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

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ADVISORY BOARD ON RADIATION AND
WORKER HEALTH

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WORK GROUP ON SCIENCE ISSUES

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WEDNESDAY
OCTOBER 12, 2011

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The Work Group convened via teleconference at 2:00 p.m., David B. Richardson, Chairman, presiding.

PRESENT:

DAVID B. RICHARDSON, Chairman
R. WILLIAM FIELD, Member
GENEVIEVE S. ROESSLER, Member
PAUL L. ZIEMER, Member

ALSO PRESENT:

TED KATZ, Designated Federal Official
JENNY LIN, HHS
JAMES NETON, DCAS
SUSAN REUTMAN, NIOSH

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(2:03 p.m.)

MR. KATZ: Well I would go ahead and get started. Dr. Richardson, by the way I sent to you, in response to your question, I sent you the --

CHAIRMAN RICHARDSON: I can see them, thank you.

MR. KATZ: Okay. Very good.

CHAIRMAN RICHARDSON: So I circulated a very brief agenda. And maybe before starting are there additions to that that people would like to make? Or revisions?

DR. NETON: Yes, this is Jim Neton. I don't think that we've seen it on our end.

CHAIRMAN RICHARDSON: Okay. I can tell you, three items on the agenda. One a discussion of the scope of work for the Working Group. The second one is a discussion of priorities and interests. So to go through

the list of topics and then to give them some sort of ranking for our attention.

And the third one was to discuss what sort of process we're imagining taking for review and discussion and reporting back to the full Board on recommendations.

DR. NETON: Great. Thanks.

CHAIRMAN RICHARDSON: So the first issue was the scope of task and I wanted, I mean partly it was for my own clarification, and I asked Ted to send me, I had misplaced or mis-remembered the description that Dr. Melius had written up describing the responsibilities for the Work Group.

And I tried to pull out what I thought were the four issues that I thought were central to it. And I wanted to just to maybe lay them out and see if there was kind of agreement, or a kind of consensus that we understood what this meant, what the Work Group was being tasked with.

So the first one was --

MEMBER ZIEMER: David, this is Ziemer, did we all get copies of that too or not?

CHAIRMAN RICHARDSON: I don't know. I didn't remember seeing it previously.

MEMBER ZIEMER: I don't recall seeing it at all. Ted, have we gotten that?

MR. KATZ: Nope. So, Paul, you know I can't recollect exactly how Dr. Melius distributed it. I think he distributed it to the Board, but in any event it was put on the NIOSH website as a Work Group description. And I can send it to you. To your email.

MEMBER ZIEMER: No, that's fine, I can pick it off the website, I wasn't sure if we had gotten it separately.

CHAIRMAN RICHARDSON: Okay. I can tell you what I believe are the key points in it and we can start from there. It looks like four sentences and I've got four points. One

of the sentences is relatively long, but it's just a list.

The first issue was that the Work Group will focus on what I would call disease risk model issues that are important to the program. So as distinct from Work Groups that are focusing on kind of exposure assessment issues.

The way that this group was tasked was to focus on those issues that relate to models for disease risks and how they've been incorporated into IREP and into the program, which I think was kind of useful for me because some of the scientific issues that NIOSH has identified relate to kind of exposure assessment issues.

The second one was the Work Group will review the current status of each scientific issue that has been identified by NIOSH in their status updates. So these include incorporation of epidemiologic studies

from nuclear workers. Questions regarding dose and dose rate effectiveness.

Questions regarding interactions between other agents, including smoking and other occupational hazards in radiation. Age at exposure and grouping of rare and miscellaneous cancers.

The third point is how the description ends is, "The Work Group may identify new science issues that may impact on disease risk models." So here the scope includes, I believe, the description is to include those issues that have been previously identified and then to be able to, if necessary, add new items to the list.

And then lastly, the Work Group will assess each issue and report back to the Board. And that gets to, I think, what I think would be useful for us to have a discussion about that's the process for what we mean by an assessment of an issue.

So that, for me, was I think the first issue on the agenda was do we understand, as a Work Group, do we have consensus on what's meant by the scope of the task of work and do we have any feedback we want to give on that?

MEMBER ZIEMER: Okay. So you're looking for comments, David?

CHAIRMAN RICHARDSON: Yes.

MEMBER ZIEMER: Well let me start, this is Ziemer. I think the things that have been identified here certainly are in keeping with the discussion that we had as a full Board when this Work Group was suggested.

