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

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

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

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

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

I'm going to say the exposure is chronic,

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

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

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

MS. MUNN: I understand, but –

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

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

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

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

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

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

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

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

Again, these are more model details. This

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

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

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

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

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

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

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

MR. HENSHAW: Okay.

DR. ZIEMER: With the same dose.

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

DR. ZIEMER: Say five.

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

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

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

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

MR. HENSHAW: Yeah, it really bears –

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

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

DR. ANDERSON: What about a cigarette smoker?

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

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

UNIDENTIFIED: Go in the middle somewhere.

DR. ANDERSON: Just go to ten.

MR. HENSHAW: Ten to 19, or –

DR. ANDERSON: Yeah, that's good.

MR. ELLIOTT: Make it reasonable.

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

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

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

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

MR. HENSHAW: Let's find out.

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

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

DR. ZIEMER: Importance analysis.

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

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

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

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

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

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

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

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

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

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

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

MR. HENSHAW: Thanks, Mary.

Before we — oops.

DR. ZIEMER: I think we lost it.

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

DR. ZIEMER: I think you lost it.

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

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

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

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

MR. HENSHAW: Oh, thank you.

UNIDENTIFIED: Russ, exposure year, was that 1981?

MR. HENSHAW: '81, right. Thanks.

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

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

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

MR. HENSHAW: Leave the other factors the same?

DR. ANDERSON: Sure.

MR. HENSHAW: There's no change.

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

DR. ZIEMER: Go ahead, Rich.

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

UNIDENTIFIED: The number of exposures.

MR. HENSHAW: Oh, right here?

MR. ESPINOSA: Yeah.

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

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

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

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

DR. NETON: Jim Neton.

MS. NEWSOM: Thank you.

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

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

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

[Laughter]

MR. ELLIOTT: We're all conflicted.

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

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

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

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

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

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

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

DR. SCHUBAUER-BERIGAN: Yes.

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

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

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

DR. SCHUBAUER-BERIGAN: Well —

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

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

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

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

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

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

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

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

for –

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

DR. SCHUBAUER-BERIGAN: Yes.

DR. ZIEMER: Okay.

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

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

UNIDENTIFIED: (Inaudible)

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

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

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

DR. SCHUBAUER-BERIGAN: Chronic would be —

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

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

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

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

DR. ANDERSON: Right.

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

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

DR. SCHUBAUER-BERIGAN: Right.

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

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

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

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

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

DR. ZIEMER: Are there any further questions at this time?

[No responses]

DR. ZIEMER: If not, let's proceed then to the next item, which is the dose reconstruction rule, 42 CFR 82, and back to Ted Katz, I believe.

Ted.

MR. KATZ: Thank you, Mary.

Hello again. Okay, I'm going to do more or less the same as what I did for or against Mary, which is to start the ball rolling for Jim, who'll give you more technical background. But I'm going to give you background on it and a general, very brief overview on the dose reconstruction methods which, as we've talked about, are already effective.

So here's my overview here. I'm going to

discuss what the purpose of these methods is, how they'll be used, what Congress requires with respect to these methods. I'm going to give you some basics of dose reconstruction under the interim rule. And then two issues, one a very core issue, which I say here, how NIOSH will balance efficiency and precision. And then a sort of extreme case that we address in the rule too, which is what happens when NIOSH cannot complete a dose reconstruction.

So the purpose of the methods is to establish how NIOSH will estimate radiation doses incurred by employees. Each employee needs dose estimates to be able to have a probability of causation determined, and the dose estimates will be used by DOL to determine that cause.

NIOSH, I make this point, will make — will conduct dose reconstructions for cancer claimants only. This is important. These dose reconstructions are entirely designed for making compensation decisions, and you wouldn't design them the same way if you were doing research. And it ends up being very important, but we don't have, in the case of a claimant, years to decide how much dose they were exposed, in effect.

What does Congress require here? First, it requires that the methods must be applied for employees, and it specifies not monitored, monitored inadequately, and with incomplete records.

Now in practical terms, it means the methods will be applied for all claims, and let me qualify that here. Someone has to determine whether they were monitored adequately or not and whether they had complete records and so on. So these are going to have to come to NIOSH to have a look, at the very least. And then the extent to which a dose reconstruction is done is determined on a case-by-case basis, depending on what you have there. But we will have to handle the cases for all the claims. And the Board has a very important role which has been discussed, which is to independently review the methods and a sample of dose reconstructions.

What are the basics? We talk about this in the rule. We rely on a hierarchy of data that starts with personal monitoring data and extends to monitoring process and source information.

The key issue, as I say here, is the completeness and adequacy of the data. And what

this requires, then, is that we address all sources of data. So the hierarchy, it's a little bit misleading for some in reading this rule, perhaps, thinking that we're just then using the monitoring data if there's monitoring data there. But no, in fact we're going to have to look at these other sources of data to interpret that monitoring data.

And a key element of this, as has been discussed earlier, is we're going to be interviewing the employees to identify and fill data gaps and help interpret the data. The employees can tell us about actual monitoring practices, perhaps, versus official practices. They can tell us about incidents that occurred that may not show in their record, and so on.

And it's important to note here that we're dealing with a lot of claims that are going to be coming as well from survivors, and the survivors typically know very little about what their spouse did. And this is why in those cases we'll be going to coworkers as a surrogate for the deceased spouse.

To continue on here, Jim Neton's going to really go into detail about this next point.

We’re going to make the use of the best science, ICRP models and a state-of-the-art internal dosimetry program.

Very importantly, we're going to provide full accounting to the claimant of the methods, data, assumptions used. They will have, at the end of the process, a report that accounts for all the information they provided, for all the information we obtained from DOE, and for all we did with that information. So they will be fully informed. They can take that information and not have to flay us for more information to understand what happened in the process.

And also importantly, the claimant's going to be very involved with us in doing the dose reconstruction. But at the end of it all, if they are dissatisfied, if they have reason, they have cause to think that we haven't applied our methods appropriately, they can seek review through DOL.

Now this is what I mentioned as a really core issue, which is I think unique to our program here, how NIOSH will balance precision and efficiency. And you see this first bullet is already outdated after a couple of weeks, because

I say 12,000 claims and they already have at DOL 15,000 claims that are coming our way — incredible, unprecedented volume that we're dealing with of dose reconstruction here. And it doesn't allow us to do dose reconstructions, as we've said, if we're going to provide timely service the way we would for research. And Congress emphasized the need for timeliness, and it's obvious for the human need here. I'm going to remind everyone we're doing dose reconstruction to permit claim decisions, not achieve precision here.

