim Neton and Tim Taulbee and Dave Allen are going to take you in a little bit more detail into dose reconstruction methodology.

We're advancing that to you because we need to make sure that we're off in the right direction. We also need to make sure that we bring along everybody on this committee with the

same level of understanding. If there's one member of the committee that feels that they don't have a grasp of the direction that we're going with this, we need to work together to make sure we all bring everybody along together on this.

This is important, I think, because not only are there legal interests here in processing a claim to final adjudication, but there's also technical interest here to do it right. And so when we're talking about accuracy of doing dose reconstruction, we're talking about giving an accurate answer in the dose reconstruction input parameters that go into the IREP to make a determination for that claimant.

We've also had a number of phone calls coming into the office -- and this is something else we're dealing with on a day-to-day basis. We're going to have to deal -- look at how the Department of Labor handles their customer service, and we're examining models and methods to react to the number of phone calls that we're getting. We're trying to get our web site page up where a claimant can tap into that and find out the status of their own claim, and we're

striving to get that in place.

We anticipate a number of claimants might want to visit our offices. In Cincinnati we're at the crossroads of three interstates, and we're in the back yard of three sites, four sites. We're not that far from Oak Ridge. We know people are going to be driving by and thinking, oh, I'll just stop in there and see my claim. I'm concerned about this because of how we present ourselves, but also because of security. There's money vested interests here. People want to know when they're going to get it and how soon they're going to get it. And we're dealing with some people who are deserving, and they're also as well frustrated in trying to understand this process. So we're going to accommodate those visits, and we're going to do our best to provide good customer service to these folks.

We provided a copy of the amendments to the Act in your briefing booklet. These are fixes that were put together and attached as amendments in the Defense Authorization Act passed in December. One of those things that came to us from these amendments is this need to do a residual contamination study of the atomic

weapons employers, with these two purposes in mind. So this is not something the Board is engaged in or is asked to review on. We want you to know we are doing it, though, and we think it will inform our efforts on dose reconstruction as we proceed with AWE claims.

We are bound to do our level best to try to meet the intent of Congress here, and provide reports back to them on this time frame as they've asked for. We have contractors in place who are doing this work right now.

So that's for your information, to give you a little broader context of what's going on with the program. Hopefully you'll see some information here that might aid you in your deliberation about answering the questions in the rule. And if there are any questions, I'll respond.

DR. ZIEMER: Larry, let me begin the questions, and we'll open it up for others, but first I'd like to ask about the staffing levels. Are the staffing levels that you showed us -- once you fill those vacancies, are those seen as being adequate to handle this program once it's going full-fledged, or do you anticipate further

staffing increases?

MR. ELLIOTT: This was the initial plan --

DR. ZIEMER: But it must have been based on an anticipated number of claims. Based on what you're seeing, are we on track?

MR. ELLIOTT: It was based on 8,000 claims in the first year. The plan was to augment technical support and expertise as necessary through contracting mechanisms. We have a dose reconstruction request for proposals on the street right now, which the proposals are due next -- the 20th, next week. That contract will support the bulk of the work on dose reconstruction, with this staff providing the oversight of that effort. We're going to have to wait and see as to whether or not we need different skills and different positions to be brought into the staff to handle what maybe we didn't anticipate. But we had -- you know, depending on how this goes and what our experience and understanding base becomes, we could go back and ask for additional support.

DR. ZIEMER: Roy DeHart, and then Jim.

DR. DeHART: Roy DeHart.

Two questions, Larry. The Special Exposure

Cohort is going a different track, at least now.

MR. ELLIOTT: The Special Exposure Cohort guidelines are being -- have been prepared as policy guidelines. They are in the Office of the Secretary for review and concurrence right now. What the Office of the Secretary decides to do with them is their discretion. They may come back at us to finalize as policy guidelines, or they may say we think it better to go with a proposed rule here. So we're waiting to see what the Secretary's desire is.

DR. DeHART: Thank you. The second question, you're telling me that the initial letters are going in to the Department of Labor, reviewed for the two criteria, then coming to you, and then going to DOL. Why can't that be short-cut?

MR. ELLIOTT: I may have confused you. The claim is submitted to the Department of Labor through the use of the forms that they have provided to the claimants. The eligibility is verified by the employment and then the medical diagnosis. Then if that happens, the claim is verified eligible, DOL sends the claim to us for dose reconstruction. We're going to DOE then to

obtain information on dose, badge data and bioassay data that can be used. We're not going back to Labor, so I may have confused you with that.

DR. DeHART: No, I'm sorry, I was confused on the question. What I don't understand, what role are you playing in the interim between the two, between the Department of Labor to you and then sending to DOE? Could Labor not simply go to DOE and ask them to start looking at exposure?

MR. ELLIOTT: We think it's important that we make that step because, first of all, we've proposed that we have a number of research data in our hands from prior studies of some of the sites, in order to diminish the impact upon DOE, and they're getting considerably impacted by requests for information, not only from the Federal side of the program but from the state comp side of the program as well.

It made more sense to us to get the claim, understand what the cancer was, where they worked, and then make the approach to the sites with the specific requests for information that we need. We didn't feel it appropriate to rely on Labor to do that in advance of sending it to

us.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah, Jim Melius.

You can defer this question if you're going to present it later or if you think it's more appropriate, but I have some questions regarding how you make a determination that the records received from DOE are incomplete. Now I believe, based on the process so far, you're doing that based on what you receive back from DOE, because you haven't really interviewed more than a -- well, I guess you've interviewed just the one worker. Are you going to be talking about that later, because I think that's sort of a critical question.

MR. ELLIOTT: I can answer that now, and then hopefully that will be embellished more with the presentations you're going to get.

We see this as a progressive set of steps to accrete information necessary to develop the case file. And as I said, first we check our in-house holdings, then we approach DOE for just a straightforward, personal dosimetry information -- badge data and bioassay data. And this is designed to accommodate our need for efficiency

in turning the claims around.

And Jim will talk, and Dave and Tim will talk about this a little bit as well in their presentations, how do we achieve that efficiency if a claim is -- apparently the dose is high enough, and we add what missed dose that we can readily add and move that through the process toward final adjudication and getting a decision, that makes sense to us.

Likewise, if the dose that we get back from DOE and the relative information needed to complete a dose reconstruction, and the worst-case scenario applied there would never achieve an award, we need to know that and we need to tell the claimant that as soon as possible so that we avoid frustration on their part.

It's the middle group that we're going to focus our attention on, on doing comprehensive dose reconstructions on. We bring the interview of the claimant into that process after we've got the first batch of information back from the Department of Energy. So once we've got the dose on an individual, we may go back to DOE requesting more information, but we're going to take the next step with the claimant interview

and start pulling that information together. We may go back to DOE more than once on an individual claim.

How do we verify what we've got from DOE? Is that part of your question, how do we test the veracity of that information? If you've gone through the implementation guides you'll see some of the underlying assumptions there, some of the types of information beyond personal dose monitoring information that we feel we need to seek to better our understanding and be more complete in our dose reconstruction process. We're working on an MOU with Energy to gain access to this information. We feel that's -- we interpret the Act to -- that is their responsibility to provide us access and provide the information necessary to do complete dose reconstructions. So this is being worked out. It's not fully there yet.

DR. MELIUS: Do you have a time table for that, because I think it's going to -- I'm not sure where the process is, but I think it's going to be hard to sort of assure that you've received everything unless you've worked out some sort of an arrangement with DOE that I won't say

guarantees that, but ensures a complete effort on their part.

MR. ELLIOTT: I don't have a time table to present to you. There are a number of different efforts, that the culmination of those efforts I hope are going to happen all about the same time, in April. I'm not prepared today to talk about how that time line looks for any given individual effort, and when and where we might find ourselves on-track or off-track.

DR. ZIEMER: Gen Roessler.

DR. ROESSLER: My question's about the dose reconstruction contractor. You've already answered part of that, but it seems to me this is -- it's very important, as I read through the documents, to make sure that whoever's doing that work, almost on an individual basis, remains objective. Because there's some details that just really that we have to, I think, as a Board assure that that's happening. Who looks at the proposals and selects the contractor?

MR. ELLIOTT: This is done according to government procurement standards. There is a technical review team that has been established -- my staff represents the bulk of that team -- to

review all the proposals. Then there's a business review that the procurement office conducts. There's weighting factors associated with the proposals. There's an evaluation guide that is prepared to evaluate the proposals against, and it's on a point basis. And then we have the -- we have a -- in that process there's a deliberation of who to award to, and negotiations are started toward the award. The award will be made, the decision for an award will be made jointly by the program and the procurement office.

DR. ROESSLER: And then I think you answered this question. Once the contractor is selected, then your staff provides the oversight?

MR. ELLIOTT: That's right.

DR. ROESSLER: And is that pretty much an ongoing --

MR. ELLIOTT: Yes.

DR. ROESSLER: -- all the time sort of -- I don't imagine it would be looking at individual decisions?

MR. ELLIOTT: We will be. We will be doing it --

DR. ROESSLER: You'll be looking at--

MR. ELLIOTT: We'll be doing dose reconstructions blind against the contractor. We will also be doing -- in our quality control program with the contractor we'll be evaluating a sample of dose reconstructions. And you play a role in your responsibility to review dose reconstructions. So that's something we're going to have to talk about, how do we frame that work, how does that happen.

DR. ROESSLER: I don't think you have enough people.

MR. ELLIOTT: Well, I appreciate those comments. But this is for information, and just to give you an insight and a context to work from. And believe me, I understand where I'm at, and we're trying to do the best we can, and I have great people doing great things.

DR. ZIEMER: And I might insert, Gen, and you may recall at our last meeting we talked at least briefly about the fact that this Board will probably need to establish a working group of some sort to look and sample the dose reconstructions as, in a sense, part of a quality control to satisfy ourselves that they are being appropriately done. So I think it's likely that

we ourselves will have some sort of ongoing role in that process.

Yes, Wanda, I believe, has a question.

MS. MUNN: Yes. Larry, this may be premature, given the state of where we are. But if I understood your presentation, about one-fifth of the cases you have received from DOE have had to involve some sort of additional interaction with them?

MR. ELLIOTT: We've gone back for additional information, yes.

MS. MUNN: And I guess what I'm wondering is whether you consider this just start-up issues, getting the program off and rolling, or do you anticipate that over the long haul that might signify about the number of double feedback interactions that --

MR. ELLIOTT: I think it's too early, it's too premature to make any type of interpretation of these statistics I've shown you today. We are getting underway. It's an evolving process.

MS. MUNN: I understand.

MR. ELLIOTT: We are working with Energy to assist them in enabling their sites, and the people who respond to our requests understand

what it is we want. Some of these that you see are AWEs, and while we got all the information right now from DOE that DOE has, we still feel the need to go after some additional information that the AWE might have and may not have.

MS. MUNN: Yeah.

MR. ELLIOTT: Some of these that you see here that went back to DOE were simply where they didn't -- the point of contact at a given site didn't understand what it was we were seeking, and sent us cumulative dose, as an example.

So this is premature to use these numbers to try to do trend analysis, but we are collecting these kinds of statistics. We're monitoring. We know how many claims are at DOL for a given site. We get a monthly update on those, so we kind of target what the work load looks like for a given site when we talk about doing profiles of a site. So there are these kinds of informative statistics that are going to be forthcoming, but we're not here yet to be able to interpret all of those.

DR. ZIEMER: Bob Presley, I think, has a question, and then Jim.

MR. PRESLEY: Bob Presley.

Larry, are they -- is there an effort underway to broaden the Special Cohort facilities in any way?

MR. ELLIOTT: Well, that's the Special Exposure Cohort guidelines, petitioning process guidelines that I mentioned earlier, that we have developed and are in the Department in review.

DR. MELIUS: To follow up on Genevieve's question from earlier, and one part of it you answered, the other you didn't. How do you deal with potential or perceived conflicts of interest with your dose reconstruction contractor? Is there a process similar to, I guess, what the Board's gone through in terms of handling those situations, or how do you do that or plan to do that?

MR. ELLIOTT: The RFP calls for a plan in the proposal from -- to speak to this point, how will conflicts of interest be handled by the contractor, should they be awarded. There are several other deliverables besides just -- within the proposal besides that plan, a quality control plan. This is a conflict of interest plan. How will they address somebody who works at a given site, or somebody who is on their staff who was

involved in radiation protection program at a site or maintaining records at a site, and how will they handle avoiding perceived conflicts of interest of individuals dealing with those?

Once we get the proposals in we evaluate those plans, and we will negotiate with the individual awardee on what we think the proper plan should be.

DR. MELIUS: Can I follow up on that? Will there then be a final plan that would be a public document or part of -- available as part of the process so a claimant would understand that if --

MR. ELLIOTT: Yes.

DR. MELIUS: Okay.

MR. ELLIOTT: Yes. Yes.

DR. ZIEMER: Henry Anderson.

DR. ANDERSON: Just quickly, you're tracking individually the process and the recall issue, and you have flags in there on time lines. Because I could see you sending a batch of requests into a specific facility, and very quickly you might get back some, but then some don't come back from that batch. And then what flags do you have that maybe they're having difficulty or there's some problem? Because I

think you'll get a kind of a standard curve of response times, and the tail that's out there --

MR. ELLIOTT: Right.

DR. ANDERSON: -- you want to be sure that you're aware when a problem has developed, because you may then go into your alternative exposure –

MR. ELLIOTT: Right. Absolutely, good question. And even those we're dealing with these on batch basis, once we send off to DOE, we watch and monitor on an individual claimant basis. We're asking DOE to turn a response around to us in 60 days whether they can find the information or not. In 60 days' time on each individual claim, we need to hear back from DOE on where they're at. Now if they find the information we've requested in advance of 60 days, certainly we've encouraged them to send us that information on an individual basis, not wait until the batch is complete.

DR. ANDERSON: Okay.

MR. ELLIOTT: So we're monitoring each claim, what its status is, has it passed the 60-day mark. Then we go back to DOE and we remind them if we haven't seen any action on it.

DR. ZIEMER: Larry, could I follow up on -- and this may be a question that I should be addressing to someone other than you -- but do we have any knowledge or sense of the extent to which DOE has dedicated resources and personnel to supporting this effort versus just handling claims as they would anyone else in their system asking for their exposure reports?

MR. ELLIOTT: Well, Josh Silverman's here from DOE, Office of Worker Advocacy. They have an office established to handle their responsibilities under this program, which include more than just responding to requests from us. They have the physician panels they have to run for the state comp program side of it. I can't speak to number of staff --

DR. ZIEMER: I wonder, Josh, if you'd be willing to comment on that briefly? Josh, are you here?

MR. SILVERMAN: Yeah.

DR. ZIEMER: You don't have to if you don't wish to, but if you're able to -- just for our benefit, so we have a feel for what's happening at DOE.

MR. SILVERMAN: Very briefly, we've been

working very closely with NIOSH and with the Labor Department, and we have provided some funding for major field sites for their records activities. So we were concerned that this not look like another unfunded mandate coming down from headquarters. We are in regular communication with our field sites and continuing to help smooth this process. It's a new type of request for many of them, and so there are many issues to be resolved. But we're working on that, I think closely with NIOSH and with Labor, for the type of information that they need from our sites.

DR. ZIEMER: Thank you.

Other questions? Henry?

DR. ANDERSON: Of the -- I noticed your phone calls is going up. We're early in February and you're already high. What types of calls -- are those people wanting to call to find out what's the status of my claim?

And then the next question would be are you thinking of having, and maybe already do, an online tracking system that would then reduce the calls coming in, because people would be able to look and see --

MR. ELLIOTT: Yes.

DR. ANDERSON: -- where their claim is in the process.

MR. ELLIOTT: Yes.

DR. ANDERSON: Because the calls will start to eat up your processing time, and it gets to be a real vicious circle.

MR. ELLIOTT: This is -- you're absolutely right. This is something I mentioned earlier, that we're -- I'm very sensitive to the claimant interests here, the number of calls that we're getting in, the fact that we may have walk-in visitors.

The calls to date have been varied, from exactly what you mentioned -- what's the status of my claim, where's it at, what are you doing with it, when can I expect a decision, why aren't you moving faster? Educating people on this program and the process that their claim must go through is a big component of what Chris does and the other folks in my office who answer the phones.

Yes, we do plan -- I mentioned this briefly in my talk -- we have one page on our web site where you can get much of this information right

now about how many claims does NIOSH have in our hands, where they're at in the process. We have had a plan from the very start to allow an individual claimant to enter through the web site and determine their status of their claim. We've had some difficulties in getting that approved and set up on our web site because of Privacy Act-related concerns. We've had to deal with those, and we're moving forward with trying to get that in place, because it will help us reduce the number of contacts by telephone. It's not going to do away with all of them, though. We know that, and we want to be responsive to these people in many ways.

That's a big side of the work that we have, dealing with the claimants. And we've been to Department of Labor's Jacksonville District Office trying to examine their operation and their organization and their flow of work. They have a whole group that deals with customer service who answers the phone, and how do they do that, and how do -- you know, we don't want to leave folks hanging on the line waiting for somebody to talk to them. Some of these folks are elderly and can't hear very well. We need to

accommodate that. We're looking into all of that, and we're -- I don't want to fail in that regard. We're going to do our level best to achieve success there.

DR. ZIEMER: Okay, Jim.

DR. MELIUS: Just one comment. I would just like to ask the Chair if we can come back to some of these issues, particularly regarding the oversight and quality control and so forth over this process. I think after we've gone through the presentations, and maybe either this afternoon or sometime tomorrow, we spend some time on this issue, because I don't think we can sort of finish our comments on dose reconstruction without at least thinking through and starting some discussion on those sort of -- our role in this process.

DR. ZIEMER: We most certainly will do that, Jim. And after we hear the discussions -- for example, the presentation by Jim Neton and others -- I think some of these will flow naturally out of those discussions, in any event. So we certainly will keep that in mind.

Larry, thank you very much. This has been very helpful, and I'm sure many of these issues

we'll be digging into in great detail as we proceed.

MR. ELLIOTT: I appreciate that. I'd just add this, that we're trying to bring you along with your understanding, and I'm trying to get that delivered in as non-technical laymen's terms as possible so that we achieve some level of transparency here and understanding. And again, a lot of what I just presented is really -- I want it to be information for your deliberations and provide a better context.

And I hope we can get to that level of talk about oversight, but I really think we need to focus on providing comments on the general rule, and then we can work together --

DR. ZIEMER: Right.

MR. ELLIOTT: -- on these other issues in the implementation guides and other things like that as we proceed.

DR. ZIEMER: It certainly has provided for us a good framework to see what sort of the big picture is as your office undertakes this extensive task.

I want to focus for a moment on the agenda and point out that after our break, which will be

coming up shortly, we have on the agenda recap of the Advisory Board's comments. That recap will not take the full hour, so it's my hope that we'll be able to start on the presentation of the Part 42 reconstruction rule a little bit earlier than shown on the agenda, because that's where we need to spend our time in any event as we dig into Jim Neton's presentation.

Before we take our break, I notice that there are many more visitors and observers and members of the public that have joined us since our opening introductions. So several comments I would make: I would ask if those who've joined us, if you've not already done so please sign in. There's a sign-in book out in the foyer. If you wish to make public comments at that point in our agenda, which is later in the afternoon, please sign up in the public comment book so that we know how to apportion the comment time and period. Again, I'd point out that there are copies of handouts on the table in the far corner over here in the room, and please avail yourselves of those handouts.

And then finally, if you were not here during the introductions, we now would like to

ask you, observers and members of the public, to identify yourselves, your name, and if you represent a particular group, what that group is so that we have this for the public record also.

MR. HARPER: My name is Jeff Harper. I'm an attorney with Harper and Associates and a contractor with DOE.

MR. McADAMS: I'm Tim McAdams. I'm a lawyer with Westat and a contractor with NIOSH.

MR. SILVERMAN: I'm Josh Silverman with the Department of Energy.

MS. KELLEY: Alice Kelley with the Department of Health and Human Services.

MR. THOMAS: I'm Cristal Thomas. I'm with the Office of Management and Budget, and I'm with the CDC (inaudible).

MS. LEVINE: Sonya Levine from the Department of Labor, Office of the Solicitor.

MR. MATHAMEL: Marty Mathamel, I'm an independent environment safety and health consultant.

MR. GRIFFON: Mark Griffon, CPS. I'm a contractor with PACE International, Inc.

MR. NETON: I'm Jim Neton. I'm with NIOSH OCAS.

MR. ALLEN: I'm Dave Allen. I'm with NIOSH OCAS.

DR. ZIEMER: I want to ask the court recorder, are there any of those names that you were unable to get --

MS. NEWSOM: Yes, there were.

DR. ZIEMER: All of them, huh?

MS. NEWSOM: Several of them.

DR. ZIEMER: Do you need us -- or you might be able to get them from the sign-up sheet.

MS. NEWSOM: Yes, I'll get copies of the sign-up sheet.

DR. ZIEMER: Okay, we'll figure it out.

MS. NEWSOM: Thank you.

DR. ZIEMER: Thank you.

We will now take our break, and I'd like to reconvene, if we can, at about quarter of -- let me see, how much -- yeah, that's about right. Twenty minutes should be plenty, so at 9:45 we will reconvene. Thank you.

(Whereupon, a recess was taken from 9:28 to 9:55 a.m.)

- - -

DR. ZIEMER: I pointed out to the NIOSH communications person who's here today that the

best tool for communication, I've found out, is this gavel. It really works well. We'll call the meeting back to order.

The first topic that we have before us now is the recommendations of the Advisory Board relating to 42 CRF 81. For the benefit of members of the public who might not have been here last time or who are involved here for the first time as observers, at our last meeting the Advisory Board did some working group activities on the second day to develop some preliminary drafts for comments to be made to the Secretary of Health and Human Services relating to the proposed rule-making, 42 CFR 81.

After our meeting, the wording on -- the proposed wording on our advice was further refined by the working group and then distributed by e-mail to the members of the Board.

The final document was acted upon and voted upon in a conference telephone call that was held -- when was that held? It's -- the time flies so fast when you're having fun, I -- yes, it was recently, a week ago or so. That was an open telephone call, open to the public.

The final document is available -- is it on

the table, let me ask? It's on the table --

MR. ELLIOTT: Yes, it's on the table.

DR. ZIEMER: -- and it appears on the Advisory Board's new letterhead. It looks like this (indicating). It has a logo and the name Advisory Board on the top.

The document consists of two parts. One is the letter over my signature to Secretary Thompson. That letter explains what we did at our first meeting. That letter also includes, in the second to last paragraph, a -- what we might think of as a recommendation, but really took the form of a suggestion relating to the composition in membership of the Board. Since the Board is not specifically asked for advice on its own composition, we simply put this in the form of a comment, and you will see that there. It has to do with the Board makeup in terms of representation from the sector which we identified as the nuclear production worker sector.

And then the document includes, as enclosure one, specific comments on 42 CFR Part 81. The comments are grouped into three parts. Those three comments are broad comments relating to the

questions asked in the preamble of 42 CFR 81, the draft rule-making, and those comments are there for your information.

These have been sent to Secretary Thompson. They were sent on February 6th. I've not yet received a letter back from Secretary Thompson telling me that this is the best advice he's ever received, but in any event, the information has gone forward.

I don't know if any of the committee or Board members wish to make any further comments on this document. Let me first ask if there are any questions or comments on the document as it went forward.

(No response)

DR. ZIEMER: Then I don't think -- oh, yes, Henry Anderson has one question.

DR. ANDERSON: Just for the public that was not -- I think it's important for them to know that there was unanimous support for the letter and the issues raised in it, so it was -

DR. ZIEMER: Okay, thank you for that comment. Yes, all of the Board members were present on the conference call, and the final vote was a unanimous vote to support the content

of the recommendations.

I might add that there was some discussion in the process as the Board developed various drafts of the document. There was discussion about how and at what point the public should be involved in the process. There is indeed some debate on how this should be handled in the public forum. It's not clear to me that we know -- it's certainly clear that our process is to be open.

The issue of at what point what are sometimes called pre-decisional drafts are made public is a question. There certainly is the possibility, and maybe even the probability, that the FACA rules, as applied to boards such as this, may not be quite the same as the rules that apply to Federal agencies as far as pre-decisional drafts.

In any event, it certainly is our intent that the process be open to the extent that we're able. Technology may have moved ahead more rapidly than even FACA anticipated, so that as we get into e-mailing each other with minor and major changes on documents, keeping the public informed becomes problematical.

On this particular document it appeared that at least one group had access to the wording and others in the public may not have had. And in fairness, I think in the future we need to think of ways that, if the process is to be open, how we can do that; and make documents, if they are to be open, available to the public early on. We were very much pressed for time, and so that some members of the public did not have access to the proposed comments until the time of the phone call when they were read into the record.

And it certainly could be argued that in fairness that does not give the public much time to review and react, so we need to be giving some thought. I think the Board needs to think about it, and perhaps with input from Board members and the NIOSH staff we can think about the extent to which we might want to even have some comments in our operational rules that we adopted last time as to how to handle these sorts of things in the future. And we can certainly have some comments on that now. I'm not suggesting that we try to solve the problem now, but certainly feedback's important.

Jim.

DR. MELIUS: Well, I am just -- maybe I'm jumping the gun, but if we're going to be putting together comments on dose reconstruction, I think we're going to have to meet -- confront this issue very shortly.