Also if we were to find, as we move forward, that there's some additional issue or sort of additional scope item that we should be addressing we can always suggest that the overall scope of the Work Group be modified.

So I don't we're necessarily, our

hands are tied or locked in by saying let's go with these four. I think these four make sense and I think it's a good place to start.

CHAIRMAN RICHARDSON: Okay. Are there other comments that other people who feel like this is reflecting what the discussion was?

MEMBER FIELD: Yes, this is Bill Field. I agree completely with Paul. I think this is a good place to start. And if we need to expand it we can do that at a later date.

MEMBER ROESSLER: Yes, this is Gen Roessler. I just joined in a bit ago. Right now I'm just listening, I'm between flights in Atlanta and I'm going to try and join in on the teleconference as much as I can.

CHAIRMAN RICHARDSON: Okay. Good. Well I will say I went through the transcript where the discussion about forming a Scientific Work Group was formed.

And I feel like it does conform

pretty well to the discussion. I think some of the things are made a little bit more explicit here about what we're talking about.

But I agree it's a good starting point. So if that's agreed then we would sort of take that as the key principles of the kind of, at least for now, the terrain that we would be moving through.

The next thing was to talk about a discussion of priorities and interests within the scope of work. So there are a number of issues listed and there's the potential to include other issues on the list.

And it seemed to me like these, given our resources and our time and the complexity of the problems, we probably want to make some priorities and not try and tackle all of these simultaneously.

And so going through the list of topics I thought we might make a pecking order and then I would open up discussion about

whether we want to focus on a single issue or maybe at most two issues simultaneously and not too much more that.

So there's incorporation of information, I guess I would call it information that's external to the life span study and to the risk models. Dose and dose rate effectiveness factor. Grouping of cancers. Age and exposure. And interaction with other workplace exposures.

So we have some, we've been tasked with at least thinking about each of these items as a starting point. And how we'd like to do that. So are there suggestions?

MEMBER ZIEMER: I guess I'd like to hear from NIOSH as to sort of maybe where we are on some of these. I know NIOSH has some studies going on that may sort of flesh out some of these and perhaps we can, maybe Jim Neton could give us an idea of where we are on some of these.

What's NIOSH doing? You sort of talked about some of this at the meeting, Jim, I know. But I think it's probably worth sort of revisiting that and renewing our memories on that.

DR. NETON: Yes. Sure. This is Jim Neton. Most of these have been fairly static to be honest with you. We have been primarily involved in the collection and, you know, assimilation and review of literature as it emerges, the scientific literature.

The one area where we do have a fair amount of work, the SENES, our contractor, has produced is in the dose and does rate effectiveness factor area.

They've put together a draft, 200 plus page review, of all the current literature on DDREF. And it's actually out for review by, I believe it's part of an ICRP committee that has it for sort of a stepping stone for a document that they're putting

together. So that does exist in draft form.

We did start an initial attempt at grouping of some rare and miscellaneous cancers. And in particular we were looking at possibly pulling out the prostate cancers from the what's now called, I forget the name of it, it's All Male Genitalia, I think is what it's called, or something like that.

It was an analysis done some time ago, I would have to dig it out, which indicated that actually the risk model for prostate cancer might go down if we did that. And we never really completed that effort.

In the area of age of exposure, interaction of other workplace exposures, again, just mostly a compilation of literature. The corporation nuclear worker epi studies DSHEFS, another division within NIOSH, still has a little bit of an active program in that area.

And Doug Daniels along with Mary

Schubauer-Berigan and others have recently published a meta-analysis of a numbers of sites. I believe it was like 25 sites or something like that. A meta-analysis of a risk model for leukemia among specifically targeted occupational cohorts.

And that was published and my recollection is the risk factor they derived was fairly consistent with what's been determined from the Hiroshima/Nagasaki studies. And that's about the extent of it right now.

CHAIRMAN RICHARDSON: Okay. Well it's useful to know. So the topic that you feel like is most advanced right now, in the work you've done, relates to DDREF. And so one option for us is to start with something that you feel like you have something that we could engage with.

Is that report at a point that this Work Group could read the draft, or would

you ask that we work in parallel to you as opposed to in response?

DR. NETON: Yes. No, I believe that the draft is in reasonable form where it could be reviewed. It's missing, interestingly, the conclusion section. Because, you know, what one makes of this body of knowledge has been the biggest conundrum for us.

