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 II

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the the Hyatt Regency Denver, Denver, Colorado, on Tuesday, July 2, 2002.

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

C O N T E N T S

VOLUME II
July 2, 2002

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

(By Group, in Alphabetical Order)

ADVISORY BOARD MEMBERS

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

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

MEMBERSHIP

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

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

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

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

Espanola, New Mexico

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

MARK A. GRIFFON
President
Creative Pollution Solutions, Inc.
Salem, New Hampshire

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

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

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

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

INVITED SPEAKERS

TED KATZ, M.P.A.
Policy Analyst
National Institute of Occupational Safety and Health
Atlanta, Georgia

NIOSH STAFF/VENDORS

MARY ARMSTRONG, Office of General Counsel
CORRINE HOMER, NIOSH

MARIE MURRAY, Writer/Editor
JIM NETON, NIOSH
KIM NEWSOM, Certified Court Reporter

AUDIENCE PARTICIPANTS

RICHARD MILLER
PHILLIP SCHOFIELD

P R O C E E D I N G S

8:29 a.m.

DR. ZIEMER: Good morning, everyone. I want to call us back to order for our second day of our fifth meeting.

I think that everybody I see was probably here yesterday. If there is anyone who was not here yesterday, I'd like to ask you to please register in the log book back on the table. I have just one other announcement at this time for the members of the Advisory Board, and that is if you have more materials than you wish to carry aboard the plane and want those shipped to you, please let Cori know and she'll make arrangements with you to ship whatever materials you want her to -- within limits, I suppose, but anyway --

UNIDENTIFIED: If you're not shipping antiques –

(Laughter)

DR. ZIEMER: Right, antiques that you've bought.

We have a full session this morning. We're pleased to have several speakers here that will be addressing the IREP risk models, the uncertainty analysis, and the radiation

effectiveness factors. Those speakers are Dr. Owen Hoffman, Brian Thomas, and David Kocher. These three gentlemen are with SENES Oak Ridge, and I might tell you that that particular group originally worked with NCI and had a contract, I believe, with NCI to update the 1985 models; and then more recently then has had a contract with NIOSH to make the NCI-IREP adapted to the NIOSH approach. So they've been very heavily involved in the risk models, the uncertainty analysis, and radiation effectiveness factors.

So we're going to begin with Dr. Owen Hoffman, and then that'll be followed by a presentation by Brian Thomas, and then presentation by David Kocher. We've set aside two hours for these three presentations. There will be time during each of those, I think, for some discussion, even though we have a separate discussion period later.

Now one thing I want to mention to you that -- and Owen has already suggested that we do this -- and that is that if there are certain questions that he feels might be better answered by others who are not here, and more specifically by Dr. Land, we will in a sense collect those

questions. Dr. Land is standing by at his office and will join us, if needed, by conference call during the discussion period. So if questions are identified that either you wish to direct to Dr. Land or that Owen or his colleagues believe would be best answered by Dr. Land, we will set those questions aside until the 10:45 discussion period, at which time Dr. Land will be available to join us by conference call or speaker phone, I guess.

So with that, Owen, we'll let you kick it off, and then your other colleagues can join you as needed along the way. We appreciate your being here.

DR. HOFFMAN: I think with all the meetings I've attended and all the times I've had to do this, that this would be automatic. It's a pleasure to be invited to address you this morning. We've been involved for a period of perhaps three years in adapting the Interactive RadioEpidemiological Program for calculating probability of causation. And as Paul Ziemer mentioned we first started this under contract with the National Cancer Institute, and most recently have had a contract to make this program

available over the web for NIOSH in facilitating their implementation of worker's compensation legislation.

When I was asked by Jim Neton to come here, the issue at hand was can we increase the transparency of IREP? Evidently at your last meeting there was quite a bit of conversation from around the table and from the audience that the web version appeared to be somewhat like a black box, and that IREP wasn't as transparent as it could be. Well, our objective today before you is to try to make things as transparent as possible, and we are prepared to answer any question that you have. If you'd like to see what changes would be made in the final result as the result of changing input assumptions, we'll do that. We've got the source code with us, and so we're prepared to give you complete insight into this code.

Those of us from SENES Oak Ridge really had involvement with the code itself. The decisions about the risk coefficients, the actual models to be used in transferring the risk from Japanese to the U.S. population have been the responsibility of the scientists working with the National

Cancer Institute.

The estimation of the probability that past exposure to radiation caused a diagnosed cancer is primarily the product of three simple factors: quantifying the organ-specific exposure, translating that exposure into risk, and accounting for uncertainty in these two steps that then is put into the mathematical transformation that accounts for a probability of causation, whereby probability of causation is simply the risk from radiation divided by the risk from radiation plus the risk from all other sources.

Probability of causation is sometimes referred to as assigned share. Assigned share is the fraction of disease in a heterogenous population that would not have occurred in the absence of that exposure for all individuals of the same exposure category, such as dose, gender, age at exposure, age at diagnosis, time between exposure and onset of disease, ethnic background, et cetera. Assigned share is a conceptually measurable quantity. You can measure it. Probability of causation for an individual is not measurable. An individual's either going to get

disease from exposure or he's not going to get disease. For an individual, probability of causation is simply the weight of evidence that the disease could have been caused by that exposure. Assigned share, however, is a attribute of a population and is a measurable quantity.

The basic calculation of probability of causation in the Interactive RadioEpidemiological Program is simply the ratio of excess relative risk divided by excess relative risk plus one. The quantity excess relative risk plus one is known in epidemiological circles as the relative risk, so excess relative risk divided by relative risk equals probability of causation.

The excess relative risk is a product of risk coefficient, excess relative risk per unit dose at sievert times the dose. And it is the uncertainty in the risk coefficient times the uncertainty in dose that gives us the uncertainty in the excess relative risk. So you see that the uncertainty in probability of causation is just a function of the uncertainty in the calculated excess relative risk.

The program IREP is probably the most

extensive use of full quantitative uncertainty analysis and risk assessment to date, so it's a major step forward in how we calculate the risk from radiation -- in fact, how we calculate the risk from any type of hazardous substance.

Uncertainty is considered using probability distributions, and probability distributions are assigned to the organ equivalent dose. This must be defined by those responsible for doing the dose reconstruction. The original relative excess risk per unit dose is also considered as a probability distribution, but what goes into this is the original statistical uncertainty in the dose response as defined by age at time of exposure, gender, attained age at the time of onset of the disease, and numerous other factors.

But there's also bias or uncertain bias that is accounted for due to the random systematic errors associated with the original dosimetry that was incorporated in the analysis of the atomic bomb survivors. Well, this accounts for the fact that -- what is it -- BS-86 dosimetry is subject to update, and what kind of uncertainties would be introduced as a result of that impending update.

Uncertainty is also assigned to the selection of different mathematical models used to transfer the observed risk in the Japanese population to a member of the U.S. population, and this primarily accounts for differences in background incidence rates and differences between an additive, a multiplicative, and/or any combination of additive and multiplicative models for transferring risk from one population to another.

David Kocher is here to talk about one of the areas where there's been a major improvement in the way we look at quantification of radiation risk, and that is the assignment of probability distributions to account for the uncertainty in the radiation effectiveness of exposure to radiation types other than high energy gamma rays. Why high energy gamma rays? It's because that's what the Japanese survivor data is primarily based on. And now we're looking at very low energy gammas like X-rays or low energy betas like tritium, alpha particles or various energies of neutrons, we will have probability distributions assigned to those. And as David will mention, these probability distributions don't necessarily overlap with the default

assumptions recommended by national committees that recommend values for radiation protection purposes.

One of the areas that I know has been a subject of interest among your committee is what do we do about extrapolation from information from the Japanese survivors to conditions where individuals have been exposed at low doses and at low dose rates. Low dose rates mean chronic exposures, where there are several exposures in sequence over a number of years.

Well, this is accounted for as what's called a DDREF. That just means a dose and dose-rate effectiveness factor. It's using the denominator of the equation, so the higher the value of the DDREF or dose and dose-rate effectiveness factor, the lower is the adjustment of risk. The DDREF is used for both acute and chronic exposures to low LET radiation. But for acute exposure it only comes in when the exposures are below something that ranges between two and 20 centisieverts. As you will see, there is a small possibility accounted for for an inverse dose rate effect for both low and high linear energy transfer radiation. This means that there is a

possibility accounted for that the DDREF may be superlinear or less than one.

Now the probability distributions used in IREP mostly reflect uncertainty that accounts for our subjective states of knowledge, as opposed to variability associated with an experimental design or repetitive observations. This is important to keep in mind. The probability distributions that describe stochastic variability from random observations in an experiment, these distributions must obey the laws of nature. Normal distributions, lognormal distributions are typically the most common that come out of such experiments.

State of knowledge distributions can be any shape necessary to represent the space within which the true but unknown value is likely to occur. And in IREP you'll see that there are a whole variety of distribution functions that are used to express our state of knowledge. Some are discrete, with weights given at specific values. Some are continuous -- normal, lognormal, uniform distributions, triangular, trapezoidal. And many are hybrids of various distributions to reflect the impact of alternative datasets. It's the

most, I would say, sophisticated use of combining various sets that contribute to our state of knowledge to represent this within a state of knowledge probability distribution.

To give you an example, here is the current distribution used in IREP for the dose and dose-rate effectiveness factor for solid tumors, except for breast and thyroid. And you can see that the primary weight is given to values between 1.0 and 3. A value of 1.0 means that there is complete linearity between health effects seen at high acute exposures and that that occurs at low doses and low dose rates. The higher the value of the DDREF, the more there is an adjustment downward in risk, the more the risk is suppressed; which means that exposure to chronic doses will give a lower risk. Notice that there is about a 80 percent probability for values between one and two; about a 15 percent probability for values at three and/or greater; a five percent probability for values less than one; and a 25 percent probability for values at one or less.

Now if we look at breast and thyroid, almost the same but not quite. There's increased weight

of evidence for linearity. Still the bulk of the distribution is between 1 and 3; a small probability out at 4.0; and about the same probability, five percent, for values less than 1. The reason for this is the increased evidence for these two organs that radiogenic cancer is linear.

Now some of you asked about, well, how does this whole thing work, and how does Monte Carlo simulation affect the final outcome? What happens is that we have the probability of causation model. This is the Interactive RadioEpidemiological Program. This is a mathematical model that translates dose and disease into probability of causation. All of the uncertain inputs are expressed as a variety of probability distributions. One value at random is selected from each distribution to produce a randomized outcome. This is repeated over and over until there are a large number of possible outcomes that are tabulated, and from this we can get a central estimate, and in this case a 95 percent confidence interval.

For the purposes of adjudication of claims, the Veterans Administration and NIOSH and the

Department of Labor -- actually it's in the -- the acronym, I can't pronounce it -- it's in the law that the upper 99th percentile of this population of numbers will be used for decision-making and the adjudication of claims. And the reason why such an extreme value is used is to give the benefit of the doubt to those who have been exposed. This is not a decision we have made. This is a decision that's was made external to the effort that we have put into quantifying uncertainty.

In fact, I read the minutes of your last meeting, and in those minutes there is numerous discussions about all the decisions that have been made within IREP to be claimant-friendly. We have made not a single one. Not a single assumption that we have made that has been intentionally made to be claimant-friendly. What we've tried to do is to capture our state of knowledge quantitatively, albeit many of these decisions are the result of our collective judgment, but subject to peer review. And we have structured IREP in such a way that in the future if there is a need for updating, it can be readily updated.

Now here's an example of results that are produced by IREP, and the example is a person exposed at age 24 who has come down with thyroid cancer at age 60. He was exposed to a thyroid dose of -- here I have 15 centigray, but 15 centigray and 15 centisieverts are identical for low LET radiation to high energy gammas. The dose is uncertain, but we've given a modest uncertainty which would be a geometric standard deviation of 1.4. That's about a factor of two either side of this central estimate.

As a result of 2,000 Monte Carlo simulations using Median Latin Hypercube Sampling -- and I won't go into that, but that's the mechanism that's used for sampling -- here is the outcome. Notice that the central estimate only shows about a 12 percent probability of causation. The upper 95th percentile often used for decision-making would still be less than a 40 percent probability of causation. However, at the 99th percentile, that percentile that has been deliberately chosen for decision-making, that would cause this person to be eligible for claims.

A feature of IREP that I know that some of you aren't familiar with, and this is an

important feature because we know that we're working in an atmosphere of imperfect knowledge. We know that although we have tried to account for all sources of uncertainty, that the state of knowledge progresses on. And so in addition to building this code so it can be readily updated, we've also allowed for additional sources of uncertainty to be included with adequate justification. This justification should require written rationale.

And what we have within IREP -- and Brian Thomas will demonstrate this -- is an additional variable that functions like an overall bias correction factor that is uncertain, with the central value and the width of the uncertainty in this parameter, will adjust the final excess relative risk. The rationale for such adjustment could be an individual whose background rates of cancer are known to be significantly different from those of the national average, updates in radiogenic cancer risk for certain disease end points, or as new information comes forward from worker populations. This back door can be used to justify additional modifications to the overall outcome.

But the point I want to make is that it was our intent that this just not be used willy-nilly; that, Larry, there should be good, strong scientific rationale for its implementation.

The default of this additional uncertainty factor is a lognormal distribution with a mean of one and a geometric standard deviation of one. What does that mean? Means it's constant. There's no effect at all currently. But if the mean were kept at one and this geometric standard deviation were changed to, let's say, 1.4, that would increase the overall uncertainty in the expression of probability of causation. If the geometric mean were to change to two, it means that we would have an overall bias whereby we felt that the current estimates in IREP were underestimating the probability of causation, and this could be used to adjust the entire distribution upward by a factor of two. If this were to go down to, let's say, .33, it means that we felt we were overestimating the probability of causation, and the whole distribution could be adjusted the other way by a factor of three.

So in summary in this introductory presentation, IREP starts with original risk

factors that come from the follow-up of the lifespan study of the Japanese cohort that is formed from the survivors of the atomic bombings of Hiroshima and Nagasaki. What's new is unlike past risk estimates that are based on mortality, this one is now based on incidence. And the basic data used in IREP is incidence-based. I think this is the first time anywhere in any radiation risk assessments that the incidence data have been used directly, as opposed to risk estimates being derived from mortality statistics.

The only organs not using the Japanese data would be the thyroid, in which case the pooled study from Ron, et al. in 1995 is the basic dataset, and for lung cancer exposures to radon is used as the primary dataset for the case where exposures to radon are explicitly quantified in terms of working level months' exposure.

These original epidemiological estimates are adjusted for errors in the epidemiological dosimetry. Those errors are further adjusted for the uncertainty associated with the transfer of risk from the Japanese to the U.S. population, and this accounts for both the uncertainty in the

models as well as uncertainty in the differences in the background incidence rates.

For low dose and chronic exposures, it's further adjusted for that dose and dose-rate effectiveness factor. And then the final excess relative risk per sievert can be adjusted using this user or claimant-justifiable uncertainty factor. To date it hasn't been used, and to date it is just simply set as a constant.

That's my introduction.

DR. ZIEMER: Thank you, Owen. I think we'll take a few moments for some questions here. Let me begin simply by asking you, in our handout there are three slides that deal with dose and dose-rate effectiveness factor that you either omitted or are holding for later. Were you intending not to cover those?

DR. HOFFMAN: You led right into the reason that I decided to hold them, because I wanted to wait for a question to come up.

(Laughter)

DR. HOFFMAN: Because I know this has been a subject of interest, but I didn't want to give you everything I knew.

DR. ZIEMER: Is there anything else you're

holding back?

DR. HOFFMAN: Hoping that a question would come forward, I used the advanced features of PowerPoint to hide these slides -- but you have them in your handouts -- to show what other distributions have people used in quantifying the uncertainty in radiogenic cancer risk.

The first attempt to formally quantify radiogenic cancer risk was in Publication 126 of the National Council on Radiation Protection and Measurements. And Dr. Charles Land, Andre Bouville, and Warren Sinclair were the principal authors of that report. That report used a state of knowledge distribution -- no named shape to this; it looks like a compounded series of triangular distributions with the left-hand side truncated at 1, peak value at 2, and then diminishing but stopping at 5.0.

Now the interesting part of this distribution is that linearity or 1.0 is not sampled at all, so there's no weight given to 1.0 here. There is weight given to values slightly above 1.0, but in a continuous distribution like that neither values at 5 or at 1 are sampled. This was a subject that was brought up in the Science

Advisory Board review of EPA's uncertainty in radiogenic cancer risk, and Gen and I were associated with that effort.

Well, here's what EPA did. And this is 1999, EPA's addendum to their radiogenic cancer risk. And this is the small report written on their attempt to quantify uncertainty in radiogenic cancer risk, and this is the distribution that they put in for all solid tumors other than breast and thyroid. Again, it goes from 1 to very small weights given to values greater than 5. However, most of the distribution is between 1 and 2. Because it's a continuous distribution, values at 1 aren't sampled. And again this was a subject that we discussed in our Science Advisory Board review, and EPA's answer was, well, if we put some weight here at 1, it would only change the overall results by about 10 percent. So they didn't do it.

This was an issue that I think over the last few years we battled and debated amongst the team of us working on IREP, and finally what influenced us to try for something different was the dose reconstruction for Rocky Flats. And this is Warren Sinclair, Helen Grogan, and

others, who looked at the NCRP distribution and said, well, there's evidence from the Japanese bomb survivors, and some animal experiments as well as some other human epidemiological studies, that says that even some superlinearity cannot be discounted. And so they went down as low as .2, but basically used the NCRP distribution and added this small probability to an inverse dose rate effect.

We looked at the information and said that, well, basically there is not a whole lot of epidemiological and experimental evidence to allow us to dictate a distribution of any shape, and that's why we put weights at discrete values and used a discrete distribution for both breast and thyroid and distributions for all other solid tumors.

Now for leukemia there is no DDREF used. It's just a -- basically it's a linear quadratic dose response. And that linear quadratic dose response has the effect that at low chronic exposures the risk is about a factor of two less than it would be at high acute exposures.

I'm not hiding any other slides. You've now seen all of them.

DR. ROESSLER: You led right into a question I have, and that's why do you use the DDREF for the solid tumors and then the linear quadratic for leukemia, when aren't they essentially the same? Or is there some fine difference that I'm not recognizing? Or are you trying to make it line up with the BEIR reports?

DR. HOFFMAN: Neither, neither. This is -- and here's a case where the ultimate authority on that is Charles Land.

But since I've got the floor I will try to mimic what I know his answer would be, and that is that the data are far better developed for leukemia than perhaps any other organ, and it is clear from the statistical analysis of those data that it follows a linear quadratic relationship. It's also clear, however, that in looking at all other solid tumors that it is not a linear quadratic relationship. And in fact, for the range over which one sees a statistically significant excess relative risk, the model is more linear than anything else.

But we can reserve that as one of the questions we ask Charles when he gets on the line to get his viewpoint on it.

MR. GRIFFON: I guess I was looking for one other hidden overhead there. You mentioned that the analysis of the Hiroshima data showed some superlinearity, and I wondered did they recommend a separate distribution for the DDREF value? You said Grogan incorporated that into their distribution. Did the Hiroshima researchers --

DR. HOFFMAN: No.

MR. GRIFFON: -- recommend any distribution?

DR. HOFFMAN: No, they just report their observations. They make no recommendations.

MR. GRIFFON: Can you give the reference for that? What reference, and what was their citation? Some superlinearity, or was it more specific?

DR. HOFFMAN: Well, I believe it's the most recent publication on cancer mortality by Preston and Pierce -- either Preston and Pierce or Pierce and Preston, 1996, *Radiation Research*. I think if you look in the back of your documentation of Charles' report that I think has been circulated to all of you, the exact citation's in there.

Yes, Gen.

DR. ROESSLER: I thought it was interesting you talked about the ability of IREP to deal with

additional sources of uncertainty. And I'm wondering on the thyroid, now that the Hanford Thyroid Disease Study -- do you feel like you're getting in a corner? -- now that the results of that study are final, will that make any impact on the adjustment of the geometric mean in IREP?

DR. HOFFMAN: I'm going to try to divorce my personal opinion on that subject with what I would consider a more direct answer, and the direct answer is that IREP is amenable to upgrades in the state of knowledge as the state of knowledge evolves. And I think the final Hanford Thyroid Disease Study has only been out for a matter of days. And I don't know about you, but I have not even had a chance to read it to know what effect that would have.

My personal opinion is I still don't think it has the power to sort out signal from the noise. And I think if one looks at the confidence intervals that would take into account uncertainty in dosimetry, especially shared sources of uncertainty and uncertainty that would be associated with what I call differential bias -- in other words, the potential to underestimate the high end of the distribution and overestimate

the low end of the distribution. You see those confidence intervals that clearly overlap risk coefficients in IREP. But I say that having seen the previous Hanford Thyroid Disease Study. I haven't look at this final version.

The bottom line is as the state of knowledge changes, IREP is amenable to updating. And one of the advantages in having it on the web is you can update it in one place and that update is available to the world, as opposed to putting it on CDs and having to generate thousands of new CDs every time there's an update.

DR. DEHART: Your comment just covered what I was going to say, that is the dynamic process of IREP over time. In that context, then, as epidemiological studies come forward, how are you validating and making adjustments?

DR. HOFFMAN: Well, our future role with IREP is uncertain, and so I can't answer that question. I can just say the design is that it's amenable to frequent updates. And each new epidemiological piece of information is a form of validation. And if it becomes clear that the upper bound of these uncertainty distributions are simply rewarding for the presence of lack of

knowledge, well, new information should justify a change.

Now of course the political difficulty is this, is what happens in the presence of lack of knowledge that a person today qualifies for compensation, and then as new knowledge comes forward the person is suddenly ineligible? That's outside the realm of our influence. That's your job, to deal with these really difficult situations whereby simply by rewarding for uncertainty that a person could be eligible for compensation today and not be eligible for compensation as the state of knowledge improves.

DR. ZIEMER: Tony.

DR. ANDRADE: I gather that if I were to ask you what was the real baseline baseline start for IREP, you would probably say the ICRP-60 risk coefficients insofar as calculating excess ERR, the excess risk -- no?

DR. HOFFMAN: I'm glad you said that. No. No, ICRP-60 is 1990. The real baseline baseline is the 1994 Thompson, et al. report and its associated datasets in radiation research.

But the National Cancer Institute made new analyses on that data, so you can't just get into

Thompson 1994 and map directly from that study onto what's in IREP. There have been -- and it's described in the write-up -- numerous re-analyses of age at time of exposure, time since exposure, attained age effects, gender effects in order to build in as much defensible specificity as is possible. And it probably could go on and on, but at some point you have to draw things to a close. And what you're seeing is the outcome of three years' worth of work.

DR. ANDRADE: Okay. Well, my point was going to be simply this, is that you've used information that has evolved tremendously since ICRP was put out, and even ICRP-60 attempted to use factors including gender, time at -- during the lifetime at which the person was exposed, age, that sort of thing.

And so what I wanted to do is just clarify or address a comment that was made yesterday, that apparently we in the health physics community have been trying to use only Japanese survival data to calculate these probabilities -- or risk coefficients, let's put it that way, let’s be more precise -- risk coefficients. And the answer to that is that that is not true. We have

used all sorts of studies, one of which, only one of which has been the Japanese survivor data. And I just wanted to emphasize that point for the audience here in general.

DR. HOFFMAN: I wish I could adopt your enthusiasm. The truth is that the bulk of this really is the Japanese survivors data. But the radon, the radon cohorts and the thyroid are exceptions to that. I think if there is a major -- a major upgrade to all of this would be to include within the uncertainty analysis other options from other studies, such as worker studies and looking at outcomes from those. But that will be the job of a committee with more resources than what was available to the committee that put this together.

DR. ANDRADE: Exactly. But for example, in the case of lung cancer, the radon data and the radon studies would heavily weigh into those risk coefficients.

DR. HOFFMAN: In this case lung cancer itself does come from Japanese survivors, as long as the exposure is coming from low LET radiation. But for radon exposure directly, the working level month being the source of exposure, then it

changes over to use radon cohorts. And the bulk of that is the uranium miners.

Well, if I might introduce the next speaker --

DR. ZIEMER: Yes, please.

DR. HOFFMAN: When we were invited to come, a person that I felt was absolutely essential to be here is the person responsible for, I think, one of the major contributions to IREP. And this contribution has been done under the sponsorship of NIOSH, and that is to address the risk of other radiation types other than high energy gammas. That was an assignment given to us, assignment that I charged Dr. David Kocher with.

Dr. David Kocher is a health physicist that's had 30 years experience at Oak Ridge National Laboratory. Some of you from the health physics community are well aware of his publications. We've had the privilege of having Dave work with us for over a year now at SENES Oak Ridge. And Dave does things the old-fashioned way -- that is, with overheads.

DR. KOCHER: Anybody remember lantern slides? That's sort of where I come from.

Owen gave a good introduction to my remarks

when he commented that we've been looking at issues of how different types of radiation differ in their effectiveness in causing cancers in humans. And we have looked at neutrons, alpha particles, photons of different energies, and electrons of different energies. We haven't yet gotten into some real exotic stuff like nuons and very high energy neutrons, things that probably aren't encountered everyday in the Department of Energy system, but who knows?

What is new and exciting about all of this, as far as I'm concerned? Well, these different effectivenesses have been taken into account in radiation protection for 40 years now. ICRP-2 had some assumptions about the effectiveness of alpha particles relative to gamma rays, and neutrons have been well known and studied, going back to the beginning of radiation biology. But what has never really been done in a broad scope before is to express these factors in terms of uncertainty.