And my suggestion would be -- I think it's simple, and Larry, you can tell me if it's feasible -- is just post all the drafts and comments on the web site, and as they come in. And we copy Larry or whoever you want us to copy on each comment, and that's posted so it's public, and drafts are public. And that can be done, I think, in a timely fashion, and I think that -- we'd announce it at the meeting, so at least people attending, the public would know about what might be coming up there, and then it would be available as it went along. Again, most of the comments are just sort of grammatical or wordsmithing or whatever, which is fine, but then it's -- everyone sees it, and then there's no question of what's being missed or whatever.

DR. ZIEMER: Yeah. And Larry, you might want to comment on that.

But let me also insert, and then also I would suggest that any public comments on the

comments be also public. On our particular draft, I received personally comments from a public group, and I think the other Board members were copied on this. But it's not clear to me that those comments themselves were public at that point.

So we did have -- those were, in a sense, read into the record. We didn't verbally read them on the telephone conference, but we asked that they be included in the public record of the telephone conference. Because I think in fairness we also want the public responses to be public, and not just to the Board members. So it's sort of fair is fair; let's get everything out in the open.

Larry, please.

MR. ELLIOTT: Yes, certainly we can put them on the web site, and that would be our intention to do so, and the public comments as well, as they are forthcoming.

DR. ZIEMER: Right. In that case, any comments -- we would ask that comments that come in not be directed to the Board, but just write to the NIOSH staff so they can be made publicly available, or both, but --

MR. ELLIOTT: What we have to achieve here is the deliberation of the Board needs to be done in a public forum.

DR. ZIEMER: Yes.

MR. ELLIOTT: And so --

DR. ZIEMER: And so we certainly want to make every effort to do that, and if this is a way we can handle it readily, certainly I don't think we even need to take any action other than to realize that that's the process.

Other comments? Roy, you were wiggling here a little bit. Does that mean --

DR. DeHART: No, I was just thinking about what we did last time and what the process would be this time. Would then we address our comments to the other Board members as we have done, and include then the address for the web site? Do we need to do that, or Larry, you would pick up on the address –

DR. ZIEMER: No, to the staff, I think, and then they would put it on the web site.

MR. ELLIOTT: I would ask that you include me and Cori on your e-mail transfers, and we will make it happen on the web site. The only limitation with the use of the web site is that

not all of the public has access to the web. And so we'll have to make accommodation for telephone requests for that kind of information as well, and we'll have to make that announcement.

We'll see how we get through here today and tomorrow. Do we need another teleconference, and if so, then we should talk about how we conduct the business of the Board after we leave here and before we have that teleconference to finalize your comments.

DR. ZIEMER: Thank you. Other comments at this point on that issue?

(No response)

DR. ZIEMER: Thank you very much.

We're going to proceed, then, with the presentation by Jim Neton, which gives us more detail on the dose reconstruction area. And then there will later be further details on both external and internal dose reconstruction by the other staff people. But we'll start with Jim Neton, and Jim will give us sort of an overview on the dose reconstruction rule.

Jim.

DR. NETON: Thank you, Dr. Ziemer. It's a pleasure to be here again. I think this is my

third time now addressing the Board, so if you're not tired of me by now, I guess you'll never be.

I'd like to talk today about the implementation of the dose reconstruction rule and provide a general overview to set the framework, really, for the two presentations that are to follow me. That would be Tim Taulbee, who's going to address the external dosimetry implementation guide, and Dave Allen, who's going to address the internal dosimetry implementation guide.

What I'd like to do is do a little bit of an overview of the actual steps in the process as the rule is written, and where we are in fulfilling some of those steps, what we've done so far; talk a little bit about the documentation that we have in place to try to have a pedigree for this program so that we can really document well what we've done.

And then I don't want to belabor the point, but I'd like to go over a little bit about the efficiency process that we've adopted, because I think that really is the heart of making this program work. And I talked a little bit about it last time, but I think I've got some -- a few

more concrete examples and some probability of causation results that we can discuss.

And then I'd like to finish up briefly with a couple of issues that are somewhat unique to the program, and that would be radon. That's not really a dose reconstruction issue; it's an exposure assessment or an exposure reconstruction. And then to talk a little bit in a little more detail about the atomic weapons employers.

There are five major steps in the rule if we outline how a dose reconstruction takes place. And the first of these steps is sort of obvious, is to collect the existing information. And there's two sources of information available to us out there.

Well, there's the Department of Energy information that's collected at the DOE facilities themselves, and that is -- that information is actually owned by the Department of Energy, and we're interfacing of course with them, and you've heard Josh Silverman talk this morning about the Office of Worker Advocacy.

There's also the piece of the information that's from the atomic weapons employers -- that

is, those contractor facilities that were not DOE prime contractors, the facilities were not owned by the Department of Energy; and thus, those exposure records are not necessarily property of the Department of Energy or NIOSH or anyone. And it's a slightly different issue that I'll talk about a little later in collecting that information.

As far as collecting information, though, I think -- I missed Larry's presentation this morning, but I'm sure he talked about what we've done so far in going out to collect personnel monitoring information workers -- I mean, from the Department of Energy related to workers at DOE facilities. We've got a number of those requests out.

We've taken a staged approach to this, and that is personnel monitoring information only at the present time. We sense that -- it's sort of an efficiency process as well. If the personnel monitoring information alone can allow us to perform a dose reconstruction, then that's well and good, and we're not going to spend time going after records that may be very difficult to obtain, such as the work place monitoring

information, or even things such as like pocket ionization chambers that workers have worn. Some of the DOE facilities themselves have indicated that may take a much longer period of time to collect that information.

So we're working it through on a staged process. And I will say at a number of the sites we've had some very good cooperation with the contractors trying to figure out exactly what we need. We're trying to get the dosimetry staff at the sites more involved. It turns out if you ask a records organization to provide records they'll give you exactly what you ask for, but if you ask a dosimetry person to help and assist in the process, they tend to know. I've talked to several people, and a light bulb goes off, and, oh, if I was doing a dose reconstruction, what would I use? Well, they can coordinate that effort with the site personnel and hopefully get a better product.

The second stage is the interview with the claimant, and we are committed in the rule to interview every claimant individually to help -- to add to their dose reconstruction effort, to fill in missing information, to do consistency

checking on the information we receive from the Department of Energy, that sort of thing.

That is going to be performed through a computer-assisted telephone interview concept -- that is, there's a computer program, there's a script that we have prepared already that has been approved by OMB. There are three flavors of that. There is the claimant himself, there is a survivor of a claimant, and then there is a script for a co-worker. We're in the process of computerizing that at the moment, and hopefully we'll have the first draft of that finished this week. It's in the process. Right now it's being programmed in an Access format. Eventually we'll migrate that over to a SQL server program that will be more compatible with our long-range goals.

We have done one interview only so far, and that was done by hand. We hope not to do that again. That's a fairly labor-intensive process.

Evaluation of completeness and adequacy of the information, we've done an initial review of a number of cases that have been sent to us. And I mentioned that we are cooperating with the contractor sites providing the information and

have given feedback to several sites regarding what we really need, and that is we need to have the individual monitoring data. We cannot have summary information. That doesn't provide us any useful -- it's somewhat useful, but doesn't tell the whole story as far as the missed dose goes and that sort of thing. So we're doing that.

As far as the atomic weapons employers go, there appears at this point not to be any real personnel data available at the atomic weapons employers. There's a lot of information regarding the source term that was there, licenses that the AWEs possess, that sort of thing, that we can sort of reconstruct a plausible exposure scenario. But personnel monitoring data is not there.

We are doing a data capture effort next week. A NIOSH team will be in Germantown, and we will be electronically capturing on CD-ROMs all the atomic weapons employer information that exists in the Germantown files at this time. And then we intend to go back and further go through some of the files to add to these things as we progress.

Calculation of dose to the organ once we

evaluate the completeness and adequacy of the data. I did mention last week, we have the IMBA program available, Integrated Modules for Bioassay Analysis. That is a stand-alone program right now that we can use to perform internal dose reconstructions. However, we are in the process of working with a contractor to update that program to add some features that are desirable. I think I mentioned that this week.

And report dose reconstruction results, we haven't done any official dose reconstructions as of yet, but we're in the process at this point of crafting what the report will look like. We intend to have a standardized reporting format that includes certain key aspects of the information that we'd like to report, that sort of thing. So we're working on putting that together.

I mention program documentation on this slide because I think it's an extremely important aspect of this program. We take this very seriously. We want to have some sort of pedigree for down the line when cases become challenged or questioned or whatever, that we can actually go to a file and point to the individual procedure,

implementation guide or whatever that was used at that time to perform a dose reconstruction.

In my mind there's four major parts of this documentation, and that starts with the case file. And all the case files that have come into our site so far have been electronically imaged. We're working with PDF files essentially, Acrobat type files. I think we've scanned well over 100,000 pages of information so far into our system. It's a nice system. We can tab the individual files with markers, that sort of thing. And we hope that we won't -- actually, the paper copies will be there for the record. But when the contractor comes on board, when NIOSH staff work with these things, they'll be available directly on your computer screen, as they are now for our OCAS staff. It's a very nice way of doing business.

The implementation guides, which we're here to talk about in more detail later, are sort of the guts of our dose reconstruction process. And I think everyone on the Board should have a copy of that by now. It is a draft, so please feel free to provide comments. And as I mentioned, Tim and Dave will address those later on.

I will say that we tried to craft them so that they were much more specific than the rule, but at the same time one cannot envision -- I learned this early on in OCAS, is you cannot envision all eventualities that are going to happen. Surprises happen daily as to what type of dose, what type of exposure a person had, how it occurred, when it occurred, those sort of things.

So the guides will provide a general framework for how this is going to work, but we're going to -- we have a plan to have these little technical basis documents, which are sort of interpretation documents that are specific for cases that are unique, something that you wouldn't want to cover every aspect in an implementation guide. But if we're presented with a situation that is extremely unusual, maybe cover a few types of cases, we'll cover that with a technical basis document.

And then we also intend to have the standard operating procedures that are even more specific in certain areas about how we do business. Right now we're talking about having -- we have a procedure draft that's in place that essentially

covers all the steps that are in the rule. Everything we said we would do in the rule, it kind of goes through step by step and ensures that we've covered everything that we committed to doing.

I'd like to shift gears a little bit now and talk about the dose processing strategy. As I mentioned, I think it's the heart of our system, and I talked about this last week, or last time we met. The low-dose processing strategy -- there's two strategies that we can do with the bracketing at the ends of the spectrum, if you will.

One is the low dose, where a person presents with a fairly low exposure profile from their work history, someone in the low, below ten rem for sure range. We would start conservatively using their monitoring data and perform an initial evaluation using worst case assumptions. A good example of that is a person who was exposed external only, an administrative personnel who may have visited the controlled areas of the sites on an infrequent basis, had no internal dose.

We could take and add into their record all

the missed dose from their external badge results. I mentioned before if someone wore a badge and there's a 30 millirem detection limit, we could assign them a flat-out 30 millirem per badge exchange, total up those doses, and evaluate the probability of causation. And if that probability of causation is extremely low, then the dose reconstruction doesn't need to progress any further. We've definitively -- we bend it on the low side in an unbiased manner. I've got some examples later of this that will tie this together, I think.

Conversely, on the high-dose processing strategy, it's the same thing except on the other end, obviously. We could take an internal dose case and only look at a piece of it. And if that piece of the internal dose, those few bioassay samples, results in a fairly large dose -- say, for instance, to the lung from an internal exposure event -- and just that one piece is sufficient to create a probability of causation that is well over the 50 percent limit, there's no need for us to go through and calculate the dose from each of those individual other bioassay samples that are in a person's file.

If it's not, we need to go in a more detailed fashion, and I think the next slide kind of covers this. This was presented last time, but the basic concept here is determine the organ of interest and the possible mode of exposure. And so in this case, if a person is, let's say, for example, working with plutonium that has a fairly low gamma component to it, one could calculate their plutonium exposure.

If that probability of causation was extremely low, we would go over to this branch and look at the external component. We already have judged that the external component may be low, but we need to look at it, use some worst-case assumptions there, adding in missed dose. If that's also low, then we're complete. There's no sense in continuing on.

On the other hand, if the probability is not low but high, we take those few points and the person's well over the 50th percentile based on our evaluation, then we'll ratchet it down a little further, tighten it up, take a conservatively low estimate. If the probability's still high, then the dose reconstruction's complete.

So the idea is to work over to this complete phase. However, there are going to be cases, those in the middle, that will fall all the way down through the bottom. And then we have to take -- even after looking at both conservatively low estimates, if the dose reconstruction is still indeterminate, it's still unknown, then it'll drop down here, and then we'll have to end up doing a very complete analysis of the whole case.

This is an example I talked about with an external exposure case. If you look over on this column there's a gamma exposure for the individual, sums to about -- what is it -- 270 millirem actually on their badge results between 1954 and '61. And over here we've included the missed dose, and the missed dose adds up to somewhere in the vicinity -- I think it's 350 millirem if you total this column. This column is a factor of five higher in dose than what was reported by the actual badge results that we received from the Department of Energy, so we've increased their dose by a factor of five.

But if you look at this next example -- let's just say, for instance, this person

presented with prostate cancer. Even with all the missed dose added in it's 1,350 millirem -- and this is just a graph of the probability of causation of prostate cancer as a function of total dose delivered -- and one can see that at the 50th percentile, even for a fairly early age at diagnosis at 40 years, the dose is somewhere in the 30 rem range. So in this particular case we would make a fairly -- it would be fairly easy to conclude that if the Department of Labor were to run this calculation using the IREP program, the person would not be qualified for compensation.

These graphs are sort of interesting. One can see the effect of the age at diagnosis on the probability of causation. There are a number of factors, of course, in IREP that drive these different curves. One is the age at diagnosis, which I believe is related to just the increase in the background incidence rate as you get older, so the chance that your cancer was caused by the radiation is diminished by the fact that the background incidence is higher. So one can see that these values are fairly well above the one and a half rem range.

This is also going to be the case for someone, for example, who was exposed internally to something like plutonium, that only concentrates selectively in essentially three organs -- four if you count the gonads -- the lung, liver and skeleton. So we could do a very worst case assumption of what their inhalation intake to plutonium may have been. The prostate gland is very -- not very -- not irradiated significantly at all from that exposure. So again, their dose would be down into this range.

If you take a look at lung cancer, however, on the other extreme end, here's a case where if a person had -- again, I hate to keep using plutonium, but it's a good example -- if a person had inhaled plutonium and received a fairly large intake that would result in a lung dose, and it would not be inconceivable that person could have inhaled enough plutonium to be in this 20 rem range.

Remember, these values are equivalent doses, not effective doses, so these are not multiplied times the .12 for the weighting factor. So a five rem annual dose limit, a person could easily receive in the 20 to 25 rem range.

So for a non-smoker at the 50th percentile, it's somewhere -- I can't see it very well from here -- but 25 to 30 rem. So if we took that one case where a person had one intake that was fairly large, we estimate it was well over 25 to 30 rem, that person would be judged -- his dose reconstruction would be complete, and it would be forwarded on.

I show these graphs just to give a sense we're working towards developing these tools for our dose reconstruction people, so that we don't -- we're not in the business of running the probability of causation calculations, but we need to develop these kind of tools that the dose reconstruction people can use to do this efficiency process, the bracketing at the extreme ends.

I think the next slide is just an example of the different probability of causations for different cancers. This is for leukemia. The solid cancers you can see were, in those examples that I showed, were in the tens of rem range at the 50th percentile. Leukemia, this is sort of an optimum condition here: five-year latency period, and a person is -- at 20 years old, you

can see it takes very small, much smaller amount of exposure, in the one to two rem range, for a person to qualify for compensation from leukemia.

So someone with an exposure profile in the past that had a large missed dose component from the external badge, in particular if they developed leukemia at a fairly early age, it would be pretty simple to determine if someone had a missed dose that was in the three to ten rem range, that the probability of causation calculation, if run, would qualify that person for compensation.

I'd like to switch over to talk a little bit about radon. I mentioned before that radon is unique in this program in the sense that there is no -- there are no bioassay methods available for radon. You can't take a urine sample or a lung count or whatever, so we're going to basically be doing exposure reconstructions.

The reason that we do the exposure reconstruction is because that's what the PC calculation is based on, cumulative working level month exposure to the worker. And it's essentially an adaptation of the risk model

developed by Jay Lubin, et al., at the National Cancer Institute, which is based on the risk values from the U.S. uranium miner studies.

An interesting feature of radon is one does need to look at natural background. We're looking at how we're going to deal with that. One has to distinguish at some point the difference between natural radon and DOE's radon. There are fluctuations about the country. It may be that if we can do the efficiency process where, even including natural background and the radon exposure, that the person is not going to fall in a compensable region, it's okay, we don't need to worry about that.

But it's been my experience that radon does fluctuate quite a bit in the work place, and we're going to have to develop some method to deal with that. Fortunately, there are not that many sites where radon is going to be an issue. The well-known ones are the Fernald site, Mallinckrodt. I used to run the dosimetry program at Argonne National Laboratory. There was a few areas that were contaminated back in the early days that maybe there's some elevated levels, but not that many. Actually, the

original site in New York where the residues went from New York to Fernald, the K-65 material, probably we need to look at.

But we do intend to include this. The way the probability of causation calculation will work is it will treat those independently. You can have an exposure -- concomitant exposure to external exposure and radon and run the program through, and it will actually sum the two risk values for you.

Unfortunately, monitoring records are probably going to be fairly poor. Having looked at the records at several of the sites that do have radon issues, the monitoring records are fairly poor. Very rarely were working levels actually measured. Air concentrations were taken, then one has to do some basic assumptions about the percent equilibrium of the radon, that sort of thing. So it's going to be a tricky exposure reconstruction.

And my final slide, I just want to touch base a little bit about atomic weapons employers. They are somewhat unique in the sense that the period of covered employment -- it's fairly obvious for a DOE facility that the entire time

the facility was in operation is covered. An atomic weapons employer, there is a covered period where a person is eligible to be in the program, but the covered exposure actually extends beyond that. So we're in the position of having to reconstruct records that go well beyond the period of time at which the DOE was involved in that operation. That's going to be a difficult issue for us. We're working on that right now.

Part of that is this residual contamination study we have in place that was enacted recently in an amendment to the Defense Authorization Act. NIOSH was charged with doing a residual contamination study at the atomic weapons employers facilities to determine if the covered employment period should be extended based on contamination at the site that was left there after DOE operations ceased. And so in looking at that, I think what's going to give us a fairly -- much better handle on what the exposure looked like in those time periods after the workers no longer -- after the DOE work was completed.

I touched on earlier about the availability of personnel monitoring data. It's going to be

interesting. I don't know that many of them actually -- atomic weapons employers actually collected personnel monitoring data, so we may have to rely more on source term analysis for these particular employees than the DOE cohort.

One possibility does exist, though. We've looked at a couple of these facilities that a number of them on the list did not appear to do very extensive processing of materials. A large percentage of the atomic weapons employers are uranium -- handled uranium as a result of -- Fernald site seems to be responsible for quite a few of those. They were a manufacturing facility, essentially a metals foundry, so they would farm out certain pieces to try a new rolling mill processor or whatnot. And in doing that, it looks like there are some instances where the facility itself did not handle fairly large amounts of dispersible material; it was solid metals.

So it may be that we can, again using an efficiency process, look at some of these facilities and determine that the dose is below a certain level that would not result in compensation for any of the employees in that

facility, and allow us to do that, evaluate that in a white paper, a technical basis document, publish it on our web site so people could review our logic, and move forward without having to do an individual dose reconstruction for anyone at that particular facility. Anyway, that's the concept on that at this point.

That concludes my formal remarks this morning. If there are any questions, I'd be more than happy to address them.

DR. ZIEMER: Thank you very much, Jim.

Keep in mind that we will be hearing a lot of detail on both external and internal dose reconstruction from our following speakers, Tim Taulbee and Dave Allen. So this presentation by Jim Neton has given us kind of an overview of dose reconstruction, but let us take at least early questions here.

Yes, Henry Anderson.

DR. ANDERSON: Are you setting this up so you can put this data into an analytic database? It would seem to me that as you gain experience here you may find -- for instance, as you showed with the leukemia -- that some specific diseases or places will fall into then the special group.

So it would seem to me that based on looking at this, you may be able to look at -- identify classes of people that have come through, that then you wouldn't have to run them through because you'd always be confident, and therefore they'd be moved into a -- this would be, rather than being -- people having to petition, you would have the actual data to show that of all of the claims from this facility for this disease coming through, they've all been well over your threshold, and therefore it would make sense that they would then move into the special category.

DR. NETON: Yeah, that's correct. We do plan on doing that, to have essentially an exposure matrix --

DR. ANDERSON: Yes.

DR. NETON: -- if you will, for certain classes of workers, whether it's a chemical operator at a certain facility, a uranium facility, take advantage of this as we learn from our dose reconstruction process.

DR. ZIEMER: Jim.

DR. MELIUS: Who is going to be doing the interviews with the claimants?

DR. NETON: Well, NIOSH staff will initially,

since we don't have the dose reconstruction contractor in place. But once the contractor is in place, they will be doing the interviews. There are certain -- the RFC, Request for Contract, stipulates certain qualifications for a person to be a qualified dose -- do an interview.

DR. MELIUS: Okay.

DR. NETON: Certain level of knowledge of DOE facilities, certain educational background, certain number of years' experience.

DR. MELIUS: And is the interview script available? I haven't looked at the web -- is that on the web site now, or is that --

DR. NETON: It's not on the web site currently. I don't know that it couldn't be. Larry might address that.

MR. ELLIOTT: It's not on -- the interview questions and the script is not on the web site. We have an emergency approval from OMB for -- under the Paperwork Reduction Act for that script, and we're currently trying to -- we have an application in for a permanent -- or an approval of that script. We can put it up. We can load it up on the site if --

DR. MELIUS: And could we also get a copy to

the Board?

MR. ELLIOTT: Sure, we'll do that. We'll do that.

I would also like to comment on Jim's comments on the AWEs. We do know that some AWEs did have radiation monitoring data, like Mallinckrodt, and we have a lot of that already in our hands. But by and large, we're still pursuing whether or not some of these AWE sites have any, if at all --

DR. NETON: Right.

MR. ELLIOTT: -- personal dose information.

DR. NETON: There are over 300 AWEs, and it's very hard to track -- some of them aren't in business anymore, have been out of business for a long time. In some cases the facility is no longer even there. So we will be pursuing that with some vigor in the next couple months.

MR. ELLIOTT: Also, the computer-assisted telephone interview, when we have the contract in place, those interviews will be done in the NIOSH facility. The contractor will live with us doing that.

DR. NETON: That's a good point. The contractor's required -- we will provide them

space to do the interviews at a NIOSH facility, primarily so we can actually get a handle on how they're going and monitor the quality of what was going on, since it's a very big piece of this assessment.

DR. MELIUS: Again, refresh my memory. I think I asked this last time also. But what information will be given to the claimant prior to the interview?

DR. NETON: They will be provided -- not necessarily the entire script, but some information as to what lines of inquiry we're going to be going through in the interview. The script right now, as I said, it sort of looks like a fill-in-the-blank kind of thing. We could use that, but I think we could cut it down a little bit so that it wasn't as long and give them the same information. But all the information that we'll be discussing will be provided to them prior to their interview occurring.

DR. MELIUS: What about the exposure information that's been received from DOE? Will they be provided with that ahead of --

MR. ELLIOTT: We talk to them about that

over the phone during the interview process, and we can make it available to them if they request it. It's been our thinking that we wouldn't automatically provide that because it might prompt confusion with what they typically get as reported cumulative annual dose from DOE.

So as we go through the interview process we'll walk them through all the information we have collected from DOE, what we have in our own hands at NIOSH, and will explain the process of going forward with evaluating that information and how their interview questions will aid us in doing dose reconstruction. So there's a highly interactive process we envision dealing with the claimant through the interview.

DR. NETON: In preparation for the interview, the person that is conducting the interview will go through the entire file, including the DOE dose records that are available, and use that to query in some depth, customize it in some ways to the individual claimant.

And we'll be looking for things like consistency. If a person says they wore a badge all the time and we received a report from the

Department of Energy that they have no monitoring information at all, that's going to take us down a different path. Or if a person was involved in a number of incidents and we have those incident reports, it'll be interesting to compare notes as to what the claimant states versus what's in the official record, that sort of thing.

DR. MELIUS: Yeah, but I guess my concern would be there's -- if you do it the way you described it, I think that's good. If you did it the way, well, I have your records from '55 to '65, we have all your exposure records so we don't need to talk about that, or -- and they just say okay without knowing what's there, or especially with someone with sort of a complicated work history, that could be problematic.

DR. NETON: This is going to require some level of expertise on the interviewer to do a good job. We've already recognized certain instances -- if you ask a person did you ever wear a badge, a monitoring badge, or were you ever assigned a badge, and they say, well, no; but in pursuing the conversation we find out that, well, they were not assigned a badge, but

they visited areas that required a badge and were issued temporary badges every month. So we would have never known that if a person didn't have good interview techniques. So it's going to require some skill.

MR. ELLIOTT: The intent of our interaction through this interview is to elicit information from the claimant that might aid us in going back to DOE seeking additional information that might not have been forthcoming. And we're not only hoping to get that, but if there's situations that no DOE record would support, we're asking the claimant through the interview process to identify co-workers that can verify or validate your claim, this aspect of your claim, and we'll get an affidavit from that individual.

