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 Holiday Inn on the Hill, Washington, D.C., on Tuesday, January 22, 2002.

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C O N T E N T S

VOLUME I
January 22, 2002

C O N T E N T S

(Continued)

Legend of the Transcript:

(phonetic) = Exact spelling unknown
— = Break in speech continuity
(sic) = Exactly as spoken

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

(By Group, in Alphabetical Order)

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Lafayette, Indiana

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Deputy Secretary
U.S. Department of Health and Human Services

MARY ARMSTRONG
Office of the General Counsel
Centers for Disease Control and Prevention

SHELBY HALLMARK
Director, Office of Workers Compensation Programs
U.S. Department of Labor

RUSS HENSHAW, M.S.
Office of Compensation Analysis and Support
National Institute of Occupational Safety and Health

TED KATZ, M.P.A.
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HELEN KUYKENDALL
Committee Management Office
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JAMES NETON, Ph.D., CHP
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ROBERT G. TABOR
ROSE TOUFEXIS
PETER M. TURCIC
DAVID F. UTTERBACK
TRUDI ZIMMERMAN

P R O C E E D I N G S

48:32 a.m.

DR. ZIEMER: Good morning, ladies and gentlemen. We're going to call the meeting to order, so I would ask that you grab your coffee and juice and so on and please take your seats as soon as possible.

Welcome, everyone, to the first meeting of the Advisory Board on Radiation and Worker Health. I'm Paul Ziemer of Lafayette, Indiana. I've been asked to chair this board. This, of course, is our first meeting, and we're all in a way sort of excited about the fact that this effort is now underway.

The operations of this Board are governed by the provisions of Public Law 92-463, which is the law that sets forth the standards for advisory committees. This particular Board is charged by its charter and under the Public Law that sets it forth is charged with very specific responsibilities in terms of the matters for advising the Secretary of Health and Human Services with respect to the public law that we're involved with. And it's my intent as Chair, and I know it's the intent of all the

Board members, that we carry out our responsibilities to the best of our abilities. We seek to meet both the spirit and the letter of the law; that's Public Law 106-398, which is the Energy Employees Occupational Illness Program Act of 2000.

Let us begin this morning by introducing the members of the Advisory Board. And they are sitting here at the U-shaped conference table, and we'll simply go around, and I'm just going to ask for the Board members to introduce themselves and their location or employer. We'll begin with Roy DeHart right here, and then proceed around. Just the Committee members, and then we'll introduce the other staff in a moment.

DR. DeHART: Roy DeHart. I'm Director of the Center for Occupational and Environmental Medicine, Vanderbilt University, Nashville, Tennessee.

MS. MUNN: Wanda Munn. I'm retired from Westinghouse Hanford Company, Fast Flux Test Facility, in Richland, Washington.

DR. ZIEMER: I'm not sure everyone can hear, and Wanda, if you wouldn't mind using the mike and repeating. You don't have to talk loud, but

just toward the mike.

MS. MUNN: Wanda Munn, retired Nuclear Engineer from Westinghouse Hanford Company, Fast Flux Test Facility.

DR. ZIEMER: Thank you.

Tony.

DR. ANDRADE: I'm Tony Andrade. I'm the Group Leader of the Radiation Protection Services Group at the Los Alamos National Laboratory. I'm also a Nuclear Engineer by training, but now a Health Physicist.

MR. PRESLEY: I'm Robert Presley. I'm an engineer at the Y12 plant, which is now the BWXT Y-12 Plant in Oak Ridge.

DR. ROESSLER: I'm Genevieve Roessler. I'm retired from the Nuclear Engineering Department, University of Florida, and I'm a Health Physicist.

DR. ZIEMER: Let me skip over Mr. Elliott a minute and go over to Dr. Anderson.

DR. ANDERSON: I'm Henry Anderson. I'm Chief Medical Officer with the Wisconsin Division of Public Health.

MS. GADOLA: Sally Gadola, Occupational

Health Nurse Specialist at Oak Ridge Associated University, Oak Ridge, Tennessee.

MR. ESPINOSA: I'm Richard Espinosa with Johnson Controls Northern New Mexico, Sheet Metal Workers Local 49, Shop Steward Union Trustee.

DR. MELIUS: I'm Jim Melius. I'm a physician with the Laborors' Union in New York.

DR. ZIEMER: Thank you.

Those are the ten members of the Board, including I'm one of the ten, so there's ten of us.

And then let me introduce the individual who is the lead staff person and serves as Executive Secretary for this Board, and that's Larry Elliott, who's Director of the Office of Compensation Analysis and Support, NIOSH — National Institute for Occupational Safety and Health — which in turn is part of the Centers for Disease Control, which in turn is part of Health and Human Services, which in turn is part of the U.S. Government, and so on.

Larry. Would you please introduce your staff who are here, or let them introduce themselves.

MR. ELLIOTT: Sure.

I think we have — they're all outside, perhaps. Oh, here's Cori. Cori Homer, who's Committee Management Specialist; and Nichole Herbert is coming; here's Martha DiMuzio, who's a Program Analyst in my office; and then Nichole Herbert, who's my secretary, who's helping us out here today; and Ted Katz, who's Policy Analyst in the Institute. And I think that's all of the NIOSH staff that are here right now.

We also have our writer/editors, Marie Murray and Kim Newsom.

DR. ZIEMER: We have a number of other guests and observers here today. We welcome you.

I might ask if you have not already done so and wish to address the Board during the public comment portion, there is a sign-up book and we ask you to sign up. We do that mainly so we can allot the time fairly amongst those who wish to make public statements for the record.

We would also like to learn who you are. And perhaps if I can ask you all to speak loudly, simply stand and introduce yourself, who you are and where you're from, and we'll try to catch the names here if we can. Thank you.

Start right here, and just move across.

MR. SHAW: Good morning. I'm Roger Shaw with the law firm of McCarter & English out of Newark, New Jersey.

MR. ELLENBERGER: I'm Jim Ellenberger. I'm a consultant with PACE International Union, the single largest union that represents workers in the nuclear weapons complex, and our union is not represented on this panel.

MS. DE PEYSTER: Good morning. I'm Frances de Peyster. I'm the Deputy of the CDC Washington Office, around the hall from NIOSH, and I'm here as an observer.

DR. ZIEMER: Thank you. Welcome.

MS. DAVIS: I'm Allison Davis. I'm the CIO Administrative Officer for NIOSH.

MS. KELLEY: I'm Alice Kelley. I'm with the Office of General Counsel for CDC at DHHS.

MS. KUYKENDALL: Good morning. I'm Helen Kuykendall from CDC's Committee Management Office.

DR. ZIEMER: Incidentally, some of these folks are actually on the program, so you'll hear from them again.

MS. ARMSTRONG: I'm Mary Armstrong. I'm with the Office of General Counsel for CDC.

MR. GIBSON: I'm Mike Gibson. I'm Vice President of the Atomic Workers Energy Council, who represents a lot of DOE sites and atomic workers at those sites.

DR. ZIEMER: Thank you.

MR. GRIFFIN: I'm Mark Griffin, a Health Physicist consultant with PACE International Union.

MS. MARTIN: I'm Fay Martin from Oak Ridge, with the Local Oversight Committee and Citizens Advisory Panel.

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

MS. TOUFEXIS: I'm Rose Toufexis. I'm also with the Solicitor's Office in the Department of Labor.

MR. NESVET: Jeff Nesvet, Solicitor's Office, Department of Labor.

MR. TURCIC: Pete Turcic, the Director of the Energy Employees Occupational Illness Compensation Program, Department of Labor.

DR. MICHAELS: My name is David Michaels. I'm at George Washington University School of Public Health, and a consultant to the Department

of Labor.

MR. KOTSCH: I'm Jeff Kotsch. I'm the Health Physicist for Pete's group at the Department of Labor.

MR. TABOR: I'm Robert Tabor. I'm from Fernald Atomic Trade and Labor Council, Fernald Lab.

MR. HILL: I'm Jeff Hill, a 27-year employee at Oak Ridge National Laboratory. I'm also one of the Atomic Trade and Labor Council Environmental Health and Safety representatives. I'm glad to see labor on the Board.

MR. LIVERMAN: I'm Jim Liverman. I'm a consultant to the Defense Nuclear Facilities Safety Board (inaudible).

MR. BURNFIELD: Dan Burnfield. I'm a Health Physicist for the Defense Nuclear Facilities Safety Board.

DR. ZIEMER: Okay. I think we may have had one or two others come in after we got underway. Did we miss anyone?

Yes, in the very back, just walked in. Can you introduce yourself? We're introducing everybody.

MS. HOMOKI: Liz Homoki, Office of General

Counsel.

DR. UTTERBACK: I'm David Utterback with NIOSH.

DR. ZIEMER: And if the bus lady comes in to change the coffee we'll introduce her as well. Very good.

Please consider yourself introduced to everyone else here, and certainly during the breaks if you want to have exchanges, consider yourselves introduced.

Let me ask if everyone has received an agenda. Is there anyone who did not get an agenda? There are copies on the table. Just take a moment and grab one if you do not have one.

I'm now going to switch positions here, and we have a number of presentations which in a sense are in the form of orientation for the Board itself.

And Larry, if you would introduce our first speaker at this point, then we'll proceed.

MR. ELLIOTT: Good morning again. This is Larry Elliott, and we do have an opening session right now with Helen Kuykendall from the Office of Committee Management, Centers for Disease

Control, to give a brief presentation to the Board about the public law that establishes advisory committees.

And you're going to have to bear with me while I get this started back up, Helen, so tell your best joke.

MS. KUYKENDALL: Oh, my goodness. I didn't know that was going to be a requirement. It's not, according to FACA.

I do want to say welcome to the first and long-awaited meeting of the Advisory Board on Radiation and Worker Health. I do work with CDC's Committee Management Office, and according to FACA, each agency must have a Committee Management Officer, and that person for CDC is Burma Burch. We have responsibility for providing overall guidance and management for CDC's Federal Advisory Committees to ensure compliance with applicable laws and regulations. We work closely with NIOSH officials and with OCG staff to help the Board do business according to the requirements of the Federal Advisory Committee Act.

And I know that you all want to get down to business as quickly as possible, so I will try

not to take up too much of your time this morning. But I do want to give you just a very brief overview of the purpose for and requirements of FACA. And also I think Mary is going to share a video with you that will give you a little bit more detail about the requirements of FACA and about your responsibilities as a special government employee, a member of the Advisory Board on Radiation and Worker Health.

And Dr. Ziemer, I was very impressed with your grasp of the way the system works and the way the flow goes. And this morning after the video and this presentation, you probably will know everything about FACA, more than you ever wanted to know but were afraid to ask because you were afraid you would fall asleep. And there is that slide up there somewhere.

DR. ZIEMER: Helen, could I ask, as you proceed do you want Committee members to ask questions as you present, or wait til the end?

MS. KUYKENDALL: It doesn't matter. Probably – I will say that because the video does go into more specific detail that a lot of your questions may be answered after that point in time. So if

you'd like –

DR. ZIEMER: That would be good.

MS. KUYKENDALL: The Federal Advisory Committee Act was enacted by Congress, Public Law 92-463, in October of 1972. Congress decided to establish a system for the creation and operation of advisory committees in the Federal branch – in the Executive Branch of the Federal government. Congress created FACA to enhance accountability of advisory committees to the public to protect against undue influence of special interest groups and to reduce costs associated with the operation of advisory committees.

A committee is considered subject to the requirements of FACA when it is established by the Federal government, and that can be either by statute mandated by Congress; it can be established at the discretion of the head of an agency; or, in this case, by the President. Actually this is by statute, but the members are appointed by the President.

The Federal government controls the activities of the committee, and committee members are other than full-time or part-time Federal employees. If the committee advises the

government and gives consensus advice — individuals can give advice to the Federal government, and if it is individual advice it is not considered subject to the requirements of FACA. But if it's consensus advice it falls under the Federal Advisory Committee Act. And the committee must have a specific purpose, organized structure, and fixed membership.

FACA defines a Federal advisory committee as any committee, board, commission, council, conference, panel or task force that is established or utilized by the Federal government for the purpose of obtaining consensus advice or recommendations on issues or policies.

The Advisory Board on Radiation and Worker Health, as Dr. Ziemer has already pointed out, was mandated by Congress, Public Law 106-398, to advise the President on the development of guidelines for making determinations related to radiation exposure of DOE facility employees who have specified cancer as stated in the law, and to advise on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program. It's to advise on the feasibility of

adding classes to the Special Exposure Cohort and other matters related to radiation and worker health in DOE facilities considered appropriate by the President.

And I know that Larry and other NIOSH officials probably are going to go into more detail about the functions for the Board, so I won't do that this morning.

The governing authorities for the Advisory Board are, of course, FACA and the Energy Employees Occupational Illness Program Act; Executive Order 13179, which delegated responsibility for the Board to the Secretary of HHS, who further delegated it to CDC and NIOSH. The Board is also governed by GSA, General Services Administration, regulations which was in 1977 given oversight responsibility for Federal advisory committees; and it is also governed by some department and agency policies.

FACA requires that a committee be chartered, that it have balanced membership, and that its meetings be open to the public, according to the government in the Sunshine Act. And FACA also requires that detailed minutes of each meeting be kept, and must contain the date and location of

the meeting, a record of persons attending — which is why, if you signed in, that's why, and another reason that we introduce ourselves; and FACA — the detailed minutes must contain a complete and accurate description of matters discussed and conclusions reached, and contain any advice or recommendations provided by the committee.

FACA also says that committee documents must be made available to the public for copying as long as the committee exists. So all of the documents that are shared with you today must be maintained, usually by the designated Federal official or executive secretary, and those terms are interchangeable. So all of these documents will be available as long as the committee is in existence.

FACA says that committee membership will be fairly balanced in terms of points of view represented and functions to be performed, and its members are appointed as special government employees and must comply with the conflict of interest statutes. And the video will go into a little bit more detail about that, and Mary probably also will be talking about that.

Members serve on advisory committees generally for overlapping terms up to four years, but in this case, I believe, with the Advisory Board, the President chose to make appointments for one year initially.

Okay. And I see you all are still with me.

The structure of the committee is the designated federal official or the executive secretary, the chair, and the members. And the responsibilities of the DFO are to supervise the day-to-day operations of the committee, to approve meeting agendas, to attend all committee meetings — the Advisory Board cannot meet without a designated federal official — and the DFO must ensure that all committee meeting notices are published in the *Federal Register* at least 15 days in advance of the advisory board meeting. The DFO can also adjourn committee meetings when he determines that it is in the public interest to do so, and he can chair the meeting when directed to do so.

The responsibilities of the committee chair or board chair are to preside over the committee meetings and to ensure public participation, and the committee chair is also responsible for

certifying the accuracy of the meeting minutes. I would also like to say that the DFO and the committee chair usually work very closely together in developing the agenda and deciding on how the meetings will be conducted. It's helpful to determine that in advance so that you can maximize the use of the committee's time and facilitate the meetings.

A special government employee — and if you all got the standards of ethical conduct for employees in the Executive Branch and completed your confidential financial disclosure report form, which is required in order for you to attend this meeting, you know that you are a private citizen appointed by, in this case, the President. But generally speaking, special government employees are appointed by the agency head or the secretary, as well as the President.

And you have been appointed based on your expertise that will contribute to the committee's objectives, and you serve with or without compensation for 130 days or less a year, and in this case your charter says that you receive compensation. And you are here to provide your personal opinion only, and you are not the voice

of your organization. You are here to give your opinion based on your knowledge and expertise of the issues, and you are legally held accountable for ethical issues, particularly financial interests.

This next slide shows a little bit of the — gives you an idea of the management for federal advisory committees. The designated federal official works with you and communicates with my office, the Committee Management Office. And we work, as I said earlier, very closely with OCG in the operation of your committee and with other matters related to the committee — the charter establishment, your recharter, which will happen in two years. And we also work very closely with the Office of the Secretary and the department committee management officer there, who is in the office of the White House Liaison; and that office works very closely with the White House.

And as I said earlier also, GSA has oversight responsibility for the Federal Advisory Committee Act, and FACA requires that the President make an annual report to Congress of all of the committee activities and costs. So we will look to NIOSH officials to provide us

information about the administrative work of the committee and the cost, and we in turn will provide that to the Secretary's office, who in turn provides that to GSA. And then GSA prepares the report for the President to Congress.

If you would like more information about Federal Advisory Committee Act, the law, applicable laws, the GSA Final Rule, there's a wealth of information at GSA's web site, gsa.gov/committeemanagement. It also gives information about all of CDC's and HHS's advisory committees.

Thank you.

DR. ZIEMER: Thank you very much.

We did indicate that we would perhaps defer questions, but if there is a pressing question that any member of the Board has, let me give you the opportunity to raise that question now.

[No responses]

DR. ZIEMER: If not, we will proceed. We're way ahead of schedule, which usually is pretty good, allows the Chair to insert more jokes if necessary.

We do have the video. Now is that video next? Some of the other official welcomers are

not yet here to welcome us, I think is going to be the problem there. Let me look here a moment. Time out.

I think we'll be all right. Let's proceed with the video, if it's ready.

[Whereupon, the video entitled *"FACA – The First Meeting"* was shown.]

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DR. ZIEMER: Okay, now we'll open the floor and see if any of the Board members have questions to direct to Helen.

Helen, are you still here?

MS. KUYKENDALL: Yes.

DR. ZIEMER: Thank you.

[No responses]

DR. ZIEMER: It appears that the presentation was either completely clear – I'll leave it at that, it was completely clear. Thank you.

Then we'll move on to the next item on the agenda. We have some particular members of the agency, of HHS and NIOSH and Department of Labor, that we want to introduce and give them the opportunity to make some remarks.

I'm going to ask Larry Elliott if he would introduce these guests this morning.

MR. ELLIOTT: Yes, we're certainly pleased to have Mr. Claude Allen here from the Department of Health and Human Services, Deputy Secretary; and Director of Occupational Worker — am I getting this right? — OWA, Shelby Hallmark from Department of Labor; and Kathleen Rest, who's the Acting Director of NIOSH. And I think we have — if you want to take the front, we have places for you.

Claude Allen, then, will begin.

MR. ALLEN: Good morning. Let's try that again. Good morning. I know, it's a little difficult after watching an ethics video, having to do that every year.

Just as a bit of advice for you, if you have questions, do ask. The rules are very complicated, but they can be simplified by asking simple questions to our counsel staff. I certainly have to do it just about every day of the year, whenever I — whether I'm traveling or meeting with someone in the office. Just keeping in touch with them is very helpful.

But I do want to reassure you that in many

ways complying with the ethics rules is very simple if you keep a very simple rule of thumb, and that is if it doesn't seem right, you'd best ask before you take the next step. But also it should not prevent you from carrying out your — not only your duties in serving as a Special Government Employee, but also in your day-to-day operations.

In fact, we labored long and hard over your nominations to this Advisory Committee. I was directly involved on behalf of the Secretary in overseeing that process, and so we do know much about you. And it's nice to finally get here to welcome you here to this effort.

First, let me start off again by first welcoming you and thanking you on behalf of Secretary Tommy Thompson. It's been an honor to work with so many other important agencies — the Department of Labor, Department of Energy, and our agencies within the Department of Health and Human Services — to try to come to grips with a challenge that we all have, and it's been a cooperative effort.

In fact, just to give you an idea, I meet with — via conference call — at least once a

month with my counterparts, the Deputies at the Department of Labor and Department of Energy, to talk about these very issues to sort through some of the challenges that we confront, some of the sometimes differing opinions that may exist between the agencies on what we should be doing. And we seem to be able to resolve those very readily in that meeting. So I do spend time looking at this very important issue.

I also want to appreciate your commitment in bringing your special talents and your skills to bear on serving not just the government, but also serving those families and those individuals and survivors of individuals who've worked for our nuclear industry and work in weapons programs. Indeed, I need not remind you that in a time like this we are busy right now looking at our bioterrorism preparedness and at how we would respond to not only bioterrorism in terms of biological and chemical, but also radiological and nuclear.

And so therefore the work that you're doing very much enables this government to fulfill its obligation to those who serve. And so I want you to realize the high importance that we place on

the roles that you serve in serving on this Advisory Committee. You bring to this program the views and the expertise of workers and independent scientists and physicians, and that is what we've looked at very carefully as we constructed the Board, which was very specific in its makeup.

We're asking you to advise us on the policies we're establishing for current and potential cancer claimants under the new compensation program. And we're also asking you to advise us on decisions whether to add worker groups to the Special Exposure Cohort. I've learned a lot about this over the last few months, more than what I had anticipated in this job, but it has been a very important component, and that is what groups of individuals qualify for coverage. We also are asking you to help us ensure the quality of our radiation dose reconstruction program at NIOSH. They will be focusing on quite a number of applications that come through, and so we're asking you for your expertise there, as well.

Larry Elliott, the Executive Secretary, will review the responsibilities of the Board with you

in detail. I wanted just to share with you again that our aim at HHS is to earn the public's confidence in this important new program, and to meet high standards of medicine and science as far as possible while ensuring that claimants and their survivors are given fair, timely and practical service. This Committee has a key role in achieving these aims.

And again, as Secretary Thompson has made it very clear in our Department that we are one department, notwithstanding the fact that we have many agencies or many components of it; but we are also one administration, so we want to work very cooperatively with the Department of Labor and the Department of Energy in arriving at the very best that we can provide to these families and survivors in terms of their claims.

So I again want to thank you on behalf of Secretary Thompson for your decision to serve. We appreciate your accepting this invitation. And please do not hesitate, if we can provide you with any service from the Department itself, to contact us through Larry or anyone else here who's serving you in that capacity, as to assistance or advice. So again, thank you again

for your commitment and your dedication to this effort. Appreciate it.

DR. ZIEMER: Thank you very much, Mr. Allen.

Now let us call on Dr. Rest to address the group.

DR. REST: Good morning to all of you, and I extend my personal welcome to you on behalf of the National Institute for Occupational Safety and Health.

In joining this Board you really have assumed a vitally important role for advising HHS and CDC/NIOSH on its responsibilities under this new compensation program. We recognize that this is no small commitment on your part, and so I'm here to thank you up front today for the contributions that you're going to make to this very important effort.

As you know, Congress established this program to provide timely, uniform and adequate compensation for the men and women who worked in this country's nuclear weapons program and sustained occupational diseases as a result of their work. These dedicated workers labored long and hard on behalf of this nation, and we owe them a great debt. For those who've become ill

in the performance of this work, we need to work together very hard to ensure that we effectively implement the program that Congress has created to help compensate them.

As you know, the Energy Employees Compensation Program Act named NIOSH to assist the Department of Health and Human Services in carrying out its responsibilities because of its — of the integrity and the excellence of its scientific expertise. As just noted by Deputy Secretary Allen, these responsibilities include making new policies to implement the program and building new programs to assist claimants, the Federal Compensation Program at the Department of Labor, and the Office of Worker Advocacy at the Department of Energy. HHS will be relying on NIOSH to take the lead in implementing and carrying out the major responsibilities assigned to HHS under this Act.

Now as those of you who know NIOSH probably realize, involvement in a compensation program is a new role for us at NIOSH, which is the primary Federal agency conducting research and prevention activities in occupational safety and health. NIOSH does have substantial expertise in this

area, however, as it's conducted epidemiologic research for many years addressing health risks to DOE workers. Now we at NIOSH feel very honored to have been entrusted with these new responsibilities, and I want to assure all of you that we have made it a top priority for us. We're working really hard to make this program successful and to get it fully launched as quickly as possible.

To date, and in the short time that the program has been up and running, NIOSH has accomplished a number of things. We've established the Office of Compensation Analysis and Support within NIOSH with Larry Elliott as the Director of that office, now located in Cincinnati. We've staffed — we've begun to staff up this office with a very impressive technical and scientific team, as well as a group of dedicated support staff.

We've established records facilities, systems and procedures for the dose reconstruction program. We've developed an interim final rule on dose reconstruction and a notice of proposed rule-making on the probability of causation. We've developed a web site that I

hope you've all logged onto. We've adapted existing software for probability of causation calculations and internal dose estimation. We've issued an RFP for a dose reconstruction program, appointed physicians to serve as panelists — as members of medical panels serving the DOE Office of Worker Advocacy. We've begun to receive cancer claims from the Department of Labor and begun the process of dose reconstruction.

And we're responsible for staffing and funding this Advisory Board. And I'm here to assure you that we will do our very best at NIOSH to provide you with the support and the resources that you need to fulfill your own significant responsibilities under this program. We recognize the enormous commitment that you've made, and we certainly look forward to working with you in the coming months.

