UNITED STATES DEPARTMENT OF LABOR

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ADVISORY BOARD ON TOXIC SUBSTANCES AND WORKER HEALTH

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SUBCOMMITTEE ON SITE EXPOSURE MATRICES (AREA #1)

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MEETING

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MONDAY,
JULY 11, 2016

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The Subcommittee met telephonically at 1:00 p.m. Eastern Time, Laura Welch, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY:

JOHN M. DEMENT
MARK GRIFFON

MEDICAL COMMUNITY:

STEVEN MARKOWITZ
LAURA S. WELCH, Chair

CLAIMANT COMMUNITY:

KIRK D. DOMINA
GARRY M. WHITLEY

OTHER ADVISORY BOARD MEMBERS PRESENT

FAYE VLIEGER

DESIGNATED FEDERAL OFFICIAL:

CARRIE RHOADS

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

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

1:05 p.m.

MS. RHOADS: Good morning, everybody. My name is Carrie Rhoads, and I would like to welcome you to today's teleconference meeting of the Department of Labor's Advisory Board on Toxic Substances and Worker Health, the Subcommittee on the Site Exposure Matrices, or SEM. I'm the Board's Designated Federal Officer, or DFO, for today's meeting.

First, we do appreciate the time and the work of our Board members in preparing for this meeting and for giving us their time today.

I will do a short roll call just to make sure that everyone is on the line.

Dr. Laura Welch is the Chair. Are you on the line?

CHAIR WELCH: Yes.

MS. RHOADS: Okay. And Dr. John Dement?

DR. DEMENT: Here.

MS. RHOADS: Mr. Garry Whitley?

MEMBER WHITLEY: Present.

MS. RHOADS: Mr. Kirk Domina?

MEMBER DOMINA: Yes, here.

MS. RHOADS: Mr. Mark Griffon?

MEMBER GRIFFON: Here.

MS. RHOADS: And Dr. Steven Markowitz?

MEMBER MARKOWITZ: Here.

MS. RHOADS: Ms. Faye Vlieger is also a member of the Advisory Board. She is also on the line.

MEMBER VLIEGER: Yes. Thank you.

MS. RHOADS: Great. We are scheduled to meet from 1:00 to 3:00 p.m. Eastern time today. Since this is only a two-hour meeting, we are not planning on taking any breaks.

Copies of all the meeting materials and any written public comments are or will be available on the Board's website under the heading "Meetings" and the listing there for this Subcommittee meeting. The documents will also be up on the WebEx screen, so everyone can follow along with the discussion.

The Board's website can be found at dol.gov/owcp/energy/regs/compliance/advisoryboard.htm. Or you can simply Google "Advisory Board on Toxic Substances and Worker Health," and it will likely be the first link that you see.

If you haven't already visited the Board's website, I encourage you to do so. After clicking on today's meeting, you will see a page dedicated entirely to today's meeting. The web page contains publicly-available material submitted to us in advance of the meeting. And I know these were posted a little late. Apologies for that. The agenda is probably up there or will be soon. And we will publish any materials that are provided to the Subcommittee on that website.

If you are participating remotely and you are having a problem, please email us at energyadvisoryboard@dol.gov.

If you are joining by WebEx, please note that the session is for viewing only and will not be interactive. The phones will also be

muted for non-Advisory Board members.

Please note that we do not have a scheduled public comment session today. The call-in information has been posted on the Advisory Board's website. So, the public can listen-in, but not participate in the Subcommittee's discussion.

I have been asked about meeting minutes and transcripts. The Advisory Board voted at its April 26th to 28th meeting that Subcommittee meetings should be open to the public. A transcript of the meeting will be prepared from today's meeting. During the Board discussions today, as we are on a teleconference line, I would just like to remind everybody to please speak clearly enough for the transcriber to understand, and when you begin speaking, especially at the start of the meeting, please state your name, so that we can get an accurate record of the discussion.

Also, I would like to ask the transcriber to please let us know if you are

having an issue with hearing anyone or with the recording.

As the authority that minutes are prepared and enter the certified WebEx share, the minutes of today's meeting will be available on the Board's website no later than 90 days from today, per FACA regulations. If they are available sooner, they will be published before the 90th day.

Although formal minutes will be prepared, we will also be publishing verbatim transcripts, which are, obviously, more detailed in nature. Those transcripts should be available on the Board's website within 30 days.

I would like to remind the Advisory Board members that there are some materials that have been provided to you in your capacity as special government employees and members of the Board which are not for public disclosure and cannot be shared or discussed publicly, including in this meeting. Please be aware of this as we continue the meeting today.

And with that, I convene this meeting of the Advisory Board on Toxic Substances and Worker Health, Subcommittee on the SEM. I will now turn it over to Dr. Welch, the Chair of this Subcommittee.

CHAIR WELCH: Thank you, Carrie, and thanks, everybody, for being here.

Carrie and I discussed what materials we might want to use for this introductory meeting, and she had sent those in an email. And now, I do see that they are also available on our Subcommittee page.

What I wanted to do initially is go over the charge to the Subcommittee, which in the materials that we had before our first Advisory Board was to advise DOL on the SEM. So, it is a very broad statement.

And then, I wanted to review the memo -- DOL made a presentation and they have a written documentation of specific requests from them. And I think that one of the big questions I wanted get resolved with all of us today is

what we think our scope of work consists of, and I have some suggestions about that.

So, just by way of background, we heard at the Advisory Board meeting that the Institute of Medicine had already done a review of the SEM, and that document is available to all of us. It originally was provided to the overall Committee and it is on our website.

And that does lay out a lot of recommendations for the Department of Labor, one of which was to establish an expert Advisory Board for the SEM. The Department of Labor didn't tell us explicitly that that is the charge to the Subcommittee or to the overall Board, but the IOM report did say that the law permitted and recommended the establishment of this Board. So, I think it is reasonable to presume that one of the recommendations from the IOM was the DOL responded to that by establishing the Board.

What DOL has asked us to do, there were four specific points on policy guidance, on links between exposure and disease.

And, Carrie, this is down on page 9, if you can provide that document all the way down to page 9, the one you have open on the WebEx. There we go.

So, let's see. Yes, so, then, starting at the top, they are not specifically itemized, but we want the Committee to provide the DEEOIC policy guidance on linkages between toxins and occupational disease.

And then, there are the specific diseases for which they want guidance about causation, including whether the ones that are listed at the very bottom, and there's some on the next page as well, but don't move to that yet. These conditions somehow affect the exposure response/linkage.

Then, the third point was how we modify the SEM to better convey information and how to help DOL set up priorities for their contractors and adding new data to the SEM.

Now the IOM already made some -- I think they are good recommendations for that

third point, modification of the SEM to better convey information. And in their report, they did a pretty good job, in my opinion, they did a nice job of laying out for us what work needs doing.

So that my overview introduction is that our overall charge is to advise DOL on the SEM. And then, DOL asked us some very specific questions that go very quickly down to policy guidance on specific diseases.

So, Carrie, could you back to my agenda for the call?

I thought, on my point No. 4 here, I thought it was helpful for us to talk among ourselves and, then, clarify with DOL if we need to the issues and scope of the Subcommittee's topic area. And if this is what we get done today, that is perfect, but there are other things on the agenda.

We are supposed to focus on SEM, but we haven't been asked to assess the entire process by which DOL assesses exposure for the

claimants. IOM, and I know I, for one, on our Committee, sees there are holes in the way that the causation analysis can be done if you only use SEM. But I guess, can we on our own say, well, we want to see -- say, for example, it is the Occupational History Questionnaire; it can be in its own right a way to demonstrate causation based on things that are reported there, exposures reported there, or TACs, for example, that may not be part of the SEM. Or do we need to make sure we are focusing on the SEM? There may be a way to do both. And I think I would really like to take some discussion to get thoughts about that. And then, we will get to the "b" and "c".

Do people on the Committee think that we should call ourselves, instead of the SEM Subcommittee, the Exposure Assessment Subcommittee? Any thoughts on that?

DR. DEMENT: This is John Dement, Laurie.