I mean there's a lot of data out there. A compilation of animal studies, epi studies and others that one can look at. And then to determine whether the current DDREF that's used in IREP is sufficient or it needs to be modified based on that knowledge. It's still up in the air, but all the literature is there, so it's available.

MEMBER ZIEMER: David, this is Ziemer again. And I think we don't have any sort of responsibility to help any of these things come to conclusion in the scientific

sense, I don't think.

As I understand it what we would do as a Work Group would be to assess where things are and report to the Board. So it seems to me it would be worth looking at, for example, that study.

And even if they're at the point where they've reviewed the literature and so on and haven't been able to sort of close it out, I think that's the kind of information the Board needs. It certainly wouldn't be up to us to sort of reach the conclusions as I understand it.

And let me make one other comment, if I might. On the sort of list. The interaction with other workplace exposure, it seems to me is one which would be low priority for us.

In part because I don't think that our Board has any responsibility for that under the legal framework that we're working

on. We look only at the radiation. I mean that's certainly an important area.

But until the law develops a sort of an acceptable way of addressing multiple exposures like that. And part B, I don't know that we would have any responsibility. Just a kind of reaction though, maybe others don't agree wit that.

CHAIRMAN RICHARDSON: No, I agree with you concerning the first point that, I mean this will get I guess to the last point on the agenda eventually of what's the process for review and what's to be reported.

But my sort of understanding was identifying needs or gaps that might stimulate some future work to move forward. It's not to propose a distribution, for example, for a parameter in IREP.

MEMBER ZIEMER: Right.

CHAIRMAN RICHARDSON: And so working through topics where we think that

there's kind of relevant recent research would make sense to me as a starting point.

The question of the interactions, I think there are some points of IREP do involve models, for example, of radiation and smoking. Where the radiation risk --

MEMBER ZIEMER: That is covered, you're correct. Right.

CHAIRMAN RICHARDSON: And so that would be, I guess, and example of where --

MEMBER ZIEMER: Yes, I was thinking more about chemical exposures. And in fact we certainly would be in a position to say this is an area that needs greater study.

I mean the chemical and radiation, I think we all sort of know, at least intuitively, that there is likely to be such interactions.

And that going forward it would be useful to know and have a scientific basis on which to evaluate that. But beyond that I'm

not sure what we would do.

CHAIRMAN RICHARDSON: Right.

DR. NETON: David, this is Jim Neton. I just thought of one more thing I might throw out on the table, if I may. One thing that we have been struggling with internally is what might be able to be done with the data that we actually collect on these workers in-house.

You know we have over 30,000 cases and right now we don't do any research with the cases. But is always seemed to us that there might be possibilities for doing some sort of research in this area using these cases in particular.

It would have to undergo IRB review and everything if we were to proceed down that path. But, you know, if the Working Group had any insight or ideas in that area it would certainly be welcomed by us.

CHAIRMAN RICHARDSON: Well that's

definitely an interesting topic.

MEMBER ZIEMER: I think that's a great idea. You guys have gathered so much information over the last decade. We probably have a wealth of data that could be mined by someone, maybe even on this.

Jim, I don't know if you were talking the interaction with other exposures, but we certainly have information that people have given us about those things.

Maybe someone could mine that. You know, some group would have to fund it and so on. But I think we could make recommendations of that type. You know, how can all the data that have been gathered be used for other related scientific studies? A great notion.

DR. NETON: Right. You know we have like a brief smoking history on all lung cancers at least. And we have a tremendous amount of monitoring data, particularly the

external data, for all workers that we've gone and retrieved the best amount of information out there.

Internal, bioassay data, it's all there. The only problem is one can recognize this as somewhat of a biased population that we have. But if one can work around those issues it seems to me that there might be some valuable research that could be done.

CHAIRMAN RICHARDSON: There's potentially several ways that that could be useful. I mean it could be useful in its own right and it could be useful for strengthening some of the other topics that the group has been tasked with.

Like incorporation of the nuclear worker cohort study information if there's questions about the confounding by smoking or questions about healthy worker effects, or selection effects.

That some of the data that you

have in-house could either resolve or account for those sort of potential biases in the worker data. So that could also be useful in that way.

In terms of the priorities, in addition to the enumerated list, one topic that I know that's out there that's not on the list, but I know it's under discussion by NCRP and maybe by other organizations.

EPA I think also, is questions regarding relative biological effectiveness and kind of the assumptions that are made in the current disease risk models and whether those are supported by the contemporary literature.