Now our aim as part of this program, the compensation program, is to serve the nuclear weapons workers and their survivors as well as possible. With your advice, we have to establish HHS policies and decisions that are fair to workers and their survivors, that are grounded to the extent feasible in good sound science, and

that are practical and timely. With your advice, we have to achieve a dose reconstruction program that meets those high standards and serves the critical needs of claimants and the Department of Labor.

Now in working with you, the Board, I can tell you that we are committed to helping you fulfill your responsibilities. Working collaboratively with you and with our sister agencies to assure efficient and effective implementation of this program, we will give you the support that you need, and we are certainly committed to open and honest communication throughout this process.

So again, on behalf of NIOSH, I want to thank you for joining in this important endeavor, and we certainly look forward to working with you in the coming months.

DR. ZIEMER: Thank you very much. And Dr. Rest, will you be able to stay with us a little while, at least through the break, so committee members can meet you?

DR. REST: I'll be with you through the break.

DR. ZIEMER: Thank you very much. I should

note this meeting would become very restless if you left.

Okay. Mr. Hallmark, please.

MR. HALLMARK: Thank you. It's my pleasure to join with Secretary Allen and Dr. Rest to welcome you in your role as the Advisory Committee on this very important topic today.

I'd like to just congratulate you for having been selected for this activity and, as the two previous speakers, thank you for accepting it. It's going to be a difficult task, but I assume, given your background and the interest that you bring, that you'll be able to achieve great things in this role.

It is going to be challenging. Usually advisory committees are focusing their help on one particular part of the government. This particular program gives you the opportunity to address three or four Cabinet-level departments, and is rather unique in that regard.

We are the Department of Labor, the agency that was given lead responsibility in actually implementing the Federal part of the Energy Employees Occupational Illness Compensation Program Act. We did not name the program; I want

the record to show that. Congress is responsible for that. But we call it affectionately EEOICPA, so if you'd like to get used to that acronym, you're going to hear it.

We are obviously, as the entity that's responsible for taking and adjudicating claims, we're vastly interested in what you do and the effectiveness and quality and speed with which you do it, because all of those things will affect us. And I'll talk a little bit more about that as I go on.

The Department of Labor has the responsibility for, as I said, adjudicating the Federal benefit program under this statute. That involves our issuing lump sum payments and medical benefits for those who are found to be eligible. It requires us to provide an administrative appeal process for those who disagree with our decisions. And ultimately we would be involved with the Department of Justice in defending those decisions in court for those who are still aggrieved after they've gone through our process.

We're eager to see the results of the Board's deliberations, primarily, I should say,

because until HHS can complete the work on their probability of causation rule, with your input and review, we won't be able to address thousands of cases that are already in hand. And that's a matter of grave concern to the agency that has those cases in hand, and people know our address. So we're interested in getting this process moving.

The other piece is that the Board has the responsibility to advise HHS and NIOSH with regard to their dose reconstruction process, and with regard to the expansion process for the so-called Special Exposure Cohort. It's very important for all the agencies involved that those processes are strong, they're reasonable, they are understandable to the public that's interested in this, so that we can have a credible program and one that everyone is proud to administer.

Just to let you know a little bit about what the Department of Labor has been up to since this program went into effect, we published our interim final regulation back in May, and that allowed us to begin taking claims and effectuating this program on the date required by

Congress, which was July 31st, 2001. We had put in place a benefit claims structure analogous to others, other parts of the Department of Labor.

By the way, Larry, I'm with the Office of Worker's Compensation Programs. The Office of Worker Assistance is over in that other program at Department of Energy.

We have — we've got 150 Federal employees in place now in four district offices around the country in Seattle, in Denver, in Jacksonville, Florida and in Cleveland, Ohio; and a national office staff including our Final Adjudication Branch, which is the ultimate deciding body for us.

We've put in place, along with the Department of Energy, ten resource centers in the major sites that DOE weapons facilities are located in, and those have been up and running since July also. And we've established a process of outreach, which has led us to do town hall meetings on more than 60 occasions, and we've done a number of traveling resource centers where we send people out to locations where we don't have currently a formal office to help people file their claims. So we've got a lot of

outreach going on. We're trying to reach the public who may be interested in filing this type of claim.

As of last Thursday, January 17th, we had 18,061 claims, so you can see the program is real. It's growing, and it will continue to grow.

Many of the claims that we have in hand are ones that Department of Labor has the authority and responsibility to take all the way to the end at this point. Those include those Special Exposure Cohort cases, individuals who have radiation-induced cancers of a kind listed in the statute, and who worked in a facility where the statute provides us with a presumption that there was occupational linkage to that particular condition. So those Special Exposure Cohort cases we can take to the end.

Beryllium exposure cases we can adjudicate and make a final decision on; silicosis cases for those who are miners involved in digging tunnels for tests; and the supplemental benefit program for those who will receive benefits from the Department of Justice under the Radiation Exposure Compensation Act – that's not a piece of

the statute that you have direct contact with. But those are the four areas where we can take the case and go all the way to the end.

And in six months, and actually less than six months since this bill became effective, we have made a good start, I believe, in trying to address those cases where we have that full responsibility. We've made 2,500 what we call recommended decisions in those four district offices. We've made 1,570 final decisions in our final branch, final adjudication branch. And we've made 1,044 lump sum payments to injured workers and their survivors, and clearly that is a substantial number. It's not as many as we'd like, but it is a good beginning, I believe, given the start-up requirements involved in this kind of a major entitlement program.

But the majority of the cases that we have in hand, and clearly the majority that we expect to get over the next several years, are cases that involve a radiation exposure and a claim of cancer caused by radiation exposure where NIOSH will have to do a dose reconstruction. That set of cases is going to require an intricate level of interaction and cooperation between the

Department of Labor and HHS, and is the source of a lot of our interest in how you do your work and the kind of advice you provide.

Specifically, just to give you a notion of the degree to which we have to interact closely with HHS, the process involves something like the following. We receive the claim and screen the claim to determine whether the individual was a DOE worker and has one — has a cancer. Having done that, we refer the case to NIOSH for a dose reconstruction. NIOSH completes that reconstruction, returns the case to DOL. DOL then adjudicates the case, makes a final decision based on the exposure report that we get from dose reconstruction and on HHS's probability of causation regulation. And having done that, if the claimant has objections or concerns, we may have to send the case back to HHS to reconsider that dose reconstruction. So you can see cases will be going back and forth between the two agencies, and that's the reason I suspect why I'm here today talking with you at a HHS-sponsored operation.

We are — I'm happy to report that that level of cooperation that's going to be needed to

implement this program has in fact been working very well in the early going here. We have had very good relationships and working coordination with HHS, and I'd like to congratulate NIOSH for the work they've done so far in terms of putting together their regulations and their procedures for going forward. This is an intensely difficult undertaking, and as Kathy had mentioned, not an area that NIOSH has been familiar with in terms of processing individual claims. The Department of Labor does that kind of work and NIOSH has not, historically, and it's been quite gratifying to see how quickly and how professionally NIOSH has moved ahead in that process.

We are, as mentioned, in the process of sending cases over to NIOSH. Fifteen hundred cases are there so far which require dose reconstruction. Another 1,500 cases will probably be delivered by April, which is the goal that NIOSH has for getting their regulation in place. And until that regulation is in place and effective, even though the dose reconstruction is complete, Department of Labor can't act on the case because we have no basis for making a

decision about probability.

So that's where your input comes in. That's where the urgency, the rubber meets the road, as far as this panel is concerned. It's not an academic exercise. There are already 1,500; there'll soon be 3,000 cases, individuals. These are workers or their survivors who have incurred a very serious or fatal disease, all of whom are currently waiting, more or less patiently — hopefully patiently — for this process to be elaborated and then to work for them.

We are also waiting patiently, and hopefully we'll be working with you. If the Board needs help from the Department of Labor with respect to our specific part of this, we'll be glad to provide any information you might need. It's a difficult task, as I said earlier. I again commend you for taking it on, and I know that the nuclear workers who suffered these exposures deserve your serious and best efforts.

Thank you very much.

DR. ZIEMER: Thank you very much, Mr. Hallmark. And I assume that you might be here for a while, and perhaps we'll have a chance to chat with you during the break, at least?

MR. HALLMARK: Absolutely.

DR. ZIEMER: Thank you.

Might I – we'll allow a few minutes for some questions here. Let me pose one to start with.

Would I be putting you on the spot to ask you to identify the ten resource centers that DOL has established around the country?

MR. HALLMARK: Not at all. I'll speak into the microphone here. We have with DOE established the centers, starting – I think our first one went up in Paducah, Kentucky. There are ten centers around the country – Hanford; Las Vegas; Rocky Flats, Colorado; Paducah; Oak Ridge; Savannah River, South Carolina – okay, now you've – now I'm starting to slow down here –

DR. ZIEMER: Los Alamos?

MR. HALLMARK: Los Alamos, yes.

UNIDENTIFIED: Idaho.

MR. HALLMARK: And the national – thank you back there, Rick.

UNIDENTIFIED: Portsmouth.

MR. HALLMARK: And Portsmouth, Ohio. How could I forget Portsmouth? Okay.

So I think that's nine, and we have Anchorage, Alaska, which is a smaller site that's

run by employees who are in the former worker program up there.

DR. ZIEMER: Thank you very much.

MR. HALLMARK: And we've done traveling centers where we send those people from those offices out to do the same kind of work in several different places – Southern California; Buffalo area of New York; Reading, Pennsylvania; western Pennsylvania, and on several occasions to the Amarillo area where Pantex is.

DR. ZIEMER: Let me ask if other Board members have questions.

Yes, Dr. DeHart?

DR. DeHART: If you can, do you have a crystal ball guess as to how many claimants there will be by the time the program runs its course?

MR. HALLMARK: I think that would be very difficult to guess. We had initially estimated at Labor something like 80,000 claims in the first two years. That probably was a little high, based on what we've received in the first six months here. However, I think it's a little early yet to say.

As you know, Congress has recently amended the statute to broaden the definition of

survivor, among other important sort of fixes, and also addressing themselves to people who have tort claims and how they need to proceed with their tort claims in light of possible eligibility under the EEOICPA benefit program. Both of those may have an impact of bringing people in who had been reluctant to come forward or who thought they were not covered. In the case of survivors, very clearly adult children, so-called, were clearly disallowed by the language of the previous statute.

So we expect — we're seeing something like 500 or 600 claims per week coming in now. We expect that perhaps to grow, and we could see as many as 75,000 in the first two years. And then it's an ongoing program. As people incur these diseases that are covered under the Federal statute, they will become eligible over time. And obviously, since the statute covers cancer and cancer applies — visits the lives of a very high percentage of the American population, we can expect this program to continue for a long time.

DR. ZIEMER: Other questions either for Dr. Rest or Dr. Hallmark? Yes.

DR. ANDERSON: Of the 1,000 lump sum payments, what's been the average payment?

MR. HALLMARK: The lump sum payments are established by Congress, and they are $150,000 for the individuals in this cohort. They are $50,000 for the supplement for the RECA beneficiaries, but there's no different amount. It's that — unless it's —

DR. ANDERSON: All of these have been in the 150 group?

MR. HALLMARK: No, no. Quite a number of them have been RECA supplements, because that was something we could do very quickly based on the Justice Department telling us, yes, these people were our beneficiaries. So in fact, the majority actually are RECA benefits as opposed to the other.

DR. ZIEMER: And there it's the difference — their original payments were $100,000?

MR. HALLMARK: These were uranium miners who originally received $100,000, and the law gave them the extra $50,000 as a matter of parity. But we are receiving and processing claims very rapidly now. And as I say, our infrastructure being in place, we expect to get a lot of the —

especially Special Exposure Cohort cases through the system in the next few months.

DR. ZIEMER: And your beryllium, the numbers you gave us for beryllium included the beryllium sensitivities where you're covering medical care as well, or —

MR. HALLMARK: The numbers of cases decided included some beryllium cases. We would not issue a lump sum payment in the case of beryllium sensitivity; that's correct.

DR. ZIEMER: Right.

Other questions?

[No responses]

DR. ZIEMER: Thank you.

It's 10:00 o'clock. We are going to take our break. Since we've already had the film on committee membership it basically puts us really a little ahead of schedule, so we can allow the break to continue till about 20 after, give you a little breathing space. So let's all take a break at this time.

[Whereupon, a break was taken from approximately 10:00 a.m. until 10:25 a.m.]

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DR. ZIEMER: Thank you, we'll come back to order now.

Before we proceed with the agenda, just a couple of items. First of all, an instruction to our Board members. When you do have comments or questions, it's been requested that you speak into the mikes. It's important not only for our recorders, but for those who are here observing to hear what you are saying.

Secondly, if you are a visitor or observer and would like to address the Board or make a public comment or have items for the record, we ask that you sign up. There is a sign-up book out in the foyer, and if you would please sign up. This is mainly so we can allow the time accordingly. But I know that there are some of you that have arrived since we mentioned this earlier today, so this is a reminder to you if you do wish to speak later when we have that public comment portion of the agenda, we need to have you on our roster to do so. So please sign up.

And then I would ask if there are those of you who arrived sort of mid-morning or after the introduction period, we would like to learn who

you are, again so we have some idea of who's here. This is, after all, an open meeting. So are there any of you that arrived after the introduction periods of this morning that are here, if you would please stand and identify yourself, and tell us who you are and where you're from. There are quite a few of you. This is a whole new group; are we in the same meeting? Okay.

Just start here on my left, and we'll sweep across. Speak loudly so the recorder can also — I know you've registered, or I assume you have, but we're also recording here as well.

MR. SPENGLER: Thank you. Good morning. I'm Bob Spengler, the Associate Administrator for Science at the Agency for Toxic Substances and Disease Registry.

DR. ZIEMER: Thank you.

MR. MAURO: I'm John Mauro. I'm with Sanford Cohen and Associates. We're a consulting firm.

MS. ZIMMERMAN: Trudi Zimmerman, Office of Compensation Analysis and Support.

DR. SCHUBAUER-BERIGAN: Mary Schubauer-Berigan, NIOSH Health-Related Energy Research

Branch.

MR. HENSHAW: Russ Henshaw, Office of Compensation Analysis and Support, NIOSH.

MR. SCHAEFFER: Mike Schaeffer, Department of Defense, Defense Threat Reduction Agency, Program Manager of the nuclear test personnel review.

MR. MORALES: Frank Morales with the Government Accountability Project.

MR. MILLER: Richard Miller, Government Accountability Project.

DR. ZIEMER: Across here, go ahead.

DR. NETON: Jim Neton from the NIOSH Office of Compensation Analysis and Support.

MR. SUNDIN: And I'm Dave Sundin, Deputy Director of the Office of Compensation Analysis and Support.

MR. CALHOUN: I'm Grady Calhoun, Office of Compensation Analysis and Support.

MR. RICHARDSON: David Richardson. I'm an epidemiologist at UNC Chapel Hill.

MR. BARAVY: Jordan Baravy (phonetic), ALF-CIO.

DR. ZIEMER: Thank you all. Did we miss anyone? Thank you for being here, and we'll

proceed now with the agenda.

The next person on the agenda is Mary Armstrong, who's with the Office of the General Counsel of NIOSH. And Mary's going to come and address us on some legal issues. This is again some information that's very important to the Board itself.

Mary, I know you're —

MS. ARMSTRONG: I'm right here.

DR. ZIEMER: Oh, there you are, standing in the wings. Thank you.

MS. ARMSTRONG: I'm Mary Mitchell Armstrong. I'm the Senior Attorney with the Office of General Counsel assigned to NIOSH.

As Kathy mentioned, NIOSH is primarily a research agency, the research agency for occupational safety and health. And until last year in October, I was the only attorney for NIOSH, so this program in particular will probably mean that NIOSH will have quite a few more attorneys. But we are primarily — it is primarily a research agency, and is also — we're relatively new in the area of rule-making.

In addition to me, Alice Kelley — if you'll stand up, Alice — is working with me, and Liz

Homoki has been working with the program.

I'm here just to do — I talked with some of you personally when we were reviewing your 450s. I just wanted to emphasize again that if you have any questions concerning those 450s and any questions regarding anything that — as far as conflict of interest, please give Larry Elliott a call, and he will get to one of us and we will try to answer your questions. And we've been working very closely with the Office of General Counsel's ethics divisions, too. So in the future, if anything happens and you have any questions, please do not hesitate to call.

But I think you've probably been fairly overwhelmed with ethics this morning with our film and et cetera, so I'm basically here to give — just to talk briefly about the rule-making process.

As you are aware, we have put out an interim final rule on the dose reconstruction methods. And as a matter of fact, NIOSH is in the process of processing some dose reconstructions. We also have put out a notice of proposed rule-making for the probability of causation. By statute, by the energy statute, you all are to provide us advice

on the probability of causation, and NIOSH has also requested advice on the dose reconstruction, and that's the purpose of you being here today.

As I think you are aware, NIOSH is hoping to finalize both of these regulations by early – by April. As Shelby mentioned, there are many claims – the cancer claims cannot be finalized until the probability of causation regs are finalized. So we are under a tight time frame to try to get these in place, which will mean that you will have to put in some extensive work during that time frame, along with the Agency.

This meeting is being transcribed. The transcript of the meeting will go into the record for both rule-makings. That includes any comments you make, any comments the public makes, the presentations, et cetera, will all go into the record for both rule-making, and we're holding open the records for your recommendations.

I wanted to emphasize, however, that we are in the comment period and are here getting your comments. The people who give presentations here are going to try to be as responsive as possible to your questions, but neither NIOSH nor the

Department has made any final decisions on the final contents of these rules. We're here to listen to what you have to say, to listen to what the public had to say previously during the comment period, and to take all those into advisement. And so they're — we're still in the process of coming up with the final reg, and nothing has been finalized.

Again, we appreciate you being involved with this, and this is quite a challenge. We have many advisory boards within HHS. There are at least 168 that are just appointed by the Secretary that are just discretionary, so I imagine we have probably over 200 advisory boards altogether. Very few of them have quite as much work load as you all do, so we appreciate your participation. And if you have any questions, need to contact any member of my staff or me, or any member of my staff, please contact Larry and we'll get in touch with you.

Do you have any questions? Yeah.

DR. MELIUS: What are the dates on the comment periods, and does that include the next meeting of the Board?

MS. ARMSTRONG: The dates on the comment

period is — we did not include the next period of this Board. This is —

MR. ELLIOTT: I'll speak to that in a minute.

MS. ARMSTRONG: Yeah.

DR. ZIEMER: Okay. Other questions?

[No responses]

DR. ZIEMER: Mary, you realize that our agenda requires you to speak for a half-hour?

[Laughter]

MS. ARMSTRONG: Well —

DR. ZIEMER: Just keep going.

MS. ARMSTRONG: I was going to say I'm among the technologically-challenged, so you didn't have to sit through a PowerPoint for me because I can't quite do that. So —

DR. ZIEMER: Thank you, we applaud you there.

MS. ARMSTRONG: So anyway, I'm sure that you'll — the less you hear from the lawyers, the better.

DR. ZIEMER: Can you give us a timetable on once the comment period closes — and I believe that's this week, is it not? Or is it next week, two weeks from now?

MS. ARMSTRONG: The comment period for the public will be closing again today – I mean, tomorrow.

DR. ZIEMER: Tomorrow for the public, yes.

MS. ARMSTRONG: But for receiving the Board's comments will be after –

DR. ZIEMER: Right. Now what's the timetable, once you have the comments and you have to deal with those, is there a target date? Or maybe I'm getting into Larry's talk here, as to when the final rule will hit the books.

MS. ARMSTRONG: We are hoping to have the final rule, as you say, hit the books or hit the street in April. This involves NIOSH having to go through your comments and consider them, draft the final rule. That has to be cleared by the Department, and there's various things that have to be done before it can be finalized. So we're on a very tight time frame. We want to get this rule, these rules finalized and so that we can get this program up and running and people paid.

DR. ZIEMER: And is it my understanding that the final rule also includes, perhaps as an appendix or something, the public and Board comments, as well as the response of the Agency

to the comments?

MS. ARMSTRONG: The Agency will address the comments in the preamble to the rule.

DR. ZIEMER: In the preamble, thank you.

MS. ARMSTRONG: Right. The comments actually are available now. You can see them on the OCAS –

DR. ZIEMER: They're on the web site, yes.

MS. ARMSTRONG: – OCAS web site.

DR. ZIEMER: Right.

MS. ARMSTRONG: But they won't be appended to the final –

DR. ZIEMER: But the responses will?

MS. ARMSTRONG: Well, but the comments will be addressed in the preamble to the rule-making as to why changes were made or not made.

DR. ZIEMER: Are there questions for Mary at this time? Questions on the other legal issues, your conflicts of interest and so on?

[No responses]

DR. ZIEMER: Okay. Thank you very much, Mary.

And if you do have private comments or questions for Mary on any of those legal issues, including your conflict of interest waiver

documents, you can talk to Mary individually on that.

Right?

MS. ARMSTRONG: I'm actually going to have to leave and go back to HHS, but Alice and Liz will be here.

DR. ZIEMER: You have staff people here to help. Thank you.

Okay, then I think we will proceed, even though we're a little ahead of schedule. That's fine. And we're going to now hear from Larry Elliott, who, as has already been indicated, serves as Executive Secretary for this Advisory Board, as well as serving as the Director of the Office of Compensation.

Larry, please proceed.

MR. ELLIOTT: Well, as many of the previous speakers have mentioned, you have several responsibilities and a huge, challenging task before you, and we're going to talk about that now. I'm going to walk you through the responsibilities as they're specified from their genesis in the Act, the Employees Compensation Program Act, as well as the Executive Order and finally your charter.

But let me step back and briefly talk about — we've reopened the public comment period for both rules, the interim final rule for dose reconstruction and the notice of proposed rule-making for probability of causation. Those were reopened last week in order that this Board and the public can provide comments during this Board meeting, and the Board will be able to provide its consensus comments to the record before February 6th. That's a daunting challenge. We're going to have a lot to do before February 6th.

Tomorrow, the close of business tomorrow, will end the public comment period, the receipt of public comments for the record. But we'll leave the record open for the Board's deliberations on its consensus comments, which again will need to be submitted by February 6th. That's a goal that we have set, and I'd like to see us achieve that goal. And it's tied in to our need and our intent to finalize and promulgate these rules so that we can use them, and so that the Department of Labor can adjudicate the claims that we have in our hands and those that we understand are forthcoming.

Any questions on our reopening of the public comment period and what that constitutes for this body?

UNIDENTIFIED: What were the two areas again?

MR. ELLIOTT: The two areas? There's two rules. Is that –

UNIDENTIFIED: Yeah, you mentioned public comment for something and something.

MR. ELLIOTT: Well, there's two rules. There's an interim final rule on dose reconstruction. That's a rule that NIOSH will use, along with technical guidelines that support that rule, to do individual dose reconstructions on cancer-related claims.

And then there's a rule of probability of causation, which is a notice of proposed rule-making, a slightly different track toward promulgation. And that rule will be used by the Department of Labor to finally adjudicate and come forward with a recommended decision on a cancer-related claim.

UNIDENTIFIED: Thank you.

DR. ZIEMER: Incidentally, these are Code of Federal Regulations, Part 42 –

MR. ELLIOTT: 42.

DR. ZIEMER: — CFR 81 and 82.

MR. ELLIOTT: Right.

Yes, Dr. Anderson?

DR. ANDERSON: Just a quick question on the choice of February 6th. Was this a statutory requirement, that you could only open it for a —

MR. ELLIOTT: No, sir.

DR. ANDERSON: I mean, it seems that you're putting a great deal of —

MR. ELLIOTT: I'm putting pressure on the Board, yes, I am.

DR. ANDERSON: You're putting pressure on the Board without having consulted the Board on — we cancelled the last meeting because you weren't able to process paperwork.

MR. ELLIOTT: Right.

DR. ANDERSON: And now we're left with a two-week period here to — and generally the advice you get is proportional to how much time one has to give to it, so —

MR. ELLIOTT: Yes, we understand that. We recognize that. And that's why I'm being very frank with the Board, that this is a challenge and a goal that we — the Department has set in

order to achieve an April promulgation deadline.

DR. ZIEMER: And I might comment, Dr. Anderson, I think the Board, by the end of the day tomorrow, will have a better feel for whether that's realistic. I think perhaps the Agency feels that the quality of our advice may be inversely proportional to the time available, so who knows. It's all in the modeling. It's like the dose reconstruction.

MR. ELLIOTT: Well, we're going to give you as much help and support to try to achieve this goal as possible. And as I've said to staff from the very start, we're going to do the best we possibly can, and we'll see what we can accomplish.