DR. MELIUS: A related question, and I think it's sort of the same issue, approaching it from a different -- tell me if you're going to present this later, because I haven't gone through all your slides yet. But how are you going to judge the completeness of the data that you're receiving from the DOE and/or the facility?

You've got a number in the draft regulation, you list a number of items you'll look at. But

that's a wide range, and it's a lot of information. And how are you going to sort of collectively build up your knowledge base that you can judge what's complete? You want an efficient process. At the same time you also want to make sure that you're getting as much information as is there and is relevant to the person's case.

DR. NETON: That's a real good question. In the beginning the process is not going to be as efficient as we'd like, because we're requesting these individual cases, we're getting a file. We don't really have a sense that we've got everything that may be available to us.

So we've envisioned early on is to have a parallel process in place where we will actually be collecting the DOE's records themselves and bring them in to NIOSH, putting them on our own computer system, developing that database, so we'll have a sense as to what information the DOE really has available, such as the work place monitoring information, air sampling data, that sort of stuff. But we need to get onto the DOE sites, get there, talk to the people that have these records, and determine if this information

is actually even available in a reasonable time frame, because time is a critical issue.

DR. MELIUS: But how will you -- will that also include going out and getting the information from the contractors as opposed to what DOE has collected? My experience has been that the DOE offices don't always have as complete information as the contractor will.

DR. NETON: That's correct. And in reality, most of the information's coming from the contractors already. The Department of Energy really doesn't have a repository per se of all the information we need. We are working through the operations offices, the DOE operations offices. But then once they forward that to the contractor, we're interacting with them directly. Once the packet has been forwarded to, say, the Savannah River site or Hanford or whatever, we're in communication with the contractor. And that would include visits to the contractor's site.

MR. PRESLEY: Bob Presley.

One of the things that I think you need to ask, make sure that you get multiple sites. A lot of the people, maybe they worked at one site, but they visited other sites during their work

experience where they would have gotten a contamination dosage at some other site.

DR. NETON: Was the question how are we going to deal with that issue?

MR. PRESLEY: Yes. Are you doing to deal with that issue?

DR. NETON: Oh, absolutely. We intend to deal with that. And a lot of that is going to be either based on the record that is in the person's file -- DOE has kept track of that to a certain extent, but not perfect, I might say -- but also this is where the interview process comes in. If a person can inform us as to where they went, what they did and how often, what time period, we'll pursue that at that other site. So we certainly have to include that in the record.

DR. ANDERSON: Going back to the previous presentation, it seems to me the only time you'll move to interviewing somebody is if you have not -- if the records you've already received would not qualify them for a sufficient exposure.

So really what you're doing -- it'll be important. If that's the case, then it would seem to me sharing what you already have with the worker so they can see the completeness of it

would be very important, because unless you interview everybody the reality is those people who have qualified you would already have short-circuited out of the system; those who are very low would be out; and these are the only ones that you're still building their dose, and you're looking for other exposures that may not have been in your base information.

DR. ZIEMER: Larry has a response.

MR. ELLIOTT: Dr. Anderson, we will be interviewing everybody, okay. And the level of detail we get into the interview will depend upon the complexity of the work history, how many sites they worked at, how many different radionuclides they might have been exposed to. So everybody will get an interview. Everybody will be able to contribute to their case file through that interview.

DR. ANDERSON: Because I thought in the previous, it looked like it was a step-wise, that if through kind of an administrative review the person would qualify for compensation, you would move them into that range rather than go through further interviews and whatever. If you're going to interview everybody, then that's a different

scenario.

MR. ELLIOTT: To achieve the efficiency process --

DR. ANDERSON: Yeah.

MR. ELLIOTT: -- we have that intent in mind, to try to categorize the claims as they come forward. Those that are obviously high enough that they're going to get an award, but they'll still get an interview. Those that are obviously low enough that they're not going to achieve an award through the final adjudication will still have an interview, and we'll use that information to make sure that -- again, we're trying to achieve an accurate estimate of dose here as much as possible.

DR. ANDERSON: Okay.

DR. NETON: There may be something that comes up in the interview, if a person appears to be qualified on face value, that might be helpful for someone else's case.

DR. ZIEMER: Sally.

MS. GADOLA: I have a question that goes along those lines.

Suppose you get someone, after all the radiation dose reconstruction is done, it looks

as if their cancer was not caused by radiation. However, it might very well have been caused by other chemicals that they worked with in that environment. Is anyone going to be advising them, because then they would want to apply to the state worker's comp?

MR. ELLIOTT: That comes back to the Department of Labor's responsibility at the point of adjudicating the claim. And when our dose reconstruction report goes forward to DOL and to the claimant, and DOL uses that information from the dose reconstruction report in the probability of causation in the IREP and they find that they're below the 50 percent mark and their recommended decision is not to award, then I assume that the Labor Department and DOE will, through their outreach program and their worker advocacy program, encourage the claimant to pursue the Subtitle D aspect of the program, which is through the state worker's comp program through the physician panels that DOE sets up. And any dose reconstruction that we have done on radiation would just travel along with that case file for that individual.

We do not, though, in our program here on

doing dose reconstruction for cancer-related claims, we are restricted to radiation exposure. We are not including chemical exposures.

MS. GADOLA: I understand that, but I'm just concerned with the workers, and especially the survivors, who would not even know what type of questions to ask, because they would not know what their family members might have worked with. Thank you.

DR. ZIEMER: Other questions or comments? Jim.

DR. MELIUS: Are you allowed to do more than one interview under your OMB approval?

DR. NETON: Yes, nothing precludes us from doing more than one.

DR. MELIUS: Okay, good.

DR. ZIEMER: Whatever it takes, probably.

DR. MELIUS: Yes, I could see it being a step-wise process with certainly some claimants, where they tell you something that wasn't in the records you've got. You go back, get that information you need to then ask them further questions, and --

DR. NETON: In fact, with survivors that would probably be routine. We will obtain names

of co-workers, just for the reason the person will say, well, I don't know what my husband or wife did at the site. It was classified. And so we'll try to obtain names of co-workers who still may be alive and work it through that way.

MR. ELLIOTT: The interaction with the claimant through the interview instruments that we've designed, we envision it to be very dynamic. It's going to have to be malleable to the situation.

We've envisioned it that we're going to have to not do some of these by telephone. We're actually going to have to do some of these interviews face to face. We're going to have to do some of these interviews with a Q-cleared interviewer in an environment where the discussion cannot be overheard. We're going to have to do some of these interviews with assistance to the claimant who perhaps cannot hear, cannot speak.

We're going to have to do some of these interviews where we give advance time and opportunity for the claimant to go through the questionnaire and prepare themselves because -- and we're going to have to fractionate some of

these interviews so that we don't consume an individual's energy in the interview process, and we have to go back to them and finish it up maybe two or three, in two or three sessions.

So we've envisioned this to be a very dynamic interaction that is situation-dependent.

DR. ZIEMER: Which means that it will also be a time-intensive process, clearly, yes.

Other questions or comments?

(No response)

DR. ZIEMER: Okay, thank you very much, Jim. Appreciate that overview, and the questions were very helpful as well.

I'd like to proceed to the presentation on external dose reconstruction guidelines. Tim Taulbee of NIOSH is with us today. This item on the agenda was originally scheduled for this afternoon, but we do have, I think, time now for both the presentation and the questions.

And Jim (sic), in connection with your presentation, you're talking about the draft internal (sic) dose reconstruction guideline, I believe, that was distributed to the Board members in advance. Is that correct?

MR. TAULBEE: I'll be talking about the

external --

DR. ZIEMER: Yes, I said -- and I said internal. I grabbed the wrong one. I meant -- everybody knew I meant external, right? Right.

So Tim, please.

MR. TAULBEE: Thank you, Dr. Ziemer.

I'd like to thank the Board for this opportunity to talk to you about external dose reconstruction as we currently envision it. And this is a draft. This is our approach as it is now, and we're eager to hear your thoughts and comments on this.

What I'd like to do is to try and take you through a dose reconstruction from us receiving data from the Department of Energy, dosimetry data, and how we would compile all of this and get to the inputs that -- the data that we would enter into the IREP program. So that's kind of the approach that I would like to take today in discussing the external dose reconstruction process.

Basically there are two types of dose reconstruction: One where have personal monitoring data, which is for the vast majority of the claimants. These are people that worked

at Department of Energy sites. And then the other type of dose reconstruction would be where we don't have personal monitoring data, where we'd use co-worker data or survey data, source term data and possibly even radiological control limits.

From the guideline that was given to you prior to the meeting here, the personal monitoring data is section two; the no personal monitoring data would be section three. What I'm going to focus on today is when we have personal monitoring data. Like I said, this is going to be the typical process going through, where somebody worked at a Department of Energy site and they were monitored with film badges or thermoluminescent dosimeters.

DR. DeHART: Could I ask whether or not we can interrupt for questions as we go along, because there's going to be definitions going through here and it's going to get technical.

DR. ZIEMER: Do you have any objection to taking questions as they arise?

MR. TAULBEE: No objection whatsoever.

DR. ZIEMER: Let's do that, then.

DR. DeHART: I have one question -- I think

I know the answer -- but source term is a term that I'm not really familiar with. I assume that would be an isotope or something of that sort?

MR. TAULBEE: That's correct. The source term information would be that at a particular uranium machining facility, we know the quantity of material, of uranium that was sent to them for processing, and we know basically what they were doing. They were milling it or they were machining it. And so from the dimensions of what they were starting with, we can estimate what their external dose is based upon the quantity of radioactive material.

So I guess the primary thing I'm going to focus on is where we have personal monitoring data. And so there are four basic components or elements to the dose reconstruction, and the first one is discussing the different components of external dose; and then the conversion of that external dose to an organ dose for the probability of causation; and then defining the uncertainty and determining the distribution surrounding this external dose that we come up with; and then the actual interface into the IREP program.

With external dose -- and you've seen some of these slides before that Jim had briefly gone over in his previous presentation here; please pardon me repeating some of them as I go into more detail -- but there's four basic components. There's the measured dosimeter dose, where a person wore a film badge or a TLD at the site. There's what we call the missed dose, or what the dosimeter couldn't read due to a limit of detection and a combination of the badge exchange frequency. And then there's the occupational environmental dose. This would be primarily from stack emissions and from other ambient sources around in the work environment. And then their occupationally derived medical dose. And the sum of these is what we consider the total dose to the individual.

We're starting with the dosimeter dose. This is a simple summation of all of the dosimeter readings that we got from the site where you add them up. And the uncertainty -- each dosimeter reading will have an associated uncertainty with them. And you combine them by summing the variances, and the standard deviation is calculated by the square root of the sum of

the variances.

To give an example for this, this would be an individual in Hanford facility at 1951, and these were all of their non-zero badge readings for that particular facility or for this particular year of exposure. And what I'd like to point out here is this is 12 readings. Well, the individual actually had 39 dosimeter readings over the course of this particular year. These are the 12 that were non-zero, so this is what we're considering the dosimeter dose, the actual dose that was measured. And the sum of them comes out to 415 millirem with a standard deviation of 49 millirem.

DR. ZIEMER: Let me interrupt at this point and ask kind of a practical question.

Clearly in 1951 the rem unit didn't exist, so their numbers would be in some other unit, maybe rep, maybe -- I guess if you go back, even some of the facilities were using what they called a sunshine unit, and I don't even remember what that is anymore. But the numbers that you get, you're not assuming these are millirem to start with, so you're --

MR. TAULBEE: No, that is correct.

DR. ZIEMER: -- this is a converted number that you're showing us to start with. Is that correct?

MR. TAULBEE: Actually, it's not. I misspoke there, and I apologize for that.

DR. ZIEMER: Okay.

MR. TAULBEE: These are in milliroentgen at this time. Later on you'll see that I'll go through a conversion in which we will get to the actual organ dose, which will then be in rem from that standpoint.

DR. ZIEMER: Right. Because you're going to have a hodgepodge of units for anything before --

MR. TAULBEE: Absolutely.

DR. ZIEMER: -- about the mid-fifties to the late fifties.

MR. TAULBEE: That is correct, yes.

DR. ZIEMER: Okay.

MR. TAULBEE: I apologize there. And as you see, the slide is incorrect there at the bottom. This really is milliroentgen, mR. This is an exposure for this particular example.

What we assume for the dosimeter dose is that it's following a normal distribution in which the mean was calculated as the average of

this distribution, the 415 millirem (sic), and then the uncertainty associated with it, two standard deviations or 95th percent uncertainty, it'd be 513 millirem -- milliroentgen.

So now the missed dose. Right now what I've showed you so far is what we've actually measured with a dosimeter on an individual. The missed dose is what the dosimeter couldn't measure due to a limit of detection and then the badge exchange frequency. In earlier years the badge exchange frequency at many facilities was weekly. By modern standards it's in many cases quarterly. And so there's a longer time period that dose can be measured, and the limit of detection has also decreased.

So really missed dose is primarily important in very early monitoring time periods. And the root of the missed dose is really the number of badges that have been recorded as a zero measurement. And I mention that it's been recorded as a zero measurement, not necessarily that that's what they measured. At some facilities they could measure lower. However, they had administrative practices to where they would not record below 30 mR, even though they

could measure at a lower dose.

For the missed dose determination we're assuming a lognormal distribution with -- and the geometric mean would be calculated by the number of zero dosimeters times the limit of detection divided by two. This is kind of the central estimate.

Yes?

DR. ROESSLER: I should have waited until you got done with your sentence.

You've already talked about two different probability distributions, and we had some last time. At some point will we get some discussion on the rationale for choosing the different distributions? Because they do look different, and the outcome can be different, quite a bit different, depending on which one is chosen. I'm not asking for it right now, but I think that's something that we need to have a little tutoring on.

MR. TAULBEE: Certainly. The thought behind the lognormal distribution for missed dose goes back to looking at individuals' doses as a whole over their entire work history. They tend to follow a lognormal distribution. And that's why

the component of missed dose we're assuming is a lognormal at this time, because of that. Underlying distribution of all of their data should be lognormally distributed.

The reason that we're using the normal distribution for the dosimeter dose is because we have a lot of individual measurements that have an uncertainty about them, and we generally believe that it's going to follow more of a normal for a particular year. And that's kind of the key across this, is making a transition in there.

We could use a normal distribution; that's possible for this particular scenario. My own experience so far, from looking at a lot of this data and below detection limit data and some of the research that I've done in the past, is indicating that it's more lognormal.

Yes?

DR. NETON: I'd just like to add to that, Dr. Roessler.

I think the first -- the measured dose on the dosimeters is really -- I think this is correct -- is really just the instrument detection -- the air on the instrument

measurement itself, and that's typically normally distributed in a laboratory environment. Every time you measure something it's plus or minus a certain percentage, essentially. I think that's the main reason for the normal distribution for the doses that are detected. And when you sum them, you end up with just a broader normal distribution.

On the missed dose determination, though -- Tim has demonstrated this in a paper he presented at the Health Physics meeting last year -- that missed doses typically are normally distributed, and I think Straume and others have demonstrated this as well. So there's some technical logic behind it, but we'd be more than happy to document that better as to the selection of those doses.

I think in the end result Tim will sum up and show you how we ended up taking all these different distributions and coming out with a final product, which is I think where he's heading.

MR. TAULBEE: Okay. And then to continue on, the upper 95 percent, the number of dosimeters times the limit of detection to get

the upper bound of what we estimate the missed dose to be.

To give an example, following along with the previous individual, 39 weeks they were monitored in a radiological area, or nine months. They had 12 positive readings, 27 zero readings, and the limit of detection was 30 mR. And the geometric mean, then, in going through the calculation, would be 405 millirem with the upper 95 percent bound at 810 mR.

This would be the lognormal distribution that will be -- all of these distributions, by the way, will be coming back toward the end as we begin to roll them all together, so I'm trying to show how we create each one individually before I sum them all together. And again, the geometric mean in this general shape there with the missed dose.

With the environmental dose -- and as Jim had indicated in the previous presentation here, and as I said earlier -- this is primarily from stack emissions, from ambient environment. There are certain locations at different facilities -- I believe you've seen a graph of the Hanford facility where you can see the plume and how it

moved in different areas -- and that's what we're talking about with this environmental dose.

And how we calculated it is the number of months that they were in the area, the average monthly dose rate for that particular year of interest, and then an occupancy factor. And the reason we use an occupancy factor here is that these average dose rate measurements were primarily 24 hours a day, seven days a week, four weeks out of the month, and the 12 months out of the year. So they're a summation, but most workers aren't at the facility that entire time.

From the interviews that we do -- at least in the limited experience that we have now -- the worker was able to identify certain time periods where they were working overtime, where they were working extended periods for a long -- seven days a week for a period of five or six months. And so that occupancy factor then can be adjusted to account for that additional time, then, on-site.

DR. ZIEMER: Tim, I have a question on this. This is on-site dose. It's submersion cloud, submersion type of thing.

MR. TAULBEE: That’s correct.

DR. ZIEMER: Largely gamma then -- well,

could be beta, but let's say gamma.

Are you assuming that the badge did not pick this up?

MR. TAULBEE: Yes. In many cases the badge -- there was a control badge in the general area of where the worker was that was then subtracted out when the measurements were done.

DR. ZIEMER: So the control badge picked it up and it was removed. I see.

MR. TAULBEE: That's correct.

DR. ZIEMER: Okay, thank you.

MR. TAULBEE: And so the calculation then for the environmental dose would be the number of months, the average dose rate and the occupancy factor, 129 millirem for this particular year. Again, we're assuming an environmental -- or a lognormal dose distribution. Again, this comes from experience of environmental doses. Environmental measurements tend to follow more of a lognormal type of a distribution, so the geometric mean of 129 millirem in the upper 95 percent of 500 mR.

So those are three dose components. The fourth and final one would be the occupational medical dose. And this comes from medical

monitoring that was going on at the facility, where they were given chest X-rays during routine physicals or during special screening that was ongoing.

In some of the early time periods we have found evidence where if you worked at a uranium facility, twice a year you were taken over and given a chest X-ray. We're not quite sure why they were doing this for just uranium workers, but it's there in the records that this was going on. I found it in procedures from Los Alamos in 1947 that this was going on. And so we're -- and actually during a claimant interview they had also indicated that every six months they were marched over and given a chest X-ray for monitoring.

What we're proposing is to look at the number of the examinations in that year and then the dose from the diagnostic procedure, and summing them together for this occupational medical monitoring dose.

The example that I'm going through right now doesn't have a medical monitoring dose, which is why now you'll see that for this particular example that I've been going through this dose

would be zero. They weren't monitored at all for that year.

DR. ZIEMER: Tim, I assume now that on the medical monitoring dose, whether or not you use that would depend on the cancer site.

MR. TAULBEE: That is correct, yes. If it is --

DR. ZIEMER: You don't automatically add this in --

MR. TAULBEE: No, if they -

DR. ZIEMER: -- before you do probability of causation, unless it would -- assuming it's a chest X-ray and there's lung cancer, that's one thing. If there's -- well, you know what I'm asking.

MR. TAULBEE: Exactly. If there is a -- for instance, if it's skin cancer and it's on their hand, for instance, certainly we would not be adding this in from that scenario.

DR. DeHART: But leukemia might be a problem as well, with this as essentially a total thorax radiation.

MR. TAULBEE: That is correct, yes. And the actual -- there are some differences as to which tissues get irradiated that I'll get to here in a

minute with dose conversion factors, and that's part of why we do this, because of the energy as well.

Yes, Dr. Roessler.

DR. ROESSLER: I can picture this dose from diagnostic procedures as being overwhelming any other dose that they might have received to, let's say, if it's a chest X-ray, to the lung. And I can also picture that it will differ -- we know it'll differ from year to year depending on the equipment, and we know it's going to differ maybe from one site to another. So it seems like this, to really define this D_i is going to be an important part of what you do.

MR. TAULBEE: That is correct. We do know in early years, from studies that have been going on at NIOSH at some of these DOE facilities, in particular the K-25 plant, the type of X-ray machine that they were doing, and have come up with dose calculations. In early time periods the doses can be very, very significant, especially when photofluorography was going on. But now is -- more from a modern standpoint with the standard 11 by 17 chest X-ray, the doses are relatively low, orders of magnitude lower than

what they were back in that time period. So, yes.

DR. ZIEMER: Let me follow up on that. Are there in the old records data sets that indicate what the beam outputs were? Did people calibrate those X-ray machines on site like they do in medical facilities now, so we have beam output data? Do we know that they had filtered beams and so on?

MR. TAULBEE: In many cases from the procedures -- one of the nice things about the Department of Energy is you typically didn't do a whole lot unless you had a procedure to do it. And so a lot of this was documented in procedures, and we have found some of the evidence of that. Is it going to be the case at all facilities? That I don't know. I would imagine some of the smaller facilities with lower budgets, this data might be more difficult to come up with, in which case we're going to have to do some general assumptions based upon the larger facilities.

DR. ZIEMER: And I think there have been studies on medical X-rays. I think the state of Illinois, for example, looked at this

extensively. And for given settings -- mAs, kVp settings -- you get a wide variation of doses, depending on such things as filtration of the beam, that can really affect the patient dose considerably, and film speeds and so on.

MR. TAULBEE: That is correct, yes.

MR. ELLIOTT: Just so we're all clear here, this would be perhaps one element of additional information we'd go back to the DOE site to seek. And we're going to find verification of this coming from the interview, but also when we go to seek records from DOE to support this, we will likely go to the medical files that may have not been provided with the case file that we get from Labor.

And additionally, I want us to make sure that everybody understands we're not talking here about diagnosis using X-ray or therapeutic radiation from a medical standpoint from a private, personal physician for health reasons. These are occupationally-required medical procedures to hold the job.

MR. TAULBEE: Yes.

DR. DeHART: Just as a point, and I don't know whether this has been discussed anywhere

along the way, but let's take a worker who's injured on the job who -- for example, the back, and undergoes a series of X-rays because of his back. That's therapeutic, but it's job-related under worker comp. Has that been touched at all?

DR. ZIEMER: You're complicating their lives here, Roy.

MR. TAULBEE: We have had some discussions about that, but in general what we're primarily focusing on is just the screening, not from an accident that would occur because -- from a standpoint of a worker is injured, and they left the facility and went to their own private physician to get those X-rays. Then we would have no knowledge of that particular information.

DR. NETON: I'd just like to add something about the medical X-rays. Before everyone gets the idea this is going to be enormously complex and labor-intensive to do, we have to go back to the efficiency process that we were talking about earlier, where a person with a very low dose record who had six or seven X-rays, if we could take the highest X-ray output that we've seen and add them to that person's record and it still is non-compensable, then our work load is much less

in that case. So this is only going to be extremely important for these people who are sort of on the borderline.

MR. TAULBEE: Okay. So now we've got the, to recap, we've got a dosimeter dose distribution, and then a missed dose distribution and environmental dose distribution, and now we need to convert these to an organ dose.

The primary factor in the conversion to the organ dose is what's the primary cancer. What is the target organ, whether it's bone marrow for leukemia; or lung cancer, the lungs; the liver. For each different organ there are different dose conversion factors that can be found in ICRP 74, which is where all this data is coming from.

There's some additional factors affecting the conversion, these dose conversion factors. And that's the monitoring device, whether it was a film badge or whether it was a TLD, and how it was calibrated. Was it calibrated on a phantom, or was it calibrated in free air? And then the two other factors are the energy of the emission and the exposure geometry.

To give an example of the monitoring device and some of the differences you can see from a

dose conversion standpoint, this is for the same photon energy of 100 keV from the AP geometry, or the anterior/posterior geometry from front to back. You can see for three different organs of interest the dose conversion factor can vary quite widely, depending upon -- the red bars are what we call the personal dose equivalent, which is the modern standard, or Hp(10), and then the green bars are the target dose per exposure or per Roentgen, with a free air type of calibration and no phantom. And as you can see if you look at the lung cancer example, the dose conversion factor would be .7. You take the monitoring dose, multiply it by .7 to get the organ dose if the monitoring data was in the modern standard of Hp(10), whereas in the historic standard you'd multiply by 1.1. So the dose, the organ dose, would actually increase where -- by older standards, and be decreased by modern standards. But this is what the organ dose is to the particular cancer site of interest.

Within the -- in looking at this particular curve, the actual dose conversion factor is a continuous function of photon energy that I'm presenting here. This is the dose conversion

factor for the Hp(10) or the modern standard. And what you can see is, well, what value do we actually use within this continuum of actual values?

And what I've -- this is for bone marrow and from the AP geometry. And what I've got here is three different -- the bars on there are set up based upon the IREP program. There are three photon energies that we have within there from zero to 30 keV, from 30 to 200, and then greater than 200 keV. What ICRP 74 recommends is that you integrate the area under the curve to come up with an average dose conversion factor over that energy band, and that's what we've done in this particular example.

Now in addition to the energy band is you have the exposure geometry, which can also affect the dose conversion factor. And if you look at greater than the 200 keV component here, you'll see that for four different geometries you can come up with four different dose conversion factors. So what we're concerned with is which one -- what do we use in order to calculate what the organ dose is from the monitored dose?

Well, what we've come up with is to use what

I'm going to call the likeliest dose conversion factor, and this is to use a weighted approach based upon the job that the individual was doing and knowledge that we have about the exposure, and upon the interview, if they can give us any information about what they were doing on the particular job, where the hazards were located. And in doing so, then we can weight their percentage of time for the different -- for their tasks in order to come up with this weighted dose conversion factor.