And so there's, you know, potentially a review that's as extensive as the review of DDREF that would be on kind of toxicological and mechanistic and what little epidemiologic evidence there is concerning the RBE for exposures to tritium or neutrons and

the other components.

And I guess I would propose considering that at some point on the list of issues. I think SENES has been involved in the review of that topic as well.

DR. NETON: Are you talking about the RBE for neutrons and tritium and stuff?

CHAIRMAN RICHARDSON: Yes, low energy photons.

DR. NETON: Actually that's sort of been done originally by SENES when we first put the program together. We were the first ones, at least to my recollection, to propose an increased RBE for photons below a certain energy. I believe 100 keV. And likewise for low energy betas, which would include tritium.

So yes we've done some of that. The study that SENES has recently done is an update on all of that information. Although I'm not sure much has changed in the area of the RBE to the lowering of photons.

But I found that to be a very fascinating piece of research that was done. Because it's not considered in any of the regulatory standards, at least in the United States these days. And it seems to be real.

CHAIRMAN RICHARDSON: So I would imagine, or I would suggest that that might be a type of topic that also at least would be worth having a review by the Work Group and reporting back to the Board with the status of those assumptions regarding RBEs.

MEMBER ZIEMER: I concur with that. I think that's a good suggestion. This is Ziemer again.

CHAIRMAN RICHARDSON: In terms of resources do you think that we have the, we would like to move through these one at a time or more than one at a time? I think I would lean probably towards one or no more than two topics at a time just to allow us to have an informed discussion of this.

MEMBER ZIEMER: You mean on those individual topics, like dose and dose rate effectiveness --

CHAIRMAN RICHARDSON: Right.

MEMBER ZIEMER: And when you're talking about resources you're just talking about the time and effort for the Work Group?

CHAIRMAN RICHARDSON: Yes.

MEMBER ZIEMER: Yes. That would make sense I think. I don't know, what do you think, Bill?

MEMBER FIELD: Yes I think one at a time. It seems like in, you know, stratifying the ones to look at first, maybe the ones to look at first would be the ones that any decision or maybe long-term outcomes that would be created because of our review, it seems like there should be some consideration put into how many worker's dose reconstructions may be affected by that.

So I guess it's the potential

impact on that. And, Jim, I had a question. You have mentioned that there is a questionnaire for smoking for lung cancer, is that right?

DR. NETON: Yes.

MEMBER FIELD: Okay. Is it just for lung cancer where the PoC will be adjusted based on smoking history?

DR. NETON: Lung cancer and I think cancer of the bronchus.

MEMBER FIELD: Okay. But those are the only two and there's --

DR. NETON: Yes, respiratory.

MEMBER FIELD: Yes, I'm just wondering what was the, well I understand the basis for it since 85 percent of lung cancers are caused by smoking, but there's other smoking related cancers as well.

And I'm just wondering were they ever considered that they should be adjusted. Or I guess who made the decision that it

should be adjusted because of smoking.

As there's other lifestyle factors that you could argue that you could adjust the PoC for based on, you know, things like obesity or, you know, there seems to be a fine line there drawn.

DR. NETON: Yes, well the decision was made after looking at all the literature, Mary Schubauer-Berigan worked on this pretty extensively in the beginning, that the only data that were of sufficient quality to make that adjustment were the lung cancer and smoking adjustments.

She did look at other organs and there were some data out there to suggest that other cancers could be related to smoking. But at least at the time that this was put together, over ten years ago now, we didn't feel that there was enough evidence to make a good quantitative model from it.

MEMBER FIELD: I guess myself, I

know Dick Lemen brought this up before. I think this is a whole area that would be worth looking at. Adjustment of the PoC based on other risks. And it may not be chemical, but it could be just lifestyle factors.

DR. NETON: Yes.

MEMBER ZIEMER: The approach on that to see what's in the literature and as to whether or not we think it's sufficiently mature for somebody to take a hard look at it or what would --

MEMBER FIELD: Well, I guess I'm just looking at it from the scientific justification. Because we know these other cancers that are affected by smoking or you have an increased risk due to smoking.

You know, when you do epidemiology studies you always look to see if you have this certain one that's increased. Not just the pharynx or the larynx, you look at several different cancers that may be associated with

it.

And I guess the rationale, or the justification, for adjusting it for one but not others, and I think what Dick was arguing that it shouldn't be adjusted for lung cancer at all.