So the basic strategy here to get to that point, to be able to do this while ensuring fairness, is to shortcut the process, in effect, for two groups.

For groups with very high doses what we're going to do is curtail data collection and analysis. There's no point delaying their compensation for us to develop a more precise, complete dose reconstruction record. So we're going to move those claims as quickly as possible, and they'll have their compensation sooner.

And then the other extreme is employees with

very low doses. Once we've collected enough information to know that, including speaking with the claimant or coworker and so on, is to use worst-case assumptions so that there's no doubt for the claimant that their dose hasn't reached a compensability level.

And then for all those claims that fall in the gray area which aren't obviously extremely high or extremely low, we will proceed with the full process.

Last issue, what happens when NIOSH cannot complete a dose reconstruction? Now we don't have a good feel, I don't think, at this point for how common this fix will be. But it's clear to us that it's going to be relatively rare, I think. And it's going to be situations where we have very little information about source and process.

Anyway, this situation has been anticipated by EEOICPA, by Congress, which allows for SEC petitions, petitions to be added to the Special Exposure Cohort. And several people talked earlier that HHS is responsible for these procedures and these are in the works. And you'll be hearing about these in future meetings.

And the last point I want to make here about these is while this is a remedy for most, there may be individuals who we can't do a dose reconstruction for who have — don't have a cancer on the specified cancer list. And in their situation this isn't a remedy. This is not an avenue for compensation.

Thank you. And would you like me to take questions, or wait for Jim?

DR. ZIEMER: Well, let's see if there are questions at this moment.

Yes, Dr. Roessler?

DR. ROESSLER: When you talk about the shortcut process and the very low doses, what's your definition of a very low dose? I mean, is there a number that you use that puts them in that —

MR. KATZ: There is — no, there isn't a number, because low dose depends on what type of cancer and a number of parameters. But given the volume of experience that's going to be gained very quickly here, we'll learn what it means in different situations. And so there's no — we couldn't say — we couldn't put out one number that's going to work for all these cancers, for

all these exposure situations, and so on. But it'll be cases where it's evident that the dose is far too low to be compensable, again in the judgment of the experts who are going to be running all this work.

Any more questions?

[No responses]

DR. ZIEMER: Okay. We'll proceed, then, with —

MR. KATZ: Thank you.

DR. ZIEMER: — Dr. Neton, who will give additional information on dose reconstruction.

DR. NETON: Good afternoon. It's a pleasure to be here and finally address the Board, after it seems like an eternity of waiting for your arrival. I appreciate your input on any of the information that we're talking about today.

In particular I should point out that what I'm going to discuss is draft. No final decisions have been made by our office on these technical issues. These are just some of the ideas that we're sharing at this time.

I am Jim Neton, and I'm the Health Science Administrator within the Office of Compensation Analysis and Support. And I've got the

challenging effort of trying to process these tens of thousands of claims with a staff of some very qualified people – health physicists and claims processors – to try to make some sense as to how we're going to approach this and do this in a timely manner to award claims, hopefully not in glacial time but in – not in real time, either, but to make it as efficient and fair a process as possible.

Now the first thing I think it's important to talk about is the difference between compensation dose and regulatory dose. We've hinted about this all afternoon in going through the probability of causation estimates and such, but there are a number of key differences between what a compliance program in the field that the DOE ran for years to try to ensure their workers were adequately protected, versus what we need to know to determine if the probability of compensation is equal to or greater than 50 percent.

The first issue is the compensation dose evaluation period is not limited, or is limited only to covered employment. For example, we're not interested in lifetime monitoring dose, which

many DOE sites have a fairly good handle on, but that's not relevant. And in fact, we need to know something more than that. We need to know the person's dose from the date of first exposure of covered employment to the date of the diagnosis of cancer. That's the only period that we're really concerned about that will be actually input in the probability of causation calculation. So in that respect we need to pull a lot of monitoring records through, sift through them, and pull out that unique time frame.

The other issue is that it includes internal, external and some occupationally-acquired medical sources of exposure. Those of you who have done health physics work in the DOE are aware that prior to the late eighties, like I think 1/1/89 comes to mind, internal doses were not really calculated at DOE facilities. They were — workers were protected based on what they called the maximum permissible body burden concept, which was dosimetrically based, but does not provide the type of information that we would need for a compensation scheme.

In addition, this occupationally-acquired medical sources of exposures is unique to our

process as well. And what we mean by that is medical exposures that were incurred by a worker as a condition of employment. For example, there are some sites where to be, in the earlier days, to be qualified as an asbestos worker, you were required to undergo an annual chest X-ray. It was required for you to do your job. In our opinion, therefore, that is occupationally-derived exposure that should be included in his compensability examination. Routine physical examinations, if they were voluntary, that sort of thing, would not be included under this.

And it's probably pretty obvious after going through the probability of causation examples that Russ and Mary did that an annual dose is required for a probability of causation estimate. We cannot use the 50-year committed dose equivalent or committed effective dose equivalent that is currently applied to Department of Energy workers.

And I know some sites have actually gone back and done sort of pseudo dose reconstruction efforts and calculated a worker's 50-year committed dose from earlier years of employment. That information would be useful for us, but not

necessarily in that form. We still are going to have to pull out the annual dose, because as you saw earlier, the probability of causation changes depending upon the distribution, annual distribution profile of that worker's exposure.

On a similar note, the committed effective dose equivalent concept, as I mentioned, is not applicable. The 50-year dose that's calculated to a worker from an internal exposure is not something useful for us, nor is the effective component of that. The effective dose component of that calculation is really a risk-based unit. I mean, it’s taking a radiation exposure and trying to equate it to a risk to protect the worker. We need to strip the effective component out, and as you saw earlier, IREP actually does, has the risk model built into it.

So in a sense, what we are ending up with with our calculations is a dose equivalent, the old Hp, H=DQN type thing, dose times a quality factor times other modifying factors. And that is in fact what we need to calculate.

Okay. Continuing on with some of the differences, at least as I see them, for external exposures the film badges and TLD badges have

been used historically since virtually the inception of DOE operations. But what that does is that measures the dose to the badge. In the earlier years it measured the dose to the badge. Under current regulatory framework, you actually measure the dose — you try to estimate the dose at one centimeter deep in the body, and we'll call that deep dose.