I think we have to look at the

totality of the information that goes into the exposure assessment. So, I would say that we ought to be the Exposure Assessment Committee encompassing the occupational history process, including the form itself, but also the process of obtaining that history and how that history is used in connection with the SEM for exposure assessment and what holes are there.

CHAIR WELCH: Do other Board members have a thought about that, about John's? I think John expressed what I was trying to, except very clearly. Do other people agree or disagree with that approach?

MEMBER WHITLEY: Garry Whitley here.

I believe I agree 100 percent because the SEM database is so large and so incomplete that we have to be that Committee and look at other things out of the database.

MEMBER MARKOWITZ: This is Steven Markowitz.

Actually, you know, the SEM includes not just exposure, but the links to diseases by

encompassing this Haz-Map database. And in the IOM report, which I know we will discuss later in the agenda, they take aim not just at SEM, but, in fact, as much as the Haz-Map database, at SEM and SEM's use of the Haz-Map.

So, you know, one could argue that, even beyond exposure assessment, that this issue really involves the linkages to diseases. I am not saying that that should be a primary goal, but I think it was to be part of the discussion. Because if we draw the limit at exposure assessment, then we will be missing a major piece.

And finally, I will say that, actually, DOL in their list of requests that Laura just reviewed, the No. 1 request was taking 20-odd diseases, including Parkinson's disease, prostate cancer, et cetera, and asking for our help on diagnostic criteria, but, also, what does it mean; what does the literature show in terms of causation, contribution, or aggravation? So, I think DOL sees this issue as broader than just

exposure assessment.

CHAIR WELCH: Okay. No, I think you are right, Steve. I didn't mean to say we were going to forget about the exposure disease links. I just thought if we are constrained to using SEM as a way to assess exposure, it would become complicated. It is not impossible, but it may be that exposure -- and IOM did point out that complex mixtures are not dealt well with in SEM. So, if they are complex mixtures that are suggested by occupational history, maybe you can use data on that without having to force it into the SEM model, that we could get there.

But, no, I totally agree it is very important to look at IOM's recommendations and see if we have others to add or how we would implement what they recommended on that disease/exposure link. Clearly, that is what the SEM is there for, and they are finding many ways in which they think it is falling short.

MEMBER DOMINA: This is Kirk. I have a couple of questions.

During our meeting in April in D.C. I asked specifically -- well, Rachel brought it up that there are two different SEMs, one that the public gets to look at and the one that DOL uses. And so, to me, not knowing what that gap is, and not having access to it because she said that she would check in to find out if we could have access to it, and we are -- what? -- two-and-a-half months later and I haven't heard anything. So, that concerns me a little bit because, you know, it could be little; it could be large.

For somebody out of the claimant side saying that you weren't exposed to chemical X because it doesn't show up on the SEM, what SEM are they talking about?

And I agree with everything else that was said before this, but there needs to be something done. And then, also, if not, then get us clearances so we can access it. Because we know NIOSH has seen a lot of stuff, and there are DOE sites that have Special Exposure Cohorts that also don't have any SEMs. And so, that is

another concern.

So, you take some of these other sites that may be smaller that don't have a SEM. It makes it that much harder for the claimant to try to get their claim through.

CHAIR WELCH: Well, that is a very good point which I didn't know about, that there are sites without SEMs.

In the IOM report they do discuss the fact that there are two different databases. And possibly in the memo that we got from DOL, the one that claims examiners use has fewer specific toxins than the one that is publicly-available. And DOL was saying that is because they are trying to consolidate across brand names that may be the same toxic exposure.

But I agree with you. I mean, we definitely need an answer to that question.

Carrie, do you remember if that ended up on the items to-do list?

MS. RHOADS: Yes, I think it did, and they have been talking about it. I will have to

make sure that I get a final answer on that probably this week.

CHAIR WELCH: Okay. And along those lines, we had asked for some general claims data, which we haven't gotten yet, either. I mean, one of my thoughts was, if a very high proportion of current claims are for specific medical conditions, we want to make sure that we have those tightened up, so that claimants can have, whether it is by presumption or whether it is by improving the SEM, so that the whole process can work smoother for a big number of the claims. But we have not gotten yet disease-specific claim data.

And I know you asked them for that, Carrie, to see if you could get it in advance of this meeting, but do you have any idea on the timeframe for getting that info?

MS. RHOADS: We have already asked them for it. They are working on it. And there are a number of outstanding ones that I will follow up on and see how much longer it will be.

CHAIR WELCH: Okay. Good.

MS. RHOADS: But I know they are working on them.

CHAIR WELCH: Okay. The point b I had here under 4, the Procedure Manual lays out what items can/should be used to assess exposure. Unless there is some circular that overrides that, it pretty much says the claims examiner can use other information. They can use the exposure information from a worker program questionnaire, for example.

If the SEM does not show a specific exposure, but they have information someplace else, they are allowed to accept that other source. It does seem that what we hear from authorized representatives and workers is that the claims examiners seem to rely on the SEM. If it is not there, other sources aren't really showing up.

But that is something that I think we should reinforce from our Committee, that the way the Procedure Manual lays out with other options

and that the SEM may be incomplete, and something else may be probative, we should at some point reinforce that.

DR. DEMENT: Laurie, this is John.

One of the things that I noted during our discussion at the last complete Board meeting was the example that we reviewed was a COPD case, and the individual had worked at a number of sites. Probably the only thing, at least in the information that we were given that was used from the actual history completed by the worker was the occupation and site and the timeframe.

And then, the SEM information was used almost exclusively, it appeared to me, for the referral to the IH for the exposure assessment. And it is really circular. I will look back at the IH exposure assessment; the only thing that comes under the Haz-Map are three different exposures for COPD, and one is a biologic agent and the other two are diesel and it is cement dust. And so, the assessment by the IH was completely based on information that came out of

the SEM and not related at all, except for occupation and site, from the history. To me, there is a major disjoint in that whole process if this is a good example of how it is essentially being used.

CHAIR WELCH: Yes, and, John, I agree with you. I mean, I think you pointed that out at the meeting. I have seen that from the claims that I have reviewed, too, that the other sources either aren't even mentioned in the file or the SEM seemed to be more important. If there was an exposure reported by the worker that wasn't in the SEM, it was not considered probative. I mean, it is just definitely something we have to keep in mind along the way.

We are probably going to have to have some conversation with the committee that is reviewing the IH role because that is very important.

MEMBER MARKOWITZ: This is Steve Markowitz.

It sounds like where we might be

heading is, if we at some point look at a number of claims to see how things actually work, that we would want to identify -- and maybe this is just repeating what you are saying -- but identify the various pieces that are used to construct the exposure and, then, the role of the various personnel in using and interpreting that information from the start to the end.

CHAIR WELCH: Right. That's good.

DR. DEMENT: I agree with Steve. This is John. I agree with Steve. I think, again, as we did with the last committee that we discussed, I think we do need to look at the totality of the process.

The example of the COPD case I think is one. I think we need others to take a look at pretty much the algorithm, if you will, that is used to come up with determination of causality or not.

CHAIR WELCH: And when John and I were both on the Committee related to the Part B lung disease, then we did request that DOL pull out

specific cases for us to review, and I do think that would be helpful. It may be a little bit harder to figure out what they are, I mean what cases they are, although it could be the last, you know, 50 that went to the IH for review. It sounds like they are all, that a lot of them are going to NIH for review. And that is something really obvious to the claims examiner. That may be the best way to get a sense of how the inputs are being used.

DR. DEMENT: I know we are driven by some questions about specific diseases, Laurie, that are on that list, and I think those are important. But it seems like the work of our Committee also ought to be driven by the some of the most frequent ones that are being processed and whether or not they are accepted or denied.

The Part B Committee looked at some data from the claims process. It came in an Excel spreadsheet. I don't think it represented the Part E claims very well; at least what we had I don't think does.

So, the question to me is whether or not we really want to look at some of that data early on to try to direct us on where we might get the most bang for the buck.

CHAIR WELCH: Yes, you know, I think we do. I think we do, both because it would be most helpful -- I mean, during the course of the meeting, I think that Rachel Leiton had said to me just in a side conversation that a lot of the claims they are getting are for COPD. I can see ways in which their process is going to continue to fail for COPD and make it very time-consuming, even if people do eventually get their claim accepted.