So from the Energy Employees Occupational Illness Compensation Program Act, it was the sense of the Congress – or you can translate that into their understanding, or perhaps their belief – that there were hundreds of thousands of workers who had served the nation in developing the nuclear weapons arsenal, and also that many of those workers have had to pay a high price for that occupational employment in dealing with the special types of exposures that they encountered.

These bullets are all paraphrased from the opening of that Act, and that really is — serves as the backdrop and the background on why we're here today. There was a huge watershed shift in philosophy and culture surrounding DOE and the weapons program that has resulted in a compensation program dedicated to those workers.

The purpose of this compensation program is to provide timely, uniform and adequate compensation for covered employees, or their survivors, who have suffered from illnesses incurred in the performance of the Department of Energy work and its contractors and subcontractors, and those entities that were in place before DOE came along that were contracted under the Atomic Energy Commission, called atomic weapons work employers.

What this body is specifically concerned with regarding the language of the Act is those claimants who come forward who have cancer. And in this part of the Federal program for this compensation program, an employee at a DOE work site who was a contractor or a DOE employee at that work site and sustained cancer in the performance of duty at that work site will be

awarded compensation if it was determined that the cancer was at least as likely as not related to the radiation exposure in the performance of that duty. What's critical here to understand is that we're only dealing with radiation. We're not dealing with inter – effects from chemicals or interrelated effects from other types of exposures. We're only going to assess radiation exposure and its potential association in relationship with the cancer as an outcome.

An individual who's a covered employee must have a specified cancer if they are within a member – a member of the Special Exposure Cohort, and those are 22 cancers that are listed that have been amended recently by acts of Congress. So we're not going to see those individual SEC cancer claims. The Department of Labor will automatically verify their employment through Department of Energy, verify the diagnosis of the cancer, assure that it's one of the 22 that's presumed in that list, and provide an award. This body will see all other types of cancer and all other – for individuals at all other sites, as well as individuals at these Special Exposure Cohort sites who do not have one of those 22

listed cancers.

I'm going to move to the Executive Order. I didn't cover a lot of territory in the Act. I hope you've had time, chance to read it. There's a lot of other information in the Act about beryllium and silica. We're only going to focus on cancer. But if you have questions about that, we would entertain those and give you a response.

So in the Executive Order we get a little bit more specific information about who's going to do what and how they're going to do it. This Order sets out the Agencies' responsibilities across four Departments in the Executive Branch, and those responsibilities are specified to accomplish the program's goals and building on the principles and the framework that was set forth in the Act. The Department of Labor, the Department of Health and Human Services, and the Department of Energy are all responsible for developing and implementing specific actions under the Act to compensate these workers.

Here's the specific responsibilities of the Secretary of Labor – and Mr. Hallmark went through these in his presentation, but just as a reminder they have the lead, as the lead Agency,

in administering the program:

They determine the eligibility and adjudicate the claims for all the Federal compensation claims that come forward, not only cancer, but the silica and beryllium. They have promulgated their regulations for the administration of the program, which Mr. Hallmark mentioned, back in May, and that's how this program is to function.

They are to ensure the availability of all forms necessary to complete a filing of a claim. And if you've been on their web site, you've seen these forms. Their resource centers provide the forms and provide guidance on how these are completed. They are to develop information materials in accordance — in coordination with the Department of Energy and with the Department of Health and Human Services, which are designed to help claimants understand the process and understand their eligibility for this program, and how to file their applications.

The Secretary of Health and Human Services have been given these responsibilities under the Act:

Specifically, to promulgate the regulations

that we have before us in draft form to establish guidelines for determining the probability of causation and for methods to conduct and complete dose reconstructions on an individual claim basis. We're also in the Department of Health and Human Services responsible for conducting those individual dose reconstructions for a verified cancer claim.

We have another responsibility, which is to consider and issue determinations on petitions by classes of employees to be treated as members of the Special Exposure Cohort. This is a distinct and daunting challenge before this committee. We will bring forward at a later meeting of this body the process guidelines, policy guidelines from the Secretary on how he wishes to proceed with this, and seeks your review and guidance on those.

We are also in HHS to appoint members to the DOE physicians' panel, which Dr. Rest indicated to you we have accomplished that, and the Department of Energy is finalizing its rule on how those panels will operate and be run. It is simply our role at HHS to provide appointed physicians to serve on those panels. Those

panels review state-based compensation claims. They don't do anything or have any auspice over the Federal side of the program.

And finally, HHS is responsible for staffing and administrative support to this Advisory Board.

The Secretary of Energy has a number of responsibilities, which take two slides rather than the one for Labor and HHS:

Energy is to provide HHS and this advisory body, in accordance with law, assistance and access to all relevant information that we need to do dose reconstructions, that we need to evaluate worker exposures, and understand how we should handle petitions for additions to the Special Exposure Cohort.

And as permitted by law, upon request from the Department of Labor or the Department of Health and Human Services, DOE is to require their contractors and subcontractors and designated beryllium vendors to provide information that would be relevant to a given claim.

DOE is also to identify and notify potentially eligible individuals of the

compensation program, and they're doing that through their outreach program jointly with Department of Labor.

The Secretary of Energy also has a responsibility to designate atomic weapons employers and provide additions to the list of designated beryllium vendors. If you've been on our site and gone to the related links and looked at DOE's site, you'll see the list. I think I shared that with you when we were talking about where we might want to meet in the future. That's a relevant list of all covered facilities around the country, and this is a responsibility that Energy has to augment that list and make it correct and as complete as possible.

They are at Energy to negotiated agreements with states to provide assistance to the Department of Energy contractor employees filing state Worker's Comp claims, and I know that they're still engaged in establishing those agreements with the states.

They at Energy are also to provide annual reports on the Worker Assistance Program regarding the claims-related statistics that are generated, both on the Federal side and the state

program side.

And they are to publish in the *Federal Register* a list of atomic weapons employer facilities that I mentioned earlier, and that has appeared and been updated.

The Attorney General in the Department of Justice has some specific responsibilities, as well, as specified in the Act.

These include developing procedures to notify each claimant of their approval of a Radiation Exposure Compensation Act claim – the RECA program – by the Department of Justice, and the availability of supplemental awards under this Energy Employees Occupation Illness Compensation Program.

The Attorney General is also to identify and notify eligible uranium workers or their survivors about the availability of this supplement, and they're also to provide information upon request from the Department of Labor needed to adjudicate claims of a covered uranium employee under this new program.

The Executive Order also provides some more specifics, in detailed outline here, for what this Advisory Board is charged with and what your

responsibilities are.

As we noted, you're appointed by the President. There's been a delegation of authority to HHS to staff this Board and provide administrative support to the Board. And you're charged with providing advice to the Secretary and also to our regulatory docket on the guidelines for determining the probability of causation.

That's the first thing we're going to take up, is that rule. And when we look at that rule and you start thinking about what you want to comment on or what you want to discuss, I would enjoin you to look at the early part of that rule, and there are three questions that we asked everybody in the public to comment on. The Secretary would like you to focus on those three questions and center your comments on that. The Secretary would like you to identify any other questions you want to advise on, but we really would seek your input and advice, counsel on those three questions. And I can go over those in a moment when I get back to my seat.

Also, you are to evaluate and review the scientific validity and the quality of dose

reconstructions. And we're going to have to discuss how we're going to go about that. Tomorrow we have an agenda item on the work of the Board and how we're going to schedule this work, how you want to arrange the work of this Board.

This is a huge task, an ongoing task, where you'll be engaged in reviewing dose reconstructions. And I'm sure that you're not going to find yourselves wanting to sit down and look at thousands of dose reconstructions that we're going to have to do, so we're going to have to talk about a sampling strategy and an approach that makes sense and is representative and reasonable.

And finally, the Board has a responsibility to advise the Secretary on how to handle, how to decide on petitions for the Special Exposure Cohort. And so we need to discuss that as a process for this Board, and how your advice will be engendered to the Secretary.

Let me talk a little bit about the structure of the Board. The charter indicates that the Board will consist of no more than 20 public members appointed by the President, so the

President still has an option here to fill ten more seats, or he can leave this at ten.

The members shall include affected workers and their representatives, and representatives from the scientific and medical communities. This is the balance that was attempted to be achieved by the appointments.

The Chair is also designated by the President, and it's an option for this Board to establish subcommittees or working groups to facilitate the work of the Board. And that's something we need to talk about with regard to this dose reconstruction review process.

Frequencies of the meetings shall be based upon the Agency needs as determined by HHS, CDC, and NIOSH. And as a Designated Federal Official, I assure you I am working very closely with your Chair, Dr. Ziemer, to establish the agenda. Looks like we need to regroup on how much time we allot, but we're — it's good to be ahead of the agenda rather than behind the agenda. So we're learning from that.

A government official will have to be present at all meetings, and we can hold meetings over the telephone. We might choose to do that,

where we will have a public meeting by phone to conduct business of the Board. If we prepare consensus comments and need to vote on those with minimal discussion, we might be able to do that before February 6th in order to accomplish that task.

So I'm trying to give you a little bit of insight. Do I expect you to finish all of this up before close of business tomorrow? No. Do I expect you to try to get consensus comments on the probability of causation rule by February 6th? Yes. How do we do that? We're going to use the rest of today and tomorrow to try to achieve that, and if we need to have a public telephone call to finalize those comments we will do so.

All meetings shall be open to the public, and public notice will be given of all meetings. So if we decide that we need to have a telephone conference call to finalize some business we will announce that, and we'll announce it as soon as possible. When we talk about the work and the schedule of work for the Board tomorrow, we'll need to take this into consideration in order for Cori to make the announcement publicly, that we

would have a meeting before our next scheduled meeting February 13th, the 12th and 13th.

All records of the proceedings shall be kept as required by the laws and the Department regulations, and they're available to the public, available, of course, to each individual Board member. As we noted, this Board is in a paid status as a Special Government Employee.

Earlier in Helen's talk and in the film you saw that there's an annual report that has to be prepared. That's my responsibility, and I want you to realize what I'm going to be reporting on in that report: How well we do in achieving our goals and moving forward in our work.

We will provide a list of all members, and we'll talk about their backgrounds and what perspectives they bring in that report. We talk about the functions and the dates of the meetings and the places of the meetings, and the purpose behind each meeting. And we also in that report present any recommendations, consensus comments or advice that's been generated from those meetings during a fiscal year.

So each fiscal year we will prepare a report containing this information. This report is

advanced to the Office of Committee Management, and it eventually makes its way up through and to the Congress through the President's office.

Unless renewed by appropriate action prior to the expiration date, which this charter has two years, this committee will terminate in two years. But I anticipate that that will be renewed, given the workload that we have.

And that's all I have to present to you. Are there any questions about the tasks, the responsibilities, the challenges that we have? We're starting to get into the meat of our work here, so it would be good if you have any doubts or thoughts that you want to — need clarification on.

[No responses]

DR. ZIEMER: I see no Board members rising to that challenge to ask a question. I know that the Board has had copies of the charter and related documents for some period of time, and has had an opportunity to study them.

Thank you very much, Larry.

I'm going to pause at this point for some housekeeping item or items, and then we'll return to the agenda. First of all, for lunch today you

will be on your own. And I believe Cori may have prepared a list of nearby restaurants or eating establishments and other fast food places, whichever your preference is.

Cori, do we have that available?

MS. HOMER: We do.

DR. ZIEMER: Let's go ahead and distribute that at this point.

I also would mention to the Board that you are basically on your own for dinner this evening. There is no Board dinner planned. We're not going to have a working lunch or dinner today, so you're pretty much on your own, whatever arrangements you make.

Now let's return to the agenda. I want to follow up on Larry Elliott's comments.

First of all, Larry, perhaps it would be good if you amplified what the three questions are that have been asked of the independent reviewers, and which are being asked of this Board to consider. Could you direct us to those three questions?

MR. ELLIOTT: Yes.

If you would turn to your tab that has the probability of causation rule presented. On that

first page under Roman numeral I, Comments Invited, you'll find three questions.

The first: Does the proposal make appropriate use of current science and medicine for evaluating and quantifying cancer risks for DOE workers exposed to ionizing radiation in the performance of duty?

The second: Does the proposal appropriately adapt compensation policy as it has been applied for the compensation of veterans with radiation exposure from atomic bombs to compensation policy for radiation-exposed nuclear weapons production workers?

And the third: Does the proposal appropriately and adequately address the need to ensure procedures under this rule remain current with advances in radiation research — health research?

Likewise, under your tab on dose reconstruction and that rule, on that same first page under Comments Invited, you'll find three additional questions pertinent to that rule on dose reconstruction. And I won't — I guess — should I read those for the record?

DR. ZIEMER: No.

MR. ELLIOTT: Okay.

DR. ZIEMER: They're similar questions.

MR. ELLIOTT: They're similar questions.

Any question from the Board about these questions, and certainly any other questions you want to add? But we're just trying to focus your discussion and deliberation in this regard.

[No responses]

DR. ZIEMER: If not, then I would like to prepare the Board for our discussion that will occur after lunch.

We're going to have a discussion on Board responsibilities, and I want to provide you with some items to think about. You can start thinking over lunch on these items, and then be prepared to discuss them.

Because one of the things that we have to do as a Board as we make recommendations is to reach what is called consensus. And there may be some question about what consensus means for a group like this. And in fact, one of the jobs that we have is to determine how it is we are going to operate as a Board. How is it we are going to reach consensus, and what does it mean to reach consensus?

So let me throw out some ideas for you to be thinking about, and then we can talk about how we can formalize these ideas, if that is — I don't have the answers, but I want to stimulate your thinking on some approaches that might be used, and then we can finalize those later in the day.

First of all, a lot of how this committee operates has already been defined in the public law, so we don't have to deal with how our membership is selected and how often we meet, and the keeping of records and so on. That's already defined in the law, and is in a sense beyond our scope.

We do have some degree of flexibility, however, in determining how we are going to operate in terms of defining issues and coming to consensus on questions or items that we want to recommend to the Secretary of Health and Human Services. So let me start — and I'll sort of break these down into categories of items to think about.

First of all, what constitutes a quorum? Now I am proposing that we will normally operate under *Robert's Rules.* Now *Robert's Rules* are designed to do two things. One is to allow the

majority to reach its conclusion, but also to allow the minority to be heard. On any question there are typically two and sometimes more views, so *Robert's Rules* are really designed so that those with what you might call minority views have a chance to voice their views and those views be taken into consideration, but that ultimately the minority does not control the final decision; that the majority can rule. And there are a variety of ways that this is done.

In Robert's — under *Robert's Rules,* particularly if you have large groups — say, 100, like you would have in the Senate, or many more in some larger assemblies — *Robert's Rules* sort of help you keep order and make sure that those who have views are allowed to air them. And so there's a large degree of formality that is carried out when you use *Robert's Rules* in a large assembly.

In a small assembly such as this, a ten-member committee, *Robert's Rules* can be used a little more informally. For example, if it's clear through discussion on some minor point that we're in agreement, the Chair can simply declare that there's agreement on this, and let's do it.

Now I'm not talking about necessarily the formal recommendations to the Secretary of Health and Human Services, but on issues where we might have some debate on what we should do next. On the other hand, we do have to have some definitions on how we go about determining, when we make the formal recommendations, what it takes to do that.

Now on the issue of quorum, that is normally well-defined. In *Robert's Rules* it's not necessarily defined. *Robert's Rules* allows by-laws, for example, to define what a quorum is. In fact, I was at one time involved in a group that defined a quorum as those present, as long as it included one of the officers of the organization. Well, that sort of covers anybody that shows up, I guess. But typically a quorum is more than half the members. In our case that would be six.

I'm unsure myself as to whether the FACA rules require that to be the quorum, but unless I learn otherwise, I think we can —

MS. HOMER: Generally it's one more than one-half.

DR. ZIEMER: One more than one-half. By my advanced math, that's close to six.

UNIDENTIFIED: Let's discuss it.

DR. ZIEMER: Yeah, let's discuss it. So I think we can assume that a quorum is six. Now that would mean that we could have a meeting and could do business with six people.

Now this leads to the next issue, and that is what then constitutes consensus? Now it's one thing if all ten members are present and you say, well, we need a majority or we need two-thirds or some percentage. But if you have just a quorum – six people, for example – a majority of six is four, but that's not half of the committee. So you have those kinds of issues.

So what I would like us to think about, for example, would be if we do talk about consensus, that we consider, for example, that consensus is at least 50 percent of the membership. That would be also six, six positive votes on something.

Now under *Robert's Rules,* the Chair does not normally vote. In fact, under *Robert's Rules* the Chair votes when there is a tie. When there are ten members, nine of whom are voting, you never have a tie, which means the Chairman would never vote. Well, the Chairman sort of objects to

that. In fact, under *Robert's Rules,* if you went with a majority of those voting, you would have five as the pass point. Is that consensus?

So one thing I would like us to think about is should we in fact specify that in cases where there are, for example, five/four votes, that we mandate that the Chairman vote. Now that can still drive it to a real tie, which means you don't have consensus. Or it can tip to a six/four vote.

So I'm not suggesting we answer that question now. I want you to think about it, but I want to talk about it when we return from lunch so we can sort of codify how we will achieve consensus. We could also say that consensus is something else. Is it two-thirds rather than one-half, in which case it would be seven votes rather than six?

Now likewise, if we don't have full membership present, is consensus a majority of those present and voting, or is it a fixed number? For example, is it always, say, six? That is, if you have only six present, do they all have to agree on something for it to be

consensus? So think about that, as well. And in fact, I think for us the issue of what constitutes consensus is one of the key things we need to establish for our working rules.

Next, subcommittees and working groups. As I understand it, we are allowed to have subcommittees and working groups.

Subcommittees would simply be subsets of this group here. The Chairman could, for example — and normally it's the Chairman's prerogative to appoint such subcommittees; always done, of course, with the input of the full committee. But for example, if we say we need a subcommittee to work on answering this particular question — for example, one of the three questions that was posed — to draft a response for the full committee to review, then we could say, okay, let's ask these three or four people to be that subcommittee. And I think that's the Chair's prerogative, and we certainly will do that as needed.

With respect to working groups, it's my understanding that the Board can in fact have working groups that might include even outside experts. Although there's a breadth of expertise

on this committee, there are some issues where we might want additional expertise, and it may be that we would have to consider establishing some sort of working group to address some particular issue that the committee perhaps feels uncomfortable or wants more detail on. I don't have anything particular in mind, but that is something that, as I understand it, could be done.

MR. ELLIOTT: Yes.

DR. ZIEMER: And then the other thing is that I want to mention that at all of our meetings, including today's and tomorrow's session of this meeting, we will have a time for public input. Generally, as we proceed, that's intended for members of the public or particular groups to give their views on any of the issues that are before us.

It is not my intent that those become sessions where we debate with people what their views are, but rather hear their views and take them into consideration as we deliberate. Whether or not you individually agree with any particular person's view, I certainly think it's appropriate if you have questions to ask of

members of the public to clarify something that they present, but it's not, certainly has not been my intention, that we use that time to debate them on their views or try to change somebody's views.

So those public sessions are simply times where we hear what other people's views are on some of these issues, and give them a chance to comment either on how we are proceeding or comment on the rules or concerns that they may have.

Now let me ask for any immediate responses. Again, I just want to sort of get a feel or feedback as to where some of you are on these issues. If there's items that you think that — and I've simply thought about some of these, and I raise them now to make sure you're thinking about them.

But are there some other issues that you may have thought about as to how we proceed?

And again, some of the timing issues — Dr. Anderson raised the issue of do we have enough time. I don't think we know right now the answer to that. But certainly this Board has a fair amount of latitude, and can decide when and where

they're going to do something. But I think we also want to be responsive to the needs.

I'm an academician who likes to take years and years to study things, but there is a sense in which this is upon us. We're not going to have all the answers to all the scientific questions. We clearly will not. And so we have to make decisions with what's available.

I open the floor for comments. Yes.

DR. DeHART: Roy DeHart.

We are not an expert committee. We're an advisory committee, which burdens us with a greater task than most similar committees would have. As an advisory committee, we sit around this table bringing our own individual expertise, whether it's health physics, epidemiology, medicine or whatever, to the table. But there are voids, major educational and scientific voids, when we start dealing with these subjects. And I think that has to be a reality and considered. It is with me. And even though there are time constraints and limitations, I don't know how quickly we can fill the void, or whether I just accept the consensus of the table and go with that. And I'm going to have to work

on that as we go through.

DR. ZIEMER: Thank you.

MR. ELLIOTT: If I could, certainly the NIOSH technical staff are here to help answer questions, help explore areas that you may not be comfortable with or have experience with or education in. And if there are other external experts that the Board wants us to bring in, we can certainly accommodate that.

DR. ZIEMER: Okay, there's a lot of pondering going on.

UNIDENTIFIED: Yeah, there is.

MR. PRESLEY: Sir, Bob Presley.

DR. ZIEMER: Yeah, Bob.

MR. PRESLEY: Under the quorum and what constitutes consensus, there's going to be times that some of us are going to have to excuse ourselves. I think we need to look at that.

DR. ZIEMER: Thank you, that's a good point. What do we do if there are abstentions? In other words, in some cases that may be due to conflicts of interest. I know on my sheet there are certain items that I'm precluded from voting on. So whatever we decide in how to proceed, we'll — and I hadn't thought of that — we'll need to

include what do we do in those cases.

Thank you, good point.

Others? Yes.

DR. DeHART: In fact, it might be wise someplace during the day to find out what areas we have to exclude ourselves. We may find that there are three or four of us that are going to be out at the same time.

DR. ZIEMER: Right. Right. A chance for the others to really exercise their power, right? Okay, thank you.

Other comments?

[No responses]

DR. ZIEMER: Thank you. If that – if there are no more comments, I think we will extend the lunch hour a little bit since not everybody's familiar with the locations, maybe give you a little more time to take your lunch. You may have to go off site anyway. I don't know if the place here will accommodate everybody at once anyway. So that'll give us a little more time. Plan to be back here at 1:00 o'clock, and we will continue. So we're in recess till 1:00 o'clock.

[Whereupon, a lunch recess was taken from approximately 11:22 a.m.

until 1:05 p.m.]

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DR. ZIEMER: Thank you. We'll now reconvene.

I trust you all had a suitable break and lunch period. We have some folks who've joined us since the lunch period, and I should tell those who've joined us, particularly observers, that earlier today we had everybody introduce and say who they were and who they were representing. And I know we have at least one and maybe more people who now have joined us after lunch.

So I'm going to start over here with Joe Fitzgerald, and Joe, if you'll stand and tell us who you are, and then we'll see if anyone else —

MR. FITZGERALD: I'm Joe Fitzgerald, I'm with SAIC.

DR. ZIEMER: Thank you.

And who else has joined us since — in the back, please.

MR. SILVERMAN: I'm Josh Silverman. I'm with the Department of Energy's Office of Environment, Safety and Health.

DR. ZIEMER: Thank you, Josh.

Any others?

[No responses]

DR. ZIEMER: Very good.

One announcement that's a repeat. If you do wish to make any public statements at the appropriate time later today, we ask again that you sign up in the foyer. There's a sign-up sheet, again simply for purposes of allotting time fairly amongst those who wish to speak.

I remind you again that – this is for the Board, others as well – but you're on your own for dinner this evening.

Let me ask Cori if there's any other housekeeping items we need to address right now.

MS. HOMER: Not at the moment.

DR. ZIEMER: Okay, not so far as we know. Thank you.

We're going to deal with the issue of Board procedures in just a moment, but before we do that I'm going to ask Larry – Larry, if you could give us very briefly the information, the general information about waiver issues. I think it – we talked earlier this morning about having people tell their waiver areas. I don't see any need that we do that right now. We're not going to be dealing with site-specific stuff certainly today

or even the next meeting, but perhaps some general information about the conditions under which committee members are required to sign waivers. And Larry, if you could provide that information, then we'll proceed from there.

MR. ELLIOTT: Certainly.

Not every member of this Board received a waiver letter this morning. There were, I believe, eight individuals who did — seven individuals who did. And it's expected that the Board will focus largely on matters of general applicability, as opposed to matters involving specific parties or matters that uniquely and distinctly affect any particular person or organization.

And so that's the background of the general applicability of the waivers that were granted. That means that this Board is going to take on discussion and deliberation on matters that have wide-ranging and general applicability, the probability of causation rule and the dose reconstruction rule.

The waivers do go further to provide specific individual guidance to each member who received a waiver regarding matters that would

come under discussion that are more specific in nature to their particular personal experience or financial involvement. And so when we come to the point of discussing reviews of individual dose reconstructions at a given site or reviews and advice to the Secretary on Special Exposure Cohort petitions, that's when an individual Board member might feel they need to recuse themselves.