In radiation protection you choose point values -- 20 for alpha particles, you're all familiar with this. But for purposes here of calculating the probability of causation of a

cancer in a real person who got a real dose, and if you want to express your state of knowledge, you must do this using uncertainty.

And there have been some limited efforts in other areas in the recent past -- for example, the Rocky Flats dose reconstruction did incorporate uncertainties in biological effectiveness of alpha particles from plutonium in that analysis. It has not yet been applied to real people. Tritium has been looked at from an uncertainty point of view in a limited context that Owen and Brian worked on for Berkeley Labs. But this is really the first time that I'm aware of that a broad approach to trying to capture uncertainty in a human health risk assessment has been done. So therefore we will be subject to lots of potshots, and deservedly so.

I know you all have read, from cover to cover, the 77-page report which was posted on the Internet not too long ago. That's an awful lot of stuff. And let me really tell you in 30 seconds what I tried to do there. I tried to disclose, as fully and completely as I could, the thought process we went through to try to develop uncertainty distributions for these different

factors. If you go into ICRP and try to discover how do they come up with 20 for alpha particles or whatever, complete silence -- absolute, complete silence.

So really the bulk of this 77-page current version of this report is I tried to explain what we did. What we did has a lot of weaknesses. It has some strengths. What I'm going to try to do today -- I don't want to go too much into a lot of technical detail here, because I know most of you aren't necessarily that interested in really the fine details. But your mother said you've got to eat your spinach every once in a while, so there will be a little bit of that. But what I really want to try to do is to give you a feeling of what we did. What were the sources of information that we had to develop uncertainty distributions for different radiation types? What were the judgments that we made to come up with our final answer? And what are the weaknesses, what are areas where I am absolutely sure that better work could be done?

And I'll try to point in those directions, because there are a couple of areas here where we really are looking -- we eagerly would like to

have positive feedback or helpful comments and suggestions from anyone. We are open to changes in any of this. But I will try to point out to you a few areas that I feel like particular attention could be paid to doing things better.

Well, there's an awful lot of information in the radiobiological literature on the biological effectiveness of different radiation types. RBE, that's the acronym in radiation biology that stands for relative biological effectiveness. But we have a new term, REF, radiation effectiveness factor, and it's explained in the report. But the short answer is that what we are coming up with is not RBEs, because RBE is what you get when you do a specific radiobiological experiment. And I can say, mercifully, that we don't have a lot of human data on what we're looking for. So we need a new word, and I'm glad that you all are using radiation effectiveness factor in your everyday lingo, because I certainly hope this term catches on.

But there's enough literature data out there that could fill this room, and we just -- there was no way to go back and review all this from scratch. So we depended very heavily on past

reviews and analysis of this wealth of data by various expert groups in this alphabet soup of organizations. Some of these you may not know. ICRU is the International Commission on Radiation Units. They're kind of like the ICRP. The NRPB is the national authority in Great Britain.

Our work has been through two rounds of external peer reviews, and we've incorporated a lot of comments that we got from experts in the field. And we have used the recent primary literature to some extent to fill out because a lot of these things are getting a little bit old. The NCRP report, for example, is from 1990, and there has been some work since then. But by and large, we relied on expert groups who know far more about radiation biology than I do to look through all this data and assess the experiments that are good from those that are not so good, and what did they think this meant in terms of RBEs, et cetera.

I'm not going to go through the equations in any detail, but I did want to show you how these things -- these quantities are used in actually calculating cancer risks. And I've got two pages of equations, and I'll really just show you one

equation to give you a sense of how this works.

The quantity we're trying to calculate over here is risk, and we express it in terms of excess -- well, it's just the excess relative risk, is what you want at the end. That's what goes into a calculation of PC, as Owen showed. You start with some estimate of absorbed dose, and here's the risk coefficient that you get from the atomic bomb survivor data. This is some kind of -- I call it an ERR per gray, some people call it an ERR per sievert. They're basically the same. This is high energy gamma rays that have a defined biological effectiveness of one.

And if you're going to -- in some of the equations, not always, this is adjusted by the DDREF that Owen talked about. This is a thing that has an uncertainty distribution with a central value somewhere between one and two. And I never remember what the central value is -- 1.6, something like that.

And then this REF is just a multiplier. It just adjusts for the effectiveness of the different radiation type. And basically all this means -- it's really a simple concept -– if you give a certain absorbed dose of gamma rays to a

mouse, and you give the same absorbed dose of neutrons to the same mice, you're going to see more cancers in the mice than you do -- from neutrons than you do from the gamma ray exposures. They have a different effectiveness in causing the response that you're looking for, and that effectiveness is captured in this REF. It's a very simple concept. So this just kind of shows you how they're used.

And I'm not going to go into the difference between high and low doses and dose rates. That's for the health physics aficionados on the committee to look at and see what you think about it. I realize that certain things are just too painful.

I'm going to skip -- well, Owen did mention this, and I'll show you again. For all solid tumors there's a linear dose response in the atomic bomb survivor data. But -- Gen, this is the answer to your question -- it's linear quadratic for leukemias, and this is what the data show. They show linear quadratic for leukemias, but they look linear for everything else. So that's the assumption that Charles Land made. And enough of that.

Now here's something -- half of this should be familiar to many of you. The column for ICRU may not be quite so familiar. But this is how biological effectiveness is taken into account in radiation protection today. And again, radiation protection is not about estimating real risks to real people from an actual exposure. That's not what radiation protection is about. Radiation protection is about controlling doses, period. So they have standard assumptions. A point estimate of 20 for alpha particles, 20 for neutrons of unknown energy -- and the ICRP has a function I'll show you later that accounts for the energy dependence of the neutron weighting factor -- one for all electrons, and one for all gamma rays.

Now as we go ahead, you'll probably be keeping score on how I'm doing relative to this curve, to this set of numbers. Well, our distributions for alpha particles will encompass this, and our distribution for fission neutrons will encompass this, but we will depart from these numbers here at the lower energies.

A question came up over here when Owen was talking about what have we done about the ICRP

assumptions as we got into this. We did not start with an assumption that these values were the correct -- were the best central estimates of anything. We looked at what the data told us. And if the ICRP numbers fell within our distributions, fine. If they didn't, well, that's the way the mop flops. That's all I can say. We did not assume that they had the right answer, mainly because they didn't really disclose where these numbers came from.

So a key point to remember here is we're applying subjective judgment to a lot of data, and we absolutely acknowledge that knowledgeable individuals could look at the same information we looked at and come to somewhat different conclusions. I don't think the conclusions could be radically different, but you could certainly -- there's a lot of judgment in here. And again, the whole purpose of my paper was to try to disclose our judgments as best we could, and to express where the weaknesses are. But we did not assume that ICRP had the right answer.

So I just want to go through the different radiation types that we looked at and give you a flavor for the kinds of data that we used and the

kind of judgments that we made. And I'm going to start with neutrons.

Historically, neutrons have been the radiations that have been the most studied of all. Back in the sixties and seventies and eighties there were a lot of data on RBEs and neutrons in all kinds of biological systems ranging from simple cells up to whole organisms, plants and animals, the whole nine yards. But there are data in mice that actually where tumors themselves were the end point. They actually measured tumor induction in mice exposed to neutrons compared with some reference radiation, either X-rays or high energy gamma rays. And as Owen mentioned, we use high energy gamma rays as our radiation that has a defined REF of one, because that's the conditions under which the A-bomb survivors were exposed.

And again, going to reviews of the literature, there was a lot of data on RBE for life-shortening and induction of specific cancers, and life-shortening in these mice is due almost entirely to cancer induction. There's very little else that's killing them. And you find a range of RBEs -– and I just give you these

numbers, you don't have to pay any particular attention to this -- and from this you can just derive some kind of distribution. And we're trying to make life simple, and we're trying to choose familiar distributions when they can be justified. And lognormal is one of the most familiar distributions in natural systems, especially when the data are highly variable. Where the range from the low end to the high end is fairly large, lognormal often describes what's going on.

And from this range of data, we just said there's a 95 percent chance that the REF in humans lies between 2 and 30. That's a fairly wide range. That's a range of 15. The central estimate here is at 7.7.

Now some of you are already maybe keeping score, and here we're saying a central estimate at 7.7, where the big boys say it should be up around 20. Well, something I didn't talk about is that this is an REF at high acute doses. It doesn't have a DDREF in it. So more or less you need to multiply this value by a factor of about two if you want to compare it with the number 20. And this is explained in excruciating detail in

the paper, but I don't want to talk about it here. So this number has to be multiplied roughly by a factor of two, and this for acute exposure only, so that's around 15 to 16, which is pretty close to 20. But there's a substantial range of 15 here between the lower and upper end of that confidence interval.

I felt like the situation for fission neutrons in solid tumors and leukemias is in pretty good shape, because there are animal data, data on whole animals with the cancers that we're interested in as the biological response that was being measured. But still there are problems that we talk about in the paper, about are the mice data relevant for humans? A human doesn't look like a mouse. And those of you who know anything about neutrons, this is a very complicated type of radiation in terms of how it interacts with tissue. You get all kinds of secondary radiations. And if you had a monoenergetic neutron incident on the skin of a mouse, the spectrum of radiations inside that mouse is going to be very different from the spectrum of radiations in a deep-lying organ of a human being.

And we really haven't done much with that, and that's an area where perhaps something could be done. We basically just said that the mice data apply to humans. But that's an area where I think, as this method gets fine-tuned as we go along, where something more could be done. It's quite possible, I think, that the mouse data tend to overestimate the biological effectiveness in humans rather than underestimate. So in a sense, if you want to claim do we have a bias, it's a little bit on the claimant-friendly side, I think. But this is a matter of science that could be worked out, and we could do more here.

This next slide is not in your package, but in case some of you have never seen what a lognormal distribution looks like before, this is the distribution that I described on the previous slide. When plotted on a linear scale -- this is REF on this scale, and here's probability on the vertical scale -- a lognormal distribution tends to be skewed to the left, and the 50th percentile is somewhere about here and the 95th is from 2 to 30. That's basically what a lognormal distribution looks like. And as this range gets bigger it gets more and more skewed to the left,

with a very long tail going out to the right. And of course, only 95 percent of the values are shown here. There are two and a half percent that lie out here, and there's another two and a half percent -- down to zero is show -- but there's two and a half percent of the values lie beyond the right-hand side of that curve. The beauty of lognormal distributions, they never go negative.

We did the same thing for leukemias, for both alpha particles and leukemias -- sorry, for both alpha particles and neutrons. There was convincing evidence from the literature that the biological effectiveness was different for leukemias and solid tumors. These are two entirely different types of cancers, so there's no reason that they have to be the same. And in general, RBEs for leukemias are less than RBEs for solid tumors, and we've incorporated that in what we did. We have separate distributions for leukemias and solid tumors for the high LET radiations. And again there are data on mice, and we went through, and it ranges from this to that, and we had another lognormal

distribution.

Now here, this is a number which you could directly compare with the ICRP, because this is at low doses and low dose rates. That's what this $_{L}$ stands for. In fact, almost all our distributions are at low doses and dose rates. The only one that isn't is the solid tumors and neutrons. And here the confidence interval we just said dose from 2 to 60. That's a range of 30, and the median is about 11. Well, 11 compared with 20, that's a factor of two. But remember, the ICRP is coming up with a single number that's supposed to cover everything, and if they had to pick a single number they would probably bias it toward the solid tumor numbers rather than leukemias to be safe. But who knows what the process is they went through, because they haven't told anybody.

Now one of the complications about neutrons -- and Owen mentioned this -- is that there's some data in the radiobiological literature, and there's a lot of calculations which show that the -- suggest that the biological effectiveness of neutrons is energy dependent. Now most of the experiments are done for fission neutrons, and

that's a spectrum of neutrons over a wide energy range. But by and large, most of those neutrons are in the energy from -- this is .1 MeV here up to about 2, is this break point. And the fission neutron experiments lay up here in the region of maximum biological effectiveness.

But there's calculations going back 30 years now, and a lot -- and some radiobiological studies which show that as you get away from this range from .1 to 2 MeV the biological effectiveness drops off in this direction, and as you go toward higher energies. And this is just a reflection of as the energy changes, you get a different mix of secondary radiations that are actually delivering the dose. That's what this is all about. Neutrons don't do anything by themselves. They cause dose only because of the secondary radiations they produce.

And this solid curve is the standard ICRP assumption that many of you are familiar with, that the value -– here’s 20 for .1 to 2 MeV. It drops by a factor of two out here down to 10 keV, another factor of two down to 5 at the lowest energies, and similar as you go up. But what really impressed me is kind of the database for

that step function curve. I don't know whether impressed is quite the right word. The data are sparse. Everybody used fission neutrons, and not too many people have studied neutrons of other energies in experiments. And I have two slides here that show, at least according to an NRPB review, really almost the entire data in this area.

Now here's one dataset. Here's the fission neutrons kind of up in here. Here's one dataset that maybe sort of shows what's going on that matches that other curve. But here's another one that it's okay up here, but there's a point way out here. And you can find other studies in the literature that don't really show much of a step function, like the ICRP said. Here's just one more example of the same thing. The open symbols, they kind of fall off as you go up here. But this, here's a dataset, who knows what that one's doing in terms of energy dependence.

So the point I want to make is that that nice little step function curve that the ICRP assumes today has a fairly shaky database in terms of the actual radiobiological information that goes into that. A lot of what goes into that is

theoretical calculation of how neutrons interact with tissue at different energies, and what are the secondary radiations they produce. But it's not really been verified experimentally. I wish -- I'm a humble physicist. I don't know much about this biology stuff. But really, no data on thermal neutrons. I guess that's a hard experiment. But we didn't find any data on thermal neutrons, which is often something of interest.

So what did we do about this in terms of the REF for different energy ranges? Here's where we get really into the idea of subjective states of knowledge distributions that Owen emphasized. What I'm going to show you next doesn't resemble anything that you would actually measure if you did the experiment. It's just to try to represent what do we know about the REF for neutrons of energies other than fission neutrons. And we assumed that these distributions should have three properties.

The first was that the REF should not be less than one, and this is a simple assumption that neutrons of any energy should not be biologically less effective than high energy gamma rays. High

energy gamma rays is our defined REF of one, so neutrons should not be less biologically effective than high energy gammas. That's assumption number one.

Assumption number two is we assumed the ICRP step function reduces the weighting factor for fission neutrons by either a factor of two or four as you step up or down in energy, and we assumed that the median of our distributions for fission neutrons should be reduced by about that amount. In other words, we assumed that the ICRP step function that I showed you more or less represents the energy distribution -- the energy dependence of REF.

But there's certainly uncertainty in that adjustment, as I showed you on those two plots of the data. The data are pretty shaky. So we reduced the upper confidence limit by an amount less than that to represent uncertainty in that adjustment. In other words, the uncertainty distribution is going to be broader at these other energies than it was for fission neutrons.

Now we started with a lognormal distribution for fission neutrons, which was already highly skewed to the left. And if you fix the lower

bound and lower the median by a certain amount, and lower the upper confidence limit by less than that, you're going to get a distribution that's more highly skewed to the left, and it's going to have a long tail. Here we tried to make life simple. We just fabricated a distribution that would have these properties but would look simple. Now this is obviously not a distribution that you would ever measure in an experiment, but it has the three properties that I showed on the previous slide.

This is just one example. This is a case where the median value is reduced by a factor of two compared with the distribution for fission neutrons, but the upper confidence limit was reduced by something less than a factor of two, around a factor of 1.7, 1.8, something like that. It's explained in detail in the report. And we just arbitrarily assumed that we would describe these distributions by what I call a piece-wise uniform distribution that had three pieces. It's uniform between one and some number, uniform between that number and another number, and then a third tail that goes way out here. And we just fixed the number of steps at three. And

furthermore, in every case we said there's going to be a 30 percent weight to this part, a 50 percent weight to this part, and a 20 percent weight to this part.

Now these judgments are obviously arbitrary. There's an infinite number of probability distributions that would meet the three conditions that I showed on the previous slide. And we just wanted to have something that was visually and conceptually fairly simple.

So all we have to do once we have these definitions is we just adjust these three numbers until we get the conditions that we wanted on the previous slide. And it's just -- it looks simple, but you would never measure anything like this. But this captures the state of knowledge about REF at these other energies, and the state of knowledge is not real good.

Okay, I'm going to move on to alpha particles. I think in general alpha particles is a radiation type for which what we have come up with would be most subject to adjustment by further input. There's a lot of uncertainty in what to do. A lot of uncertainty in what to do, and our judgments could be wrong, or they could

be not as good as they should be. And I want to try to indicate where the weak parts are.

Let's look first at solid tumors. Here again we're fairly fortunate in that there's a lot of data in various small mammals -- dogs, rats, mice -- looking at induction of bone and lung tumors by alpha-emitting radionuclides like plutonium and americium, a lot of data on RB and E systems, a lot of data on different kinds of responses in cell systems. And you find a wide range of RBEs, down from about 5 at the low end -- these are central estimates -- range from about 5 at the low end to somewhere in the range of 60 to 100 at the high end. And here again, just to keep life simple, we describe this range of values by a lognormal distribution where 95 percent of the values were in the interval from about 3 to 80, and the median here is 15.

Now here's an area -- and this is not in our report, but I'm going to put it out to you. It's possible that the median of this distribution is a bit too low, that we might actually be better off in this case coming up with some kind of a hybrid distribution that has this confidence interval, but has the median shifted up somewhat.

And if you just kind of look at -- if you just plot all the data, you get the impression that it possibly could be a little higher, but not by a great deal. But this is an area where I think as this work evolves we might want to look at this again. Of course, this is not the final answer. We have this inverse dose rate effect that hasn't been applied yet that I haven't talked about. So that's one area where we might do a little bit more. I think I'm pretty comfortable with the range here. There's just not very much beyond 80, and there's hardly anything, virtually nothing below 3.

Where we're really skating on thin ice -- and I think no one really knows what to do about this -- is the question of alpha particles and leukemia. What's the problem here? The good news, in a way, is that there are data in humans, possible data in humans for the effectiveness of alpha particles in causing leukemias. The problem with the available data is that they're contradictory, and that there's a lot of problems in the data themselves. And it's very, very hard to sort this out.

The essential problem with alpha particles

and leukemia is this: The question of how to estimate the dose to radiosensitive cells in bone marrow. The whole problem of dosimetry is highly uncertain, so it's very, very hard -- when you try to look at the various human studies it's very, very hard to sort out issues of dosimetry versus issues of biological effectiveness of alpha particles. And what we have attempted to do -- what I have attempted to do, I can't blame this on Owen or Iulian -- what I attempted to do was say, look, if the dosimetrists have a problem, go fix it. I'm not going to bury uncertainty in -- I'm not going to bury a problem with dosimetry in the REF. I want to try to assess what is the REF, assuming that the dosimetry is right. And if you have a dosimetry problem, go take care of it, but I'm not going to blame -- I'm not going to incorporate your dosimetry problem in an estimate of REF. But I'm sure we have done some of that, just because the data are all we have.

Now let me just briefly try to describe what the problem is and what we tried to do about it. There's a group of medical patients out there called the Thorotrast patients. These are people

that were given a special substance that contained thorium for medical treatment. And these people received fairly high doses of alpha particles to bone marrow. And these people, these patients were followed over time, and lo and behold, there were excess leukemias seen in these populations. And you could derive an estimate of leukemia risk in those patients. And by comparing the leukemia risk in those patients with leukemia risks in the A-bomb survivors, you could estimate an RBE for alpha particles in leukemias, and you get something that ranges from about 1 to 15.

Well, this is a good dataset in the sense that it's data on humans. It shows an effect. You could use it. But the problem here is that Thorotrast is a special chemical form. It's called a colloid. Colloids are kind of large globs of stuff that kind of remain suspended in a liquid medium. Milk is a colloid. Milk is a colloid. So what happens in the Thorotrast patients is that the thorium in this stuff remains suspended in bone marrow, and perhaps more or less irradiates the marrow uniformly. But radionuclides that DOE workers get exposed

to, they're not colloids. And they probably get deposited very quickly on the surfaces of bone, and in some cases then translocate into the bone volume. And of course alpha particles have a very short range in tissue or in matter. That's a fundamental problem here.

So the way that marrow is irradiated by the Thorotrast patients is very different from what you get from a DOE worker who is exposed to plutonium. So this dataset may have nothing to do with exposures of DOE workers. It doesn't describe the exposure pattern at all. So it's questionable whether you could really use this.

There are other groups of populations that were exposed to alpha particles, the radium dial painters being the example that people are most familiar with. These are a group of young women who received high doses of radium, and the data seemed to suggest -- well, there's been no observed excess of leukemias in the dial painters.

Now here again, there's a lot of problems with this study. What do you mean by no excess leukemias? I haven't yet seen a really good statistical distribution that showed a confidence

interval in a risk coefficient. People just tend to focus on a central estimate, and say I don't see anything. But there needs to be more work done in uncertainties in this population.

There's a group of medical patients exposed to radium 224. No excess leukemias, statistically significant excess leukemias seen in those populations.

Another problem with the dial painters is that leukemia is a disease that, if you're going to get it, it tends to come fairly early after a radiation exposure. And there are some serious questions about whether the early follow-up of the dial painters was sufficient to have actually caught the leukemias that they might have gotten. So there's a lot of problems in this dataset.

But if you take the standard ICRP dosimetry model for radium in bone, you would predict a substantial increase in leukemias in these populations where none is seen. Well, there are two ways you could interpret this. Either the RBE is very low, or there's a problem in dosimetry -- and I personally think that there's a problem in dosimetry, that we don't want to muck up our REF with that. But here's a dataset

that shows no effect.

A third source of information is data on neutrons. It's been widely understood for many years that neutrons and alpha particles are quite -- should be quite a bit alike in terms of their biological effectiveness. They're both high LET radiations. The calculations all show that the effectiveness should be more or less the same. So there are the data on the mouse studies that I showed you previously that could provide a marker for what the leukemia risk for alpha particles is.

So we have these different datasets, and here's an example, a clear example of applying just purely subjective judgment. We constructed a hybrid distribution where we gave different weights to these different pieces of evidence. The weights that we assigned are obviously somewhat arbitrary. And we've gotten feedback already -- you know, I wouldn't do it that way. And that kind of feedback is welcome, and we want more of it.

We gave, as indicated here, 50 percent weight to the data in the Thorotrast patients. Here again, we clearly are irradiating the right cells

in this group. So if the dosimetry model for the other alpha emitters was correct, this probably gives you some idea of what it ought to be.

We gave 25 percent weight to the fact that there's no excess leukemias in these other human populations. Here again, we did not allow the value to go below one, and we feel pretty confident that if the cells are being irradiated that alpha particles are at least as effective as high energy gammas in causing leukemia. If you take the data straight away, what EPA did here is they assigned a uniform distribution from zero to one, what they called the effective RBE. We said it really shouldn't be less than one, if the dosimetry's right.

And we gave a 25 percent weight to the distribution for fission neutrons. But I would say this is the weakest. This is the weakest distribution we came up with, just because the data are so contradictory and there are serious problems with dosimetry here.

Something else that I think I would do, if I revisit this again, is see what we might learn from animal studies about alpha particles and leukemia. And most of the animal studies have

focused on bone cancer and not leukemia, but what can we learn from the animal studies in regard to alpha particles and leukemia? I think there's a lot of work to be done here.

What does a distribution like this look like? I just gave you a couple of plots here. Here's our 25 percent weight at the value one gives you a spike, and the other two, which were lognormal distributions, give you something here with a very long tail going out. Distributions like this are sometimes a little easier to understand if you plot them in terms of a cumulative distribution. In other words, sort of integrate under that curve as you go from left to right. What this number is, this says here that 50 percent of the values are less than this number, 75 percent are less than this number, going on up, you have this long tail. This is a cumulative probability distribution rather than a frequency distribution.

Owen mentioned this inverse dose-rate effect. For both neutrons and alpha particles, there is weak evidence in animal studies and some weak evidence in the uranium miner data for radon of something that's been called the inverse dose-

rate effect. And what this means is -- suppose you did two experiments where you deliver the same total dose to two groups at different rates. One group gets the same -- a given dose at a fairly high dose rate, and the second group gets the same total dose but at a much lower dose rate. There's weak evidence that at the lower dose rate that the risk increases slightly. This is what Owen referred to as a superlinear response.

And the evidence is weak, and because the evidence is weak the correction that we applied for this is small. It's a small correction to the REFs for chronic exposure to neutrons and alpha particles. Well, all exposures to alpha particles are chronic, because these alpha emitters have fairly long half-lives. And I don't think we have anybody that was standing in an unshielded beam of a pulsed alpha source, and I don't think you're going to find that one very often. So alpha particles are always chronic. Neutrons in some cases certainly are.

And we used a discrete distribution where we gave most of the weight to the value one simply because the evidence that this effect actually

exists is quite weak. But there's some evidence that the inverse dose-rate effect could be as high as three, and we gave successively smaller weights going from one up to three. And on average, the correction was 40 percent for neutrons and 20 percent for alpha particles, fairly small. But it's in there. It's in there, and you can certainly change this. But you just don't see this in all studies.

My personal opinion is that it's already incorporated in the data for alpha particles because they are delivered chronically to begin with.

And if you apply the inverse dose-rate effect to the data for alpha particles in solid tumors you get something that's kind of lognormal, but it's even more skewed to the left than before. We started with a lognormal distribution from 3 to 60, I think it was -- 3 to 80, and adjusted by the inverse dose-rate effect. It now goes from 3.4 up to 100, and there are a few values that straggle out here beyond 100. And the median here is 18, and this is the number that you would compare with the standard ICRP assumption of 20, because again all exposures to alpha particles

are chronic.