Well, that may or may not be applicable to a worker's compensation analysis. For example, organs that are very deep in the body, such as, you know, the liver or a lung, which is covered by five centimeters of overlying chest tissue, may be lower than the badge reading that the worker received.

Now for most scenarios — and I'm going to talk about this in some detail tomorrow — it's pretty close for high energy photons. The situation where you get into very low energy exposures, such as from americium-241, 60-keV gammas or plutonium X-rays, there can be massive differences between the recorded badge dose and the actual dose delivered to the organ. And we need to take a look at that and bring some sanity to that calculation.

A very important point is that undetected dose, also known in the business as missed dose, is an important factor. In a regulatory framework one is interested, particularly in the earlier years, of maintaining employees' exposure below some regulatory limit, and the monitoring programs could have a fair amount of dose that was undetected and still be considered adequately protective of the worker. We need to take that into account when reconstructing the worker's exposure.

I'm going to go over a couple of little examples of that later on, but the classic example is the film badge has a certain detection limit. In the earlier years it could have been as high as 30 millirem received on a weekly basis by an employee. And if that badge was exchanged, like I said, every week, then there's a potential — I'm not saying it was received — but a potential for the worker to receive upwards of one and a half rem of exposure and had gone undetected. So we are developing ways of dealing with that in our guidelines.

Another factor is uncertainty distributions are allowed. In the compliance-based world

they're point estimates. I've never seen any errors associated, unless maybe some massive dose reconstruction for some really big incident like a criticality, errors are not typically assigned because they're below the limit, and that's fine. We have the opportunity here to characterize these uncertainty distributions for each worker.

We've demonstrated earlier with IREP as to what the change in the standard deviation of that estimate can do to the probability of causation. We're taking a long, hard look at how we actually apply those, particularly in the area of internal dose where geometric standard deviations – well, if it's lognormal distributed, a gSD of two or three is probably not unheard of.

And the other, one of the nice features that we have available to us, is we're not constrained by regulatory-required science. All the current standards – the Department of Energy right now is based on the old ICRP 30, 26 dose limitation philosophy, which is fine. But there are more current and appropriate models out there that we feel are better science and do a better job at estimating the actual dose to the organ. And we'll talk a little bit about that.

Okay, a technical approach. The first thing we need to do is to take a look at all doses of record and evaluate them for data quality shortcomings. We are not going to accept even personnel monitoring data at face value and assume that it's adequate. I mentioned in the earlier days at some facilities there were plutonium exposures that — it's well known that the badge was not capable of detecting those low energy X-rays, so those were unrecorded. We need to make some adjustments to those data as we develop our knowledge base of the technology at the different sites.

As I talked about, we're going to assess the capability of external programs over time, look at the badges, their response to neutrons, gamma, X, and in particular the radiochemical techniques for bioassay sampling needs to be taken a look at. In the early days some of the radiochemical processes, although they were good, were — tracers weren't necessarily used all the time, so one does not really know about the chemical recovery of the method that was used, different issues like that; the efficiency of the alpha proportional counters that were used. We're

going to take a look at all those types of information.

I talked about earlier looking for the potential for undetected dose. And for external exposures we've concluded that we're going to use — and I'll talk in much more detail tomorrow if there's time — about what they call the limit of detection divided by two. If a badge could read 30 millirem, there are a number of papers out there — Hornung, et al. and others — have suggested that the detection limit divided by two is an appropriate metric to estimate the central tendency estimate of that exposure for that monitoring period. But it's a little more complicated than that, whether it's a lognormal or normal distribution. We can talk about that tomorrow.

And a parallel note, the minimum detectible internal dose is even more complicated because bioassay monitoring programs have a certain detection limit, but depending on how frequently a sample is collected for a worker, the dose could be — is quite — the undetected dose is quite variable. It's sort of intuitive that if one takes a sample on an annual basis, the worker

could have received a lot more dose and been undetected than if a sample is taken on a weekly basis or a daily basis. So we're taking a long hard look at that as well.

I talked about using these ICRP – Internal Commission on Radiological Protection – models. In particular we are embracing the ICRP 66 lung model for our dose calculation efforts. We have a contractor, ACJ & Associates, has developed a program for us. It's a beta version at this point. It's called IMBA, Integrated Modules for Bioassay Analysis, and that's what we're going to be applying.

We also believe that some of the more recent ICRP models take advantage of recycling of material in the body. The old ICRP 30 models are sort of what comes in one end goes out the other, and it never mixes back in the blood pool, that sort of thing. These new plutonium models allow for that type of analyses. So we feel it's a better representation of the biology.

In the external dosimetry evaluation the ICRP 74 model, ICRP 74, we're going to use to do those evaluations. And again I can talk in some more detail about that, but it takes into account

effects of conversion of the badge dose to what the organ actually received; also evaluation of the effect of the geometry of exposure.

For instance, if a person wears a badge on the front of their chest and is exposed in isometric fashion, then the badge that's calibrated from a beam impinging directly on the body is not necessarily calibrated properly. We're evaluating all those various factors and trying to incorporate that uncertainty into the overall analysis.

Ted touched on this earlier, but we do — once we evaluate the quality of the data, we do preferentially want — will use individual monitoring data if it appears to be adequate. And that makes sense. It was the actual — the person's own monitoring information at that time at that place, and that's where we intend to start if it's available.

As that information becomes less and less available, we'll have to back off and go to other strategies, and that would — the hierarchy goes area dosimeters, radiation surveys, air sampling, those type of things, what I consider work place monitoring data. And then as Ted alluded to, if

there's nothing out there, we can use a source term to evaluate that information. And surprisingly, source term information can do a — go a long way towards bracketing a worker's potential exposure.

I always use the example, you know, did a worker — when you're interviewing a claimant, did you work with grams, kilograms or tons of this material, and was it in dispersable form or was it contained in a rod. With those kind of bracketing assumptions — I have an example tomorrow — it's possible to put some — an estimate of central tendency, and put some confidence limits about that information.

These are just — this is sort of what I consider to be the universe of information types. This is in the rule, in 82. It's not all-inclusive. Some folks have pointed out there's a few items that probably could be included on there. For instance, continuous air monitor data is not in there. But I think it's a pretty good list, and gives us an idea of what types of information we would use.