And so I think — I hope that is adequate background information on these. And they are — of course, the waivers are available under the Freedom of Information Act, and I'm sure that — and I know that we will have a such request, if we don't already have it in our hands. And we will respond to that request by providing a copy of the waivers that have been signed. And those are not available today, but they will be available as we get back into the offices and get these on file and make all appropriate notations to them.

DR. ZIEMER: Thank you.

We want to proceed now with the agenda item that's called Board Responsibilities and Operating Procedures. You recall that we had

some preliminary discussion before lunch at least to stimulate your thinking on some of the issues that we need to consider as we more or less codify the procedures that we will use to develop recommendations to the Secretary of Health and Human Services.

What I propose that we do at this point is get individual feedback from the Board members on your views on the issues that I raised before lunch. I'm not proposing that we draft something here as we sit at the table, but try to get some idea of what the views of the members are on the issues that were raised.

And then we will draft a – probably this evening, and the Chair will ask for some volunteers to help draft that – but we will get a straw man draft that we can use tomorrow. I don't think we'll be at a point today where we need to be voting on any issues. Today is still an informational day. So we really have into the day tomorrow to finalize how we proceed.

So again, particularly what we want to be talking about is the voting procedures, as to how we come to what we were calling consensus. And I know there's some debate about the meaning of the

word consensus itself. I understand, and I've asked that we even get a dictionary definition of that. Preliminary indication is that even the dictionary's a little vague. It does not — in the dictionary is not defined as unanimity, but we'll actually get the formal definition of that. But the issue really is how we agree to develop recommendations that we take forward to the Secretary.

So I would be glad just to open it up if you have individual views on any of those issues that we raised on how we vote, what constitutes — well, what do we do if we have less than the full committee here, those kinds of issues. Have you had a chance to think about that, or was the food so distracting that you didn't think about it at all? Okay, let's start with Wanda, and —

MS. MUNN: The food was not that distracting. You know, when you first posed these questions it was fairly clear in my mind what I thought should be done, and then someone threw a curve at us when we started thinking about those of us who had to recuse ourselves and how many of us there might be.

That issue notwithstanding, my personal

feeling is that in a board of ten individuals, a quorum really and truly should be more than just one over five. I would prefer to call a quorum seven people in order to be able to do business. I think that's reasonable, given the small number that we have, the intensity of the work that we're going to have to be doing, and the kinds of decisions we're going to be making.

Having said that, consensus in a group that size or in the full committee, from my point of view, would be certainly – a number of six would be to me acceptable and probably reasonable, especially given the fact that I've suggested a quorum be seven.

DR. ZIEMER: Thank you, Wanda.

I might ask the staff, and perhaps Mary or someone else can – Mary Armstrong can tell us if the FACA act defines quorum, if that's already – yes?

MS. KUYKENDALL: Actually –

MS. NEWSOM: Could you use the microphone, please?

MS. KUYKENDALL: Yes.

DR. ZIEMER: If it is defined, then we'll have to use what the definition is in the Act.

Otherwise —

MS. KUYKENDALL: Quorum is not defined in the Act, but it is addressed in Department — in the Department manual. And quorum, according to the manual, is one-half plus one of the committee membership.

Consensus neither is defined in FACA, but in the GSA regulations it states that — it refers to a common viewpoint. But consensus can sometimes be a little problematic, and it is okay to have opposing viewpoints or minority viewpoints because certainly sometimes you want those. So it is good that you all are having this discussion and deciding early on what your consensus vote is going to be.

DR. ZIEMER: Okay, thank you.

Others? Yes.

DR. MELIUS: Two points. One is that no matter what we define as a quorum, I would hope that the people in setting up the meetings would make every attempt to make as many people as possible available for the meetings, that we not try to just go to six or seven, whatever it is.

And probably as important as that is that in all our deliberations and major recommendations

that we involve all the committee members in those – in that process, so even if someone can't make it to a committee meeting that we – we may want to defer a formal vote or recommendation until the Chair's had a chance to communicate with that person or persons and get their viewpoint, or defer to the next meeting possibly on some decisions where we really should try to reflect everybody's input into the decision, give them the opportunity to participate.

Secondly, on the issue of consensus, I guess I'm particular thinking of this extremely tight time frame we've been given by Larry and others here in terms of the regulations, and that however we define consensus that we make sure that our – whatever report or however we communicate that should reflect everybody's viewpoint, so if there's different viewpoints or a minority viewpoint or whatever that that be included.

And I would particularly see with this time frame we have that maybe what our communication is is a collection of our comments or our reflections on the major issues with these – scientific issues with these regulations, that if

we really try to achieve a consensus document that we would all agree on and vote on, that — I'm not sure that's even going to be really possible in the extremely short time frame. So — whereas I can see other issues where we have a longer time frame, that we would try to spend a longer amount of time and reach closer to a consensus in terms of what the — how the recommendation should read.

But I just think that the time frame is going to really dictate a lot of what we'll be able to do.

DR. ZIEMER: Thank you, Jim.

Yeah, Roy.

DR. DeHART: Paul, you had in the earlier statements raised the question of your voting. As I mentioned earlier, this isn't a technical panel; it's an advisory panel. And we all bring different experience, different education, different viewpoints, perhaps. I think you are critical. Every one of the ten should be voting if a vote is what's required.

On consensus, I'd just remind you that in many situations consensus does not require a vote.

DR. ZIEMER: Yes. Thank you, Roy. I always appreciate people feeling that I'm really needed.

Other comments? Yes.

DR. ANDERSON: Just following up on what Roy said, I think again issuing advice, it's important to get all the advice that's out there, as I wouldn’t want to have a viewpoint, since ten is relatively small, in a very controversial area. In some instances the one person, if you leave one person out, that might be the most knowledgeable person who's going against the others who may not know as much.

So I think it's important for us to identify when we are unanimous on something, and I think that's fairly understandable, and we wouldn't spend much time on issues that we all say that that looks just fine. I think then it depends on what the issue is, how close to that we want to get.

I think – I have somewhat of a problem calling a consensus a simple majority. I would rather use the term “the majority” or whatever it is, and just move on from there. And I think it then depends on – if we're into word-smithing, we may then want to go for – we'd have something in

between the simple majority and a unanimity. If we want to call that something else, whether it's seven or eight, I think that might be another level of significance to the Agencies if eight out of the ten people felt this is the best we can do. That certainly is a very significant level, and I wouldn't be overly concerned about not reaching unanimity.

So I think it is important to get all the viewpoints out so people can see that, and I do think it's important for the Chair to be part of the voting.

It's hard to know what we're going to call what, since we really haven't seen anything that we're going to vote on yet. So I think that – I think we can have some general terminology, that if we're going to take a position it ought to be the lowest level of a position would be simple majority; and in this case, if there's ten of us voting, that would have to be six. So then you'd have the far – the other side would be unanimous; and then maybe something in between, which would be a seven or eight.

DR. ZIEMER: Thank you.

Other comments? Gen.

DR. ROESSLER: Consensus is a word that to me, whether it's in the dictionary or not, really implies we're all agreeing. And I think maybe that's what the public perception is, or maybe our colleagues' perception is.

So I would recommend if we can get rid of that word, if we're not bound by our charter, just to get rid of that word and use the words that have been suggested here. And I like Jim's approach, is that whatever word we use, we make sure that every Board member's vote or comments are a part of it.

DR. ZIEMER: Okay, thanks.

Other comments? Yes, Roy.

DR. DeHART: Not to dig this hole any deeper, but there is one other alternative to voting – abstention. And I could see a situation dealing with a technical question that I'd simply have to abstain from because I don't know. I have no opinion.

DR. ZIEMER: Yes, Tony.

DR. ANDRADE: Paul, I think that trying to put all these ideas together, I've kind of – it falls into line with what I thought about over the lunch break.

There are going to be some of us that are not able to render an opinion on some issues because of the very reasons that Dr. DeHart brought up. There are going to be cases in which one is not ready, willing and able, simply because of perhaps conflict of interest situations, to render an opinion on a certain situation.

When there is unanimity I think it'll be obvious, and I think we're already in agreement about that, okay. However, I think we should go ahead and stick with just the simple definition of quorum, and those people who are ready, willing and able to put forth a decision or to make a decision, and those who — well, can do that. Then we should require a majority vote on any issue, because it is those consensus positions that are our most important product back to HHS through NIOSH, and those things that are going to be recognized.

So I really believe strongly that it should be a majority. And even if all members are present, okay, that majority does not necessarily have to be a majority of those who are here. It is simply a majority of those who have not

abstained. And I think if we go along with something that has that as a bases, we'll be able to move forward from here.

DR. ZIEMER: For clarification, Tony, you're arguing for majority of those present and voting?

DR. ANDRADE: And voting.

DR. ZIEMER: And voting.

DR. ANDRADE: Right.

DR. ZIEMER: As long as there's a quorum.

DR. ANDRADE: Yes.

DR. ZIEMER: Okay. So in some cases, if the quorum is six and – I'm hypothetical here –

DR. ANDRADE: Sure.

DR. ZIEMER: – and one of those abstains, you've got five voting, three would carry the day.

DR. ANDRADE: Three would carry the day.

DR. ZIEMER: Okay.

DR. MELIUS: Well, what if five abstain?

DR. ZIEMER: That's one view –

DR. MELIUS: What if five abstain? I just don't –

DR. ZIEMER: No – well, obviously we can get all sorts of extremes.

DR. MELIUS: Yeah.

DR. ZIEMER: Right now I think we're simply getting some viewpoints that we can write together into a formal —

DR. ANDRADE: If I might follow onto that, this would also serve to put more pressure on the administrative end of this body, in that whatever we're going to be discussing that we should be quite specific about what we want to accomplish in future meetings, in the agenda, so that not only the people that need to be there and have a strong opinion about that will be there, or can at least make a bigger effort to be there, but the public as well will also be informed about the specific issues that are going to be discussed.

DR. ZIEMER: Very good.

DR. ANDERSON: I would just say that I think we can, depending on what the issue is, it's very easy electronically to go out and the day after get everybody involved. So I would try to avoid the issue of a critical position really being only taken based on three out of ten. I mean, whatever we call it, the Agency's going to look at, well, it went three out of ten. It's not going to carry as much weight.

So I would think we ought to set up a system, either we're going to have an electronic mechanism, or since it's a FACA we probably have to have it public, so we do a teleconference. I would think we ought to, just as part of the process here, set up a teleconference for one hour two days after the meeting in case there is something that needs follow-up. If — you can always cancel a call like that, but putting aside an hour two or three days later would be a process I think we probably could do. That would be announced in the *Federal Register* so you could meet your time lines.

And I would ask staff to maybe look at that, and that would be a way that you could get whatever the issue was out to people if it came up, wasn't on the agenda but a vote was taken. Then you'd still have that time for the others to get up to speed. So I think we could —

DR. ZIEMER: Agreed.

DR. ANDERSON: — we could work around people's schedules.

DR. ZIEMER: Tony.

DR. ANDRADE: Agreed, and I don't believe that it's — that what you're saying is counter

to anything –

DR. ZIEMER: Use the mike, Tony.

DR. ANDRADE: I don't believe that it's counter to anything that I brought up, and I really feel strongly that we're always going to have seven out of ten people voting on an issue.

DR. ZIEMER: Okay, Sally.

MS. GADOLA: I just had just a little aftermath. I think it's important – and this is probably going to be already stated in other ways – and that is that it's clear as to who abstained, and those that objected, who they were that objected and why they objected, because that might be something important later on.

DR. ZIEMER: Thank you. And certainly that would all be in the record, yes.

Other comments?

[No responses]

DR. ZIEMER: I'm going to ask if any of the Board members want to volunteer to help a little while tonight in drafting something.

Okay, I've got Roy – this becomes a working group – Roy and Tony. Okay, we've got Wanda, Sally. Last chance. Okay, and I'll work with them. That's half the committee.

Now for the other half, guess what you have to – no. We don't have a job for you right yet.

Okay, good. Any other comments, staff comments? I would like to have at least one staff member with us. Larry, you or some of your staff –

MR. ELLIOTT: Always be here.

DR. ZIEMER: Help this evening on this, yes. Right.

MR. ELLIOTT: It goes without saying –

DR. ZIEMER: We'll allow them to eat supper, but –

MS. MURRAY: Excuse me, Dr. Ziemer, I only heard three names.

DR. ZIEMER: Oh, I've got Roy DeHart, Tony Andrade. I think we've got – Wanda also volunteered, Wanda Munn. Sally did, and I did.

MS. MURRAY: Thank you.

DR. ZIEMER: Okay.

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: Is that – no, that's not a quorum. We can't conduct – we're not going to conduct business. It is a working group. Actually, it's a subcommittee. It's not a working group; a subcommittee. Call it a

subcommittee.

MR. ELLIOTT: But I would add that there's clearly a definition on quorum for us to hold a meeting. We must have six to hold a meeting, so that's a clear definition we do have. But that's separate from the quorum –

DR. ZIEMER: Right, but I think the sentiment that we heard was that – but let's not do that if we can avoid it. Let's find time when all can be there if possible, or most. And then if there needs to be a vote, possibly we do some electronic things yet.

Okay, I think we have the comments recorded. I hope mine agree with what the official recorders' are, otherwise the document may look very different.

Okay, we're going to proceed with the agenda item. The next item on the agenda is to get a lot more detail on the probability of causation rule – background, scientific and technical basis. And for that Ted Katz of NIOSH is here.

And Ted, are you going to – yes, there you go. Please proceed.

MR. KATZ: Thank you. And special thanks to the Board. We're really very happy to finally

have you here. It's been a long wait to get your advice on these rules. I've been involved in the development of these rules since the beginning, and we've been wishing for six months to have you. So it's great to finally have you indeed.

I'm going to be giving background — as you see, I'm Ted Katz, I'm sorry, with NIOSH — I'm going to be giving you a general background. This whole process of helping you, help you get into, find your way into our shoes so that you can advise us on how to finalize these rules in the best way possible.

And then I'll be followed on each of these rules by Jim Neton and Mary Schubauer-Berigan — in the other order, actually — who'll be giving you a lot more technical and scientific detail. So my presentations are going to be very general, surficial maybe.

Okay, this is the overview of my talk. I'm going to be discussing the purpose of the HHS guidelines. What are they going to be used for, how are they going to be used? What are the basics of determining cause? My presentation's going to be very elementary, but I think important for public discussion on these issues.

And then I'm going to speak about what Congress requires of us with respect to probability of causation, and finally what our goals are here, what we bring, NIOSH brings to the table. And let me start right away, then, with the purpose here.

Congress requires the DOL to determine whether or not a cancer was at least as likely as not caused by radiation arising from DOE employment. What are the basics of determining cause — sorry. It requires DOL to make these determinations using these guidelines, so this is the only recipe that's going to be applied.

And the requirement applies — and Larry spoke to this earlier — to all non-SEC — that means Special Exposure Cohort — claims. And as Larry explained earlier, that also means people who are in this Special Exposure Cohort but who have a cancer that doesn't fall within the list of specified cancers. And there's all sorts of cancers. To give you some examples, skin, prostate, cancer of the larynx.

What are the basics of determining cause? We have four elements here. There are actually five — I'll add to this. First, cancer risk

models. We need to know the relationship between radiation dose and the chance of getting cancer. And scientists have developed ways to bring together the science base and mathematics to produce an estimate, an estimate of cause, at least for an individual in this case.

We also need associated with that — which I've left off this list here — the type of cancer. Cancers differ in their sensitivity to radiation, so we need to know that. We need to know the radiation dose for the claimant, or doses, as it may be. We need a policy for addressing uncertainty, and we need a policy for addressing unknowns, and I'm going to get more into this.

And in my talk I'm going to answer questions as I go forward, so you may want to bust in and ask a question, but you may want to just let me roll first.

Addressing uncertainties: There are no methods that will prove whether or not a cancer was caused by a person's radiation dose. So what we have instead are research on populations that have been exposed to higher levels of radiation than the normal population, and comparisons of

the rate of cancers among those populations with higher doses than the normal population.

So in those studies when you have — when you find that the higher exposed population, for example, has double the number of — rate of cancers as the normal population, something that's referred to as a doubling dose, that would — you would apply that to an individual and say that person has a 50 percent chance of having had his cancer caused by the radiation. Or if there were triple the number of cancers, then that person would have a two-thirds chance that his cancer was caused by the radiation. But this is the basis of these mathematical models.

And then EEOICPA applies what's a pretty common rule of thumb for deciding causation, which is at least as likely as not, or a 50-50 percent chance.

But it isn't quite as simple as this, and that's what this is about with respect to uncertainty, because the cancer studies that I just referred to are not perfect. They have limitations, and that means there is uncertainty about the estimate that they would give you. In addition, you're applying those cancer studies

possibly to a different population that has differences, so there again you have uncertainties that arise that affect the reliability of the number that you come up with for an individual.

All these uncertainties in the process, and you have uncertainties with dose estimates, too. You have uncertainties because the technology of dosimetry is limited, because procedures may not be applied correctly, because doses may not be recorded, all sorts of reasons. You have uncertainties about the dose that you're bringing to the formula, to your mathematical model as well.

And all these uncertainties result in you really not having, at the end of the day, a single estimate you can give people. I mean, you may come up with a single estimate, but there isn't a single estimate that represents that person's chance that their cancer was caused. You really have a range of estimates with something's that's called by scientists a “central tendency” to it. Scientists like to use that central tendency or that sort of best estimate when they're doing research for

describing the experience or describing that cause, that level of cause.

But we have a different situation here because the decisions we're making aren't decisions related to research; they're decisions that affect people's lives directly. And so you can actually do away with this problem of uncertainty. You can minimize that or reduce your uncertainty by instead of taking your best estimate, your central tendency, going towards the extremes.

If you go up and you go to a higher estimate of dose within that range of estimates, you can be more certain that that estimate, if you apply that to the individual, is going to be at least as high if not higher than the true level of causation that might be, if you could ever know the truth. Likewise, you can go to the other extreme below. If you go to a very low estimate within the range of estimates, a very low dose, you can be very certain that that person's dose was above that low estimate that you assign.

So there's — ironically, by going to extreme levels in the estimates, you can be much more certain about your decision, which ends up being

important. And the policy question is, how certain should our estimates be? And I'll answer this, that Congress actually answers this for us to a large extent.

But let me talk about addressing unknowns. There are many cases for which we will not — there are various issues for which we have unknowns, and there are many cases for which we will not know, for example, the primary cancer of the employee. Now this is important because all epi models are based on the primary cancer, the place where the cancer started, not where it metastasized to.

In addition, cancer models. You have for very rare cancers — the rarer the cancer, the fewer the cases, the fewer — the less experience you have about that cancer, the more uncertainty you have about your estimates. And so you have a situation where in some cases with rare cancers you have a choice between using a more general model of cancer that lumps several cancers together and has more certainty, or using a very specific model of cancer that has a very high level of uncertainty. And I think if you've seen the public comments, you've seen that this is an

issue that's of concern to many people.

So there's not always a single best cancer model in any event. Science won't sort out that issue for you where you have too small numbers. And the policy question is, again, how can DOL make fair, objective decisions in the absence of a single best scientific answer?

Now what does Congress require of us here? They require — and I'm going to amend this first bullet a bit, not that it's not okay, but it raises issues for dose reconstruction, which we'll talk about later — but it requires that we use the dose estimates, we use dose estimates. And it requires that we enable DOL to determine whether a cancer was at least as likely as not. That's the 50 percent chance or better caused by radiation.

It requires that we take into account other factors as feasible, and it mentions among factors we might take into account, smoking. It requires that we use the radio-epidemiologic tables and the upper 99 percent credibility limit.

Now using the radio-epi tables and 99 percent limit, one, ensures that we're on the

tract of using risk models. That's what we have to do. We don't have an option there. And using upper 99 percent credibility limit answers that question that I raised earlier about how certain we have to be.

Well, Congress says we need to be very certain, in effect, and we need to be very certain on the safe end for claimants. In other words, we need to use a very high estimate, that 99 times out of 100 is going to be higher than the estimate or the actual number, if such an actual number could be known, the true number of what probability there was that that cancer was caused.

So we thank Congress for that major issue being resolved. And that, by the way, is consistent with policy that's already applied by the Department of Veteran Affairs for atomic survivors, veterans.

Now we're also required to address every type of cancer. Though this isn't explicit, it's implicit. Nothing is excluded in the legislation. So this is different from the Special Exposure Cohort where there's a list of cancers. We're not giving a list. And this has

implications when it came to our having models available for determining probability of causation for all cancers.

And finally, it requires that we obtain your advice in producing these guidelines.

But what are our goals? And Kathy Rest spoke very well to this. In the big sense, our goal is to honor the intent of Congress here to the best of our ability.

In particular, we want to make the best available use of the best available science. A lot of our work is based on work that preceded us at the National Academy of Sciences; at NCI, which did the developmental work; the National Academy of Sciences, which gave recommendations about that work, and that's NIOSH-IREP. And Mary, who follows me, will be talking about that in detail. And then building on that with NIOSH experience in doing epi research.

And we want to ensure that claims receive the benefit of the doubt in terms of uncertainty and unknowns. And uncertainty, the biggest fish in that pond we've just talked about, Congress made the decision there, although there are other issues.

With respect to unknowns, I'll just give you a couple of the most salient examples. With certain leukemias which are rare we don't have a best cancer model. We have a very specific model to that leukemia, and we have a more general leukemia model. And what we have said in effect, to give the benefit of the doubt to the claimant, not being able to make a scientific answer as to which is best, is we've said try them both, and whichever produces the higher probability of causation, use that.

To give you another example, primary cancers. Again, as I said, for many people — and this is particularly going to be true or almost always going to be true when it is true for where the person's deceased, and we're working with a death certificate and we don't have medical records — we're not going to necessarily know the primary cancer. And so what we've said here in effect is take all the likely primary cancers, from what science can tell us as to what's likely, and run them all; and whichever produces the highest probability of causation, use that. And of course, if you run into one that already puts them over into being compensated, then you

can stop.

Now we've, through these sort of measures, established procedures that DOL can apply objectively and consistently for every claim. We didn't want to produce a process, given the volume of claims we're dealing with. Especially in our strivings for transparency and so on, we wanted to set out objective, hard, fast rules rather than, for example, assembling a committee to deal with certain cases or whatever, and dealing with them subjectively and not necessarily consistently throughout the program.

And then my final point about making procedures as transparent as possible for the public, we do that again through these objective criteria that we give versus a black box sort of operation. And as Mary will talk to you again about, too, NIOSH-IREP is available for everyone to use. To operate you can plug in your own numbers. You can look at the basis for all the assumptions that are in IREP and all the science that's in IREP. It's a completely open process that someone else can make the determinations just as we can, and understand how, where they came from and why.

And that concludes my prepared presentation. And I'd be glad to take — I'd be glad to take questions now, or you may want to await Mary's presentation, as well. It's really your call.

DR. ZIEMER: Well, let's take a moment and see if there are immediate questions on Ted's presentation.

[No responses]

DR. ZIEMER: Let's then proceed with Mary's, and then we can cover both in one swoop.

DR. SCHUBAUER-BERIGAN: Good afternoon. Can everyone hear me, first of all? I have a tendency to speak somewhat softly, so if those of you in the rear can't hear me at any point, just sort of wave your hand and I'll speak up.

My name is Mary Schubauer-Berigan, and I'm a research epidemiologist in the Health-Related Energy Research Branch, which many of you may be familiar with. It's a group that conducts research related to epidemiologic studies of Department of Energy workers.

I'm very happy to be here today to talk to you about the basis, the technical and scientific basis, for the probability of causation rules. And I'll be attempting to go into a bit more

detail on several of the issues that Ted has already covered.

First I'd like to sort of walk you through the basics of probability of causation, and some of this may be reiterating Ted's points, once again. First, it's important to recognize that the concept of probability of causation is based on the concept of assigned share. This is a term that has been used in the insurance industry and several other applications. It really applies to populations and not to the individual, and so as Ted has indicated, it's really impossible to determine for an individual whether or not — what actually was the cause of their cancer. The assigned share, which is also sometimes referred to as the attributable fraction in epidemiology, estimates the proportion of disease in the population that would not have occurred had that exposure not taken place.

We are approximating the probability of causation — I'll call that PC for short — by the calculation of assigned share. Some have pointed out that it's not technically accurate to equate probability of causation with assigned share, but because this is the best way we have to

approximate it at the present time, we will be using that term interchangeably.