So we're pretty close. But I think some justification could -- some thought could be given to whether we could start with something other than a lognormal distribution and maybe have this median go up a bit. But that's -- it's all judgment. It's all judgment. We just don't have any data.

I'm going to skip the next one, I think. Oh, here's our funky hybrid distribution for leukemias with the inverse dose-rate effect. This is the one where we had 25 percent weight for one, and then kind of a lognormal-looking distribution that tailed out here. Now when you apply this inverse dose-rate effect where almost all the weight gets at one, you have a spike here and very skewed to the left, but still numbers dribbling on out here to the high side. Here the median is four. This shows a clear difference between leukemias and solid tumors for alpha particles. Here the median was four. On the previous one it was 18.

And again, I think a lot of work needs to be done here. I can't tell you -- I don't have any confidence in my state of knowledge about what

alpha particles and leukemias are all about because the dosimetry problems are so severe. My gut feeling is that if you use the standard ICRP dosimetry models and you put this REF in those models, you're probably going to overestimate the leukemia risk. But again, I think if the dosimetrists have a problem they should go fix it, and we shouldn't bury their problems in the biological effectiveness factor. And if you have ideas about that, we welcome them. But that's my bias. I don't want to take their problems under my tent.

And this just shows the same thing in a cumulative distribution. It rises very steeply, and then this long tail.

So for neutrons and alpha particles, our distributions clearly encompass what the ICRP has done. We have a broad range of uncertainty, which is different.

Now when we get into photons, things change. Here's a curve that the ICRU published 15 years ago in a nice little report; it's only about 20 pages thick. This is a calculation of the quality factor for photons as a function of energy. Our reference radiation is cobalt-60

high energy gamma rays, which is out at this end of the curve. And you can see that in the calculation, the biological effectiveness goes up. And here in the range of X-rays, it's about twice as effective as high energy gamma rays.

And this report had an extensive discussion of the data that supported this conclusion. And the ICRU report said there is clear evidence that X-rays, 280 to 250 kVp X-rays are twice as effective as high energy gamma rays in causing stochastic effects, said that right there in the report. And this is a dataset and a conclusion that the ICRP has never adopted in anything they did. They have assumed that the biological effectiveness of photons of any energy from 50 electron volts up to 100 MeV is the same. And if we look in ICRP-60 for an explanation of this, they say we don't think it would be helpful to do anything different.

But here's a hint. The evidence is fairly compelling. This is a calculation, but there's a lot of data that say that X-rays are twice as effective as gamma rays. And I'm going to kind of go through the data and show you what we did about it. So here's a place where we part

company from ICRP.

Somewhat surprising to me, historically there were not that many experiments that were designed to study the biological effectiveness of lower energy X-rays. X-rays were one of the reference radiations that people often used to study neutrons. But there weren't a whole lot of studies that just looked at X-rays themselves as the radiation under study, but there was a lot of data on a particular kind of end point in a cell system. And you could say, well, what relevance does this have for induction of cancers in humans, and that's a fair comment.

DR. ZIEMER: Could I interrupt and ask you to clarify? Are you or they using the kVp value like -- is this --

DR. KOCHER: Okay --

DR. ZIEMER: In other words --

DR. KOCHER: This is a double dose of spinach.

DR. ZIEMER: Yeah, because the --

DR. KOCHER: The energies --

DR. ZIEMER: A 250 kVp X-ray spectrum has virtually no 250 kVp X-ray -- or kV X-rays in it.

DR. KOCHER: I will take the time to explain

why we assigned REF to this energy range. But Dr. Ziemer's point is this: If you have an X-ray tube that you apply this potential difference to, the energies of X-rays tend to be a lot lower than this --

DR. ZIEMER: About a third.

DR. KOCHER: -- by about a third. The peak of this -- you get a spectrum of X-rays, and the peak is in the 50 to 70 keV region. It depends on how it's filtered, and everybody does it different.

But yeah, what you're actually measuring here is the biological effectiveness of X-rays in the 50 to 70, 50 to 80 keV region. And I'll have to come back in a second as to why we assumed that those data apply in the energy range of 30 to 250. That's a good point.

These are the studies that the ICRU pointed to to say that there's a clear difference between X-rays and high energy gamma rays. And all the data ranges from a low of about 1.5 up to a high of -- central estimate of about 4, with fairly large uncertainty. And it was on the basis of this that the ICRU said that there's a clear difference of about a factor of two between these

low energy X-rays and high energy gamma rays.

Now here's another case -- initially we were just going to use this dataset. But as a result of one of the rounds of technical reviews and some further thinking on our own part, there are data in humans that can be used -- well, I'm skipping ahead. Let me go to this line here.

These are studies where the biological effectiveness of X-rays was studied directly. But there are other studies where you can infer the RBE for X-rays indirectly in the following way: You do a study of neutrons, you're trying to investigate the biological effectiveness of neutrons. And you do one set of measurements with high energy gamma rays as your reference radiation, and you do another set of measurements with X-rays as your reference radiation. The difference in RBE for those two studies gives you an indirect measure of RBE for the X-rays. Because you're going to see a difference in the two results for neutrons, and you can compare those two to infer what the RBE for X-rays was. And there's a lot of studies, and they're listed in nauseating detail in the report. And these again show a clear difference of about one and a

half to about three between X-rays and high energy gamma rays.

Now the third piece of information, there are data in humans that can be used to investigate the question of are X-rays biologically more effective in causing cancers in humans than high energy gamma rays, because you have the A-bomb survivors where children had their thyroids irradiated by high energy gamma rays, but there are all these studies of children who were given X-rays for various medical treatments. These are fairly large populations, and they've been studied. And so you can compare the thyroid cancer risks in the A-bomb survivors with the thyroid cancer risks in these other medical groups to infer an RBE. And unfortunately, the statistics are so poor in these data that the RBE that you infer ranges all over the map. You can get -- the 95 percent confidence interval ranges from an RBE of .2 up to 4, so you can get any number you want.

But what I think is kind of striking -- and they are even poorer datasets for other cancers, like breast cancer and colon cancer and a few others -- none of these datasets show a clear

difference between X-rays and gamma rays. By the same token, none of them show that there's not a difference. You can't infer anything from something like this about the effectiveness of X-rays relative to gamma rays. And what I think is kind of striking is that the central estimates tend to cluster near one to two. You don't ever find an outlier out there, which is kind of what you would expect on pure random grounds. So we took this as a dataset that we could apply some weight to.

So we have different sets of information, and as I did for alpha particles and leukemias, we just gave different weights to this information to come up with some kind of a hybrid distribution. And here we felt that the evidence from the non-human studies was just fairly compelling, so we gave a 75 percent weight to a distribution between one and five. It was a combination of the data on the dicentric chromosomes and all the indirect inferences -- there were about 10 or 15 of them that I listed in the report, all of which showed a clear effect -- so we gave a 75 percent weight to that.

But we gave a small but still substantial

weight to the possibility that there's no difference in humans. Again, the human data neither support nor refute any assumption you want to make. So we just said, well, maybe there's no difference. So we just assigned a 25 percent weight to the fact that there would be no difference. And the result is a 95 percent probability that it's somewhere between one and nearly five, and a median of about 1.9.

Now how did we take this data for a very limited range of X-ray energies and assume that it applies between 30 and 250 keV? Well, that goes back to this curve right here. We said we're going to trust the ICRU calculation where the radiation quality is flat over this entire energy range. And this mean here is at 30, roughly. And your guess is as good as mine as to where you want to draw the cut-off up here, but we put it at 250, which is about here. So we said everything in here is twice as effective, roughly, as out here, which is our reference radiation. So the 30 to 250 comes from assuming that this curve is right. But in fact, as Dr. Ziemer pointed out, all the data are in a fairly narrow range of energies down here, so it's an

inference from the calculation.

Well, the other thing that you see from this curve is as you go below 30 keV that the biological effectiveness starts to rise, and so below 30 keV we assumed that this curve would be more or less correct. We were not aware of any actual radiobiological data that investigated this low energy range, but we assumed that this curve was more or less correct in going below 30 keV. And because of that, we increased the previous distribution by a triangular distribution as we went below 30 keV. The mean of that rising curve is about 1.3. We didn't figure that it was worth actually having this be energy-dependent. We just applied the same distribution at any energy below 30 and gave it a triangular distribution. So that increases the biological effectiveness even more as you go below 30 keV.

And what you get when you do that -- here's our 25 percent weight at one, smeared out by a triangular distribution, and then the rest of the lognormal similarly smeared out. This is a probability distribution for the lowest energy photons, median of about 2.4. And there are lots

of calculations out there. This is an interesting problem for breast cancer in women, because they're starting to use really low energy X-rays to do this. And people have done a lot of calculations using different assumptions about radiation quality. And they come up with numbers that agree with the ICRU curve, but I don't know of any real data to describe this problem. If those of you in the medical community on this Board know about it, let me know.

So for photons we are certainly departing from the standard ICRP assumption that it's one for everything. So we have an increased effectiveness as we go below 250 keV, a further increase as we go below 30, but some weight given to values less than one. There is this little tail down here.

The last category is electrons. The only radiation that I know of that's been studied is tritium beta particles, because tritium is a radionuclide that's encountered often in the work place. It's been studied six ways from Sunday, as reviewed by Tore Straume and Carsten and documented in our report. The history of this in terms of radiation protection, I think, is quite

interesting.

What did ICRP do 40 years ago, Paul? Do you remember this?

DR. ZIEMER: I can't remember back 40 years.

(Laughter)

DR. KOCHER: Well, I was in high school, so I can't be expected -- anyhow, in ICRP Publication 2, the exposure limits for tritium incorporated an RBE of 1.7. This is 1960, so this phenomenon was known. But that increase -- this was the famous N factor in the equation H equals DQN. I'm really digging deep into ancient history here. This N factor was -- the ICRP had was to account for anything else that you wanted to put in the equation. It went from absorbed dose to dose equivalent. And they assumed N equals 1.7 for tritium beta particles back in 1960. Well, that was dropped beginning in publication 26, and it's still not there. So this has a history of being used, but it's not used today. ICRP today says the biological effectiveness of tritium beta particles is one.

Well, you could argue this till the cows come home. There's all kinds of data on various kinds of biological systems that says it's not one, and

this has been written about by many different people. No data on cancer induction in humans, so who knows what the story really is. But we said there's all this data in various biological systems; we ought to use it. There's probably 20 or 30 good experiments out there that show a clear increase in biological effectiveness for these very low energy electrons.

The RBE's range from about one to two at the low end up to about six at the high end, and we've excluded these really unusual chemical forms of things that get bound to DNA and don't really mimic what tritiated water would do in the human body. But still you get up to about six. And here again, the standard ol' lognormal distribution from a low of about 1.2 up to about 5, median of about 2.4; 2.3 is a number that you'll find in ancient literature in some cases. So this is a clear effect that the ICRP doesn't have in their model.

One of the problems here, of course, is that these energies of beta particles are very low; 4.7 keV, I think, is the average energy of that spectrum, and the endpoint of that spectrum is less than 15 keV. So these are very, very low

energy electrons, but they show a clear effect. And you're going to have tritium exposures in your claimants, that's for sure.

Well, at that point we kind of went off the deep end, and here's where I don't really -- I won't give you an extra dose of spinach on this one. But we just wondered, these energies of tritium beta particles are so low, is there some intermediate energy electron, range of intermediate energy electrons where the biological effectiveness would be lower than for tritium beta particles, but would still be greater than one? And we went through a long song and dance -- and it's in the report -- that for energies from about 15 to 60 keV there ought to be an increase, just based on physical grounds, looking at what are the radiations that electrons produce when they interact with matter, and going back to the ICRU curve for photons. But I won't take time to do that here.

But if the Board members who are interested in this problem want to review what I have in the report and comment on it I'd appreciate it, and I think NIOSH would, too. I don't think you're going to encounter a lot of cases where

intermediate energy electrons, say between 50 and 60 keV, are important. Carbon 14 is the only one that I know of that falls in that group, and I don't really know what kind of exposures to carbon 14 you're going to have out there. But we haven't done anything about that.

The other thing that we did not touch is this whole question of these really low energy Auger-emitting radionuclides, and these are electron energies that are often a keV or thereabouts or less. And sometimes those radionuclides get incorporated directly into DNA, so the RBE can be huge. But that's a special problem that we have ducked, and I think rightly so. If you think somebody was exposed to Auger-emitting radionuclides in the work place and they were incorporated into DNA, you really need to look at that as a special case.

Okay, let me just try to sum up here what we have done, just a kind of two-page summary of the different radiation types and what we developed.

Photons is a case where we clearly have departed from the standard ICRP assumption. We have separate distributions of an REF that are greater than one, and entered one distribution

for energies less than 30 keV and another for energies between 30 and 250. This distribution is based on data for X-rays, most of whose energies are in the 50 to 80 keV region, combined with the ICRU curve which says that radiation quality should be flat between about 30 and 250. Applies to all cancers equally.

Electrons, we have just a single distribution for tritium beta particles, for reasons that are explained in the document, we assume applies out to energies of 15 keV, but nothing in the intermediate energy range. That's something that could come in the future, I think. Again, applies to all cancers.

What's really nice, I think, that helps kind of tie this all together, the distribution for the tritium beta particles is essentially identical to the distribution for the lowest energy photons. Which if you know about the physics of how photons interact with matter, this is as it should be. Less than 30 keV photons, the dose is delivered by electrons whose energy is 15 keV or less. So this is really nice. The radiobiological data and the calculations have a nice story that ties together, so I'm pretty

confident about this.

For alpha particles we have separate distributions for leukemias and solid tumors, again based on the evidence which says that for high LET radiations the difference in effectiveness does depend on whether you have this kind of cancer or this kind of cancer. Again, I think that the shakiest part of our entire analysis is alpha particles and leukemias. And I really welcome comments about what we might do about this.

These distributions are independent of energy. The good news about radioactive decay is that the range of alpha particle energies is very limited. It's about four to eight MeV is all you get.

And we apply an inverse dose-rate effect in all cases. All exposures to alpha particles are assumed to be chronic. And again, the central estimate here at the end of the day was about 18, which is more or less 20, but it's a broad range of values. Again, you have to think about uncertainty, not just where the central estimate lies, and there's a lot of uncertainty in these REFs.

And lastly, for neutrons, again we distinguish between leukemias and solid tumors; and furthermore, we have an energy-dependent REF. We have these five energy bins as defined by ICRP. So we have three sets of distributions, each for the two different types of cancer. And we have a correction for the inverse dose-rate effect that would be applied only in cases of chronic exposure to neutrons.

Well, after that spinach you can have some chocolate ice cream for lunch, I guess. You've got to balance the diet here. I'm sorry about that, but I really didn't know how to talk about this without making it painful.

DR. ZIEMER: Thank you very much. An extremely interesting approach that's been used to what clearly would be a difficult problem if point values were used on all of these things.

DR. KOCHER: Yeah, I might comment. The atomic veterans' dose reconstructions haven't done any of this. Of course, the presumption was that they don't have a lot of problems with alpha particles and neutrons, but of course they do have some. The veterans got some neutrons, and some veterans got some plutonium. But they have

basically in that work assumed point estimates as developed by the protection authorities, so this is breaking new ground.

DR. ZIEMER: And it's taking into consideration a wide variety of studies, some of which appear to us now to conflict in terms of what they tell us.

DR. KOCHER: Yes.

DR. ZIEMER: So you've given some weight to --

DR. KOCHER: And there were always questions about how to apply data in different biological systems to humans. This is really in the realm of what do you do. That's a problem for neutrons, could be a problem for alpha particles. The dicentric chromosome aberrations, is that relevant for induction of cancer in humans or not? I don't know. We've gotten feedback both ways as to whether those datasets are useful. But we tried -- again, we tried to be honest about what we did, warts and all, warts and all.

DR. ZIEMER: And Owen, we appreciate the comment, a sort of correction that we have assumed that you built in biases. Actually those biases come, in terms of application to

compensation, come in terms of where you draw the cut-off, and that's more of a political/legal issue. So I think we're seeing at least an attempt here to be sort of neutral on how you do this.

DR. KOCHER: Yes, sir, I --

DR. ZIEMER: And let the science try to speak for itself.

DR. KOCHER: Exactly. That's exactly what I did. And the science is imperfect, there's no question about it. But we did not try to start out -- I did not try to start out with a certain bias as to what we should do, just let the data speak to us and see what we get.

DR. ZIEMER: Well, let's take a couple of minutes here for additional questions, then we need to take a break. Yeah, Gen.

DR. ROESSLER: Well, David, that was wonderful. I read your report on the airplane, and I wasn't even tempted to look at my novel. It was so interesting and so refreshing to see --

DR. KOCHER: Are you having trouble sleeping at night?

(Laughter)

DR. ROESSLER: No, well, except thinking

about a few things here. But I think the science, the degree to which you've applied science, really should be applauded. And the honesty with which you talk about things, because I was going to really nag at you about the leukemias and alpha particles.

DR. KOCHER: Please.

DR. ROESSLER: Well, you already -- there's nothing left, because you already admitted the weak points. And I guess the one thing that maybe isn't quite reflected correctly in your paper is when you put that 50 percent weight on the Thorotrast patients, it seems as though it all came from that one paper, the Hunacek and Kathren. But in fact, it really -- there's more --

DR. KOCHER: They reviewed -- they did a review of the other studies as part of their work, is where that comes from.

DR. ROESSLER: Yeah, so it's really not based just on those two autopsies, but --

DR. KOCHER: No.

DR. ROESSLER: -- the rest -- yeah. And I think maybe in the way the paper's written, it implies that it was just that one.

DR. KOCHER: Yeah, I need to make it clear that when we used that paper that I was using information that they got from all the previous studies.

DR. ROESSLER: Yeah, I think that would help.

DR. KOCHER: They were really the ones that pointed out the uncertainties in dosimetry in the other studies. And that's where the range in values comes from, is the difficulty in estimating dose. But yes, I will do that.

DR. ROESSLER: That's my only comment.

DR. ZIEMER: Other comments? It's the point at which the desire for a break overcomes the desire to --

DR. HOFFMAN: Just a suggestion, that is definitely have a break now, after which there's a discussion period?

DR. ZIEMER: Yes, we're coming back.

DR. HOFFMAN: Much of what Brian Thomas is scheduled to present leads right into discussion, because this next rather brief presentation is an attempt to sum it up. And the bottom line is two individuals with the same disease and the same dose don't necessarily get the same probability of causation.

DR. ZIEMER: That’s right, we do have to hear from Brian yet. But I think we're close enough to the hour, and there's enough squirming going on, to necessitate a break.

(Whereupon, a break was taken at 10:21 a.m.)

- - -

DR. ZIEMER: Before our discussion period we're going to hear from Brian Thomas.

Brian, if you're set, let's go.

MR. THOMAS: Now I'm sure everyone had a good time so far with the previous presentations, and what I'm going to do is just run through a real quick PowerPoint presentation that I've prepared that has two or three case studies in it.

Then we're going to get right into the model, and I have some bad news about the model, and then some accompanying good news. The bad news is that the Internet server that houses NIOSH-IREP is not accessible this morning, for one reason or another. We -- wonderful, we hear. We have some people working on that, because there are some things that we would like to show you that we’ve just added in the past week, and that's under the view model details button on the web.

So in the event that we don't get to access that web site today, next time you get on it look down at the bottom of that main screen. There's a button that says “View Model Details.” You can access lots more details now than you could just two or three weeks ago. And there's even some additional calculation buttons under the view model details now that will show you the exact original ERR per sievert value that was used for the case you're running. And then you can see the ERR per sievert after it's been adjusted for the errors in dosimetry, after the values have been transferred to the U.S. population, and then after they've been adjusted by the DDREF, and then the final. So all of those are there as buttons you can click and calculate.

Probably what we'll do today, once I run through this real brief PowerPoint talk, is we'll get right into the source code, and I'll show you kind of how it's laid out. It's not as user-friendly for it to give you a copy. It'd be a little harder for you to browse through than it would be to run it on the web. But we'll go through some of that. If there's questions that come up, we'll immediately be able to address

those within the model.

So I'm going to start out by just discussing some of the required model inputs. You guys are extremely familiar with this, but I at least have a slide that will touch on them. I'm going to show you some results from two or three case studies that we've come up with. And the purpose of this entire talk is just to show you that two people that were exposed the same way might not have the same probability of causation.

And just a note about the results that I'm going to be showing today, the slides up here were done with 1,000 iterations. And if you guys have read the rules, the Department of Labor are going to be using 2,000 iterations for all their runs.

The inputs for the personal information include the individual's gender, their year of birth, the year that they were diagnosed with a particular cancer. Then you'll need to select from a pull-down menu a cancer model. There are 30 cancer models included in NIOSH-IREP, and there's even a category called other and ill-defined sites. So if someone has a cancer that's not included with one of those models, that would

be the model that would be used. A couple of other things that need to be entered, if the individual has lung cancer, the smoking history needs to be selected. If the individual has skin cancer, they need to select the ethnic origin.

The exposure to be entered, this will be done by the people who do the dose reconstruction from NIOSH. All these things will be entered: The number of exposures that an individual had -- this could be multiple exposures in one year, some acute exposures that a person had; could represent one exposure per year, which would be a chronic exposure over an entire year, and so you could have several of those; the year of each exposure; the exposure rate -- whether they got the dose acutely just in a short period of time, or whether they got it over a long period of time; the radiation type, which is what David Kocher just went into; and of course the organ dose.

Now some of the advanced features. Owen touched a little bit on the user-defined uncertainty distribution already. Also, the simulation sample size can be edited. By default, the Department of Labor will be doing

2,000, but anyone else looking at the model on the web, you can pre-select that, any value you'd like. Same thing with the random number seed, and that simply is just a value which the Monte Carlo simulations use as a starting point.

So the main question is will two individuals who receive the same dose have the same probability of developing cancer? Here's a case. This is a female -- there's actually going to be two cases. Age at exposure for the first female, she's 20 years old. She gets cancer when she's 50. Liver cancer, one exposure to chronic photons, energy range 30 to 250 keV, and I've just entered a constant dose of ten centisieverts.

And what you see in the first column here is the first individual. This is the one that was exposed at age 20, and this is the individual exposed at age 40. And so what this shows you is the dependence on age at exposure. You can see that the person who was exposed at a younger age would qualify under the current regulations, and the person who was exposed at an older age would not.

I have a case here, just to show you a little

bit how smoking history affects the probability of causation. We have a male exposed at age 20, diagnosed with lung cancer at age 50. Case 2A, he never smoked, case 2B, he smoked one to two packs per day. And I just put a dose in here of 50 centisieverts. I selected the dose in a way that the 99th percentile would be at or around the 50 percent. So you see the person who never smoked has the higher probability of causation than the person who did smoke.

And here's an example just to show the time since exposure effect, the time between when they're exposed and when they're diagnosed. And so what we have here is an individual exposed at age 20. One of them gets cancer at age 25, the other at age 35. This is lung cancer, and neither individual has smoked, 50 centisieverts. And so what you see here is that the person who got the cancer earlier has a lower probability of causation. And so immediately you think, well, that's kind of weird, but not really. With all cancers, as you know, there's a latency effect. And so if I get exposed today and get cancer tomorrow, that's not really practical. It takes time for those cancer cells to develop.

And there is an S-shaped curve then in NIOSH-IREP to account for this. It doesn't just go five years and then have a steep incline there. It's an S-shaped curve. And so there is still some probability that a person who gets the cancer five years later is -- there's still some probability that that exposure caused their radiation, but not as likely as someone who got the cancer 15 years later from the same exposure.

And so normally at this point what I was planning on doing is click this button, and it would take us right on line and we'd run a few more examples. I don't know if you guys have been on line recently, but one of the neat advancements that we've added to this thing since we traveled around to the Department of Labor sites in April is that right on the front screen there are two buttons now instead of just one. The Department of Labor claims examiners had expressed an interest in reducing the number of mouse clicks that it took to process a claim.

And so what we've done is right on that front page we've provided the option. They can -- well, an individual using the code can click on the first button, and that will take you right

into the input screen. You can manually input everything. Or you can click on the second button, and what that will allow the claims examiners to do is to use a pre-formatted input file prepared by NIOSH. They'll just locate it on their hard drive, upload it. All the fields will be pre-selected for them, so it reduces the possibility of errors in entering it more than once.

So what we're going to do at this point -- so you saw with the slides my conclusions that two people can have a different probability of causation for the same dose. So now we're going to get right into the model, and I'm going to show you just a little bit in here -- I might run one example, and then we'll start with some questions and run some specific examples.

Now when we first began working with the National Cancer Institute -- do we already have a question, before I get started?

MR. GRIFFON: Yeah, just one question.

MR. THOMAS: Sure, go ahead.

MR. GRIFFON: This model you're running right now, it is Version 5.2, and it's running in Analytica. Is this -- we've been told that this

new version of IREP isn't available on CD, and it looks like this might be. This is something the Board has asked for for review purposes.

MR. THOMAS: I stayed awake late last night cleaning this thing up to be able to show you just in case, and it still would require some time to clean up a little more. And we can have some discussions about how feasible that would be. I think the primary concern with spreading a lot of CD versions around would be that -- well, let me start by saying the reason that we went to the web was two-fold.

First of all, almost everyone is familiar with a web browser, and they can navigate around with the little finger and click back and forth. Most people aren't that familiar with the Analytica programming platform, and so it's a little harder to navigate around in there. So that's one reason we went to the web-based approach.