I think very concretely, if we were to try to fix something related to these common diagnoses, if we understood the process and the inputs, we would end up probably improving the process for all the claims.

But we did ask for it. I mean, what we asked for was a breakdown by ICD code of the claims, of applications and accepting and

denials, which should be similar to the spreadsheet that we saw for beryllium. It has just got a lot more ICD-9 codes in it. But if they were able to produce that for beryllium, I am confident they could product it for us, which has got thousands and thousands of claims.

DR. DEMENT: That is just computer work.

CHAIR WELCH: Exactly. It is just John's computer work. I want to tell the rest of the Committee he did a beautiful job on doing something with that Excel spreadsheet with beryllium cases.

So, yes, I thought that we would kind of get our charge together, but we might not be able to do -- well, there is probably a lot we could do, but I would really, really like to see, and I am sure the whole Committee would like to see some statistics on the kind of claims that are coming in and, also, how many of those have been approved or denied.

I think No. 5 was already discussed,

No. 5, on how will our Subcommittee interact/overlap with the Subcommittee assessment role of IH. I mean, once we do what Steven suggested, look at reviewing all the inputs, who reviews it, how they use it, all through the process, that certainly would overlap with the other Subcommittee. But that is fine because we may approach it from one point of view and they may approach it from a different one. I don't think it is inefficient.

Does anybody have any thoughts on that? Otherwise, I will just keep going.

DR. DEMENT: My thought is to get pretty much the database on the claims in totality, Laura.

CHAIR WELCH: Yes.

DR. DEMENT: And then, based on that, we can look at the frequency of acceptance and of denial based on some of these ICD codes. And then, I think we ought to pull some kind of stratified sample of the ones that are by some of the major categories and take a look at them in

more detail.

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: It is Steve Markowitz.

We should also look at some of the less common diseases or outcomes that people make claims for. I am sure you didn't mean that we are only going to look at the most common, but some of the less common may be looked at differently in the process. We just want to make sure we don't entirely bypass them.

DR. DEMENT: Yes, I agree, and the list that they gave us, some of them are fairly common, but with low-probability of occupational linkage on some of them. And some of the more rare ones may have even a greater probability of occupational linkage, if we look closely at the literature.

CHAIR WELCH: Yes. So, when we get a database back, we can look at some or even all of the ones on their short list. I mean, we can get a sense of, when they said the ones that are

associated with aging, dementia, and Parkinson's disease, you could see this whole population as aging. People are developing more of those conditions. And then, it is important to have DOL define how you could determine in any individual case whether it is work-related.

So, once we get the overall claims analysis by ICD code, we can -- John suggested a stratified sample to look at some illustrative cases with more detail on there around common diagnoses, but also be sure to include definitely some on their list, if not all the ones on their list which they specifically asked for our assistance.

MEMBER MARKOWITZ: Steve Markowitz.

I just want to look at the timetable a little bit in reference to this idea about looking at certain claims and when it might happen. We are waiting for DOL to produce some database, some information about what different diagnoses are, occurred within claims, the frequency.

We meet October 19th, or something like that, 18th, 19th, so roughly two months, three months from now. Are we hoping, is this Subcommittee, as a Subcommittee, are we hoping to, once we get the next round of information from DOL, hopefully, within a few weeks, we are hoping to request a certain number of de-identified claims to look at before the next full Board meeting, so we have a better understanding? I just want to see where we are heading. That's all.

CHAIR WELCH: That would be my hope, yes.

MEMBER MARKOWITZ: Okay.

CHAIR WELCH: And so, it is really more how do we get DOL to move on that request. I mean, there are probably a lot of requests that went in, I mean action items, some of which are less important than this, in my opinion. Maybe there is some way to move this request up higher.

But, yes, what we could do -- and we do have the timeline down there -- we could

decide we are going to schedule another conference call, say, a month before the October meeting, with the idea that, prior to that, we would have been able to look at the database. And Carrie and I, maybe by email, we can decide which claims we want to look at, get a chance to look at them, and have at least some time to discuss at the end of September.

MEMBER MARKOWITZ: This is Steve Markowitz. I mean, I'm just there, Laurie.

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: If we have a call, this Subcommittee has a call September 20th and hasn't looked at claims, we know it is going to take them a while to prepare 50 claims, or whatever number we want, de-identify and prepare them. I am just wondering, I know we are held up right now because we don't have the database we need to sort of look at, but we, nonetheless, I think need a plan.

Ideally, we would look at those claims before we talk again towards the end of

September. That is, I guess, my point.

CHAIR WELCH: Yes, that was my thought, too.

MEMBER MARKOWITZ: Okay.

CHAIR WELCH: It would be great if we had the database today and we could all choose what we want to look at, or at least discuss it and email Carrie what we want to look at.

Now we are kind of imagining what the database might show us when it comes to diagnoses. In abstract, we could say we want to look at so many files of the top three diagnoses and so many files of their shorter list. That is one way to approach it, so that we don't need two calls. You could leave it up to me to choose some once we get the spreadsheet and, then, we would have our call in September and people would then say, "Well, these are useful, but we are going to need more. I mean, there is something I really wanted to see." I think that might work.

Or we could get the data. Carrie would send it out to everyone, and people could,

then, respond to her with their requests of what files they would like to review. So, there are a couple of options.

But I agree, whether it will get done in that timeframe, but we would give DOL -- I will say we would get it from DOL in three weeks and, then, we could request cases.

Steven, do you think we want to try to have a conference call to discuss the large dataset? I was feeling like we can't quite get that scheduled; we can't have two calls before the October meeting.

MEMBER MARKOWITZ: Probably not. I mean, it requires six weeks' lead time, right, the Federal Register notice? So, probably not.

But I think, once Carrie finds out the timetable for getting the first round, either plan you suggest, either you selecting or people write in with their requests, then we can formulate the request for claims. And hopefully, that won't take all that long for them to produce the claims, that we could have looked at

something by the end of September for a useful discussion.

CHAIR WELCH: Yes. I'm happy to take responsibility for selecting some claims. But, if people would like to see the spreadsheet and comment on that as well, that's fine.

What does the rest of the Committee think? Once we get a spreadsheet with data by ICD code, would everyone like to see it?

MEMBER VLIEGER: I think it would be helpful if we all got to look at it.

This is Faye.

CHAIR WELCH: Okay. And then, Carrie and I will formulate some questions and a process by which you would send back requests for files to review.

So, I guess the most important thing for there is for Carrie to figure out how to pressure DOL to get us the specific, you know, the ICD code specific data analysis of the claims. And it can look just like that nice beryllium spreadsheet. We just need all the

diagnoses.

MEMBER MARKOWITZ: Yes, this is Steve Markowitz.

I will help Carrie with it.

CHAIR WELCH: Okay. Great. Thank you. Okay. So, that's a plan.

And then, also, Carrie and I can send out or Carrie can send out an email asking for dates, maybe the third week in September, so we can have another call.

So, for my agenda item No. 6, I think --

MEMBER MARKOWITZ: Laura, Laura, this is Steve Markowitz.

CHAIR WELCH: Yes, go ahead.

MEMBER MARKOWITZ: I just didn't want to skip over 4c --

CHAIR WELCH: Okay.

MEMBER MARKOWITZ: -- which, for people who aren't looking at it, it says, raises the question of, having looked at the DOE data for how frequently what diseases people submit

claims for, would developing presumptions for frequent conditions fall under this Committee? So, I just wanted to --

CHAIR WELCH: Yes, thank you for doing that.

MEMBER MARKOWITZ: Yes.

CHAIR WELCH: You know, the DOL staff said they would like our help, would like the Board's help with developing presumptions. So, my view is, since we were asked, we could take that on.

Steven, do you have a thought about that?

MEMBER MARKOWITZ: Yes. Steve Markowitz. Absolutely. You know, they have moved somewhat towards presumptions based on their own experience and difficulty in trying to nail down the specifics about exposure and diseases. I think that says a lot about what the program has needed, and "program" meaning administration of the program. The reality of that, plus SEMs specifically asking us about

input into presumptions, and presumptions involve exposure and disease linkages. So, that really is something we should move ahead on.