As Ted indicated, as these methods have been developed, we allow for the incorporation of uncertainty in both dose, the dose-response relationship for various cancers, and also uncertainty in the importance of various factors that modify that risk.

As Ted indicated, EEOICPA requires the use of a standard referred to as “likely as not,” or a 50 percent probability of causation after the incorporation of uncertainty. This approach has been criticized by some, and it's difficult to get into the issues that have been criticized at this point, but it's been fairly well acknowledged that this is — the probability of causation method is really the only available method we have at this point to use with this population.

Okay, I wanted to illustrate a calculation of the assigned share of the probability of causation. It is defined as the risk from radiation exposure, also known as the excess relative risk, divided by the sum of the background risk and that risk from radiation

exposure. And there's an alternative way of expressing this, which is since the excess relative risk is equivalent to the relative risk minus one, it's simply the relative risk minus one divided by the relative risk. And those of you who are epidemiologists or are familiar with risk assessment understand the concept of relative risk.

In general terms, this is defined here as the relative risk of cancer at a given dose level compared to a similar unexposed population at a specified age, sex, age at exposure, time since exposure, or whatever other factors have been found to modify that relationship. So you might correctly guess at this point that we estimate relative risk from epidemiologic analyses, and you would be correct.

Because we know so much about the relationship between ionizing radiation and cancers, it's actually possible to produce separate models for each cancer or for different groupings of cancers, depending on the rarity of the cancer and the population that's being studied.

One factor that is very important that may

not always be evident is that it's not always clear how the relative risk that you observe in one population should be transferred to a different population. Here an example might be the study of the Japanese atomic bomb survivors, which is considered one of the premier studies of the association between cancer risk and radiation exposure, how to apply those risks that were observed to the population of Department of Energy workers who might be claimants under EEOICPA.

The models also may incorporate uncertainty. Those of you who do epidemiologic research or who are familiar with it understand that you're usually estimating relative risks with some uncertainty about them, just due to statistical uncertainty in the models that have been produced. That's one source.

A second source is the uncertainty that's associated with the exposure of the population under study. And to continue my analogy using the Japanese atomic bomb survivor study, there's uncertainty about the doses that were experienced by those atomic bomb survivors.

A third source of uncertainty is uncertainty

in what's known about the effects of confounding factors, such as age, sex, race, ethnicity, et cetera.

As I mentioned earlier, there's also uncertainty about how those relative risks should be transferred to a new population.

And lastly, there's additionally uncertainty associated with the exposure of the claimant.

And this slide gives you an illustration of how uncertainty about all of these factors could contribute to uncertainty in the estimate of probability of causation.

As an example, we have a man who is exposed to 11 rem of high energy photons at age 40. If he was diagnosed with leukemia at age 50, one might try to estimate the probability that his leukemia was caused by that radiation exposure. Using studies of people exposed to radiation and observing the levels of radiation exposure that led to increased levels of cancer risk, the best estimate of probability of causation for this population in this exposure is 34 percent, defined as the median estimate of the probability of causation.

However, after considering the various

sources of uncertainty, given what we know about the radiation exposure and leukemia risk, you actually have a distribution of values with variable likelihood or probability, and that leads to this probability density function.

As Ted mentioned earlier, we might want to use a very conservative estimate of the probability of causation, and Congress has in fact specified that we do so. So for this individual, the upper 99th percentile on their estimate of probability of causation is actually 65 percent. And under EEOICPA this is the value that would be used to determine, by Department of Labor, what the probability of causation is for this person.

I wanted to talk a little bit — because we've mentioned that this program has some historical precedent, I'd like to talk about that precedent for a few minutes.

The first experience was by the development by the National Institutes of Health of a series of radioepidemiologic tables in 1985. This method was reviewed by the National Academy of Sciences at that time, and it was based on epidemiologic analyses, primarily of the Japanese

atomic bomb survivors' experience. There were also models incorporated from studies of radium 224 for bone cancer.

The method modeled risk for 12 different cancers, and was primarily concerned with external radiation. The cancers are listed here. Those of you who are familiar with the radiobiology literature or radiation epidemiology understand that there is a lot of controversy about factors such as dose-rate effects — that is, does the risk of a certain dose of radiation depend on the rate at which it's received?

The original tables assumed no adjustment for dose-rate effects, but used a linear-quadratic dose response model for all cancers except for breast and thyroid, which has the effect of reducing the risk per unit dose at low levels of dose. And it applied a constant relative risk model for most cancers except leukemia and bone, which was transferred in an additive fashion to the U.S. population.

Some of the aspects of the 1985 tables that are relevant here are that it did have some rather serious limitations. It really was designed to be used only for external radiation,

with a couple of exceptions. And it had poor assessment of probability of causation from high energy, high-LET dose, such as alpha dose from plutonium exposures. It also — it did incorporate uncertainty, but it did so rather crudely, using multiplicative factors.

It was also rather difficult to implement. I don't know if any of you are familiar with these tables, but the book is about a couple hundred pages long, and the tables are very extensive throughout them and require a bit of prior knowledge and experience to actually implement. Also very importantly, these were meant to be updated every few years.

Currently they're being used as source models for the Atomic Veterans Compensation Program, and in general it's believed that these are a rather good fit to the dose scenario, although there is some concern about high-LET exposures among those atomic veterans.

Expert judgment is frequently used. As I mentioned, there are only 12 cancer sites that are modeled in there, so if you've got a cancer to consider with — outside that list, you must use expert judgment to determine the adjudication

of a claim. This apparently posed less of a problem for the VA than it might for DOL, because they were processing approximately 300 to 400 claims per year.

It was recognized — several of these limitations were recognized to be rather serious, and several years ago the National Cancer Institute agreed to update these radioepidemiological tables. And I saw earlier that one of the developers is here with us, Dr. Charles Land from NCI.

This was done because of the availability of new data. Atomic bomb cancer incidence data through 1987 was newly available to do this. Improved computational methods for both the risk modeling from the A-bomb survivors and the incorporation of uncertainty made it easier to produce better models and ones that could be implemented more easily.

I'd like to outline some of the changes that the NCI tables, as of their review by the National Academy of Sciences in November of 2000.

Some of the changes that were implemented is that they increased the number of cancer sites

quite dramatically, from 12 to 13 up to 33 total. They did eliminate the radium 224 bone cancer models and the radon lung cancer models at that point in time.

They incorporated much more detailed uncertainty analyses, adding factors for dose-rate adjustment for low-LET radiation. Low-LET radiation, for those of you who are not familiar with that term, is what we refer to as penetrating ionizing radiation, such as photons or X-rays. They also added radiation quality factors for high-LET risk estimation.

However, this was still directed at the time towards the VA's Atomic Veterans Compensation Program, since EEOICPA didn't exist at that time. And it produced, very importantly, a program, a computer program, that could be used by individuals with less experience in these areas rather than the set of complex tables that had been produced previously.

Their methods were also reviewed, as I mentioned, by a National Academy of Sciences panel, and responses received. The status of the NCI version is that it's in draft, as I understand it. I don't know when the final is

expected, but perhaps Dr. Land could address that sometime today if those of you who may be interested want information about that.

As we reviewed the NCI's program, we identified limitations that we felt were important for compensation of DOE workers. While there was the addition of quite a bit of extension of the models to apply to high-LET exposures such as plutonium, there still remained no radon in lung cancer models.

The RBE values, the relative biological effectiveness values — which are similar to quality factors — were highly uncertain for bone marrow and several other sites. And these are important exposures for the DOE work force, so we felt that those needed more intensive attention. And the dose-rate adjustment factors for high-LET radiation were not addressed in that draft.

Also, as Ted mentioned, we had the responsibility to consider all cancers, not just specific cancers that happened to have models associated with them, and there were several that we felt were very important that needed to be addressed — skin, bone, male breast cancer, and several others came to mind.

An additional problem is that several of the cancer sites result in models that are unlikely to result in a compensable claim for cancers that have been shown to be elevated among the DOE work force. And this raises the question of whether supplementation of the Japanese atomic bomb survivor data should occur with the results of other studies, especially studies of DOE workers.

One factor we identified as important for our program is temporal changes in U.S. background cancer rates were not incorporated, and the NCI program emphasizes the current cancer rates, which may be relevant for the VA because they are processing more current claims. However, EEOICPA is the first program of its kind for DOE workers, and it will be expected that claims could come in from all periods of time through which DOE has been in operation.

And Ted already covered this point, but how should we handle metastatic cancers when the primary site's unknown? And I believe this is lastly, how should probability of causation be estimated for multiple primary cancers?

As all of the other agencies can attest, there was a very aggressive time frame for the

development of probability of causation rules under this program. And our approach was to use the existing NCI methodology where appropriate, especially given the level of scientific review that this method had undergone, and we included being very interested in their modifications that were developed to address the NAS panel review comments.

We attempted to separate the limitations into those amenable to short-term versus long-term solution. And we tried to work with NCI and its contractors to address some of the limitations. For example, the radon in lung cancer model was incorporated, and this was highly recommended by the NAS panel as well.

There was much more attention given to a variety of different radiation exposure types, and we have, I believe, now a total of five or six radiation exposure types in the NIOSH-IREP model. These have separate RBE and dose-rate adjustment factors for each radiation type specifically developed.

Finally, the software that NCI had developed with its contractor was implemented into a NIOSH version called NIOSH-IREP, which you'll see

demonstrated hopefully in about an hour or so. And lastly, we do remain involved in developing long-term solutions to limitations in these models for DOE workers.

Now what are some of the modifications that were made for NIOSH-IREP? Well, initially we recognized the need to add certain cancer models for EEOICPA. For skin cancer we incorporated analyses of the atomic bomb survivor skin cancer incidence data that were done by Elaine Ron and colleagues very recently.

Bone cancer has proven to be quite challenging. There are data from the atomic bomb survivor cohort. It's a very rare cancer, and so there are not large numbers of bone cancers among that group. However, there has been publication of bone cancer risk coefficients by Pierce and colleagues in 1996, which were used in a risk assessment for plutonium in bone cancer risk by Grogan and colleagues.

Since there was no male breast cancer risk model, we used female breast cancer risk coefficients applied to background male breast cancer rates in the U.S. and Japan. And we added models for connective tissue cancer, cancers of

the eye, non-thyroid endocrine glands and “ill-defined” cancers, and these were done using the miscellaneous cancer risk model produced by NCI, applied to these individual cancer background rates in order to transfer the risk to the U.S. population.

Very importantly, we determined that the chronic lymphocytic leukemia should be excluded at this time on the basis of the lack of qualitative evidence that radiation exposure causes CLL, and the lack of any quantitative models available to estimate risk for this specific type of leukemia.

We also developed an objective list of cancer models that should be used to adjudicate claims in which the primary cancer site is unknown, and we did this using available data from the National Center for Health statistics relating cancers — secondary cancers to their likely site of origin.

And lastly, we developed operational smoking definitions for use in the lung cancer models that are part of the NCI-IREP program.

What do we see as the future of probability of causation calculation? Well, first, the NCI

program is itself interim, and they anticipate that periodic updates will result from new scientific information.

One of the most important of these is the recommendations of the BEIR VII panel, which is an NAS-NRC group. Also very importantly, we need to rely on the recommendations of the Advisory Board for any changes to the models that are required. And also very importantly, we are working on ways to incorporate relevant changes that need to be made based on the scientific and public review comments that have been received and that will still be received as part of this process.

I just in the last few minutes — I think I do have some time here — I wanted to talk about some of the potential modifications that could result in the future from new scientific information.

Some of these possible long-term changes include improvements in the risk models, or reduction or better estimation of uncertainties. I already mentioned the BEIR VII committee, which is working to update risk coefficients for various cancer models. We also believe that it's

very important, where possible, to incorporate input from epidemiologic studies of Department of Energy workers, and that is a very important future possible amendment that we believe needs to be considered.

Changes that result from changes in dosimetry practices, either at DOE sites or just in our general knowledge about radiation dosimetry, would also be elements that could be amenable for long-term change.

One of the recommendations, or one of the specific adjustment factors mentioned by the NAS review of the National Cancer Institute models, was consideration of adjustments for radio-sensitive subpopulations. And you've all heard a tremendous amount about the human genome project and some of the fruit that that might bear for our knowledge of cancer causation. And it's just probably too early at this point to incorporate information about radio-sensitive subpopulations into these models.

Also, the EEOICPA language strongly suggests consideration of interactions with other work place exposures, and that is something we felt was amenable to long-term consideration, but

really couldn't be handled in this version of the IREP program.

And now I'll be happy to take some questions from those of you who have them.

DR. MELIUS: You mentioned the issue of temporal change in cancer incidence rates.

DR. SCHUBAUER-BERIGAN: Yes.

DR. MELIUS: Do you have any idea what the magnitude of that effect would be in terms of individual —

DR. SCHUBAUER-BERIGAN: Right.

It varies by cancer, obviously. Some cancers have become much more common over time. I think their incidence has increased in the U.S. population. In some cancers it has decreased. The extent of that contribution to a change in the probability of causation estimate is difficult to assess without actually going through the process of modeling it. That's just one of the factors of uncertainty that is incorporated into these models, and we haven't tried to model that specifically.

DR. MELIUS: Okay. That was my question.

DR. SCHUBAUER-BERIGAN: Yeah.

DR. DeHART: You mentioned the epidemiology

studies of DOE workers. Many of the plants have had those studies ongoing for a period of time. Do you have any feel for what the relative risk overall might be? Are we talking about 1.2, 2, 3, 4 — as you look, generally.

DR. SCHUBAUER-BERIGAN: It would be really difficult to answer that question without getting very specific about details of the exposure. I mean, anytime you talk about relative risk you really have to define the exposure group. And of course, workers who are exposed to higher levels of radiation would be expected to incur higher levels of risk.

And so without knowing the general exposure or the average exposure among the DOE work force, it's very difficult to estimate. And some studies have found much larger increases than that for specific cancers. Others have found no elevation of risk or a smaller elevation of risk. But it's very difficult to generalize across the entire DOE work force.

Yes?

DR. ROESSLER: I might get myself mixed up in presenting this, but when you talk about cancers that — about which you have a lot of

information, you will then have tighter bounds or lower uncertainty levels, so it would be closer to this best estimate. If you're talking about something that's very uncertain you're going to have these great big uncertainty bounds.

It seems like that if you pick — which, I mean, Congress has done — the 99 percent level, and you take two individuals, one who comes in with a cancer for which there's a lot of information known, it seems like that person's going to be jeopardized because you're living with those uncertainty limits which are much tighter.

DR. SCHUBAUER-BERIGAN: Yes, that is a source of a lot of the comments that have been received.

And I don't know, Ted, if you wanted to address that.

But the — in our discussions it was felt that that's a very valid point. However, we were basically — our hands were tied because of the specifications of Congress on how this should actually be — the compensation should be awarded. It was on the basis of that upper bound of uncertainty. And you are correct, that the less

you know, the more uncertain you are, the higher that upper bound becomes.

In a practical sense — and maybe Dr. Land can speak to this — this is also a point that the NAS panel brought up. And one of the amendments that NCI has made has been to try to group cancers into larger groups to avoid having these extremely high estimates of uncertainty for very rare cancers.

Charles, is that a fair —

DR. LAND: That's fair.

DR. SCHUBAUER-BERIGAN: — summary?

DR. LAND: Right.

DR. DeHART: We've been talking a bit about the Special Exposure Cohort. Was any of these kinds of studies applied in order to determine that they would be sort of automatically found to have a causation issue?

DR. SCHUBAUER-BERIGAN: You mean in establishing the initial Special Exposure Cohort?

DR. DeHART: Yes, exactly.

DR. SCHUBAUER-BERIGAN: I don't believe so. I couldn't speak to the minds of anyone who established the Special Exposure Cohort, but I don't believe that that was done.

Yes?

MS. GADOLA: Under modifications made for NIOSH-IREP, it says that you developed operational smoking definitions for use in lung cancer models. Could you elaborate on that a little bit?

DR. SCHUBAUER-BERIGAN: Yes. There is an adjustment for smoking status for lung cancer only, and this was a feature of the original NIH 1985 tables that had been carried through the NCI version of the tables. And we believe that those were valid to incorporate on a scientific basis, but in some cases – specifically how you define a non-smoker – we had to develop a definition that was based on the best sort of scientific definition that's currently used.

And the one that we decided on was a lifetime smoking rate of 100 cigarettes or fewer throughout an entire lifetime, you would be considered a never smoker, up to the point of your cancer occurrence. And in cases of defining your smoking level, we instruct Department of Labor to question the person on their habits up until the previous five years of the cancer diagnosis. So whatever category you were in at

the point five years before your cancer diagnosis is your definition for the purposes of estimating your probability of causation.

MS. GADOLA: Is smoking, then, the only type of cancer that something else like another carcinogen is really considered?

DR. SCHUBAUER-BERIGAN: Well, not necessarily. I mean, one of the biggest carcinogens is aging, the aging process. And age is certainly an important factor that modifies your risk, so that is incorporated. Cancer risks due to radiation exposure differ in many — for many cancers by your gender, and so that's also incorporated in many of the risk models.

We did — and this is very important to mention, so I'm glad you raised this question — in the skin cancer models that were developed, because skin cancer is primarily a function of skin pigmentation which is a function of race/ethnicity, we've incorporated a different set of background incidence rates that are race- and ethnicity-dependent. And so that is one other cancer that has a different risk modifier added to it.

MS. GADOLA: Okay. I was familiar with

that, and I'm glad you included that. But I was also thinking — and I think you have already answered this — was some of the other chemicals, because we don't know enough about them. Is that true, although they are listed as carcinogens and some of these employees might have been working with them?

DR. SCHUBAUER-BERIGAN: Well, Larry alluded to this in his presentation just before lunch. You might remember that he mentioned we're limited to considering radiation risk. So the only extent to which we can consider chemical exposure is the extent to which it modifies the effect of the radiation. So if exposure to a chemical increases the effects the radiation has on your cancer risk, then those should be considered. And at this point there's just simply not enough information to allow us to do that.

MS. GADOLA: Except for those in cigarettes.

DR. SCHUBAUER-BERIGAN: That's right, because it has been intensively studied.

MS. GADOLA: Thank you.

DR. SCHUBAUER-BERIGAN: Yes?

MS. MUNN: A couple of times you referred to

specific types of cancer that had found to be excess in DOE workers. I don't know whether I should address this to you or to Larry. I don't think there was anything in the materials that I received that identified those specific categories of cancer. It would be very helpful to me if I had something to –

DR. SCHUBAUER-BERIGAN: Yes. I don't know that any of you have received or read many of the studies of DOE workers, but one that's of great interest is multiple myeloma, which has been found to be elevated in certain cohorts. Another cancer that frequently is mentioned is brain cancer in the Rocky Flats cohort. And I'm sure the OCAS staff would be happy to provide the Board with papers and reprints on these things.

Yes?

DR. MELIUS: Can you comment on how the model deals with age at first exposure, initial radiation exposure?

DR. SCHUBAUER-BERIGAN: Well, actually, for most cancers, I'd prefer to defer to Charles Land on that. I actually have a slide later on that talks about some of these effect modifiers, and age at exposure's an important one. But it

varies for different cancers. For most of the cancer sites, age at exposure – increasing age at exposure is thought to be associated with lower cancer risk, so the younger you are at exposure the greater your cancer risk. But it doesn't apply to all cancers.

DR. MELIUS: If you're going to talk about it later, that's fine.

DR. SCHUBAUER-BERIGAN: Anything else?

DR. ZIEMER: No other questions?

Now we will be looking at the IREP specifics after the break, and that might raise some additional questions as well. So –

DR. MELIUS: I was trying to figure out if this was our last chance to ask questions –

DR. ZIEMER: No, no.

DR. MELIUS: – on some of these issues, that's all. It wasn't clear.

DR. ZIEMER: This is just the first cut, okay?

Okay, then we are going to take our break. We'll reconvene at 2:45.

[Whereupon, a recess was taken from approximately 2:25 p.m. to 2:47 p.m.]

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DR. ZIEMER: I'd like to call us back to order. And we're going to proceed with the next item on the agenda, which is a review of the Interactive Radio-Epidemiological Program, IREP. And I think Russ Henshaw is going to kick us off on that.

Russ, are you ready?

MR. HENSHAW: Yes, sir.

Good afternoon. It's a pleasure to be here. I'm Russ Henshaw. I'm an epidemiologist with the Office of Compensation Analysis and Support. I'll be giving this presentation along with Mary Schubauer-Berigan, who is serving two combat tours today, two in a row. I'll start off and talk a little bit about NIOSH-IREP and then do a demonstration of the software, and then Mary will come on and talk in a little more detail about some of the features.

Now what is NIOSH-IREP? Basically it's an interactive software program that, as the name implies, is NIOSH's version of IREP. It's designed under the guidelines of the EEOICPA to calculate the probability that a worker's compensation – that a worker's cancer was caused

by occupational radiation exposure. It's currently posted on the internet for public use and comment.

The program incorporates cancer risk models derived from tables developed in 1985, as was mentioned previously, by the National Institutes of Health, and then updated later by the National Cancer Institute and the CDC.

Although the NIOSH version builds upon the National Cancer Institute's methodology, it was designed very specifically – NIOSH-IREP, that is – to address the exposures and the risks associated with the production of nuclear weapons – that is, the cases of cancer among workers at atomic weapon facilities, Department of Energy employees, and contract workers.

What are the primary goals of NIOSH-IREP? Well, the primary purpose, in a nutshell, is to calculate the best possible estimate of causation for each individual cancer claim. To accomplish this the software incorporates statistical risk models, as has been noted, for the various types of cancer adjusted for individual risk factors, such as age at exposure and age at diagnosis.

Of course, as has been mentioned, there are

uncertainties, uncertainties associated with the radiation dose and also with the probability distributions that form the basis for the statistical calculations. Under the provisions of EEOICPA, however, NIOSH-IREP is designed to utilize these uncertainties in a way that's intended to give the benefit of doubt to the claimant.

Additionally, the intention was to make the process of calculation open, accessible, and self-documenting by including on-line descriptions of model details wherever feasible. It's designed to be user-friendly, and to the extent possible, given the complexity of the statistical risk models, really to demystify, if possible, the process of probability of causation.

And a lot has been said about providing the benefit of doubt to claimants, and that is a major goal, by applying the “as likely as not” standard that's incorporated under the provisions of EEOICPA — that is, is it as likely as not that an individual's cancer was caused by his or her work place exposure to radiation rather than by something else?

To meet this standard, the program basically overlays a range of causation likelihoods, similar — known as credibility limits. That's similar to confidence intervals. And that probability distribution is overlaid around the causation point estimate for each claim. If the upper 99th percentile of the distribution falls at 50 percent or higher, then the claim is considered compensable.

For our demonstration of the program, we'll go through each step using input data for a hypothetical claim, maybe two or three depending on the time, and then we'll view the subsequent probability of causation result. We'll also show you some of the documentation in the help files that are incorporated into the web version of the software.

First, though, how do you actually find NIOSH-IREP on the web? Well, the most direct way is to type in the exact internet address, which is shown on the screen and also in your handout. But given that that looks like a series of numbers from a random number table, there is an easier way to get to it. For one thing, you wouldn't have to have that address in front of

you. And that way is to go directly to the cdc.gov/niosh site. When you reach there you simply click on OCAS, Office of Compensation Analysis and Support. That's the OCAS, the link to the OCAS home page. And at the home page you click on Probability of Causation, NIOSH-IREP — and I'll show you this later, if we have time, when we access the software live, so to speak. Finally, you would click on NIOSH-IREP, and then click on the actual link to the NIOSH-IREP software.

When we get to the demonstration, by the way, you might want to turn to one of the two operating guides in your handouts and in the notebook. One is a two-page short version. The other is the longer, more documented version. It might help you if you attempt to run some claim scenarios yourself at a later date.

Anyway, what input information do we need for NIOSH-IREP? Well, first we need the gender, the year of birth, and the year of diagnosis.

We need the type of cancer; and ethnicity, but only if it's skin cancer, otherwise it doesn't play a role in the causation estimate. We need smoking data, if lung cancer, and that

also includes cancer of the trachea and bronchus. And of course, as Dr. Schubauer-Berigan pointed out earlier, we're only interested in smoking data prior to the diagnosis of cancer.

We need the equivalent organ dose — and incidentally, there's a typo there. That should be small cSv for centisievert, which is the same thing as a rem. We need the year or years of exposure, the exposure rate, the radiation type and range, the organ dose, et cetera. And Mary will go into that in more detail later after we demonstrate the software.