The other reason is that as updates occur, it's much easier to change it once on one server computer, and then everyone accessing it from that day on is getting the current version. So the fear is that we would float a lot of CD

versions around, the model gets updated, and then someone would run one of the CD versions and get a different answer than what comes on line. So perhaps there's a way to release a CD that's just for review purposes, never to be intended to process claims with or to compare to what's on line.

DR. ANDERSON: Self-destruct.

MR. THOMAS: Self-destruct in five days, okay.

DR. ANDERSON: Like all that test software you can get off the --

MR. THOMAS: Exactly, yeah. Okay.

So what I'm going to do is -- yes, we are in software called Analytica. When we began working with the National Cancer Institute we chose Analytica because when presenting to the public it's really nice to be able to show diagrams and things like that as opposed to trying to show them some C code or Fortran code, or even Excel is really hard to go through that with the public. And this does the same calculations, and deals a lot easier with arrays of data. And so we chose Analytica for that reason. It includes uncertainty analysis software right in it, so

it's really nice. And we did release a CD version, Version 2.1, for the NAS review committee to have. And overwhelming comments were it's too hard for them to navigate through, and so that just again pushed us to go towards the web version.

And it's not going to look exactly like what you're used to on the web, but still has the same inputs. Just to let you know how this works is this program is housed on a server computer. Every time you log on to the web, enter all your inputs, and click calculate it is submitting those inputs into the server, opening a copy of this software, running it, and then submitting the answers back to your web page. So every calculation is done live. A lot of times what you see on the web is a calculator, but it's just look-up tables. This thing is done live every time -- 2,000 iterations, 10,000 iterations, whatever you choose.

So this is our main input screen that we've created in Analytica. Notice there are quite a few more pieces of personal information to be entered on the web version, or that you can enter on the web version. Those are programmed in the

HTML. They don't even need to call out here, because it's things like the claimant's Social Security number and those sorts of things that don't need to be passed across the web. They can just stay right on your machine.

And so -- but you can see a pull-down menu for gender; the birth year, you just type it in; the year of diagnosis; you select from the type of cancers. On this version the ethnic origin I have right on the screen. On the web version it's down one level; there's one more button to press to get to that. The lung cancer entries are here. This is where you would enter things like the smoking history, the radon exposures.

Advanced features would include the user-defined uncertainty distribution, and on the web there's an advanced features button which -- that's also where you would change the number of iterations or the simulation sample size and the random number seed.

Here in this step three, enter exposure information, this is where you would first of all type the number of exposures, and then based on the number of exposures you type there that's how many doses will be used from this table. And so

what we have done is -- this is one of the things that's sort of confusing about this version. When we first created it, it would create -- it was sort of an interactive table. Depending on the number of exposures you typed right on the front, it would create only one column for only one exposure, you type it in and go on.

What we've done is we have allowed up to 200 exposures from the web. So the web version works just like that. You type in two exposures, you're going to get a place to type in two doses and all the corresponding information. But in this version, what you have to realize is that only the first column is going to be used in the calculation because I only had one on the previous screen. So if I had had ten there, it'll use the first ten columns of data.

Now another thing that's not as friendly in this version is that you need to physically type in the distribution to be used. It's not in a pull-down menu like on the web, so you have to know the spelling and you have to capitalize the first letter. And we have three parameters to define. This is just like on the web, so the first number would be for a lognormal, the

geometric mean. And there's a lot of help right on the web site if you click, and it'll tell you what to type in for each distribution.

Now the exposure rate is either a lower case C for chronic or a lower case A for acute. On the web it's a pull-down menu between acute and chronic. Radiation type, there are eleven different radiation types that you can choose from. Again, on the web it's a pull-down menu, and here you have to know that E-1 stands for electrons, energies less than 50 keV. So if something like this ever did get distributed, we'd need to put a little help file right beside that to tell exactly what those energies are so you can play with the different ones. I've made myself a little list, so if we go in and play with them today, we're all set.

So the one example I'm going to run first, it's for a male born in 1900 -- and the reason I picked 1900 is because it's easy to add 30 and 50 or whatever to -- so they're born in 1900. They're exposed in 1930, so they're 30 years old. We're going to define their dose as a lognormal distribution with a geometric mean of 20 centisieverts and a geometric standard deviation

of 1.4, which is about a factor of two. This person was exposed to a chronic dose of high energy photons. This is energies greater than 250 keV. And they got cancer, they got liver cancer, in 1950.

So let's run NIOSH-IREP. And you notice I have two buttons here. One is this table of results. All it is is just the percentiles, the 1st through the 99th percentiles. The other one has a little bit more information in it, summary, it'll list their cancer type and those sorts of things, the birth year and year of diagnosis. Okay, so we see that this individual clearly qualified for what I entered. So that's how the results look here.

If you remember, on the web you get a really nice page that you can either save electronically or print out that has every piece of information that went into the run, including simulation sample size, the random number seed, all the exposure information, so that years from now you could take that sheet of paper and rerun the model and get exactly the same result.

Now it just turns out that this projector is the same projector that we own at our office, so

I know that it has this feature where it will let us enlarge, if I aim it right at it, and you can see those results. I apologize for those of you in the back. I didn't think to do that earlier.

So again, the 99th percentile is what we're concerned about for compensation purposes.

Okay, so that's an example that kind of shows you how this Analytica version works. Let me show you one more piece of information that is really cool, and this is also available on the web just as tables. There's a button down at the very bottom called intermediate results or -- I can't remember the exact wording, but it's more results that you can go in and see the excess relative risk that was calculated, and you can see the breakdown of the contribution to variance.

So what I have here -- and I apologize, because I know that at least one person has complained that on the web we used to have these pie charts like this, and I just created these in a little picture editor program just to show that it's broken into three pieces. This doesn't -- this is not intended to show which one is -- they're all equal size. But when you click this

little calculation button, you're going to get a table that is live that has to do with this exact case we just looked at.

Now what you see at the very top -- there's really no need for us to look at this one because we have sources other than radon. If we had had radon sources and we had had some user-defined additional uncertainty, then this would be broken into three components. When we click it now, it's only broken into one component; 100 percent of it goes to the excess relative risk, sources other than radon. So you can see the little arrow that goes across here. If we had had radon sources, we could go here and see the breakdown of the ERR for radon. Since we don't, we're going to go to the left, and we're going to look at a breakdown of everything that it takes to calculate the excess relative risk.

One component is dose, and you'll remember we had some small uncertainty on the dose; the RBE, which has now been updated to be REF; and then the adjusted ERR per sievert. Now the word “adjusted” just simply means that it's been through all the adjustments now. This is not looking at the original ERR per sievert. This is

including all the uncertainty for the DDREF, for the transfer to the U.S. populations, for bias and uncertainty with everything else.

Okay. So then let's go and look at that. And what you see, that the organ dose plays a little bit into it. So the organ dose plays a little bit into the uncertainty because it had a GSD of about 1.4.

But you can see that the ERR per sievert dominates the uncertainty here. So let's zoom out, and let's go find out -- let's look at a breakdown now of the adjusted ERR per sievert. So what you see in this list is the original ERR per sievert. This is what came straight from the -- this just includes the statistics on the Japanese survivor data.

Errors in dosimetry accounts for a very small amount of the uncertainty. Transfer to the U.S. population in this case is the largest uncertainty, and that has to do with the backgrounds, it has to do with whether they use an additive or a multiplicative approach when we use the Japanese data for U.S. population. This is your DDREF that Owen went into and showed you the distribution for. You can see that it

affects about 23 percent. And again, this is not 23 percent of the total uncertainty. This is 23 percent of that 80-some percent that we looked at before. So it's 23 percent of this piece, which was 80 percent of the total.

Now of course this lung -- adjustment for smoking doesn't play into this because we're looking at liver cancer. On the web when you click intermediate results, it'll bring up separate tables for lung so you won't see that blank line, because that might confuse someone if it says lung cancer and they know they selected liver.

So that's a really nice tool for analyzing like what you guys want to do, to look through the model.

Okay, what's next? Any questions? What do we want to look at?

DR. HOFFMAN: Brian, last evening when we just arrived, I think it was Rich Miller cornered us and said he really doesn't like what we've done through the DDREF. He says that it isn't really conclusive that DDREF is absolutely linear, and therefore we should use 1.0 and not this 20 distribution that we've put in. Well,

now that Brian has pulled up the source code, go in and change the DDREF to 1.0 and see what the difference would be. Show them the original calculations that we have here, and then replace the distribution with just simply 1.0 and show them what the difference would be.

MR. THOMAS: I'm jotting down some numbers.

DR. HOFFMAN: Yeah, here it's -- you'll have to memorize it -- the 99th percentile, it falls at 50.8, and 50th percentile is at 12.6.

MR. THOMAS: So what we've done on the web version under view model details is just taken screen shots of each of these screens that I'm going to go through. This is the screen that I was mentioning earlier. Now there's calculation buttons -- there's actually a link which will show up right here on the page. You click that, and it'll bring you to another web page that will have all the buttons on top of each other. You can just click each one and see the adjustments, see what effect the adjustments have.

So we are going to go right into this DDREF, and instead of using a distribution we're going to replace all this -- I'm going to cut it so I can paste it back in a moment. Don't anyone

worry, this isn't the official one that's on -- this is just -- this is only my copy, don't worry.

(Laughter)

MR. THOMAS: Okay. So we've changed the DDREF, and I'm going to click run here to show you that one, that's what it's going to use now for the DDREF. So we'll go right back to the front page, put calculate, see what difference it makes.

Well, it's not exactly the same number, and you can see -- remember we had about 13 or 14 for the midpoint, now we have 19. And the 99th percentile used to be 51, now we have 55. And this is based on 2,000 iterations. So it makes some small difference, which we saw previously when we looked at those pie charts. We saw that it did have some effect on the overall uncertainty, but it's not a significant source of uncertainty.

DR. HOFFMAN: The other thing to show there is by changing the DDREF, the midpoint comes up almost a factor of two, but at the 99th percentile --

MR. THOMAS: Well, it was 13 and -- well,

okay, if you round down to ten or up to 20 --

DR. HOFFMAN: But the 99th percentile is just a few percentage points.

DR. ZIEMER: Let's see if there are additional questions or comments. Anything you'd like demonstrated here, or varied or massaged?

Larry.

MR. ELLIOTT: Brian --

MR. THOMAS: Yes.

MR. ELLIOTT: -- on the web version from the early Version 2.1 Analytica that was sent out as a disk, in that 2.1 version there was the ability to look at the risk coefficients in the models. And we've had some concerns and comments that in the web version that's been up lately we weren't showing that. And there's good reason for that, that that was based on NCI's release of their documentation and what we had adapted from them. But now, as of today, the risk coefficients are viewable and available. Correct?

MR. THOMAS: Yes. Now that's a good point, Larry.

MR. ELLIOTT: If we can get the server up.

MR. THOMAS: Yes, exactly. Larry, that's a good point, and perhaps what I could do is take a

moment just to show you, or maybe those of you who have not browsed through a CD version, where those things are, and kind of how they're used in NIOSH-IREP.

What you'll have access to on the web, those five buttons that I discussed, one of -- actually one of the buttons will be before any truncations are made. So for cancers like uterus, where there's a negative dose response in some cases, the negative values are preserved. They're there. You can see them. The very next step truncates everything at zero, because we won't use the negative values in the calculation. So you'll see both of those buttons, and it'll be for the case that you have selected on the front screen. So if you wanted to look at a different cancer type just select a different cancer on your pull-down menu, and go right back and click calculate and that'll let you see any of those coefficients.

So we're going to go right into the original ERR per sievert data, and these are actually the nodes that get referenced from the web, so it calls out and uses those. This ERR per sievert database is actually a separate Analytica file.

And we had toyed with the idea of putting these things into an Access database and hitting it. It might even make it a little more efficient.

If you've played with the web version, let's say two months ago versus last week, you see a significant speed increase. It used to take somewhere around -- just for a really simple case it would take somewhere around 10 to 15 seconds to get your answer back. For a very complex case it would take minutes to an hour to get back. This is someone who might have been exposed to 100 different exposures, three exposures per year for 30 years. So it's probably not that uncommon.

So for that reason we went into the model, and we ran some diagnostics on it and found out where the roadblocks were, and we tried to alleviate as many of those as possible. And so now, after you do the very first run on the web, what that does is establishes the connection. So that one's still going to take anywhere from five to ten seconds. After that it's almost instantaneous. As soon as you click the button -- and I don't know how this all works -- but it sends it across the line and right back to you

just really, really fast.

So anyway, I digressed from talking about Access. These are in a separate file, and what we've done is created some different groups. There's a PDF file you can download right from the web. If you click on this node on the web, it'll give you the option to download a PDF file that discusses these different answer groupings, and it shows you all the elaborate equations that went into those.

Now Charles Land did all the statistical analysis on this data, and he sent us a list of about 15 percentiles, ranging from the 1st to the 99th, that described the distribution that he felt best represented the Japanese data for all these cancer types. What we have done is taken that list of 15 and done just one more step of analysis, and instead of having only 15 values to describe it we've done some cubic spline interpolation, and what that has done for us is created 100 values that we can sample from as opposed to just the 15. And so what you will see, if you look at any one of those cancers, is a list of 101, actually, 101 values, because we had to have a midpoint, and these are in

increasing order.

Yes.

MR. GRIFFON: I should say we won't see this on the web, am I correct or incorrect?

MR. THOMAS: That's right, you won't see 101 values. Every time we've presented this we've had the opportunity to explain what those 101 values are. For just someone that got a hold of a CD, it might be a little harder -- or even if we had that on the web -- it's a little harder for someone to understand what those 100 values are. So what we present is the step right after this, where we create the distribution out of it. So we show the distribution on the web, and it'll allow you to see seven to ten percentiles from the 1st to the 99th. So you'll see a range similar to this, but it won't be 100 values. And so at least on a CD version this is the place where someone could look at those 100 values for every cancer type.

And then what's done immediately is we pull in that ERR per sievert from the database. We use 101 probabilities. These probabilities go from zero to one, and that just defines what each of those values are. And then we create the

distribution in this step. And so this is, again, for liver. So this is very similar to what the web version will show you, and actually it'll look more like this, so you'll get a table that looks a lot like that now. And again, this is the original ERR per sievert.

We have a step here where we correlate for multiple exposures. This is the value before it's truncated, so that's the one that gets pulled out. This is after it's truncated to zero.

Then we make the adjustments for errors in dosimetry, and this is discussed very well on the web. The exact numbers and distributions that we used in the model are provided on the web. This is where we adjust for the model mixture factor. There's a good discussion of that in Charles Land's report on IREP.

The last step is to adjust for the DDREF. And as Owen showed you, that's in the denominator, so you divide by that and it takes you right to the final ERR per sievert. You multiply that times the organ dose. Within this organ dose is where Dave Kocher's work comes into play, the RBE, which now is the REF. And so what

you see here is the programming behind the photons, electrons, alpha, and neutrons. This pulls all of them into one file, one database, and then this one pulls out just the one that we need for the model. This is what sends it out to the Internet version.

So there's lots of nodes in here that won't mean much to the average person looking at this code. But we have tried to at least keep it relatively easy to understand. Most people who program in Analytica use it with influence diagrams, and so in this case they would have excess relative risk sitting here, relative risk sitting here, and probability of causation down here with arrows going in, just showing that that node depends on those. What we did is we just created a little equal sign, a line, a times, and a 100 so that we could make it look like the equation really looks. Now if you go into the probability of causation you can see the syntax that's used in Analytica, so the total ERR divided by the total ERR plus one times 100.

Now one of the strengths that we found early on of Analytica is it first of all it provides you a place to type in a variable name. This is

-- anytime you use this variable anywhere else in Analytica, you just reference or type in A-S, and it'll use this node. You can type a title, anything you want there. In this description, you could put paragraphs of information there, references of where it came from. And then of course you type the equation in here, shows you all the inputs to that. Of course, this one only has one input, the total ERR, and it shows everywhere that this node is used throughout the model.

A lot of our uncertainty, Monte Carlo-type calculations that we did five, six years ago, we were doing in a software called Crystal Ball, and add-in to Excel. It was a really great program. The problem is Excel's two dimensional, and so it's hard to program some of these things in Excel. And if you guys have done things in spreadsheets, you know that if you want to get a calculation for different scenarios, you have to have it in different cells. All your results would be in different cells. The equation is just duplicated. And it's easy enough to copy down and that sort of thing. But someone reviewing that spreadsheet, what we ran into in

the past, is they have to review every cell of it, and they have to make sure that you've copied properly, and that you've held constant the rows and the columns and that sort of thing.

What's nice about Analytica is that the equation is only entered one time. So what you saw there, that simple equation for probability of causation here, is entered one time. So it's really easy for the people who have reviewed this so far to just browse through and make sure that everything is kosher.

All right. What else?

DR. ZIEMER: I think since we actually have Dr. Land sort of standing by, I'd like us to see if we have questions. We had the one that got answered, but if we get Dr. Land on the line we may re-ask that question, just to validate the answer.

But are there any other questions that any of you want to direct to Dr. Land? Remember now, he generated the original NCI stuff upon which this is all based. I think originally there was some question in the Board as to how we got from the NCI stuff to the NIOSH stuff and that kind of thing. Maybe that's all clear now. Or are there

still questions? I don't want Dr. Land just to be twiddling his thumbs for the next two hours waiting to hear from the Pentagon or something.

MR. THOMAS: Yeah, we don't want him to think we've stood him up. And we can leave this up on the screen, too, and so if more questions come up --

DR. ZIEMER: Yeah, we can come back. But I want to see, identify --

MR. THOMAS: Certainly.

DR. ZIEMER: Do any of you have questions that you would like Dr. Land to address, which in a sense goes back to the original NCI stuff? Would that be a fair way to state it?

MR. THOMAS: (Nods affirmatively)

DR. ZIEMER: Or are you comfortable now with that as the starting point?

MR. GRIFFON: I think my answer's neither to that. I'm not comfortable with it, but I don't know if I have questions right now. I've e-mailed back and forth, and I need to do more work on Charles's report that we just got. Some things are clearer now.

I think the reason I'm pushing for this CD version again is that -- just in terms of being

able to review this. I know the ERR per sieverts, as Larry points out, are now going to be on the web version. But as I understand it, it's still going to be on a case-specific basis. In other words, you have to put in age at exposure, attained age, and then you get a generated profile, as you just showed, that generates distribution of the ERR per sievert. If we're looking -- if we're concerned about factors like age at exposure and how that was handled, then that puts the onus on me to sit at home and generate -- plug in different ages and make my own table, when in fact it already exists. So that's the frustration on the transparency in terms of being able to review it.

I should add, I'm not sure that needs to be in the web-based version. I'm not even saying that. I just think that it would be helpful for us to understand.

DR. ZIEMER: Also I might, before you respond there, in terms of Dr. Land, he did indicate that he might even prefer, if we had detailed questions, that we could just prepare them in writing and he would answer them in detail, rather than the top of the head on his phone.

So maybe what we want to do is call him and indicate that the folks this morning did such a great job that there are no --

DR. ANDERSON: That he could take the afternoon off.

DR. ZIEMER: Owen.

DR. HOFFMAN: I took the trouble to read the minutes of your last meeting, and what stood out to me was this outstanding question: Why is there such a big difference between what you get out of IREP and what you got out of the CIRRPC table in 1985? I think that's the underlying question that needs to go to Dr. Land, and I think he's prepared to answer it. And so just the general question of can you elaborate why the differences.

DR. ZIEMER: That deals with that table that was pointed out yesterday, I think.

Mark, did you have anything?

MR. GRIFFON: Yeah, I've asked him that in e-mail format, and it's still not -- I think he's answered it qualitatively. I'm looking for more of a quantitative, and I need to work through the math and have -– he's shown the factors that were modified that contribute to that difference, but

until you sit down and play with some hard numbers then -- and part of it's just my understanding of how they went from A to B. I'm not even -- it's just the ability to review.

Part of the other thing about transparency was, as Owen pointed out in his presentation, this was based on the Thompson data in the 1994 report, find that's available. I've looked at it. However, as Charles pointed out to me and Owen said again, they re-analyzed that data. So we can't -- so in terms of comparison, you can't really turn to that. So again, we're left as -- we didn't have the data. Now we might have some form of it on the web, but we haven't really had the opportunity to look at that to make -- to go from A to B.

DR. ZIEMER: And so the bottom line, though, is that a brief telephone discussion now may not be suitable to answer the question, because you want to see some additional -- or have additional time to study the material?

MR. GRIFFON: I don't want to speak for everyone.

DR. ZIEMER: Yeah, for yourself.

Owen.

DR. HOFFMAN: The reason why I'd like to encourage you to talk to him is this is what we've just gotten via e-mail from Charles, which is an attempt on a spreadsheet to explain the differences between CIRRPC and IREP.

DR. ZIEMER: Okay, so --

DR. HOFFMAN: So I think you bring Charles on, we get detailed insight to that question.

DR. ZIEMER: Okay.

Is Cori still here?

MS. HOMER: I'm right here.

DR. ZIEMER: Okay, so I guess we will at least ask him to -- and he has a copy of this before him, I presume --

MR. THOMAS: Yes, he just e-mailed this to us just a few minutes ago.

(Whereupon, Dr. Charles Land was contacted via telephone.)

DR. ZIEMER: Dr. Land, can you hear me?

MS. HOMER: Dr. Land?

DR. LAND: Yes, speaking.

DR. ZIEMER: Okay, can you hear me from there? I'm on a mike here, Dr. Land.

DR. LAND: I can hear you.

DR. ZIEMER: Great. Okay. Well, we have the

full Advisory Board here. Sorry we're a little later than we had planned on. Our original papers went a little longer, and then we had trouble getting through the phone line here, but at least we're here now.

One of the items that we have before us now is some material that I think you just e-mailed to the group, because one of the issues that has arisen is the differences in the CIRRPC and the IREP values that are shown in the June paper. We're looking at the material that you sent -- what is this table called?

DR. LAND: Is it the last table, or the last --

DR. ZIEMER: Well, it's the last table in the paper, and then -- yes, table E-4 --

DR. LAND: Uh-huh.

DR. ZIEMER: Is it E-4? Yes. And the differences between the CIRRPC values and the IREP values, that has been a bit of an ongoing question. And then I guess you have sent, relative to that, you have e-mailed some information which includes transfer rate and DDREF's and so on. So I'm not even sure what to ask at this point, but maybe you can simply begin

by helping us understand the differences between those two. And Mark Griffon has an additional comment.

MR. GRIFFON: I may be able to give people a -- Charles, this is Mark Griffon. And I think your spreadsheet is what I was also trying to do with the e-mail values you sent me, so this is helpful. I think what you're trying to demonstrate in this spreadsheet is to go from table 4-D-2 or D-4-2 -- I forget which -- anyway, from the ERR per sievert values to the -- how the transfer from the Japanese population and the other factors that would affect that to get back to the final IREP ERR per sievert value, if I set that up right.

DR. ZIEMER: Did you catch that?

DR. LAND: Yeah. It sounds as if you have the spreadsheet that goes from the median values for the uncertainty distributions, the statistical uncertainty distributions, and then there's a correction for -- immediate correction for the uncertainty introduced by the dose reconstruction, which is a .82. And then there's a -- I'll divide by the DDREF, and then again is the median value, and then multiply by a transfer

factor which depends on -- really on whether the baseline risks are higher or lower in Japan. And then the product is essentially the median of the IREP, which is -- I think it's in table -- this particular case it's table E-2, it's Appendix Table E-2.

DR. ZIEMER: Okay. For the group here, that's page 108 of the document, that Appendix E-2, right.

MR. GRIFFON: So Charles, just looking at your spreadsheet here because we don't have it, we're looking at it on a projector, is it column M? Is that the IREP value? And I think column C, if I could look back, was the original ERR per sievert -- yes, column C, or D and E. D and E would have been the original values.

DR. ZIEMER: Mark is looking at the spreadsheet that you e-mailed us.

DR. LAND: I e-mailed -- is that the -- could I ask Owen, is that the same as the spreadsheet I --

DR. ZIEMER: Yeah, the one -- oh, you e-mailed to Owen? Was it, Owen?

DR. HOFFMAN: (Nods affirmatively)

DR. LAND: Okay, right. Okay, then we're on

the same page.

DR. ZIEMER: Okay.

DR. LAND: The IREP value is in column I.

DR. ZIEMER: Column I, where it says Japan?

DR. LAND: It's sheet two of the spreadsheet.

DR. ZIEMER: Oh, okay. Okay, here we are. Okay, we have that.

DR. LAND: Okay. Then the column N is the CIRRPC value, and column G is the multiplication, because I don't figure this exercise involving columns C, D, E and F is going to be exact, but it's good enough. It gets there. And so you can see that -- you're starting with C. C is the median of the statistical uncertainty distribution. Column D, then, is this correction factor for the dose reconstruction for the A-bomb survivors. That's a .82 except for --

DR. ZIEMER: Right, except for thyroid.

DR. LAND: -- thyroid. And then there's one over the DDREF, right, because you divide by the DDREF. It's simpler just to multiply across, and that's .6 for most everything except for breast and thyroid, which is .66, and for leukemia, which is 1. And then there's the transfer, which is the -- that's the least easy to explain, but

anyway, there you have a really big factor for liver and smaller factors for many other things. Transfer -- I'm not sure I believe the value for stomach.

UNIDENTIFIED: Yeah, I was questioning --

DR. LAND: I don't think that's right.