Now I'm not suggesting that we're going to use all of this information on every claim. That

seems to be a common misconception out there. What it really says is, you know, if we can't — if we can find some of this stuff, we'll use it. And we need to get out there and verify, is some of this information out there? And not only is it there, but is it in usable form, readily available for us to apply to a compensation program in the near term?

It does us no good if there are air sampling results distributed over 50 facilities, paper copies in offices. It would take us three to five years to data-capture and code. So we need to go out there and do what I call a dosimetry information resource evaluation to determine how much we're going to use this information. I think we owe it to the claimants, though, to at least uncover all these stones and determine why we did not use this — these types of information.

Okay. Talk about processing strategy. I'm going to try to give you a little example of how this might work. We're going to start conservatively, using simple available monitoring data. And for example, let's take the case where have adequate either bioassay or TLD information, and we determine it to be of adequate quality.

Perform an initial evaluation using extremely worst-case assumptions in some cases, and if it looks like the probability of causation's going to be low, we're done.

Now the question was raised, well, what's the number? We really have no number at this point. We're in the process of constructing tables that you can kind of run through. If you can automate your IREP inputs, you can do continuous runs of IREP and generate tables of distributions of doses that can bracket certain scenarios. You can take a cancer type and an optimum, say, exposure scenario — optimum exposure condition set for a cancer and try to get an idea on this. But we're still working on really what these cut points are going to be.

Here's a flow diagram. It looks somewhat complicated, but it's really quite simple. Let's just take through one example. For instance, the top box, if you take the top box here, determine the organ of interest and most probable mode of exposure. What we're saying there is this is where a health physicist has to apply some degree of professional judgment.

If a person worked at a uranium facility, I

think it would be fairly well agreed upon that uranium and internal exposure would be the most likely high source of exposure. Uranium facilities, at least not enriched ones, are fairly low in the gamma component. If you took the ratio of internal to external, internal would always have a higher potential.

So if one went through and first picked and said, okay, I'm going to go through and do an internal dose calculation for this person using worst-case assumptions, and I go through and it's a low probability — and by worst case, I mean very insoluble material, worst-case missed dose, minimum detectible dose — if it's a low probability, we still need to consider what his external exposure was. So we would go through and use worst-case assumptions for his external exposure, accounting for all that missed dose based on badge exchanges, et cetera. If it's still a low probability, then there's no way that this number would likely be compensable, so the dose reconstruction is done. We bypassed a fair amount of work.

I have a couple of short examples I can show on this. Likewise, if it was not a low

probability, say it came out very high for the internal exposure based on these insoluble materials, and then we went and said, okay, let's do a conservatively low estimate for that internal exposure as well. So we've gone high. It looks like it's high. Let's figure out what the lowest plausible exposure was, and if it's a high probability — if it's still a high probability after you've taken your least — most conservative assumption, then you're done.

So this is a process that we've outlined, and we've gone through several scenarios. And it appears like it will allow us to gain a great amount of efficiency in this process, where we're not going to have to go through a very detailed analysis for every case.

Here's an example — and these are some fairly real-world type examples of an exposure at — I believe this was Hanford. The person was exposed from 1954 to 1961, had fairly low annual doses for X-ray and gamma exposures. And so we would go in and account for this missed dose, the undetected dose, add it back in and input — not input this into IREP, but use our experience base from IREP and realize that this case is going to

be — has a very low probability for compensation, especially if there was no external component available. I think when you saw — for solid tumor particularly, you saw the runs that were done earlier. Solid tumors with under a rem of exposure, whatever that amounts to, are very, very low probability of compensation.

On the other hand, we would take something like this plutonium bioassay data, and this is urine concentration of plutonium at picocuries per liter. The dates aren't really relevant, but say that this was over a several-year time span. The detection limit for this fellow was .05 picocuries per liter, so that's right around in here. And you can see that he's had a series of acute intermittent exposures, which I suppose could be modeled as chronic exposure.

But in our first worst-case assumption we're going to ignore it, and we're going to say, let's just look at this thing. This is a fairly large exposure. Let's take these points and assume that the exposure for these points occurred way back here at the date of first employment.

So what you end up is wildly over-predicting this intake, ignoring all this low stuff. And if

that calculation still came out very low, then you're done. You'll never have to even mess around with these other 20 or 30 data points because you've demonstrated that. This may be the case for some very soluble material like UF4 that leaves a lung very quickly as opposed to insoluble.

Conversely, say if this exposure came out very high based on this, which you would expect if it was insoluble, then we could go over here and say, well, let's just look at this intake by itself. Let's see if this intake alone is high enough for the person to be compensated. We still haven't had to calculate any of these data points. And if we model this intake — just these points right here — and the probability of causation was very high, we're also done. So it does a lot for us.

Now one thing that's not obvious until you start looking at it is it really has a lot to do with the organ that you're calculating the dose to. For internal exposures it's somewhat self-limiting in the fact that the only organs that really get a fairly large exposure are the organs that tend to concentrate the material. For

plutonium that would be something like the lung, the liver and the skeleton. If you have a cancer for any other organ and I wildly over-estimate this dose, I can pretty much bet that the dose to those non – what I call source organs, is also going to be low because plutonium does not concentrate in the prostate or the gallbladder or other organs like that. And in fact, if you run through the models, it is very low.

We've actually had our IREP or IMBA program, Integrated Modules for Bioassay internal dose program, we've had them go through, and we calculate a dose to each of the 36 ICRP 60 type organs that are out there now, and we can see these large differences. Virtually the only dose you get to a non-source organ is the crossfire from the organ – one organ to another. And there may be some ways of looking at the transfer compartment and adding a little dose back, but I still suspect it's going to be low.

Okay. This slide is woefully out of date and probably needs updating. I apologize, but I guess I got lazy at the last minute. This is essentially our attempt to demonstrate what an input to IMBA would look like – IREP would look

like when we provided it to the Department of Labor. And you've seen the demonstration where we have to determine what the type of distribution we expect the exposure to be, and we put in our best estimate of central tendency, and we also insert our geometric standard deviation if it's lognormal. If it was normal, of course that would just be the regular standard deviation.

So we do this for these — you know, in this case, 1951 through '58 — from both an internal and an external perspective, and identifying whether it's an acute or a chronic exposure. We just had that conversation that we are going to default, unless known otherwise, an external exposure will be classified as an acute exposure, because we cannot tell from badge monitoring data what the exposure scenario was unless there was something in the person's file that was involved in an incident, a criticality or something like that. For neutrons, however, we're in the position to be claimant-friendly of calling neutron exposures chronic exposures, and all alpha exposures from internal are going to be chronic. So we defined those parameters.