Before I get into the actual demonstration, I do want to just touch again on this issue of multiple primary cancer sites. This is a source of some confusion among claimants and others who call about the program. And basically, as has been stated, if you have more — if a claimant has more than one primary cancer site, it's necessary to run each cancer independently through the software and come up with separate, independent probability of causation results.

Following that, you take the results and plug them into this equation, and I have an example here at the bottom. In this case, let's

say that hypothetically there were two primary cancer sites. We ran each of them through the software and came up with a probability of 40 percent. That's the upper 99 percent credibility limit, or .4 in the equation. And the second one, let's say hypothetically also was .4. Well, taken — either cancer taken by itself would not be compensable under the guidelines. However, by plugging them into this equation, wind up with 64 percent, .64, and that would be a compensable claim.

Now we'll actually demonstrate the software. Hopefully it's still somewhere in this little laptop from our web site. We'll run a hypothetical claim scenario. Questions are welcome at any time, and with any luck perhaps either Mary or I can actually answer the question. So let's, without further ado, as they say, let us begin.

For the sake of time, I've already navigated through the NIOSH — the CDC and NIOSH screens to get to the opening page of NIOSH-IREP. This is the opening screen. The first thing — and if we have time, if anyone is interested, I'll be happy to back up and actually navigate to it later.

First thing to do is click on the BEGIN button. That is the data input screen.

For a hypothetical example, let's take a case of lung cancer. We'll leave the default as male. The birth year is 1951, and the year of diagnosis is 1991. It's not necessary just to calculate causation to enter in the name, claim number, and Social Security number. Of course, when the Department of Labor calculates probability they will need to do that.

Then we click on ENTER A DIAGNOSIS. And this plays no part in the actual calculation, but at the end of the — after we wind our way through the software the program prints out a summary report, and this will appear on the summary report. So we'll type in lung; date of diagnosis, 1991; and click on SUBMIT DIAGNOSIS.

Now we go to the cancer model. Again, this is lung cancer, and the cancers are arranged basically in numerical order by ICD-9 code. Lung is 162. We enter that. Should an alternate cancer model — oops, I think I clicked on something by mistake. Let me back up.

In addition to the uncertainty of the statistical risk models, there's some uncertainty

with my vision. I have bifocals, and right on the cusp of trifocals here, so. In fact, I'm going to change glasses for a minute.

Okay, so we go to should alternate cancer model be run? The answer is no in this case. And the purpose of that, by the way — again, it does not play a part in the calculation. It is really a reminder, if there is more than one cancer to be run through the software, it's a reminder to the Department of Labor person who will be actually operating this that when the summary's printed out, he or she will see that and remember to go back and run the second or third or whatever cancer.

So we go to enter data. This is the inputs for skin and lung cancer only. This is lung cancer, so we'll enter that, we'll press that button. Since it's not skin cancer we can disregard ethnic origin. And in this case let's say that — I'll pop this open for you, just to show you the three choices are radon, radon plus other sources, or just other sources. We'll say, for this example, it's just other sources, no radon exposure. And we'll say never smoked.

Now if you'll notice, there's — even though

this is not a radon exposure, there is a one in the block for number of radon exposures. I'm going to – just to show you, so you don't make the same mistake yourself if you play around with this later, I'm going to change that to zero, as one might intuitively think one should do, and click on SUBMIT DATA. I can see the screen, but I can't see any of you, by the way, so.

If you'll see there, there's a red error message, number of exposures cannot be less than one. If you're running this and forget and enter the zero, then just disregard that. The way the software is set up right now, unless either radon or radon plus other sources is selected for the exposure from – can't see the screen, either – for the exposure from input, the software actually disregards anything that's in the radon box. However –

DR. ZIEMER: There's a question here, Russ.

DR. ANDRADE: Just a quick question –

MR. HENSHAW: Sure.

DR. ANDRADE: – while we're still on the screen. I'm really curious as to what the menu for smoking history is.

MR. HENSHAW: Sure. It's never smoked,

which as Mary – Dr. Schubauer-Berigan indicated earlier, for our purposes means smoked less than 100 cigarettes in a lifetime prior to the diagnosis – prior – is it up to five years of the diagnosis, Mary?

DR. SCHUBAUER-BERIGAN: (Nods affirmatively)

MR. HENSHAW: And then the other choices – former smoker, current smoker, unknown number of cigarettes a day, and so forth.

DR. ANDRADE: Thank you.

MR. HENSHAW: Incidentally, if I'm bypassing any of the screens, please feel free to shout out and tell me to open it up, even if it's not needed for this particular scenario. Be happy to do that.

So I'll change this back to one, even though it won't be counted in the calculation, just so I can submit the data.

Oh, while I'm here, one other thing. I mentioned that we'd look at some of the on-line documentation – let me back up a second here. I just clicked on VIEW MODEL DETAILS, and you will see an explanation of the model. And you'll see that – you'll see things like this here and there throughout the software, should you go back and

play around with this yourself. When you see anything like – any of the screens that have VIEW MODEL DETAILS or anything like that, you're likely to see some interesting information. In fact, you're likely to – you're liable to see it more than once or twice here, if you're as clumsy as I am with your fingers.

But anyway, we'll go back and submit data, and that was accepted.

DR. ZIEMER: Russ, why wouldn't you on that one, that chart where you have confusion about one or zero, why not just label that radon or other sources, number of exposures, since that's the category it's under? Wouldn't that remove the confusion, or –

MR. HENSHAW: If it was labeled radon plus other sources, it would – the program would assume that there was radon exposure and factor that into the calculation.

DR. ZIEMER: No, I'm talking about labeling the instruction part for the user –

MR. HENSHAW: So the on-line –

DR. ZIEMER: If you go back – go back to the other screen there.

MR. HENSHAW: Okay.

DR. ZIEMER: Where it forced you to put in the one –

MR. HENSHAW: Um-hum.

DR. ZIEMER: – for exposure, it says for exposures to radon, number of radon exposures, you're having to put one in there anyway 'cause you have to show that you're exposing to something, right? Is that why the one's there?

MR. HENSHAW: Just – yes, just to make the program work, even though it disregards the input. And they're working on fixing this. It's a –

DR. ZIEMER: Oh, it needs to be labeled differently.

MR. HENSHAW: Yeah, it can be confusing. But I think the main point to remember is that no matter what you have in there, it's not factored into the calculations if you have OTHER SOURCES checked for exposure.

MR. ELLIOTT: If this claimant was from Fernald, though, you would want to choose radon exposure for that entry. Right?

MR. HENSHAW: I would assume so, but I'd refer that to one of our health physicists here.

UNIDENTIFIED: Possibly.

MR. HENSHAW: Okay, we've entered the data. Now we skip over – oh, I'm sorry. Now we go to enter doses since it was other sources, not radon. Then – well, let me back up a second here just to clarify something.

You'll notice there's an input field for number of exposures under exposure information. We're going to – for this hypothetical case, just for simplicity, we're going to say there was one exposure. Now we need to enter the dose information. Now had I typed in a two into that field – if you'll notice, there's one line for input data, one line for exposure. Had I typed a two into that field there would be two lines; three, three lines, et cetera.

So for this case we're going to say the exposure year was 1981.

DR. DeHART: Where is the employee getting that data? From DOE records, or what?

MR. HENSHAW: Well, initially, yes. But part of the program also includes actually interviewing each claimant or survivor, or sometimes coworkers, to verify that and maybe obtain additional information if it's available.

I'm going to say the exposure is chronic,

and let's say this is – the radiation type is alpha, we'll say from plutonium. We use the lognormal distribution, and for the parameters – the first parameter we put the actual number of rems, the dose in rems, into the box for parameter one, and we'll say it was 20 rem. Leave that at two, and leave that at zero, although for lognormal it doesn't matter what's in the third box. For lognormal the parameters are only the first two, the median and the geometric standard deviation.

MS. MUNN: So what did you do in box two? You had only one exposure?

MR. HENSHAW: Right. The two – it's not – it doesn't – it's not related to number of exposures.

MS. MUNN: I understand, but –

MR. HENSHAW: For – I'd probably refer that question to Jim or one of the health physicists for – or perhaps Mary, if you can answer that.

DR. SCHUBAUER-BERIGAN: The question is why is there a two in there?

MR. HENSHAW: Why is there a two in box two?

DR. SCHUBAUER-BERIGAN: Right. My understanding is that a dose of record is not in

the form of a distribution; it's in the form of a single number. And so that could be approximated using a distribution for organ dose that's called constant in the pull-down menu, if you'd like to do that.

However, as I mentioned in my presentation, we have the ability to incorporate uncertainty in the radiation dose of the claimant. And a very typical distribution for an uncertainty distribution is a lognormal for exposure data. And so this is just a hypothetical example, but for the case of Department of Labor, the health physicist would reconstruct the dose and would develop that particular dose distribution, and would give the parameter estimates from that process.

So this is something that a claimant is likely to not know how to do before seeing their dose reconstruction, which is why there is a pull-down in there, as Russ is showing, for a constant.

MR. HENSHAW: It's also, incidentally, perhaps a good segue to clicking on this help screen.

Again, these are more model details. This

attempts to provide some more information about the distribution parameters. And there's also, by the way, a good deal more information on this and other model details for the program and for probability of causation in your handouts and notebook.

I'll close this help screen, and now we'll submit the dose data.

Now we're back to the earlier screen, the input screen. And now we've done — we've entered all the information we need to enter to calculate probability. All we need do is click on SUMMARY REPORT and wait for the little invisible wheels to turn, and we'll grind out some results.

And there it is. You'll notice that much of the information that I mentioned was not actually necessary for the calculations appears in the summary report, including the information on the primary cancer, the date of diagnosis, and so forth, and the demographic information, name and Social Security number. Pretty much spits out just about everything we've plugged into it.

And we scroll down to the bottom, and there are the actual calculation results. And as you can see, this — this is driving me nuts. Bear

with me here with the glasses change. But as you can see, this individual's claim did not turn out to be compensable because the 99th percentile, the credibility limits, fell below 50 percent.

DR. ZIEMER: Russ, it might be instructive to now go back with the same dose and increase the uncertainty by raising the standard deviation of the lognormal distribution from two to, say, five.

MR. HENSHAW: Okay.

DR. ZIEMER: With the same dose.

MR. HENSHAW: I haven't tried that. I've tried playing around with the data, with the amount of rem, but not this one, so this might be interesting. Did you say five?

DR. ZIEMER: Say five.

MR. HENSHAW: If you're doing this at home and you happen to have a cable internet connection, by the way, it goes really quickly. This is a dial-up we're using here today.

So we'll scroll down to the bottom of the page and – about 75 percent.

DR. ZIEMER: Yeah. This is instructive, and I think points out that uncertainty in the numbers does in fact help the claimant. This was

in fact the intent of Congress, that if we don't know very well the decision is made in favor of the claimant. And I think it shows up here in the model, and I just thought – 'cause I've tried some of these, and I –

MR. HENSHAW: Yeah, it really bears –

DR. ZIEMER: – thought it would be helpful to see how this plays out. And this, not only in the dose numbers but also in the epidemiological information, uncertainty in either one tends to raise that number.

MR. HENSHAW: Yes, this does bear out the point someone made earlier. Play around a little bit more with the input data –

DR. ANDERSON: What about a cigarette smoker?

MR. ELLIOTT: Leave the dose and GSD as is, and change the smoking history.

MR. HENSHAW: Oh, okay. Should we go all the way to the extreme?

UNIDENTIFIED: Go in the middle somewhere.

DR. ANDERSON: Just go to ten.

MR. HENSHAW: Ten to 19, or –

DR. ANDERSON: Yeah, that's good.

MR. ELLIOTT: Make it reasonable.

MR. HENSHAW: The original result, before we changed the second parameter, was 43 percent. And then went — go to 80-something, I believe, wasn't it? Claimant still meets the compensation guidelines. It's significantly lower, though.

DR. DeHART: Try the next higher smoking group, because people will say they smoke a pack, typically.

MR. HENSHAW: That sets it up so you have to scroll down to see it, too. It builds up the suspense. It didn't have any effect, I don't think.

DR. ZIEMER: Russ, if you'd put the uncertainty on dose back at the original two, how would the smoking have affected — the smoking is — obviously is having some reduction on the —

MR. HENSHAW: Let's find out.

DR. SCHUBAUER-BERIGAN: Russ, I would suggest the importance analysis. You might want to click on the importance analysis first before you do a lot more scenarios, just to show how you can look at that.

MR. HENSHAW: I'm sorry, Mary, I can't hear you. Could you say that again?

DR. ZIEMER: Importance analysis.

DR. SCHUBAUER-BERIGAN: You might want to click on the importance analysis button before you do a lot more individual scenarios, intermediate results.

And I'll just say a word or two about that before it shows up. This actually was designed to kind of show the impact of changing various factors or factors that are — of uncertainty that are incorporated into the software program.

And first you see the range of doses in the first little table there. That says absorbed dose in centigray. And since there was one exposure, it gives you the percentiles of the actual exposure distribution given that level of uncertainty in the exposure.

Then there's a factor for the quality factor or relative biological effectiveness factor, which was used because this is a high-LET alpha exposure. And so you can see the range of uncertainty that's in that factor.

And then thirdly, there's the excess relative risk, which is derived from the epidemiologic models, and you see that there's quite a bit of uncertainty associated with those as well.

Then you can go to two different pie charts which show the different components of the probability of causation calculation and the various contribution of different sources. So in the first pie chart all the uncertainty comes from the excess relative risk for sources other than radon, since we only had a non-radon exposure here. And then the second chart shows — breaks down that particular excess relative risk uncertainty into various factors.

One of them is the organ dose. And we've seen, because the geometric standard deviation is five, that that's the majority of the uncertainty, is contributed from that organ dose. There's a smaller amount of uncertainty contributed by the uncertainty in RBE, and then a fairly high amount is due to the risk coefficients from the epidemiologic models.

And Russ, I think there's another one down below that, isn't there? Or is that the last one? Scroll down — yeah.

Then the last pie chart takes that adjusted ERR per sievert, since that has many adjustments in it. The original ERR per sievert is the uncertainty derived from the risk coefficients in

the atomic bomb survivor analysis. The second one is errors in dosimetry for that group, the A-bomb survivors. Thirdly, there's uncertainty in how those risks should be transferred to the U.S. population, but again that's a pretty small contribution. There's a fairly hefty chunk from the DDREF, the dose and dose-rate effectiveness factor; and then an adjustment for smoking.

So this kind of bears out the observation, which was that adjustment for smoking had a relatively smaller impact on the uncertainty than the change in the dose value for this model.

MR. HENSHAW: Thanks, Mary.

Before we — oops.

DR. ZIEMER: I think we lost it.

MR. HENSHAW: I clicked on the wrong thing there.

DR. ZIEMER: I think you lost it.

MR. HENSHAW: Can you get that back up, Larry? Do we have time for that, or —

Well, as it turns out we do have time to actually negotiate — navigate through the screen. So we're on the OCAS home page. We click on PROBABILITY OF CAUSATION, click on NIOSH-IREP, and on the link to the software.

One thing I do want to do before we get out of the lung cancer scenario, if we recall the very first scenario we ran, we used an exposure of 20 rems. I just want to show you what happens when we change that to 30 rems. If you recall the result in the first case was 43 percent. Change that to 30 —

DR. ZIEMER: I think you need alpha there, though. You had electrons for exposure. That's going to make it —

MR. HENSHAW: Oh, thank you.

UNIDENTIFIED: Russ, exposure year, was that 1981?

MR. HENSHAW: '81, right. Thanks.

By upping the dose in rem from 20 to 30, you'll see that we go from a probability of causation of 43 percent to 53 percent. So that upping the rem dose would make this claim compensable.

How are we doing with time? Should I continue with —

DR. ANDERSON: Can you do an age, an older person? I mean, a 40-year-old non-smoking lung cancer is pretty rare. Change the birth year to 1925.

MR. HENSHAW: Leave the other factors the same?

DR. ANDERSON: Sure.

MR. HENSHAW: There's no change.

Any other scenarios anyone would like to see, or should I —

DR. ZIEMER: Go ahead, Rich.

MR. ESPINOSA: On the other screen you've got exposure information, and you've got the factor of one in there. What is — is one a one-time exposure? Is one lifelong history as a DOE employee? What does that one stand for? Right there on exposure information.

UNIDENTIFIED: The number of exposures.

MR. HENSHAW: Oh, right here?

MR. ESPINOSA: Yeah.

MR. HENSHAW: Okay. Yeah, we're using in this case one exposure in the year 1981. If the person, say, worked in a facility, had exposures in a number of different years, there would be a separate exposure for each year.

DR. NETON: Those are effectively exposure years, your annual exposure for a particular radiation type. So for instance, if you had an exposure to alpha concomitant with exposure to

gamma, you would have two blocks for 1981, one for the alpha component, that annual component, and one for the gamma component.

MS. NEWSOM: What's your name, sir?

DR. NETON: Jim Neton.

MS. NEWSOM: Thank you.

MR. HENSHAW: Larry, we're kind of running out of time for Mary's presentation. Should I –

DR. ZIEMER: Yeah, I think that's probably enough examples. We need to move ahead.

Is that agreeable? Do we need to vote on that?

[Laughter]

MR. ELLIOTT: We're all conflicted.

DR. ZIEMER: By consensus, we're going to move ahead.

DR. SCHUBAUER-BERIGAN: Okay, in the remaining ten minutes or so for the schedule, I wanted to talk about some of the special issues in running the IREP software for EEOICPA. And some of these we've already talked to you about earlier, but I wanted to just illustrate how this would be done in practice.

One of the situations is claims for which more than one IREP run must be conducted. Russ

has gone over the example of two or more primary cancers and how that would be treated. I also wanted to illustrate the effects of age at exposure on leukemia and specific leukemia subtype PC estimation, and then one final example of a metastasized cancer with an unknown primary site.

I wanted to briefly cover the issue of specifying the exposure type, acute versus chronic, when that's unknown, and how that's handled. And also just briefly touch on the issues of effects of gender, ethnicity and age at exposure on the PC estimate.

This shows an example scenario, a male exposed in one year to five rem who was diagnosed with acute myeloid leukemia 17 years later. For AML there is no adjustment for age at exposure. However, for the general leukemia model within IREP there is an adjustment for age at exposure. Since there is uncertainty about which factor — i.e., the leukemia subtype or age at exposure — is more important to adjust for, we've taken one of the steps that Ted referred to from a policy standpoint, which is to give in the face of these types of unknowns to give the benefit of the

doubt to the claimant.

In this particular example, the highest probability of causation produced by each model that's run would then be used by DOL to adjudicate that claim. So for this example, for someone exposed at age 23, the general leukemia model produces a higher PC estimate. And for the same person exposed at age 43, the type-specific model produces the higher estimate. So in this case both would be calculated, and the value giving the highest PC estimate would be actually used.

This is a similar type of pattern for chronic myeloid leukemia, and again the same process and the same outcome for this specific example would be used.

Just to illustrate what would happen when you have a secondary cancer with an unknown primary site, the example claimant is a white Hispanic man — and it's important to illustrate that you've got to actually collect ethnicity and smoking histories for secondary cancers with unknown primary site, because frequently you'll need to calculate the PC value for lung cancer and skin cancer.

In this case we, as I said, developed lists of likely primary sites based on NCHS data, and these are tabulated in 42 CFR Part 81, Table 1. For lung cancer in men, the list of likely primary sites includes the ones that you see here – colon cancer, lung cancer, malignant melanoma of the skin, prostate, bladder and kidney cancer. So because of this uncertainty, Department of Labor would calculate the PC value for each of these likely primary sites, and the site producing the highest probability of causation estimate would be used to adjudicate the claim, in this case malignant melanoma.

For the same cancer, and mostly the same conditions – this is woman this time – her secondary lung cancer produces a different list of likely primary sites. And of the four, the lung cancer estimate produces the highest PC value, and then would thus be used in adjudicating the claim.

All right. This slide illustrates a couple of different things that are, I think, of interest. First, it shows how the probability of causation estimates could – can differ by gender, by exposure, and by cancer site. Under the same

exposure conditions, for many cancers the probability of causation estimates tend to be higher for females than for males. And in large part this is due to the finding of increased risk per unit dose among women.

Just as an example, the lung cancers are shown in red on this slide, and the results for females are shown in squares and the results for males in triangles. So you can see that the female lung, and then in blue the pancreas cancer, probability of causation estimates are higher for females. And here for males, the dose producing a probability of causation of 50 percent at the upper 99th percentile estimate is about ten rem, and for females it was lower than that, at about six rem for lung cancer. And for pancreatic cancer the same tendency is found, and for males the dose is about 30 rem and for females it's about ten rem. And this slide also shows you that the risk values for each sex are greater for lung cancer than they are for pancreatic cancer, at least for a non-smoker, a never-smoker.

Lastly, I wanted to say a few words about acute versus chronic exposure, and I don't have a

slide for this, unfortunately. For most DOE workers within a given badging period, it'll be unknown to us whether the dose received in that period was received as an acute or a chronic dose. All we might have is their recollection of what they were working at, what they were doing, and what the badges say.

Because for most radiation types there's a dose-rate reduction factor applied, assuming that the dose was chronic tends to lead to a lower estimate of probability of causation than by assuming that the dose was received in an acute basis. Since this cannot be known from the available data, again, give the benefit of the doubt to the claimants and use the assumption producing the highest probability of causation estimate.

I think that puts us at about a quarter till, but I have time for a few questions, at least.

DR. ZIEMER: I have a question on that, on the last item. As I understand it, what's being done on the acute versus chronic is to apply a dose-rate factor to the Japanese data.

DR. SCHUBAUER-BERIGAN: Yes.

DR. ZIEMER: Now acute in terms of the Japanese exposures is an exposure in, what, microseconds or something like that.

DR. SCHUBAUER-BERIGAN: Uh-huh (affirmative).

DR. ZIEMER: I think one would be hard-pressed to find any occupational exposures where the total doses were, outside of accident situations, where you could really argue that we come anywhere close to the acute dose rates in Japan.

DR. SCHUBAUER-BERIGAN: Well —

DR. ZIEMER: So what is meant by acute here? And I guess I'm raising the question as to whether one really should apply such a factor for those cases.

DR. SCHUBAUER-BERIGAN: The justification for use of a dose-rate reduction factor, in my opinion, doesn't stem really from the Japanese atomic bomb survivor data.

DR. ZIEMER: Oh, it doesn't? I see.

DR. SCHUBAUER-BERIGAN: In fact, the most recent analyses of that cohort show that the risk per unit dose is about essentially the same, regardless of the dose. There's no — for total

solid cancers there doesn't appear to be attenuation of risk at these very low doses. But there's a body of evidence from many other types of studies that supports this. So in defining what is an acute versus a chronic dose, I don't necessarily think that you have to compare the Japanese exposure scenario to a DOE worker.

This topic did come up in a NAS review panel of the NCI model, and I believe that the operating definition that was suggested was something on the order of hours to be considered an acute dose. Charles can correct me if that recollection is incorrect.

DR. ZIEMER: Is this based on epi data or on in vitro or cell data, or do we know? Anybody know?

DR. SCHUBAUER-BERIGAN: It's, I would guess, based on an amalgam of many different types of studies, and there's been many committees established to evaluate dose-rate effectiveness factors. We're most concerned about the operating definition that should be used in this application. And if we're talking the order of hours or days to define an acute dose, then I think we have probably a greater need to allow

for –

DR. ZIEMER: Yeah, I was looking for clarification. I think it's certainly appropriate, if you have a – let's say a film badge or a TLD badge where you have some reading and you know the person's worn that badge for 30 days, it would be prudent to assume they got the dose all on the first day or something. So it's acute in the sense that it's within, say, eight hours or some lesser number of hours, maybe one hour, but – is that what we're talking about by acute here in this case?

DR. SCHUBAUER-BERIGAN: Yes.

DR. ZIEMER: Okay.

MR. ELLIOTT: We know of criticality incidents like 1958 at Y12 where several individuals were exposed, and that would be one we would count as an acute event. Am I correct?

DR. SCHUBAUER-BERIGAN: Yes. Yes, and here's – there's also an example of –

UNIDENTIFIED: (Inaudible)

DR. SCHUBAUER-BERIGAN: Well, an opposite type of example would be an alpha – a plutonium exposure to bone, where it's well known that you received that exposure, and then you get these

tissues irradiated over — on a chronic basis throughout the life of the individual. So that would be a clear example where we know it's a chronic type of exposure, and then that would be used.

DR. ANDERSON: That was my question in the program there. When would chronic be chosen?