If you can think of, in the example here, a person working at a glove box line, 90 percent of their time they're going to have their hands in the gloves, and the exposure's going to be coming from the front of them in the AP geometry. But walking in and out they're going to be walking by glove box lines, and so they're going to have more of a rotational type of a geometry. So using the weighted approach, we can come up with a weighted dose conversion factor.

Now we recognize this is quite uncertain, that we don't really know for sure what exposure geometry the individual experienced, how they received their exposure. So what we're proposing

is to use a range, from the lowest within the energy band of interest to the highest dose conversion factor. And since we know the lowest dose conversion factor and the highest, and we think we know what the likeliest is, we can easily set up a triangular distribution.

And this gets back to how we came up with this. We really don't have any other information to try and base this on other than a lower bound, an upper bound, and what we think the central tendency of the distribution is. And so this is why we're proposing to use a triangular distribution for the dose conversion factor.

Now I've talked about the dosimeter dose, the missed dose, the environmental dose, and now dose conversion factors and how we get them all into an organ dose. And then now the final uncertainty, it's easier to describe altogether; but as I mentioned, to recap the dosimeter dose was a normal distribution. The missed dose was lognormal. The environmental dose was lognormal, and then the dose conversion factor is triangular.

Using a Monte Carlo sampling technique, we can go through and sample from each distribution

in order to come up with what we think the central dose estimate is for this individual and to bound the uncertainty associated with it.

In walking through this slide here with you, if you look at the top line only, what you have is that initial dosimeter dose distribution multiplied by the dose conversion factor will give you the organ dose from the dosimeter alone, from the measurements on the dosimeter.

Within this dose distribution, multiplying by the same dose conversion factor, you'll end up with the missed organ dose.

The environmental dose distribution, you'll notice that the dose conversion factor is much smaller from this case, and this is because, as Dr. Ziemer pointed out, we're talking about somebody immersed in a cloud, and so the exposure geometry is isotropic. It's from all directions at all times. Therefore the dose conversion factor has a narrower uncertainty associated with it.

And when you multiply those two together, you get the environmental dose distribution. You add these three together, and you end up with a final bone marrow dose for this individual.

Now what I want to point out here on this is in modern times, with quarterly monitoring using TLDs at a detection limit of ten millirem, this missed dose becomes relatively small. It's way down here at the far end, with a maximum of about 40 millirem. In addition, the environmental doses have also decreased over time because we don't emit things out of the stacks like they did back in the 1950s during the green runs and that kind of thing. So these two components right here will greatly decrease in more current times.

What's interesting is as you see -- as you look at a person's dosimeter dose information and where there's one of these changes that occurred from a missed dose, you'll see the missed dose will decrease and the dosimeter dose will increase, because we started measuring more of what we missed. And so you can see that in individuals' exposure histories.

So what we end up here is with the bone marrow dose associated with this particular claim or individual. Well, upon inspection you can generally see that it tends to follow kind of a lognormal type of a distribution, which is dominating by this missed dose being so large.

However, if these two were small, you would see it's probably going to follow more of a normal distribution.

And so we need to have some kind of a test in order to determine which -- is it more normally distributed or more lognormally distributed. So what we're proposing is to use a goodness-of-fit test for normality. What I've chosen to use here is the Chi-square goodness of fit. And what this will tell us is what's the tendency of that particular distribution, because in IREP we have to pick one. You have to put in one type of distribution and assess the parameters associated with it. What you can see from the Chi-square goodness-of-fit test, the -- it follows more of a lognormal distribution with a geometric mean of 754 millirem with a geometric standard deviation of 1.28.

I want to talk about the geometric standard deviation a little bit here, because I've had some questions from other colleagues who have been plugging in some different geometric standard deviations for different doses and coming up with some really interesting answers coming out of IREP. And part of that is because

of the -- if you plug in like a geometric standard deviation of five, well, you're going to have a huge uncertainty associated with the particular dose.

What you'll see here is the geometric standard deviation of 1.2 is really too tight for the distribution; 1.25 is pretty close, the actual calculated value was 1.28; 1.5 is spreading out the data too much, as well as 2.0. So in going through this process of Monte Carlo sampling, we can actually come up with what the geometric mean is and the actual geometric standard deviation. It can be calculated, and that's what we're proposing.

So now that we've got this distribution, we know the exposure year, the rate of exposure, the radiation type. The example I just took you though is photons greater than 200 keV. Lognormal distribution, the median being .754 centisieverts, the geometric standard deviation of 1.28, and that is the dose input for one photon energy for one exposure year.

You go through this entire process and repeat this process for each radiation type, each energy, and each exposure year. If somebody was

exposed to three of the three different energies of photons and four different neutron energies, that would be seven for each exposure year. If they were at the site for ten years, that would be 70 of these distributions to be developed to enter the data into IREP.

And with that, I'll answer any questions you have.

DR. ZIEMER: Thank you, Tim. We obviously had a number of questions as we proceeded, but what about additional questions now? Comment?

MR. ELLIOTT: While you're all thinking of your questions, I would like to give you a little bit of insight into how we come to be at this point with our knowledge and understanding, and what we're proposing here in dose reconstruction as a process.

What information besides the individual dose badge results, bioassay results that we talked about earlier, what information exists beyond those at the sites?

This is a little book; it's titled *Los Alamos Handbook of Radiation Monitoring.* It was given to me yesterday. We know that these kind of documents exist, have been prepared and

distributed across the DOE complex. This is a 1958 third edition of this book. This book has set some benchmarks for us in understanding this time era and what the technology was capable of doing for this time frame. Feel free to pick this up and look at it. I ask you not to walk away with it, and it is fragile.

But it has information in here that is relevant to what Tim has just presented to you. It gives us an understanding of what the limits of detection were for certain pieces of monitoring equipment in use in this time frame for this site. And we know from our experience in research on these sites that Los Alamos -- what was used at Los Alamos was adopted at other sites. What was developed at Oak Ridge was adopted at other sites. What Hanford had in place, they put in place from their own experience and technological advances, as well as those that were done at Los Alamos and Oak Ridge.

The medical diagnostic X-ray information is listed in this book for this time frame, so we have a source to go to. This is just an example of the additional type of information we would go back to DOE on certain types of claims and

requests. We would accrete this type of information to use on future claims relevant to a given site. So feel free to look at this as you wish.

DR. ZIEMER: Tim, I have a question on missed dose that relates to neutrons. You didn't really cover it here, but it is in your paper.

We know that certainly in the early times and to some extent even today there are certain bands of neutrons not easily picked up by dosimeters. You pointed out, for example, I think, a case of knowing the thermal dose and knowing perhaps the fast neutron and some band maybe below 500 kilovolts or so that would be missed. However, that's not new information. I think the people at the time knew that they were missing part of the band, and many -- I think in many cases had algorithms that, based on what their source terms were, that corrected for that in the dose record.

I assume that you're not automatically going to say that a dose was missed simply because of some certain type of monitoring used, or you'll use information like this, I guess. I'll answer my own question, I suppose. But maybe you can

clarify that issue on particularly missed neutron dose.

MR. TAULBEE: That is absolutely correct. There were some sites that did have algorithms that were used, and we knew what neutron sources they were using at the time period and how they went about in doing their calibrations. We also know that at other, some other facilities they weren't quite that sophisticated at that time period, and so there'd be a window of five or six years where they weren't accounting for it.

But we do go back and we look at what their calibration procedures were for the particular site at the particular time period in order to determine whether or not we need to make this additional correction that's discussed there in the external guideline.

DR. ZIEMER: Jim.

DR. MELIUS: Can you give me an idea for the example you presented here today how much person time is involved in doing this calculation?

MR. TAULBEE: There's a lot of -- I won't say a lot -- there's some development time in setting up your spreadsheets in order to do this. The program, the Monte Carlo sampling program

that I used, was Crystal Ball, which is -- it runs on a PC in an Excel type of format. Plugging in the data takes some considerable time to get there, probably a day or so to get everything all set up. But then the actual calculation when you run through it takes the computer five, ten minutes. So the front-end part is what takes the longest time period.

DR. MELIUS: So just so I -- for this example, that would take some technical person a day's worth of work to do this, or how would this -- I'm trying to think how this process works, or will work with your contractor and so forth. What will be involved? Who will be doing what and so forth?

MR. TAULBEE: Well, it doesn't take a full day to enter all of this data at all, but in order to enter probably 10 years or 20 years, or 10, probably 15 years of data, it could take you a full day in order to get up to that. So it really is dependent upon how long the work history was for the individual and how complex it is in order to come up with these calculations.

DR. NETON: If I could just elaborate on that a little bit, though, there is a lot of

detective work that goes into the up-front aspect of this, which is what were the detection limits, the medical X-rays, what type, what kVp or mAs settings, that type of thing.

So I think in the very beginning the dose reconstructions are going to move slower because we're setting the baseline for a lot of these facilities. Once that's in place, then I think what Tim is saying is true; then it's a matter of setting up your spreadsheets and running through. But for some of these smaller facilities we don't know maybe about the -- finding out what the exchange frequency was might even be difficult.

So there's a lot of front-end detective work that I don't think we can say right up front that it's going to take one day per dose reconstruction. I think in the very beginning it'll go slower, and then efficiency will take over as time progresses.

DR. ZIEMER: Tim, I'm going to make a comment here, maybe for you and Larry.

Some of you know I retired recently, and I was going through documents and tossing out stuff like this (indicating) into my wastebasket. And then I had this sudden flash in my mind, and I

got on the phone and called Paul Frame at Oak Ridge, who's a kind of a curator of old instruments and documents, and I described for Paul what I had. I said, Paul, I just filled up a wastebasket with these old documents. He said, oh, send them to me, so I filled up boxes and sent them to Paul.

But it may be that if you're looking for things like this (indicating) -- and Paul probably has my copy of that Los Alamos one right now -- but that would be a good source of old documents from the DOE/AEC system, Paul Frame, Oak Ridge National Lab. Or is it ORAU? ORAU, yes.

MR. TAULBEE: Thank you very much, because I don't know why, but many of the documents that I've obtained so far have been from DOE public reading rooms. And I know of Paul Frame, and I know of his experience with historical monitoring information, and I never really made that connection. So thank you.

DR. ZIEMER: He may not appreciate my volunteering his documents, but I think he does want them to be useful to people, and more like an archival library that might be helpful.

Other questions? Okay, Wanda, please.

MS. MUNN: One other similar kind of comment -- and again, I don't doubt that he'd appreciate my commenting on this -- but I'm assuming that you have checked with Ron Catherine (phonetic). He also is a great collector of this type of thing, and probably has several hundred boxes stored in his basement somewhere.

MR. TAULBEE: Okay, thank you.

DR. ZIEMER: Yes, Ron Catherine's wife would like you to get most of Ron's documents out of -- you probably shouldn't put that in the record.

(Laughter)

DR. ZIEMER: Other comments or questions?

(No response)

DR. ZIEMER: If not, we're going to adjourn. Our experience last time indicated that sometimes an hour for lunch pushes us a little. There's no formal arrangement made for the lunch hour; everybody's on their own. Last time we had a list of eating places.

Cori, do we still have a list somewhere for -- it's out on the table or back here. So we'll reconvene about 1:00 o'clock.

(Whereupon, a luncheon recess was

taken from 11:40 a.m. to 1:10 p.m.)

- - -

DR. ZIEMER: We are ready to reconvene the afternoon session. I'd like to remind members of the public if you wish to make a public statement later in the agenda, please sign up in the booklet out in the foyer so that we can allot the time accordingly.

I'd like to call on Larry Elliott briefly. Larry, would you give us a, particularly for the members of the public, an update on the comment period for 42 CFR 82?

MR. ELLIOTT: Yes, Dr. Ziemer.

Just so that everyone knows and for the record, the public comment period and the opportunity for the Board to get its comments in on the guidelines for determining methods for dose reconstruction, 42 CFR 82, are open again during this meeting, and that comment period will close March 1st for the public to provide any further comments that they have. So March 1st would be the deadline for the public to provide written comments beyond this meeting.

DR. ZIEMER: Thank you.

We'll begin the afternoon session with

presentation on internal dose reconstruction, and that will be given by Dave Allen, who's on the NIOSH staff. Dave.

MR. ELLIOTT: As Dave's taking the podium, if you look in your briefing book and you don't find this presentation let us know, because we just found that one member didn't have a copy of it. So -- you don't have a copy, Rich?

MR. ESPINOSA: I've got a copy.

MR. ELLIOTT: Okay.

I'm sorry; go ahead, Dave.

MR. ALLEN: No problem, Larry.

Afternoon. My name, as the slide says, is Dave Allen, and I'm here to talk to you about internal dosimetry. Obviously there's no way I can cover in great detail the entire implementation plan in one afternoon, but I wanted to try to touch on a couple of key points.

This slide is -- you've seen it before, once last time -- and just as a little refresher, this is the types of information we can use for trying to reconstruct internal dosimetry. Bioassay data, which is basically a direct measurement or directly related to the actual intake a person received; in-vivo is often referred to as a whole

body counter. It's a way of counting the -- it's assessing the amount of material in a particular organ or in the entire body. The other ones you see under bioassay are simply ways of measuring concentration in different excreta to try to assess how much uptake of a radioisotope a person received.

Incident reports are on there simply because they give you a lot of information. Obviously there won't be an incident report every time for every dose reconstruction we do, but they do tell you all the upset conditions, if you can find them. Upset conditions are very important because a lot of the internal dosimetry is going to rely on averages, so to speak. Anytime we don't have the bioassay data we have to rely on air sample data. A lot of times we're going to be relying on the typical amount of work time a person's in an area, or the typical air sample concentration in that area. So upset conditions are important for that assessment to get it accurate.

And air sample data, like I just mentioned, it's somewhat of an indirect way of estimating the intake a person received.

DR. ZIEMER: Dave, if I could interrupt. Are you agreeable to allowing questions as you proceed --

MR. ALLEN: Sure.

DR. ZIEMER: -- on this. And if you are, let me insert one at this point, or maybe two.

On bioassay data, you hadn't listed the possibility of activated blood. There are cases where certain -- well, criticality doses, that's another -- or actually not just blood, but other body samples activated. And then also things like nose swabs.

MR. ALLEN: These were -- that slide was intended for some examples of the type of information. We can, of course, use a whole myriad of information, and we intend to use whatever we can find for the most part.

Blood activation, like you said, that's -- I think I'm being told to step closer to the microphone. Blood activation from criticality, that's more external for the most part. You do get some activated blood, but that's as a result of a massive external. But yes, like you say, we can go ahead and assess the various elements that were activated, and how much dose he's continuing

to get from that, et cetera.

DR. ZIEMER: Yes, it's true that it is external exposure; but it is, in a sense, a sort of bioassay.

MR. ALLEN: Yeah, it's kind of a bioassay for an external program. In fact, we were looking at a paper recently on that.

To move on, bioassay is what we intend to use primarily for the internal dosimetry. There are several reasons why -- we will use a myriad of information. We will try to use all the information we can get our hands on. But bioassay's got to be considered the primary resource.

The reasons for this I've tried to list up here. The data is directly related to an individual. Any other type of, like, say, air sample concentration for inhalation exposure, you have -- air samples are generally related to an area. And somehow you have to then relate that person to that area and for that time frame.

Also, the air samples inherently are averaging over some period of time, such as an eight-hour air sample is going to find an average concentration for that time. If the person's in

there for an hour, often he's -- the people are doing the work and they are causing the airborne. So that average concentration isn't necessarily the greatest concentration to use.

So preferably we'd be using bioassay. It's more directly related to what the person received.

I think I just basically covered the first two on that one. And the last one, the data is likely to be more retrievable. Air sample data, contamination survey data, that sort of stuff was typically considered project data, and it may or may not exist after a project ends or a piece of equipment is decommissioned. Sometimes that data was not archived decades ago.

Bioassay data, on the other hand, it was typically considered dosimetry data. It was normally kept in a file with that person's name on it, and is usually archived even after the employment. We still expect to have some problems getting some of this bioassay data, but it's most likely we're going to get the best handle on.

DR. DeHART: Help me understand -- this is Roy DeHart -- help me understand. The half-life

of a urine sample, for example, where there has -- I can understand it when there's been a point exposure. And the half-life I'm talking about is not radioactive half-life; I'm talking about the excretion half-life of whatever the salt or mineral happens to be. I can understand it with point. But if you're trying to monitor over time, how do you consider that?

MR. ALLEN: Well, the way we do that is by -- we use the same model that we're going to determine the dose for the individual tissues. This is the ICRP general biokinetic model, and it describes different routes of entry and different routes of elimination, and also the transport of a particular radioisotope within the body. It gives various rates for the individual organs to absorb and to remove the various elements.

Using this model, you can see where down at the bottom you can determine at a particular point in time how much of that radioisotope is coming out in the urine or in other excreta. What you get if you, say, get one quick inhalation of some amount of plutonium, say, for example, you would get a curve. If you were to monitor the, say, urine, and check the

concentration from day after day after day, you would end up getting a curve similar to what you were just talking about, some sort of decay type of curve, which would look like that (indicating).

This one is an example. It's a typical excretion curve, and this is for an acute inhalation of insoluble plutonium. You can see the time scale on the bottom is days after the intake, and it does, believe it or not, go through all that system and start coming out in the urine very quickly after the intake.

DR. DeHART: I understand that for a point exposure, a point in time. But are you using it for monitoring over a period, over a length of time when you don't know when the dose occurred, and then try to use this to extrapolate back, or -

MR. ALLEN: When we don't know when the intake occurred?

DR. DeHART: Yes.

MR. ALLEN: Yeah.

MR. ELLIOTT: Did you guys work together -

(Laughter)

DR. ZIEMER: And could I insert in here,

too, Roy, I think in principle for a sort of a chronic case, you could assign -- if you go back to the model, you could assign a rate of intake. You could -- just like the excretion rate, you could have, let's say, a constant intake rate, and you could even have a model where you reached equilibrium in some organ where the intake and -- so I think they can model it mathematically with probably differential equations would do it if you had the ideal case. Now obviously you're up and down even in the chronic cases for different inputs. But in principle, you can do that mathematically.

MR. ALLEN: Yeah. I'm going to have some more slides there, too.

As you were mentioning, this one shows one bioassay point -- if I can remember where the pointer is on there -- that little dot right there is one bioassay. Once you get this sample, you get a detectable amount of plutonium in this example, you still don't know how much intake an individual received. Even if you know the type of plutonium material and that it was an inhalation, you still don't know how much.

The important parameter, as you were

alluding to there, is the date. In this example, that bioassay sample could correlate to a 1.3 picocurie intake inhalation, if it were to occur two days prior to the sample. But it can be as much as a 10 picocurie intake if it was 30 days prior. That's almost a factor of ten. That's a pretty large difference. So a lot of internal dosimetry is ways to narrow down exactly what that date was.

That's another reason the incidence reports I was talking about earlier are very important. They can zero in on the date right away. Also, a lot of samples are taken as a result of an incident, so you have some sort of information that this is a non-routine sample. It was probably taken the day of or day after an incident.

One of those tricks -- well, for lack of any other information, if we have nothing else we can go on, on a routine sample like this -- like, for example, if this was a 30-day sample frequency, we would pick the midpoint, is the standard philosophy. So on a 30-day frequency we would pick the 15-day point. It's not necessarily the most conservative, but you can see even at 15

days it's fairly close to the most conservative. If the intake occurred near that bioassay, we would be overestimating by quite a bit.

Another method we have for trying to narrow down that date with limited information -- this looks like the same slide, but this is what happens after an incident. Often you'll get follow-up samples, or even any positive bioassay sample, a lot of times you will get follow-up samples.

In this example I'm showing two additional samples on here, and you can see even though this is a nice and pretty theoretical curve here, but you can see on this example how it would follow that curve down. These three samples, following that curve, you could line them up and say this must be an inhalation that took place two days prior to that first sample, so that correlates to that 1.3 picocurie intake.

If the backup or the follow-up samples ended up being pretty much the same level, you'd be on this straight line here. You wouldn't necessarily be able to tell the difference between that 15-day exposure and that 30-day exposure, but you would be zeroing in on the,

say, nine to ten picoCurie intake range rather than the one picoCurie intake range. So it might not be a perfect way of doing it, but it will zero you in on getting it close.

Now that was a nice, pretty, one acute inhalation. This type of thing I've actually seen. This is a theoretical example here, but there is plenty of examples out there in real life where it's not one nice, clean intake. It's multiple intakes.

What I want to do is run you through this example to show you what would happen in that case. The reason this is a theoretical example is this way I can show you what it really is. In real life we would estimate it. We would know we're pretty close, but there's no way we'd know exactly what happened.

So what I've done here is I've picked some random dates somewhat and some random intakes, and I calculated out what the bioassay samples would be on a routine frequency. And this is the result there. These are bioassay samples on particular dates. Then from that, the analyst would not know this information here. I wanted to show you how he can actually come up with

something relatively close.

Now here it's partially done. Obviously it's not completely done. The purple curve is the estimate, what the analyst would be predicting to be bioassay from the intakes that he estimated. On the first sample, with nothing more to go on, I ended up picking the midpoint, and from that midpoint I ended up picking 10,000 picoCurie intake, which turned out to be just exactly what reality was. But again, the analyst would have no way of knowing that.

Since that intake was off a couple weeks, that air kind of starts promulgating it to a point. The next intake I picked was April 1st, and in reality we know that it was the end of February. That's off by a month. I still ended up with the same amount, but after that things start getting a little bit off. When I'm to this point here, I've got five intakes estimated. We know for real there was five intakes. But in reality, the analyst knows he's not done at this point. He's going to assume there's another intake that occurred at this point in here somewhere; had to be.

So when he's all said and done, he ends up

adding a couple more intakes. This large intake here is the 15,000 picocuries you see, and that ended up giving me a line that was a little bit below here. When I added one more smaller intake on this date, it brought it up to where it looks like I have a scenario here that it seems like it should be right. We know, because it's theoretical, that it's not exactly right. The scenario's off quite a bit on dates and on numbers.

The key number, though, the important part here, is that total. What I've basically done is showed that there's two scenarios that could give you the same bioassay, can predict the same bioassay points, but they do give you the same total inhalation intake. The scenario might not be right, but the total should be relatively close.

Another example on this, even if you knew the exact dates of intake -- say the person only went into an area at least five times. You know the exact dates, you know when he had to have these intakes. But say for some reason you've messed up on the highest one here, and you call it zero. Instead of 25,000 we know it is, he

thinks it's zero. You still, in order to match these data points here, he had to overestimate those, not realizing it of course, but his estimate here is considerably higher than what reality was. Again we end up with the same total intake.

Now this is obviously not going to happen. Nobody's going to think that this is a good match on this area of the curve right here. But sometimes sample data is missing. Sometimes samples get missed or routines get missed, or we get a flawed sample. This graph here indicates that even with a flawed sample or even with some missing data, we can still reconstruct this accurately.

Now the difference here, the effect it has on dose, since this is an inhalation of some insoluble compound, I figured the lung was probably the biggest effect. What I've done here, and I should have labeled it, is the annual lung dose from -- this is for the actual case; this is for what the analyst predicted (indicating); and this is in rem, rem to the lung.

You can see in 1979 they had the exact same

numbers. That's because my estimate was exactly the same. 1980, you can see the numbers vary a little bit. That's because this 25,000 picocuries that really occurred, we estimated as happening two and a half to four months later. Therefore the lungs, with this material in the lungs, the lungs were not exposed as long; therefore they got a little less dose that year.

When you look down at the following year, the lungs haven't had as much time to clear it out. So now, by our models, we think there is more material in the lungs than actually is, so we're assigning more dose to the lungs than there really was. So being off -- and in following years, if I were to carry this on out further, the differences get smaller and smaller, and the total would end up being equal.

So this shows even being off two and a half to four months on this material, the difference here is the biggest, and that's about a five percent difference or so, give or take. So it's still a reasonable estimate with limited information, and in this particular case with a couple samples missing.

Now somebody was mentioning earlier about

chronic exposures, essentially. Chronic exposures just -- not every time is it an incident, and not every time does somebody get one big inhalation of some material. Sometimes it's a routine operation that has some low air sample activity and the person is inhaling a small amount every day. That would be a chronic type of exposure, and that does affect the curve somewhat on this elimination curve.

You can see on this graph, the blue line is the one that you saw earlier. This correlates to a ten picoCurie inhalation of insoluble plutonium. The purple curve here is also ten picocuries of insoluble plutonium, but this time it's he inhaled one picoCurie a day each day for ten consecutive days. So you can see a classic chronic type of curve on this, but you also have to notice that once you get 20, 25, 30 days out, the difference is almost non-existent in this example.

You also have to realize that this is a 30-day period. Bioassay samples are seldom more frequent than a 30-day period, so there's going to be one sample attained in that period of time, more than likely. If it's caught in this point,

we're going to either underestimate or overestimate, depending on whether we think it's a chronic or an acute exposure.

But as I showed in the other slides, it tends to come back around. If we've underestimated on this exposure, we're going to underestimate the effect of that exposure on other bioassay samples down the road. And then we'll have to estimate higher intakes to account for those, or additional intakes to account for those.

The reason this comes out to be pretty close after only 20, 30 days is, in all reality, a chronic exposure is just a series of acute exposures. Since we probably don't have data points to associate with all those, it can make a difference in what we reconstruct.

And I can show you that example here. What I've done here is one more example or yet another example, same type of thing as what I did before, but this time the real dose is a chronic exposure. So I took a -- I assumed a 1,000 picoCurie per day intake for 31 straight days, so doing the math, that's 31,000 picoCurie intake.