CHAIR WELCH: I did not attach it as our documents, but they did recently develop a presumption on COPD, which I can make sure everybody gets a chance to see. And they had previously developed one on the specifics related to ZEEP I think. So, there aren't a lot that I'm aware of, but I will make sure that those go out to the Committee.

MEMBER GRIFFON: Laurie, this is Mark Griffon.

I agree with, basically, everything you have been saying and the idea of looking at a stratified sample. I was curious. I mean, I don't want to make this more difficult necessarily. But, similar to what we did on the Radiation Board, we did a stratified sample. We based it more than on just the ZEEP, though. We did stratify based on site.

This is a different animal, but I

think it might be useful to stratify it on site at least. We had several other factors that we stratified, but that was different because we also had more data for the radiation side.

And then, the only other comment I have was, maybe I missed it, but what is our goal in reviewing these, once we get a sampling of cases to review? Are we going to review all these cases individually and go through them one by one and have findings if we disagree with the way the claim was processed or are we doing this to get a sense of how the overall procedure and how, in general, they are processing claims? Or what is our goal at the end of this?

CHAIR WELCH: That is an important point for discussion.

MEMBER GRIFFON: Sorry, I thought I missed it maybe.

CHAIR WELCH: No, no, no. I was presuming something already without expressing it, which was I was thinking the latter, that we need to understand how the claims process works

and what is going into the assessment of the individual exposure and, then, the exposure/causation link.

MEMBER GRIFFON: I agree with that, by the way. I think this will allow us to understand it better. And maybe, then, we will decide to go in another direction, but that is a first step. I think I agree with that.

CHAIR WELCH: Yes, and I would suggest that we all look at the same cases rather than doing more cases and dividing them up and reporting back to each other. Because, anyway, I think it would be easier to have the conversation if we all looked at 20 cases, five of us each look at 20 and present to the group, if we are looking at the same cases to start with, even though it will be maybe less representative, because different cases may show us a different part of the process. But I can't think of a more efficient way to understand it.

MEMBER GRIFFON: I totally agree with that. I think, depending on if you just

stratified by disease, I just think we should try to also select a representative number of the large DOE sites because I think, well, you have different claims assessors' office; you have different exposure data available from the different sites. So, they may look very different, but a COPD case from Rocky Flats versus Los Alamos may look very different, just because of what they have available to work with, or whatever. So, I think that would inform us a little bit more on the exposure side as well.

CHAIR WELCH: Yes, I think that is a really good point. I totally agree.

And Kirk pointed out that some of the small sites don't have a SEM. So, at some point we want to see how do they address those.

MEMBER GRIFFON: Yes.

MEMBER MARKOWITZ: Steve Markowitz.

One way is to have some of those claims that we look at come from non-SEM sites.

CHAIR WELCH: Yes.

MEMBER GRIFFON: Yes.

MEMBER MARKOWITZ: But, I mean, I would also just like to propose a second goal, which is not just to understand the claims process, but also to understand what data points exist within these claims, that if later we move to a more systematic look at what they are doing, that we will understand how to structure the kind of data we are after.

MEMBER GRIFFON: I agree, yes.

DR. DEMENT: This is John again.

I agree with Steve. And looking at the small number of these occupational histories that we have seen so far, many of them seem to me to be very incomplete. I am wondering how much these sites are supposed to be helping the worker compare these, how much guidance they are actually giving the worker with regard to preparing these occupational histories.

MEMBER VLIEGER: I can answer that question. This is Faye.

DR. DEMENT: For example, the ones we have seen so far, I have seen very little

information with regard to description of the task that we actually did. As a hygienist, the task and the material really dictate pretty much what the exposure intensity would be anyway. At least somehow I would like to learn more about that process of collecting this history. Who does it, how are they trained to help the worker, and how they are trained to look at these when they are done and critique it, see if it is complete? That is just a piece missing for me.

MEMBER VLIEGER: This is Faye.

The Occupational History Questionnaire is either completed by the worker or by the worker in conjunction with the Resource Center. The information that you would expect them to know about their exposures does not exist. It doesn't exist in the worker's employment records and it doesn't exist with the U.S. Department of Energy in their records.

And so, the worker does the Occupational History Questionnaire to the best of their ability. The only time I have seen a

detailed list of what someone was exposed to is when they were one of the chemists or metallurgists in the laboratory setting and they knew what was on their lab bench, and they could report what they used.

DR. DEMENT: I think that is a good point. But what would help, for example, in an occupational history would be provide some cues to the worker with regard to tasks that are, for example, known to increase the risk of intense exposure.

In the Former Worker Programs, we try to, one, use workers to collect the information, to help the individual. The interviewers have experienced personal or collecting occupational histories now so many times a lot of experience outside. And so, I think we stimulate some better history, we call it, than I think we are getting on these histories that I have seen so far in the compensation program.

CHAIR WELCH: Yes, and that was the item I had. I think we have kind of already

answered the question already about the item of should we develop a plan for improving the Occupational History Questionnaire. And I think people have already said yes to that.

We have asked how it get administered, and what Faye said is what we also heard at the meeting, completed at the Resource Centers, but there doesn't seem to be any training on history interviewing. But part of the form is not designed to ask about task or exposure. It is designed to ask about where you worked.

DR. DEMENT: No, that's right, and ask about incidents. But I don't see much in there of asking about specific tasks. Although in the SEM there are some specific tasks that are listed, it is quite incomplete, based on my just cursory review so far. But, even there, it would be a linkage that would help the worker.

CHAIR WELCH: And along this line, Trish Quinn, who is the coordinator of our med Program, John Vance contacted her after the Board meeting to ask if the Building Trades Program

could help improve the Occupational History Questionnaire.

So, you must have impressed him, John, with your comments.

DR. DEMENT: Yes, to make sure --

CHAIR WELCH: But the DOL would be open to that. I think it is a pretty big task.

DR. DEMENT: It is. We help so many different labor categories from production through labor, our construction and non-construction. It is a pretty daunting task to have one history.

CHAIR WELCH: Yes. But I would think that, at a minimum, we should make recommendations to DOL, as our Committee looks forward, of how to improve it, even if we are not going to development it for them, because we could have codified the discussions that we have had about what needs to be in it and the best way to obtain that information.

MEMBER MARKOWITZ: Steve Markowitz.

So, I get involved with the Former

Worker Program on the production side. And I want to emphasize -- and Mark Griffon has been involved as well -- I just want to emphasize how many job titles we have at the various sites --

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: -- and how they have evolved over the decades.

I think it would be very ambitious to get high-quality information from people's memories about job task, that it would really need to be a cadre of well-trained interviewers who know these sites and know the kind of work people have done in order to get that information. And so, I would say no one is underestimating that, but I just wanted to emphasize how challenging that would be.

CHAIR WELCH: Right. Yes. No, absolutely.

MEMBER WHITLEY: Garry Whitley here.

I think, first of all, the Resource Center and the claims examiner, neither one helped these people with even the SEM database.

They have to come back to the Worker Health Program or to us and ask us, well, what chemicals did a pipefitter or a sheet-metal worker work with?

Even if we have got one of these in the SEM database, neither one of those two groups will help the people at all, the claimant at all, with that SEM database. They don't pull it up and say, "Well, see, here you worked for" so-and-so. They don't do that, and they won't look under the SEM. They will make a decision on your case with the SEM, but they won't help you look it up and say, "Well, did you work with this chemical or did you not?"

I think, personally, the presumption thing would be the best thing we could do to help the claims examiners. Because I have got cases, have seen cases where the claims examiners tell people, "Well, if you're a sheet-metal worker, you didn't work with anything." If you go to the SEM database that we see and look at sheet-metal worker, it is there that he worked with that

chemical every day.

So, I think the presumptions could help with our claimants a lot better than maybe some other ways we could help.

CHAIR WELCH: I think that is a good point. I mean, when I think about COPD, I do think that writing a process, you know, distilling the literature and saying these kinds of exposures are causative or contributory, rather than trying to make it fit into the SEM matrix, which would be difficult.