DR. SCHUBAUER-BERIGAN: Chronic would be —

DR. ANDERSON: Would it be related to certain elements, what types of exposure, or —

DR. SCHUBAUER-BERIGAN: It would absolutely be related to type of exposure. And in most cases — and Jim and some of the other health physicists can speak to this — but I think in most cases an alpha exposure would be considered a chronic exposure.

DR. NETON: There's really no plausible alpha exposure that we could come up with that would be considered an acute case with possible exception of radon daughters, but that's handled in a whole separate risk model. It's not covered under this model.

DR. SCHUBAUER-BERIGAN: There's another example of where we might call it a chronic dose, and that is neutron exposure.

DR. ANDERSON: Right.

DR. SCHUBAUER-BERIGAN: There is the incorporation of an inverse dose-rate effectiveness factor for neutrons as a high-LET emitter.

DR. NETON: This is something we're wrestling with, because you could have the same film badge, record the same exposure, and in one case you'd be forced into calling neutrons chronic and gamma acute. And so it's a policy issue that we have to deal with.

DR. SCHUBAUER-BERIGAN: Right.

DR. ANDERSON: I was only asking as it relates to an individual getting on your web page and trying to do their own profile versus yours that you would do for adjudicating a claim. You know, they might get the wrong — if this allows them to use acute when in fact it's chronic, you may —

DR. SCHUBAUER-BERIGAN: Right. Well, that —

DR. ANDERSON: — want to program it such that it doesn't allow you to do that if it's almost always one or the other.

DR. SCHUBAUER-BERIGAN: Yeah, that's one of the dangers of making the program publicly

available, is that there's — until the dose reconstruction is complete and the rule is finalized, there is no way for a claimant to guarantee that when they do their own probability of causation calculation that it would be the same as the one that DOL will eventually compute for them. And that's just one of the many factors that weights, plays a part of that.

DR. ZIEMER: Are there any further questions at this time?

[No responses]

DR. ZIEMER: If not, let's proceed then to the next item, which is the dose reconstruction rule, 42 CFR 82, and back to Ted Katz, I believe.

Ted.

MR. KATZ: Thank you, Mary.

Hello again. Okay, I'm going to do more or less the same as what I did for or against Mary, which is to start the ball rolling for Jim, who'll give you more technical background. But I'm going to give you background on it and a general, very brief overview on the dose reconstruction methods which, as we've talked about, are already effective.

So here's my overview here. I'm going to

discuss what the purpose of these methods is, how they'll be used, what Congress requires with respect to these methods. I'm going to give you some basics of dose reconstruction under the interim rule. And then two issues, one a very core issue, which I say here, how NIOSH will balance efficiency and precision. And then a sort of extreme case that we address in the rule too, which is what happens when NIOSH cannot complete a dose reconstruction.

So the purpose of the methods is to establish how NIOSH will estimate radiation doses incurred by employees. Each employee needs dose estimates to be able to have a probability of causation determined, and the dose estimates will be used by DOL to determine that cause.

NIOSH, I make this point, will make — will conduct dose reconstructions for cancer claimants only. This is important. These dose reconstructions are entirely designed for making compensation decisions, and you wouldn't design them the same way if you were doing research. And it ends up being very important, but we don't have, in the case of a claimant, years to decide how much dose they were exposed, in effect.

What does Congress require here? First, it requires that the methods must be applied for employees, and it specifies not monitored, monitored inadequately, and with incomplete records.

Now in practical terms, it means the methods will be applied for all claims, and let me qualify that here. Someone has to determine whether they were monitored adequately or not and whether they had complete records and so on. So these are going to have to come to NIOSH to have a look, at the very least. And then the extent to which a dose reconstruction is done is determined on a case-by-case basis, depending on what you have there. But we will have to handle the cases for all the claims. And the Board has a very important role which has been discussed, which is to independently review the methods and a sample of dose reconstructions.

What are the basics? We talk about this in the rule. We rely on a hierarchy of data that starts with personal monitoring data and extends to monitoring process and source information.

The key issue, as I say here, is the completeness and adequacy of the data. And what

this requires, then, is that we address all sources of data. So the hierarchy, it's a little bit misleading for some in reading this rule, perhaps, thinking that we're just then using the monitoring data if there's monitoring data there. But no, in fact we're going to have to look at these other sources of data to interpret that monitoring data.

And a key element of this, as has been discussed earlier, is we're going to be interviewing the employees to identify and fill data gaps and help interpret the data. The employees can tell us about actual monitoring practices, perhaps, versus official practices. They can tell us about incidents that occurred that may not show in their record, and so on.

And it's important to note here that we're dealing with a lot of claims that are going to be coming as well from survivors, and the survivors typically know very little about what their spouse did. And this is why in those cases we'll be going to coworkers as a surrogate for the deceased spouse.

To continue on here, Jim Neton's going to really go into detail about this next point.

We’re going to make the use of the best science, ICRP models and a state-of-the-art internal dosimetry program.

Very importantly, we're going to provide full accounting to the claimant of the methods, data, assumptions used. They will have, at the end of the process, a report that accounts for all the information they provided, for all the information we obtained from DOE, and for all we did with that information. So they will be fully informed. They can take that information and not have to flay us for more information to understand what happened in the process.

And also importantly, the claimant's going to be very involved with us in doing the dose reconstruction. But at the end of it all, if they are dissatisfied, if they have reason, they have cause to think that we haven't applied our methods appropriately, they can seek review through DOL.

Now this is what I mentioned as a really core issue, which is I think unique to our program here, how NIOSH will balance precision and efficiency. And you see this first bullet is already outdated after a couple of weeks, because

I say 12,000 claims and they already have at DOL 15,000 claims that are coming our way — incredible, unprecedented volume that we're dealing with of dose reconstruction here. And it doesn't allow us to do dose reconstructions, as we've said, if we're going to provide timely service the way we would for research. And Congress emphasized the need for timeliness, and it's obvious for the human need here. I'm going to remind everyone we're doing dose reconstruction to permit claim decisions, not achieve precision here.

So the basic strategy here to get to that point, to be able to do this while ensuring fairness, is to shortcut the process, in effect, for two groups.

For groups with very high doses what we're going to do is curtail data collection and analysis. There's no point delaying their compensation for us to develop a more precise, complete dose reconstruction record. So we're going to move those claims as quickly as possible, and they'll have their compensation sooner.

And then the other extreme is employees with

very low doses. Once we've collected enough information to know that, including speaking with the claimant or coworker and so on, is to use worst-case assumptions so that there's no doubt for the claimant that their dose hasn't reached a compensability level.

And then for all those claims that fall in the gray area which aren't obviously extremely high or extremely low, we will proceed with the full process.

Last issue, what happens when NIOSH cannot complete a dose reconstruction? Now we don't have a good feel, I don't think, at this point for how common this fix will be. But it's clear to us that it's going to be relatively rare, I think. And it's going to be situations where we have very little information about source and process.

Anyway, this situation has been anticipated by EEOICPA, by Congress, which allows for SEC petitions, petitions to be added to the Special Exposure Cohort. And several people talked earlier that HHS is responsible for these procedures and these are in the works. And you'll be hearing about these in future meetings.

And the last point I want to make here about these is while this is a remedy for most, there may be individuals who we can't do a dose reconstruction for who have — don't have a cancer on the specified cancer list. And in their situation this isn't a remedy. This is not an avenue for compensation.

Thank you. And would you like me to take questions, or wait for Jim?

DR. ZIEMER: Well, let's see if there are questions at this moment.

Yes, Dr. Roessler?

DR. ROESSLER: When you talk about the shortcut process and the very low doses, what's your definition of a very low dose? I mean, is there a number that you use that puts them in that —

MR. KATZ: There is — no, there isn't a number, because low dose depends on what type of cancer and a number of parameters. But given the volume of experience that's going to be gained very quickly here, we'll learn what it means in different situations. And so there's no — we couldn't say — we couldn't put out one number that's going to work for all these cancers, for

all these exposure situations, and so on. But it'll be cases where it's evident that the dose is far too low to be compensable, again in the judgment of the experts who are going to be running all this work.

Any more questions?

[No responses]

DR. ZIEMER: Okay. We'll proceed, then, with —

MR. KATZ: Thank you.

DR. ZIEMER: — Dr. Neton, who will give additional information on dose reconstruction.

DR. NETON: Good afternoon. It's a pleasure to be here and finally address the Board, after it seems like an eternity of waiting for your arrival. I appreciate your input on any of the information that we're talking about today.

In particular I should point out that what I'm going to discuss is draft. No final decisions have been made by our office on these technical issues. These are just some of the ideas that we're sharing at this time.

I am Jim Neton, and I'm the Health Science Administrator within the Office of Compensation Analysis and Support. And I've got the

challenging effort of trying to process these tens of thousands of claims with a staff of some very qualified people – health physicists and claims processors – to try to make some sense as to how we're going to approach this and do this in a timely manner to award claims, hopefully not in glacial time but in – not in real time, either, but to make it as efficient and fair a process as possible.

Now the first thing I think it's important to talk about is the difference between compensation dose and regulatory dose. We've hinted about this all afternoon in going through the probability of causation estimates and such, but there are a number of key differences between what a compliance program in the field that the DOE ran for years to try to ensure their workers were adequately protected, versus what we need to know to determine if the probability of compensation is equal to or greater than 50 percent.

The first issue is the compensation dose evaluation period is not limited, or is limited only to covered employment. For example, we're not interested in lifetime monitoring dose, which

many DOE sites have a fairly good handle on, but that's not relevant. And in fact, we need to know something more than that. We need to know the person's dose from the date of first exposure of covered employment to the date of the diagnosis of cancer. That's the only period that we're really concerned about that will be actually input in the probability of causation calculation. So in that respect we need to pull a lot of monitoring records through, sift through them, and pull out that unique time frame.

The other issue is that it includes internal, external and some occupationally-acquired medical sources of exposure. Those of you who have done health physics work in the DOE are aware that prior to the late eighties, like I think 1/1/89 comes to mind, internal doses were not really calculated at DOE facilities. They were — workers were protected based on what they called the maximum permissible body burden concept, which was dosimetrically based, but does not provide the type of information that we would need for a compensation scheme.

In addition, this occupationally-acquired medical sources of exposures is unique to our

process as well. And what we mean by that is medical exposures that were incurred by a worker as a condition of employment. For example, there are some sites where to be, in the earlier days, to be qualified as an asbestos worker, you were required to undergo an annual chest X-ray. It was required for you to do your job. In our opinion, therefore, that is occupationally-derived exposure that should be included in his compensability examination. Routine physical examinations, if they were voluntary, that sort of thing, would not be included under this.

And it's probably pretty obvious after going through the probability of causation examples that Russ and Mary did that an annual dose is required for a probability of causation estimate. We cannot use the 50-year committed dose equivalent or committed effective dose equivalent that is currently applied to Department of Energy workers.

And I know some sites have actually gone back and done sort of pseudo dose reconstruction efforts and calculated a worker's 50-year committed dose from earlier years of employment. That information would be useful for us, but not

necessarily in that form. We still are going to have to pull out the annual dose, because as you saw earlier, the probability of causation changes depending upon the distribution, annual distribution profile of that worker's exposure.

On a similar note, the committed effective dose equivalent concept, as I mentioned, is not applicable. The 50-year dose that's calculated to a worker from an internal exposure is not something useful for us, nor is the effective component of that. The effective dose component of that calculation is really a risk-based unit. I mean, it’s taking a radiation exposure and trying to equate it to a risk to protect the worker. We need to strip the effective component out, and as you saw earlier, IREP actually does, has the risk model built into it.

So in a sense, what we are ending up with with our calculations is a dose equivalent, the old Hp, H=DQN type thing, dose times a quality factor times other modifying factors. And that is in fact what we need to calculate.

Okay. Continuing on with some of the differences, at least as I see them, for external exposures the film badges and TLD badges have

been used historically since virtually the inception of DOE operations. But what that does is that measures the dose to the badge. In the earlier years it measured the dose to the badge. Under current regulatory framework, you actually measure the dose — you try to estimate the dose at one centimeter deep in the body, and we'll call that deep dose.

Well, that may or may not be applicable to a worker's compensation analysis. For example, organs that are very deep in the body, such as, you know, the liver or a lung, which is covered by five centimeters of overlying chest tissue, may be lower than the badge reading that the worker received.

Now for most scenarios — and I'm going to talk about this in some detail tomorrow — it's pretty close for high energy photons. The situation where you get into very low energy exposures, such as from americium-241, 60-keV gammas or plutonium X-rays, there can be massive differences between the recorded badge dose and the actual dose delivered to the organ. And we need to take a look at that and bring some sanity to that calculation.

A very important point is that undetected dose, also known in the business as missed dose, is an important factor. In a regulatory framework one is interested, particularly in the earlier years, of maintaining employees' exposure below some regulatory limit, and the monitoring programs could have a fair amount of dose that was undetected and still be considered adequately protective of the worker. We need to take that into account when reconstructing the worker's exposure.

I'm going to go over a couple of little examples of that later on, but the classic example is the film badge has a certain detection limit. In the earlier years it could have been as high as 30 millirem received on a weekly basis by an employee. And if that badge was exchanged, like I said, every week, then there's a potential — I'm not saying it was received — but a potential for the worker to receive upwards of one and a half rem of exposure and had gone undetected. So we are developing ways of dealing with that in our guidelines.

Another factor is uncertainty distributions are allowed. In the compliance-based world

they're point estimates. I've never seen any errors associated, unless maybe some massive dose reconstruction for some really big incident like a criticality, errors are not typically assigned because they're below the limit, and that's fine. We have the opportunity here to characterize these uncertainty distributions for each worker.

We've demonstrated earlier with IREP as to what the change in the standard deviation of that estimate can do to the probability of causation. We're taking a long, hard look at how we actually apply those, particularly in the area of internal dose where geometric standard deviations – well, if it's lognormal distributed, a gSD of two or three is probably not unheard of.

And the other, one of the nice features that we have available to us, is we're not constrained by regulatory-required science. All the current standards – the Department of Energy right now is based on the old ICRP 30, 26 dose limitation philosophy, which is fine. But there are more current and appropriate models out there that we feel are better science and do a better job at estimating the actual dose to the organ. And we'll talk a little bit about that.

Okay, a technical approach. The first thing we need to do is to take a look at all doses of record and evaluate them for data quality shortcomings. We are not going to accept even personnel monitoring data at face value and assume that it's adequate. I mentioned in the earlier days at some facilities there were plutonium exposures that — it's well known that the badge was not capable of detecting those low energy X-rays, so those were unrecorded. We need to make some adjustments to those data as we develop our knowledge base of the technology at the different sites.

As I talked about, we're going to assess the capability of external programs over time, look at the badges, their response to neutrons, gamma, X, and in particular the radiochemical techniques for bioassay sampling needs to be taken a look at. In the early days some of the radiochemical processes, although they were good, were — tracers weren't necessarily used all the time, so one does not really know about the chemical recovery of the method that was used, different issues like that; the efficiency of the alpha proportional counters that were used. We're

going to take a look at all those types of information.

I talked about earlier looking for the potential for undetected dose. And for external exposures we've concluded that we're going to use — and I'll talk in much more detail tomorrow if there's time — about what they call the limit of detection divided by two. If a badge could read 30 millirem, there are a number of papers out there — Hornung, et al. and others — have suggested that the detection limit divided by two is an appropriate metric to estimate the central tendency estimate of that exposure for that monitoring period. But it's a little more complicated than that, whether it's a lognormal or normal distribution. We can talk about that tomorrow.

And a parallel note, the minimum detectible internal dose is even more complicated because bioassay monitoring programs have a certain detection limit, but depending on how frequently a sample is collected for a worker, the dose could be — is quite — the undetected dose is quite variable. It's sort of intuitive that if one takes a sample on an annual basis, the worker

could have received a lot more dose and been undetected than if a sample is taken on a weekly basis or a daily basis. So we're taking a long hard look at that as well.

I talked about using these ICRP – Internal Commission on Radiological Protection – models. In particular we are embracing the ICRP 66 lung model for our dose calculation efforts. We have a contractor, ACJ & Associates, has developed a program for us. It's a beta version at this point. It's called IMBA, Integrated Modules for Bioassay Analysis, and that's what we're going to be applying.

We also believe that some of the more recent ICRP models take advantage of recycling of material in the body. The old ICRP 30 models are sort of what comes in one end goes out the other, and it never mixes back in the blood pool, that sort of thing. These new plutonium models allow for that type of analyses. So we feel it's a better representation of the biology.

In the external dosimetry evaluation the ICRP 74 model, ICRP 74, we're going to use to do those evaluations. And again I can talk in some more detail about that, but it takes into account

effects of conversion of the badge dose to what the organ actually received; also evaluation of the effect of the geometry of exposure.

For instance, if a person wears a badge on the front of their chest and is exposed in isometric fashion, then the badge that's calibrated from a beam impinging directly on the body is not necessarily calibrated properly. We're evaluating all those various factors and trying to incorporate that uncertainty into the overall analysis.

Ted touched on this earlier, but we do — once we evaluate the quality of the data, we do preferentially want — will use individual monitoring data if it appears to be adequate. And that makes sense. It was the actual — the person's own monitoring information at that time at that place, and that's where we intend to start if it's available.

As that information becomes less and less available, we'll have to back off and go to other strategies, and that would — the hierarchy goes area dosimeters, radiation surveys, air sampling, those type of things, what I consider work place monitoring data. And then as Ted alluded to, if

there's nothing out there, we can use a source term to evaluate that information. And surprisingly, source term information can do a — go a long way towards bracketing a worker's potential exposure.

I always use the example, you know, did a worker — when you're interviewing a claimant, did you work with grams, kilograms or tons of this material, and was it in dispersable form or was it contained in a rod. With those kind of bracketing assumptions — I have an example tomorrow — it's possible to put some — an estimate of central tendency, and put some confidence limits about that information.

These are just — this is sort of what I consider to be the universe of information types. This is in the rule, in 82. It's not all-inclusive. Some folks have pointed out there's a few items that probably could be included on there. For instance, continuous air monitor data is not in there. But I think it's a pretty good list, and gives us an idea of what types of information we would use.

Now I'm not suggesting that we're going to use all of this information on every claim. That

seems to be a common misconception out there. What it really says is, you know, if we can't — if we can find some of this stuff, we'll use it. And we need to get out there and verify, is some of this information out there? And not only is it there, but is it in usable form, readily available for us to apply to a compensation program in the near term?

It does us no good if there are air sampling results distributed over 50 facilities, paper copies in offices. It would take us three to five years to data-capture and code. So we need to go out there and do what I call a dosimetry information resource evaluation to determine how much we're going to use this information. I think we owe it to the claimants, though, to at least uncover all these stones and determine why we did not use this — these types of information.

Okay. Talk about processing strategy. I'm going to try to give you a little example of how this might work. We're going to start conservatively, using simple available monitoring data. And for example, let's take the case where have adequate either bioassay or TLD information, and we determine it to be of adequate quality.

Perform an initial evaluation using extremely worst-case assumptions in some cases, and if it looks like the probability of causation's going to be low, we're done.

Now the question was raised, well, what's the number? We really have no number at this point. We're in the process of constructing tables that you can kind of run through. If you can automate your IREP inputs, you can do continuous runs of IREP and generate tables of distributions of doses that can bracket certain scenarios. You can take a cancer type and an optimum, say, exposure scenario — optimum exposure condition set for a cancer and try to get an idea on this. But we're still working on really what these cut points are going to be.

Here's a flow diagram. It looks somewhat complicated, but it's really quite simple. Let's just take through one example. For instance, the top box, if you take the top box here, determine the organ of interest and most probable mode of exposure. What we're saying there is this is where a health physicist has to apply some degree of professional judgment.

If a person worked at a uranium facility, I

think it would be fairly well agreed upon that uranium and internal exposure would be the most likely high source of exposure. Uranium facilities, at least not enriched ones, are fairly low in the gamma component. If you took the ratio of internal to external, internal would always have a higher potential.

So if one went through and first picked and said, okay, I'm going to go through and do an internal dose calculation for this person using worst-case assumptions, and I go through and it's a low probability — and by worst case, I mean very insoluble material, worst-case missed dose, minimum detectible dose — if it's a low probability, we still need to consider what his external exposure was. So we would go through and use worst-case assumptions for his external exposure, accounting for all that missed dose based on badge exchanges, et cetera. If it's still a low probability, then there's no way that this number would likely be compensable, so the dose reconstruction is done. We bypassed a fair amount of work.

I have a couple of short examples I can show on this. Likewise, if it was not a low

probability, say it came out very high for the internal exposure based on these insoluble materials, and then we went and said, okay, let's do a conservatively low estimate for that internal exposure as well. So we've gone high. It looks like it's high. Let's figure out what the lowest plausible exposure was, and if it's a high probability — if it's still a high probability after you've taken your least — most conservative assumption, then you're done.

So this is a process that we've outlined, and we've gone through several scenarios. And it appears like it will allow us to gain a great amount of efficiency in this process, where we're not going to have to go through a very detailed analysis for every case.

Here's an example — and these are some fairly real-world type examples of an exposure at — I believe this was Hanford. The person was exposed from 1954 to 1961, had fairly low annual doses for X-ray and gamma exposures. And so we would go in and account for this missed dose, the undetected dose, add it back in and input — not input this into IREP, but use our experience base from IREP and realize that this case is going to

be — has a very low probability for compensation, especially if there was no external component available. I think when you saw — for solid tumor particularly, you saw the runs that were done earlier. Solid tumors with under a rem of exposure, whatever that amounts to, are very, very low probability of compensation.

On the other hand, we would take something like this plutonium bioassay data, and this is urine concentration of plutonium at picocuries per liter. The dates aren't really relevant, but say that this was over a several-year time span. The detection limit for this fellow was .05 picocuries per liter, so that's right around in here. And you can see that he's had a series of acute intermittent exposures, which I suppose could be modeled as chronic exposure.

But in our first worst-case assumption we're going to ignore it, and we're going to say, let's just look at this thing. This is a fairly large exposure. Let's take these points and assume that the exposure for these points occurred way back here at the date of first employment.

So what you end up is wildly over-predicting this intake, ignoring all this low stuff. And if

that calculation still came out very low, then you're done. You'll never have to even mess around with these other 20 or 30 data points because you've demonstrated that. This may be the case for some very soluble material like UF4 that leaves a lung very quickly as opposed to insoluble.

Conversely, say if this exposure came out very high based on this, which you would expect if it was insoluble, then we could go over here and say, well, let's just look at this intake by itself. Let's see if this intake alone is high enough for the person to be compensated. We still haven't had to calculate any of these data points. And if we model this intake — just these points right here — and the probability of causation was very high, we're also done. So it does a lot for us.

Now one thing that's not obvious until you start looking at it is it really has a lot to do with the organ that you're calculating the dose to. For internal exposures it's somewhat self-limiting in the fact that the only organs that really get a fairly large exposure are the organs that tend to concentrate the material. For

plutonium that would be something like the lung, the liver and the skeleton. If you have a cancer for any other organ and I wildly over-estimate this dose, I can pretty much bet that the dose to those non – what I call source organs, is also going to be low because plutonium does not concentrate in the prostate or the gallbladder or other organs like that. And in fact, if you run through the models, it is very low.

We've actually had our IREP or IMBA program, Integrated Modules for Bioassay internal dose program, we've had them go through, and we calculate a dose to each of the 36 ICRP 60 type organs that are out there now, and we can see these large differences. Virtually the only dose you get to a non-source organ is the crossfire from the organ – one organ to another. And there may be some ways of looking at the transfer compartment and adding a little dose back, but I still suspect it's going to be low.

Okay. This slide is woefully out of date and probably needs updating. I apologize, but I guess I got lazy at the last minute. This is essentially our attempt to demonstrate what an input to IMBA would look like – IREP would look

like when we provided it to the Department of Labor. And you've seen the demonstration where we have to determine what the type of distribution we expect the exposure to be, and we put in our best estimate of central tendency, and we also insert our geometric standard deviation if it's lognormal. If it was normal, of course that would just be the regular standard deviation.

So we do this for these — you know, in this case, 1951 through '58 — from both an internal and an external perspective, and identifying whether it's an acute or a chronic exposure. We just had that conversation that we are going to default, unless known otherwise, an external exposure will be classified as an acute exposure, because we cannot tell from badge monitoring data what the exposure scenario was unless there was something in the person's file that was involved in an incident, a criticality or something like that. For neutrons, however, we're in the position to be claimant-friendly of calling neutron exposures chronic exposures, and all alpha exposures from internal are going to be chronic. So we defined those parameters.