One thing that's not shown on here, though, is the IREP allows for 11 different types of radiation exposures. There are five neutron energy intervals. There are three gamma energy intervals, and then also there's electron exposure, beta exposure, as well as a tritium exposure – it has a slightly different radiation weighting factor – as well as the alpha factor. So we can select – I'm not suggesting that we're going to know every claimant's exposure scenario down to that level of detail, but it is there if it's known.

Okay. How long are we going to expect these dose reconstructions to take? It's going to vary all over the board. My guess – and I said complex – you know, it may vary depending on level of complexity. I said days to months.

I've seen, in looking through some of these cases, that there's some that can probably be done in a day or so, depending on – some of these low dose ones where a person after interview realizes that's their entire history, where it's a fairly low potential external exposure environment and the missed dose is fairly low.

The internal exposures, if we do our

bracketing worst-case assumption and then go to our conservative assumption and they still come out kind of on the bubble, that's where we're going to have to take and do a whole full-blown dose reconstruction and account for every data point and model the exposure, and that could take months, particularly if we really don't know the exposure very well, the exposure conditions of the claimant.

I also say cases with extensive internal exposure I expect to be the most complex. I guess I just talked about that.

And additional time required for previously unexamined locations and processes, we have these atomic weapons employers. There's almost 300 of them out there where we have almost no monitoring data, and we know very little about the process. That's going to take some time. I mean, it's not intuitive, we're going to go in there and be done in a day or two. That's going to take some research and investigation to accomplish those cases.

Okay. Where are we so far? I think it was mentioned there's about 13- or 15,000 claims hanging out in the system somewhere. We have in-

house within NIOSH — I think last guess was about 1,500, is that close? — so we have about 1,500 claims in-house. So we're frantically working to try to get this process in place.

It was never envisioned, though, that the NIOSH staff itself would actually do all the dose reconstructions. We have fairly limited resources. We, in addition to myself, we have a staff of three health physicists who are right now working on getting the program in place. We've — just a week or so ago the first draft of the implementation guides themselves for external dosimetry and internal dosimetry were completed, and that's moving along.

We're working toward a Memorandum of Understanding with the Department of Energy in sharing their information. That right now is undergoing internal review. The DOE is expecting us to provide them a straw man version of that Memorandum of Understanding, and hopefully that will be issued sooner than later.

We are going through the process right now of requesting DOE personnel monitoring information. We're not right now going after any of the work place information. We feel it's most

appropriate right now to go for the personnel monitoring information, to look at it, to evaluate it to see how it can be used, and that's going to be our starting point. In cases where there is no monitoring information — for instance, many construction workers were never monitored — we need to then go out and start looking at the on-site work place monitoring data.

I think we've issued somewhere around 700 DOE requests for information so far, so we're working to close that gap. Hopefully shortly there'll be sort of a one-to-one correspondence when the claimant's notified, that then we receive their claim, that the DOE request for information goes out.

We are looking at the records availability at certain facilities. We have a pilot study — two pilot studies that we've started, Oak Ridge and Hanford. Those are moving slower than we'd like. The Memorandum of Understanding will go a long way towards, I think, helping define the roles and responsibilities of the players involved in doing these records searches.

We are developing a computer database. It's

been talked about earlier that the Health-Related Energy Research Branch within NIOSH has been doing DOE workers studies for nine or ten years now. They've developed a considerable database of occupational monitoring records, mostly oriented towards doing epidemiologic studies. We are working in cooperation with HERB to collect that information and assemble it in a form and format that's useful for doing dose reconstructions. And we hope to grow that database and go and get more DOE information, essentially have a very large internal database that will allow us, as time goes by, to be less and less dependent upon Department of Energy as a resource for much information.

And most importantly to me at this point, we have a request for contracts for dose reconstruction assistance. It was in procurement, but as of last week it is available. We're expecting proposals due from the contractor, I believe, February 19th, fairly short turnaround time. We are working as fast as we can to get a contractor on board who will do the bulk of the dose reconstruction effort under our guidance and quality control and oversight.

Okay. I've come to the end of my formal comments, be happy to answer any questions if anyone has any.

DR. ZIEMER: Thank you, Jim.

Who has a question? Maybe I'll start it out.

It seems to me there's a possibility that, as you use newer models and do depth-dose calculations for external, that your numbers could come out quite different from what some would call the dose of record in the agency. That would seem to cause some problems with potential claimants who would look at that and say, well, there's my dose record. They tell me that's my dose, and you guys are saying it's much less than that.

DR. NETON: That issue —

DR. ZIEMER: I'm not asking you to answer that, but it seems to me that's a problem that the agency's going to have to deal with in terms of talking to claimants. I'm pretty sure some of the new ICRP 60 will give lower internal doses on some of those organ doses than the older models do.

DR. NETON: Not across the board.

DR. ZIEMER: No, not across the board, so it depends on what it is.

DR. NETON: Right.

DR. ZIEMER: I'm just saying it seems to me there is that possibility.

DR. NETON: I agree, I think there's a —

DR. ZIEMER: The film badge dose, which is — you know, the depth dose is one centimeter and you're going deep, it's going to be a different number.

DR. NETON: It's going to be — have to be a very intensive communication campaign to educate the claimants as to what we've really done. We intend to do our best to get that out there in a fairly comprehendible or comprehensible fashion to the claimant.

I think in many cases this difference will not be obvious, because most DOE programs don't calculate a dose over the time period we're looking at. I mean, we're going to look at the time of first employment to date of diagnosis on an annual basis, so internal exposures won't — there will be no one-to-one correspondence with those. External exposures, yeah, I think so. But I think those are going to be closer. We're

not doing anything fancy there, other than accounting for some of the obvious geometrical differences, which I think can be explained.

Another factor is that when you run IREP, if you notice, what happens is we use the ICRP 60 weighting factors, radiation weighting factors, to come out with an equivalent dose so that we can report to the claimant something that makes sense to them based on their past experience. I mean, they're used to seeing like an equivalent dose type number. But when IREP is run, it uses the distribution for that radiation weighting factor and applies it, so in a sense it's going to be inflated – not inflated; it will be sampled over its total distribution, so there is no point estimate for the radiation weighting factor.