Now without -- same story again, without the

analyst knowing that information, and he's going to attempt to -- let's just assume that he attempts to estimate this as an acute exposure, or a series of acute exposures. It's pretty clear when he looks at the data that something happened in here, so he ends up taking a midpoint and estimating a dose. When he takes the midpoint between sample dates, it ends up doing something like this. It overestimates the bioassay samples down here, so he has to adjust that date. He ends up adjusting the date up some until some of these samples line up, like I showed you in the one previous graph.

So I ended up choosing June 7th, and that equated to a 28,000 picoCurie intake. That gets you relatively close there, but obviously not all the way there. What happens at that point is then this curve is actually down below here, and the analyst would have to either rethink it and think it's a chronic exposure, or he's going to have to assume there's some additional acute exposures.

In this case, trying to estimate this as a series of acute, you can see what the values are I ended up estimating. Much smaller than that

initial one, but they all tend to continue to add up to where I ended with a total of around 30,000 picoCurie intake.

So the 30,000 picoCurie intake compared to the real intake of 31,000, it's 3-point-something percent difference, less than a five percent difference. And you have to remember, that's without even trying to model it as a chronic, without any other information, just simply putting a series of acute intakes to try to mesh the data.

Okay, I'm going to shift gears just slightly here. It seems like it's a big shift, but it's not. I want to talk about missed dose a little bit. Missed dose, if you remember, is just a person could receive a very small amount of inhalation exposure and not submit a detectable bioassay sample. It may not be enough to reach the detection limits of the equipment. So the question is how are we going to deal with that? How are we going to add this back in?

I wanted to -- with the external dosimetry you know detection limits for equipment, et cetera, that once the badge is exchanged that is gone. It's not true with internal dosimetry. As

the other examples already showed you, once you get an intake it's going to affect the bioassay sample for quite some time. So this missed dose does affect what happens after the fact. That's the correlation effect I'm talking about on that slide, must be correlated with subsequent samples.

So I'm going to run through another example. I'm going to take the previous example of the chronic exposure. This time I'm going to assume there's a detection limit of .022 picocuries - not that that's a real number; it just worked well on my slides. This time I'm going to assume there was a missed dose, a missed chronic exposure of 152 days consecutively, 87 picocuries per day.

It sounds like an odd number, I know, but the reason I picked that number is that gets you just below this detection limit on some of those previous samples that we called zero. So that's about maxed out in this case for that time frame. And it doesn't end up, even though that seems like a smaller number, it doesn't end up being small. That adds 13,000 picocuries to what was a 31,000 picoCurie intake. So it's not a small

difference, and that would be a significant amount of missed dose if it actually were missed.

What I want to show you or what I want to point out, like I said, is the bioassay samples that come after that fact have to change. With that amount of intake, that has to affect the concentration in the urine after the fact. What I wanted to point out is what would happen if the analyst didn't consider the missed dose in this example.

This was the previous prediction superimposed over the new bioassay samples I've calculated out. And obviously the analyst would not have thought this was a good fit. These four right here are the missed dose that I was talking about. I put them on there simply to show you where they are, but we're going to assume that they're just recorded as less than minimum detectable activity. So as far as we're concerned, it's a zero there.

This obviously is much better fit. This is what happens when he's taking this bioassay sample, he's ignoring missed dose, and he's trying to estimate this chronic exposure as a series of acute exposures. With all those

mistakes in mind, he comes up with a new estimate of 41,000 picocuries. And we know -- he doesn't know, but we know the real intake was 44,000, which is approximately a seven percent difference. Still not the end of the world.

With little effort and without trying very hard, making lots of mistakes, we're talking a seven percent difference here in this example, which is essentially what that says. And remember, that missed dose, that 13,000, which was not a small amount, there was no indications that it ever existed. It was just recorded as less than minimum detectable activity.

And again, that's because adding the missed dose will -- if you were to go back now at this point and try to add in some missed dose in the beginning, you have to recalculate your predicted bioassay samples that happen after that. If you were to take that example, go back and try to calculate some missed dose in the beginning, add it to that, you're going to have to lower the estimates on those acute exposures that you estimated.

What it ends up happening, because I went back and did that -- I'm not going to show you

yet another graph of it, but I went back and did that, and what I got was a five and a half percent error instead of a seven percent error. That shows you the difference in trying to account for that missed dose or not account for it. It didn't make a lot of difference. The big difference here that the five or seven percent, most of that is trying to estimate that long acute or long chronic exposure as a bunch of acute exposures.

So what it comes down to is if you have a series of positive bioassay samples that you have good readings on, if you account for the missed dose or don't, it's not going to make a whole lot of difference. We intend to go back and do the best we can and try to estimate some of that, but it very well could end up -- with other information it could show us that there probably was no missed dose, and if that's the case we'll drop that value down. We'll be able to tell if there was some missed dose or not once we have a series of positive bioassay samples.

This graph shows you the other end of the spectrum there. This is the same thing, just stretched out over a longer time period. Once

you've gotten a series of positive bioassay samples, like I said, it's going to affect the bioassay for some time to come. And I've got to point out, this straight line is -- yes, it's far too straight; that's wrong. This line actually should be down around in here (indicating). It should have curved on down.

But it does show you that it's well above the detection limit for -- this is somewhat like a 15-year time span in this example. So what this indicates is once you have a series of positive bioassay samples, it's very likely you, by definition, don't have any missed dose after that.

If you already accounted for enough intake to give you detectable concentrations for years to come, you can't have missed dose. You could have a small intake that's lost in variations. That's a matter of uncertainty, but it's not a matter of missed dose at that point, which is essentially all that slide is reiterating.

So as I said, these are examples of somewhat trying to be careless. I was trying to be careless and come up with the wrong answer, and it was somewhat difficult once you got some data.

So even though this seems like it's very difficult, you can see where the data's very important on a single intake. Once you get a series of detectable samples, it really does end up giving you the right total intake. You can come up with that. You can determine the amount on the missed dose, or at least account for it, anyway. It's not as sensitive as you would think at first glance.

That's essentially all I have for you, unless you -- anybody have any comments?

DR. ZIEMER: Thank you, Dave. We probably have a number of questions.

Let me begin with one, and this may have been addressed last time we met; I don't recall. If you have a long-lived material -- that is long-lived in the body -- such as plutonium, are you truncating the dose calculation so that you don't count numbers that are close to the time of the identity of the cancer -- that is, dose that because of time delays could not have contributed to the tumor?

MR. ALLEN: No. We are calculating annual dose to the tissue from the day he got an intake until the day of diagnosis. IREP accounts --

DR. ZIEMER: But the -- okay. I guess --

MR. ALLEN: IREP accounts for latency periods, et cetera, so it'll essentially be -- if it's a 20-year time span, he got 20 different doses to, say, the liver and then he got liver cancer, IREP will account for 20 different doses and 20 different latency periods and essentially sum all that up. So it give you --

DR. ZIEMER: Okay, it looks at each latency period, though, so the dose -- the year prior to the diagnosis will have, depending on latency period, maybe no effect, then, on the --

MR. ALLEN: Right. It'll be accounted for, but --

DR. ZIEMER: Accounted for, but then -

MR. ALLEN: -- there should be virtually no probability from that.

DR. ZIEMER: Yes, got you. The weighting factor will cover it. Thank you.

Now, Jim, did you have a question? Other questions? Yes, Jim.

DR. MELIUS: And I apologize if I missed a little bit of this, this has already been answered.

I'm, I guess, trying to figure out where

some of this information's coming from, and clearly this is going to be a difficult area to piece together all the information on. As part of your MOU with DOE, are you going to be routinely asking for incident reports, or how is that going to -- process -- or are you going to wait until an individual reports it during an interview? How are you going -- what's the process? Is it a general request? Is it a request at the time you are interviewing the individual? Is it before that? How -- what's that --

MR. ELLIOTT: It comes -- when we go after incident reports, will come after the interview has been done, after we've gained the information from DOE, we've seen what kind of bioassay sample results they have. Then we have the interview. We augment that DOE information with the interview information and any affidavits we might have collected through the interview. Then we go back to DOE and we say there appears to have been some instance here where this individual claims to have had an intake. We don't have bioassay results to show that, perhaps, but we need to see incident reports that might reflect

that. So that's when we would go after it.

DR. MELIUS: Okay. And then what happens if you get an incident report without any monitoring being done, or monitoring records are not available? There may have been monitoring, they may be missing, may not have been done. What's --

MR. ALLEN: Well, again, we're going to use whatever we can get our hands on, and if there's an incident report there'll be at least some contamination surveys done. We can, if nothing else, we can take that and estimate an airborne concentration for that particular intake.

DR. NETON: This is Jim Neton.

I'd just like to expand a little bit on what Larry was saying. What Larry said is true; we're getting incident reports after we see some evidence that there possibly was an incident. But if -- I know some sites have the incident reports in the person's own bioassay records and files. And to the extent that they're in there, we're certainly going to welcome them if they come along with the case in the very beginning, because it'll make our job a lot easier. But if they do have to go back and dig, and these

incident reports are buried somewhere like in the medical records or some archived files, that would be the path we would take later, then, is to go back and try to retrieve them at that time.

DR. MELIUS: Just two questions in terms of follow-up. One is -- is this more like procedural -- are you ever going to present to us how you're going to handle missing data as opposed to missing doses, what we've talked about here?

MR. ALLEN: One of those slides mentioned, if you remember, at one point it mentioned a couple of data points missing, still came out to where I got the right estimate, as long as I had some information and it was detectable information on bioassay.

DR. MELIUS: I guess I'm not as much directed it at you, but a more general question, because it seems –

DR. NETON: Yeah, I think what Dave addressed here is -- and he mentioned at the beginning of his talk that it's impossible to cover the entire gamut in half an hour or whatever was allotted.

But where they're missing data, of course

that's when we would go back and look at other sources, which is covered, I think, in the implementation guide, dealing with things such as air sampling data to help ascertain the extent of the level of contamination in the work place, co-worker data, those sort of pieces of information. And I think we've covered it in a general sense to the best we could in the implementation guide.

But I don't think there's really any one set formula that one can present for handling all the different scenarios that might present themselves. But we will use whatever's available, whether it's air monitoring, breathing zone air samples, co-worker data. And there are some techniques out there for averaging adjacent samples, those sort of things that we have referenced. But I guess there's no one set answer for that question.

DR. MELIUS: Yeah, and this is speaking, I guess, personally -- I don’t know how the rest of the committee feels -- but it seems to me that that's going to be something that's going to be a controversial issue on an individual basis. That's going to be something of concern.

And so your procedures for doing that, I think, are going to be important. They may actually be very important for an individual's dose, but they may also sort of be psychologically or personally more important to the individual. They're going to be very concerned about this. And I would certainly like to hear a presentation on that issue at some point, because I think we're going to, as a Board, have to deal with those questions and how you're doing that. So I think in the future we ought to be talking about that.

The other question I have relates -- and this may be getting a little bit off your talk, but I think it came up, at least the thought occurred to me during your talk -- was the whole security issue. My recollection from my former work when it involved DOE facilities, a lot of these incident reports and so forth were classified, probably because they occurred way in the past and there were security issues and so forth.

How are the security kinds of issues going to be handled in terms of collecting information, the interviews, what's presented to the -- what

can be presented to the individual when you're mailing information to them and so forth? Because again, it seems to me that's going to be an issue of concern to the individual, and yet there clearly are security issues that arise in doing that. Have you worked out a process for that? Is this part of what you're doing with DOE now?

MR. ELLIOTT: This is part of the MOU that we need to strike with DOE.

In our research experience and the MOU that we had with DOE on that, we have a model to work from, a starting point in that model. We have Q-cleared staff who deal with classified information of various types. Once we identify from that information the relevant pieces that are needed for whatever the work is, research, or in this case compensation, we'd seek declassification, or if that cannot be done, then we seek a summary report that is declassified.

We have to work out with DOE how this information is going to be held, because we have -- in HHS we have no classified vaults, per se. When we get to the point of appeals and final adjudication process, that's a whole nother area

that we have to explore with DOE, on how a judge can be brought into the understanding and knowledge of classified information that has been used to develop the case.

DR. MELIUS: I would just say I can see a whole variety of -- where this is going to become an important issue, and I'm glad you're pursuing it.

DR. ZIEMER: Has there been any provision either by NIOSH or DOE to consider taking bioassay samples from individuals who may have retired a number of years ago but for whom the record indicates may have long-term body burdens, and therefore, if the records are inadequate, get some current bioassay samples?

MR. ALLEN: The only word I've heard on that came from Jim Neton, so I'll let him --

DR. NETON: Yeah, we have thought about that. There are some new bioassay techniques such as thermal ionization mass spectrometry that have detection limits an order of magnitude or so below what's traditionally been used in the workplace. In fact, I know out at Livermore they're taking the old electrodeposited planchets that were sometimes positive, sometimes not,

redissolving them, reanalyzing them, and getting very nice clearance curve data for some of these workers.

So we've thought about it, but we've not really considered it as part of our routine program. It is cost-prohibitive. Those samples tend to run several thousands of dollars per analysis. However, it may be possible to use them in some sort of a verification role in our process, where if we sense that there is no -- say a claim is awarded and we take a sample, we could verify whether or not it makes -- do sort of a sanity check on what we've been doing. That's not been clearly defined in our process yet, but we certainly have thought about it.

DR. ZIEMER: Thank you.

One question not related to that at all has to do with the source term evaluations as a method of determining body burdens when you have to do that. You mentioned in your paper -- I don't think you mentioned it here -- but in your written paper the use of resuspension factors. And I noticed -- the sentence says that if limited information is known, conservative default values for resuspension factors would be

used.

What are these conservative default factors? Does somebody have some generally-accepted resuspension factors? I know there are tables of these that people have proposed for decades, but does anybody know of --

MR. ALLEN: There is no right answer on that one –

DR. ZIEMER: -- what might become the agreed-upon default values?

MR. ALLEN: There is no right answer, of course, on that one. But like you said, there are tables out there. I would think if you were stuck using something to that as a fact, you would go to the tables and go to the research that is associated with those tables and see what applies or if they apply to your situation, and get the best --

DR. ZIEMER: So a priori, there are no --

MR. ALLEN: No.

DR. ZIEMER: -- resuspension factors that you have said, these we will use.

MR. ALLEN: No. That's why I said the conservative resuspension –

DR. ZIEMER: It'll be on a pretty much an ad

hoc basis, that whatever seems to apply for a given situation --

MR. ALLEN: Yes.

DR. ZIEMER: Right.

DR. NETON: We haven't committed to anything on that line, but we have looked early on at the use of values that are published in new Reg 1400, which is the document that one would use to determine if air sampling is required in the workplace. And using those resuspension factors, it starts with the old Allen Brodsky ten to the minus sixth, and it is modified --

DR. ZIEMER: Right, the so-called magic number --

DR. NETON: Magic number.

DR. ZIEMER: -- which is exactly what I was leading toward.

DR. NETON: Exactly.

DR. ZIEMER: If all else fails, use the Brodsky number.

DR. NETON: I'm not suggesting we're going to use that, and if they have allowed for modifications in 1400 to account for dispersibility, confinement factors, those type of things, whether it's a solid, liquid, gas, and

ventilation. But I think that would be hard to defend in a general basis across the board, although they may have some value in bracketing the potential as very low or very high, again in the efficiency process.

DR. ZIEMER: True enough. But if in fact they are in, for example, in a new reg or something like that, I think they're a little easier to defend if there is any question about what you use. It seems to me something like that is a little more defensible than, say, arbitrarily picking up a Brodsky number or something like that.

MR. ALLEN: Yeah, that's why I put it down as resuspension factors, not just an arbitrary number. I mean, it would be some table, some published values. I'm just not willing to commit, because there's so many different situations. It'd be up to the analyst to determine what best fits, and what would be conservative if there's that much uncertainty in it.

DR. ZIEMER: Uh-huh.

MR. ELLIOTT: Let me make sure we're clear on a couple points here.

You're quoting from the draft implementation guide, and one of the editorial things that we'll have to make -- take account here and make change to this draft is how we define certain words. And when we're talking -- when we use this word "conservative," which I think is important for everybody's understanding, we're talking that way in regard to being -- giving benefit of the doubt to the claimant, and so we're looking at worst-case scenario. Those would be the things we think of when we're saying conservative in this approach.

DR. ZIEMER: Yes, I understand that. On the other hand, I would not want the word "conservative" to mean that as a worst case we assume that all the material present gets suspended, because that just does not happen. So conservative might be taking a number of published values for some nuclide under certain circumstances and taking the most conservative of those values, and that I could understand.

MR. ALLEN: Yeah, that's the intent of that sentence.

DR. ZIEMER: Right.

MR. ALLEN: It was the conservative end or

the claimant end of the realm of possibility.

DR. ZIEMER: Right.

MR. ALLEN: Or the realm of reality.

DR. ZIEMER: Jim has a question.

DR. MELIUS: Yeah, somewhat along these lines of conservative and dealing with this issue, but you presented a series of examples, and I think they're illustrative examples at the level that I could understand.

Have you done a more formal analysis that would look at the -- might be called a sensitivity analysis or something to look at how -- to try to put some parameters on when you have to use certain assumptions or certain approaches? And this sort of applied both here, but I think more generally to this area where there's missing information and so forth, that would let you focus your efforts on certain types of data or certain information and so forth?

I mean, it just -- examples are nice, but they're sort of selected out of a wide array of potential problems out there.

MR. ALLEN: I don't know if I fully understand what you're asking, but as far as like a sensitivity analysis, put some parameters, some

bounds on these.

You have to remember, too, and I know I didn't make that clear, all those examples were for insoluble plutonium. It'd be a totally different example for a more soluble form of plutonium or for an insoluble uranium, or -- there's so many possibilities out there. A lot of the actinines (sic) will end up giving you a long curve, a longer half-life essentially for that, so that the topic will -- applies to a lot of the type of materials we will see -- not all, but a lot of them. But the values and the sensitivity changes, so it's hard to put a hard core number on anything.

MR. ELLIOTT: If you recall Jim Neton's presentation earlier, he talked about we -- in my comment, in my presentation, we're being progressive with delivering information, and amount of information and level of technical detail information. We gave you the rule first. Now we're talking about implementation guidelines under that rule on dose reconstruction.

Jim also on his slide showed technical basis documents, and that's where I think this comes in from your question. We have to work on given

situations that are presented in cases to us, working with our contractor to come up with a technical basis on how we handle those things as they present themselves, and then those are shown to be established and used for the next case coming along that is similar in nature and situation.

DR. MELIUS: Just to elaborate, just -- I guess what I'm trying to get also, are you doing that, which is good, but also are you prioritizing that effort so that your limited resources are being spent on areas where it's going to make the most impact in terms of cases? And right, you're not going to know that until you've gone through a number of cases, at least not completely.

But it's going to be important. You can spend a lot of time doing some of this work technically, but it's not going to make much difference in terms of what a person's dose or where they're going to end up in terms of probability of causation. And so are you going to focus it in that way also, because that seems to me what would be important, given the limitations on resources.

MR. ELLIOTT: Yes, I -- very good comment, suggestion; and we are. We're taking first things first. And this is definitely on the record now. That's something we plan to incorporate as we move through, as cases are presented and working with the contractor once they're on board, to develop the technical basis documents that serve as models for how future cases are handled.

DR. NETON: One area I'd like to comment on that I think we're looking at, and it's going to pay off some large dividends, is how much effort we put into refining the precision of these estimates.

It turns out for some of the more uncertain risk models, if you spend a lot of time reducing the uncertainty of the internal dose estimate way down, you've wasted your time because it virtually doesn't change the risk -- the probability of causation at all, because some of the models have so much inherent uncertainty built into them. And IREP has a nice feature that one can run, and it apportions the probability -- uncertainty to the different factors.

And if you run some of the more uncertain models -- I think probably bone cancer is one of those -- you'll find that no matter what you do to beat your brains out to get the uncertainty of the internal dose down, it's all driven by the uncertainty in the models. And we can use that to our advantage and not waste time trying to refine these uncertainty distributions below a certain level. I think that area is very, going to be very fruitful for us.

DR. ROESSLER: You might be touching on an area that I have a question with, I guess, and that's in your report, which you didn't address, but the organs not included in the ICRP models, and how you come up with dose to them. Once you do, it seems like you're going to have a lot of uncertainty associated with it.

And also, I'm thinking that these organs might be some that a claimant might have cancer, come in with the claim. These organs may very well be some that are not associated very much with radiation exposure, and on that case you have a great deal of uncertainty. It just seems -- and I haven't put it together mathematically -- but it just seems like you have a real problem

with uncertainties here.

MR. ALLEN: There's a potential problem there, yes. I have played with some of the possibilities. And as Jim was saying, there's -- or as you mentioned, some of these organs are not very radiosensitive, so there's not a lot of information, and ICRP did not deal with them very well.

The truth is, if they're not very radiosensitive, the risk factors are usually -- should be somewhat higher. And as Jim pointed out, sometimes they'll be compensated with the uncertainty associated with the risk factor. And the uncertainty associated with the dose almost becomes irrelevant at that point. You can calculate your best dose -- you're always going to calculate the best estimate of what the dose was, and if you go to the IREP program, you can put in a large uncertainty for the dose or you can put it in as a constant. If you find out on both of those land on the same side of whether to compensate or not, the uncertainty doesn't need to be refined anymore.

DR. NETON: Yeah, but the bottom line, I think, is that if an organ is not metabolically

involved in the metabolism of a radioelement, such as the prostate gland for a plutonium intake, the dose is going to be extremely small. And I think the concept of using that upper bounding estimate and applying it to that organ will demonstrate that since it's not metabolically active there's very low dose, and we can deal with it that way.

Now the prostate is one of the 36 organs that ICRP models. I think the original question was what about organs that aren't even in those 36, in the ICRP models? And I think I touched on it last time, is the concept at this point is to take the highest non-metabolically involved organ and assign that dose to that organ. So if you take the metabolically-active ones -- for plutonium would be liver, skeleton and lung, if it was inhalation, and the gonads are one of the sites -- and then take the next lowest one.

And what happens is that that would essentially be the dose to the transfer compartment, a partition among the volume of blood that flows through that organ, and that would be the dose assigned to the non-ICRP model. Does that make sense?

DR. ROESSLER: Yes, that makes sense. And I think what you're saying is that that dose is going to be low, and it --

DR. NETON: Yeah, it --

DR. ROESSLER: It doesn't really matter, then, how --

DR. NETON: Right.

DR. ROESSLER: -- uncertain it is, because it's going to be so low. And probably that's why those organs are not included in ICRP to begin with.

DR. NETON: That's right. That was my thought process all along.

And I think Dave knows this better than I do, but I think if you look at it, I think they're several orders of magnitude lower than the metabolically-involved organs, typically. And if we conservatively picked our next-highest one that's not metabolically involved -- I'm not sure that's the right word, but I think you know what I'm talking about -- virtually it's almost impossible to inhale enough material to get the probability of causation up there for most of them. I can't say we'd cover all possible cases, but I'm pretty sure that's going to be the case.

DR. ZIEMER: I think Henry's been waiting to ask his question.

DR. ANDERSON: Yeah, I just wanted to follow up a bit on that using sensitivity analysis. But it's very difficult for us to address the issue of your -- the thrust of the whole law is to be conservative on the behalf of the client, and that gives a certain sense of comfort if it is.

But the bottom line question is how conservative? And as we just heard, that in many of these internal doses it ultimately makes no difference in the probability outcome. And so I think -- or it may not make much difference at all because of a variety of factors, and therefore while we're saying we're being conservative there, in reality it's -- it isn't, because it doesn't impact the outcome.

And what I'm asking is have you taken a series of scenarios where you have -- and of the most data you would want, and then remove some of those data elements to see how does the system operate when you have some of that missing, to get a sense of is it always erring on conservative side; and if so how much?

Because you could have it go -- I think the

last time we talked a little bit about that if you have a great deal of data, that may in fact -- because you reduce the uncertainty so much it's not -- you're far more certain in the actual dose, and this could then be to the individual's detriment because now their probability drops below, where if some of their data had been lost the system would err on the other side.

I think it's hard to understand --

MR. ALLEN: I realize --

DR. ANDERSON: -- how much of that is there, and where are the soft points in this system that may need to be subsequently tweaked. You could either wait till you have a lot of field experience, or you can take like the Monte Carlo system and pick a number of these to run through in a theoretic sense, and then have as the gold standard a actual dose -- complete exposure model that you would have and say what does it predict, and then which of these elements are playing the most in the system.

Has any of that been --

MR. ALLEN: Long question.

DR. ANDERSON: Yeah, it's a -- I don't want to read the transcript. I think you got the idea

what I was trying to get at.

MR. ALLEN: I think I got the idea. If I'm sure of what you're asking, you want to know how much effort we put into determining what individual parameters, how sensitive the dose is to –

DR. ANDERSON: Yeah.

MR. ALLEN: -- individual parameters such as maybe the date, et cetera.

What you saw today was essentially our effort towards determining how sensitive it was to date, to the date of intake, or how sensitive it was to chronic -- estimating it as chronic versus acute. So you've seen a portion of it. And no, we're not complete with that yet. And we probably won't be complete with every possibility when we start doing dose reconstructions. And as Larry said, there'll be technical basis documents coming up. As we need to learn something, we will attempt to learn it. We will document it, and we will finish that case.

Does that make any sense?

DR. ANDERSON: A little. It's how do you know, though? You'll go through it, you'll end up with a result, but unless you run it through

the model with multiple scenarios you won't really get a sense of when you need more data or not.