One thing that's not shown on here, though, is the IREP allows for 11 different types of radiation exposures. There are five neutron energy intervals. There are three gamma energy intervals, and then also there's electron exposure, beta exposure, as well as a tritium exposure – it has a slightly different radiation weighting factor – as well as the alpha factor. So we can select – I'm not suggesting that we're going to know every claimant's exposure scenario down to that level of detail, but it is there if it's known.

Okay. How long are we going to expect these dose reconstructions to take? It's going to vary all over the board. My guess – and I said complex – you know, it may vary depending on level of complexity. I said days to months.

I've seen, in looking through some of these cases, that there's some that can probably be done in a day or so, depending on – some of these low dose ones where a person after interview realizes that's their entire history, where it's a fairly low potential external exposure environment and the missed dose is fairly low.

The internal exposures, if we do our

bracketing worst-case assumption and then go to our conservative assumption and they still come out kind of on the bubble, that's where we're going to have to take and do a whole full-blown dose reconstruction and account for every data point and model the exposure, and that could take months, particularly if we really don't know the exposure very well, the exposure conditions of the claimant.

I also say cases with extensive internal exposure I expect to be the most complex. I guess I just talked about that.

And additional time required for previously unexamined locations and processes, we have these atomic weapons employers. There's almost 300 of them out there where we have almost no monitoring data, and we know very little about the process. That's going to take some time. I mean, it's not intuitive, we're going to go in there and be done in a day or two. That's going to take some research and investigation to accomplish those cases.

Okay. Where are we so far? I think it was mentioned there's about 13- or 15,000 claims hanging out in the system somewhere. We have in-

house within NIOSH — I think last guess was about 1,500, is that close? — so we have about 1,500 claims in-house. So we're frantically working to try to get this process in place.

It was never envisioned, though, that the NIOSH staff itself would actually do all the dose reconstructions. We have fairly limited resources. We, in addition to myself, we have a staff of three health physicists who are right now working on getting the program in place. We've — just a week or so ago the first draft of the implementation guides themselves for external dosimetry and internal dosimetry were completed, and that's moving along.

We're working toward a Memorandum of Understanding with the Department of Energy in sharing their information. That right now is undergoing internal review. The DOE is expecting us to provide them a straw man version of that Memorandum of Understanding, and hopefully that will be issued sooner than later.

We are going through the process right now of requesting DOE personnel monitoring information. We're not right now going after any of the work place information. We feel it's most

appropriate right now to go for the personnel monitoring information, to look at it, to evaluate it to see how it can be used, and that's going to be our starting point. In cases where there is no monitoring information — for instance, many construction workers were never monitored — we need to then go out and start looking at the on-site work place monitoring data.

I think we've issued somewhere around 700 DOE requests for information so far, so we're working to close that gap. Hopefully shortly there'll be sort of a one-to-one correspondence when the claimant's notified, that then we receive their claim, that the DOE request for information goes out.

We are looking at the records availability at certain facilities. We have a pilot study — two pilot studies that we've started, Oak Ridge and Hanford. Those are moving slower than we'd like. The Memorandum of Understanding will go a long way towards, I think, helping define the roles and responsibilities of the players involved in doing these records searches.

We are developing a computer database. It's

been talked about earlier that the Health-Related Energy Research Branch within NIOSH has been doing DOE workers studies for nine or ten years now. They've developed a considerable database of occupational monitoring records, mostly oriented towards doing epidemiologic studies. We are working in cooperation with HERB to collect that information and assemble it in a form and format that's useful for doing dose reconstructions. And we hope to grow that database and go and get more DOE information, essentially have a very large internal database that will allow us, as time goes by, to be less and less dependent upon Department of Energy as a resource for much information.

And most importantly to me at this point, we have a request for contracts for dose reconstruction assistance. It was in procurement, but as of last week it is available. We're expecting proposals due from the contractor, I believe, February 19th, fairly short turnaround time. We are working as fast as we can to get a contractor on board who will do the bulk of the dose reconstruction effort under our guidance and quality control and oversight.

Okay. I've come to the end of my formal comments, be happy to answer any questions if anyone has any.

DR. ZIEMER: Thank you, Jim.

Who has a question? Maybe I'll start it out.

It seems to me there's a possibility that, as you use newer models and do depth-dose calculations for external, that your numbers could come out quite different from what some would call the dose of record in the agency. That would seem to cause some problems with potential claimants who would look at that and say, well, there's my dose record. They tell me that's my dose, and you guys are saying it's much less than that.

DR. NETON: That issue —

DR. ZIEMER: I'm not asking you to answer that, but it seems to me that's a problem that the agency's going to have to deal with in terms of talking to claimants. I'm pretty sure some of the new ICRP 60 will give lower internal doses on some of those organ doses than the older models do.

DR. NETON: Not across the board.

DR. ZIEMER: No, not across the board, so it depends on what it is.

DR. NETON: Right.

DR. ZIEMER: I'm just saying it seems to me there is that possibility.

DR. NETON: I agree, I think there's a —

DR. ZIEMER: The film badge dose, which is — you know, the depth dose is one centimeter and you're going deep, it's going to be a different number.

DR. NETON: It's going to be — have to be a very intensive communication campaign to educate the claimants as to what we've really done. We intend to do our best to get that out there in a fairly comprehendible or comprehensible fashion to the claimant.

I think in many cases this difference will not be obvious, because most DOE programs don't calculate a dose over the time period we're looking at. I mean, we're going to look at the time of first employment to date of diagnosis on an annual basis, so internal exposures won't — there will be no one-to-one correspondence with those. External exposures, yeah, I think so. But I think those are going to be closer. We're

not doing anything fancy there, other than accounting for some of the obvious geometrical differences, which I think can be explained.

Another factor is that when you run IREP, if you notice, what happens is we use the ICRP 60 weighting factors, radiation weighting factors, to come out with an equivalent dose so that we can report to the claimant something that makes sense to them based on their past experience. I mean, they're used to seeing like an equivalent dose type number. But when IREP is run, it uses the distribution for that radiation weighting factor and applies it, so in a sense it's going to be inflated – not inflated; it will be sampled over its total distribution, so there is no point estimate for the radiation weighting factor.

So there's a lot of these things that are different that need to be explained to workers as to why they are different, and why we did what we did.

DR. ZIEMER: Other questions?

[No responses]

DR. ZIEMER: Okay, thank you very much.

We now come to the part of our agenda which is the public comment period. We have requests

from three individuals to speak.

Richard Miller requests to speak at 4:00. Does that mean Rich is not here right now? You are here, okay.

And David Richardson — David, how much time do you anticipate you would need?

MR. RICHARDSON: Five minutes, maybe.

DR. ZIEMER: Oh, okay. I was just trying to get a feel for this.

And Richard, about how much time do you need? How much time do you need?

MR. MILLER: Five minutes.

DR. ZIEMER: Five minutes, okay. Then none of these are extensive. I wasn't trying to force anybody to use up the hour. So Richard, if you would approach the mike, and you can use either the mike here or maybe preferably go to the very front so we can see you easily.

Richard is with the Government Accountability Project. Richard Miller.

MR. MILLER: Greetings. I — the Government Accountability Project, just to explain what it is and why I'm here today, has been tracking the implementation of this legislation, I guess largely because I moved over there. I had

previously worked for the Oil, Chemical and Atomic Workers Union and then PACE, which had spent a significant amount of effort trying to pass this legislation. So it's quite interesting for some of us who were involved in the negotiations over the bill and the drafting of the language and the lobbying that followed it to now watch it play out before your eyes.

Needless to say, the law of unintended consequences prevails, despite what we thought were our best insights and what was politically achievable. And I want to just focus on two areas today.

The first is the composition of the Board, over which you really have no control. But I — just for what it's worth, and it is frankly beyond the control of NIOSH or CDC by statute, as the President, of course, appoints you all to this Advisory Board, and the statute's very clear on what the appointment process is supposed to consist of. And I'm just going to read from the statute one paragraph, if you can indulge me, which is Section 3624 on the Advisory Board.

It says, (Reading): The President shall make appointments to the Board in consultation

with organizations with expertise on worker health issues in order to assure that the membership of the Board reflects a balance — key word — of scientific, medical and worker perspectives, and the President shall designate a Chair, which he has done.

The question is whether the Board in fact is constructed with a balance, as was intended by Congress. Now balance can mean a number of different things to different people. But if I see three criteria and there's roughly ten people on the Board so far, a third should fall into each of those categories, give or take. You've got a little bit of wiggle room there; you can have four in one category and three in others. And likewise, if the Board were increased in size, you would still expect some kind of proportional allocation.

Now it doesn't specifically say what the areas of science are or are not, but from the outside at least — and again, it is not a criticism of any individual here on the Board or whether they should or should not have been appointed — but it is an observation for those of us who are watching you deliberate on providing

advice that the constitution of this Board woefully underweights worker representation. And it is indisputable, at least from my perspective, that the only worker here is Richard Espinosa on the committee, as I think Congress had intended, what they meant by worker perspectives. And — well, each person's entitled to their views, and I will offer mine.

If — with that in mind, the question becomes — everybody, by the way, is a worker, because if everybody's collecting a paycheck you're effectively a worker. The question is whether you are or were in a position to be in management control or not. And this was a law which was intended to benefit, in effect, those who had the least power in a process that was largely conducted in a self-regulated and generally under significant secrecy.

So today, when you look at this body deliberating within this framework on this matter, from those of us from the outside at least, some of us believe that the Board is not adequately constituted. Will this affect the outcome of the deliberations? You know, it's a social science experiment.

Nevertheless, I just thought I would put that on the table because it is something that we very much would like to see done, and I want it on the record that this body, at least as constituted from our perception, does not meet those criteria. And we've communicated those views to the President.

The second issue which I wanted to address has to do with the – what Jim Neton was talking about, which was the forthcoming contract. And I've brought a letter which I sent to NIOSH – and I apologize, I only brought nine copies, so we'll have to get an extra one – but I brought some along, and I apologize for being one short. I think somebody borrowed one of my ten copies.

And what this gets to is the fact that as NIOSH moves forward with its dose reconstruction contracting process and the RFP's on the street, NIOSH has been, I think, sensitive to, at a staff level, concerns about conflict of interest. And the concerns around conflict of interest largely rest, at least from my perception, that there are likely to be perhaps only two bidders for this dose reconstruction contract.

I don't know that there will only be two,

but I have every reason to believe there will only be two based on conversations with the — sort of the contractors who showed up at the bidder's conference that was held in Cincinnati. And those two contractors, so that there's no mistake and no secrets about it, are going to be one team headed by SAIC and likely include Battelle, and a second one which is going to be headed up by Oak Ridge Associated Universities and may include MJW or someone else. But they're going to be the — those are going to be the two folks.

Now the statute, specifically the energy employees statute, when it spoke to the question of performing dose reconstruction work, was very specific in precluding either the Secretary of Energy or his or her designees or subordinate officers from performing the dose reconstruction work. It didn't say DOE contractors couldn't perform it, but it sought by assigning out this work for dose reconstruction away from what's perceived to be the agency, which could in some respects be considered culpable if there's harm involved.

And so what do we do? What do you do if the

folks who were involved in doing the work are involved in doing the dose — who are doing the dose reconstruction contract have relationships within the Energy Department?

Now NIOSH has done an excellent job of putting a crisp paragraph in its contract RFP that is on the web now which says, you know, if you're performing work at a given site you can't be involved in doing the dose reconstruction work at that site. Does that go far enough? I think it's an important first step.

Our concern and perception, as our letter lays out, is that there needs to be transparency, that the individuals that are hired by the teams need to be disclosed. What is their work history? Where did you work, who did you work for, both at an organizational as well as an individual level? And it needs to be transparent to the claimant. It probably needs to be transparent to you, as you provide quality assurance over this process as well.

We don't know if there's a way out of this conflict of interest problem because it's a small pool of highly-qualified individuals with a great deal of expertise. And in fact, in some

respects, the RFP almost constrains you to using DOE contractors for the very work. You have this — it's the classic conundrum, right? How do you get independence at the same time you have concentrated expertise?

Well, our sense is that there needs to be a high degree of transparency, a clear-cut list of do-nots, which include such things as acting as an expert witness or supporting litigation in defense of claims involved in — where there's an allegation of radiation causing occupational illness at a particular site. We've got to have a clear-cut set of do-nots and a clear set of transparencies that go back and forth between the claimant and NIOSH, so that you don't get down the road into the dose reconstruction and people stick up their hand when the case becomes appealed and say conflict.

So we would just like to suggest — although it's not on your agenda for today, it did get raised by Mr. Neton — and I just thought I'd segue off your presentation and encourage you to think about what can be done to raise the level of confidence that the claimants will have in a system where, as the Congressional record and the

hearing record — I happened to testify in this legislation several times and worked with many workers who did testify, and went to many of the field hearings that Dr. Michaels, who I guess is here in the back of the room, held when he was the Assistant Secretary at the Energy Department, and those hearings revealed a high degree of irregularity in the dose estimation and dose collection processes.

And if there's a concern about a high degree of irregularity, coverup — we had documents where major DOE contractors like Lockheed-Martin were actually doctoring the data in order to avoid culpability in worker compensation claims, and these documents are out there in the public record. You know, the names may be redacted, but the facts are all there.

And so I think it's important for you all to think about how to build credibility into the contracting process, because the best procedures in the world won't overcome that skepticism. So that's all I had to add.

Thank you.

DR. ZIEMER: Thank you, Richard, and your comments will indeed be in the public record.

I might ask if any of the committee members have questions of Richard that you'd like any points clarified?

[No responses]

DR. ZIEMER: Thank you.

Next, David Richardson from Department of Epidemiology, University of North Carolina at Chapel Hill.

MR. RICHARDSON: Hi.

I want to, I guess, talk to you a little bit first about my background. I've worked in epidemiology on studies of U.S. DOE workers at Oak Ridge and Hanford, and participated in the case-control study that took place at multiple DOE facilities.

And so I want to make a couple of points just in response to the discussion that I heard today from the perspective of an epidemiologist, and maybe also just to start out by saying I think NIOSH has done an impressive job so far. I mean, I think the approach that you're using is certainly cutting edge, and you've done a lot of hard work in trying to think about both issues of bias and uncertainty.

And those are certainly two key points, and

I — so as my first point as — raising is to move beyond talking about bias and uncertainty to talking about effect modification. And it's something that a few people have raised already on the edges, so it's something to think about.

From studies of U.S. DOE workers that I've been involved with and that other people before me have been involved with, and after the work that I've done I've been involved with, I think one interesting example of effect modification comes with the issue of age at exposure. So under the current probability of causation tables for a given dose history, for a worker's dose history, the excess relative risk or the — and therefore the probability of causation for that worker tends to decline with older ages at exposure. That is — I'll maybe modify that and say it's either constant or it's declining, and there's a tendency for the solid cancers for it to decline.

In contrast, in a number of studies of U.S. nuclear workers you see the opposite pattern. And that's to say people who accrue radiation exposures at older ages appear to have larger excess relative risks. There's a larger increase

in cancer.

Now I'll stress here that this is not – I'm not talking about the difference between infants or children and adults. I think that's – I think it's clearly established in the literature that the developing fetus, the growing child is extremely sensitive to the effects of radiation. I'm talking here about a range of age that's going to be something like 18 to 20 years when you start work, to 65 or 70 years of age when you stop work.

And the evidence from a series of U.S. DOE nuclear worker studies is that – kind of similar to what you see for lots of other occupational hazards. As people get older they become increasingly vulnerable to injury on the job – here, radiation-induced injury – and the biological plausibility would be related to either declining ability of the body to accurately repair damage to genes and/or declining ability of the immune system to scavenge up damaged cells.

So to take some examples, the early – I think the early evidence of this came in early reports of the Hanford cohort, which was one of

the first studies. That was when you began compiling nuclear worker records in the atomic weapons complex. Subsequent to that there was the evidence of increased radiation effects at older ages of exposure in the Oak Ridge workers cohort, then in a multi-facility study across the DOE complex of multiple myeloma where older ages at exposure were associated with larger increases in cancer risk, and then in the Rocketdyne study that was done out by the University of California group.

So there's different ways of thinking about this. One is that there's a conflict of evidence between the life span study of atomic bomb survivors, which I think it's important to stress is really the numerical quantitative foundation of the tabulations that you're seeing that are spinning out of almost a black box computer; that there's a study there of people who were wartime survivors of an atomic attack, and the exposure conditions are different than the DOE workers.

Another at least issue to raise with that would be effect modification coming from — I think an interesting point that a lot of people have already raised, yes, you've looked at

smoking as an effect modifier, but workers are getting exposed to chemicals, and they're accruing other exposures on the job. There's a possibility that it's not a simple either additive or multiplicative translation of the life span study to the DOE complex; that workers have a different set of initiating and promoting carcinogenic exposures on the job, and that the age at exposure pattern is different.

And what I would propose is that at minimum that inconsistency in the literature is recognized and in some way accounted for. And one way that I would propose that is there is a series of factors now going on that reflect uncertainties. There's uncertainties in translation of additive or multiplicative effects. There's uncertainties in dose measurements, both in the DOE complex and dose measurement in the A-bomb studies, that you begin to have also reflecting an uncertainty in the effect of radiation at older ages of exposure.

You don't have to incorporate any bias or anything, but you say there's — the literature is not consistent in the range of exposures. So when you begin to look at effects of exposures

that are received at the older span of a worker's life, you say the effect is more uncertain than the simple point estimate coming from the life span study.

So that would be my — that would be the first point that I'd like to raise.

Kind of following from that, I'd like to also just briefly talk about an issue that maybe at minimum needs a point of clarification and maybe some more exploration, which relates to the discussion that by default external radiation exposures are treated as acute. And the implication here is that the DDREF, the dose and dose-rate effectiveness factor, therefore undergoes a shift.

It goes from treating it as an exposure that was accrued slowly over time to one that's accrued in a point blast, and therefore that the DDREF is one, or that there's — let me take a step back and say that external doses are going to be treated as acute, and therefore this issue of is the effect attenuated because it was a chronic exposure, is that set aside.

And in fact, as I understand the current way the program is running, it's proposed that any

external dose that's less than 20 or 30 rem, which from my familiarity with the Hanford/Oak Ridge/Los Alamos data this is going to incorporate 99.9 percent — I'm making up a percentage — but it's going to be the vast, vast majority of the dose is substantially — any annual dose record is substantially below 20 or 30 rem for a worker. I mean, workers did accrue doses in the DOE complex, but it was over decades of employment.

So here the DDREF factor, you begin to say the effect of a worker's dose is going to be divided by a factor of two, three, four or five — the effectiveness of that dose — because it was a low dose. That is not — it's not because it was a chronic versus acute, it's because it's in the low — the spectrum of the lower end of the dose distribution.

And as Mary Schubauer-Berigan brought up, in fact, the evidence now, if you're going to take the recent RERF reports from the life span study, they're not supporting a departure from linearity. I would argue that, from the perspective of an epidemiologist, a DDREF factor of multiples of two, three, four or five for

these low — these doses, which is almost all the doses that you're talking about in this program, is — I'm not sure it's supported by the epidemiologic evidence.

And so you have to then turn to evidence that's accrued from studies of animals' exposures or cellular responses. I think the literature — studies of the effects of low-level exposures to animals, it does get iffy. Most of the literature is higher dose exposures to animals. When you're looking at low-level exposures, the end point is not going to be cancer incidents, or very rarely.

Anyway, so I think that's another issue that I would open, and I think particularly if you're talking about issues of benefit to the doubt for the worker from the perspective of epidemiology, I think that's a really important point to consider and debate further.

DR. ZIEMER: Thank you. David, I'd like to ask you to clarify one thing. Are you arguing that the dose-rate effectiveness factor should be one, and not two or three or some other value?

MR. RICHARDSON: I would argue —

DR. ZIEMER: Because I'm understanding this

in almost the opposite way. I think lowering it lowers the effective dose. Is that – are you arguing that we're over-estimating doses at –

MR. RICHARDSON: The effects of a dose, a lower dose, is going to be divided. The way that this factor is applied for low-LET radiation –

DR. ZIEMER: I guess I may have misinterpreted how they're using it, then.

MR. RICHARDSON: I don't know. Mary, could –

DR. ZIEMER: I thought we were multiplying, but I would ask that we get that clarified.

MR. RICHARDSON: I think Mary could answer that.

DR. ZIEMER: Typically a dose-rate effectiveness factor operates like a quality factor. It increases –

DR. SCHUBAUER-BERIGAN: Actually, it –

DR. ZIEMER: It would increase the probability of causation rather than decrease it. I believe that is the case.

DR. SCHUBAUER-BERIGAN: Well, what acts like a quality factor actually is the RBE. Those two are sometimes used interchangeably. But David is correct, that when the DDREF factor is applied, a

factor of greater than one implies that the risk per unit exposure at a very – at a low dose or in a chronic dose is divided by that value.

MR. RICHARDSON: Right.

DR. SCHUBAUER-BERIGAN: So if it's two, the effect of that dose is divided by two.

DR. ZIEMER: Thank you.

MR. RICHARDSON: Right. And so the question is, is there – here, I think, everything is being essentially treated as an acute dose for the external here, talking again about the low-LET doses. So it's not – the issue of dose-rate is not really so much a consideration. It's is the dose-response association linear in the low dose range? And, I mean, that is something that people talk about.

DR. ZIEMER: I understand what you're saying.

MR. RICHARDSON: But the current – I'd say a lot of committees are taking now, and a lot of the literature, is supporting the opinion that a linear dose response is a reasonable association. And I – you know, I would argue maybe yes, that you would have a factor centered around one, and then you allow uncertainty in that.

DR. ZIEMER: Are the studies that you cited in your written comments that were submitted to the agency earlier?

MR. RICHARDSON: Yes.

MR. ELLIOTT: Yes, they're referenced and we have copies of those.

DR. ZIEMER: Thank you.

Next we have – I think it's Roger. Is it Roger?

MR. SHAW: Yes.

DR. ZIEMER: I couldn't read your writing here – Roger Shaw from McCarter & English, Ltd.

MR. SHAW: Yes, this will be less than five minutes.

Let's go right to DREF. I just want to mention DREF. I know that the Board will look at it. It's an important item. For low-LET, UNSCEAR, ICRP, NCRP and BEIR V support a DREF for low-LET of anywhere from two to five. I think I heard Mary earlier – I asked her specifically on a break if there'd be a range of maybe between less than one to five, and that's something that is a little different than maybe what the RERF may be saying in one of their recent studies.

But I think it really deserves a lot of

caution and is something that should be looked at. A lot of important national, international bodies support that you use a DREF. And for example, if it was two, that would mean that the risk would be less by a factor of two. So that is something I just — I know you'll look at. I just want to mention that.

And if we do start to define acute versus chronic in a different way, if we start to say that an acute dose is something received over a month or two months or a quarter, over a quarterly badge reading period for TLD or film, then we're going to have to start rewriting textbooks and doing that fairly quickly, because that is not historically how acute dose has been defined.

The second item is with the dose uncertainty and how critical that is. Dr. Ziemer pointed out, as we went through NIOSH-IREP, or Russell did, Mr. Henshaw — and showed exactly what happens when you change the uncertainty associated with those doses. And it can make huge differences. As I'm sure you get home and you work tonight, and you start to go through and do your own iterations with NIOSH-IREP, you will

start to see these differences.

And if you simply change and go and look — and they're different for different cancers — but if you look at one leukemia, you look at CML, and you take and change that, you just leave all the parameters the same for a certain dose. If you took 25 rem, five rem for five years, and put in the information you want to put in, just change constant, which means no uncertainty — not really realistic — and change that to normal geometric standard deviation, gSD. Well, for gSD that's 40 percent PC. And if you just change that to constant alone, it goes to 93 percent probability of causation.

So as Congress has said, let's err on the side of the claimant. We should. It sounds fair. It is fair. It doesn't mean that we need to add undue uncertainty on top of an already large amount of uncertainty that we're going to be stuck with and also have to deal with in a reasonable fashion.

Those are the two points.

DR. ZIEMER: Thank you, Roger.

And again, are there any questions or issues to be clarified?

[No responses]

DR. ZIEMER: All right. Thank you.

This completes today's agenda. I would ask that the four other members of the subcommittee stop by here for a moment before we adjourn — or right after we adjourn, and we'll talk about the assignment for this evening.

We thank all of our guests who were here today. We will reconvene tomorrow at 8:00 o'clock; 8:00 o'clock, not 8:30, okay? So we'll see you all in the morning at 8:00 a.m.

Thank you very much.

[Whereupon, the meeting was adjourned at approximately 5:05 p.m.]

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C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 128 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 _____ day of February, 2002.

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KIM S. NEWSOM, CCR-CVR
CCR No. B-1642

[SEAL]