And then, as you point out, Garry -- I mean, and Steve has said the same thing in a different way -- you really need an interviewer who understands the site and the processes that are used there to get the right information out of the worker. The SEM doesn't really have it all. But you are saying that, even when the SEM has it, nobody really helps the worker bring it forward. And someone needs to bring it forward for him to put forward a good claim.

So, yes, presumptions would make

sense. We probably could link it. And again, if when we see how many claims fall into the top ten diagnoses, maybe it would be. It would certainly make their workflow more efficient if there were good presumptions.

The problem with presumptions, because presumptions are supposed to be the easy ones, and then, even if you don't meet the presumption, your case can be adjudicated based on more specific individual information. But you can imagine how this system meet the presumption of the yes/no.

MEMBER WHITLEY: Right.

CHAIR WELCH: And this kind of makes you want to make the presumption a little more inclusive, but, then, there is this balance of when you start including cases that clearly aren't related, but they might meet the presumption.

So, it is hard, but it has been done so many times. The trust funds that were set up for asbestos claims have presumptions and a whole

process which people can demonstrate that, even though they don't meet a presumption, they meet the intentions of the trust. And you wouldn't be reinventing the wheel on that if we made those recommendations.

I hate to say it; we have covered our agenda, probably because I am moving us all too fast.

Now we have time to go back. Because we have talked about the data information we have requested already, that we want to review example claims and challenging cases.

Oh, I guess, you know what? Let me go back. The IOM report, I think I am happy to summarize for people what is in the Executive Summary, if people would find that helpful, because I think they are questions that -- this is the IOM rate or many of the same things that DOL does.

But, again, before we do that, do people have any other thoughts about the Occupational Health Questionnaire? I think it is

what we said; we think it needs work. It is not collecting all the information that the claimants should be giving to the claims examiner. It is pretty clear that the worker is not getting a lot of help in filling it out. We haven't necessarily made a plan to revise it.

MEMBER VLIEGER: This is Faye.

Regardless of what a worker puts on OHQ, it is not considered probative. It is not even considered many times in the decision at all when they look for labor categories or they look for exposures. The only information that the Department of Labor considers valid is what they pull from the SEM, and the SEM is incomplete for labor categories and exposures.

So, what I think would be helpful when we ask for the information from the Department of Energy at the meeting was for them to say whether or not they ever monitored for these things from the workers and, if they didn't, then to say so, because they know the employee, the worker, has to say that they were exposed, has to prove they

were exposed with monitoring data.

CHAIR WELCH: Right, or the SEM. But, actually, if it is that post-'95, it is supposed to have monitoring data.

MEMBER VLIEGER: Right, and there's no monitoring data. And so, it wasn't in the list of things that I saw we were requesting. But I found it in the transcript of the minutes where Pat Worthington said she would be willing to look for that information, but she needed to know where to look first because, of course, they had many sites.

CHAIR WELCH: And which information was she going to look for? I didn't quite understand.

MEMBER VLIEGER: She was going to tell us whether there was monitoring data or not.

CHAIR WELCH: Oh, okay. I have always presumed that, if there wasn't an OSHA or a DOE standard that needed to be met, no one would be monitoring the exposure.

MEMBER VLIEGER: Well, then, DOL comes

back to the worker and says, "There's no monitoring data. Therefore, you weren't exposed."

CHAIR WELCH: Right.

MEMBER MARKOWITZ: This is Steve Markowitz.

Or they could take the monitoring data and say, "We have monitoring data and you weren't exposed." It cuts both ways, actually.

MEMBER VLIEGER: Well, no, where are you going to find as many of the chemicals and concerns for these workers we never monitored for?

CHAIR WELCH: No, that makes a lot of sense.

So, I think that that memo that says, after 1995, DOL is going to presume that the work places were all completely safe, is -- I don't; I can't think of a good adjective. I disagree, and they are making it up because they have no monitoring data that shows that it is or isn't. But I think we have to keep this on our agenda.

I don't know that -- right, that is not the first thing we are going to address, but at some point we need to address the fact that workers will describe exposures and the SEM describes exposures linked with those, and diseases linked with those exposures and the timeframe for when the exposures occurred.

If DOL would like help with timeframes for exposures, then that would probably have to go into a presumption with specific disease/exposure relationships. And then, those post-'95 thing could be addressed exposure by exposure. But I don't know; I say let's defer that for our next -- maybe after the big meeting, because it would be pretty difficult to demonstrate that they are wrong because the monitoring data doesn't exist before or after 1995 for many of these standards.

MEMBER DOMINA: This is Kirk.

I need a comment on that. You know, a lot of times, you know, just because they put this in the 1995 -- you have got to look at where

the sites were at that point in time with whoever the contractor was. Because if they are going to come in the middle of the contract and say, "We want you to start doing all this," and you don't provide funding for it, they are going to ask for requests for equitable adjustment. And if they don't do that, they are not going to do it.

A prime example is Hanford's last SEC from '84 to '90 for the building trades. There is a reason that one went through, because they were supposed to do bioassay sampling. They provided no funding. So, I believe there was like six bioassay samples for like 4400 workers. And that is part of the reason that one went in.

And it is no different with this. Like I look at these other sites that I talked about earlier that have SECs with no SEM, so they have got no rad data. You know they have no chemical data. And that would be that way for a lot of them.

I mean, I have been on here a long time, just like Garry was out there a long time

at his site. They didn't monitor for things because at that time it wasn't considered a hazard or we were in a Cold War effort. You have to look at all those things that come into play.

CHAIR WELCH: Right. No, that's right.

Steven, do you want to give your thoughts about when we can address that 1995 memo?

MEMBER MARKOWITZ: So, we are going to need some background on this from DOL as to how they arrived at that conclusion.

CHAIR WELCH: That's true.

MEMBER MARKOWITZ: And I think that the presence or absence of monitoring data post-'95 is not going to be determinative of the what needs to be done. The post-'95, or post whatever date you want, time moves on; maybe workers need to describe from their more recent memory their work tasks and the ways in which they may have had exposure with or without monitoring. Even if they show monitoring results at no levels or low

levels, we are not necessarily going to trust that that represents the workers' exposure.

So, I think that it is part of exposure assessment that we are talking about, and I agree we are going to have to keep it on the radar and find out more before we can really kind of weigh-in here.

CHAIR WELCH: Okay.

MEMBER VLIEGER: I'm sorry, this is Faye.

As part of DIAB and NLAB's work, we queried Pat Worthington from DOE Headquarters and Greg Lewis about where the information came for the establishment of the post-1995 criteria. The Department of Energy responded that they did not provide Department of Labor any information that these sites had no exposures after '95. I can provide a copy of that to you all. But, specifically, the Department of Energy did not provide DOL any exposure information for the post-1995 Toxic Exposure Circular.

CHAIR WELCH: Well, that is

interesting. Okay.

MEMBER MARKOWITZ: Yes. Steve Markowitz. It would be interesting to see that email, sure.

MEMBER VLIEGER: I mean, we did say, "We at DOE are aware of the two circulars you referenced, but we are not involved in the policymaking process at DOL and we are in no position to comment on how and why these two decisions were made."

CHAIR WELCH: Well, they could have provided information and they are not going to tell us. So, we should probably get even more specific, you know.

MEMBER VLIEGER: Well, you know, I can send you this. I have very specific questions that they answered. Basically, it was what monitoring data are they saying it is from and DOE basically said, "We didn't give them anything specific. They are basing their decision off of when orders were published to make workers safe, not when workers were safe."

CHAIR WELCH: Okay. Well, that would be great to see that.

MEMBER VLIEGER: Okay. I will send it.

MEMBER MARKOWITZ: But this is Steve Markowitz.

So, we are trying to figure out how to improve exposure assessment here and how DOL can better use whatever information becomes available. Well, that is going to imply that our recommendations on that are going to apply the post-'95 exposures, just as they do to pre-'95 exposures. We are not going to make an arbitrary distinction about that.

But I think as we make progress in sharpening, helping to improve this process, that will pertain to this pre/post-artificial distinction of '95. Does that make sense?