So there's a lot of these things that are different that need to be explained to workers as to why they are different, and why we did what we did.

DR. ZIEMER: Other questions?

[No responses]

DR. ZIEMER: Okay, thank you very much.

We now come to the part of our agenda which is the public comment period. We have requests

from three individuals to speak.

Richard Miller requests to speak at 4:00. Does that mean Rich is not here right now? You are here, okay.

And David Richardson — David, how much time do you anticipate you would need?

MR. RICHARDSON: Five minutes, maybe.

DR. ZIEMER: Oh, okay. I was just trying to get a feel for this.

And Richard, about how much time do you need? How much time do you need?

MR. MILLER: Five minutes.

DR. ZIEMER: Five minutes, okay. Then none of these are extensive. I wasn't trying to force anybody to use up the hour. So Richard, if you would approach the mike, and you can use either the mike here or maybe preferably go to the very front so we can see you easily.

Richard is with the Government Accountability Project. Richard Miller.

MR. MILLER: Greetings. I — the Government Accountability Project, just to explain what it is and why I'm here today, has been tracking the implementation of this legislation, I guess largely because I moved over there. I had

previously worked for the Oil, Chemical and Atomic Workers Union and then PACE, which had spent a significant amount of effort trying to pass this legislation. So it's quite interesting for some of us who were involved in the negotiations over the bill and the drafting of the language and the lobbying that followed it to now watch it play out before your eyes.

Needless to say, the law of unintended consequences prevails, despite what we thought were our best insights and what was politically achievable. And I want to just focus on two areas today.

The first is the composition of the Board, over which you really have no control. But I — just for what it's worth, and it is frankly beyond the control of NIOSH or CDC by statute, as the President, of course, appoints you all to this Advisory Board, and the statute's very clear on what the appointment process is supposed to consist of. And I'm just going to read from the statute one paragraph, if you can indulge me, which is Section 3624 on the Advisory Board.

It says, (Reading): The President shall make appointments to the Board in consultation

with organizations with expertise on worker health issues in order to assure that the membership of the Board reflects a balance — key word — of scientific, medical and worker perspectives, and the President shall designate a Chair, which he has done.

The question is whether the Board in fact is constructed with a balance, as was intended by Congress. Now balance can mean a number of different things to different people. But if I see three criteria and there's roughly ten people on the Board so far, a third should fall into each of those categories, give or take. You've got a little bit of wiggle room there; you can have four in one category and three in others. And likewise, if the Board were increased in size, you would still expect some kind of proportional allocation.

Now it doesn't specifically say what the areas of science are or are not, but from the outside at least — and again, it is not a criticism of any individual here on the Board or whether they should or should not have been appointed — but it is an observation for those of us who are watching you deliberate on providing

advice that the constitution of this Board woefully underweights worker representation. And it is indisputable, at least from my perspective, that the only worker here is Richard Espinosa on the committee, as I think Congress had intended, what they meant by worker perspectives. And — well, each person's entitled to their views, and I will offer mine.

If — with that in mind, the question becomes — everybody, by the way, is a worker, because if everybody's collecting a paycheck you're effectively a worker. The question is whether you are or were in a position to be in management control or not. And this was a law which was intended to benefit, in effect, those who had the least power in a process that was largely conducted in a self-regulated and generally under significant secrecy.

So today, when you look at this body deliberating within this framework on this matter, from those of us from the outside at least, some of us believe that the Board is not adequately constituted. Will this affect the outcome of the deliberations? You know, it's a social science experiment.

Nevertheless, I just thought I would put that on the table because it is something that we very much would like to see done, and I want it on the record that this body, at least as constituted from our perception, does not meet those criteria. And we've communicated those views to the President.

The second issue which I wanted to address has to do with the – what Jim Neton was talking about, which was the forthcoming contract. And I've brought a letter which I sent to NIOSH – and I apologize, I only brought nine copies, so we'll have to get an extra one – but I brought some along, and I apologize for being one short. I think somebody borrowed one of my ten copies.

And what this gets to is the fact that as NIOSH moves forward with its dose reconstruction contracting process and the RFP's on the street, NIOSH has been, I think, sensitive to, at a staff level, concerns about conflict of interest. And the concerns around conflict of interest largely rest, at least from my perception, that there are likely to be perhaps only two bidders for this dose reconstruction contract.

I don't know that there will only be two,

but I have every reason to believe there will only be two based on conversations with the — sort of the contractors who showed up at the bidder's conference that was held in Cincinnati. And those two contractors, so that there's no mistake and no secrets about it, are going to be one team headed by SAIC and likely include Battelle, and a second one which is going to be headed up by Oak Ridge Associated Universities and may include MJW or someone else. But they're going to be the — those are going to be the two folks.

Now the statute, specifically the energy employees statute, when it spoke to the question of performing dose reconstruction work, was very specific in precluding either the Secretary of Energy or his or her designees or subordinate officers from performing the dose reconstruction work. It didn't say DOE contractors couldn't perform it, but it sought by assigning out this work for dose reconstruction away from what's perceived to be the agency, which could in some respects be considered culpable if there's harm involved.

And so what do we do? What do you do if the

folks who were involved in doing the work are involved in doing the dose — who are doing the dose reconstruction contract have relationships within the Energy Department?

Now NIOSH has done an excellent job of putting a crisp paragraph in its contract RFP that is on the web now which says, you know, if you're performing work at a given site you can't be involved in doing the dose reconstruction work at that site. Does that go far enough? I think it's an important first step.

Our concern and perception, as our letter lays out, is that there needs to be transparency, that the individuals that are hired by the teams need to be disclosed. What is their work history? Where did you work, who did you work for, both at an organizational as well as an individual level? And it needs to be transparent to the claimant. It probably needs to be transparent to you, as you provide quality assurance over this process as well.

We don't know if there's a way out of this conflict of interest problem because it's a small pool of highly-qualified individuals with a great deal of expertise. And in fact, in some

respects, the RFP almost constrains you to using DOE contractors for the very work. You have this — it's the classic conundrum, right? How do you get independence at the same time you have concentrated expertise?

Well, our sense is that there needs to be a high degree of transparency, a clear-cut list of do-nots, which include such things as acting as an expert witness or supporting litigation in defense of claims involved in — where there's an allegation of radiation causing occupational illness at a particular site. We've got to have a clear-cut set of do-nots and a clear set of transparencies that go back and forth between the claimant and NIOSH, so that you don't get down the road into the dose reconstruction and people stick up their hand when the case becomes appealed and say conflict.