MR. GRIFFON: I think it might have been 9.4 in the e-mail you sent me.

DR. LAND: Yeah, I think it's supposed to be 9.4, and so the value is much larger.

DR. ZIEMER: We had a different table that -- or Mark did, that showed that value as being 9.4 for males and 9.3 for females, or something like that.

DR. LAND: Oh, yeah, 9.4. It should be -- somehow it got here as 2.4. Well, I'll just change it. And you could change it, too, I guess. It's --

DR. ZIEMER: Right. Right, and that -- and then the new product, then, is .547 --

DR. LAND: Yeah.

DR. ZIEMER: Yeah.

DR. LAND: And then I have the IREP here as .13, so I don't --

MR. GRIFFON: Charles, in looking at that one

you just changed there, I'm looking at column G versus column I now, and that's quite a disparity. Unfortunately, that was the one that I picked out to try to replicate at home, and I was wondering if I was doing something wrong. But .54 versus .13 in IREP, seems to me that -- and maybe it's the simplistic form that we're doing this analysis in, is that --

DR. LAND: I don't understand this particular one, and I -- the first thing that's brought up is one that I don't understand.

(Laughter)

MR. GRIFFON: It's the first one I reviewed, too.

DR. LAND: Yeah, I really don't understand that. I'm going to look at Iulian Apostoaei's paper on that, in which he gives the factors.

DR. ZIEMER: Well, that's something you'll need to follow up on, then, and --

DR. LAND: Yeah, I'll follow up on it, yeah.

DR. ZIEMER: But then can you speak more generally to the original question about the differences between the CIRRPC and the IREP values?

DR. LAND: Okay. The differences are --

first place, the NIH -- the table, figure K -- sorry, column K, these are the medians or the point estimates that were developed by the NIH, the 1985 NIH committee.

DR. ZIEMER: Right.

DR. LAND: And they assumed, except for breast cancer and thyroid, assumed a quadratic dose response. And CIRRPC, which actually sort of acts the same way as the DDREF correction in the present, except it doesn't have the amount of uncertainty in it. And CIRRPC, in the column L that's labeled FDL, that's their way -- they're moving -- they're making -- they're assuming linear dose response, so they're correcting for what it would be if the dose response were linear. So in effect they're taking away the DDREF. This is one of the conservative things they did in order to get a screening rule that would tend to let in things that -- well, the idea was that if something got screened out that it would definitely not be qualified for compensation, all right?

And then the other one here is this factor FB, which is in column M, and that's taking the baseline -- it's a baseline factor, and it has to

do with substituting -- rather than the baseline for the whole U.S. population, it's the baseline, the ten percent baseline -- that is, in the lowest ten percent of counties, what was the baseline? So there you have this multiplying factor here.

So these two things multiplied together, that's a factor of about five. It varies, but it's about five, on average. And that's why the product in column N, which is the median for this distribution or this uncertainty distribution, is so much higher. But it's intended to be higher. It's deliberately intended to let in as many cases as possible that would then be evaluated more stringently.

So there's two things going on here. One is these factors here that are intended to boost values; and the other thing is that the NIH, in the NIH model the transfer between populations was assumed to be additive. And that means that the coefficients for something like stomach would be higher than they would be if you used a multiplicative transformation. But anyway, it's expanding things, and then for something like breast where the U.S. rates are higher, then it

would make the excess -- I'm sorry, that would make -- yes, that would make the excess relative risk lower.

DR. ZIEMER: Okay. Let me now ask the Board if they have any follow-up questions on that at this point.

Mark Griffon.

MR. GRIFFON: Just one follow-up, are these values documented in your report? I don't know if these transfer values are documented in your report, the recent 2002, June 10th, I guess, report.

DR. ZIEMER: June 11th, yeah.

DR. LAND: It's -- no. They're described, and it tell you how we got them. But that's something we just noticed, that we really should have a table of them, and we will be putting that in either as an errata sheet or as an addendum to the report.

MR. GRIFFON: And just the -- I'm going to run through the spreadsheet, too. I think it's very useful. I should note there's a couple of other differences on the e-mail that you sent me, so -- it has liver cancer with a value of 8.3 for transfer ratio, so --

DR. LAND: Oh, you know what? The stuff I sent you was -- here's what it is. This was for white males or white females, whatever, whichever. Anyway, it was for whites, and for the -- the ones we're using are for the whole population in the country, and there are a number of population subgroups that have higher baselines. And liver cancer and stomach cancer are sort of major examples of that.

DR. ZIEMER: Let me ask again now, any other follow-up questions by the Board here for Dr. Land?

(No responses)

DR. ZIEMER: Okay. Dr. Land, thank you very much. What we'll do, if additional questions arise I think what we'll do is ask that the Board put them in writing --

DR. LAND: Sure.

DR. ZIEMER: -- and then we'll shoot them back to you.

DR. LAND: Okay.

DR. ZIEMER: This has been very helpful. We appreciate your taking the time out of your schedule to sort of stand by and wait for us to call, so we appreciate that.

DR. LAND: You're welcome.

DR. ZIEMER: Thank you very much. Good-bye.

(End of telephone conference.)

DR. ZIEMER: Okay. Now does that help some? You --

MR. GRIFFON: Yes, yes.

DR. ZIEMER: Okay. Let's open it back up for any questions on any of the material. We are going to need to break for lunch, but I think we have a few minutes we can continue.

And Owen, you and the others are going to be here for a while after lunch as well, so --

DR. HOFFMAN: We're at your disposal all day.

DR. ZIEMER: Okay. Well, it is 12:00, and we do need to grab a bite to eat. We are shooting for a 4:00 adjournment because a number of folks have to get to the airport by about 6:00, 6:30 -- that is, they have flights by 6:30, which means they need to be at the airport shortly after 4:30 or roughly. So we're going to shoot for adjourning by 4:00, which means the public comment period will be moved up.

Is anyone signed up for public comment today? Are any of you that are here know that you're going want to --

MS. HOMER: No.

DR. ZIEMER: We'll certainly accommodate if there are additional public comments, but we do want to shoot for adjourning by then.

We have not only additional discussion on this, but we have an updated report on the dose reconstruction subgroup, and also a report from the group that was looking at comments on the rule-making. So we have all of that to do, and then talk about when we meet again.

So it's now 12:00. Let's try to be back by 1:15 if we can.

(Whereupon, a lunch break was taken from 12:00 noon until 1:21 p.m.)

- - -

DR. ZIEMER: Folks, we need to jump ahead a little bit on the schedule and do some administrative housekeeping, partially because I think the earliest flight out now is Tony's, and --

Tony, what time do you have to leave us? You have to leave here about 2:00?

DR. ANDRADE: Around.

DR. ZIEMER: Around 2:00.

DR. ANDRADE: Maybe 2:00, 2:30.

DR. ZIEMER: 2:00 to 2:30. In any event, we want to talk about work schedule and meetings and so on.

A couple of things to keep in mind. Number one, it may be by the end of the day today that we will still need to polish some comments for the proposed rule-making. That would require either a face-to-face or a telephone conference.

Also, the subcommittee workgroup, the subgroup, working group -- I forget what the proper term is -- the working group dealing with our process for overseeing, as it were, the dose reconstructions -- that is, the Mark Griffon working group -- also wants to plan a meeting in Cincinnati, which would include an opportunity to see the facilities and look at some dose reconstructions and so on.

One thought was that it might be possible somewhere mid to late August to combine those two things, so that we could all see the Cincinnati facilities and have an opportunity to see what the group is doing there, and also to take care of both the subcommittee's activities and have even some input on their final recommendations, as well as do the final polishing on our

comments.

Now the negative side of all this is that between now and then the NIOSH staff is going to be extremely busy taking care of the road trips, public comments, and related things. I know that Larry's availability schedule is very limited. His wife is even insisting on some vacation time in there. I can't understand why, but in any event, those are some options we need to think about.

If it were in August, it would have to be the third week, I think.

MR. ELLIOTT: The week of the 12th.

DR. ZIEMER: Is that the third week, or it's the second full week as far as -- that's the only week Larry's available in August, and it's available theoretically. You'd be barely back from the road shows.

MR. ELLIOTT: Right.

MR. PRESLEY: The 12th?

DR. ZIEMER: The week of the 12th is --

MR. ELLIOTT: The only week I have available in August.

DR. ZIEMER: Then it could be toward the end of the week.

MR. ELLIOTT: Yeah.

DR. ZIEMER: But I guess we'd like a little input both from staff and from the Board as to what your druthers would be.

I don't know, Mark, on your working group how soon you were thinking about meeting in Cincinnati, or had you thought about that?

MR. GRIFFON: As soon as possible.

DR. ZIEMER: But the staff is not likely they're going to want to have you showing up before mid-August, because they're going to be gone.

UNIDENTIFIED: Can you just leave a key?

DR. ZIEMER: Under the mat, okay.

MR. PRESLEY: Can we come up, the working group, the first part of the week, say Monday and Tuesday or Tuesday and Wednesday, and then have the Board meeting on Thursday and Friday? Or --

DR. ZIEMER: Or 13th, 14th, or something?

UNIDENTIFIED: The working group would only need two days?

MR. PRESLEY: Yeah. That's what Mark's talking about.

DR. ZIEMER: Jim, how much of that would be sort of seeing the sights, the facilities, that

the full Board might want to be involved with?

DR. NETON: Well, our facilities aren't very extensive.

DR. ZIEMER: So allow a few minutes for that.

DR. NETON: I think a five-minute tour -- no, a couple of hours to do that.

I was thinking in terms of the working group. To actually sit down, maybe go over a few case studies that we could set up with our health physicists, and maybe back up a step and actually go over our implementation guidelines; and then to sit down in a room with some CD-ROMs that has data on them would take a couple of days, I think. Maybe not full two days, but it would be hard-pressed to cram it into one day, I think.

DR. ZIEMER: That part of it, the working group part, would mainly involve you, Jim, and --

DR. NETON: Yeah, that's --

DR. ZIEMER: -- some of your immediate staff, so it might not require the rest of the staff?

DR. NETON: Right, right. I think it's --

DR. ZIEMER: I'm trying to think in terms of impact on the ongoing work.

DR. NETON: Right. Primarily the health physicist. We have three health physicists on

the staff, and we can move them in and out as needed. Each has its own specialty. They have an internal dosimetry person, an external, and then sort of an overview person, so we could rotate them through. We could set you up in a conference room with computer terminals and whatever we need to facilitate the reviews.

DR. ZIEMER: Let me ask this question at this point. Is there anyone that could not -- we'll start with the working group. Anyone on the working group that could not do it that week if that turned out to be a desirable week?

MR. ESPINOSA: On the 16th I've just got to be back in Albuquerque by 1:30.

DR. ZIEMER: All right, on Friday. Yeah, okay. But perhaps we could be talking about 13th, 14th, 15th or something. I'm not even sure this group would have to meet the full two days. We might overlap on the afternoon of the second day or something, and then go into the next day. I'm just -- just top of the head. I don't know.

MR. PRESLEY: Jim, you think -- you said two days. Could we schedule Monday and Tuesday for us?

DR. NETON: Yeah, maybe even a day and a

half. I think one day would be optimistic to be done with everything we wanted to do to go over. We spend hours on a telephone conference, and we're barely scratching the surface on where we're heading. So I'm just -- I think a day, day and a half. A day and a half, if not two.

MR. ELLIOTT: Don't cut yourself short.

DR. NETON: Okay.

MR. ELLIOTT: We want to allow you ample opportunity to go through all the information you want to see.

DR. NETON: Yeah, I'd rather do it now than have to come back for a second trip.

DR. ZIEMER: Would the 12th and 13th work? Are you -- in other words --

UNIDENTIFIED: Is that a Monday and Tuesday?

DR. ZIEMER: When do you finish the road show?

MR. ELLIOTT: Well, let me go over our plans for the road show so everybody can factor that into their schedules here. Right now we're trying to -- folks back in Cincinnati on my staff are trying to work out the logistics. That means getting a room where we can have these meetings in these locations.

But we have targeted, for the week of July -- it'll be starting the 23rd, 24th, and 25th, one of those three nights. We would be up in Amherst, New York, and then come back to Cincinnati and hold a second meeting, a second stakeholder meeting somewhere in the Cincinnati area. So that's the first two.

Then the second two would be done the week of -- it'd actually be August 7th we would hope to be in Richland, and then August 8th we would be in Espanola. So you can see what we have lying ahead of us. That's if we can get the logistics worked out.

We're going to make one *Federal Register* announcement for all four meetings. We have a press release that will be developed and will be distributed to the local area media for each of these four sites. We have talked with Department of Labor about who their points of contact have been at these sites to set up their traveling resource center meetings or their town hall meetings that they've had. And of course we'll be working with DOE to try to get the word out for those three sites, or three areas where we have current active DOE sites that they could get

the news to the workers and former workers.

So today that's the plan. It’s being worked on and developed as we speak.

DR. ANDRADE: Larry, to give you a breather, just in case you end up going late that week before, would it be better to plan the working group on the 13th and the 14th, and the regular Advisory Board meeting on Thursday and Friday?

MR. ELLIOTT: Well, Monday --

DR. ZIEMER: Rich has a problem --

MR. ELLIOTT: Monday's always a good day for us when we come back off a weekend and off a series of travels, to get our heads back clear and collective on a topic. And I appreciate that offer. I think Monday -- if you could give us Monday the 12th to do that, that would be helpful.

DR. ANDRADE: I think for both meetings, for both meetings in case you have to -- in case the agenda is such that you don't have to go the full second day. That still would be fine, wouldn't it?

MR. ESPINOSA: If it make it easier, I can cancel the meeting on the 16th, my meeting. I've got plenty of time to cancel that.

DR. ZIEMER: Is Rich the only one with a conflict that week?

DR. MELIUS: I've got a problem on the 16th also.

DR. ZIEMER: The 16th also?

DR. ANDERSON: Yeah, I do, too.

MR. ELLIOTT: Well, I just wonder maybe if you think about the --

DR. ANDERSON: Well, I could -– I was going to cancel it.

MR. ELLIOTT: I think it would be helpful to me if you'd talk a little bit about what your agenda might be, and whether or not you need two days. Maybe you only need a day and a half. But I know that won't allow you to get back to where you need to be on that Friday, perhaps.

DR. ZIEMER: He gains a couple of hours, though.

MR. ELLIOTT: You might gain a couple of hours, I don't know.

DR. ZIEMER: Right now it appears that the main thing on the agenda would be --

DR. ANDERSON: Finalize our comments.

DR. ZIEMER: -- to finalize the comments on the special cohort rule, and possibly have some

input on the oversight of the dose reconstructions, because the workgroup will have a better feel for how that should proceed. So those would be the two main items. I don't know that we would even need any speakers -- that is, outside speakers -- to come in.

DR. ANDERSON: Yeah, unless we wanted to hear from the VA.

DR. ZIEMER: Well --

DR. ANDERSON: That would be the only one I would think --

MR. ELLIOTT: DTRA.

DR. ANDERSON: Yeah, I'm sorry. Yeah.

DR. ZIEMER: So it might well be possible to call a day and a half meeting, and the last half-day could be primarily workgroup output so that those that had to leave before midday could slip out.

MR. ELLIOTT: Let me suggest this. What if the workgroup met all day Tuesday and the first half of Wednesday, and you started your meeting on the second half of Wednesday and continued it through Thursday? And if the workgroup still needed to -- absent Rich, maybe -- if you needed to stick around, we could still work with you on

the Friday morning or Friday all day, if you wish.

DR. ZIEMER: And perhaps that -- that's a good suggestion. Perhaps that second half of the second day might be the time in which you bring the full Board into what your thinking is on the dose reconstruction.

MR. GRIFFON: That sounds good.

DR. ZIEMER: It appears that we may have some degree of unanimity on the 13th, 14th, and 15th. Is that right? Or 13th, 14th, 15th, and half the 16th.

MR. PRESLEY: Let me throw something out. Would we want DTRA to come in that first -- the afternoon of the first day, and do their presentation before we make any of our presentations as a working group? Do we need to listen to their presentation?

MR. ELLIOTT: I can see if they're available for that.

DR. ZIEMER: You're looking at them to present to the working group only, or to the full Board?

MR. PRESLEY: No, to the full Board.

DR. ANDERSON: But on the afternoon of the

14th.

DR. ZIEMER: The afternoon of the 14th.

MR. PRESLEY: The 14th?

DR. ZIEMER: Yeah.

MR. PRESLEY: That way then we've got the night of the 14th or the afternoon of the 14th when they get through to get our presentation ready to give to the full Board on the 15th.

DR. ZIEMER: As a tentative approach, does that sound okay staff-wise, Larry?

MR. ELLIOTT: If I can get a nod from Jim and Cori, because this is going to require Jim's staff to support it and Cori to put it in place. I think -– we can do it?

DR. NETON: (Nods affirmatively)

MS. HOMER: (Nods affirmatively)

MR. ELLIOTT: We'll make it happen. We'll contact the DTRA and see if we can get their commitment to present on the afternoon of the 14th, but that might be contingent on their availability.

DR. ZIEMER: Again, for clarity, working group 13th and 14th, full Board afternoon of the 14th and the 15th, and possibly the first half of the 16th -- or did we say --

UNIDENTIFIED: The working group.

DR. ZIEMER: -- would stay over if needed, okay. So the workgroup would hold -- okay.

Is that agreeable to everyone? So unless some major issue arises that impinges particularly on the staff between now and then and with the arrangements, I will proceed on that basis. And that gives us a little breathing space on finalizing comments, so we won't feel pressured to try to wrap that up necessarily today, although we want to move along on it.

Cori has distributed a calendar, and I'm going to suggest that even though we have already set these dates up that you go ahead and block off your known conflicts between now and December so that they have those.

Is that good, Cori or is that --

MS. HOMER: We can go -- I'm guessing that November will be enough.

UNIDENTIFIED: Go through November?

MS. HOMER: Yeah, because going as far as December is probably --

MR. ELLIOTT: December is always a confused month with the holidays.

MS. HOMER: Yeah.

DR. ZIEMER: Well, the other question to ask was does the Board wish to tentatively schedule ahead beyond August?

MR. PRESLEY: It'd be nice.

(Affirmative responses)

DR. ZIEMER: To block off dates, not necessarily settling where it will be even, but to say okay, when would we meet.

DR. ANDERSON: The week of the 18th.

DR. ZIEMER: Of what?

DR. ANDERSON: November.

MS. MUNN: We can’t do that.

DR. ANDERSON: Well, we’re meeting already in August, so

DR. ZIEMER: If we meet in August, probably would not need to meet in September. I'm not sure about October. Again, it's perhaps a little dependent on where we feel we are at that point, but --

MR. ESPINOSA: Well, as I've said before, I'd like to invite everybody to New Mexico. The balloon fiesta's in October, at the first, so --

DR. ZIEMER: Is that a bad time to travel there, with all the --

MR. ESPINOSA: Not necessarily a bad time to

travel. It's a bad time to make hotel reservations and such. But if we do it now, it might be a possibility to get in.

MR. PRESLEY: Possibility.

MR. ESPINOSA: Possibility.

DR. ANDERSON: Those $400 a night rooms.

MR. ESPINOSA: Yeah, it's a big event.

MS. HOMER: That's in October?

MR. ESPINOSA: It's October, the first week of October.

DR. ANDERSON: First week of October's okay for me, so --

DR. ZIEMER: Well, as a practical matter, as much as everyone may want to see the balloon festival, that in fact is not a good time to go to Albuquerque, because that's where we're going to have to fly into.

MR. ELLIOTT: If I may, a practical matter also would be to consider what you're going to do at that meeting, and I would think it would --

DR. ANDERSON: Watch balloons.

MR. ELLIOTT: The heavy lifting at that meeting probably will be looking at your first reviews of completed dose reconstructions. And if we are successful in awarding our contract, as

we hope we are, I think it's going to be November before we're going to have a goodly number of those for you to select from. Maybe November might be a better time to look at a date. Just a suggestion.

MS. HOMER: And if we need to get together for a shorter amount of time, just to address a specific issue or two, we can always have a conference call.

DR. ZIEMER: Uh-huh.

MS. MUNN: Would it be worthwhile to look at possibly setting aside a couple of days in late September?

DR. ZIEMER: In what -- when?

MS. MUNN: In late September, just in case? We can always -- it's very easy to cancel. Nobody's ever going to cry if we take those dates off our calendar.

MS. HOMER: I have to make all the arrangements, and we have to pay late fees if we cancel.

MS. MUNN: Yeah, I understand.

MS. HOMER: There's cancellation fees, and --

DR. ROESSLER: Then if we juggle other meetings and we commit to them, then we move

other meetings, and it -- I think we should go with what we think is pretty definite.

DR. ZIEMER: It's a little difficult for me to see that we would need to meet as early as September if we're meeting in mid-August, and Larry suggested November might be a good time in terms of having some reconstructions in place.

DR. ROESSLER: How's your weather in November?

MR. ESPINOSA: Well, you can still get a chartered balloon ride.

(Laughter)

MR. ESPINOSA: I just feel that it's -- because of the outreach that I've done with Los Alamos POWs and other groups in New Mexico, I just feel it's really important that this group go to New Mexico. For the Board, I would like them to see the balloons and everything else like that, but it doesn't have to be in October.

DR. ZIEMER: Let's find out what availability is in November. How about the week of November 4th, any conflicts?

MS. HOMER: I can’t. I have a meeting that week.

DR. ZIEMER: That week's out. Okay. The

week of November 11th?

MR. ESPINOSA: If I can speak on Andrade's behalf, he said that every week -- any time in October (sic) except for Thanksgiving weekend.

DR. ZIEMER: November.

MR. ESPINOSA: Did I say October?

DR. ZIEMER: Yeah.

MR. ESPINOSA: Oh, I meant November.

DR. ZIEMER: Actually the week of the 11th, I'm out of the loop.

DR. ANDERSON: The 11th is Veteran's Day.

DR. ZIEMER: The week of the -- when is Thanksgiving Day? How about the week of the 18th?

MS. MUNN: I'm gone all week.

DR. ZIEMER: All week?

MS. MUNN: Uh-huh (affirmative).

DR. ZIEMER: The week of the 25th getting too close to the holidays?

DR. ANDERSON: Yeah.

MR. PRESLEY: That is the holiday week.

DR. ZIEMER: Bad time to travel.

MR. PRESLEY: Bad time to travel.

DR. ANDERSON: First week of December.

MR. ESPINOSA: What about the first -- the

11th?

MR. PRESLEY: Who had problems with the 11th, anybody?

DR. ZIEMER: I'm out all week the 11th. Let me ask about the last week of October.

MS. MUNN: I'm out.

DR. ANDERSON: I'm out.

MS. MUNN: But the first few days, the first half of the first week in November I could make it.

DR. ZIEMER: Well, somebody --

MS. MUNN: Through the 4th, 5th.

DR. ZIEMER: Somebody had a conflict in November.

DR. ANDERSON: I do.

MS. HOMER: Yeah, early November I can't --

DR. ZIEMER: November isn't looking good, is it?

MS. MUNN: No, it isn't.

DR. ZIEMER: How's the third week of October? Week of the 21st of October?

MS. MUNN: Gone.

DR. ZIEMER: Bad?

UNIDENTIFIED: Bad.

UNIDENTIFIED: We're gone. Different places.

UNIDENTIFIED: I'm on vacation.

UNIDENTIFIED: So am I.

DR. ZIEMER: How's the week of the 14th of October?

MS. MUNN: 14th? Can do.

DR. ZIEMER: Bad?

(Inaudible conversations)

MR. ESPINOSA: Yeah, keep on going, keep on going.

(Laughter)

DR. ZIEMER: You can see the slow balloons that week, right?

MR. ELLIOTT: Nobody said they couldn't do the 14th, I don't believe.

MR. ESPINOSA: I don't know about Tony. He just talked about November.

DR. ZIEMER: I think all we would want to do is pencil in dates and not ask for hotel reservations until next meeting, right? We just want to get the Board to block off some dates.

Do you want to -- is early in the week better or --

DR. ANDERSON: Early.

MS. MUNN: Early.

DR. ZIEMER: Do you want to travel on a

Sunday and meet Monday/Tuesday?

MS. MUNN: Sure.

DR. ANDERSON: Monday's a holiday.

DR. MELIUS: Monday's a holiday.

DR. ANDERSON: Which is fine.

DR. ZIEMER: What is it?

MR. ELLIOTT: Columbus Day.

DR. ZIEMER: Columbus Day.

DR. ANDERSON: It’s not in Wisconsin. It’s a federal holiday. Too bad.

MR. ESPINOSA: Would anybody have objections traveling that Monday?

MS. HOMER: Dr. Andrade might.

MR. PRESLEY: If we have it at Los Alamos, he won't have to travel.

MS. HOMER: Yeah, so he won't have to worry about it, will he?

DR. ZIEMER: We'll have it in Santa Fe or Albuquerque. It's very hard to get to Los Alamos. Rooms are much more expensive in Santa Fe, too.

MS. HOMER: Yeah, they are. But there are places that are covered by per diem.

DR. ZIEMER: It's not clear to me -- let's not spend too much more time. Are we talking

about meeting on the 15th and 16th or 14th and 15th?

UNIDENTIFIED: 15th and 16th.

UNIDENTIFIED: I was hoping 14th and 15th.

MR. ELLIOTT: Can we just block those three days out right now, and then make a decision in August? In August we would need to make a decision so that we can effect a contract with the hotel.

DR. ZIEMER: We'll block off 14, 15, and 16.

MS. HOMER: Yeah, I'll have to have information soon.