Why is it just adjusted for one when we know it's associated with others and those aren't adjusted. I guess it's there you go with the way the attributable risk due to smoking. But I guess it's just the whole case that is made that you, at just smoking, that you adjust the PoC for lung cancer because they smoke.

But yet there's many other lifestyle factors that affect our, I guess not ability, but the propensity to develop cancer that we're not looking at.

And I'm wondering when this was all written up what was the justification for saying we're going to pick this one lifestyle

factor out and we're going to ignore the others. And I was just trying to figure out if there was a historic basis where this was considered.

And my guess is it was considered because the attributable risk is so great from smoking that you had to build in some factor. But I think, based on my conversations with Dick and other people, this is an issue that's going to come up.

CHAIRMAN RICHARDSON: Yes, well I think it's certainly a topic that would probably be useful for us to look at and understand a little bit more regarding the methods that have been used. You know, right now what they've done, it's sort of, as Jim said, Mary made a case that there was perhaps enough evidence.

It wasn't so much that smoking was a strong cause of lung cancer and there was less evidence that smoking was a cause of

other types of cancers.

Because I think that that's been, I mean a list of smoking associated cancers has been on the table since the 80s and probably not long after the Surgeon General's report.

But it was that she thought there was enough evidence regarding kind of the question of whether smoking and radiation interacted in a multiplicative scale or an additive scale.

And then there was a critique that came forward on IREP and I wrote one of the critiques and several other people wrote comments about the evidence was really fairly ambiguous about whether these joint effects were additive or multiplicative.

And the data were too sparse in the life span study, for example, to try and understand how those joint effects were happening and whether, which model fitted the

data better.

So there's right now IREP has got this hybrid where they fit an additive model for the two effects and a multiplicative model and I think they average them.

And if that's the resolution to that then you're right you could also fit additive and multiplicative models for other disease risk factors.

Or for smoking and its effects on lots of other cancer sites, if you were so motivated. And --

MEMBER ZIEMER: Well, David, was Mary, or maybe Jim can answer. Was Mary saying that the interaction for radiation and smoking for lung cancer that the data were more robust than for the other organs where you might have interaction between radiation and smoking?

DR. NETON: Yes.

MEMBER ZIEMER: Was that the

issue?

CHAIRMAN RICHARDSON: Yes.

DR. NETON: Yes. That's true, Dr. Ziemer, that the data were better for smoking and lung cancer, obviously. And my recollection was, I think this might be documented in the technical basis for the IREP model on our website.

MEMBER ZIEMER: If that's the case maybe one should ask the question whether or not that's still situation. Maybe there, I mean, that's been a decade ago I guess.

CHAIRMAN RICHARDSON: Right.

DR. NETON: Right, that's true.

MEMBER ZIEMER: So maybe only to revisit it, or at least to revisit it in terms of saying do we have more robust data for either other organs, well I guess other organs. Ted, as a starting point we'd be talking smoking, whether we get into obesity or something that's a whole -- another ball

game too.

CHAIRMAN RICHARDSON: Yes, and in fact in the last couple of years there was substantially more work on the relationship between smoking and radiation in the A-Bomb survivors too.

They went back and did a lot more linkage work with what they call the Adult Health Survey in the cancer incidence data. So that's been remodeled as well. I mean there probably is maybe time to look at that assumption.

MEMBER ZIEMER: It might be worth revisiting that at least.

DR. NETON: Well we actually did go back. And maybe this was before, David, your time on the Board. Went back and modified our smoking adjustment for lung cancer based on the Pierce re-analysis that was published.

And at that time what we ended up

doing was including both Pierce and the original analysis and picked the higher Probability of Causation for the results.

And we did indicate at that time that as the data became clearer we might drop the original one if it seemed to us to be reasonable. We haven't gone back an looked at that since then. One thing I'd also --

MEMBER FIELD: Yes, I think it would be very interesting to go back and look at that. And I'd be really interested to see what information is collected to quantify smoking history.

Because there's so much to these interactions are based on total pack years and pack-year rate can be important. Year, date first started smoking. So it'd be very interesting to see can be captured in the questionnaire and if that's what's being used.

DR. NETON: The questionnaires are very rough. I don't think there's anything

such as a pack-year calculation. It's really more have you smoked and how many packs per day.

And I think if you quit smoking within the last five years. I've forgotten. I'd have to go back and look at the form but it's pretty basic.