So we would just like to suggest — although it's not on your agenda for today, it did get raised by Mr. Neton — and I just thought I'd segue off your presentation and encourage you to think about what can be done to raise the level of confidence that the claimants will have in a system where, as the Congressional record and the

hearing record — I happened to testify in this legislation several times and worked with many workers who did testify, and went to many of the field hearings that Dr. Michaels, who I guess is here in the back of the room, held when he was the Assistant Secretary at the Energy Department, and those hearings revealed a high degree of irregularity in the dose estimation and dose collection processes.

And if there's a concern about a high degree of irregularity, coverup — we had documents where major DOE contractors like Lockheed-Martin were actually doctoring the data in order to avoid culpability in worker compensation claims, and these documents are out there in the public record. You know, the names may be redacted, but the facts are all there.

And so I think it's important for you all to think about how to build credibility into the contracting process, because the best procedures in the world won't overcome that skepticism. So that's all I had to add.

Thank you.

DR. ZIEMER: Thank you, Richard, and your comments will indeed be in the public record.

I might ask if any of the committee members have questions of Richard that you'd like any points clarified?

[No responses]

DR. ZIEMER: Thank you.

Next, David Richardson from Department of Epidemiology, University of North Carolina at Chapel Hill.

MR. RICHARDSON: Hi.

I want to, I guess, talk to you a little bit first about my background. I've worked in epidemiology on studies of U.S. DOE workers at Oak Ridge and Hanford, and participated in the case-control study that took place at multiple DOE facilities.

And so I want to make a couple of points just in response to the discussion that I heard today from the perspective of an epidemiologist, and maybe also just to start out by saying I think NIOSH has done an impressive job so far. I mean, I think the approach that you're using is certainly cutting edge, and you've done a lot of hard work in trying to think about both issues of bias and uncertainty.

And those are certainly two key points, and

I — so as my first point as — raising is to move beyond talking about bias and uncertainty to talking about effect modification. And it's something that a few people have raised already on the edges, so it's something to think about.

From studies of U.S. DOE workers that I've been involved with and that other people before me have been involved with, and after the work that I've done I've been involved with, I think one interesting example of effect modification comes with the issue of age at exposure. So under the current probability of causation tables for a given dose history, for a worker's dose history, the excess relative risk or the — and therefore the probability of causation for that worker tends to decline with older ages at exposure. That is — I'll maybe modify that and say it's either constant or it's declining, and there's a tendency for the solid cancers for it to decline.

In contrast, in a number of studies of U.S. nuclear workers you see the opposite pattern. And that's to say people who accrue radiation exposures at older ages appear to have larger excess relative risks. There's a larger increase

in cancer.

Now I'll stress here that this is not – I'm not talking about the difference between infants or children and adults. I think that's – I think it's clearly established in the literature that the developing fetus, the growing child is extremely sensitive to the effects of radiation. I'm talking here about a range of age that's going to be something like 18 to 20 years when you start work, to 65 or 70 years of age when you stop work.

And the evidence from a series of U.S. DOE nuclear worker studies is that – kind of similar to what you see for lots of other occupational hazards. As people get older they become increasingly vulnerable to injury on the job – here, radiation-induced injury – and the biological plausibility would be related to either declining ability of the body to accurately repair damage to genes and/or declining ability of the immune system to scavenge up damaged cells.

So to take some examples, the early – I think the early evidence of this came in early reports of the Hanford cohort, which was one of

the first studies. That was when you began compiling nuclear worker records in the atomic weapons complex. Subsequent to that there was the evidence of increased radiation effects at older ages of exposure in the Oak Ridge workers cohort, then in a multi-facility study across the DOE complex of multiple myeloma where older ages at exposure were associated with larger increases in cancer risk, and then in the Rocketdyne study that was done out by the University of California group.

So there's different ways of thinking about this. One is that there's a conflict of evidence between the life span study of atomic bomb survivors, which I think it's important to stress is really the numerical quantitative foundation of the tabulations that you're seeing that are spinning out of almost a black box computer; that there's a study there of people who were wartime survivors of an atomic attack, and the exposure conditions are different than the DOE workers.

Another at least issue to raise with that would be effect modification coming from — I think an interesting point that a lot of people have already raised, yes, you've looked at

smoking as an effect modifier, but workers are getting exposed to chemicals, and they're accruing other exposures on the job. There's a possibility that it's not a simple either additive or multiplicative translation of the life span study to the DOE complex; that workers have a different set of initiating and promoting carcinogenic exposures on the job, and that the age at exposure pattern is different.

And what I would propose is that at minimum that inconsistency in the literature is recognized and in some way accounted for. And one way that I would propose that is there is a series of factors now going on that reflect uncertainties. There's uncertainties in translation of additive or multiplicative effects. There's uncertainties in dose measurements, both in the DOE complex and dose measurement in the A-bomb studies, that you begin to have also reflecting an uncertainty in the effect of radiation at older ages of exposure.

You don't have to incorporate any bias or anything, but you say there's — the literature is not consistent in the range of exposures. So when you begin to look at effects of exposures

that are received at the older span of a worker's life, you say the effect is more uncertain than the simple point estimate coming from the life span study.

So that would be my — that would be the first point that I'd like to raise.

Kind of following from that, I'd like to also just briefly talk about an issue that maybe at minimum needs a point of clarification and maybe some more exploration, which relates to the discussion that by default external radiation exposures are treated as acute. And the implication here is that the DDREF, the dose and dose-rate effectiveness factor, therefore undergoes a shift.

It goes from treating it as an exposure that was accrued slowly over time to one that's accrued in a point blast, and therefore that the DDREF is one, or that there's — let me take a step back and say that external doses are going to be treated as acute, and therefore this issue of is the effect attenuated because it was a chronic exposure, is that set aside.

And in fact, as I understand the current way the program is running, it's proposed that any

external dose that's less than 20 or 30 rem, which from my familiarity with the Hanford/Oak Ridge/Los Alamos data this is going to incorporate 99.9 percent — I'm making up a percentage — but it's going to be the vast, vast majority of the dose is substantially — any annual dose record is substantially below 20 or 30 rem for a worker. I mean, workers did accrue doses in the DOE complex, but it was over decades of employment.