DR. DEHART: Could I suggest we get an alternative week as well in November? I realize there was a conflict or two, but if we don't meet in October then we'll probably need to.

DR. ZIEMER: We haven't found any weeks in November where everyone's clear.

DR. DEHART: I understand. That's a secondary goal, recognizing that some --

DR. ZIEMER: Plan B.

MS. MUNN: Unless we want to have Thanksgiving together.

DR. ZIEMER: The week of the 4th, Cori is not available. The week of the 11th, I'm not

available. I think the Chairman has to be there, and I think Cori's --

MS. HOMER: Yes, you have to be there.

DR. ZIEMER: The week of the 18th?

MS. HOMER: No Chairman, no meeting.

DR. ZIEMER: How many people had conflicts on the 18th? One, two --

DR. MELIUS: Depends on what day it is.

DR. ANDERSON: Yeah, early is all right.

DR. MELIUS: Early is okay.

DR. ANDERSON: 18th and 19th is okay.

DR. ZIEMER: This is a back-up time. Okay, November 18th, 19th.

MS. HOMER: And that's still in Santa Fe?

DR. ZIEMER: Possibly. Don't make any reservations yet.

MS. HOMER: No, I won't.

MR. ELLIOTT: In August we'll need to make a decision, which of these two dates you've held.

MR. PRESLEY: So what's the date?

MS. HOMER: First date was October 14th through 16th. We're setting aside November 18th and 19th.

DR. ZIEMER: Pencil those in, folks. Set them aside. Thank you.

A couple more housekeeping items.

Larry.

MR. ELLIOTT: Okay. Under this agenda item of housekeeping, if you would please make sure before you leave today to give me your preparation time so that -- we put a lot of information in front of you for your reading pleasure, 300-plus pages. The working group worked hard and long, I know two different sessions. So we need to get that accounted for.

Secondly, if you haven't noticed in the roster, the Board membership roster, your names are presented along with your address and affiliations and also your appointment dates. And you'll notice that your appointment dates, I think across the board, expire August, almost all of them. Which doesn't mean you're off the hook. Under FACA you continue your boardmanship until you either extract yourself fully or you're relieved from your appointment, even if your appointment expires.

So they do expire in August, but we are working diligently toward extending those. And so the White House will be -- I hope -- making an appointment to extend your memberships to this

Board before we have our next meeting. If they don't, then you're still on the hook as a Board member to continue your involvement until your appointment is extended.

Any questions on that?

(No responses)

MR. ELLIOTT: Okay. And I think everybody's travel and pay has made your -- I hope. We have not heard any complaints to the contrary that you've not been -- your automatic deposits haven't made it. So we'll leave it at that.

MR. PRESLEY: Is there any way that we can find out when those are made?

MS. HOMER: That's a good question. Contact your bank.

DR. ZIEMER: Check with your bank.

MR. PRESLEY: Yeah, that's what we have to do, is just call the bank.

MS. HOMER: We do have -- there are some folks that I can contact to get that information to you, or just keep an eye on your statement. I don't know how you manage your accounts, but we check all the time what's coming and going. So if you keep a copy of your voucher sheet, then you should know exactly what that amount should

be. Your travel, nothing is deducted from that like it is from your salary, so you'll know exactly what the amount is going to be.

DR. MELIUS: I'm on some other CDC boards, and they have some sort of system. They usually e-mail me saying expect a travel or whatever deposit within the next week, or something like that. So there must be some sort of system down there.

MS. HOMER: Well, I know that we have that -- as full-time employees they usually let us know by e-mail when a travel payment's going to be making it to your account. If you're not receiving one, I'm not sure how to request that, but I'll check into it. Now you know that you're getting salary because I'll send you your earnings and leave statement.

Now Dr. Melius, you're a little different. We file a manual on you because you do belong to more than one board, so it keeps the accounting straight if we file a manual time card for you.

DR. ZIEMER: Thank you.

I'm going to ask at this time, since we didn't actually call for public comment before lunch even though it was on the agenda, were

there any public comments?

(No responses)

DR. ZIEMER: I think we heard yesterday from several of those who were attending. I just want to give the opportunity if there are any further public comments.

MR. MILLER: Just to take two minutes very briefly, I thought -- it's Richard Miller.

One of the issues that Owen Hoffman was very helpful in bringing up was I guess sort of the adaptability of the model. And with the exclusion of the worker studies on radon, the model does not -- particularly lung cancer models -- doesn't particularly account for many of the worker epidemiology studies that have been done.

And I just would encourage you all, recognizing you have a full plate at least for your next meeting, to think about on a going-forward basis some kind of examination of worker epidemiology and how it could, should, might, ought not fit in. It's certainly in the statute that you're to account for worker epidemiology. I certainly think there's room for debate about whether the model adequately accounts for the uncertainties that exist around the age at

exposure question.

But leaving that for debate for another day, I would just strongly encourage you all to think about it. This is a worker compensation program, and yet very little worker epidemiology has been brought to the table in terms of the discussion. And the model looks like it's equipped to kind of compensate for or adjust for that.

And one of the issues that's come up is should the healthy worker effect be a factor that's considered when you look at the baseline risks, or whether you want to use population averaging. And again, these are the kinds of questions which would be, I think, very valuable to have examined perhaps at some later date.

The second question was just a technical one. When I was in Los Alamos, we had gotten a number of individuals who have already filed claims who are survivors for people who worked at the accelerator and the Meson facility there. And the question was, is NIOSH going to be in a position to adjudicate those claims if IREP doesn't have that currently in its list of energy levels or types of radiation to account for? And if so, how are you planning on accounting for

those types of claims, or are those just automatic candidates for a special cohort?

I think those are sort of the two key points, worker epidemiology and what to do about the accelerator population.

DR. ZIEMER: Thank you very much. On the accelerators, I don't know that that would necessarily be excluded. We're basically -- are these unique particles that aren't covered, or do you know? Because they usually are looking at secondaries from these --

DR. NETON: Right. I don't know that it necessarily follows that these people were exposed to particles other than what we've covered --

DR. ZIEMER: They are monitored.

DR. NETON: -- first of all. They are monitored.

Secondly, if there are those instances -- and we've thought about this when we were moving forward with the rule -- that the population of personnel or workers that would be exposed to such particles would be so small that we would address those on an individual basis within the dose reconstruction themselves. It would

essentially require an effort to go and quantify.

And given the magnitude of the exposures, there may be some -- using our efficiency approach, there may be some extremely conservative values one could apply, and evaluate the case using an efficiency approach thing. And as it gets closer and closer to where we had to do a full-blown dose reconstruction, we of course would commission some sort of a study into that. But it doesn't follow that these unusual type particles are going to be the predominant exposure in those workers at those facilities.

DR. ZIEMER: Did you have an additional comment?

MR. MILLER: To the extent that -- correct me if I'm wrong -- it was my understanding that the monitoring devices are relatively recent developments, say, in the last 20 years, particularly for those types of particles. And I wasn't quite sure, is that something that is going to pose an obstacle for adjudicating claims for, say, prior to 1980 or so?

DR. ZIEMER: That may be something that has to be looked into by the group, but I think the

accelerator people have been monitored -– and maybe, Tony, you can answer this -- for as long as others. And aren't we still looking basically at a lot of secondary gammas and maybe some other particulates?

DR. ANDRADE: You're going to have -- of course, the potential exists in accelerator situations to be -- the highest potential is to be irradiated by the direct beam itself or a scatter of the direct beam. But then afterwards, it's the decay products from the target or target areas or misaligned portions, or portions where misaligned beams may have hit. And you run the gamut of beta gamma emitters, anything that can be produced by energetic particles, either proton, electron, or heavier ion.

DR. ZIEMER: There are anecdotal stories about early cyclotron workers who aligned beams visually -- yes. So there I think -- and the biological endpoint was cataracts, which wouldn't be covered here. But very definitely an issue with some early cyclotron workers.

Thank you for the comments, though.

Jim.

DR. MELIUS: Just to follow up on Richard's

comment, there's some epidemiological points that have come up relative to the worker populations, the healthy worker effect, there are differences there. There's also regarding the Japanese population in terms of a survivor effect or something like that. And I think, to follow up on Richard's comment, that it would be worth us starting to develop some background and discussion on those. And if we could start that with the next meeting, it would be helpful. Again --

DR. ZIEMER: That would be an item to add to the laundry list that we've been accumulating.

DR. MELIUS: Yeah.

DR. ZIEMER: Thank you.

MR. SCHOFIELD: Can I just make one comment? In relation to the healthy worker effect, one thing that needs to be taken into consideration when this is done is the fact that I can't speak for other facilities, but at least at Los Alamos you go through a physical exam and your (inaudible) exam. So people who go into those jobs have to be above average in health. And those people who start falling down in health that normally would be able to keep their

positions are weeded out. So that introduces a definite bias.

DR. ZIEMER: Okay. Thank you.

Now we want to allow a little time for additional discussion relating to the papers we heard this morning. Owen is still here. I think Dave is still here. They're all still here.

Is there an additional question or comment or --

MR. ELLIOTT: Also at this point on the agenda, which is really what we had targeted at the 10:45 mark, if there were any questions or issues or comments relevant to the NIOSH-IREP documentation that was provided to you for reading. You heard about the REF from David Kocher.

You've also been provided the subject matter expert comments and how those were addressed by Mary Schubauer-Berigan through the NIOSH review process. So we wanted to -- Mary could not be here today. She's in Lyon, France, at IARC. Somebody had to do the tough job there. But we would like, if you have any issues or questions you want to raise about our technical documentation, that we can bring Mary back or

another NIOSH technical expert back, we'd like to hear those and table those till we can get you an answer.

DR. ZIEMER: Mark.

MR. GRIFFON: I did want to ask -- I think I've mentioned this a couple of times -- but I would want to request officially that all the Board members get copies of this most current IREP model on CD. I think we've seen it's available. I really think it'd be useful for review purposes.

Larry has a comeback. He doesn't want to give it to me.

MR. ELLIOTT: Well, no, I don't. And here's the reason why. We think it needs to be on the web in the current version, and that's the version that will be used to adjudicate claims. If we have a version on a CD floating around, we're legally concerned that that version might be used to advise a potential claimant what their PC might be, and that may be inadvertent and cause frustration and disillusionment among the claimants population.

So this is a policy decision that we're examining right now. We have to take into

consultation general counsel's advice on that before we can take a step forward. We've talked about this at each meeting. It's present in each of the transcripts. And each time I've said, no, there's not one available. We are still deliberating on whether we can provide it. But that's basically the background on why we feel strongly we can't provide it.

MR. GRIFFON: Then if -- I'm not sure that's a hurdle that can't be overcome, but if that is the case then I would argue that can the on-line model include some of these tables.

I think we're close, and the Excel spreadsheet e-mailed today was helpful in explaining how you get from X to Y. But it just doesn't make -- from a review capacity, from my personal need to review this, I really am getting kind of tired of entering one at a time cases when I know that data's there, and I don't want to have to recreate age at exposure distributions when I know they already exist in 2.1. But that's old, that's old ERR per sievert distributions that I'm looking at. I can't turn to the Thompson data because they're reanalyzed it specifically for this report.

So just for the need of transparency, I think somehow we have to be able to get to this. And I think -- I don't care if it's on the web that way or on a CD. I'd prefer a CD, as you know, but --

DR. ZIEMER: The concerns are so noted in the --

DR. MELIUS: Can't we just get this resolved, though? It's --

DR. ZIEMER: Well --

DR. MELIUS: If the counsel has objections let's hear them next meeting, and --

DR. ZIEMER: Right.

DR. MELIUS: -- at least get it settled, because --

DR. ZIEMER: Legal counsel does carry weight in the agencies, I know. But it may be that some of this can be on the on-line version that will allow -- and that would probably be the better solution.

MR. GRIFFON: Is there a technical hurdle for having the tables? I don't know if that slows down --

UNIDENTIFIED: (inaudible response)

MR. GRIFFON: It doesn't slow down any -- no. So having all the tables there would not be a

problem on the web version? Okay.

DR. ZIEMER: Any further comments or questions on that material from this morning?

(No responses)

DR. ZIEMER: Okay. Now I want to go back for a moment to the Special Exposure Cohort, and Ted has asked for some additional time to amplify some things he talked about yesterday.

MR. KATZ: Yes. If you recall, I had that little snag with the projector not being able to go in reverse, and that managed to fluster me enough to not say some things I meant to say. And I didn't really realize I hadn't said them until Tony made the comment that it was his perception that -- and here I'm talking about the use of a threshold for health endangerment, and the use of averaging threshold that you would get from using a solid tumor and leukemia as a basis. That's creating a threshold in a case where you have external exposures, external exposures, external dose.

So when Tony said that seemed to him arbitrary, it sort of shocked me into thinking what is it I missed saying. And this morning I realized that I had sort of skipped through that

slide because I couldn't reverse, and hadn't said what I wanted to. And then as a result we also didn't talk about the slide that we did have up there, and I think you all have handouts. And this should at least be explained, so you know what you have there as well, so I'd like to do both those things.

What I'd like to do is give you as full an understanding as possible -- meaning everything -- about how we came to the decision of what's in there, arriving at that threshold, how that evolved, and what the reasoning is. And I hope this helps you understand why that's not an arbitrary threshold. You may disagree with it, and that's good, that's the whole point here is to get your feedback.

DR. ZIEMER: Now which handout are you referring to?

MR. KATZ: I'm sorry. I'm referring to -- it's the handout that was provided late. It was a slide that was not in my prepared presentation, because it was developed over the weekend at night, (inaudible) hard work. So at the top of the handout it says “PC Values, 99 Percent Credibility Limit.” Everybody on the same page?

Okay, so let me just talk about how we got there. We started off with really a theoretical or a conceptual basis for how we would establish this threshold. And the conceptual basis was this: We knew that we would have to be making subjective judgments about what the actual dose levels could have been, as high or higher than what. We knew we'd have to do that because we can't do a proper dose reconstruction in these cases when we're talking about Special Exposure Cohort groups.

As a result, we wanted to have a threshold that was as bulletproof as possible in the sense that no claimant would take issue with the threshold itself. Since they're going to already be addressing then the subjective judgment that's applied using that threshold, we wanted that to be sort of as plain and simple and unarguable as possible.

So we started off as a -- again, it's basically purely conceptual -- that we would simply have the most radiogenic cancer that applies to the exposures that occurred, that would be the determinant of the threshold dose level. Does everyone follow that? So what that

would mean is wherever there were external doses, what we would be talking about is using leukemia. Simple, simple and plain. Where it was a matter of internal doses you'd be going to the relevant cancers, right. That's where we started.

Then we had review of this position, and people who didn't have their nose quite so close to the paper saw the implications of just that conceptual approach which we hadn't considered, which is, well, okay, so you're using leukemia with external radiation, and that means that you could be as low as using a threshold of around one rem. And that just seemed to them to be a stubborn fact to want to question, then, what is the basis for this? How do you end up having a threshold which I think would be hard for many to accept as a threshold for evaluating health endangerment for a class, a threshold that low?

And explicating further, there was this different view which is one we hadn't considered, which was that you are -- the job here is to characterize health endangerment for the class -- not for a conceptual member, single member of the class, the most vulnerable potential conceptual member. Does everyone follow that?

So that was what was posed to us. Well, really this should be representative of the class, and how do you do that? And the response that we thought of on the cuff there was, well, how would we do that if we wanted to do that, most simply have a perfectly representative threshold? Well, there we then would have to have what is in effect a weighted average of the doses for all the cancers that are potentially related to the exposure, and you would weight them by incidence rates. Right? So that the more prevalent the cancer in terms of expected occurrence among that population the more weight that value would have, and you would average that. And that would be representative, sort of straight, no question about it, representative of the class in that sense.

Now there's problems with doing that approach. We didn't think it was feasible to do that to start with, as a first issue, because we would be working with then expected values for a dose that we don't know that we're going to assume it could be so high or higher. That's what the subjective judgment's going to be made. You'd be using that subjective judgment to then

come up with a threshold that you're applying your subjective judgment against. It just doesn't carry water. So we said, that can't be done.

So the next step, then, was what is then a practical approach to this if we need a representative value? And we also, frankly, were concerned because we thought we should be more claimant-friendly than that as well. And so that made us uncomfortable anyway, that approach, even if it were feasible.

So what's a practical solution to this? And the practical solution that occurred to us was the one that you have before you, which is to simply average, in this case, the two different types of cancers, the classes of cancers -- the solid tissue cancers and leukemia -- to average those dose thresholds and to use that.

Now I guess it would be more proper if you were still working with their incidence rates still and weighting it. But again, I just explained what the problem is with doing that. And in this case we felt that this was a much better solution in the sense of being claimant-friendly. Because certainly given the difference

in the incidence you would expect for the solid tissues and the leukemia, the leukemia is going to have far disproportionate weight when you're just averaging them. Is that clear? Is that clear, what I've explained there?

So that's how we came about this approach that we put before you. And I think that explains that fully. I would like to give some air time and for you to consider the table and the approach we have proposed if we're going to go down that route. I don't know, does everyone have this table before you? I just want to sort of run down these values.

Now this is just an example. This is just one case example. And what we've done here is simply taken these PC values you see in the box above, the fixed inputs. What these are are basically just median values for all the claims we've seen so far. So this isn't really -- this is just to show you how this would work, but these values that you get in the table below obviously would differ depending on the values that you would actually input. The values we used are just median values for all the claims that we've received so far.

So we have proposed that you would use, in the absence of other evidence about the class, you would use in effect the lowest latency for leukemia, because that would be giving the benefit of doubt to the claimants, that would be most claimant-friendly. And you can see -- and you're also using the most radiosensitive of the leukemias, CML in this case, and that ends up with a 1.5 rem dose.

And we would use the highest latency for the solid tissue, solid tumors. And in this case it turns out to be thyroid, and the dose level is nine.

You're averaging one and a half and nine, and you're ending up at what, four and a half? So that would be the threshold that we would establish if this were a case here, if these were the values we were using.

MR. ELLIOTT: If it were a Special Exposure Cohort petition.

MR. KATZ: Right, exactly.

MR. ELLIOTT: Not a case.

MR. KATZ: No. Case, meaning a case of a Special Exposure Cohort petition, I'm sorry. We're not talking about individual dose -- this

isn't about dose reconstructions.

Then there's, I think, just one other thing to say about this when we're talking about extremely low levels of exposure, which is when we're doing dose reconstructions, if there's a component of the dose reconstruction where we don't have good information, one approach is to simply cap it and do that dose reconstruction with that, in effect, maximum dose for that element of the dose reconstruction. And that's talked about in our rule and so on, how we do that.

So some of these cases, even though you can't properly estimate a very low dose, those cases would go away. In effect you would still do the dose reconstruction. You would give it a maximum value. So extremely low dose levels, also you have to consider that some of those are going to get taken care of by individual dose reconstructions, despite the problems there are with doing the dose reconstruction about that element of the exposure history.

So anyway, that fully explains what I omitted and wanted to address, really to address Tony's concern, which is a very important one.

DR. ZIEMER: Okay, thank you. Let's see if there's any questions on what was just said here now.

Roy.

DR. DEHART: If I'm understanding this correctly, the petitioning group need not have leukemic or thyroid cancers in them?

MR. KATZ: That's right.

DR. DEHART: And the threshold that you're establishing at 5.5 or whatever becomes the threshold used in what specific way?

MR. KATZ: It's the threshold for establishing health endangerment. So it is -- right. There may not be any cases of either in that class. It's simply the threshold that will be used as the bar for making a judgment, then, were radiation doses possibly as high as this or higher.

Which raises another point that I have omitted that I should point to, when we're concerned about the possibly or known leukemia case in a class, which is these values that I just went through on this table are given the most propitious circumstances, that's the value you would come up with. But your actual leukemia

case may not have incurred the leukemia within a five-year latency period, and all the other factors may differ. And as you see in this one example, the leukemia actually level rises above the level of hard tissue in certain circumstances.

So that's just an important, again, complication, but to keep in mind.

DR. ZIEMER: Thank you.

Now while Tony is still here I'd like us to move to the rule-making, which is the 42 CRF 83. You recall that yesterday we raised a number of issues to be considered. We had a small working group last evening or late yesterday afternoon that identified some potential -- I don't necessarily want to call them fixes -- but potential recommendations that were felt perhaps would improve the document. And I've asked Tony if he would lead us through some of those. I think it's safe to say that perhaps the group didn't identify everything or capture everything that was brought out in the discussion, but this is at least a start to what was felt might help clarify some of the issues.

So Tony, if you would take the floor at this

time. I know you have to take off soon. Are you still okay for a few minutes?

DR. ANDRADE: Yes. Before I get into detail insofar as proposed, very draft proposed changes to wording, let me tell you a little bit about the philosophy with which we approached the issue of trying to clarify some of the language in the proposed rule.

Number one is we wanted to first and foremost explain clearly and up front, at least in the rule itself -- and perhaps if you all want to go back into the preamble and change that, that's fine -- that establishing or petitioning for a special cohort status is not necessarily a next step or a proposed next step seeking remedy in case the Secretary has determined that a particular -- a particular case now; we're not talking about a group of people, but a particular case -- just does not meet the threshold for action. So that was one.

DR. ZIEMER: It's not an appeal process for --

DR. ANDRADE: It's not an appeal process.

DR. ZIEMER: -- for a reconstructed dose that did not meet the 50 percent POC.

DR. ANDRADE: Exactly.

Okay. And then when we got down into 83.1, what is the purpose of the procedures in this part, we wanted to be very clear about how a Special Exposure Cohort might be constructed. And it appeared to us that the language as written leaves the onus on the petitioner, on the individual, to go back and petition for such status. Again, that conflicts with what I just talked about with what I think the philosophy is, and it would almost force the person into believing that this is the final recourse.

But beyond that, what is new in our thinking, in our collective thinking -- and this was Dr. Anderson, Paul, Wanda, and myself -- is that we felt that NIOSH and/or NIOSH's contractor should bear some responsibility. Now we're not talking about putting this in a statement of work, but at least being aware of what is going on as dose reconstruction efforts occur, such that if they start to find commonality in a situation -- in other words, somebody has petitioned, yet it seems like the dose -- several people, individuals, have petitioned. They come from the same facility. They've done the same kind of

work at the same -- during the same relevant period of time, and they start to see commonality in activity, that there was a potential for missed dose, for example, that they should be at least aware of and report that back to NIOSH or to HHS.

And so we wanted to take the onus off the individual, who may not be aware of what he, her, or their buddies were doing at the same time, and put a little bit of responsibility, perhaps personal responsibility, back on the contractor.

Thirdly is just as we were briefed on yesterday by the good doctor from Rocky Flats, new information can come to light during any part of this process. They've just discovered that there are body burdens out there for which we may not ever find records. I think that in itself should trigger or potentially trigger a petition for special cohort status. So again, in addition to the language that is already in 83.1, we propose two more triggers for special cohort status.

And finally -- and perhaps Dr. Ziemer can talk a little bit more in detail to this -- we felt that as a Board that a lot of the procedures

that are described in here, starting under 83.2 -- how would cancer claimants be affected by the procedures in this part, and going on through the rest of the proposed rule -- talk about a process by which the Board would become involved in those decisions, where we would review the decisions of HHS in which it has already been determined that they're going to go forth with a special cohort decision, a positive decision.

We felt very strongly that it would be nice to keep this Board involved, but that we shouldn't second-guess the HHS. This is part of being petitioner-friendly insofar as positive outcomes with respect to going forth with a special cohort. We would like to be informed, but that's it.

On the other hand, I think it is more important that we be informed of decisions not to go forth without some of the details that are in here. In other words, we would like to be informed of the decisions as to why one would not go forth with a petition. I don't think that we would like to have people who are personally involved come up and petition us. I think that would turn us into an adjudicative body. And so

we really believe that language in that regard should be struck from the record.

Now I don't have my notes with me. I just sealed them in my Fed Ex box. But I know that Paul is taking very good notes, and actually completing sentences that might be used as proposed language. But that's to give you an introduction as to what we did yesterday, how we feel about the situation, and I think points to clarify what this rule is for, what trips this rule, and what our role as a Board should be with respect to this rule.

DR. ZIEMER: Thank you, Tony. And with that sort of introduction to it, perhaps I can add some specificity to specific items here that will maybe help clarify some of those issues.

For example, in 83.1 -- and we may need help in the interpretation here -- in 83.1 it appears, as Tony has suggested, that the process of becoming part of the cohort -- there's a cohort, and there's new classes that can be added to it. As you read this, that there are not new cohorts. There is a special cohort; it exists now. There are new classes that are to be added as the definition gives here -- yes, class of employees

to be added.

The language in 83.1 says:

(Reading) HHS will consider adding new classes only in response to petitions by or on behalf of the employees.

So it's an employee or a group. I think it could be a union group representing employees. But nowhere does it speak to NIOSH taking the initiative on its own to develop a new class based on what its findings are. And as has been suggested, perhaps somebody's dose has not been reconstructed, and they say, well, I'm not going to pursue this any further. But over a period of time, perhaps NIOSH finds that there are 10, 15, 20, or other people from that facility doing a similar job for whom doses have not been reconstructed. And perhaps these folks don't know about each other, don't know that they may be a class.

Was the intent not to have NIOSH be proactive in initiating a --

MR. ELLIOTT: Yes, Ted.

MR. KATZ: Yeah, thank you. Let me -- it's Ted Katz -- just address that. When we can't complete a dose reconstruction, part of the

report that goes to that individual, whether it be employee or survivor, saying that we can't complete a dose reconstruction, part of the service we provide at that point is to tell them about the Special Exposure Cohort, and to provide them materials to be able to petition and encourage them to petition. So --

DR. ZIEMER: Understood. But if they don't?