MR. ALLEN: Right. A lot of times we can come up with -- if we're not certain about some parameter, we can come up with various theoretical scenarios and run through any number of scenarios to see how sensitive it is that way.

As far as any other type of sensitivity, we don't know exactly what intakes a particular person got, so -- our whole job is estimating these, so we don't have anything to compare with it, once we've done our best job on that.

DR. ANDERSON: Yeah, but I'm focusing on the model output, and therefore what goes into the model. How it reflects reality is nice, but how the model works and accounts for when things are missing is where we get into how conservative is the output from it. So if you kind of remove all of the units, basically we're saying the outcome here is 15 and the outcome here is one, and if you change this one from a 1.1 to a 1.2, here's what may happen. And that may be, again, the question about defaults, for instance. Here, if

you're -- depending on what your default is for an internal dose, it becomes very important.

DR. NETON: Right. There are a number of things we haven't talked about today, that I think maybe I've given a misimpression that we're always going to try to bracket these so that they are not qualified for compensation.

In fact, when we talk about conservatism, there's a number of things we haven't discussed, which is the default solubility classification. If we did not know anything about what the worker was exposed to, whether it was an oxide or a nitrate, we would in a conservative basis -- that is, a claimant-friendly basis -- use the most insoluble material. For instance, if it was a dose to the lung, that would be consistent with the bioassay data we were presented. So that's what we mean by being conservative, so the dose would be an overestimate, but it would be -- it would have to be an overestimate consistent with the data that were presented to us.

Particle size is another area where we have some latitude. The default particle size for this model is five micron aerodynamic median -- activity median aerodynamic diameter. It's

likely that many workers, particularly in uranium fabrication facilities, were exposed to larger aerosols. But unless we can demonstrate to the contrary, we will use a more conservative default size that would tend to maximize the worker's dose because we couldn't prove otherwise.

So I don't know if that gives you a little better sense. And we do need to look at those parameters as to how much difference it makes; you're right.

DR. ANDERSON: That's really my point, is that the five microns, if you assume it's 95 percent of them are below five or not, the question is what difference does that make.

DR. NETON: Right, and --

DR. ANDERSON: And rather than say, well, we're using the most conservative, it may be most conservative by .2 percent.

DR. NETON: Right, and we're doing that, and --

DR. ANDERSON: The workers, I think, are going to want to know. They're comforted by saying it's conservative, but you'd like to know --

DR. NETON: Right, and we're doing this.

And Larry mentioned that kind of one-step-at-a-time approach. We just got finished doing a comparison of this whole ICRP 66 default particle size insolubility classes to the old ICRP 30, so we're ready to address that issue if and when it arises. So what you're suggesting makes a lot of sense, and we need to do that.

MR. ELLIOTT: The accuracy we're trying to achieve here is accurate decisions at Labor, okay. And I think where your point is well taken and where it comes to play is in those dose reconstructions, in that middle group toward the high end, say, 40 to 49 percent. And what do we need to do, what do we need to understand about the uncertainty, the soft points, what contributes most to that probability of causation? Is it the risk model? Is it the dose reconstruction that went into the input parameters of IREP? And those are the things we're going to spend our time on looking at in this point that you're making.

DR. ZIEMER: Thank you. Any further comments or questions?

(No response)

DR. ZIEMER: Thank you, Dave.

We are due for a break, actually, and let's take a break till 2:35.

(Whereupon, a recess was taken from 2:20 to 2:40 p.m.)

- - -

DR. ZIEMER: We have on our agenda a Board discussion period. This was intended to be a discussion of the two presentations that we just had. However, much of that discussion has already occurred. Let me just ask if any of the Board members have any additional questions or comments they wish to make relating to the presentation by Tim Taulbee and Dave Allen.

(No response)

DR. ZIEMER: If there are none, then I'm going to proceed on the agenda, with the permission of two individuals who have signed up for public comments.

Mr. Alvarez and Mr. Miller, do either of you object to proceeding with your comments at this time?

UNIDENTIFIED: No, we don't.

DR. ZIEMER: All right. Then -- well, we're going to go alphabetically here. I always like that because it makes me last. But Bob Alvarez

will go first. And Bob, if you wouldn't mind, would you use the podium up here, and then I don't have to turn around.

MR. ALVAREZ: Yeah. Thank you for giving me a few minutes. I won't take very long.

DR. ZIEMER: Bob is with the Institute for Policy Studies here in the D.C. area.

MR. ALVAREZ: And some of you know me in different, other incarnations.

I wanted to cover a couple of issues with you, and I'll be as brief as I can.

One is the, I guess, the basic overarching question of conflict of interest. Given that this was an activity undertaken by the Federal government itself for a national security purpose where people were put at risk in certain instances under circumstances where deliberate decisions were made to not provide protection or not to inform workers, the fact that the government itself is essentially the liable party in this places, I think, a very -- an additional special burden on this committee, on the institutions of government that have to implement this program, to address those issues. And it's not easy to do, because the Federal government is

the Federal government. But what I wanted to propose to you is at least some possible ideas or concepts to consider in terms of addressing this conundrum.

One thought that I had, especially in terms of the work that eventually will be undertaken by whoever is chosen to -- as a contractor to conduct the rather mammoth task of individual dose reconstruction, is for this committee to set up a subcommittee that would report to the full committee that would be comprised of worker representatives.

That subcommittee should be provided with necessary resources to hire technical people to be able to do some quality assurance work on the effort of the contractor, particularly with respect to review of work scope, spot-checking ongoing work, and at least some sort of review of the general approach that's going to be undertaken; and for the committee to do some periodic spot-checking and reporting to the full committee itself, not being separate, but being a function of this committee.

It would be a way, I think, of adding a layer of quality assurance; but I think also, in

a way more important, adding, I think, an element that could really build public trust in this process. And I think public trust is very, very important to this.

The second sort of issue that I wanted to raise with you really has to do with where this committee will be heading once this is -- once the individual dose reconstruction issues are addressed, and that is the issue of the special cohorts themselves. And I think -- as you know, if you look very carefully at the circumstances that led to the enactment of this law and the issues that were raised, is that we're not just dealing with an issue of dose and effect and response. We're dealing with social policy. How do we -- how does science inform social policy, which has to do with making right with the past?

And then you get into questions of ethics. And I think this committee should consider having on its -- as one of its members an ethicist, because there are circumstances when you start especially to get into the issue of the special cohort, if you see -- if some of you who were around or if you look back at some of the legislative history that led to the creation of

this particular provision of law, was the revelation that there were workers who were put at -- knowingly put at risk without their knowledge, and were denied any protective measures in a deliberate manner.

The infamous 1960 memo that came out of Paducah where someone was asking if -- was pointing out that workers were probably getting heavily exposed to neptunium particularly in the fluorination processes, the bag house workers, people who were hitting large cloth bags laden with neptunium with metal rods in street clothes. And the reply that came back was we are not going to measure them, any exposure for neptunium. We are not going to provide them with necessary protection. And by the way, there was also a request to do postmortem. We're not even going to look at them after they die, because we are afraid that this information would lead to the union demanding hazardous duty pay.

There is a huge ethical issue being put on the table by that memo. I think you need someone to help you sort these kinds of issues out because there were decisions made, shortcuts made, and the like.

I also want to draw your attention to an effort that came out in March of last year that has never really -- that was never really completed, but it is what it is, which was an attempt to establish an understanding of the mass balance flow of recycled uranium in the Department of Energy complex. This undertaking sort of went to a preliminary phase, and then was shut down when the new administration came in, and it never really sort of went further beyond that.

But that particular set of studies, documents, I think, provides some very important insights. Approximately a quarter-million tons of uranium was recycled for the purposes of the United States nuclear weapons program. That's a very large amount. That material wound its way throughout many of the existing plants and a lot of defunct plants, and to a lot of outsourcing facilities that were doing contract work for the AEC during the fifties and sixties.

And I'm mindful of a couple of things. For example, in reviewing the Hanford report and the Oak Ridge site-specific reports, it was very clear in these reports that the initial product

that was coming out of the U tank, the tank farms, from the U farm where they were extracting uranium from waste that was coming out of the bismuth phosphate extraction process, that that plutonium did not meet spec for Oak Ridge. In other words, there were excessive levels of plutonium in there, and Oak Ridge was rejecting this, not for health and safety reasons, because they were just starting up their gaseous diffusion plants and didn't -- were afraid of, quote, gumming up the works.

So what happened when they weren't meeting spec? This material wound up in Cleveland, Ohio, in Harshaw, and those workers conducted the fluorination process, which had the effect of reducing the plutonium content that made it allowable to be received by Oak Ridge. And think about those workers who might have been hitting cloth bags laden with neptunium and plutonium from the first batches coming out of the U tanks.

These are issues that I think you really need to look at. And I think it's important to look at these issues as you start to move toward the special cohort problem in the context of understanding the flow sheets. There are still

flow sheets that are still not public that need to be addressed. For example, we really know very little about the thorium U-233 flow sheet of the AEC/DOE. Where did all that stuff go, who handled it, what was going on? Ultimately at least a ton of uranium 233 was produced, and it's sitting around at the DOE complex. There was a flow sheet involving this. Where is it? Where were those workers?

I also think that some of the work that has been done in the past in the previous years, particularly in the year 2000, looking at the occupational -- the history of occupational protection at the gaseous diffusion plants that was done by the DOE Office of Environment Safety and Health, I think, are very instructive.

And it would be useful to have more of these studies done as you pursue that issue of the special cohort, because these are things that -- where you need to have -- it's almost like putting together a painting where dose reconstruction, in and of itself, gives you some part of the image, but to really get the image sharper in focus and add more to the picture itself, you have to start to look at the issues

that were swirling around at the time -- whether or not, for example, there is any evidence that workers were knowingly put at risk and no protective measures were provided in a deliberate manner.

You have to look at whether or not any of -- what kinds of jobs really have -- may constitute high-risk jobs from the point of view of a special cohort, again looking at the -- for example, workers who may have been handling uranyl nitrate in the calcining operations in the 300 Area at Hanford when they were getting the first batches out of the U tanks and converting that material.

What's abundantly clear in the DOE report, the site-specific reports about recycled uranium, is that, one, there were no protective measures, no limits set for exposure to neptunium, technetium, or plutonium, for that matter, in these settings, and that each site had its own way of measuring for it for purposes of material transaction, which leaves huge questions about inventory discrepancies.

So these are things that I'm just urging you to think about as you move forward in terms of

establishing a conceptual basis for addressing special cohorts.

Thank you very much.

DR. ZIEMER: Thank you, Bob. Before you sit down, let me ask if any of the Board members have questions that you'd like to address to Bob, or things for clarification?

(No response)

MR. ALVAREZ: Thank you.

DR. ZIEMER: Thank you. Next we have comments by Richard Miller from the Government Accountability Project. Richard.

MR. MILLER: Good afternoon. I would be remiss if I didn't come with handouts, and so I have. I was even thinking about handing out what I handed out last time so we could talk about it again.

I'm going to sort of touch on a number of points very quickly. I am also going to pass around, once you have that memo in hand, a picture. I don't have one of those beautiful overheads to make it visible for everyone.

But today's discussion on dose reconstruction -- and I may be misreading both the guidance for internal and external, and I may

be misreading the rule in terms of the process steps that are followed -- but the appearance is that NIOSH will receive initially internal and external dose badge -- internal bioassay data and external dose badge data, and then based on that two things seem to happen.

One, there's a culling process that goes on that seems to weed out low dose and sort of the obvious high dose cases, and the high dose cases that may be eligible you sort of push through.

But then there seems to be this second step, which is that if you're not sort of weeded out presumptively and you go through an interview process, there is a -- it appears to be that there is a presumption of regularity in the dose record unless either the interview or some other intervening event clues the folks who are the contractors doing the dose reconstruction that they should not presume that this paper record, as delivered, can be massaged and analyzed as it was in our presentations today.

Now both the legislative history of the Act, and more particularly some of the studies that actually Bob Alvarez mentioned earlier on the history of the radiation protection programs --

and this was done at Portsmouth, Paducah, and Oak Ridge with special allocated funding by Congress at some expense, with a team of about 35 people -- not quite a tiger team, but reminiscent of -- and conducted in cooperation with the unions at these three sites in order to encourage a high degree of participation in interviews.

So many people received information under Q-clearances, and needed to be encouraged they were comfortable to disclose what they knew. Secondly, people were concerned about retaliation if they're active employees, which they were in many cases. And the union actually sort of nudged people and say, it's okay to talk to these guys, right? Don't be shy.

Well, out of the course of approximately 125 transcribed interviews done at each site -- there was about 375 transcribed interviews, coupled with an extensive paper review of not -- and the interviews were done with both hourly and salaried people in health physics and management, as well as on the ground floor in production. And what came out of at least those three reports was that the history of radiation protection is pretty darned spotty. And let me just give you

sort of some of the kind of interesting findings.

One was that they -- for many years you had the Monday morning urinalysis that was provided. And that was sort of a point of bemusement, because after you'd spent a good weekend drinking some beer, if you had soluble uptake most of it was gone by the time you were there. Now that was good for flushing it out of your system at the beginning of the week to set a baseline, but it might not have been too good at capturing what happened the week before. And so you had corrections over time to improve and obviously avoid and create obvious post-incident and other forms of sampling methods, but you saw a lot of irregularity.

You had irregularities with respect to even external monitoring. We saw for the people who were involved in making uranium derbies from magnesium reduction furnace -- in the magnesium reduction furnaces, and they were told to go in and chip all the slag off, right, to get the uranium derby out. Well, lo and behold, they didn't have any extremity monitoring.

Bob Alvarez talked about the poor folks who had to go into the bag houses with the caked,

thick dust that was -- with very high concentrations, up to 15 percent of neptunium 237, and take steel rods and literally beat the bags, and you have big clouds of dust. This doesn't turn up in the dose record, and it doesn't turn up in the paper record very readily. It came back through sort of historical research.

And so the challenge that I saw was, whether it be at -- or take a good example at Portsmouth, which NIOSH actually was quite instrumental in uncovering, was the absence of neutron monitoring. You had freeze-outs in the uranium enrichment process which would lead to what folks euphemistically referred to as the slow cooker effect, and you would have unmonitored neutron exposure.

Now only certain people would be even potentially at risk, mostly maintenance people. But you don't have any dose record with which to come back and sort of reconstruct it. Was it significant, was it not? That's certainly debatable about the degree of significance, and some have suggested you go back and re-examine the glow curves. But it's going to be quite a challenge where you don't have monitoring to

start with.

So the concept of missed dose, as I sat, at least, in the back row today and watched it, I had a different meaning of the word "missed dose," and it's not that which is unrecorded because it falls below the limits of detection. It's purely either unmonitored for dose or improperly accounted for dose. And so the paper record itself doesn't provide a very firm foundation.

Now how do you get clued in that that paper record is or is not a good basis? And what I don't get is, from reading the rule, is what automatically makes the contractor leap into the sea of all of the other forms of information that can be out there. Most of the occurrence reports at certain sites have never been made public.

For example, at Los Alamos they have never been made public. That's a very interesting source of data which is not organized in electronic form, and if you don't have those occurrence reports readily available or the claimant doesn't have the ability to go and get access to them, and NIOSH isn't clued in as to whether there was even an occurrence report

associated with a particular event, you're left with, as a claimant, operating in a vacuum. What's to push it forward?

Well, it seems to me that two things serve as sort of important obstacles in what needs to be done. The first obstacle is what I see in the request for proposal for the contractor. And the obstacle that seems most evident is -- and I'll just read it here from the RFP on dose reconstruction research:

(Reading) NIOSH does not expect that the contractor will be responsible for the physical collection and retrieval of records at the DOE and DOE contractor facilities.

And then it goes on to say:

(Reading) Plans for site visits and the research to be performed must be approved by NIOSH.

DOE, on the other hand, is the single largest impediment to NIOSH's access to this information, and the biggest single opportunity. And at this point, if the contractor doesn't have the freedom to in effect go do a deep dive on what's in the vaults, and you're left with what DOE chooses to give you and rely in large part on

what the claimants may be able to tell you as best they can recall, recognizing they operated for many years on a need-to-know basis, this process seems significantly disadvantaged.

And one way to crawl out of this -- and it's clearly not something that you've gotten a statutory directive to do, so this is not implied as a criticism of your failure, NIOSH's failure to do what they should be doing -- but the kinds of reports that were generated by DOE sort of for the three GDPs gave us a road map, as it laid out the systemic irregularities in the entire system of radiation protection from the beginning of the sites up to present.

And you can -- that tells you a lot about what kinds of questions you need to ask. And most sites don't have that. Most sites don't have that history laid out. And I don't know whether NIOSH is going to be in a position to do it. But it seems to me absent that, claimants are going to be clueless, in many respects, to direct you around whether the systemic programmatic approach was proper or improper, and whether the paper record that underlies it has any basis. And that's a larger question than

many claimants can surmount.

Secondly, I wanted to talk a little bit about -- just very briefly -- this memo I passed out. Bob actually -- Bob Alvarez unfortunately stepped on my story a little bit, but this was the famous Paducah memo. And I don't know if any of you had seen it before, but I want to just highlight it because it's hard to read. It was never of very good quality. It fell out of the drawer, so to speak, when the Office of Environment Safety and Health went to do its oversight assessment. It never surfaced in all of the years of litigation, worker comp claims that had been brought at that site. I don't know how this thing never came to light for all of these years, but it was sitting in the file drawers.

Nevertheless, there it is. And what it says is that workers were handling neptunium 237. It was in a very fine particle form, about a half-micron in diameter, so the masks that -- the respiratory protection they had was completely inadequate, even if you wanted to put those old World War II Army masks on in these very physically hot facilities inside. And what they

found was, if you look -- I don't know -- it's on page two here, it says that they were supposed to wear nose and mouth face masks, and there's a little part marked in the right-hand column:

(Reading) I watched one man push up his mask, smoke a cigarette using potentially contaminated hands and gloves. They've devised some air scoops, but lo and behold, it doesn't seem to be a very good job of ventilating the cascades when they cut them open.

The conclusion of the memo on page three is that there are possibly 300 people at Paducah who should be checked out -- this is for neptunium 237 -- but they -- I presume referring to the contractor, in this case Union Carbide -- hesitate to proceed to intensive studies because of the union's use of this is an excuse for hazardous duty pay.

They then go on to suggest, well, look -- on page four -- you know, we really ought to go ahead and do some toxicological studies here. We should get our arms around this. And they pointed out the need to get postmortem samples on any of these potentially contaminated met -- this is on the top of page four -- for correlation of

tissue content with urine output. And the memo goes on to say:

(Reading) But I'm afraid that the policy at this plant is to be wary of unions and any unfavorable public relations. So they weren't willing to test the living, and they weren't willing to test the dead.

So you get to the bottom of the memo, and it says, well, it appears we've got a neptunium problem, but we don't have the data to tell them how serious it is, and on life goes.

Of course, the workers were never told about this. And the first monitoring for transuranics was conducted at that site on a voluntary basis in 1992, so some 30-odd years later. And even then there wasn't a mandatory transuranic bioassay program for several years thereafter. And you know, the only reason people even knew that these materials were in use and that there should be some assay program was because the newspapers were reporting they were finding it in ground water.

Now when the Department of Energy ended up contracting for sort of some kind of general exposure assessment at this plant, one of the

things that was startling was that although there were very low quantities of neptunium 237 in the parts per million range in any given ton of uranium, what they discovered was that this stuff preferentially accumulated and deposited out on certain pieces of equipment. And only when you cut them open to do maintenance work -- say the compressor blades, for example, where you had to take the barriers apart -- would you wind up with up to 55 percent concentration of neptunium 237. And there was no radiation protection program in place, and all of the paper trail that existed at that site which sought to assess this risk never accounted for that.

Now we've been blessed with a lot of money being spent on answering the questions about what happened to people in the feed material building, the 410 building and others at Paducah. And so now, today, lay people like myself can talk about it with some degree of confidence because it's been so well-documented.

What do you do, though -- and this is the challenge, I guess -- how do you get this kind of understanding at many of the other types of facilities in terms of the vast missed dose

problem? Because to me this is what missed dose is. It's not whether it goes unmonitored below the limits of detection. It's do you -- is this going to be a case of garbage in/garbage out in terms of dose reconstruction, with high degrees of precision and error bars around measures of central tendency that bear no relationship to what is an accurate characterization of what happened? That's a real challenge.

And we shouldn't be misled by the high degree of precision that we saw in terms of estimating the tweaks around the uncertainties when we may be missing the forest for the trees. And frankly, if you went and picked up the telephone and started interviewing workers at Paducah three years ago, before this story broke on the front page of *The Washington Post,* they couldn't have told you one iota about it. They couldn't have told you.

So this is a real challenge, and I think it's such a profound challenge that I would encourage you perhaps to sort of -- both to inform as a process step, and secondly maybe as a recommendation to the Secretary -- hint, hint -- that you bring a panel in of folks who've done

this kind of what I would call forensic dose reconstruction, which is very much what you're doing here, right? You're trying to basically come in and pick up the scene of what in some respects were either cover-ups or mismanagement or error, or maybe well-managed programs, but for which in many cases there's a high degree of irregularity.

The tiger team reports, when Dr. Ziemer was at DOE, and Leo Duffy and you and Admiral Watkins were pushing these tiger teams through, and although it became a dirty word to talk about how wonderful tiger teams were when the next administration came in, those reports uncovered extraordinary irregularities in your radiation protection programs. And these really should be the centerpiece about informing the questionnaires and the thinking that goes into it.

Now perhaps -- there's been some interesting dose reconstruction projects underway. There's a very expensive one underway now in its concluding phases at the Mound facility that MJW has been doing as an outcome, frankly, of litigation that was brought there for the failure of the

radiation protection program.

And it will be very interesting to sort of hear how did they attack those problems, and what were the records access issues they dealt with. Because one of them, we learned, was that the books -- much of the data was handwritten in books, and the books were shipped to Los Alamos -- I mean, to Albuquerque, and they were stored in warehouses far from the Mound facility. And then they had to bring these books back, and it turns out the books were contaminated. So they had to copy them in a special copying machine, because you had a serious hot records problem both on-site and off-site.

And so these are some interesting -- now they're spending six, seven million dollars on this dose reconstruction. And I'm not suggesting you spend that per site, but I am suggesting that there's a lot to be learned about all of the particular obstacles they stumbled over.

Likewise, the work that Dr. Arjun Makhijani did at the Fernald facility, which as been well-published, and a number of you may be familiar with it, but it would be worth, I think, your all's time to hear about what Dr. Makhijani

encountered where he had access to records you may never see, because he got them compelled through discovery and through the lawsuit for the lawyers that where he was working with.

And you wound up with the documents that showed what the pattern of cover-up was, and what he also learned was that at the Fernald facility, at least with respect to uranium, over half the work force was exposed in excess of the prevailing standard at the time for a decade, and in one year it was 90 percent of the work force, the production work force itself. Pretty startling, and that was based on a urinalysis, post hoc urinalysis. Maybe it would be worth it to hear from him.

And likewise, whether it's worth it or not -- and I don't want to step on politically sensitive turf -- but Mark Griffon's research, and the work that he went through at Paducah where he took the electronic record and decided should we just accept the paper record of dose, external and internal, and what happened when you dove underneath the surface of that paper record and what did you find.

In other words, when given -- I don't know

how much money they got; six, eight hundred thousand, a million bucks between them and the University of Utah to do the deep dive with lots of resources and lots of staff, what did you discover? And are there questions and methods that need to be looked at, because I think the task of the contractor here is as much forensic as it is scientific.

Lastly, I would pass around, mostly for amusement value, a photograph. This particular photograph is appearing in a copy of *The Bulletin of Atomic Scientists,* and I'll give you a copy of the magazine for your record. This is a picture of an individual who is stamping a uranium derby, and he is straddling the uranium derby between his legs. His dosimetry badge, however, is pinned to his lapel, nowhere near his gonads.

And the question is, when you were -- when the discussion occurred this morning about, well, we're going to make all these assumptions about how effectively these dose badges are capturing it, and we're going to have some uncertainty bars around it, and we're going to look at the geometric -- what's the relationship of whatever's being emitted to the body, lo and

behold, this is not capturing that dose, or not very much of it.

And so the question becomes how are you going to account for what few workers would ever bother to tell you, which is that they straddled uranium derbies? And then how are you going to go estimate that dose thereafter?

And so the real world uncertainties are not just simply giving the benefit of the doubt. The real world uncertainties have to be accounted for because you have to overcome all of this. This is nothing -- that reality is in no way captured or reflected in the methods that are given in the guidance, that I've been able to perceive.

And does the uncertainty, the 95 percent error bars around your dose estimate, does that capture that or not? Does that fall outside of those kinds of everyday work experiences? And if it doesn't, then what are you going to do if it's not captured? What are you going to do to account for that? How are you going to account for that?

Lastly, it's hard -- at least from the outside, as an outsider, just sort of reading documents and listening to the discussion -- to

figure out how your proposed dose reconstruction rule fits in with the special cohort determinations. And the dovetail is I don't know how you cannot fit the two together. I don't know how you can deliberate on this rule and not look at that policy or rule or whatever it's going to be down the road.

How are you going to determine whether it's feasible to estimate dose with sufficient accuracy? That's the policy question, coupled with whether people may have been endangered, to put someone in a special cohort. What in this process that we see here would lead you to the conclusion that it's not or it is feasible to estimate dose with sufficient accuracy?