CHAIR WELCH: Yes, it does to me, absolutely.

MEMBER MARKOWITZ: Laurie, I would like to go back to the IOM report.

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: Oh, I'm sorry, you said you were offering to summarize that for the people on the phone.

CHAIR WELCH: Yes, I will, and it is a very short summary at the moment, relatively-long report.

So, the Department of Labor asked the IOM specific questions, and they wanted them to focus on the link between exposure and disease in the SEM, which we know is derived from Haz-Map. So that they were focusing on that part of the SEM, not necessarily somewhat of how the data got in there, but not really so much where the exposure information came from, but really on the exposure. They asked what tasks and toxins are missing, and if there is other information that could be used to inform that same process, the exposure/disease link or other databases.

So, then, IOM noted -- the things I have read reviewing the report, again, that I thought were useful and worth repeating was that

the Haz-Map was not intended to be used for this purpose; that the links in Haz-Map are strong, but probably narrow; that for carcinogenicity they used it to say, if a substance causes cancer, it has to be an IARC Group 1 carcinogen, but there is no clear criteria for non-cancer outcomes, about what they establish.

It was based on textbooks and authors' experience, and it tends to be well-established links and established for causation and not for contribution. They noted that this Haz-Map and the SEM don't handle complex mixtures or exposures well at all, and that Haz-Map is not very systematic.

So, after that review, I only came up with three big points, one of which was to incorporate other information sources beyond Haz-Map. And they recommended the ATSDR tox profiles, data from EPA and IRIS, substance-specific reports from the National Toxicology Program, and some information specifically from the California EPA. And they acknowledged it

would be difficult to get all that information in there, but these are all expert-based reviews that have also been through a peer review. But it wouldn't be requiring DOL or the Advisory Board to be continuously reviewing the medical literature and deciding about causation if we relied on other agencies to opine on causation and level of risk, to some degree. Many of those do, like IRIS or the NTP. But DOL would have to establish some kind of process for having that done.

The other main point was that the functionality of SEM could be improved greatly, and they made some very specific recommendations. One point was that, if you want to look at, say, a worker who worked at multiple sites, you have to go to each one of those sites and look at the data for each one of those sites; that there would be ways to improve it.

They also pointed out, as far as they could tell, there has never been any quality assurance on the data entry into SEM, not a

review to make sure that what was on the source documents is actually what was put into SEM. It is recommended that should be done on an ongoing basis.

And the third point was that they should set up an expert advisory panel for SEM. I said in the beginning I think that is us. There were some specific points in that that I can bring up pretty easily.

Sorry, I am just finding the right page.

So, they said the expert advisory panel would have immediate tasks which are:

Establish the criteria for the evidence base for causal links. Criteria might be expanded to include a category of evidence "no association," such as the way IARC does.

Determine what information sources might be relied upon.

Develop worksheet or documentation, so that it is clear what data is going from the source material into the SEM.

And then, oversee revision of SEM to add appropriate fields such as chemical interactions, rad exposure, supplemental information sources.

And then, they said the expert advisory panel would also have ongoing responsibilities such as peer review of links in SEM, assessment of occupational diseases that result from complex exposures, identification of potential new links, including those suggested by external sources, and a periodic review of the toxic substances/disease links for both accepted and rejected claims to determine which SEM links are actually assisting in the claims process and what improvements should be made.

I think in the list we made we are adjusting some of those right away, such as a periodic review of sample of claims to see what links are being used. We are not yet suggesting a systemic review of all the causal links.

I think that the IOM report makes a very good case for having these exposure links in

SEM be created by more than one person and that there be a transparent process and expert review of such links.

And I think we, as a Committee, have to decide if -- I think one question is, why didn't DOL do that yet? It appears as if we are being asked to address the same questions or maybe even bigger ones.

And this document I think was 1993. Am I right? I mean, sorry, 2013. It was published in 2013. So, the Committee met in 2012. It could be that the plan was to wait for the Board to be constituted, which did take some time.

But I also think, if there are parts of these recommendations out of the Institute of Medicine that DOL just flat out says we can't do, we should know that before we recommend them again. I mean, it doesn't mean we wouldn't recommend them again, but the process of -- they still have a contract with the physician who developed Haz-Map, and I don't think that that

has tended to figure out how to incorporate from these other data sources.

So, I am not sure of the process for that. Maybe just at the next meeting we could ask for them to make a presentation to the Board about what they have implemented and have not implemented from the IOM report.

MEMBER MARKOWITZ: This is Steve Markowitz.

That's a good idea. I think we should ask them what they have implemented, what they haven't, and what's their thinking about this.

CHAIR WELCH: We could get that on our next Subcommittee call. Do you think that would be helpful? We can wait until the big meeting? I guess we can wait because at our next Subcommittee call we would sort of be focused on understanding the inputs and throughputs for the claims.

MEMBER MARKOWITZ: This is Steve Markowitz again.

I would have to repeat it; it is a big

Committee meeting regardless.

But can I raise a different point on this? I think I disagree with part of part of your formulation about whether the current Advisory Board constitutes what IOM describes as needed.

CHAIR WELCH: Uh-hum.

MEMBER MARKOWITZ: The IOM called for some very big tasks, like -- and this is really just repeating what you said, Laurie -- peer review all new links in SEM. So, anytime there is enough information that a given disease is caused by a chemical, that the expert advisory panel, according to IOM, would actually do that review of all that literature and weigh-in on that link or that link would be done by Haz-Map and, then, the expert panel would review that work.

There are other things that they call for. These are the ongoing responsibilities of the expert advisory panel.

Even something, one of the immediate

tasks, establish the criteria for the evidence base for causal links, let me describe what -- for cancer, that means the way that the World Health Organization does that, the way that the National Toxicology Program does that, is they have criteria on how we are going to decide that something causes cancer. How are we going to look at human epidemiologic studies? How are we going to look at animal studies? How are we going to look at studies in the lab, mechanistic studies, and weigh all that information in order to make a decision? That is a well-worn path. Even then, there is controversy, but at least it is a well-worn path.

For non-cancer outcomes, there is, to my knowledge, no generally-accepted approach. And yet, the IOM report is calling for this expert advisory panel potentially to do that for non-cancer outcomes, which is way beyond, I think, what our charge is.

So, I just want to point out that I think that we need to be careful about what tasks

we think we can do from the IOM critique and, otherwise, weigh-in on, if we believe it, how DOL could address the broader path.

CHAIR WELCH: I totally agree with you. This is Laurie. Yes.

And I think we should spend some time talking about that. I do feel like if DOL says, well, we couldn't do those immediate tasks because it would be so time-consuming -- you know, establish the criteria for the evidence base, oversee revisions to SEM, all this stuff, and peer review all the new links -- if they just don't have the money to hire people to do that, then I think we need to say, the Board needs to say, either "Yes, you have to" or "Here's an alternative that would be acceptable and better than what we have," if we can come up with an alternative that is not as work-intensive.

But I do think we need to find out why they didn't implement them and, then, at some point say this is an acceptable path or we agree with this essential task and you have to do it.

And either the Board will do it or the Board will hire someone else to do it.

Does that make sense to you, Steven, in terms of what you were just saying? Because I agree with you those are big tasks.

MEMBER MARKOWITZ: Well, yes. I mean, we should decide what we can feasibly do and, otherwise, recommend the plan that is going to require resources for them to pursue it. Even if you look at their request to us from the April meeting, one of the documents, page 9 where they list 20-odd outcomes, they say they, quote, "want to know what toxins are at least as likely to cause, contribute, or aggravate these diagnoses". End of quote. And then, they list 20 conditions, including breast cancer, neuropathy, diabetes, heart disease, very broad conditions.

It, frankly, is kind of an immense set of tasks. So, at the very least, we need to describe how these tasks can be accomplished and what resources are required, what the structure should look like feasibly --

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: -- not pie-in-the-sky. I think IOM was a little pie-in-the-sky, frankly, but feasibly that it can be done.

CHAIR WELCH: I agree. I agree with you.

DR. DEMENT: This is John.