MR. KATZ: No, I understand. I understand, I understand. But the interpretation of the law, EEOICPA, that was given at least, was that the starting process for considering a class was a petition by a class of employees. So EEOICPA didn't authorize HHS to establish petitions on its own initiative, but that in response to petitions, and that's why it's written the way it is.

DR. ZIEMER: Does it prohibit it?

MR. KATZ: No, and there's no language in EEOICPA that says HHS must not, cannot, should not, whatever. And of course, EEOICPA addressed the President, not HHS. But anyway -- do this on its own initiative. It laid out that these classes would be considered in response to petitions.

DR. ZIEMER: Well, that was a concern, though, that it gives the impression, even though in reality this might not occur. You do advise them to do this and so on. It gives the impression that unless that individual does something, even if we know that there appears to be a class out here, unless those folks do something nothing's going to happen.

DR. MELIUS: Can I just ask some clarification? I guess if I understand you right, Ted, you're saying that there has to be some sort of active, affirmative process back by the claimant to request --

DR. ZIEMER: To trigger --

DR. MELIUS: -- being part of the Special Exposure Cohort. Does that necessarily, though, have to require them to name the class and things like that? I think --

MR. KATZ: Right. No --

DR. MELIUS: If it were like a check box --

MR. KATZ: And in effect, it is.

DR. MELIUS: -- yes, I want to be considered –

MR. KATZ: Yes, and --

DR. MELIUS: Well, that's not clear.

MR. KATZ: Well, that's -- no, that may not be clear. But in effect, all they are providing is their personal information, their contact information and so on, and the finding that NIOSH, in their case, couldn't complete a dose reconstruction.

DR. MELIUS: Right. You already have all this. You've already sort of know their -- you know all this about them. If all you need is some sort of an affirmation back that they want to be considered --

MR. KATZ: Well, and that's in effect what we're getting, right.

DR. MELIUS: Well, it's not clear --

MR. KATZ: I don't know, a check box or whether they're filling out their name and address. But it's not a burden, what we're asking, just for them to affirm that they want to be part of the class, part of the cohort.

DR. ANDRADE: Well, once again, Ted, it's just appearances, I think. You all may be planning and actually doing this already, and advising them about the possibility. However, I think it would be wise to consider just an extra line or two in the proposed rule, such that it is

clear that if evidence to that effect comes up, if there is some possibility that they could be part of the cohort, they might want to petition.

MR. ELLIOTT: I appreciate the fact that -- this has been very beneficial to hear your thoughts on this. And it is not clear, I believe, as I've read it, reread it myself. And we can certainly take your comments into account and reflect upon them.

I wanted to comment on the second point you made about putting the burden on us. We believe the burden is on us, and we need to make that clear. It's not on our contractor, it's on us. And it's on us to monitor the results of dose reconstructions coming out of our contractor, and observing where dose reconstructions seem to be on shaky ground or they can't do a dose reconstruction, and what that means for that potential class and how we can get an affirmation from an individual or individuals from that class. And yes, we may get one that says no, but hopefully we'll find somebody else who will stand up and say yes, we need to have a review for us as a class.

DR. ZIEMER: And our thought is that this

again is partially a perception thing, but you certainly want to show that NIOSH is going to be proactive in making some of these things happen, even if you still require the petition.

In 83.5 there's a definition of the class of employees that says they have similar experience, they worked at a similar facility, and so on. We felt that it was probably also important to include -- and I think you intended to do this -- include the similarity of time periods. It's not just that here's somebody in 1955 that worked at Los Alamos as a, let's say, a glove box operator, and someone in 1980 that did that. Generally these are also time-related as well as -- and so we're simply suggesting that that be included in some way in the definition there.

In section 83.1 --

DR. MELIUS: Paul, before you --

DR. ZIEMER: Oh, yeah.

DR. MELIUS: On that same issue, it's the issue I brought up when we were at lunch. And part of it's a factual question. Are there itinerant groups of workers that move from facility to facility? Because you've got classes, a person at a facility -- and again,

this may be a small portion of who's out there -- but it may be easier to identify the class as a particular group that does a task, moving from facility to facility. Certainly in the commercial and nuclear power there's a more highly --

MR. KATZ: This is another issue of interpretation of the legislation, which defines classes as being at a facility, though -- so the legislation seemed pretty clear to HHS in interpreting the legislation that the definition is -- adheres to a facility, and hence that's why we discussed before about needing different petitions separately for different facilities.

DR. ZIEMER: But it wouldn't really exclude, Jim, I think what you're talking about, because one of these special classes may be part of their time at some particular facility where such an exposure did occur, or multiple facilities.

DR. NETON: On a practical basis --

DR. ZIEMER: You could even name multiple facilities, but there --

DR. NETON: No, it would have to be one facility. But on a practical basis -- I could think of an example, health physics technicians,

rad techs that jump from -- to support certain things. Their exposure profiles are going to be very different, more than likely, at different facilities. So it wouldn't be easy to group them if they worked at Los Alamos and then moved to Fernald. Fernald you'd have uranium exposures; Los Alamos you have something else; Rocky Flats. So I don't think it even makes a practical sense to lump them into one category of workers who jumped from facility to facility. They could be considered at multiple facilities, I suspect, a Special Exposure Cohort if there was evidence.

DR. MELIUS: Yeah, but -- again, I'm not sure how practical this is or meaningful, and I don't want to belabor it. But in essence it may be their cumulative exposure over those facilities, because that exposure differs so much, it makes it hard to reconstruct their doses, so to speak. And I'm just thinking --

DR. NETON: I'm having trouble envisioning a class like that, but you are right. If there was such a class, I think --

DR. ZIEMER: But all they really need is one facility where you couldn't reconstruct.

DR. NETON: Well, and --

DR. ZIEMER: They were all -- that was common to all the exposed --

DR. NETON: But the exposure would have to be sufficiently large to --

DR. ZIEMER: Correct.

DR. NETON: -- pass the bar test.

DR. MELIUS: Yeah, but because it would be -- it's depends on obviously the fact pattern.

DR. NETON: Right.

DR. ZIEMER: Yes, a comment?

MS. GADOLA: From attending some of the employees meetings in Oak Ridge, there have been employees that claimed that they were construction workers or maintenance workers that moved from facility to facility, and they envision that their dose reconstruction would be very difficult to obtain, and that sometimes they were working -- this is according to them -- sometimes they were working in areas which at first they were told they did not have to be badged, and then after they were there for a while they were given dosimeter badges.

MR. PRESLEY: That's correct.

MS. GADOLA: So it would seem that maintenance workers and construction workers

might possibly be their own cohort or fall into a special cohort. But according to how you're defining it, they wouldn't be able to. Is that correct?

DR. ZIEMER: They still have to link it to some facility, not just be a construction worker, right? They would have to -- you would want to be able to show that when they worked, say, at Oak Ridge they didn't have -- they couldn't reconstruct.

MR. PRESLEY: What Sally's talking about is at Oak Ridge they had three plants -– I'm sorry, Bob Presley -- at Oak Ridge you had three plants. And so what we did is we had one prime construction contractor for all three plants, and those people would move around. One week they may be working at Y-12, the next week they may be working at ORNL, the next week at K-25. So that did happen in Oak Ridge.

MR. KATZ: So that get at the question of how you define a facility, too.

DR. ZIEMER: Right, right.

MR. PRESLEY: Yes, that's correct.

DR. ZIEMER: But all it would take would be for one of those, let's say Y-12, where the dose

couldn't be reconstructed, even if the others could, and it was sufficiently large, then they meet the criteria.

DR. MELIUS: Yeah, I'm just worried about them getting defined as a class. I don't have the law here, and I'm not sure what your counsel said. But if we could sort of look in and follow up on this it would be helpful to make sure we're not -- by some of these definitions we're not excluding somebody, a group that moves from facility to facility, or that we may change the definitions here somehow to make it -- facilitate that kind of a designation.

MR. PRESLEY: And the other thing is, since a lot of these people, they're in their seventies, late sixties, early seventies, even eighties, we've changed prime construction contractors about four or five times. Records, things like that, are almost nil.

DR. ANDERSON: This is just partly a follow-up on should NIOSH be proactive. Do you foresee that NIOSH will publish on a regular basis the characteristics of those people that don't -- you can't do dose reconstructions?

I think our group concern was it's kind of --

it's all very individual-oriented, but the individual is very isolated. And so to expect that individual to either go out and find these, unless your report back to them that says, well, you ought to contact da-da-da, or we're aware of X, Y, Z, you then -- you could either be proactive and do it yourself, or if you put out a report then unions or others who could file petitions could analyze that data. But if the individual data isn't available, the only people who could do any kind of characterization to look for commonality would be NIOSH.

So that was our concern, is that you will know something but the individual won't, and so they won't move forward, and therefore there's some view that a class is being covered up because you can't let people know about it.

MR. KATZ: But so -- I just want clarification on part of what you're saying. You're saying that when we let an individual know that we can't do their dose reconstruction, we tell them that they should file for a class. You're saying that they would be more persuaded to actually do that if they knew other individuals were in their same bag, than they

would be -- is that what you're saying?

DR. ANDERSON: Well, if you get a letter back saying you your dose can't be reconstructed, does that mean de facto you're -- if you just say, oh, maybe I'm a special class, I'm going to ask you, NIOSH, to investigate whether I am in a special class. And all I have to do is say, okay, am I in a special class? Then you evaluate whether you're going to evaluate it, and you turn around and say, yes, we'll evaluate it. If that's the intent, then it's very easy. But if --

MR. KATZ: Right, but that part is, I hope, clear in the rule. In fact, in that case we are telling them that they should petition to be part of the Special Exposure Cohort, and there's no further consideration about the petition being evaluated. It will be evaluated.

DR. ANDERSON: See, I don't think that's clear in there, that in fact everybody who you can't reconstruct their dose is --

MR. KATZ: I see, so --

DR. ANDERSON: -- all you've got to do is mail it back to you.

MR. KATZ: Let me explain. And maybe this is addressed in the preamble, maybe it's not. But

the dose reconstruction rule states very clearly that whenever we can't do a dose reconstruction, we will provide them with the materials and information about filing to be part of the Special Exposure Cohort. That's part of the --

DR. ANDERSON: Yeah, but I mean to say --

MR. KATZ: -- dose reconstruction rule already. It's separate from this rule, but that's a guaranteed element of completing that dose reconstruction, and in effect not being able to.

DR. ANDERSON: Yeah. I mean I guess the how to file is a different issue from --

MR. KATZ: That's what their --

DR. ANDERSON: -- you are eligible to be evaluated.

MR. KATZ: And this Board actually gave us advice on this, and we took the Board's advice about giving them -- not just telling them that they're eligible, but in fact telling them how to do it and giving them the materials do to it. So that is part of the dose reconstruction rule already, to not just tell them they're eligible, but to give them materials to file, encourage them to file. And that part will happen.

So I guess an individual might decide, well, I don't want to be bothered or whatever, but we're certainly going to encourage them to file, and we're giving them all the materials to file. And there's nothing more to be done. That petition will be evaluated by NIOSH, by the Board, by HHS.

DR. ANDERSON: Okay. See, I'm confused by when you say materials. To me, that's the form you need to fill out, versus here is the rationale we've provided for you why you could be a class, and that you will then evaluate that, as opposed to they send it back and you say, no, we won't accept this --

MR. KATZ: No.

DR. ANDERSON: -- evaluate this.

DR. MELIUS: They do say they will accept it.

DR. ANDERSON: Okay.

MR. KATZ: It's a --

DR. MELIUS: I think what we were saying before is that should be as claimant-friendly as possible.

MR. KATZ: Yes, and I --

DR. MELIUS: You're going to have survivors that have waited some length of time and so

forth.

The other part of that, though, I think would be useful is if you could publish in a non-identifiable form sort of a listing of those people that you couldn't complete dose reconstructions on. That's my point about there's no really criteria out there for people to understand who that -- so for people --

MR. ELLIOTT: It gets in a class.

DR. MELIUS: Yeah --

MR. ELLIOTT: How do we define the class?

DR. MELIUS: Right.

MR. ELLIOTT: We think there's a class here.

DR. MELIUS: Yeah.

MR. ELLIOTT: And we're going to have the Board review it after we've done our research to define the demographics of that class. And once the Board says, yeah, we agree, and then we go forward with announcement, publication --

DR. MELIUS: No, before that, though. I'm saying --

MR. ELLIOTT: Jim --

DR. MELIUS: -- it's when you have individuals of why you can't complete their dose reconstructions, can you publish or make

available in some way that as a listing, not identifiable?

MR. KATZ: Right, this is entirely separate. Jim's just wanting some accounting of when we can't do dose reconstructions, let the world know that we can't.

DR. MELIUS: That way if I'm a potential -- a union, say, or somebody that would be -- or someone in a similar situation, maybe rather than applying individually, I say look, that's -- you ought to get together a petition and do that. You've already got some information on this. You've already made a preliminary finding. It should be easier to go through with. It would also, I think, help inform people about this on this case-by-case --

DR. ZIEMER: Mark.

MR. GRIFFON: Just a question to follow up on Larry's part of it, which is once you have a class established and you release the criteria in the *Federal Register*, I'm wondering, in establishing that it seems to me that NIOSH may actually identify coworkers from the original -- as you're going to do this research you're going to identify potential people that would fall into

that SEC.

So I'm wondering about notification. Obviously once that SEC is released, defined and released to the *Federal Register*, people can apply and say that they meet it or don't meet it. But if you already know a group and found some -- maybe they didn't fail a dose reconstruction. Maybe you've never heard from them before, but you identify them in doing your coworker analysis. Would there be a proactive sort of notification process to reach out to those people and say, hey, in our -- just asking.

MR. ELLIOTT: It's a point worth considering, but we've not examined it in that way as to whether or not we need a notification piece here. We have talked with Labor, and have an understanding of how they see their job in dealing with claims that come forward and identifying them -- oh, well, NIOSH has established or HHS has established a new class for the Special Exposure Cohort and this claimant fits into that, so we don't send it to NIOSH for dose reconstruction. It's got one of the 22 cancers, they're awarded their compensation. And so we have that in place.

But we've not talked about or thought about or considered -– this is something we should, I think, take up and deliberate on. The risk you run is you don't know where to find some of these people. You may not know how to get at them. You miss people. But it's probably better -- a benefit rather than a detriment to do it.

DR. ZIEMER: You're saying if you know already because you maybe interviewed them to try to reconstruct somebody else's dose or something like that.

MR. GRIFFON: Yeah, or in just doing your analysis for, say, if one person fails, you can't reconstruct a dose, and in doing that analysis you find all these other coworkers. They may not have even applied through the process.

DR. ZIEMER: They may not have cancer.

MR. GRIFFON: May not have cancer, but you know that they fall into the Special Exposure Cohort. So rather than put the burden on -- I think it's just the proactive --

DR. ZIEMER: Okay, let me continue a moment.

In section 83.1, Tony made the remark about making it clear to people that this is not an appeal process for individuals for whom dose

reconstruction didn't lead to compensation. And we're actually going to suggest possibly adding a statement in 3.1 that says what are the purpose of the procedures, and we're suggesting to add a sentence or two that also says what the purpose is not, and it's not an appeal process. If you had a dose reconstruction that failed to lead to compensation, this is not plan B. So that's just a clarification for people to understand what this is about.

Then in section 83.10, this is a section that gets very specific about some roles for this Board. And our small group felt like we were much too involved in the sort of day-to-day operation of the process, or in the loop too early.

For example, in 83.10 subparagraph (b)(2) it talks about petitioners who fail to meet the requirements. If they have a petition that doesn't meet the requirements, and so they're going to be turned down, it basically says that they're going to be turned down -- this recommendation for turning them down is going to be reviewed by the Board, as if the Board is going to second-guess this in some way. It's

already stated they don't meet the requirements of the petition. That's the basis for turning them down. We felt like that's a staff function at this point, and we were -- unless we misunderstood this.

And then in the subparagraph (3) it says HHS will report the recommended finding and its basis to the Board. HHS will consider recommendations of the Board before producing a final decision on whether or not to select the petition. But we felt like at that point, we're not creating a new class. We're just saying somebody -- the petition didn't meet the requirements. If it doesn't meet the requirements, why do we need to even review it?

MR. KATZ: Right. And the reason that's there -- and this is a valid issue for comment, particularly by the Board -- but that's there because it was our view that claimants would expect that they would get some sort of hearing by the Board because the Board's named in EEOICPA, and so on; that in their cases, then, for those individuals, if the Board didn't look at that decision they would feel like, well, I was supposed to have a chance with the Board, to

petition the Board, and in fact I never even -- HHS never let me get to the Board. So that's -- that's why that's there.

DR. ZIEMER: Well, and perhaps this needs further discussion, but is it really a petition to the Board, or is it a petition to HHS?

MR. KATZ: Well, in the language of EEOICPA, in effect it's a petition to the Board. It's a petition to the Board to consider their class, in effect. But HHS -- there's prerogative here. HHS is given the role of considering these petitions to the full Board before advancing them to the Board, and you could read it to say that HHS has the right to decide without involving the Board where it doesn't believe a petition meets sort of basic requirements for being a valid petition.

DR. ZIEMER: I think that was our point, that -- there's two prongs to this. One is the petition doesn't meet the requirements, so it's not going to go any further. The other is the petition does meet the requirements, and it's going to move up and has the potential of becoming a new class, which definitely requires some Board action.

But we just wanted to raise this issue with the full Board. Our small group felt like the Board's involvement was too early here. We're getting more involved in the day-to-day management of that activity. And we haven't discussed this with the full Board, but we're just raising this issue and wanted to get some feedback.

And then in item (4), or item (c), 83.10(c), NIOSH will present the petitions selected for evaluation to the Board, with plans specific to evaluating each petition. What we think is intended here, and it's not clear, is that it's petitions that NIOSH intends to evaluate, or maybe we both are. But this has to do with informing the Board that here's a petition we plan to evaluate, and here is the evaluation plan that we plan to use.

Is that correct, Ted?

MR. KATZ: That's completely correct. So the next step, after you've decided which petitions need to be evaluated, is to present those so you're aware of these are new petitions that are going to be coming up. You won't be having to address them at that point --

DR. ZIEMER: But this evaluation is NIOSH's evaluation?

MR. KATZ: NIOSH is the first step, right. Exactly.

DR. ZIEMER: It sounds like NIOSH is presenting this to the Board for evaluation. It's just a wording --

MR. KATZ: Okay. It's NIOSH that takes the first step at --

DR. ZIEMER: It's just informing us that you plan to evaluate it, and here's the evaluation --

MR. KATZ: Right. The Board will be evaluating it later, too, so it's --

DR. ZIEMER: Right.

MR. KATZ: The whole process of evaluation will have to occur. That's what --

DR. ZIEMER: We're just asking for clarity there, so at this step it's the NIOSH evaluation.

DR. MELIUS: If I read this, I think literally it says it takes two Board meetings to get something into an evaluation -- the first Board meeting for the Board to say go ahead, the second Board meeting for NIOSH to present its evaluation plan for the approved petition.

MR. KATZ: No, because the Board doesn't have

to say go ahead. So we will go ahead as soon as -- as soon as a petition meets, we will be going ahead. And when the next Board meeting arises, we will then go -- there'll be a generic plan for how we evaluate these, but we'll present specific plans when that Board occurs. But we'll have gone ahead.

DR. MELIUS: Okay. I don't think it's completely clear in here.

The other point, I think, going back to the earlier issue also, is that I think -- maybe this was my other meeting with you, the stakeholder's meeting -- but the idea that there's this 30-day period. If there's something missing in the application, you'll get back to the -- NIOSH will get back to the petitioner asking for whatever's missing, further information and so forth, and give them time to present that. So then it should be -- hopefully a lot of this stuff gets addressed -- either makes it or it doesn't at that point.

MR. KATZ: That's right. That's right, that's not a 30-day period. It's as long as it takes between us and the petitioners. But we'll do what we can to help the petitioner do all the

petitioner can.

MR. ELLIOTT: For 83.10(4)(c), we just thought the Board would want to be -- would want to have an opportunity to weigh in on the plan, for a specific plan, the specific petition plan --

DR. ZIEMER: Yeah, I don't think we have trouble with that. We had more trouble with trying to figure out whether this was telling people that the Board is going to do the evaluation, NIOSH is presenting this to the Board for evaluation. It's just getting the wording clear that -- it needs to be will present its evaluation, NIOSH's evaluation package to the Board. It's a semantics thing there.

And then later there's a Board review process. NIOSH comes back and says here's our findings, then we weigh in. And then conceivably NIOSH could say we turned it down, and the Board could say, well, we think it should go forward. Both could turn it down. Both could endorse it. And then it's reported to the Secretary.

Now one question in 83.13, then, is the Board will review the petition and NIOSH evaluation at a meeting to which the petitioners are invited.

And we're just asking the question at this point, is it necessary to invite the petitioners to this meeting? Or does that -- would you only do that in cases where you thought there was going to be some really big issue that has -- we're concerned, particularly if there's 90 cases, that petitioners are going to want to come and not just tell you in two minutes what their petition is.

MR. KATZ: The petitioner is likely to want to come if they see our report and the report is not an affirmative report. They're likely to want to be able to make a case to the Board. And since it's the Board they're petitioning, we thought they should have an opportunity to actually come before the Board, as opposed to being kept at, in effect, at arm's length with us in between.

DR. ANDERSON: I think our discussion was more if your recommendation is to accept, then I think our sense on the Board is why would we necessarily stand in the way of that? Why would you ask somebody to come in to make an impassioned plea when the decision is to move forward?

MR. KATZ: Well, in an affirmative case, they're not likely to -- they don't have a lot of motivation to come in and make a plea. But I suppose they could still want to address you.

DR. ANDERSON: But we could turn down your proposed --

MR. KATZ: You could reject our --

DR. MELIUS: See, I don't think there's a way of avoiding inviting them.

MR. KATZ: I just think that's a necessary element.

DR. MELIUS: There's also issues of -- remember, it’s not just the petition, but it's also --

DR. ZIEMER: This is more than inviting. This is inviting them to present views and evidence. And suddenly you're going to have attorneys present, and then the Board's going to say, well, then do we need attorneys present? It seems to me that this starts looking more and more like a formal adjudication process of a document.

What is the wording that is driving this in the original -- do you have the original legislation that says the -- that talks about

petitioning the Board versus --

MR. KATZ: It's actually in the rule.

DR. ZIEMER: But what are the words?

MR. KATZ: I have it here. Liz just handed it to me, so let me just read it to you verbatim.

DR. ZIEMER: While you're looking at that, because it's really the Secretary that makes the decision; the Board does not make a decision. It's one other piece of information that the Secretary weighs together with the staff recommendation. So I would sort of argue, is that really a petition to the Board if the Board doesn't make the decision? The Board makes a recommendation. It looks more like a petition to the Secretary. Otherwise, the only thing the Secretary could do is accept that, unless they're --

Sally's got a question, while they're --

MS. GADOLA: I'm good at complicating things. I brought this up yesterday, because it also says in the rule about the silica and about silicosis. And the way that I read it is that it is also possible for people that have silicosis to also petition for a special cohort. I know that the rest of this all talks about radiation, but when

you go right back to the very beginning it says people that worked with silica and developed silicosis with the Department of Energy. And so if there is a special cohort out there, can they come in? No?

MR. ELLIOTT: Somebody'd better help me out here, but I don't believe the Act specifies the Special Exposure Cohort to include silicosis, silicosis or beryllium. It's only cancer. It's radiation injury only. And whatever Congressional rationale for all of that was, we'd have to go back to Dave Michaels or Richard Miller or somebody else. But the Special Exposure Cohort that's been established is for radiation injury -- i.e., cancer. Not a deterministic effect, but stochastic effects.

DR. ANDERSON: Because it's tied into dose reconstruction.

MR. ELLIOTT: That's right.

DR. ANDERSON: You don't have to do dose reconstruction for silicosis.

DR. ZIEMER: Right. And endangered health for this thing is defined as reasonable likelihood that radiation dose may have caused a specified cancer.

MS. GADOLA: I guess I was reading it when it talks about the background and the statutory authority right at the beginning. And when it talks about that it was established benefits as compensation to covered employees suffering from designated illnesses occurred as a result of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy.

MR. ELLIOTT: But that is referring to the Act itself, not to the Special Exposure Cohort. That's the background on why the Act -- that's the enabling legislation.

MS. GADOLA: And they did establish one special cohort.

MR. ELLIOTT: There's only one Special Exposure Cohort. That's it. One. And we're talking about adding classes to that Special Exposure Cohort, and those classes have to have had their health endangered by radiation exposure where we cannot do a dose reconstruction. Simply put, that's where we're bound by the Act.

MS. GADOLA: Okay. I just wanted to have it clarified again.

MR. ELLIOTT: If I can, I think Liz has

pointed out -- this may be what they're discussing back there -- but of the Act, this is the EEOICPA Act, Section 36.26, Designation of Additional Members of the Special Exposure Cohort, (a), subsection (a), Advice on Additional Members:

(Reading) The Advisory Board on Radiation and Worker Health under Section 36.24 shall advise the President whether there is a class of employees at any Department of Energy facility who likely were exposed to radiation at that facility, but for whom it is not feasible to estimate with sufficient accuracy the radiation dose they received.