And where is the continuum between the dose estimation process and falling off the cliff by saying, eh, it ain't feasible here? And that is, is the decision, well, we'll toss the claim because we don't have enough information, or is it we'll send them down to the petitioning process? And it would be helpful to see how these fit together to know whether there's a seamless web of coverage for a potential claimant. And I would encourage you all to think

about grouping those together before you give recommendations on whether this is the appropriate approach.

DR. ZIEMER: Okay. Thank you for those thought-provoking comments.

Let me ask if there are any questions here that the Board may have. Yes, Roy.

DR. DeHART: Mr. Miller, I'm curious, how are we to handle the unknown? How are we to handle that which we don't know, which perhaps no one knows? Or the unusual events, such as the photograph that you show, in dealing with this situation? Should all become special cohort?

MR. MILLER: Well, I think that -- I'm going to turn the question around just for the moment, and maybe it would be useful for the committee to get a good grounding in the degree and scope of irregularity in the way in which radiation protection programs have been historically run, at least as DOE has done its own self-assessments. And I would only -- this is not to not answer your question, but to say should you presume regularity in the sense -- in the paper record that NIOSH will receive?

My answer to that is that I don't think you

should presume regularity. And then I think your inquiry that follows, which I don't know that can be -- there's sort of a couple of ways to do it. One is to look at the problem collectively. Can we get enough information on the history of the radiation protection programs at these sites?

And in Hanford, in the cases of many subparts of the various sites, or the big ones, Los Alamos and of course Oak Ridge, you're going to have to subgroup how effective were these programs in each of these different areas. And then once you have some larger sense about whether there's regularity, whether the sort of radiation assessment procedures, as we understand them, were followed, then you can say okay, at X-10 they had a great program for assessing internal dose, and we have a high degree in confidence that the methods they followed were the best, and we know how to correct for them even. And you may find that at other facilities you can't presume that regularity.

Then the issue becomes what do you do with the special cohorts? I think in the special cohorts you've got a group, the people you know that were at the greatest risk, take the high

risk occupations, and you match them up in some sort of what I would consider to be crude assessment of who falls in and who doesn't, because you're always going to have somebody complaining right at the margin they didn't get in, right? But you're going to have to sort of come up with a box that says these are the people that were really at risk, and assign in a sense a collective risk criteria because we can't pin it down for them. Which is what Congress did with the special cohorts for the facilities it covered.

I think that this is a real challenge. This was the compromise. You're asking the question about what was the compromise. I happened to be in the room -- privileged, in fact, to work for the union that represented a lot of nuclear workers in the complex. And if I'm not speaking out of turn here, I'll sort of relay the debate that took place in Congress that punted this issue to you all to grapple with.

First there was legislation that was filed that said, look, let's treat people like they're treated in RECA and just presume. And people said, look, we can't throw out sound science.

You're right. So we said, let's apply sound science where it exists, and where it doesn't and there's really good reason to believe that people may have been put in harm's way and there's irregularities, you shift them to the special cohort.

And so the debate was between those that wanted to just do it, just provide the broad special cohorts, and those who just simply wanted to use a dose concept. And the lesson actually came out of the Veteran's Administration program, which said wait a minute, the dose estimation is -- there's so little data upon which to do good dose estimation that where you can't come up with good dose estimates you've got to give people the benefit of the doubt, right? And I think that's really where you need to come down at the end of the day.

Otherwise, what's going to happen is as your dose reconstruction estimates come out and you have -- and this will only -- sort of hindsight's the only way to know this -- but as you have lots of these coming out, and they'll come before your committee and you start looking at these cases, and you're saying people you think should qualify

aren't qualifying, what are you going to do, right? Then it's going to sort of dawn on you, wait a minute.

So my recommendation is the most thoughtful way out of this box is to -- and perhaps -- is to get the best histories of radiation protection programs put together in the most critical way possible, as was done for the three GDPs, because it is a road map to what you can rely on and can't rely on on a building-by-building-by-building basis. It's enormously illuminating to look at that. And then you can decide from looking at this, they did an okay job with the folks in this part, but they didn't here. So we can narrow that cohort, perhaps, to those that were put in harm's way but weren't properly monitored, weren't told.

One thing we do know -- and it really is an ethical question -- if you're going to put people in harm's way and you're not going to tell them, as this memo made a very conscious decision -- and this was not isolated to Paducah, and this was not freelancers in the DOE complex. This was the official government policy, as was uncovered at site after site after site after site in the

DOE complex. We have a stack of documents that look like this going back.

Why? Well, because the government didn't want -- the insurance division of the Atomic Energy Commission didn't want to deal with claims and the costs. They were concerned about adverse publicity. They were concerned about demands by unions for hazardous duty pay. They were concerned about trial lawyers suing them. And they were also worried about the consequences that if this wound up in court you could lose classified materials, or classification, rather.

So those were all -- so when you're dealing -- my perception of this is that when you're dealing with evaluating how to estimate dose, you have to view it through the historical lens through which it was done, and the notion that this is remedial legislation that was intended to, in a sense, cure cover-ups.

That's a long-winded answer.

DR. ZIEMER: Additional questions or comments?

MR. MILLER: If I could --

DR. ZIEMER: Thank you very much.

MR. MILLER: Just with your indulgence, and

because I just came across my one last point I just wanted to re-underscore from last week.

Larry, today, Larry Elliott, I think we were discussing sort of the contracting process. And I think it was you who responded to a question from Dr. Melius about, well, how are you going to deal with conflict of interest? And you said, well, we're going to have a conflict of interest plan that we'll negotiate with the contractor after we select somebody. Is that a sort of a roughly fair characterization, based on the RFP language?

MR. ELLIOTT: Yes, there's -- the RFP calls for a conflict of interest plan to be submitted along with the proposal. That's part of the evaluation of each proposal.

MR. MILLER: Right. Because we don't know what the minimum criteria are for your conflict of interest review, other than what was stated in the RFP, I just want to re-underscore, because by the time we all meet you may have selected the contractor, at the end of March, I guess, right? Is that -- you're planning on meeting by the end of March, is that right? Advisory Board?

MR. ELLIOTT: Tentatively the next meeting

is set for the 25th of March, yes.

MR. MILLER: Do you have a rough estimate of when you think the contract's going to be awarded for dose reconstruction, rough time frame?

MR. ELLIOTT: It depends upon the number of proposals we receive and the complexity of those proposals that we have to review, and March could be the earliest. I can't really predict at this time.

MR. MILLER: Okay. Well, I'd just conclude by sort of wanting to revisit one point, which is that I think that transparency is one of the few things that can build public confidence. And to the extent that this question of transparency with respect to conflict of interest can be addressed in whatever plan that NIOSH comes forth with for its contractors would be very valuable.

If the bidders don't propose it, I guess is my point, to assure transparency, meaning that the individual claimant knows who's reconstructing their dose and what their work history is and their corporation's work history with any given site or claim, if they don't know it's hard to have a lot of confidence in knowing who's on the other side, because at least the

character -- at least two of the three bidders that I understand are going to be submitting bids.

And to that extent transparency, I think, is sort of one of the things you all can impose that's not stated explicitly in your RFP, but I think would raise comfort levels so that people know who's doing the work on the other side.

I think that's it.

DR. ZIEMER: Thank you.

Are there any other members of the public who have comments? I just had the two had signed up, but certainly offer the opportunity if there's others that wish to comment.

(No response)

DR. ZIEMER: Let me ask if there are any other members of the public who have come in this afternoon who were not here when we had introductions this morning, so we know who you are for the record and who you represent. Anyone that did not get introduced?

Actually Bob, you were one of those, but you've now been introduced; Bob Alvarez.

Anyone else?

MR. MORAN: I'm Frank Moran from Westat

Company in Rockville, Maryland.

DR. ZIEMER: Others?

(No response)

DR. ZIEMER: Thank you.

Since we're a bit ahead of schedule, I think in the interest of time we are going to proceed with some of the materials that we would have started with tomorrow morning, particularly looking at the proposed rule 42 CFR 82. We, the Board, has to deal with this proposed rule-making in a manner analogous to what we did on 42 Part 81 -- that is, we are asked to review the rule and comment, comment specifically on three questions that are in the preamble to this rule.

In order to expedite that process, I suggest that we proceed at this point in a fashion similar to what we did at our last meeting, and that is to go through that rule section by section and see if there are questions for the staff or comments that people wish to make. And we'll go through the rule, and then we can prepare ourselves for considering how to address the three questions that are posed for us.

Is that agreeable, then, that we proceed in that fashion?

(No response)

DR. ZIEMER: Okay, let's turn to the rule itself. Page 50978 is the introductory material that summarizes the rule and calls for public comments. There's background on the following page on statutory authority. There's information on the legal requirements for dose reconstruction, information on the purpose of dose reconstruction, an explanation of how doses are reconstructed, how they are conducted, and so forth. The actual rule -- and then a history of the rule development.

The actual rule begins -- I'm looking for the page, the actual beginning here, just a moment -- 50985. And of course at the very beginning there's kind of an index to the various sections, starting with Section 82.0 and so on.

So let us then begin with page 50986, and we'll look at this section by section. We're not going to read the sections, but we will pause at each one, assuming the Board members have read this again and again for their evening pleasure.

Section 82.0, any question on the background information, or comments?

(No response)

DR. ZIEMER: I'll push us along here on some of these questions if it's clear that there are no comments.

82.1, purpose of the rule?

(No response)

DR. ZIEMER: 82.2, basics of dose reconstruction? Roy.

DR. DeHART: I have a question under item (a) of that. It says specifically that we are to -- or in constructing the dose reconstruction that the accuracy of the dose that has been calculated -- and all of that information that would come in, I assume, from DOE -- the question that was raised by Mr. Miller on the accuracy of that information, could NIOSH comment about how they would attend to address that issue on the accuracy of dose information provided to you?

DR. ZIEMER: And it may go beyond accuracy. The dose information may be accurate, but I think one of the questions being raised was does that reflect the actual workplace situation, perhaps was --

DR. DeHART: That's what I mean by accuracy.

DR. NETON: Yeah. The statement reads, if found to be complete and adequate --

DR. DeHART: Yes.

DR. NETON: -- individual worker monitoring data such as dosimeter readings.

That speaks to that issue, which is NIOSH intends to use personnel monitoring data only after a thorough review that the data themselves were -- accurately depicted the exposure environment of the worker themselves. And that would require an analysis of the type of materials that were in the workplace, the energies of the emissions for the dosimeters, and the adequacy of the bioassay monitoring program to measure the workplace exposure elements.

So we would be relying on the process information at the sites, a technical review of the bioassay programs. We know for certain cases bioassay samples were taken but no tracers were used, so one doesn't know whether that represents a ten percent recovery of the material or 95 percent. There are some studies out there, so it will be review of those studies that have been published that have evaluated those circumstances.

So it would -- it's going to be very facility-specific. But we certainly would not

use the data without first making a determination if it was representative of the worker's exposure.

DR. ZIEMER: And can you also comment on the nature of your documentation of that? Would there in each case, then, be some sort of a report or an analysis that you provide?

DR. NETON: Yes. It is our intent that we develop a facility profile for the facility that documents such things as the detection limits, the quality of the monitoring programs, that could be used for the individual sites.

DR. ZIEMER: And this would be a public document, so that if workers at that site felt that it did not reflect what was going on there would be ample opportunity for that information to emerge?

DR. NETON: Yes.

DR. ZIEMER: If somebody said, you know, we always straddled these things --

DR. NETON: Yeah, that's --

DR. ZIEMER: -- or whatever.

DR. NETON: That's our intent.

DR. ZIEMER: Well, I notice in that picture it appears that the guy is wearing wrist badges,

and those would be very accurate determinations of gonadal dose. That's not an anatomical statement, but more of the -- I mean, I do know my anatomy.

(Laughter)

DR. ZIEMER: The location of the wrists in that case were similar. But -- I'd better stop.

In any event, is there some level of confidence that the process -- I think this is perhaps Roy's question, I don't want to put words in your mouth -- would uncover irregularities that might otherwise not appear.

MR. ELLIOTT: Let me add to Jim's response.

Yes, we're very aware of many of the reports that Mr. Miller has mentioned, and the dose reconstruction processes underway at like Mound and Rocky Flats. Having those available to us is a benefit. Our interview process, we hope to establish some of these other types of things that are not obviously evident and available in records.

How do we try to get at that, beyond that? That is something we're wrestling with. We appreciate anybody's thoughts and suggestions on how to improve in that regard. We feel that as

we go forward and accrete information and create these profiles for a site, not only will that be made public and available for comment, but a report on each individual dose reconstruction will go to the claimant as well as DOL for the adjudication of the claim, and relevant information from that individual dose reconstruction effort in that report will be pulled out and incorporated into the profile as it's built.

So that will become part -- the individual dose reconstruction report for a claimant won't be public information, but the relevant new information gained from that piece of the process will be.

DR. ZIEMER: There was also some indication that even the workers themselves may not be aware of irregularities, so we certainly need to be cognizant of other indicators that would suggest that something was amiss, whether it's a mass balance issue or some other sort of indicator.

DR. DeHART: Roy DeHart again.

The issue of the employee remembering what their dose is and being able to refer to that on interview, of course, is important, and probably

can only be done correctly if they're given that information.

When it comes to the rule, once the rule becomes final, I can't remember in reading through this whether it allows you the flexibility to adjust and make change. Does it?

MR. ELLIOTT: Yes, it does, and as with the IREP - and you wanted to see the significant changes that were made to those -- you would have opportunity to review those. You'll also have opportunity to review significant changes that would occur in dose reconstruction methodology that's in the implementation guidelines or the technical basis documents.

That becomes part of the information we present to you for your understanding and your review of dose reconstructions, as well as your review to comment and say this makes sense, this should be -- this is a change that should happen. Or if you feel conversely, you can express that as well.

DR. MELIUS: But just to clarify that point, that is not in the regulation, is it, that review, that process? It's in the preamble again. Do we have the same issue we had with the

other --

MR. ELLIOTT: (Nods head)

DR. MELIUS: Okay.

DR. ZIEMER: Right, and we may want to return to that.

Henry.

DR. ANDERSON: Just a somewhat interpretive question. Are you going to have to make for each case a determination that the data is complete and adequate?

I mean, like (a) here is if found to be complete and adequate. That assumes that you make a -- in order to begin, you're going to have to make a determination, which might be from your site-specific or -- what I think we've been seeing through this whole thing is you're going to use all the information you have available, which is quite different from having to make a determination, is it adequate. You could say it's inadequate, but it's the best we have so we will use it. And I just want to be sure you don't get caught subsequently with being challenged that it should not have been considered adequate.

DR. NETON: I guess it's an issue of

semantics, but yeah, we will -- we do intend to on an individual basis determine that the information's complete and adequate to conduct a dose reconstruction. Now that does not necessarily mean that we have every shred of available evidence out there. We just have enough of it to be able to complete a dose reconstruction, to make an unbiased determination as to whether or not the person has a significant exposure or not.

DR. ANDERSON: Okay.

DR. ZIEMER: But the rule does not require that there be adequate dosimetry to do the dose reconstruction.

DR. NETON: No.

DR. ZIEMER: It only -- it says if it is adequate, you do it from that monitoring data.

DR. NETON: Right.

DR. ZIEMER: If not, you go to sort of plan B.

DR. ANDERSON: To B, yeah. And what we haven't seen is what's the model for plan C. How would you use -- how would you do dose reconstruction based on --

DR. NETON: Okay, I think I know where

you're coming from. I covered that --

DR. ANDERSON: It's kind of the levels. You go A -

DR. NETON: Yeah.

DR. ANDERSON: And we really dealt with -- we're assuming you're going to have some level A information and we're going to move from there. I'm just curious as to -- C almost gets us into the special --

DR. ZIEMER: No, but that's source term and so on.

DR. NETON: Right, yeah. I gave an example last meeting of how we would approach it from a source term analysis based on the amount of material that were there, the types of operations, whether it was grinding, welding, cutting, and to give a bracketing dose estimate for the individual, keeping in mind that we are not constrained to have single point estimates for a person's dose. We can put a distribution, and I think I indicated at that time that may well be a range --

DR. ANDERSON: Okay.

DR. NETON: -- a uniform range, saying our estimate ranges between one and ten rem. And

that would be a viable input to be able to put into the IREP program.

DR. ANDERSON: Okay.

MR. ELLIOTT: If I could add a comment here on this topic.

The paragraph right before (a), I think, sets us up for this hierarchical approach. And I would add that to advance forward and say the dose reconstruction is complete -- whether it's done by (a), just using the radiation dosimetry data from the site and saying that's enough, because the person's automatically is going to achieve an award; or it's done by (c), through source term and lot more of uncertainty associated with it -- before we advance that forward, we get the claimant to understand what we've done, how we've done it, and seek their agreement to move it forward.

DR. MELIUS: Yeah, one comment on that, and then just to move it on to level D, which isn't there.

I would, as I said before, I think it would be very helpful to get a presentation at some point on how you're going to do sort of A to B to C, particularly how you're going to handle C at

that point.

My concern also, though, then extends to D. We're -- D would be where you can't do dose reconstruction because you don't have adequate -- it's not clear here. This comes up in a later section also, that what the criteria will be, and that one is where we really get, hit the Special Exposure Cohort. We're going to back into Special Exposure Cohorts, but we don't know what that -- how those will be defined or what the process will be.

And it makes it very hard to comment on this section of the proposed rule, and it also makes it very hard to address one of your specific questions, particularly -- I think it's question -- the second question regarding the efficiency of the process. Because I think as you get into this -- go down from A to B to C, you're talking about more and more resources going into the effort.

And then we get into this issue of the special incidents or whatever or missing information. Really, you're talking about more and more resources being drawn into this process. And at some point it seems to me it makes sense

to just stop the resource, the effort, and just put people in a Special Exposure Cohort. If you could short-circuit that in some way.

And I'm just having trouble looking at this process not knowing what the way out is, and how much we have to -- how much of an effort we have to put into this rule without knowing that. And I understand the bind that you're in also, so --

MR. ELLIOTT: You understand the bind we're in? Or do you not understand the bind we're in? I didn't --

DR. MELIUS: I don't understand well enough for -- I think you should speak to it.

MR. ELLIOTT: It seems to me that I hope -- well, I hope that Kim and Marie caught your language, because it seems to me that's some comment the Board might want to consider adding to their remarks about this rule.

Would I have liked to have given you the Special Exposure Cohort guidelines to review today in addition to this? Certainly. Am I able to? No. Suffice it to say that if we can't do a dose reconstruction, then we have the ability to say that's a class of workers that need to be added to the Special Exposure Cohort.

Now that's -- I can't predict that that's what you're going to see in these policy guidelines, but that's the only comment I can make at this point.

DR. MELIUS: Yeah. Just to elaborate, I think from looking at it from this rule, this is a continuum, and that's what we're sort of wrestling with to comment on this part of the rule. That has to be the ultimate part of the continuum, and I think we're having -- I certainly have difficulty commenting until I know where that continuum's going.

MR. KATZ: Let me -- I'm sorry, Ted Katz here.

Just to add to what Larry said just for clarity in the record, though, it's not only can we not do a dose reconstruction, but is there some evidence there that there were substantial exposures? Because clearly you could have a situation where you can't do a dose reconstruction, but the evidence suggests there weren't substantial exposures, and you wouldn't be adding that to the Special Exposure Cohort.

DR. ZIEMER: Yeah, that's understood, I think. Right.

DR. MELIUS: You seem to be defining this differently at different points in time, including in your instructions to the contractors, the bidders. I'll show you later.

DR. ZIEMER: Okay. Let me interject here while we're going through this, and just remind the Board of the three questions. So I want to back you up just briefly to 50978, the right-hand column, comments invited. These are questions similar to those that were developed for the Part 81 rule-making.

Question one: Does the interim rule make appropriate use of current science for conducting dose reconstructions to be used in an occupational illness compensation program?

Question two: Does the interim rule appropriately balance the potential precision of dose reconstructions and the necessary efficiency of the dose reconstruction process?

Question three: Does the interim rule implement an appropriate process for involving the claimant in the dose reconstruction?

I don't believe we're necessarily limited to those three questions, but as a minimum the staff seeks comments along those lines. And those

somewhat parallel the questions we -- not completely, but somewhat parallel what we addressed for the other rule.

Now back to section 82.2, are there any further questions or comments on that section?

(No responses)

DR. ZIEMER: 82.3, What are the requirements for dose reconstruction under E-E-O-I-C-P -- how do you pronounce that acronym again?

MS. MURRAY: EEOICPA.

DR. ZIEMER: The court recorder knows how to pronounce it. She's the only one that does, because she's saying it into her mike there.

Anyway, any questions on that section?

(No responses)

DR. ZIEMER: 82.4, How will Department of Labor use the results?

(No responses)

DR. ZIEMER: Subpart B, Definitions. No questions or comments?

(No responses)

DR. ZIEMER: Subpart C, the Dose Reconstruction Process; 82.10, Overview of the dose reconstruction process.

(No responses)

DR. ZIEMER: Paragraph (a)?

(No response)

DR. ZIEMER: (b)?

(No response)

DR. ZIEMER: (c), concerning interviews?

(No response)

DR. ZIEMER: (d), the NIOSH report summarizing its findings?

(No response)

DR. ZIEMER: (e), concerning the use of information provided by the claimant?

(No response)

DR. ZIEMER: (f), concerning the confirmation of claimant's information?

(No response)

DR. ZIEMER: (g), request of additional records from DOE?

(No response)

DR. ZIEMER: (h), NIOSH review of adequacy of -- and completeness of records provided by DOE? To some extent relates to what we've been discussing here.

I have one question on that section. There is a requirement that the Department of Energy certify that record searches have been completed.

Is that a simple statement, yes, we've completed the records searches, or what is that certification?

DR. NETON: Yeah, that's the intent, that they provide some written confirmation that they have searched their records and have completed it.

DR. ZIEMER: Do you ask them to spell out the extent of that search, where did you look?

DR. NETON: We direct them to search in certain locations for different types of records, and they would be confirming that they have searched throughout all those archives or inventory of types of records.

However, we do intend -- I think somewhere in the rule it specifies that we -- I'm pretty sure it's in here, that we will actually visit certain sites and to confirm, to do sort of a quality control check, if you will, that all available records have been brought forward for that site. So there will be some site visits conducted by NIOSH to help confirm that as well. I don't recall exactly in the rule where that is, but I'm pretty sure we've committed to that.

DR. ZIEMER: Other questions on (h)?

DR. ANDERSON: Just a question that came up with an example over lunch, and Department of Labor will make a determination that they were in fact employed at a facility. And the question I have is there may well be, for instance, even internal NIOSH studies that have been done that will have some industrial hygiene or personal badge measurement data, that it's possible the records of employment may have been lost and DOL will up front say, no, we have no record that you were ever employed there; yet searching through somebody else's database you might find that in fact the name appears, that he was interviewed in XYZ study.

That's probably a DOL issue. But it would seem to me there may well be some university and research records, that somehow you may want to try to inventory to see if there are lists of who participated in what studies that people might otherwise be lost in the official system, but through other studies would have some indication that they in fact worked there.

MR. ELLIOTT: It's a -- your point's well taken with us. It is a Labor, Department of Labor requirement, issue; and they have other

mechanisms that they're employing -- Social Security account or Administration files, Internal Revenue approach toward verifying employment -- beyond DOE saying we can't seem to find a record for this person.

DR. ZIEMER: Aside from the employment records, has the staff considered, as far as characterizing the workplace, independent records?

For example, records that might be under the purview of state regulatory agencies such as the New York Department of whatever they call it there, the radiation safety folks, or Illinois Department of Nuclear Safety, those folks that might have monitoring records for sites. I'm not referring to the DOE contractor labs per se, because there's no jurisdiction there. But some of the other sites that we might be talking about, the atomic workers and other contractors who might have worked under licenses, and are -- at that time AEC licenses, either old AEC records, which now are sort of -- who has those, NRC or DOE?

DR. NETON: NRC, I believe, would have those records.

DR. ZIEMER: And other union records --

DR. NETON: Right.

DR. ZIEMER: -- what about those?

DR. NETON: We've considered that approach. In fact, one of our near-term visits will probably be the Nuclear Regulatory Commission to look through, in particular, as you mentioned, for the atomic weapons employers. A license itself will go a long way to establishing the source term.

To the extent they have monitoring records, that would be great, although it's my understanding of historical AEC licenses, they typically did not require the monitoring results to be sent to them or held by them. That's my understanding. I'm not saying that's in all cases. But we're certainly going to look through the different avenues, the Nuclear Regulatory Commission, AEC, precursor of the NRC.

DR. ZIEMER: Thank you.

See where we are here; (i), yes.

DR. ANDERSON: We probably covered this a little earlier, but it talks about may use default values if there's no process for how your -- it gives some examples here and says what they

ought to be, but no method as to how you would go about developing those. Or are there existing default values that you --

DR. ZIEMER: Is it safe to assume that that would appear in the guidelines rather than in the rule-making?

DR. NETON: Yes, that's correct. And I think the example we talked about earlier is the five micron particle size for ICRP 66, that sort of thing. I'm not sure that we want to commit to the exact default values in the regulation itself.

DR. ANDERSON: I just -- it ought to -- sometime you're going to have to -- and we ought to --

DR. NETON: Get off the fence, yeah.