One thing I just want to point out. I looked up the original Act. And when the Act speaks of NIOSH producing guidelines for Probability of Causation there's a Section 3C that says that we should take into consideration type of cancer, past health related activities, such as smoking, and other information on the risk of developing a radiation related cancer from workplace exposures and other relevant factors.

So that really is in the Act itself.

MEMBER ZIEMER: So it opens the door for anything that we think might be

relevant?

DR. NETON: It does. And it specifically calls out smoking in their language, so one of the reasons I think also we focused on that. And that was doable at that time.

MS. LIN: Sure. But I just want to point out the regulations sort of pin down exactly the type of personal and medical information that you should use to determine the Probability of Causation and in Section A 1.5(f) you should see smoking history if the claim is for lung cancer or a secondary cancer for which lung cancer is a likely primary cancer.

And it stops there instead of saying all the other factors, X, Y and Z. So within the regs you have a very specific list.

MEMBER ZIEMER: Yes.

DR. NETON: There's no doubt that we would have to, if we were to develop

quantitative models for other factors, the regulation would need to be changed.

MS. LIN: Right. And obviously we'll talk about it when we get there.

DR. NETON: Yes. In the preamble I think we said as much. That there were no quantitative models we can develop at this time but we would continue to look at them and evaluate them as the science emerged.

MS. LIN: Yes.

DR. NETON: That's true.

CHAIRMAN RICHARDSON: Jim, could I ask for one clarification? You had talked about the work on RBE, is that that SENES has done for you, is that wrapped within that 200 page draft report on DDREF?

DR. NETON: No. No, it's not. I might have misspoke when I was speaking of that. No, the RBE work was actually published in the Health Physics Journal shortly after it was incorporated into IREP. It went out there

in the peer review literature.

CHAIRMAN RICHARDSON: Right. And you know the UK NRPB has put out a report on RBE and I think the Canadian, whatever they call themselves, Radiation Protection Organization also has done something. At least for like tritium and low energy photons. Something like that.

DR. NETON: Right.

CHAIRMAN RICHARDSON: So there would be several reports that might be useful to review that have come out in the last 18 months or two years.

DR. NETON: Yes. Agreed.

CHAIRMAN RICHARDSON: So I could propose a pecking order and then we could start shuffling. Maybe to start with the DDREF and then move on to RBE. And then maybe adjustment of the Probability of the Causation for other factors, such as smoking.

And then look at age at exposure.

The incorporation of nuclear worker studies. And end with grouping of rare and miscellaneous cancers. Oh and we also have the issue of the use of data in-house. We should have that on the list.

MEMBER ZIEMER: Can you repeat those, David? So it's DDREF?

CHAIRMAN RICHARDSON: And then RBE, and both of those I think we'll be able to start by kind of a review of existing documents.

MEMBER ZIEMER: Right.

CHAIRMAN RICHARDSON: And then the issue that we were just recently discussing, the adjustment of the PoC for other factors that are risk factors for the disease that the claim is.

And then age at exposure. And then incorporation of nuclear worker studies. And then the last two. Grouping of rare and miscellaneous cancers and use of data in-

house.

MEMBER ZIEMER: I'm okay with that.

MEMBER FIELD: Yes, David, this is Bill. I think that's a reasonable order.

CHAIRMAN RICHARDSON: Okay. Now if that's agreeable that would keep us busy for some time.

MEMBER ZIEMER: Yes.

CHAIRMAN RICHARDSON: In terms of what the deliverable is, in terms of each review and the sort of process that we might take. As I understood it in the notes I took from the discussion it was to assess the issue where possible.

Evaluate what needs to be done to address the question with the hope that we might stimulate additional work, if necessary to move forward on the issue, as it relates to the risk models used by the program.

And if there are considerations

that impact on timeliness or scientific validity to kind of raise those and point those out to the Board. And so if that sort of the objective of the review the question is how do we do that.

I assume what we would do is break into some sort of group where one person takes maybe primary lead for writing a first draft of a review, document based on the information that we pull together.

We rely on the rest of the Board to help identify relevant literature. Then we circulate that draft and we begin working together to think about what the aims of kind of a short report would be on the topic.

And I'm imagining sort of a deliverable that's probably not very long. So it wouldn't end up being another 200 page document based on a review of a 200 page document.

But maybe more like a two-page

document. Does that sort of sound like a reasonable idea for what the review would be?

MEMBER ZIEMER: That certainly makes sense to me. In other words we would tell what we did and what our recommendation is?

CHAIRMAN RICHARDSON: Right.

MEMBER ZIEMER: Is that right? And basically these are reports to the Board?

CHAIRMAN RICHARDSON: Yes.

MEMBER ZIEMER: And then if there was implications beyond that it would be up to the Board to pick up the ball and carry something forward or, you know, if they're going to recommend somehow that the legislation needs to be modified that would have to be handled by the Board.

CHAIRMAN RICHARDSON: Right.

MEMBER FIELD: That sounds good, David.

MR. KATZ: This is Ted. I just

wanted to respond a little bit to what Paul just said about legislation. I mean I think the aim here is the regulations were set up with the anticipation that science would continue moving forward.

And that more could be done down the road on this front, specifically as well as others. And so I think the aim for the Board, as entire, is as this work develops to be able to make recommendations, give guidance to NIOSH about changes that it can make on any of these factors.

And it sounds like the timing's pretty good. It sounds like NIOSH has done quite a bit of work and it's getting close to at least producing sort of a evaluative works, on this first topic at least. But so, again, the Board is here to give guidance and advice on this topic.

But I don't anticipate that this really, that you'd need statutory changes.

And Jim gave an example where you might need a regulatory change to implement something.

But I think what you're aiming to do is give guidance to NIOSH where the Board believes it can move forward. That there is enough science, enough water under the bridge, to make a change.

MEMBER ZIEMER: Ted, I was really only referring to the remark that Jenny made that the legislation, well I guess both you and Jenny had talked about what the legislation said, and the comment that if you were going to go beyond that there would have to be a modification.

And of course that would have to generate with NIOSH, not with the Board. The Board --

MR. KATZ: I understand, Paul. I think Jenny was talking about the regulation not the legislation. But it's just --

MEMBER ZIEMER: Well that's what I

meant, yes.

MR. KATZ: Okay. I'm probably splitting hairs with you.

MEMBER ZIEMER: Yes, right. No, that's what I intended to address was that comment.

MR. KATZ: Okay.

CHAIRMAN RICHARDSON: Okay. So as we start on this, well choosing, Jim, would you be willing to share with us the document that SENES Oak Ridge has produced on DDREF and circulate that to the Work Group? With the understanding that it's a draft.

DR. NETON: Yes. Provided a draft not for circulation, that sort of all the provisos and such. But, yes.

CHAIRMAN RICHARDSON: Of course. And I think it would be, well I hope for your purposes it's useful to receive our comments on them. I think it's terrific if an organization like ICRP is looking at it as

well. I'd imagine that we'll bring a different perspective to it that ICRP would.

DR. NETON: Oh yes.

CHAIRMAN RICHARDSON: In the sense of the difference between thinking about DDREF in terms of radiation protection versus the framework here of compensation, which really may recast thinking on some issues. But, you know, there's certainly an overlap between them. But it could be that --

DR. NETON: Right and there's one other thing. I think Bill Field, Bill mentioned an interesting point to me, which is which of these parameters are going to have the biggest effect on the dose reconstructions.

And, you know, I've not done this but it always seemed to me that DDREF would be a fairly insensitive change in the final outcome of the dose reconstruction.

Partly because how we default to

an acute exposure, unless we know otherwise. But you know there's a lot of conservatism built in to our calculations, so I'm not sure how much the DDREF really kicks in in many of these dose reconstructions.

That's something we might think about as we look through this paper and review the literature and such.

CHAIRMAN RICHARDSON: Okay. Yes, it's useful. And maybe you can remind us of that again.

DR. NETON: Yes, I will. And it's almost, you know, I'm not trying to make more work for myself. But one might want to do a sensitivity analysis and see how much change would result in --

Essentially what I think if you look at the literature, and I don't want to prejudge this, but it would be sort of tweaking the central tendency on the DDREF and maybe looking at the spread, the range a

little bit.

And I don't think we can justify a huge change at this point. But anyway, I've said enough on that. I don't want to bias you guys.

CHAIRMAN RICHARDSON: In terms of writing is there somebody who's chomping at the bit to take a lead on draft of a first document on this first topic? If not, facing a lot of silence --

MEMBER ZIEMER: Nobody's chomping at the bit.

CHAIRMAN RICHARDSON: I'd be willing to write something that's rough as a starting point for us to discuss.

MEMBER ZIEMER: Sure.

CHAIRMAN RICHARDSON: And I think we'll, if this is actually 200 pages, we'll need more than a week or two in order for me to do that. But --

MEMBER ZIEMER: Well there's not a

big urgency on that in terms of a time table is there? I mean --

CHAIRMAN RICHARDSON: I don't think so, no.

MEMBER ZIEMER: I mean I assume that, for example, at our next regular meeting you would simply report that the Work Group has gotten underway and that we're looking, for example, at that particular issue.

CHAIRMAN RICHARDSON: Right.

MEMBER ZIEMER: And then at some point down the line, when we're done doing that, we'd have the report.

CHAIRMAN RICHARDSON: Good.

MEMBER ZIEMER: Does the Board have to approve the scope, or has that already, or the scope of the Work Group?

CHAIRMAN RICHARDSON: Ted, I think --

MR. KATZ: This is Ted. I think it's approved. I don't remember the process

but I believe Jim let out that statement that is now on the web. And everything that you've talked about fits within it.

MEMBER ZIEMER: Right.

MR. KATZ: So there's nothing changed here. I think you're good in terms of you have your task already. As far as the Board entirely is concerned, there's nothing more to do there I don't think.

MEMBER ZIEMER: And we've agreed to follow that and we've agreed on the order in which we'll address these issues. And we're going to get underway with the first one. And when we're done we'll report, right?

MR. KATZ: Right. That makes good sense to me.

CHAIRMAN RICHARDSON: I think that sounds good. I think the question that Jim posed of kind of the sensitivity of different hypothetical claims to DDREF, I think is maybe an interesting one also to bring forward to

the Board.

I don't know if we would want to return that to you, Jim, as something down the line, not thinking this in the near term, or whether we have other resources for kind of exploring those sorts of questions.

But that's the sort of thing that I think would have to, it would involve somebody using the IREP program under different scenarios.

DR. NETON: Yes, that could just be a recommendation of the Board. I mean, it might ought to be done. And maybe a recommendation as to how we go about it, a little bit. You know, something like that.

CHAIRMAN RICHARDSON: Okay.

DR. NETON: I'm not trying to make more work for myself, I think that's important to be done in the context of this whole review. It doesn't make much difference and we could spend a lot of time discussing the

subtleties of adjustments and not much really return on our investment.

MR. KATZ: This is Ted. And just to add on to what Jim's saying, I mean SC&A's not on the line for this, but doesn't, I mean they have resources too so if this is something that, it makes a lot of sense to me too since it impacts how important the repeat work is, in a proximal sense.

But, so if this is something that you recommend and DCAS doesn't have resources to get to in a timely fashion and you want to plunge forward on that then you can consider using SC&A to do that kind of technical work.

CHAIRMAN RICHARDSON: Okay. Because I agree that as we report back to the Board it would useful to kind of contextualize the relative importance of some of the different issues that are out there in terms of scientific uncertainty.

And specifically within the

context of this program. Again it's going to be different that ICRP would bring to it.

So we might want to, that's where this Work Group might be able to add some value to this discussion, for this context. Well, that's what I had for the agenda. I think we, at least we have a way forward.

MEMBER ZIEMER: Sounds good.

CHAIRMAN RICHARDSON: So if there's no other questions. Bill, you'll get to your 3:15 meeting.

MEMBER FIELD: Sounds good.

CHAIRMAN RICHARDSON: Great. Would you like me to write up minutes of this conversation? Or how does that happen, Ted?

MR. KATZ: Well there'll be a transcript. That ordinarily takes 30 days or so to come out. So I think the only, I mean, we have a Board meeting on October 20th, I believe, the teleconference.

But I think reporting out there is

pretty simple right. So you don't need to produce any minutes of this meeting, we'll have that. But you probably should give a few minutes to tell the rest of the Board where we're headed.

CHAIRMAN RICHARDSON: Okay. Well great. Thanks.

DR. NETON: Okay. And I'll work to get that DDREF document out to the Board. Probably not until later in the week though.

CHAIRMAN RICHARDSON: Okay.

MEMBER ZIEMER: To the Board or just the Work Group?

DR. NETON: I'm sorry. The Working Group.

MEMBER ZIEMER: The Work Group.

MR. KATZ: Sounds good, so are we adjourned?

CHAIRMAN RICHARDSON: I think we are.

MR. KATZ: Thank you everybody.

CHAIRMAN RICHARDSON: Bye.

(Whereupon, the above-entitled matter went off the record at 2:58 p.m.)