So here the DDREF factor, you begin to say the effect of a worker's dose is going to be divided by a factor of two, three, four or five — the effectiveness of that dose — because it was a low dose. That is not — it's not because it was a chronic versus acute, it's because it's in the low — the spectrum of the lower end of the dose distribution.

And as Mary Schubauer-Berigan brought up, in fact, the evidence now, if you're going to take the recent RERF reports from the life span study, they're not supporting a departure from linearity. I would argue that, from the perspective of an epidemiologist, a DDREF factor of multiples of two, three, four or five for

these low — these doses, which is almost all the doses that you're talking about in this program, is — I'm not sure it's supported by the epidemiologic evidence.

And so you have to then turn to evidence that's accrued from studies of animals' exposures or cellular responses. I think the literature — studies of the effects of low-level exposures to animals, it does get iffy. Most of the literature is higher dose exposures to animals. When you're looking at low-level exposures, the end point is not going to be cancer incidents, or very rarely.

Anyway, so I think that's another issue that I would open, and I think particularly if you're talking about issues of benefit to the doubt for the worker from the perspective of epidemiology, I think that's a really important point to consider and debate further.

DR. ZIEMER: Thank you. David, I'd like to ask you to clarify one thing. Are you arguing that the dose-rate effectiveness factor should be one, and not two or three or some other value?

MR. RICHARDSON: I would argue —

DR. ZIEMER: Because I'm understanding this

in almost the opposite way. I think lowering it lowers the effective dose. Is that – are you arguing that we're over-estimating doses at –

MR. RICHARDSON: The effects of a dose, a lower dose, is going to be divided. The way that this factor is applied for low-LET radiation –

DR. ZIEMER: I guess I may have misinterpreted how they're using it, then.

MR. RICHARDSON: I don't know. Mary, could –

DR. ZIEMER: I thought we were multiplying, but I would ask that we get that clarified.

MR. RICHARDSON: I think Mary could answer that.

DR. ZIEMER: Typically a dose-rate effectiveness factor operates like a quality factor. It increases –

DR. SCHUBAUER-BERIGAN: Actually, it –

DR. ZIEMER: It would increase the probability of causation rather than decrease it. I believe that is the case.

DR. SCHUBAUER-BERIGAN: Well, what acts like a quality factor actually is the RBE. Those two are sometimes used interchangeably. But David is correct, that when the DDREF factor is applied, a

factor of greater than one implies that the risk per unit exposure at a very – at a low dose or in a chronic dose is divided by that value.

MR. RICHARDSON: Right.

DR. SCHUBAUER-BERIGAN: So if it's two, the effect of that dose is divided by two.

DR. ZIEMER: Thank you.

MR. RICHARDSON: Right. And so the question is, is there – here, I think, everything is being essentially treated as an acute dose for the external here, talking again about the low-LET doses. So it's not – the issue of dose-rate is not really so much a consideration. It's is the dose-response association linear in the low dose range? And, I mean, that is something that people talk about.

DR. ZIEMER: I understand what you're saying.

MR. RICHARDSON: But the current – I'd say a lot of committees are taking now, and a lot of the literature, is supporting the opinion that a linear dose response is a reasonable association. And I – you know, I would argue maybe yes, that you would have a factor centered around one, and then you allow uncertainty in that.

DR. ZIEMER: Are the studies that you cited in your written comments that were submitted to the agency earlier?

MR. RICHARDSON: Yes.

MR. ELLIOTT: Yes, they're referenced and we have copies of those.

DR. ZIEMER: Thank you.

Next we have – I think it's Roger. Is it Roger?

MR. SHAW: Yes.

DR. ZIEMER: I couldn't read your writing here – Roger Shaw from McCarter & English, Ltd.

MR. SHAW: Yes, this will be less than five minutes.

Let's go right to DREF. I just want to mention DREF. I know that the Board will look at it. It's an important item. For low-LET, UNSCEAR, ICRP, NCRP and BEIR V support a DREF for low-LET of anywhere from two to five. I think I heard Mary earlier – I asked her specifically on a break if there'd be a range of maybe between less than one to five, and that's something that is a little different than maybe what the RERF may be saying in one of their recent studies.

But I think it really deserves a lot of

caution and is something that should be looked at. A lot of important national, international bodies support that you use a DREF. And for example, if it was two, that would mean that the risk would be less by a factor of two. So that is something I just — I know you'll look at. I just want to mention that.

And if we do start to define acute versus chronic in a different way, if we start to say that an acute dose is something received over a month or two months or a quarter, over a quarterly badge reading period for TLD or film, then we're going to have to start rewriting textbooks and doing that fairly quickly, because that is not historically how acute dose has been defined.

The second item is with the dose uncertainty and how critical that is. Dr. Ziemer pointed out, as we went through NIOSH-IREP, or Russell did, Mr. Henshaw — and showed exactly what happens when you change the uncertainty associated with those doses. And it can make huge differences. As I'm sure you get home and you work tonight, and you start to go through and do your own iterations with NIOSH-IREP, you will

start to see these differences.

And if you simply change and go and look — and they're different for different cancers — but if you look at one leukemia, you look at CML, and you take and change that, you just leave all the parameters the same for a certain dose. If you took 25 rem, five rem for five years, and put in the information you want to put in, just change constant, which means no uncertainty — not really realistic — and change that to normal geometric standard deviation, gSD. Well, for gSD that's 40 percent PC. And if you just change that to constant alone, it goes to 93 percent probability of causation.

So as Congress has said, let's err on the side of the claimant. We should. It sounds fair. It is fair. It doesn't mean that we need to add undue uncertainty on top of an already large amount of uncertainty that we're going to be stuck with and also have to deal with in a reasonable fashion.

Those are the two points.

DR. ZIEMER: Thank you, Roger.

And again, are there any questions or issues to be clarified?

[No responses]

DR. ZIEMER: All right. Thank you.

This completes today's agenda. I would ask that the four other members of the subcommittee stop by here for a moment before we adjourn — or right after we adjourn, and we'll talk about the assignment for this evening.

We thank all of our guests who were here today. We will reconvene tomorrow at 8:00 o'clock; 8:00 o'clock, not 8:30, okay? So we'll see you all in the morning at 8:00 a.m.

Thank you very much.

[Whereupon, the meeting was adjourned at approximately 5:05 p.m.]

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C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 128 pages, was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this _____ day of February, 2002.

_____

KIM S. NEWSOM, CCR-CVR
CCR No. B-1642

[SEAL]