DR. ANDERSON: -- discuss it here, I guess is what I'm saying, at some future meeting. It's probably worth looking at what's out there, what might be appropriate, and us to be able to comment to you on it before you get into having used it and then have it subsequently challenged.

DR. NETON: Certainly.

DR. ZIEMER: Item (j), dealing with incomplete records?

(No response)

DR. ZIEMER: Item (k)?

DR. ANDERSON: Paul?

DR. ZIEMER: Yes.

DR. ANDERSON: Just a word that I look for in our state things, is under (j) you have once the resulting data set has been evaluated and validated.

Validation tends to be a real difficult thing to do. So I guess the question would be how -- what would you view as validation versus -- you could certainly evaluate it quite easily, but validating measurements, it's pretty tough, especially old -- unless you're going to review the QA/QC program in place at the time. What is your intent here, just -- you may want to look at that word, because it carries a great deal of time and effort.

DR. NETON: I've developed a new appreciation for the meaning of the word "validated" in the last several months, I'll agree with that.

The intent here was to evaluate it, and to validate it in the sense that it accurately depicts the exposure situation, is the intent of

that word. Now whether that has special legal meaning beyond that, I guess we'll leave to our legal counsel.

DR. ZIEMER: Okay, let's move on to Item (k), which has a lot of subparts to it, goes through a step-wise procedure.

(No response)

DR. ZIEMER: Item (l), which deals with the draft dose reconstruction for a claimant?

MS. GADOLA: I have a question about the compiling of all of this that would fit in with (k) and (l).

If, while you're collecting all of the information, if it becomes apparent that there are certain types of cancer that seems to be turning up in certain jobs -- example, if there seems to be a lot of bladder cancer, and it's found in one particular job at four sites, and then there's two other sites where it's extremely low, would this type of information be utilized in determining the validity of maybe the two sites where it's very low? Anybody?

DR. ZIEMER: Okay, who wishes to answer that? I think that's a question for the staff.

DR. NETON: I guess I'm not sure of the

thrust of the question. The validity of the dose reconstructions, or is it would be advisable for us to turn that over to someone for future epidemiologic research possibly? I'm not --

MS. GADOLA: Probably both.

DR. NETON: Yeah.

MS. GADOLA: I could see where you could do it in the future, but like it would -- it seems like it would cause you to question the validity if you seem like you have a high percentage at the majority of sites for this particular job, and then at two sites it seems extremely low. Would it give you more reason to question the dose reconstruction at these two other sites?

DR. NETON: I'm not sure. There are a multitude of other exposure agents that we're not evaluating in the dose reconstruction process, particularly the chemicals, exposure to asbestos, that sort of thing. So it would be of scientific interest, but I'm not sure how we would incorporate that into our program of dose reconstruction.

MR. ELLIOTT: Well, I understand your question better now, I think. And my response to you would be that -- and I think we've talked

about this among team discussions we've had -- that we would look for those kind of anomalies, where we seem to do dose reconstruction for one site for one type of cancer that seems to result in a propensity for award, and all of a sudden at another site where you've got the same cancer, but we don't see, you know.

MS. GADOLA: Uh-huh.

MR. ELLIOTT: So what's going on? Is it the dose?

MS. GADOLA: Right.

MR. ELLIOTT: Okay, maybe it is the dose. Maybe this site has distinct internal dose that contributes to that and this other site doesn't. That may be something that the Board wants to take up in its evaluation of dose reconstructions as a way to set your sampling strategy on what you review.

MS. GADOLA: It does bring up several other questions, and it also reminds us of the amount of data that will be collected during this whole process. And hopefully it can be used in the long term to really give us a better idea of actually what did happen with these people, and what is going to be happening to other people

that might be working in similar situations.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah. I think following up on that more from, say, the exposure information side, I don't think you've really presented to us how you're going to maintain the data and so forth, and I think we would be interested at a future meeting in hearing about that.

But there would be, I think, situations where you're going to learn more about a site or a particular process at a site two years down the road than you know now, so that could possibly change the dose reconstruction for a particular individual who came through earlier. We'd hope it wouldn't be common occurrence, but it might occur. And I think that would be -- I think it's important that there be a data system in place that would allow you to use your past experience, and also, if it is necessary, correct any past errors in reconstructing dose.

So I'm assuming you're doing that, but I would be interested in hearing more about it at a later meeting.

MR. ELLIOTT: We plan to do that, and we've talked with Labor about a feedback loop. When we

experience a change in the way we do a dose reconstruction and looking at those claims that went before that, and which of those did not receive an award and reevaluating those under the new dose reconstruction change. And I've noted that you do want a presentation on more on our statistics that we collect and how we monitor and track the claims.

DR. DeHART: Rather than dose reconstruction, might this not actually represent a change in the risk for that cancer, which goes back into the computerized program, not the dose? Because here, as has already been suggested, you may be dealing with something entirely different from radiation.

DR. ZIEMER: Can I partially respond to that, Roy?

I don't think NIOSH is going to be in a position to be adjusting risk values because you're using -- that data could become available to -- for the database for those who are -- you're using NCI risk values, I believe. Is that not correct?

DR. NETON: Well, it's a combination of -- so to a large extent we are. But there are

several models that the NCI did not include that we needed, such as a bone cancer model that is included in the NIOSH/IREP.

But I would caution the usability of our data for epidemiologic risk modeling, because we are only carrying the dose reconstruction far enough, because of the large volume of cases, to get an answer. If a person falls low or high, it will not necessarily be the exact dose to that person's organ. So the ones that are carried full through the process, of course, would be useable. And the information that Tim provided where we're correcting for a lot of these other exposure scenarios, I have never seen that extent done on an epidemiologic study to really -- to try to determine what the actual organ dose is versus what the badge result is. And there are, as Tim pointed out very well, very distinct differences.

DR. ZIEMER: I'm going to exercise the Chair's prerogative and declare a comfort break of approximately ten minutes, then we'll reconvene.

(Whereupon, a recess was taken from 4:05 to 4:16 p.m.)

- - -

DR. ZIEMER: Continuing our review now of the proposed rule-making, we're at subsection (l) on page 50988. Any questions on that section?

(No response)

DR. ZIEMER: Section (m)?

(No response)

DR. ZIEMER: Then section (n), concerning the NIOSH report to DOL?

DR. ANDERSON: Just a question.

DR. ZIEMER: Henry.

DR. ANDERSON: Are you anticipating that under (m) there there'll be a back and forth? Because I can see a 60-day time line for a next of kin who's trying to generate the information you need, they may run into that. So is the --

MR. ELLIOTT: Yes.

DR. ANDERSON: -- to send a form back, they're not going to be -- you have to have a time line at some point, but when will the ticket start to run? So under the first one, it'll be back and forth, and then you'll finally say, well, we think we have -- we haven't heard from you in a while. Here's the form you have to sign saying you're finished.

MR. ELLIOTT: Well, as (m) says, we have -- before we would forward the report on to DOL for final adjudication of the claim, we have to have the claimant's agreement to do that in OCAS-1.

DR. ANDERSON: Okay.

MR. ELLIOTT: So we're not going to forward that until we get that. So if we send that -- we had the conversation with the claimant about the final dose reconstruction draft report and we ask them to sign OCAS-1, and they say let me think about all this and get back to you, we're going to follow up with them.

DR. ANDERSON: Okay.

MR. ELLIOTT: We can't go forward with it until we have their consent to do so.

DR. MELIUS: Shouldn't that be more explicit, then? Because that's not the way I read this, was that the fact -- I guess what I'm concerned about is what Henry was saying, is that the person that's trying to provide you with more information, they're next of kin, they're having trouble getting that information. They may have requested it, some additional information they don't think you got from DOE or whatever. And what you're saying is that they're really going

back, they haven't really done the final interview –

MR. ELLIOTT: Yeah, we're not done with them at that point, then.

DR. MELIUS: Yeah.

MR. ELLIOTT: We're not -- at that point -- I misunderstood your comment. At that point we're not saying sign the OCAS-1 form. We're not trying to force them to do that. We'll still be waiting there for them to produce that information.

DR. NETON: It says may administratively close the claim. It's not an automatic.

I think the intent was to cover situations -- correct me if I'm wrong, Ted -- but a claimant who would just refuse to sign the OCAS-1 form. But I -- they're not signing they agree with the dose assessment, dose reconstruction itself. They're actually signing that we have put forward all of the information that they provided us, and it's included in their claim.

Now we may have at some point chose not to use their information for whatever reason, and they can disagree with that. But when they sign the OCAS-1 they're not saying that they agree

with the actual dose estimate itself. But if a person says I'm not going to sign it, then we have to have some outlet to close the record.

DR. MELIUS: Yeah, but wouldn't that then be -- answer this question. Would there be then a notification -- see, up until this point it's sort of an open-ended, back-and-forth process. Now you're suddenly cut him off. I would presume that there would be a notification to them, a formal notification saying, look, we think we've gone as far as we can, blah, blah, blah. Here's the form. We're giving you 60 days. If not, then you have -- we're going to close out the claim.

DR. NETON: I think that was the intent. Is it in there?

DR. MELIUS: Is that -- okay.

MR. KATZ: Sixty days.

DR. MELIUS: I know that 60 days is in there, but it wasn't clear to me where the process stopped being interactive, and where you're cutting it off.

MR. ELLIOTT: I think what you're asking, what you're getting at, is do we go back to the claimant with some final correspondence --

DR. MELIUS: Yeah.

MR. ELLIOTT: -- saying, okay, we've chosen to exercise our right to administratively close the file --

DR. MELIUS: Right.

MR. ELLIOTT: -- and move the dose reconstruction report forward for final adjudication.

DR. MELIUS: Uh-huh.

MR. ELLIOTT: And I would -- I don't know if my lawyers are here, but I would think they would weigh in on that and say yeah, we need to have something like that to make that step happen.

MR. KATZ: Yeah, I mean at the point where we realize -- or it appears that we have a claimant that's simply not going to sign is when we would notify them formally that they have 60 days, upon which we will then go ahead and close the claim. So then they would have an additional 60 days, in effect, to make a decision to sign the form and let it go forward or not.

DR. MELIUS: I think what's not captured in all of these going back is that it's sort of a back-and-forth process. It sort of looks sequential here, and it's really not because --

or may not be, that there's -- this information goes. And that gets a little bit confusing. It's hard to write the regulations, I think, to capture the back and forth that goes on, but I think it is important. Maybe it's in the preamble and I missed it, but --

DR. ANDERSON: Yeah, it seems to me in (l) you provide them with a draft of the dose reconstruction. And what I was concerned is you say here it is, you have 60 days to come up with additional information or not; as opposed to we all agree that we have -- you've done the best you can, and now we want to ask you, we need to have your permission to move it forward, and here's the paper that gives the permission, versus you telling them we're done. You either generate something more in 60 days, or it's finished.

And that puts the pressure potentially on them to generate data, as opposed to they're saying here's the draft, we're still looking for Uncle Joey. We know he's around somewhere, but we think he's out elk hunting and hasn't come back, and we'll never find him in 60 days.

MR. ELLIOTT: It appears to me from this

discussion we need to make this very clear, what our intent is here for you, and for the claimant.

DR. MELIUS: Yeah, I think maybe the way to clarify it is that there are two situations. One is where it's a good claim, you just need to move it forward. Second one is where it's really -- the dose reconstruction hasn't shown that they have sufficient exposure to warrant the claim, then I think that's where you're going to get into this process. And I think maybe clarifying that in the regulation would be helpful.

And I'd almost rather give a little bit more than 60 days, but at some point it depends on how open the previous prior process is. Because I really think there's going to be situations where a next of kin or something is really going to be struggling to try to find someone who knows something that they -- they remember their father telling them something about the plant, and they're trying to find somebody to corroborate that or whatever, and I think that could be a hard process. I think giving them some more time may be better, again, but it shouldn't go on. You shouldn't have to keep the claim open forever, either.

DR. ZIEMER: The wording here sounds to me to be one in which the claim is not automatically closed after 60 days. It says they may close it, not that they must close it. Is that intentional? And likewise for Department of Labor, they may then close the claim, but it doesn't appear to be mandatory. It seems to be discretionary. They may close the claim.

DR. ANDERSON: Well, (o) says shall be closed --

THE COURT REPORTER: Use your microphone, please.

DR. ANDERSON: -- unless reopened.

UNIDENTIFIED SPEAKER: Microphone.

DR. ANDERSON: Yeah, (o) says it shall be closed unless reopened. That's the next item.

DR. ZIEMER: But that's once the actions in the previous thing are done. Once they do --

DR. ANDERSON: Yeah.

DR. ZIEMER: But it doesn't appear that they're required to exercise that prerogative under part (m) or (n), but if they do, then it becomes mandatory. Am I reading that right?

MR. ELLIOTT: Yes, I think you have the right sense of that, what we intended it to be.

DR. ZIEMER: Wanda, please.

MS. MUNN: And in any case, (o) clearly says it still may be reopened. It isn't as though this falls off the end of the earth. There's -- if we find Uncle Joe, surely we can come back and the Department of Labor will accept that information.

DR. ZIEMER: Thank you.

Other comments?

(No responses)

DR. ZIEMER: Section 82.11?

DR. DeHART: A point of clarification.

DR. ZIEMER: On this section or previous?

DR. DeHART: On 82.11.

DR. ZIEMER: 82.11, okay.

DR. DeHART: If for efficiency we have used a high dose and we see that the claimant has had an experience where it would be awardable, is that considered at that time a reconstruction of the dose? Because it says here you will do a dose reconstruction on every claimant.

DR. NETON: That's correct, that would be considered a dose reconstruction.

DR. ZIEMER: Okay. Further questions on that section?

DR. NETON: It would fall for consideration under the Special Exposure Cohort guidelines, that's correct.

DR. ROESSLER: Yeah, that makes sense.

DR. NETON: There may be some low dose situations, but like I say, almost by definition if we feel that it's a low dose scenario, we should be able to demonstrate that the compensation probability is fairly low.

DR. ZIEMER: Okay, then we go to section 82.13, Sources of information for dose reconstructions.

(No response)

DR. ZIEMER: 82.14, Types of information to be used in dose reconstructions.

(No response)

DR. ZIEMER: 82.15, Completeness and adequacy of individual monitoring data.

(No responses)

DR. ZIEMER: I suspect many of the questions have already been answered that pertain to some of these sections.

82.16, how will NIOSH -- oh, question. Jim, please.

DR. MELIUS: I'm a bit slow, I'm back to

82.14.

DR. ZIEMER: Am I moving too fast for you here?

DR. MELIUS: Well, it's just when there's sort of what appears or attempts to be an exhaustive list, it's hard to figure out what's not there. And maybe this is a question of how you interpret some of this, but yeah, like under (g), information regarding exposure, so on, is there a place there where you talk about getting information from co-workers? And 13, did I --

DR. DeHART: 82.13 takes care of that.

MR. KATZ: That's actually –

UNIDENTIFIED: 82.13?

MR. KATZ: Yes.

UNIDENTIFIED: The previous section.

DR. MELIUS: Okay. Okay, okay.

DR. ZIEMER: Okay? Then back to 82.15, How will NIOSH evaluate completeness and adequacy of individual monitoring data?

(No response)

DR. ZIEMER: 82.16. Wait, 15, Henry?

DR. ANDERSON: Well, I'm going back to the dose reconstruction. I was looking for the medical --

DR. ZIEMER: What section are you at?

DR. ANDERSON: Under 82.14, is --

DR. ZIEMER: Fourteen, okay.

DR. ANDERSON: Is the X-ray machine from the surveillance program somewhere there? I'm just quickly looking.

MR. KATZ: Yes, it's in there.

DR. ANDERSON: Okay.

UNIDENTIFIED: That's (f)(1).

DR. ZIEMER: Third column.

DR. ANDERSON: Ah, okay. I see, okay. I took that to be measurements that may have been made in the facility, not in the medical -- there's medical screening, I see. Thank you.

DR. ZIEMER: Yeah, we got it. Thank you.

Let's see here, we're back to -- I think we did 15. Sixteen, 82.16, okay.

(No response)

DR. ZIEMER: Seventeen, 82.17. Co-worker data shows up here, too, as well.

(No response)

DR. ZIEMER: 82.18, on calculation of internal dose to the primary cancer site.

(No response)

DR. ZIEMER: 82.19?

(No response)

DR. ZIEMER: Okay, Subpart D, Reporting and Review of the Dose Reconstruction Results; 82.25, When will NIOSH report dose reconstruction results and to whom?

(No response)

DR. ZIEMER: 82.26, How will NIOSH report dose reconstruction results?

(No response)

DR. ZIEMER: No questions, okay.

82.27, How can claimants obtain reviews of their dose reconstruction results? No questions?

(No response)

DR. ZIEMER: 82.28, Who can review NIOSH dose reconstruction files on individual claimants?

I have one question. I don't know that this would be something that would be in the rule, but is there a plan to provide summary information that's not identified by persons, but the particular claims and or groups of claims, numbers that have been processed and the decisions and so on, or how will that sort of the summary information be made available?

MR. ELLIOTT: Yes, we intend to provide

summary information, and I'll speak about it in two ways.

One, statistics like I showed you this morning on number of claims received, where they're at in the process, dose reconstructions completed, DOL will maintain statistics on award versus non-award.

Secondly, we talked about technical basis documents that support the implementation guidelines, and summary information from learned experience in dose reconstruction will be incorporated into those and available to the public.

DR. DeHART: Just to follow one, I would think that the medical literature that could be generated from these studies are critically important, because the assumption is going to be made by some that what you are doing is identifying causation, and that is not necessarily the case. And there needs to be a separation in that through the medical literature, through publication.

DR. ANDERSON: Yeah, I would -- I think the last sentence there under (b) of researchers will not receive names of claimants is a pretty

categorical statement, and it would seem to me you may want to put in without the individual's permission. Because in reality, this is saying if the workers would like to participate in a -- or their families, in a research study that would help elucidate the health impacts, and you want to combine this dose reconstruction with a previously-identified cohort, there'll be no linkage.

And I think if there's benefit accrues to the individual to at least be offered -- we've received a request, would you be willing to have your whoever it is provided to them, at least give the opportunity of the individual to decline, rather than decline up front in the statute on their behalf, basically saying that these results won't be available linked, so there'd be no way to do a mortality study linking it to specific individuals without their work history.

MR. ELLIOTT: There's two points to be made in your comment here.

One is that -- generally a response here is that the Privacy Act controls how we disseminate information that has personal identifiers on it.

This item (b) here that you're speaking from allows researchers who come forward with Institutional Review Board-approved protocol to gain -- that is supported by a NIOSH funding source, either through a grant or a contractual mechanism -- identifiable data through our records, systems of records held under the Privacy Act. So all of the case file information that is incorporated into our systems of records can be released to a researcher with an approved, IRB-approved protocol, okay.

If there are researchers out there who have an interest to utilize this information but do not have a NIOSH funding mechanism that brings them into our routine use authority under our Privacy Act system of records, then they would have to approach us for a de-identified data set.

DR. ANDERSON: See, I -- the way I read it, it says researchers will have limited access, which says not everything, and that's subject to provisions, I agree. But that last sentence basically, to me, defines that limited access means you will not get, and it says researchers, whether they're part of the Privacy Act or not, will not receive names or claimants or covered

employees.

MR. ELLIOTT: This needs to be written better for clarification, because researchers inside NIOSH and researchers supported through NIOSH grants program who have an approved protocol would be eligible to receive identifiable information.

DR. ANDERSON: Right.

MR. ELLIOTT: Researchers who are not within that realm would have to request information, but they would be getting a de-identified data set.

DR. ANDERSON: Right, I'm just saying that the way I read it here. I would interpret this to say --

MR. ELLIOTT: I can see that.

DR. ANDERSON: -- since you say it's limited up front, it's limited in that in no case, IRB or not, you won't get it. So I would suggest you might want to reword that, or you'll eliminate all that research.

MR. KATZ: Yeah, just to clarify intent here, that's helpful. And this provision is here because the Act itself required that we make some provision to provide general information from these to researchers and the public who wouldn't

come under our umbrella of the Privacy Act.

DR. ANDERSON: Then I think you need to say, for those who do not have an IRB approval. I mean, researchers versus the public.

DR. ZIEMER: Well, clearly it needs to be clarified.

DR. ANDERSON: Yeah.

MS. KELLEY: Larry, there is an exception to the Privacy Act or an exemption. An person, an individual can waive their right to privacy for certain conditions. I don't know that that would be something that would be normally done for a large study, but an individual can waive. So if they wanted to make their situation public, I suppose they could.

DR. ZIEMER: Well, I think Henry's point is this would seem to preclude even that, the way it's written.

DR. ANDERSON: Yeah.

DR. ZIEMER: Right.

MR. ELLIOTT: That's true, Alice, but I want to make sure everybody understands. We are not seeking from claimants, from the Energy employee or their survivor who's filing a claim, a release of such sort. We're not making that a matter of

practice or policy.

DR. ZIEMER: Okay. Then it appears that we have completed the sort of overview review of the document.

I am going to propose that we have a working group that could prepare some preliminary statements for us, even this evening, statements that could be presented publicly tomorrow so that we don't get into the kind of bind we had before in having to do a document sort of off-line and by e-mail and so on.

And so I would like to seek volunteers again who -- and it could be a few or all, but if I had three or four folks who believe they have enough energy this evening to make an early stab at some wording, at least in answering the three questions. And we can certainly add a couple of other things, such as the point that Henry just made on that clarification. I think, Jim, you had another point earlier that I don't recall what it is, but a couple of those comments would be appropriate to add as sort of general comments. And then try to address the three questions.

So are there those who are just anxious to

draft this? I know everyone's avoiding making eye contact.

DR. DeHART: Some of us would like to get home in the evening tomorrow, since it is February the 14th.

DR. ZIEMER: Yeah, there –

DR. DeHART: It's already costing me.

DR. ZIEMER: Right. Make good eye contact and we'll help you out.

Larry has a suggestion here.

MR. ELLIOTT: We are ahead of our agenda, to a certain extent. I suggest to you that you might be able to do this tomorrow morning. If individually you --

DR. ZIEMER: If everyone's too tired.

MR. ELLIOTT: Yeah, if individually somebody wanted to work on their comments and bring them forward in the morning, we could work together on them tomorrow morning.

DR. ZIEMER: Let me ask the group, because this has been a long day. I don't want to overdo it, but if you'd rather give some thought and maybe jot down, rough out some ideas tonight, and then we'll get them on the table tomorrow and have a chance to work through them, I think we

would have, time-wise have the opportunity because we are a bit ahead of schedule.

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: I'm sorry?

UNIDENTIFIED: That's an off-the-record comment.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah, I would agree that doing it tomorrow morning, I think, would make more sense. I think if we got some general discussion going about the sort of generalities, then I think it's a lot easier to come to agreement on specific statements at that point.

But I guess it would be helpful if we clarify the schedule issue, though, before we adjourn, because there's issues related to public comment and so forth. Are we planning on meeting for the whole day tomorrow, or is there --

DR. ZIEMER: Our main job tomorrow is to develop these comments. And to the -- and basically we are already at least an hour ahead of schedule because we just completed doing what we had scheduled for the 9:15 hour tomorrow, and we have basically blocked off also two additional hours in the afternoon. So there's -- really the

bulk of the time tomorrow was set down for this very task, so we certainly can pick it up first thing in the morning and get it underway.

DR. MELIUS: I would just add that maybe we want to move up the public comment period if we think we might finish earlier, do that around lunchtime, either before or after lunch.

DR. ZIEMER: Yes. Although in fairness, since the agenda was publicly promulgated and some of the public may have scheduled themselves to be here at that time, we would still need to allow a public comment period at that point. But we can certainly entertain public comments earlier as well, sure.

Henry.

DR. ANDERSON: Just as we talk about drafting here, I'm just wondering do we want to have a brief discussion now, or do we want to recommend in this rule, as we did in the previous one, a role for the Board? I notice in the preamble again it talks about the role of the Advisory Board in reviewing --

DR. ZIEMER: Right. We actually sort of referred to that earlier, and then the idea that we would probably do something similar in

codifying --

DR. ANDERSON: I think it's a good idea.

DR. ZIEMER: -- codifying the Board's role there.

Larry.

MR. ELLIOTT: Along that line, I would call your attention to the agenda item tomorrow morning, 10:30 to 11:30, to discuss the Board work schedule.

We need to make a decision tomorrow about our tentative meeting date of March 25th and 26th, and what we would have as an agenda if we want to go ahead and hold that meeting that date. If not, then what would look like the next best available date for us to meet. I'm not sure that we can guarantee that we're going to have the Special Exposure Cohort guide, petitioning guidelines available by March, so we need to talk in terms about that.

DR. ZIEMER: Okay. So that's an issue. Again, you can cogitate on that this evening and be ready to discuss that also in the morning.

DR. MELIUS: Be up all night.

DR. ZIEMER: Yes. Any other -- is that agreeable? Any other comments?

(No response)

DR. ZIEMER: Do I take it, then, that by consent that you're prepared to work on your own this evening to the extent you're able, and come prepared to work through this tomorrow morning? And if we can finish earlier in the day that will be fine, and those that need to leave will be able to do so.

Everybody's making eye contact. I take that as a definite plus, okay. Yes, let's do that. That sounds great, okay. If that's agreeable, and it appears to be, then we'll be in recess until tomorrow morning. Thank you very much.

(Whereupon, the meeting was adjourned at 4:50 p.m.)

- - -

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 6th day of March, 2002.

_____

KIM S. NEWSOM, CCR-CVR
CCR No. B-1642

[SEAL]