So Ted, is that where you're --

MR. KATZ: Here it is. And it's the way it's written, it's tucked under, so you have to refer to another paragraph to know what they're talking about. But in paragraph 3(1) it says:

(Reading) The President shall request advice under paragraph 1 -- that's what I think you were reading -- after consideration of petitions by classes of employees described in that paragraph for such advice.

So petitioners are petitioning for advice by

the Board. That's what their petition is for, advice for their -- they want the Board to advise the President about a class of employees. Does that -- it is actually straightforward, except it's not written neatly.

MR. ELLIOTT: And the President has delegated that duty to the Secretary of HHS.

DR. MELIUS: Does that explain this appearance and present evidence portion of it? That's my -- I think that's our question. It's not -- that actually sounds to me --

DR. ZIEMER: My question had to do with who is the petition to.

DR. MELIUS: Right.

DR. ZIEMER: That's your point, too, then. The President shall request advice under paragraph 1 after consideration of petitions -- this is the President after consideration of petitions, but now HHS Secretary becomes the surrogate for the President, so he's considering the petitions in that paragraph.

DR. ANDERSON: Asking for advice.

MR. PRESLEY: But would they not come before the Board and present their case, and then we would be the ones to go back to the Secretary of

Health and Human Services with advice on who? That's the way I understand it.

DR. ZIEMER: Well, I don't know if we can -- I think the staff has interpreted this to mean that the petitions come to the Board.

MR. KATZ: The petitions are addressed to the Board, in effect. By this language --

DR. ZIEMER: By this language.

MR. KATZ: Yes.

DR. ZIEMER: In the law.

MR. KATZ: Right.

DR. ZIEMER: Yeah. I think I'm asking whether -- I think it could easily be interpreted differently than that.

The Advisory Board advises the President -- i.e., the Secretary of Health and Human Services -- whether there's a class of employees for whom it's not feasible to estimate dose. The advice of the Advisory Board shall be based on exposure assessment by health professionals, and so on. And the President shall request advice after consideration of petitions. It doesn't say petitions to whom, but it does say petitions by classes of employees in that paragraph.

MR. KATZ: It's petitions for such advice,

and the advice is coming from the Board, so it's for Board advice. This is what these are petitions for, for Board advice.

DR. ZIEMER: I don't see where you're linking that.

MR. KATZ: It's the rest of that sentence. After consideration of petitions by classes of employees described in that paragraph for such advice, the last three words of that sentence.

DR. ZIEMER: Shall request advice under paragraph 1?

DR. ANDERSON: A mistake has been made.

(Laughter)

MR. GRIFFON: Yes, we're here.

UNIDENTIFIED: About those submissions for extension of term.

(Laughter)

UNIDENTIFIED: You want to back down now?

DR. ANDERSON: August 4th is looking real good.

MR. ELLIOTT: I sense the Board interest to get out of a little work here. Welcome to my world.

(Laughter)

DR. MELIUS: But don't worry, Larry, you'll

suffer under this one, too.

DR. ZIEMER: To me, this wording is not at all clear cut, but I think --

MR. PRESLEY: Let Mary speak.

MS. ARMSTRONG: As I understand it, the concern is having a Board meeting turn into a hearing.

DR. ZIEMER: Is the petitioner really petitioning the Board, or is the petitioner petitioning the Health and Human Services Secretary? Because that is the person who makes the decision, based on advice from (inaudible).

MS. ARMSTRONG: The Secretary -- and I'm just saying he at this point because the Secretary is a he at this point -- makes the final determination. That's clear from the statute. It says that the Secretary determines upon advice of the Board. At this point we have it set up that, because of the wording in the statute, that the petition is for a petition for that process to begin, including the petition to the Board for that advice.

Your concern is you don't want this Board meeting turning into a hearing. These Board meetings are public. There's always going to be

-- the petitioner, if they want to sit in the audience and make their public comment, that's what FACA is. These are public meetings. If there's a concern that we're going to have a trial type hearing at these particular meetings, we can take a look at this and try to make sure that this is a determination based on a written record with an opportunity for a public comment period, but not necessarily a representation and hearings and witnesses, et cetera.

Is that what the concern is, basically?

(Affirmative nods)

DR. ZIEMER: Actually, what our subcommittee -- and again, we're just raising this to the full Board as to what our -– our concern was really with the paragraph that says that petitioners are going to be invited to present views and evidence at a Board meeting.

MS. ARMSTRONG: And what you, I think, were wanting is that all evidence be presented to the Agency at the time the petition is made, and that you all will be able to make your recommendations based upon whatever has been presented to the Agency. Is that basically --

DR. ZIEMER: Well, I'm not even sure we got

that far. We really were concerned about the implications of this, because it starts to look like an adjudicatory hearing.

MS. ARMSTRONG: A hearing, or a trial-type hearing.

DR. ZIEMER: And maybe the intent there was simply that this is going to be on the docket for that meeting, and that you're invited to attend and listen to the deliberations and whatever. The wording in here looks very much like it's a formal hearing because it talks about presenting evidence and so forth.

MS. ARMSTRONG: Okay.

DR. ZIEMER: We're only raising it today as a concern. We don't have a proposed solution, but I think we would like to think about it and maybe have the staff --

MS. ARMSTRONG: And have us think about it, too.

DR. ZIEMER: I don't think the issue of who to petition; that's sort of secondary.

MS. ARMSTRONG: As much as how the hearing or how the Board's consideration --

DR. ZIEMER: (Inaudible) -- the issue remains the same. Does our thing become a formal

hearing?

MS. ARMSTRONG: Right. Okay. And I think that would --

DR. ZIEMER: If we can find words to take care of that, at least for our subgroup that was what our concern was.

MS. ARMSTRONG: And I guess I should identify myself for the record. I'm Mary Armstrong. I'm the senior attorney for NIOSH.

DR. ZIEMER: And our concern is not so much getting out of work, as much as it is when -- for example, it was suggested there might be 90 such petitions. And we're going to have a hearing that takes less than an hour, there's 90 hours. Well, let's see, that's only about ten days a year out of -- that's about how many days we'll meet this year.

MS. ARMSTRONG: Right. Right. I can understand the concern, and I think we need to look at how this is structured.

DR. ZIEMER: And then -- let's see. Well, I think that took care of sort of the major things we were wrestling with. There are probably some other details, but I'm going to suggest to the Board that if it's agreeable we'll ask the four

individuals -- and I'll take the lead in this -- to put some of this stuff in more formal words for our next meeting, and we'll work amongst ourselves and then prepare a straw man, if that's agreeable, with any other input that --

DR. ANDERSON: Yeah.

DR. MELIUS: Yeah. Who should we get that input to, that's my question.

DR. ZIEMER: Me.

DR. MELIUS: Okay.

MR. GRIFFON: I was just going to ask --

DR. ZIEMER: I don't want to volunteer Tony.

MR. GRIFFON: I was going to ask if -- it was a working group, so maybe minutes of your -- did you take minutes?

DR. ZIEMER: It was really an ad hoc --

MR. GRIFFON: It was ad hoc, okay.

DR. ZIEMER: -- group. But we can formalize it, I think, if that's necessary. I'll simply exercise the prerogative to appoint this as a working group. And it's Henry and Wanda and Tony and me. We can probably add another person if somebody wants to be involved -- okay, and Sally -- and we'll work up some straw man words for the next meeting.

MR. GRIFFON: Did you consider other issues, particularly one of my favorite issues that I've been talking to Jim Neton to some extent on, with sufficient accuracy and how that was handled. And also definitions of feasibility. I don't know if you got around to discussing those.

DR. ZIEMER: We didn't.

MR. GRIFFON: I know we brought them up as issues.

DR. ZIEMER: And if there are particular places -- what we're trying to do is say where would you put some of these things, and what would you say. And if you have suggestions -- insert the following -- we can add that. Thank you.

MR. ELLIOTT: I'd just remind, as a working group, whatever your deliberations come to be and you exchange those, we can do that on the web site because we have to make that public.

DR. ZIEMER: Right.

MR. ELLIOTT: So keep that in mind.

DR. ZIEMER: So I'll copy you on anything that we send out.

Now let's -- do we need a break yet?

UNIDENTIFIED: Yes, we're over.

DR. ZIEMER: Oh, we do. Can we make this break fairly fast?

How long will your report take, Mark?

MR. GRIFFON: I hope not long. It's similar to the presentation, so we just refined some language around those four major --

DR. ZIEMER: We don't need final action today, or do we?

MR. GRIFFON: No. We did word it in a formal recommendation, but we wanted to do our follow-up with NIOSH.

DR. ZIEMER: Let's take ten, and then we'll reconvene.

(Whereupon, a break was taken at 3:22 p.m.)

- - -

DR. ZIEMER: Brian Thomas has some additional information, I think, on why -- perhaps it's why disks cannot be made available.

Is that a good way to put it, Brian?

MR. THOMAS: I grabbed my laptop computer after this whole thing came up just a little while ago, and I was trying to look at the feasibility of putting some tables on line and trying to answer some of the questions that Mark had. What Mark was saying, that he liked the CD

version because it provides all the data at once without having to select different cancer types and ages at exposure. And in fact, the CD version doesn't do that. We're kind of limited by the same sorts of things that we have on the web now. Let me bring it up.

We had thought at some point that we'd like to have printed tables, printed tables had been requested of us. And at that point we got to thinking about how in the world could that happen, because what we're talking about here is three and four-dimensional tables. There's just lots of data. That was one of the main reasons we went away from the look-up tables that they did back in 1985, because now this thing is so much more complex. And let me show you what I mean.

I had showed you this earlier, the way the different cancers are grouped, but let's just look at this again. Group one cancers, the data here is a function of age at exposure, and there's 70 of those; so just imagine now in Excel you have 70 rows. Attained age, we now take those up, I think, to 80, and so there's 80. So you've got 70 by 80, that sounds simple.

But then you've got all the uncertainty. And so if you put at the very minimum five of the percentiles -- the 1st, 5th, 50th, 95th, and 99th -– then that's five more tables just like that. And on top of that, we have gender. And so just immediately, with all the group one cancers and most all of the group two cancers, you have four dimensions to try to print out or to provide on the web. Group three cancers, some of those are a little simpler and could be on one page.

But that's the reason that we had gone with the approach that we have on the web now, which is doing a calculation for one age at exposure and one time since exposure, and it provides all your uncertainty with it. Now, what the web version or what this version does, what we looked at before is that it brings it in still just for one age at exposure, time since exposure, whatever's selected on that main screen is all we see here in this column.

And so I'm sensing what Mark's question is here -- and so I'm going to go right back to that main data real quickly -- and he's thinking what about this 101 values? It's really simple there. And in effect, it is. But you notice there there

is no attained age effect, there's no age at exposure there yet. That's a multiplicative factor. It's another uncertain factor that we apply after this point.

And so these values could easily be provided, but then there would need to be this multiplication of the additional factor in some cases. And where to apply that and what that factor is is discussed in that PDF file that comes along with this.

MR. GRIFFON: Can I just -- is that the -- that would be the newly-analyzed Thompson data?

MR. THOMAS: Yes.

MR. GRIFFON: I think, for me, that's useful, too. Also, I guess I'm thinking back to 2.1, you're saying that in those cases the tables were constructed differently, so therefore you had -- I think you had tables going across for attained age, or for age at exposure versus your --

MR. THOMAS: That's right. For a number of the cancer types in version 2.1, the way we handled attained age and age at exposure was different. And so these tables did include all the information. And one of the nice things I had mentioned about Analytica is the way that it

handles multi-dimensional arrays. But that's hard to print that out. It's hard to visualize four dimensions for someone.

So anyway, that was my only comment. We can now --

MR. GRIFFON: That data right there would satisfy my need. I think that data, along with the PDF document describing the equations and the age-dependency on those various equations for cancer groups, you can get from the beginning point to your endpoint. So that would suffice what I was requesting.

MR. THOMAS: Okay. And so maybe what we could do instead of the 101 values there -- because what we'd have to do with that as well is provide you with the 101 probabilities that went along with it -- but perhaps we could provide a smaller number of those. And then with that information, plus what you'd have with that PDF file, you could essentially work through the calculation yourself.

DR. ZIEMER: Well, let me suggest that perhaps you folks can discuss that further, and if others want copies they can work on that or talk to you about it.

Thank you very much.

MR. THOMAS: Sure.

DR. ZIEMER: I'd like to ask Mark Griffon now to present the status of your recommendations from the working group.

MR. GRIFFON: I think we worked on this yesterday afternoon in our working group. And we tried to put -- this is again a straw man of some recommendations of what I presented in the morning yesterday, and basically broke up into three groups: the independent panel, this notion of forming the independent panel; the case selection; and then the scope of work for the panel.

First, the working group recommends having a review panel with independent experts, along with Board representation and Board oversight. That's exactly as we stated yesterday in the presentation. The working group proposes that the panel be comprised of two groups, each consisting of one expert -- parentheses, contractor -- and two Board members. And in addition to that, we're recommending four to six experts in total be identified so that they're available on an as-needed basis.

The reason for that is we're envisioning -- and if I get this wrong from the rest of the group, please chime in -- but we envisioned we might need to rotate subgroups. We might need certain expertise at certain sites or certain -- for example, like accelerator exposures or something like that. So you may have to rotate these experts on these two groups.

And the reason for the two groups, at least initially, we felt we've got to start at least with two groups just to be able to scale up for the number of cases we're going to be reviewing. And we may need more, but we also recognize the total pool that we may have to work from for experts may be limited. So we have -- that's where we came out on those numbers. And again, this being a draft.

Why don't I go through it all, then people can comment on it and give us --

The groups within the -- this is as mentioned yesterday -- the groups within the panel would work separately, but as a control we'd give the same case to both groups and see how they came out on it -- hopefully they came out the same -- for quality control purpose.

Case selection was the next topic we tried to cover. The workgroup recommends that the Board should select the cases for review. Again, that was in the presentation yesterday. The workgroup recommends a stratified sampling of cases based on the following parameters:

The site -- and when we said by site, we do say weighted based on number of claims per site. And we also felt that we might -- we want to revisit this a little bit, because we didn't know the distribution by sites. We didn't have that data with us yesterday to look at. But at least some parameter based on site, we thought was important. Some percentage of the awarded claims -- that's awarded claims; some percentage of denied claims; some percentage of the cases for which the dose could not be reconstructed, as well.

And I just wanted to mention one thing we did consider initially was -- and I think Henry brought it up yesterday -- was the idea of having some sort of appeals process. And if people appeal their dose reconstruction, then we might sample a group, might sample from that group of people that appealed.

Larry met with us yesterday about -- that basically reviewing appeals was not a good idea because it's getting into the adjudication process, right. However -- and it's not in our parameters here, but I'm just throwing out there; it's something we discussed, and I still feel like we might want to consider it -- is if we had a group of the appeals pooled and we sampled them on a deidentified basis, it might be a parameter we might want to sample from. And I don't know if that steps over that line, and I would ask for advice on that. But it's something we discussed. It didn't make our recommendation here, but it's something that I was interested in and just wanted to throw it out there for discussion possibly.

The workgroup also recommended that the first ten cases which are completed be assessed by the panel. Part of this was we understand, or at least we get the sense, that the first ten cases that are completed are likely to be awarded, and probably low-hanging fruit, if I can use that term. But we thought it might be beneficial at least to get the independent panel, their feet wet on what these cases are going to look like,

how much time may be involved. Although these may be simpler cases, it was a starting point to get the panel engaged on these cases. So that was a recommendation.

Finally, the scope and protocol. The workgroup recommends that the Board establish the scope of work and the protocols for the panel. The workgroup recommends that the scope include the following:

One -- and this was not in our presentation yesterday, but it came from comments -- the panel should assess the methods for dose reconstructions. And that comes from the statute where there were actually two items, two tasks.

Second, the panel should determine whether or not the dose reconstruction -- or the reconstruction of the dose provides a reasonable estimate of the dose, at least as needed to determine eligibility.

Three, the panel should determine whether or not the assumptions, individual case assumptions or assumptions applicable to multiple cases, made for the dose reconstruction are credible.

And finally, the panel should determine whether or not the data from DOE or other source

is of sufficient quality necessary to obtain a reasonable estimate of dose. All right.

And I think that's it. That's what we boiled things down to as a start of the recommendation for this.

DR. ZIEMER: This recommendation, in essence, comes to the full Board as a recommended procedure for the Board to use in going forward. Keep in mind that if it is adopted it can be modified at any time. This is not set in stone forever. It could be viewed as a starting procedure, that we would expect as we gained experience to modify, add to, change, and so on.

Further, this is not a recommendation to the Secretary or anything like that. This is an internal document.

MR. GRIFFON: We feel --

DR. ZIEMER: The existence of a procedure to do this could, of course, be reported to the Secretary as part of our ongoing work, and the fact that this is being done.

But I guess what I would ask the Board today is are you ready to adopt this now, or do you feel like you need more time to look at it, again keeping in mind you could adopt this today and

change it at the next meeting, or modify it? This is not a once for all thing.

DR. MELIUS: I would suggest that we do adopt it, recognizing that there will be some changes along the way. At the next meeting the workgroup is going to be going over some of the records, and may deal with some of the procedural issues in more detail and so forth. But at the same time I think, since some outside consultants need to be hired and we know that's going to take some time, that we get started on this.

So I really think we should try to adopt these recommendations at this meeting so that we can at least get that part of the process going, have a basic understanding of the parameters of the review, and so through the August meeting we'll be able to get underway a little bit more with this process.

DR. ZIEMER: Thank you.

Wanda.

MS. MUNN: I guess I'm not really wild about what we're seeing here. I think an objective reader could probably, with appropriate selection of a few numbers, work into two FTEs for the next year, given this. And maybe that's a part of the

objective. I don't know.

I'm really concerned, first of all, that any, for example, search for outside consultants has to come from somewhere. Whether this Board is expected to do this or whether this is going to fall on staff again, while they're out there trying to expedite all this other stuff that we're asking them to do, go out and also do a worldwide search for the appropriate experts to fit on here.

And I had thought that our earlier discussions had focused around the possibility of a very small number of cases being overviewed, with perhaps a couple of experts and possibly one member of this Board. I was a little surprised to see two Board members and a hired gun being proposed.

I understand -- I think I understand -- what the workgroup is trying to do here. But I really have to express some reservations about the extent of what I think I see here.

DR. ZIEMER: Larry, do you want to comment on that?

And Mark, you may wish to respond.

MR. ELLIOTT: I appreciate your comments,

Wanda, but I am very pleased to see this. I think that we need to have this, because it falls upon us at NIOSH to put in place the support to the Board and these contractors. And the sooner we can get started on that, the sooner the Board can start its review of dose reconstructions. And I don't see that's an inordinate amount of resources that's being requested here. I think it's an appropriate amount at this time, and certainly can be modified as we go forward, as needed.

I would also like to make sure that you understand that the first ten cases that are going to be completed that we're working on now, they are the low-hanging fruit, but they're both extremes. So the first ten are going to represent awards and denials -- we think. We think --

UNIDENTIFIED: Parenthetically, it might be the easier ones, then, right?

MR. ELLIOTT: We think. We don't know how they're all going to shake out, and which of the first ten is going to be really representative. But we're working on those that we think are going to be awards, or compensable and non-

compensable cases.

And the last thing I'd like to comment on is your -- what didn't make this list. I would just ask you -- I know the workgroup took to heart what Mary had to say. And I would point to the fact that you are looking at denied cases, and in those denied cases you are going to see some that represent those that go forward for appeals. That, I think, should be sufficient to attend to your interest about what an appealed denial looks like versus a denial that somebody just said, okay, I accept it. So I would ask you to make sure you consider Mary's advice and counsel on --

MR. GRIFFON: Well, I actually think we, as a group, I think the majority was in that opinion. And that's why I presented it kind of as a minority. And I'm not sure where I come down on it yet. I just wanted to leave it on the table a little bit, and partially because -- Henry introduced that concept, so it did some up as a comment yesterday from the Board, and so I didn't want to just rule it out from there.

Also partially because I felt like maybe that was at least some indirect way that we were paying attention to those that did appeal the

process, without stepping over the bounds of the adjudicatory process. That was another thought in my mind, was that it was a way -- while we are sampling from -- we may not be -- denials, but if we could say we were sampling from appeals that may still not satisfy that individual that appealed, because we may not get his or her case. But it was sort of one way to pay attention specifically to that subset of denials. I hear what you're saying, but --

The other thing I wanted to respond to was -- well, two things. One, I think that I just want clarification. I think Wanda's question about who is going to find these experts, and we have been going around on this, and who are going to be the available pool of experts that can do this work. But I think that the Board -- it is a Board task to identify the experts. It's NIOSH's role to contract with them, certainly. But I think if this panel's to have independent expertise to review NIOSH, I think we have to make sure that these are our picks, the Board's picks. I think that's a very important distinction in defining independence for this panel. I'll leave it at that.

Then the other question about the amount of work and the two full-time equivalents, Wanda, we specifically -- because we had this discussion, too. And part of the reason we left out in yesterday's presentation, I put down a tiered approach of different levels at which we might review cases. And we just said, geez, at that third level, the most in-depth level, it's getting into a lot of work. And before we can even get down into those kind of protocols, we thought it wise to go to NIOSH and review some real cases and see actually what the magnitude of what we're asking for is.

So I thought that we tried to stick to the broad scope in protocol rather than -- but we still want to define, and that's where this would just be a first draft of a procedure or something, but we want to further define protocols. And then I think the Board will respond to those protocols as well.

DR. ZIEMER: Mark, in presenting this you didn't explicitly recommend its adoption. But I think that was implied in the presentation, and since this is a subgroup of the Board that's recommending its adoption that becomes an

official motion. I'm going to consider it as such.

It doesn't require a second, since it's from an official body of the Board. And we've already had some discussion, but adoption of this protocol as a procedure for moving forward is officially on the table for discussion.

Further -- Jim.

DR. MELIUS: I have another plan. It's not directly relevant to -- concerning the motion. So we can either do it now or do it later, but one -- so stop me if you want to, into this. It shouldn't take long.

One way around this dilemma, this getting involved in an appeals process and so forth, is that there's certainly also -- there's a back and forth that goes on between NIOSH and the claimant during the dose reconstruction process. And there'd be awareness on the part of the NIOSH staff that there's some dispute over some of the factual information, or there may be a particularly difficult technical issue involved in the dose reconstruction or whatever.

It would seem to me that there should be a way for NIOSH to refer some of these issues into

this review Board group to look at in a way that would address these, short of the appeals process and staying out of that appeals process. And I think that may be a way of also helping with the credibility of the process. Because if there is this kind of issue that's in dispute, or sort of new area or whatever, conflicting approaches or whatever, that having -- the Board having reviewed it as part of the process, I think, may be helpful.

And I'd like -- I guess I would request that Larry and Jim and other people sort of explore ways of doing that, again keeping us out of the appeals process.

DR. ZIEMER: Right, you want to be sure that we're simply reviewing the process, and not part of the process.

MR. ELLIOTT: I guess that would be my concern. I appreciate your comment, Jim, and I think it merits our consideration and discussion. But we do want to do that. You're to review completed dose reconstructions. And I don't know if that really -- we need to talk about that. We need to get general counsel's advice on that as well.

DR. ZIEMER: Well, again, as experience is gained, we'll have some further insights.

DR. NETON: I would point out, in a random sampling process you're going to run across these, I guess what you'd consider contentious dose reconstructions, because the administrative record that is associated with all of these cases has every single piece of correspondence and transmittal and whatever we've done in that administrative record. So you will, on a random basis at least, tend to run into these cases in your sampling.

DR. MELIUS: I guess it's when they're contentious in a technical way or something, not as -- as opposed to -- I think that's what we're trying to get at, process for you to access us, because those are the ones where the credibility of the process is more at stake than -- if somebody's going to appeal --

DR. ZIEMER: Well, and there may be issues that can be brought to the Board in a generic fashion that are triggered by a particular --

DR. MELIUS: Right.

MR. ELLIOTT: It may not be claim-specific, but methodologic issue-specific.

DR. MELIUS: Yeah.

MR. ELLIOTT: Maybe that's the way to get at. But it's something we need -- we certainly should look at, and I agree. But I'm worried about -- we can't violate this what we consider to be the development of the claim and the administrative record that goes forward, and that's what you need to review as a completed dose reconstruction.

DR. ZIEMER: Roy has a comment.

DR. DEHART: Can I call for the vote? I'm having to leave.

DR. ZIEMER: Yeah. The question’s been called for. I'm going to take that as an informal call for the question.

DR. DEHART: Yes, it is.

DR. ZIEMER: We're not going to vote on limiting debate.

All who favor adopting this procedure, say aye.

(Ayes respond)

DR. ZIEMER: All opposed, say no.

(No response)

DR. ZIEMER: The procedure is adopted.

Thank you very much, Mark, and the working

group for that.

MR. ELLIOTT: If I could make one more comment, and that is the surrounding -- I appreciate the Board's need to be independent and identify, but it's a procurement issue. So we're going to have to work together on how we put that in place. There are certain ways we can do sole source, and there's certain ways we can't do sole source. We also have to wait and see what this pool of available remaining experts looks like.

DR. ZIEMER: As the Chair packs up his things to catch a plane, I'm going to ask for a motion to adjourn.

MR. GRIFFON: Motion to adjourn.

DR. MELIUS: We all want to spend time discussing that.

(Laughter)

DR. ZIEMER: All in favor will head out.

(Whereupon, the meeting was adjourned at 3:58 p.m.)

- - -

C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 270 pages, was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this 23rd day of July, 2002.

_____
KIM S. NEWSOM, CCR-CVR
CCR No. B-1642

(SEAL)