You know, we just didn't hear anything from the DOL with regard to just a work plan for addressing those comments. I think that is really sort of the missing link right now.

Yes, I agree with Steve, a lot of the IOM reports fall, while the recommendations are good, they are a little bit impossible to implement in a practical way without extraordinary resources. So, I think we need a little more direction maybe related to that. We have to have a little more practicality.

MEMBER MARKOWITZ: Steve Markowitz again.

I don't think we should wait until we hear from them about what they have implemented

since then, since it is likely, looking at the recommendations, likely they have implemented very little. And so, we should assume that not a whole lot has been done and proceed there as opposed to waiting until October to hear, you know, frankly, a modest set of things are likely to have been accomplished.

CHAIR WELCH: Yes. Partly because of the way I think about things, I feel like looking at examples, looking at cases will help me with this. The more the obscure the disease, the less common the disease, the less likely there is data to link it to exposure, but also the fewer claims there are that would present with that disease. And I feel like some of the process of helping them develop a process to review very broadly all disease/exposure links will end up being lost in some of these very difficult decisions.

I mean, I think the same way about the SEM. The SEM has already got 17,000 specific toxins in it. And the contractor is out there collecting more exposure information. It would

seem to me the exposure information they are finding now would be rare exposures, short-term exposures, things that may be hard to assess, and that we would be better off trying to get the SEM and the whole process to help with the claims they are having a difficult time with that are frequent. But that would mean that we are leaving some workers hanging who have relatively-rare diseases for which there is little exposure information.

DR. DEMENT: This is John again.

Looking at that list that we were provided with these conditions, a lot of them are already pretty well addressed by IARC in most of their reviews; for example, kidney cancer and TCE, benzene, cadmium, asbestos. So, it has been looked at. So, I don't quite get the reason for it being on there. Also, the non-Hodgkin's lymphoma and TCE and benzene, you know, they have been looked at a lot with regard to IARC and others. So, some of those can be referred to existing reviews.

CHAIR WELCH: You're right, six of the list are cancers.

DR. DEMENT: Yes, I don't quite see why those are problematic.

CHAIR WELCH: If the criteria in Haz-Map, if you were using Haz-Map, now the cancers, I haven't memorized the list of cancers that are considered radiation-related. Mark I know would look at that list and say, yes, a specific cancer, it isn't.

If what is on this list are the ones that go to Part E because they are not radiation-related --

DR. DEMENT: Oh, yes, these are Part E.

CHAIR WELCH: Yes. So, they needed some guidance to say benzene is known to cause non-Hodgkin's lymphoma or not. That seems to be what they're asking up there. But there are existing reviews, absolutely.

MEMBER MARKOWITZ: Steve Markowitz.

My guess is that Haz-Map might be not

quite up-to-date on some of these cancers. So, they, then, get questions.

DR. DEMENT: Yes, I agree, and that was one of the IOM comments about Haz-Map as well. The criteria for "causality," quote, is quite, you know, pretty much it has to be in a textbook, let's say, versus more contemporary literature.

CHAIR WELCH: Yes, but I think I agree with you, John, that it should be easy to say that, I mean, if IARC has done a review and it is now a Group 1 carcinogen, the link has been established and it doesn't have to appear in a textbook to get into SEM. But, again, I don't know the process. I mean, we sort of know the process. I think that probably that is happening, but what kind of delay are we getting between when there's some excellent review that comes out and it gets into SEM.

MEMBER MARKOWITZ: Yes. Steve Markowitz. The problem is people don't update those textbooks fast enough, right? Yes.

CHAIR WELCH: Oh, yes.

DR. DEMENT: Most of the time, by the time a textbook gets published, it is out of date.

CHAIR WELCH: Yes, and if you are using, you know, let's say you are using Selvin and Krieger, which is every five years. Even if you used three different textbooks, what is in a textbook would be six years' out-of-date. By the time the new edition comes out, it could be.

And I think that is what the IOM was saying. If you have something like the National Toxicology Program, there's no reason to wait until somebody puts that into the textbook. If you can pick other sources that can be considered probative, but the DOL could accept their causal links without additional review, you could add things more quickly.

I can't really get my head around how to approach those recommendations from IOM right now, though. I haven't thought about it enough. I have to listen to other people. You know, what

is the process for adding new data sources and what is the process for peer-reviewing new links? Is that necessary? So, those are really big topics. And I agree with you, Steven, we shouldn't just ignore them, but --

MEMBER MARKOWITZ: Well, you know -- Steve Markowitz -- just to use a different federal compensation program, which is Agent Orange, the VA contracts with the Institute of Medicine which reviews and produces a report every few years on a single agent, Agent Orange, looking at the diseases in the literature. And they have a whole ongoing committee, led by some very well-known people, who look at this and struggle with this single agent and a limited amount of, frankly, scientific literature to look at. It is still controversial.

So, here we are talking about 17,000 chemicals, give or take, hundreds of outcomes. And I don't say that to be discouraging. I am sure DOL did what they had to do, which was rely in 2005 on whatever existed, which was Haz-Map.

How to move forward with that process concretely, feasibly, it is difficult. We just have to see what can really be done there.

CHAIR WELCH: Yes. Well, I made myself a note to at least try to understand better the data sources that IOM recommended like IRIS, which I haven't really used much in my life. And EPA is making statements about disease causation and exposure levels for a different purpose, but it may be very useful because they do cover way more chemicals than maybe the ATSDR tox profiles do.

So, it seems to me it will be helpful, and I don't think we are going to get somebody else to tell us all about it, about IRIS and the National Toxicology Program and how could those be considered sufficiently develop to add them, to ask their contractor or Haz-Map to add them to Haz-Map. That is a more narrow question, but it could be very helpful to say, yes, these other data sources are informative, and if they say that it is causative, we could add it. That is

one way to approach one part of what IOM is recommending.

MEMBER MARKOWITZ: But should DOL have its own unit that does that, that monitors the literature or does some sort of expedited peer review with some supervision and, then, directly modifies its exposure/disease database so that it doesn't have to rely on Haz-Map, entirely on Haz-Map? Should DOL have its own unit to do that, which can perhaps do it in a more timely fashion and use its own criteria, not rely on whatever Haz-Map is doing? I am not saying we need to give that answer, but as an example of what might be done.

CHAIR WELCH: It is an idea, but, then, on the other hand, you know, the other agencies go back to CMS and do that. I mean, the Air Force wanted to know if beryllium exposure was a problem in Air Force operations and should they be screening people, and what should the medical surveillance program look like. And they asked the IOM to do that. In a way, that was a

more simple question than Agent Orange, definitely. But we know how expensive -- I mean, you know, those committees cost millions of dollars.

MEMBER MARKOWITZ: Right.

CHAIR WELCH: I think when NIOSH asked the IOM to do sort of an expedited review of their total Worker Health Program, it was still hundreds of thousands of dollars to convene meetings.

But, on the other hand, we have a program here that is paying dollars in claims. So, they should be getting it right. Yes, I think we should talk about whether DOL should have a unit to do that or they would be using existing, you know, things like the IOM and spend more money on it.

MEMBER MARKOWITZ: By the way, this IOM report did not recommend an IOM committee to do this.

(Laughter.)

CHAIR WELCH: Well, maybe that would

have been considered a self-referral, you know. Well, of course, it is not, but --

MEMBER MARKOWITZ: Maybe or maybe they thought that it was extremely difficult to do.

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: Rosie could give me some insight into that, actually.

CHAIR WELCH: Rosie is very clear she didn't want anything to do with this Subcommittee. She could give us some insight, but she said she was very tired of the topic. So, I feel like she was saying, you know, the IOM gave them lots of good recommendations and now they are coming back and asking the same questions. They already told them what to do.

So, I think your synthesis, Steven, is good, that they haven't acted on it. We see it is a very big set of recommendations. Is there something that we can propose that would be effective but not as complicated or as expensive?

MEMBER VLIEGER: This is Faye.

Just so you know, the recommendations

that IOM made have been used by claimants to try to prove your claim and the links to their diseases. But, because the Department of Labor doesn't accept those studies and reports unless someone with the appropriate degree behind them writes a letter in support of the claimant, those studies are not even considered factual. And so, even saying to the Department of Labor, "You must accept these sources" would be useful.

DR. DEMENT: All right. This is John.

Or criteria by which they may accept these sources might be useful.

CHAIR WELCH: The other thing about it, too, is that the claims -- so, let's say you develop the causal relationships in the SEM more fully because there aren't as many gaps. In the end, the claims examiners are sending these claims to a contract medical consultant to help them opine on causation.

The cases that I see are ones where the contract medical consultant has gotten, in my humble opinion, completely wrong, and there is

plenty of evidence to show that that case is related to exposure that DOE but the contract medical consultant really isn't up-to-date.

It is a different question, but it is almost as if the SEM is not enough. Having a disease link in the SEM is not enough unless there is also a presumption, because you get a contract medical consultant and the contract medical consultant is considered the one to provide the answer, or maybe the industrial hygienist can provide the answer. But the industrial hygienist tells them that the exposure occurred at a certain level that is medically-significant and, then, the CMC says, then, that is causally-related to their disease.

In theory, a worker could apply, provide information that is not in the SEM. It could go to the contract medical consultant and they could award the claim based on their own review process. It doesn't happen that way, but it might be happening and we don't know about it, because we all hear about the claims that didn't

make it through.

MEMBER MARKOWITZ: This is Steve Markowitz.

This is where, actually, looking some claims initially will give some insight into how --

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: -- these medical consultants pay attention or not to the SEM and what the quality of their own review is --

CHAIR WELCH: Right.

MEMBER MARKOWITZ: -- or how they go about doing a review.

We will need a larger sample to get a truer picture, but even an initial review gives us some insight.

CHAIR WELCH: I agree.

MEMBER WHITLEY: Garry here.

I would like to see those slides that they give the claims examiners for their training and what DOL is telling the claims examiner this is what to use to deny or recommend that claim,

because sometimes I think it never gets to the CMEs, and the claims examiner just makes a recommendation and denies it. I believe sometimes it is only on the SEM, nothing else.

CHAIR WELCH: I think that was on our request after our April meeting, was the training for the claims examiners. I am going to see if I have that.

MEMBER GRIFFON: Laurie, this is Mark Griffon.

Also, just to go on with what Garry was just saying, I think it might be useful as we look at the sampling of claims to also look at the procedures that they are using, sort of the process they go through, as Steve said, in assessing a claim.

I mean, as far as I can tell, some of the procedures are on the website, but I don't know -- like I am looking at these Part 2 procedures, and specifically one that applies is the 2-0700 establishing toxic substance exposure. There's a couple others that also probably apply,

including the Resource Center.

But I don't know if this is all of the procedures or there are other internal procedures. For instance, on this thing they mention a script that the Resource Center should follow in doing the Occupational Health Questionnaire, and I don't see the script attached as an appendix or anything. So, I wonder if there are other procedures that the Resource Center, that the claims examiners, all these different levels, if they have different procedures that they are following.

Because I think another thing that got raised during our discussion is, even more so than on the radiation side, I think this side of the program could be quite reliant on professional judgment. And I wonder where -- I think because we looked through these claims and the procedures -- we might think about where does professional judgment come into play and how is DOL assuring consistency in quality in those? You know, is it the luck of the draw? If I get

one claims examiner, I am not going to go through versus another one I am very likely to get through? I mean, that is all part of this, I guess.

But I think we should have the procedures along with these plans to look at. I think that would be very helpful.

CHAIR WELCH: Very good point.

MEMBER MARKOWITZ: Steve Markowitz.

So, to formulate the request -- I am getting this down and Carrie is committed to getting this down -- it is to request the additional materials, at least request the training materials or PowerPoints that are used specifically for the claims examiners, but, more broadly, any written sources of guidance, instructions, or procedures beyond those that are available on the website that are used by claims examiners, the physicians, the industrial hygienists, or whichever other personnel, to process claims. Is that what it is? Is that the request?

MEMBER GRIFFON: Yes, that's great, Steve. That sounds good.

CHAIR WELCH: And the other Subcommittee, I don't know if they have had their call yet, but it would seem like that is what they would be asking for as well.

MEMBER MARKOWITZ: The IHMD? Yes.

CHAIR WELCH: Yes.

MEMBER MARKOWITZ: They haven't had the call yet?

CHAIR WELCH: But, yes, I think you've got it.

I know we have transcript and meeting minutes, but I can summarize our conversation and have Carrie see if she caught all the same action items and send it to all. And then, we can be sure we have captured everything we talked about.

And then, Steven and Carrie will do their best to get the data on distribution of claims, including sites, you know, diagnosis accepted, rejected, site. I am not sure what else we would want, but we could think about

that. We don't really know what their fields are, but that would get us started. And we could get that fairly quickly and, then, ask for some files to review in advance of a call at the end of September.

DR. DEMENT: This is John.

In the Part B claims data file, now we will receive information that, basically, the site, the disease, whether or not it was accepted or rejected, but we never got anything with regard to the reasons for denial. Now I would request, if we did a dataset for Part E, that we specifically ask for, either in the coded fields -- and if it is not coded, the pretext description of the reason for denial would be acceptable.

But allow us to look at a lot more claims quickly and summarize them, as opposed to getting a much smaller list of claims to go through in great detail, I think will be a good supplement to that detailed review.

CHAIR WELCH: Yes. And if they don't

collect that information at all, that will be helpful to know.

DR. DEMENT: Yes. I would assume, I would hope, though, the database that was used for processing claims would also have something there with regard to the reasons for denial.

CHAIR WELCH: Yes, I hope so.

Of course, specific requests are going to be the claims data, what we just said in terms of training materials and guidance for the IH, CMCs, for processing the claims. And we are going to want them at the DOL's Board meeting to discuss did they have a plan for implementing the recommendations.

And then, we have a whole lot of other points that we have discussed that we will keep our eye on as we move forward through the discussions. We wanted to know, in addition to that source of guidance for examiners and claims, we also want details on the Occupational History Questionnaire, the interview. Is there a script? How do they help the worker? Is there any

quality assurance? And I will go through my notes and see if there is any other specific data requests and make sure to get those off right away.

MEMBER MARKOWITZ: Steve Markowitz.

Can I just mention something that we haven't really discussed? I think we ought to take a look at the examples when DOL has evolved toward using presumptions. It is a limited number of instances. It is the asthma, the stuff that is COPD. But to look at how they have done that, so that we can understand their thinking. And, also, it is helpful because it sets certain precedents. If we decide to encourage the further development of presumptions, it will give us some understanding as to how they have approached it so far and, therefore, how it could be extended.

CHAIR WELCH: Okay. Good.

And I'm just adding a note that, if we get around to developing, to talking about presumptions, we would want to outline a process

for that --

MEMBER MARKOWITZ: Right.

CHAIR WELCH: -- and include some external peer review in some way, even if the Board were to develop it, to be able to send it for input from others.

MEMBER MARKOWITZ: You know, the importance of that is that the very ambitious scientific process that IOM laid out, which is long-term and difficult to achieve, that short of achieving that level of scrutiny, us a describing a presumptions process can use limited science and at the same time inform what the intent of this whole program is, which is to give the claimants the benefit of the doubt and, also, acknowledges the fact that the exposure information is extremely limited going back decades. Anyway, yes, that's it.

CHAIR WELCH: All right. Okay. So, I will work with Carrie, and she is going to get the request off to DOL, and write up notes so you all can see what I think we talked about, which

you can completely pick apart.

And we will schedule a call for September.

Any last thoughts before we go?

(No response.)

CHAIR WELCH: Thank you all so much. I feel like I prepared and, then, just got fantastic ideas from everybody on the call. We really have a fantastic group.

And if anybody else wants to take over the chair, any one of you could do better than I did, but I know someone has got to do the task. So, I will keep it up.

But keep coming in with those great ideas. Thank you so much.

And we'll be in touch.

(Whereupon, at 2:53 p.m., the teleconference was concluded.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Subcommittee on Site Exposure Matrices (Area 1)

Before: Toxic Substances and Worker Health Adv. Bd.

Date: 07-11-16

Place: teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter