U.S. DEPARTMENT OF LABOR

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ADVISORY BOARD ON TOXIC SUBSTANCES
AND WORKER HEALTH

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THURSDAY
NOVEMBER 16, 2023

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The Advisory Board met in the Zia Boardrooms at the Eldorado Hotel & Spa, 309 W San Francisco Street, Santa Fe, New Mexico, at 8:30 a.m., Steven Markowitz, Chair, presiding.

SCIENTIFIC COMMUNITY
AARON BOWMAN
MARK CATLIN
GEORGE FRIEDMAN-JIMENEZ*
MIKE VAN DYKE

MEDICAL COMMUNITY
MARIANNE CLOEREN
STEVEN MARKOWITZ, Chair
MAREK MIKULSKI
KEVIN VLAHOVICH

CLAIMANT COMMUNITY
JIM H. KEY
GAIL SPLETT
KIRK DOMINA

DESIGNATED FEDERAL OFFICER
RYAN JANSEN

ALSO PRESENT
KEVIN BIRD, SIDEM
D'LANIE BLAZE, CORE Advocacy for Nuclear & Aerospace Workers
AMANDA FALLON, DOL
CARRIE RHOADS, DOL
TONYA TAYLOR, DOL
JOHN VANCE, DOL*

*Present via video teleconference

CONTENTS

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

(8:31 a.m.)

MR. JANSEN: Good morning, everyone. My name is Ryan Jansen and I'm the designated federal law officer for the Department of Labor's Advisory Board on Toxic Substances and Worker Health. I would like to welcome you to day two of this meeting of the Advisory Board here in Santa Fe, New Mexico.

Today is Thursday, November 16th, 2023. We are scheduled to meet from 8:30 a.m. to 11:30 a.m. Mountain Time. I am again joined by Carrie Rhoads from the Department of Labor and Kevin Bird, our logistics contractor. There will be no public comment period today.

As I mentioned yesterday, the Board's website, which can be found at DOL.gov/owcp/energy/regs/compliance/advisoryboard.htm, is the page dedicated to this meeting. The page contains all materials submitted to us in advance of the meeting and will include any materials that are provided by our presenters

today. There you can also find today's agenda, as well as instructions for participating remotely.

If any of the virtual participants have technical difficulties during this meeting, please email us at energyadvisoryboard@dol.gov. If you are joining by Webex, this session is for viewing only. Microphones will be muted for non-Advisory Board members. So the public may listen in, but not participate in the Board's discussion during the meeting.

A transcript of minutes will be prepared from today's meeting. As the designated federal officer, I see that the minutes are prepared and ensure that they certified by the Chair. The minutes of today's meeting will be available on the Board's website no later than 90 calendar days from today. If they're available sooner, they'll be posted sooner.

Although formal minutes will be prepared according to the regulations, we also prepare verbatim transcripts, and they should be

available on the Board's website within 30 days.

During the discussions today, please speak clearly enough for the transcriber to understand. When you begin speaking, especially at the start of the meeting, make sure that you state your name so it's clear who is saying what.

I would also ask our transcriber, please let us know if you have trouble hearing anyone or any of the information that is being provided.

As always, I would like to remind 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 suitable for public disclosure and cannot be shared or discussed publicly, including during this meeting.

Please be aware of this throughout the discussions today. The materials could be discussed in a general way which does not include any personally identifiable information, or PII,

which is names, addresses, or a doctor's name if we are discussing a case.

With that, I convene this meeting of the Advisory Board on Toxic Substances and Worker Health. I will now turn it over to Dr. Markowitz.

CHAIR MARKOWITZ: Good morning. We should as a matter of process do introductions again. Steven Markowitz, occupational medicine physician, epidemiologist at the University of New York.

Mr. Key?

MEMBER KEY: Good morning. Jim Key, 49-plus-year worker at Paducah Gaseous Diffusion Uranium Enrichment Facility. I started at the inception of this program and EEOICPA.

I represent the labor claimant community, and assisting them in getting their worker health protection physicals and filing their claims. I'm glad to hear the comments of other Board members today.

MEMBER VLAHOVICH: Good morning. My

name is Kevin Vlahovich. I'm an occupational medicine physician, and I'm an assistant professor at the University of New Mexico in the Department of Internal Medicine.

MEMBER BOWMAN: Good morning as well. My name is Aaron Bowman. I am a professor at the School of Health Sciences at Purdue University. I'm a toxicologist and specialize in neurotoxicology.

MEMBER SPLETT: Good morning. I'm Gail Splett. I'm retired from the Hanford Site. I worked for the Department of Energy for 45 years with various administrative functions, including Records Officer and the EEOICPA Program Manager for Hanford.

MEMBER MIKULSKI: Good morning. My name is Marek Mikulski. I'm an occupational epidemiologist with the University of Iowa Occupational and Environmental Health. I direct an Iowa Former Worker program for the former workers from the State of Iowa.

MEMBER DOMINA: I'm Kirk Domina. I'm

a retired Hanford worker. I'm here to represent the claimant community.

MEMBER CLOEREN: I'm Marianne Cloeren. I'm an Associate Professor of Medicine at the University of Maryland School of Medicine, occupational medicine and internal medicine certified.

I have a lot of experience with workers' compensation systems with a focus on federal ones, and I'm also the National Medical Director for the Building Trades former worker program.

MEMBER VAN DYKE: Good morning. Mike Van Dyke. I'm an associate professor and industrial hygienist at the Colorado School of Public Health.

MEMBER CATLIN: And good morning. I'm Mark Catlin, retired industrial hygienist.

CHAIR MARKOWITZ: Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Good morning. I'm George Friedman-Jimenez. I'm an

occupational medicine physician and epidemiologist at the Bellevue NYU Occupational Medicine Clinic, and New York University School of Medicine.

CHAIR MARKOWITZ: Okay.

MS. TAYLOR: Good morning. My name is Tonya Taylor. I'm with the Department of Labor Office of the Ombudsman for the EEOICPA.

MS. FALLON: Good morning. My name is Amanda Fallon, and I'm the Ombuds for the Energy Program.

MS. BLAZE: Hi. I'm D'Lanie Blaze. I'm with CORE Advocacy for Nuclear and Aerospace Workers.

CHAIR MARKOWITZ: Okay. Thank you. So let's go over -- actually, before we just review the agenda today, if Board members could just let us know, does anybody need to leave before the designated close of business at 11:30?

Aaron? Okay, so 11:00. Okay. That's good to know.

Let's just go over what we have from

yesterday and what we need to cover this morning. We need to just finalize a plan around the follow-up on the SEM, what we are going to send to the Department and also if there's any additional conversation around the demonstration that they've offered to provide us. We need to come back to the industrial hygiene recommendation, our response to it.

We're going to come back to our response to the DOL's response on our CMC recommendation. We should close out the conversation we had about the meaning of significance and the various levels of exposure designated by the industrial hygienists in their report.

We have a brief discussion on the claimants who report being terminally ill. We're going to just briefly review the request from the Department regarding Board review of a newly classified 2A carcinogen.

And then I think we can briefly discuss public comments. There was one public

comment yesterday. We received a couple of written comments this morning. I think two are actually from the same person. We can briefly discuss that.

There is also follow-up, I think, on the Parkinson's issue. We were going to request to take a look, I think, at the list of agents that they have added to the SEM as being related to Parkinsonism.

Was there any other follow-up from yesterday? I think -- Dr. Cloeren?

MEMBER CLOEREN: Hi, Marianne Cloeren. We talked about reviewing recent -- I guess we need a plan for reviewing literature on hearing loss, what has changed in the hearing loss literature.

CHAIR MARKOWITZ: Right. Okay. If anything else arises, just chime in. Okay. So let's just work our way down the list here.

What's the next step on our discussion around the Site Exposure Matrices? Ms. Splett?

MEMBER SPLETT: I think we need to

prepare a draft list of questions for the Board. And I would be more than happy to commit to drafting that and having it out to the other team members by the 22nd of December.

CHAIR MARKOWITZ: I'm sorry. Questions to the Department?

MEMBER SPLETT: Excuse me. Yes, to the Department.

CHAIR MARKOWITZ: Okay.

MEMBER SPLETT: Excuse me. Yes, for the subteam. I've got some other specific examples that have been provided since yesterday from other sites, and I'll get those together. And then maybe by the 16th of January, our subteam can have the questions finalized for the Department of Labor and then schedule the demonstration.

CHAIR MARKOWITZ: Okay. So you're going to initiate a draft of questions, circulate it, get additional comments and questions, finalize it by January 16th?

MEMBER SPLETT: Yes.

CHAIR MARKOWITZ: Okay. And with request for a demonstration, which should probably be scheduled before -- well, sometime during the month after January 16th.

MEMBER SPLETT: I think that seems reasonable, if the Department of Labor agrees to that.

CHAIR MARKOWITZ: Okay. So if demonstration would occur sometime hopefully before mid-February, I was thinking ahead whether that will give enough time before our next meeting for that same working group to do additional work, if it wants to.

MEMBER SPLETT: If you want to move that schedule up, I'm certainly agreeable to that.

CHAIR MARKOWITZ: No, no, I'm just thinking out loud whether it's a reasonable time frame, that's all. But if it sounds reasonable to you, then it's fine.

MEMBER SPLETT: Okay.

CHAIR MARKOWITZ: Any other comments

on this? That was easy. So let's discuss the industrial hygiene comments. We have a PowerPoint, the second slide of the PowerPoint.

Dr. Cloeren, do you want to just walk through this?

MEMBER CLOEREN: Yes. Marianne Cloeren. The assumption here is that the recommendations that were previously made and were accepted by the Department still stand, including the use of a table to summarize the pertinent details whenever an exposure is determined to be some level of significant. So we didn't add that here.

The recommendation would be that the Board recommends that the Department of Labor modify its exposure assessment and communication procedures as follows. The first part is related to the IH consultant specifically, that the IH consultant specifically address the content of what was in the occupational health questionnaire in the industrial hygiene report.

And then the second part is that they

would be required to describe what exposure-relevant information was found in each of the data sources reviewed, including the DAR. And if none, that should be explicitly stated.

The rationale for this is to guard against the implication that these data sources contained information about there not having been exposures. Right now the reports tend to group the review as these were the sources reviewed, without providing detail about what was in them.

And then the second part of the recommendation is that the claims examiner would share the OHQ itself with any physician that is asked to use the IH report for causation analysis. So in addition to what's normally provided to the physician for causation analysis, the OHQ would be another source of data provided to the physician.

CHAIR MARKOWITZ: Comments? Dr. Bowman?

MEMBER BOWMAN: I agree with this recommendation in full. Going back to the

rationale that you described, I'm wondering if we might edit 1B at the end, the final sentence, to be more something explicitly stated to avoid the possibility of a false assumption or something like that.

CHAIR MARKOWITZ: Our recommendation also is accompanied by a rationale. So certain things -- I'm not saying this needs to go -- it could be put here, but it could also be put --

MEMBER BOWMAN: I'm sorry. I would be fine if that concept is just contained within the rationale that accompanies this, in which case I withdraw my amendment.

CHAIR MARKOWITZ: Dr. Van Dyke?

MEMBER VAN DYKE: Mike Van Dyke. I also agree with this recommendation. I would just say that the 1A has to be just a little bit more specific because just saying address the content, that's a big ask. If we say address all reported exposures, that might be more specific.

CHAIR MARKOWITZ: There's a thumbs-up, Kevin, from the writer of this proposed

recommendation to Dr. Van Dyke's added language.

One of the parts of the response from the Department was that whatever change they make in this process, they were going to run it by the CMC contractor, presumably CMCs, to get some feedback on any changes that are made and how they work.

Do we need to include that in our recommendation, that we request feedback on the use of any designated? Or do we just assume they've made that promise and we'll receive that information?

MEMBER CLOEREN: I don't understand your question.

CHAIR MARKOWITZ: I'm sorry. Let me just quote actually from the Department response. Based on the context of -- I'm quoting from August 21, 2023. This is a letter from Christopher Godfrey to myself, as Chair of the Board. The penultimate paragraph quotes:

Based on the context of the Board's recommendations, DOL has undertaken action to

engage with our CMC contractor to solicit information regarding improvements in how information is communicated in IH assessments.

This is an opportunity for CMCs to provide input on whether any additional metrics in an IH report will aid them in making their determinations. DOL will share any feedback it receives from the Board that further advance our shared interest in ensuring the publication of accurate and understandable characterizations of toxic substance exposures.

End of quote. I think with that promise, we probably don't need to repeat that here in this recommendation.

MR. VANCE: And Dr. Markowitz, this is John Vance.

CHAIR MARKOWITZ: Go ahead.

MR. VANCE: Very quickly, I do have an update for you. We did ask our contractor to provide any input. They did go out and discuss this issue with their CMCs.

The unfortunate response that we got

was, no comment. They didn't really want to provide any additional specific recommendations for improvement or any real thoughts on what could be done to improve. Their general impression was that the information was sufficient for them to inform their opinions, and that's where they left it.

So I was going to maybe take that up with the director and just see if there was anything more that we could do to encourage more forthright feedback, but we were not getting much of a response from the contractor on that. So I thought I'd share that.

CHAIR MARKOWITZ: That's interesting. Thank you.

Dr. Bowman?

MEMBER BOWMAN: Just reflecting on that, this sounds to me like a case of they don't know what they don't know.

CHAIR MARKOWITZ: Dr. Cloeren?

MEMBER CLOEREN: Marianne Cloeren. I just wanted to point out that the CMCs are not

the only end users of these reports that are performing causation analysis.

And so while I think the input of the CMCs would be very valuable, we should keep in mind that also treating physicians and sometimes former worker program physicians and others are asked to review and comment. It may be harder to get input from that community.

CHAIR MARKOWITZ: Mr. Catlin?

MEMBER CATLIN: Mark Catlin. When you're mentioning getting the feedback from the CMCs, from the contractor, does that also include the industrial hygiene consultant? I'd be interested if they had feedback on this recommendation and if we can get that, if that occurs.

CHAIR MARKOWITZ: I wonder, Mr. Vance, whether that's been done at all?

MR. VANCE: The way I can respond would be the Department of Labor will consider any input that's provided by the Board. So the recommendations that you're discussing right now,

that would be something that we would engage with our industrial hygienist about and see how we could facilitate a response that could either agree or not with the recommendations of the Board.

And we involve our industrial hygienists in all of our interactions with the Board proposals or recommendations. There are even things that we come back to share with them about ideas that are discussed during Board meetings.

So our industrial hygienists are working quite frequently with our contractors to try to figure out better ways to accommodate recommendations and improvements in the process.

And so what you'll notice with regard to the prior recommendation is the result of our response to the table issue that was discussed. I mean, that was something that we had a multitude of meetings and discussions with how to best accommodate those improvements in how we report the exposure analysis.

So our industrial hygienists are engaged quite rigorously with our process in evaluating Board recommendations.

CHAIR MARKOWITZ: That's great. Maybe the CMC contractor could learn something from the IH contractor.

Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes, very minor. In 1A, I think it's a little awkward seeing the word in twice the way that it is.

What I would suggest is take the best four words in the IH report and put it after address. So it would read explicitly address in the IH report all reported exposures in the OHQ.

CHAIR MARKOWITZ: And I would just add that that's what you get when you have professors on a board.

MEMBER CLOEREN: It's funny because I was about to suggest that too.

(Laughter.)

CHAIR MARKOWITZ: Two professors on a board. Thank you, Dr. Friedman-Jimenez. Okay.

Other comments or questions? We're going to vote on this recommendation. Okay.

Do we need to read this out loud or can everybody see it clearly enough? Okay.

I think then we can just take a vote. How do we do that again?

MR. JANSEN: I will record the vote.

Dr. Bowman?

MEMBER BOWMAN: Yes.

MR. JANSEN: Mr. Catlin?

MEMBER CATLIN: Yes.

MR. JANSEN: Dr. Cloeren?

MEMBER CLOEREN: Yes.

MR. JANSEN: Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes.

MR. JANSEN: Dr. Markowitz?

CHAIR MARKOWITZ: Yes.

MR. JANSEN: Dr. Mikulski?

MEMBER MIKULSKI: Yes.

MR. JANSEN: Dr. Van Dyke?

MEMBER VAN DYKE: Yes.

MR. JANSEN: Dr. Vlahovich?

MEMBER VLAHOVICH: Yes.

MR. JANSEN: Mr. Key?

MEMBER KEY: Yes.

MR. JANSEN: Ms. Splett?

MEMBER SPLETT: Yes.

MR. JANSEN: Mr. Domina?

MEMBER DOMINA: Yes.

MR. JANSEN: There are 11 yes votes and no no votes.

CHAIR MARKOWITZ: Okay. Let's move on. If you go to the first slide, this is a recommendation. Let me just read it. It's regarding the CMC.

The Advisory Board recommends that the Department of Labor expand its quality assessment of CMC performance by implementing peer review of the validity of the content and analysis reflected in a quarterly sample of an appreciable number of CMC reports. Such peer review would be conducted by a small panel, two to three physicians, of medical experts in causation analysis of occupational diseases.

Those are multiple: one, to estimate the size of the problem of major errors contained in the CMC reports; two, to identify and correct systemic problems in CMC causation analyses, plural; and three, to identify CMCs who repeatedly commit major errors in causation.

The floor is open for discussion. Ms. Splett?

MEMBER SPLETT: My only question would be the terminology of appreciable member. Is there any way to quantify that so the Board would understand the Department of Labor had completed that?

CHAIR MARKOWITZ: Well let me just -- right now the quarterly quality assessment report has analyses of 50 CMC or related reports.

Those 50 reports are, the aim is to have, as I understand it -- Mr. Vance, correct me if I'm wrong. Actually, Mr. Vance, maybe you should just explain this to us.

MR. VANCE: All right. Okay, so this is John Vance. Very quickly, we have actually

supplied to the Board the two most recent quarterly reports that are reporting out the findings of an analysis that's done on qualitative measures of performance by our contractor.

And so what we are looking at in those reviews is basically the quality of the input going into our CMC referral process, looking at how well the physician is formulating a response to a specific referral question.

As Dr. Markowitz mentioned yesterday, the topics that can be reviewed relate to anything that a CMC could potentially be opining on, specifically: causation, reviewing a file based on diagnostic or clinical information to help assist with the diagnosis of a particular condition, the appropriateness of prescribed medical benefits, and referee and second opinions.

These are in-person or file reviews by second opinions, or referees that are done. So we're conducting an analysis event to make sure

that the opinions meet the expectations of quality for the contract, that they're answering the question that has been posed to them, that the physician has some reasonable conclusion that's based on the facts of the case, and that they have some sort of justifiable rationale that they apply to arrive at whatever conclusion that they reach.

We're not looking necessarily at the right or wrong. We're looking at how well the doctor formulates the response, and the justification that's provided for the conclusion offered.

And those reports are available to the Board. So you'll see the results of those analyses that are performed.

CHAIR MARKOWITZ: Let me just add, I think the aim is to do ten of each of five different types of medical reports. And if there aren't enough reports in any one category, then they'll do additional reports in another category.

MR. VANCE: That's correct.

CHAIR MARKOWITZ: I think the Board had previously recommended actually that the numbers be selected in relation to the proportion of overall reports in every category. So the categories that from the outset had a much larger number of reports, they disproportionately get more reviews.

The Department came back to us with, no, we're going to do ten of every type. But if there's room for fewer than ten and they want a given type, then we'll do more of other types.

So my own view is that more than ten causation quarterly reports would need to be reviewed to accomplish this recommendation. And the question is should we come up with a number or range of numbers, or should we just leave it more general, like appreciable or substantial?

MEMBER FRIEDMAN-JIMENEZ: This is George Friedman-Jimenez. I'd like to comment on that. I think the whole issue of designing the sampling of cases is a relatively technical

issue. You know, exactly what are we trying to accomplish? That will affect how we sample the cases.

For example, we may want to do a stratified random sample. The sample size, whether we're actually going to do a hypothesis test and if we need enough to do that, and what statistical analyses are we going to do?

And I would be in favor of doing some sort of a correlation or predictive value type of analysis similar to the way we do it in diagnostic testing theory. And I can give a lot more details on that. But I think that this whole issue of designing the sampling of the cases is beyond what we can discuss right now and make a decision.

So I would agree with sticking with a more open-ended term, like appreciable or appropriate, without specifying that number. I think that's something that we should do systematically based on what statistical analyses we plan to do. And I think we can gain a lot

from this.

Another related issue that I wanted to comment on is the pool of peers. I think that we are doing, in a sense, a peer review, but the experts that we're looking for are really experts in causation analysis, which may or may not include some or all of the CMCs. There are a lot of people that are experts in causation analysis, in occupational medicine.

And I think it would be a great advantage to have an outside panel, i.e. outside of the CMCs, because if there is some sort of a systematic tendency to make particular judgements or errors, this may be obscured by using the CMCs as the judges of their own performance in the program. And they may feel somewhat defensive.

So I think it should be an external panel, i.e. external to those who are making the determinations that we're going to be reviewing.

CHAIR MARKOWITZ: That's a good point.

Dr. Cloeren?

MEMBER CLOEREN: I agree with that

recommendation that it be an external panel for the same reasons.

CHAIR MARKOWITZ: Dr. Bowman?

MEMBER BOWMAN: Just as a counterpoint for discussion -- this is Aaron Bowman -- one advantage of having it be peer, meaning CMCs, is they are perhaps the most knowledgeable about the processes in place of what's going on with that.

I wonder could there be -- you all can think -- a way to avoid the conflict of interest that is the reason to seek for external? Is there a way that avoidance of that conflict of interest could be used to get sort of the best of both?

CHAIR MARKOWITZ: I'm sorry. Could you just explicate a little bit? I'm not sure I understood.

MEMBER BOWMAN: Yes. So I would imagine there is an advantage of using someone who has performed the work of a CMC in evaluating the quality because they're most familiar with the work.

But we would want to avoid a conflict of interest that was mentioned earlier for the recommendation for external review, which is also important to avoid. And I'm just wondering is there some compromise that would allow both of those to occur.

CHAIR MARKOWITZ: This is Steven Markowitz. Let me just respond. The CMC process is not that complicated actually, but the CMC is a particular role that's described in the procedure manual. And it's described in the contract that the Department has.

Quality assessment is something different from the CMC process. So I don't -- I have a hard time imagining that so-called CMCs would also be the peer reviewers because they're really separate functions.

Also, in our previous recommendation relating to this, we explicitly said this mechanism should have sufficient independence of the current method of developing and obtaining CMC opinions in order to avoid actual or

perception of conflict of interest.

End of quote. So we could add that certainly to the rationale of this recommendation as well.

Dr. Cloeren?

MEMBER CLOEREN: Marianne Cloeren. I don't think that the job of the CMC in evaluating the data and providing causation analysis is that much different from other causation analysis in other systems.

So I think I'm agreeing with Dr. Markowitz that a peer reviewer would be somebody that is an expert in evaluating causation of occupational diseases in a variety of different system settings.

CHAIR MARKOWITZ: Other comments or professorial interest in wordsmithing? By non-professors too, by the way. You're welcome.

Dr. Bowman?

MEMBER BOWMAN: Just to follow up on my request, I do accept the expert opinion of those on the medical side of our Board on that.

That sounds reasonable. I only thought that because I know when we were given these claim packets to review, there is a lot of complexity and just figuring out how that all goes together, but I accept that notion.

And I would then agree with an edit to say by implementing external peer review in this recommendation. I would then make that an explicit part of this recommendation.

I was wondering, just given -- I guess I'll stop there. I've got one more comment, but maybe discuss that first.

CHAIR MARKOWITZ: Dr. Van Dyke?

MEMBER VAN DYKE: Mike Van Dyke. You invited professorial comments, right?

CHAIR MARKOWITZ: Absolutely.

MEMBER VAN DYKE: Okay.

CHAIR MARKOWITZ: I knew they were going to go come anyway, so I wanted to make you feel welcome.

(Laughter.)

MEMBER VAN DYKE: So short of this

being a really big number that you evaluate, the results that you get are going to be a relatively small number. If you evaluate 50, maybe you'll find five problems.

I'm just throwing it out there. That's a lot of work for those five problems. I wonder if there is any way to think about how to enrich the pool, to make it more likely that you're going to find those problems.

So is there any way to think through what categories of outcomes, what categories of exposures? Because the randomness is just going to make it unwieldy in terms of the amount of work.

MEMBER FRIEDMAN-JIMENEZ: This is George Friedman-Jimenez. I'd like to respond to that. Yes, I think you're right.

However, I think that the randomness is critically important here, because that's the key to interpreting the data. It's the key to being able to generalize from our sample of 50 or 100 or 500 to the whole population of cases that

are being evaluated.

So we need some sort of random sampling. But that's what I meant by stratified random sampling, exactly what you're saying, that we randomly sample in a way that will allow us to do specific statistical analyses that are the key analyses that we want to do.

For example, what is the false positive rate? What is the false negative rate? Using in lieu of a gold standard the external causation analysis experts' gold opinion on whether there was causation or not, admitting that this is not a true gold standard but this is the way that it's done in diagnostic testing when there's no gold standard, because the gold standard test would be either too invasive, or it's not been invented yet.

So there are statistical techniques for addressing this by stratified random sampling. And I agree with your sentiment.

As far as sample size, I think if this is going to be a quarterly exercise, the first

quarter and the second quarter are not going to give us enough numbers. And you're right. We may get one, two, maybe five errors out of 50, if we do 50.

However, over a year or two years, I think we would have an adequate sample size to actually do a hypothesis test that would give us a reasonable degree of power to make some statistical judgement of whether there is a problem or not.

Essentially, we're looking to see: is there a problem? And is it big enough to require some sort of systemic solution or could it be addressed by some minor fixes that we could do, some training of the CMCs or something like that?

CHAIR MARKOWITZ: I think -- this is Steve Markowitz. This idea of enriching or stratifying would be very interesting. I don't think it's a first-order issue. It's something that if the Department accepts this recommendation, we'd be glad to help them figure that out. It's a really interesting question.

For instance, there may be a disproportionate number of CMC reports that are done by a relatively few number of CMCs. So perhaps you'd want to look at that group more closely because if there are errors there, it could be more meaningful in terms of the number of claims that are affected. So that's one way of enriching.

Or we could enrich by, say, if we suspect there are certain conditions prone to problematic opinions -- beryllium disease, COPD, or the like -- that's another way of enriching. So there are ways of thinking about this.

It's not clear what the solution is, but it's an interesting set of questions. But I don't think -- I think it's second order. I think if they accept this, what we're proposing here, and if they want our input into designing the assessment, then we'd be happy to provide that.

Mr. Domina?

MEMBER DOMINA: Yesterday Ms. Pond

mentioned that they're getting 300 claims a week. It used to be like 220-230. Over a year's time, that's over 4,000 more claims.

To me, if we're going to go down this path, there's a percentage, not a finite number of 50. You're going to miss basically 25 percent.

And then with that, she also mentioned in the medical benefits part of adding more people in that. So is there going to be more CMCs? Or you've got the same number doing all of the claims? It sounds like it's a problem.

CHAIR MARKOWITZ: Right now it looks like the plan is 50 per quarter, but of those 50, only ten involve causation. That's 40 per year. That's clearly not enough to get at what we're trying to figure out here. So that would have to be rethought. I agree.

Dr. Cloeren?

MEMBER CLOEREN: Marianne Cloeren. I wonder if this -- what we're proposing has room for referring potential problems. So if somebody

notes that they're getting the same, it seems like, erroneous causation analysis over and over, that person's reports might never enter the pool of random review.

And what might the process -- what is the process? Maybe the Department of Labor already has a process for reviewing the work if something is brought to their attention.

CHAIR MARKOWITZ: Comments? Further comments? Dr. Bowman?

MEMBER BOWMAN: Yes. This is Aaron Bowman. In regards to the implementation, we talked about any variety of ways it could be implemented.

And that we would, as a Board, of course be willing to advise on that implementation with the addition of a final sentence to the recommendation saying that the Board requests feedback on how a recommendation will be implemented and its outcomes once active, just to make it clear that we are interested and willing to provide input on implementation.

CHAIR MARKOWITZ: I don't think we need to -- Steve Markowitz -- express our interest in the outcome, because generally we do get feedback over time.

However, expressing interest and our willingness to assist in implementation or in further steps, design, et cetera, we could include that in the recommendation or in the rationale. We could put it in the recommendation. So if you want to give Kevin some words to put in?

MEMBER BOWMAN: Sure. I'll put the first half of what I said and then we can wordsmith afterwards. The Board requests feedback on how our recommendations will be implemented. Is that sufficient? Or the Board would be happy to participate in the implementation.

CHAIR MARKOWITZ: Offers assistance.

MEMBER BOWMAN: Yes. The Board offers our assistance in the implementation of this request and planning for the implementation.

CHAIR MARKOWITZ: You got that, Kevin?

(Laughter.)

MEMBER BOWMAN: And planning for the implementation of this request.

CHAIR MARKOWITZ: If accepted.

MEMBER BOWMAN: Okay. Thank you. Perfect. While we're editing, do we want to add external in front of the words peer review?

CHAIR MARKOWITZ: Which line is that? Is that the fifth line?

MEMBER BOWMAN: The third line down.

CHAIR MARKOWITZ: The third line.

MEMBER BOWMAN: Implementing external peer review.

CHAIR MARKOWITZ: It's not obvious what that word would mean in this context. What you mean is other than CMCs?

MEMBER BOWMAN: Other than CMCs, yes.

CHAIR MARKOWITZ: Yes.

MEMBER BOWMAN: Is there a better word for that? Or do you think it -- independent peer review?

MEMBER VAN DYKE: I think you need to remove peer if you're going to put external.

CHAIR MARKOWITZ: The word peer is important because right now the assessments are done, as far as we know, by non-health providers.

MEMBER BOWMAN: Right. Yes.

CHAIR MARKOWITZ: The peer is an important concept here.

MEMBER FRIEDMAN-JIMENEZ: Well, analogous to the NIH peer review system, peers are all investigators in that field. So that doesn't necessarily have to include the person that's applying for the grant. So in that way, the peer is assumed to be external or independent. I think independent is a good word here.

MEMBER BOWMAN: I agree.

CHAIR MARKOWITZ: I think the rationale can get a little bit into this.

MEMBER BOWMAN: Yes. And then of course, since we're in it, the typo of the apostrophe, CMC's. We're trying to eliminate the

apostrophe.

MEMBER FRIEDMAN-JIMENEZ: So it would be CMCs' and then causation analyses with an E. Is that correct, Professor Bowman?

MEMBER BOWMAN: I will defer to you on this, George.

(Laughter.)

MEMBER CLOEREN: Well, in the line above, just get rid of the apostrophe-S. CMC causation analysis, I think, works.

MEMBER FRIEDMAN-JIMENEZ: Yes.

MEMBER BOWMAN: I think that could work too.

CHAIR MARKOWITZ: So the analysis should be plural, analyses with an E, S-E-S, not S-I-S.

MEMBER CLOEREN: Just make it CMC. No S and no apostrophe.

MEMBER FRIEDMAN-JIMENEZ: Right.

MEMBER CLOEREN: There you go.

CHAIR MARKOWITZ: That was easy. Any further comments?

MEMBER CATLIN: Yes. I'd just make one.

CHAIR MARKOWITZ: Go ahead.

MEMBER CATLIN: In the last line, I'd replace request with recommendation.

CHAIR MARKOWITZ: Good point.

Dr. Cloeren?

MEMBER CLOEREN: Well, I think what I said -- this is Marianne Cloeren -- what I said before about if somebody is identified outside this process where the reports might need review. Maybe what I'm requesting is information from the Department about how that is addressed, what's the mechanism for bringing that to attention so that there could be a review.

CHAIR MARKOWITZ: Steve Markowitz. Could you just -- I don't quite understand the comment or question.

MEMBER CLOEREN: Marianne Cloeren. Yesterday Ms. Pond said that from our previous meetings, the examples that we had given of a particular CMC that repeatedly made errors in

causation analysis related to asbestosis not being possible without pleural plaques, that was an example where they did take that information and did some reviews and addressed it.

It's not at all clear to me what the process is for bringing such kind of situations to the attention of the Department.

CHAIR MARKOWITZ: Steve Markowitz. We don't have a bunch of claims that we're looking at or the Board is looking at. So what are the circumstances where that problem would arise?

MEMBER CLOEREN: Marianne Cloeren. I imagine that advocates and former worker programs may get word about or may have the opportunity to be reviewing opinions that have the same analysis that appears to be erroneous and needs to be looked at. And I'm just concerned that this process might never capture that in the random assignment.

I'm not saying the Board would be making the referral. I'm saying what is the process for referring a possible problem

consultant for evaluation.

CHAIR MARKOWITZ: But wouldn't that input from the advocate or from the former worker program or whatever provider, wouldn't that be in the context of a specific claim, right?

MEMBER CLOEREN: Or ten claims. It's not a pattern if it's one claim.

CHAIR MARKOWITZ: I see. Okay.

Mr. Vance, do you want to address that if you're still here?

MR. VANCE: I'm not really sure how I can respond to that. The program is always going to be responsive to issues as they're brought forward. We have to consider how to best approach each kind of situation.

So what Ms. Pond was talking about yesterday -- and I'm not familiar with the full context -- I don't think that we were looking specifically at the question of -- the plural plaque question in asbestos. I think that there was some other issue or concern brought to our attention about a qualitative issue with regard

to one of the CMCs.

And when we went back and looked at it -- there can always be differences of opinion about how certain things are addressed with regard to causation opinions, but it was deemed that the manner in which the doctor was doing his work was not cause to take any kind of corrective action. And we have taken corrective actions in the past with training, and going back and reiterating the responsibilities of the contractor to manage their process well.

That's the purpose of the CMC cross-process, which is that quality assurance thing. So we are constantly engaging with a contractor to identify flaws and how doctors do impairment ratings or whatever aspect of the work that they're doing.

So it's -- we're responsive as much as possible to issues that are brought to our attention, but that's a matter of weighing and deciding, is this a matter that is warranting action by the program or is it just some other

issue of concern about the process that has to bear out during a case adjudication process.

CHAIR MARKOWITZ: Thank you.

Other comments? Okay. Then we're ready to take a vote. We're looking at the recommendation. I don't really think there's a need to read it, so maybe we can just move to the vote.

MR. JANSEN: I will record the vote.

Dr. Bowman?

MEMBER BOWMAN: Yes.

MR. JANSEN: Mr. Catlin?

MEMBER CATLIN: Yes.

MR. JANSEN: Dr. Cloeren?

MEMBER CLOEREN: Yes.

MR. JANSEN: Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes.

MR. JANSEN: Dr. Markowitz?

CHAIR MARKOWITZ: Yes.

MR. JANSEN: Dr. Mikulski?

MEMBER MIKULSKI: Yes.

MR. JANSEN: Dr. Van Dyke?

MEMBER VAN DYKE: Yes.

MR. JANSEN: Dr. Vlahovich?

MEMBER VLAHOVICH: Yes.

MR. JANSEN: Mr. Key?

MEMBER KEY: Yes.

MR. JANSEN: Ms. Splett?

MEMBER SPLETT: Yes.

MR. JANSEN: Mr. Domina?

MEMBER DOMINA: Yes.

MR. JANSEN: There are 11 yes votes and zero no votes.

CHAIR MARKOWITZ: Okay. So our next topic is significance, really just to close out the discussion from yesterday.

This is about the industrial hygienists' use of six different categories to categorize exposure, including three levels of significance and three additional levels. From our discussion yesterday, it wasn't as if there was any consensus, or even a particular problem that was identified and agreed upon.

So the question is, do we simply want

to drop this topic? Or do we want to somehow continue the conversation? And not necessarily today. It'd be in a working group or otherwise.

Dr. Bowman?

MEMBER BOWMAN: This is Aaron Bowman. With our current recommendation relating to the IH reports, I would be okay with the sunsetting of that subcommittee until some later time.

It seems very complex. I'm not sure what else we can do. Maybe with the implementation of that recommendation, some of those issues will resolve.

CHAIR MARKOWITZ: Dr. Cloeren?

MEMBER CLOEREN: Marianne Cloeren. I overall agree with what Dr. Bowman just said.

I wonder if it might make sense to solicit -- if there is a mechanism for soliciting the input of the IH consultants about any struggles or just feedback on how the system, especially the low-moderate-high, works for them in the incidental -- not significant, but more than incidentally.

I think it would be useful to get feedback from or input from the people that are asked to use the system before making any kind of changes. And I agree, it's very complex. Such a -- that could be obtained possibly through some kind of a focus group, just as an idea.

CHAIR MARKOWITZ: Other comments? So let's just explore that. Your idea is that the program or the contractor would identify two willing industrial hygienist consultants either from the contract and/or the national office to meet with a few interested Board members and discuss how this works in practice.

I think more than incidental but less than significant is a new-ish category. So to understand how that actually is used in practice and how it's helpful or not, that's what you're driving at?

MEMBER CLOEREN: Correct.

CHAIR MARKOWITZ: Okay. Do any Board members have --

MEMBER CLOEREN: But I also think it

could wait because we are making some other recommendations right now. And if those are implemented, it might make sense to wait for a while.

CHAIR MARKOWITZ: Do you think that if accepted, the implementation recommendation is going to have a significant impact on the use of these categories?

The question is, things take time when we interact with the Department. And if we do it in sequence, then it could take a lot of time.

Dr. Bowman?

MEMBER BOWMAN: I would be interested in hearing from some IH consultants that are happy and willing to talk to the Board. I think that could be very informative. Any time maybe prior to the next Board meeting would even be fine.

I don't know if they'd be willing to speak to us virtually at the next meeting as well. We could just have a conversation. I'm good either way.

CHAIR MARKOWITZ: All right. If we're going to -- Steve Markowitz -- make a specific request to the Department, then we should probably specify whether it's done in a smaller group interaction or whether in appearance at a Board meeting. Those are going to serve different functions, I think.

Also, if the contractor's IHs aren't available, we're limited to the national office's industrial hygienists. Would that be helpful?

Let me ask the Board members who are not industrial hygienists. Would you have interest in participating in this interaction where you hear directly from industrial hygienists how they use -- for those of you who aren't around the table, Dr. Friedman-Jimenez, I'm seeing a bunch of heads nodding yes.

MEMBER FRIEDMAN-JIMENEZ: Yes. I think also I agree with Dr. Cloeren's suggestion that the users of the IH report be questioned also. And I think it would be very interesting to hear how the CMCs process a rating of

incidental or greater than incidental but not significant.

Does incidental essentially rule out causation? Do they make an exception for substances that may have an allergic or sensitization type of a dose response rather than a toxicant type of a dose response?

How do they think about this incidental category as opposed to greater than incidental, less than significant, or significant? So yes, I think that would be of great interest to see how these categories are used in making the decision.

CHAIR MARKOWITZ: Dr. Vlahovich?

MEMBER VLAHOVICH: Kevin Vlahovich. Yes, I agree. Knowing how the IH goes through, evaluates the evidence, and comes to a conclusion would be helpful in formulating a medical opinion on the case.

CHAIR MARKOWITZ: Steven Markowitz. I think we would have to do that through looking at CMC reports and claims because we heard at the

beginning of today's meeting from Mr. Vance that the CMC contractor expressed a disinterest really in just giving basic feedback on any change to the industrial hygiene form.

So we're unlikely to get any further with that contractor. Plus even if we assembled a few CMCs, I'm not sure how representative it would be of the totality. We could more directly look at that issue by looking at some claims and how the CMCs are interpreting the IH reports.

Dr. Van Dyke? Sorry, I was thinking for a moment.

MEMBER VAN DYKE: Mike Van Dyke. Sorry, I didn't know if you saw that. I think we're talking about two problems. We're all assuming that since there's no definition of terms, that there's no calibration among the people that are doing the assessments.

And then the other problem we're talking about is really, we're unsure how the results of an IH assessment are interpreted by a CMC. And I think we could talk to these IHs to

figure out how they go through their process, but I'm not sure that that's really going to be productive in changing anything.

Would it be helpful to come up with a series of questions where we can give an example and say, how would you interpret this? And then we could distribute a questionnaire to a broader group of CMCs and industrial hygienists and get responses to those.

And then I think that will answer our question to say, are they miscalibrated? Are they interpreting this different? And the questions would probably be different for the CMCs versus the industrial hygienists, but it would be a way of getting a broader response. It would be a way of asking more specific questions to get at what we've been talking about for a long time.

And I think the other thing is, is when you ask somebody, do you have any improvements, versus you ask somebody a very specific question, I think that your response is

much different.

CHAIR MARKOWITZ: Mr. Key?

MEMBER KEY: I agree with the basic context you just stated. But as we've seen, we cannot get any voluntary suggestions from the CMCs to improve as a response to us. So how do we as a Board mandate and dictate that they fill out these forms and review them?

CHAIR MARKOWITZ: Steve Markowitz. We can't. That would be a voluntary survey. If the program can't do that with a contractor, that's one thing. If a contractor is not interested, that's another thing. It's possible the IH contractor might be interested to cooperate with such a survey, but it certainly sounds like the CMC contractor wouldn't be interested.

Was that an idea that we want to explore in a smaller group, sort of brainstorm it a little bit and see if we can articulate an idea that we want to pursue?

Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes. I'm

just thinking about Dr. Cloeren's comment that maybe we should wait on some of this. And I'm wondering, maybe the contractor would respond more positively if we had a focus for what is the problem.

We haven't yet demonstrated in a convincing way or transparent way that there is a problem. So if we do this review of the causation analyses and we don't find a problem, then this is really moot.

If we find that there's a particular kind of problem that is systemic or seems to be repeated and could be potentially correctable that's related to exposures, an exposure assessment, then that could, I think, change the contractor's view toward collaborating with us and participating in more exploration of what the exposure assessment process is.

CHAIR MARKOWITZ: What's our goal here? Our goal is to try to understand how the industrial hygiene process is using its various categories of exposure.

The ideas are we could ask to meet either in a smaller group or as a Board with a few of the industrial hygienists and national office contractor. Another idea is that we put together a survey to get the input from a broader number of industrial hygienists.

Dr. Van Dyke?

MEMBER VAN DYKE: Mike Van Dyke. I think I'm persuaded by Dr. Friedman-Jimenez. We've made several recommendations. They've accepted some changes on how the report gets done. I think the implementation of that table for the significant exposures might start to really enlighten the thinking of the industrial hygienists in terms of exposure.

So maybe in terms of -- I've heard some people say maybe we should wait a bit on this. But in the meantime, maybe we should ask for some of the redacted IH reports over the next six months that really use this table so we can have some more data to evaluate that, and then make a decision from there.

CHAIR MARKOWITZ: Okay. Mr. Catlin?

MEMBER CATLIN: I think I support that from Dr. Van Dyke. I would also be interested if maybe our small group, the working group, could have just a discussion with some of the industrial hygienists.

I feel like there might be some real benefit to just having that conversation. I'm not making an assumption that's there's problems, but it'd be really good to hear the thinking of the folks who are doing the program so that we could hear that directly, if that's possible.

CHAIR MARKOWITZ: All right. Those two suggestions aren't mutually exclusive.

Other comments? How do we want to proceed? What do we want to do? One proposal is that we request either a subset of the Board or ask the full Board meet with a few industrial hygienists to basically discuss how they work, how they implement changes, problems they face, et cetera.

Dr. Cloeren?

MEMBER CLOEREN: I think I was pre-empting you. I think the second one, what was discussed earlier was the possibility of appearing to the Board, I would be against that one. I think that's too formal and too high-pressure, but I think an informal discussion would be great. I'm not sure what the mechanism is for requesting that.

CHAIR MARKOWITZ: I'm sorry. So not the full Board, but a subset of the Board?

MEMBER CLOEREN: Not a formal appearance at the next Board meeting. I don't think it matters how many of the Board are there.

CHAIR MARKOWITZ: Actually, if the full Board --

MEMBER CLOEREN: It probably has to be a subset because if it's the full Board, then it's formal.

CHAIR MARKOWITZ: Right. If it's the full Board, it's going to look like this. So anything short of the full Board. If it's ten people, not 11 Board members, then that's a

subset of the Board.

I agree that format, if we can achieve it, would be more fruitful. And I'm sure there's a volunteer from the Board who would volunteer not to participate in that and hear about it secondhand.

MEMBER CLOEREN: I volunteer as tribute. The Hunger Games. I had to get the Hunger Games thing in.

CHAIR MARKOWITZ: Okay. So this is not a recommendation. This is a request to the Department. We have to write up our request.

It doesn't have to be extensive, but who would like to do that? Dr. Cloeren?

MEMBER CLOEREN: I'm willing to take the lead on writing that up.

CHAIR MARKOWITZ: Okay.

MEMBER CLOEREN: You don't need it right now, do you?

CHAIR MARKOWITZ: No.

MEMBER CLOEREN: Okay.

CHAIR MARKOWITZ: There's a form to

fill out. It's easy. I'll send it to you and go over it. Okay. That's that piece of it.

Then the second idea that came up was to actually see some industrial hygiene reports over the next period of time and to see how changes are actually used in practice. I think that's a pretty good idea, personally.

Dr. Friedman-Jimenez, there is various positive nodding of heads around the table.

MEMBER FRIEDMAN-JIMENEZ: I have to unmute myself every time. Yes, I agree. I think it's a good idea. We'll see how they accept or don't accept the table, what parts they fill in, if there's parts that they don't fill in or don't like to fill in.

And then we can get some response from them on how they like it, if they feel it helps them or it's a pain in the neck, or it's invalid or parts of it are very important. This kind of feedback, qualitative feedback would be very useful. I agree.

CHAIR MARKOWITZ: So we need someone

to write up that request with a little bit of specificity, including calendar time from when the reports should be drawn. I don't know whether accepted versus denied claims.

Dr. Bowman?

MEMBER BOWMAN: On the request, I think the two requests are related and can probably be in a single document. And then in terms of what we'd review, I think we'd want to review the ones that have actually utilized the table.

CHAIR MARKOWITZ: Right, but the Department is unlikely to look at the claims and see which ones have used the table. So if we define it by calendar period, we're more likely to actually get some results, I think.

By the way, when we write up this information request, maybe what we should do is we'll circulate it among Board members for input to see if there's anything else to be included.

Mr. Catlin?

MEMBER CATLIN: I was just going to

volunteer on that second task and do the first draft or work with Dr. Cloeren and others.

CHAIR MARKOWITZ: Okay. I think that could be a single information request. Again, I can show you some previous ones. If there are any residual questions, they'll come back with clarifying questions.

MEMBER FRIEDMAN-JIMENEZ: This is George Friedman-Jimenez. I'd like to volunteer to work with this group to help with designing the sampling strategy, what exactly do we want to find out, and what case sampling do we need to do in order to get there.

CHAIR MARKOWITZ: So is this the industrial hygiene feedback effort that --

MEMBER FRIEDMAN-JIMENEZ: Is this the case review for the -- okay. Maybe I'm getting this wrong.

CHAIR MARKOWITZ: No. We accept your willingness to volunteer. I was just looking for a name, what to call this.

MEMBER FRIEDMAN-JIMENEZ: We're

consolidating the two, the industrial hygiene feedback and the causation review in one? Or are we --

CHAIR MARKOWITZ: No, we're not.

MEMBER FRIEDMAN-JIMENEZ: -- combining industrial hygiene feedback and the users of the industrial hygiene report?

CHAIR MARKOWITZ: No. What we've been lately discussing is restricted to industrial hygiene, either looking at recent reports that have used a modifying table or speaking with industrial hygienists who are using this. This does not include the CMCs.

MEMBER FRIEDMAN-JIMENEZ: Okay. I misunderstood that.

MEMBER BOWMAN: Sorry. This is Aaron Bowman. If I'm following, what we're talking about is sunsetting the significance working group and having it roll into an IH working group.

CHAIR MARKOWITZ: Yes. That's what we're doing, yes. Okay.

So we've got Mr. Catlin, Dr. Cloeren, Dr. Friedman-Jimenez, and Dr. Bowman, who raised his hand, and Dr. Van Dyke. Okay. I think we've closed that out.

So I want to just follow up on a brief discussion we had yesterday about an issue that's come up before before the Board, either in public comments or in Board conversation.

We decided just to formalize this into a simple communication to the Department that the Board recommends that the program designate a single program staff person as an initial point of contact for claims that involve people who report that they are terminally ill.

We've heard from the program that they addressed this problem, and yet we continue to get feedback about this as being an issue. This is kind of a de minimis recommendation, a minimal recommendation about a process suggestion that there would be a single person who is responsible for attending to the requests that come in around this.

We understand it's a thorny issue. It's a challenging issue. Nonetheless, this at least would simplify how it's addressed by claimants, by their representatives, advocates and the like.

Comments? Mr. Key?

MEMBER KEY: Yes. This issue has been brought up previously. At our last meeting, I questioned Mr. Vance. He said to raise the issue.

When we contact CEs, they are unaware or uninterested or don't know who to contact within the Department that we can get this case fast-tracked. And since I brought the issue up at the last Board meeting, we've had three individuals who have passed away as a result of never getting their claim adjudicated, approved, and moved through the process.

I would recommend with our recommendation that we add a time frame for the Department to designate this staff person and provide us with the initial point of contact, a

contact number where we can alleviate some of these. And this is not only happening at one site. It's across the entire program.

CHAIR MARKOWITZ: So if I understand that correctly, you want to add a few words here, line 2, designate a single program staff person within -- how many days? What did you say; how many days? Within 30 days, okay. Within 30 days of the date of this recommendation.

Okay. Ms. Splett?

MEMBER SPLETT: Would it make more sense to have one DOL staff person at each of the district offices who would have the direct access to the claims examiners in that office?

CHAIR MARKOWITZ: Mr. Key?

MEMBER KEY: That's a good idea, but do they have the power to fast-track? That's the unknown. Who within a program can pick up a phone and make something happen within a matter of one to two days?

MEMBER SPLETT: I guess my sense is it would be someone relatively high up in the

district office. And I'm going to only speak from my experience at Hanford, and that's somewhat dated, but all the Hanford claims went to Seattle. I spoke routinely to the district director, who had that ability to fast-track.

We also came up with a little different of a designation. We had terminal claimants and we had imminently terminal claimants, which meant we just had a few days to do things. Both offices knew exactly what that meant.

I never had that issue, but I do understand in the last four years when the claims are now diversified throughout the country, it's a lot different. And those personal relationships are not nearly as strong.

CHAIR MARKOWITZ: I think the rationale could make the point that the person should be in the position of actually influencing the process. And if that ends up meaning that there's more than one, but a very limited number, that that would be a more effective way of doing

it, that would certainly seem to comply with the spirit of the recommendation.

Is that right, Mr. Key? Okay.

Dr. Cloeren?

MEMBER CLOEREN: Marianne Cloeren. I am not familiar enough with the procedure manual to know if there is currently a procedure for fast-tracking. There's certainly precedent for it in other programs, such as Social Security.

That's a much bigger ask, that there be a procedure established for fast-tracking with parameters, putting somebody in that track, but I think that's what's really needed. A contact person is a good start, but if there's not a procedure, what's that contact person supposed to do?

CHAIR MARKOWITZ: Ms. Splett?

MEMBER SPLETT: Could Mr. Vance answer that, whether there is a procedure? I know that operationally, we worked it and it worked very well, but I do not know whether there is an actual procedure. And I think Mr. Vance should

be able to answer that.

CHAIR MARKOWITZ: So Mr. Vance, in the procedure manual now, is there some procedure that addresses this issue?

MR. VANCE: This is John Vance. Yes, there is. I'll just explain the process as it exists right now.

When we do have notification that we do have someone that is terminal, that is open to a very wide interpretation of what that means. Generally what is going to happen is that we are going to look for medical documentation that clearly defines or can be interpreted as being supportive of a terminal designation.

So that would be indications that someone is going into hospice or someone is in a hospital setting with a very limited life span. We will identify that case and it will be evaluated by the district director of each office.

They will then identify that case with a designator in their energy compensation case

management system. That will then fast-track the case. So an identifier in our energy compensation system that identifies the case as terminal. That will then move the case through our process as quickly as we can.

Now, that being said, we are still obligated to ensure that if we are even expediting the case, that means we still must overcome whatever claim hurdles exist that we must go through as far as our process is concerned.

So we will try to obtain expedited industrial hygienist reviews, CMC reviews. We will try to process the steps involved with getting a decision out the door, getting any kind of waiver, getting final decisions issued.

And then processing as quickly as we can expedited payments. We can do a bypass of the routine payment process to do same-day or next-day payments. Again, those are all steps that need to occur in these cases.

There is a procedure for it, but keep

in mind that even if you identify someone as terminal status and you have someone that's shepherding you through the process, in some instances we're still going to be reliant on getting documentation that supports a case adjudication outcome for that claim.

So even if we would want something to happen fast, if we don't get a document from the claimant or their family, that could slow things down.

So there is a process. I'm very familiar with a lot of the efforts that we take in the program and try to prioritize terminal payments for individuals that are due money. But again, a lot of those require a lot of steps to make happen.

So there is a process. We do work very actively to make these cases move along very quickly. Unfortunately that doesn't always work out, but we do try to do what we can to make those things happen quickly.

CHAIR MARKOWITZ: Thank you.

Mr. Key?

MEMBER KEY: Yes. As Mr. Vance stated, the process is through each separate division office or district office. So we need a listing of those people, names and contact numbers associated with each district office.

CHAIR MARKOWITZ: Ms. Splett? And then we'll get back to Mr. Keys' idea here.

MEMBER SPLETT: I do have to say also that not only did DOE inform DOL that we had a claimant that we felt was terminal or imminently terminal, but they did the same. Sometimes we would be processing a claim and not realize that there was an end-of-life issue.

The Department of Labor would reach out to us and say, put this in the front of your list because we've got to get moving on this one. So it was bilateral notifying if one agency or the other knew that the claimant was terminal.

That happened routinely that they would call me and say, you've got a claim on the way in. This is the name. Go ahead and start

working on it. And we'd start pulling their records immediately.

CHAIR MARKOWITZ: The system seems to work well in Hanford, but perhaps in one or more other places it's not working so well. So what's the difference?

MEMBER SPLETT: It did used to work that way. My understanding now is all Hanford claims don't all go to Seattle any longer.

There was that personal relationship where we would call one another. It was not uncommon to talk once or twice a week. I would get calls at 10:00 on a Friday night that, you've got an imminently terminal claim coming in.

Once I retired, I understood that claims go all over the country. So those relationships no longer exist, I believe, from Hanford to Jacksonville or Cleveland. That just doesn't work in the same way any longer.

So I do want to make that distinction. We're talking four years ago it worked very well. I do not believe from what I'm hearing

from others on-site that it works out that well any longer.

CHAIR MARKOWITZ: Mr. Key, getting back to you, your request is for each district office to learn the name of the person who's responsible for this?

MEMBER KEY: Yes. As Mr. Vance says, the process is through each district office. They have those people designated. We need the names of each district office person and their contact number so that the advocate or whoever can pick up the phone, make the contact, and fast-track it as well as possible.

CHAIR MARKOWITZ: Okay. It seems like a reasonable request. Does the Board need to turn that into a written information request? Or can this occur as a result of the minutes of the meeting? I'm looking at Ms. Rhoads for a way in here.

MS. RHOADS: If it's just an information request, I think we can pass it on.

CHAIR MARKOWITZ: Okay. We'll write

it up. We'll write it up just for clarification.

Mr. Key and then Dr. Cloeren.

MEMBER KEY: Yes. I'd rather submit it as a Board request officially so it would be on document and record.

CHAIR MARKOWITZ: Okay. Good idea.

Dr. Cloeren?

MEMBER CLOEREN: From what I heard of the process, I'm a little fuzzy on the first step of flagging it as terminal and fast-tracked. It sounded to me like it might sit in the same pool of claims of everybody else before somebody gets to it. I'm not sure who does the first pass, like the triage.

I think what I'm asking is, is there a triage process that will quickly identify that this is one that needs to be expedited, understanding that you still need to get all the information?

CHAIR MARKOWITZ: I'm sorry. Is that a question for Mr. Vance?

MEMBER CLOEREN: Yes.

MR. VANCE: Let me get into the details of how it works. So generally, what you're talking about is a claims examiner who is responsible for case adjudication.

As part of their daily activity, what they're looking at is their daily inventory of newly imaged information coming into the VOIS system. This is where new mail is recorded as an image. They will get a flag that they have a certain amount of time to review that information.

Now, if an authorized representative or a claimant or some indication is coming in on one of these newly submitted documents that identifies that an individual is terminal or that there's a need to prioritize the case because of the status of the employee, the CE will conduct an evaluation of the case.

What they're going to do according to procedure is look for medical documentation that supports that the information that's being reported to them is accurate.

We have a lot of folks that will try to identify terminal cases to expedite cases without any corresponding medical documentation. And that's just something that we have to work through. But they're going to try to seek out medical documentation from the claimant or their representative that affirms and testifies to the terminal status of the employee.

That information, once that's been received, will then be transmitted to the district director or designated manager in that district office who is responsible for then identifying whether they agree that there is sufficient justification to identify that case as a terminally flagged situation.

Once that occurs, that then transmits to the claims examiner and others involved in the process that steps need to be taken to try to move this case along as quickly as possible. So it's generally going to be notification from an authorized representative that is somehow getting into the case file requiring a review by the

claims adjustor or claims examiner.

Sometimes we will get emergency phone calls and you can just gauge from the interaction with the caller. I've had these calls where the circumstances are such that we need to move this case very quickly based on the circumstances that are being described to us from the authorized representative or whomever.

So it's a judgement call, but we also tend to try to rely on getting good information about the status of the employee, the survivor, or whoever it is that we're trying to get through the process as quickly as possible.

And you can imagine there's a lot of instances where we have to look at it because we get a lot of representatives who like to say a lot of their clients are terminal to try to move those cases to the front of the line.

So there is this bifurcation where we have to look at, okay, is it truly a terminal situation or what is it that we're getting here? That's just the reality of the claims process.

But it generally is going to start with some sort of notification that we've got to look at someone because of their status.

CHAIR MARKOWITZ: Thank you.

Dr. Cloeren, your name tag is up.

MEMBER CLOEREN: Can I ask one more clarifying thing? When a claim is submitted, is there a way for the system to -- it sounded to me like it depends on somebody giving a heads up.

I'm wondering if there's a system method for flagging a claim that this is terminal and maybe prompting what information is going to be needed for the claims examiner to act on that really quickly so that at the time the claim is sitting in the queue for the claims examiner, it's already tipped that this is one that needs to be prioritized, and the person submitting it hopefully has a chance to have submitted whatever is needed to triage it.

MR. VANCE: This is John Vance again. It's going to rely on someone at some point taking a look at something that has come in.

That can be a phone call that's been recorded into our telephone management system. It could be a document identifying someone as petitioning the program to treat the case as a terminal status. It could very well be medical documentation that we receive that the CE screens to identify someone as potentially terminal.

Any of those triggers have to be made by someone looking at case file information and making a judgement that this has got to be processed through that referral mechanism to the district director to make sure that's there's a sufficient justification to treat this as a terminal case.

The key thing to understand is when you treat someone in a terminal situation, you're taking claims examiner staff and contract resources away from the routine cases to try to prioritize these terminal situations. So it really does rely on some mechanism that triggers that review.

And it does mean somebody has got to

be looking at something and saying, you know what? Here it is. I've got a situation that we need to evaluate for a terminal designation.

CHAIR MARKOWITZ: Go ahead, Dr. Cloeren.

MEMBER CLOEREN: Just one more question. I promise this is the last one.

How long does the claims examiner have to get to -- what's the time expectations for getting to a case in the queue? What's the maximal time that something might be sitting there before the claims examiner looks at it and says, oh my gosh, this is one that needs quick action?

MR. VANCE: It's going to depend on the circumstances of what it is that you're looking at, but generally they have a limited amount of time looking at incoming new OIS images that are registered as unreviewed.

So if we get some documented into a case file, the claims examiner has a limited amount of time -- I don't know what the exact

standard is, but it's not a significant period of time -- to review and classify. They call it indexing where they have to go in and categorize this document as being -- this is what this information is and this is how it's being characterized.

When they do that and they're looking at something that's talking about this person entering a terminal status, or their situation is medically dire or whatever it is, they have to trigger that mechanism. So it's not that it's going to sit for a while on that initial screening. It's going to then move through that process.

Now, how long it takes once that terminal designation exists, how long is it going to take for all the steps needed to get to a positive outcome, that's where you end up with some of these -- we want to move it quickly, but we can't do anything if we're asking for information that we need and we're not getting that response in a timely manner. So you're kind

of dependent on that.

But I do know that in many situations that we encounter, once we have the information and are able to make the decision, especially if it's an affirmative one that's going to pay money, we've done those kinds of outcomes in a matter of a day or several days.

It's just a matter of getting the decisions out the door, getting the necessary paperwork back from the family, and getting the payment into the account of the payee. So those things can move quickly when we have all the necessary documentation.

CHAIR MARKOWITZ: Okay. Thank you.

So we have a pending recommendation. It's combined also with an information request, which the Board will make regarding the names of the people at each of the district offices who are responsible for this.

Are there further comments or questions? Ms. Splett?

MEMBER SPLETT: I would recommend

after the single program staff person, add each district office within 30 days.

CHAIR MARKOWITZ: Okay. Mr. Key?

MEMBER KEY: Yes. Specific to the district office director or who they appoint at that level, because our experience with the a claims examiner on one recent case of terminal illness -- a gentleman was in the hospital dying.

The CE said that he was not eligible for SEC, having worked at the Paducah Gaseous Diffusion Plant, one of the original four contained SECs within the legislation. So clearly, the CE either was not well-trained, not well-informed, or didn't know what they were doing.

CHAIR MARKOWITZ: Thank you.

Dr. Bowman?

MEMBER BOWMAN: Just for clarity in reading this, I wonder if after the words within 30 days of the date of this recommendation, the words to serve would make this make more sense.

CHAIR MARKOWITZ: That's an

acceptable, friendly amendment.

Any other suggestions?

Okay. We should take a vote.

MR. JANSEN: I will record the vote.

Dr. Bowman?

MEMBER BOWMAN: Yes.

MR. JANSEN: Mr. Catlin?

MEMBER CATLIN: Yes.

MR. JANSEN: Dr. Cloeren?

MEMBER CLOEREN: Yes.

MR. JANSEN: Dr. Friedman-Jimenez?

MEMBER FRIEDMAN-JIMENEZ: Yes.

MR. JANSEN: Dr. Markowitz?

CHAIR MARKOWITZ: Yes.

MR. JANSEN: Dr. Mikulski?

MEMBER MIKULSKI: Yes.

MR. JANSEN: Dr. Van Dyke?

MEMBER VAN DYKE: Yes.

MR. JANSEN: Dr. Vlahovich?

MEMBER VLAHOVICH: Yes.

MR. JANSEN: Mr. Key?

MEMBER KEY: Yes.

MR. JANSEN: Ms. Splett?

MEMBER SPLETT: Yes.

MR. JANSEN: Mr. Domina?

MEMBER DOMINA: Yes.

MR. JANSEN: There are 11 yes votes and zero no votes.

CHAIR MARKOWITZ: Okay. It's roughly 10:10. Let's take a ten-minute break and then we'll come back. I don't think we have any more votes, but we do have some other work that we need to consider.

(Whereupon, the above-entitled matter went off the record at 10:07 a.m. and resumed at 10:20 a.m.)

CHAIR MARKOWITZ: Okay. We're going to resume. The Department has requested that we review some work on carcinogens. You may recall a couple of years ago, maybe in the previous Board term -- I think it was -- we had a working group on carcinogens.

We looked at the IARC probable human carcinogens, the 2A carcinogens. IARC is the

International Agency for Research on Cancer, part of the World Health Organization.

We made some recommendations to the program that they add certain toxic substance links in the SEM to selected cancers. That was accepted by the Department.

PTS, Paragon Technical Services, has conducted a review of the IARC 2A Carcinogens that have been determined to be 2A over the past period of time. I can't recall what the period is. They have produced a report for us.

The Department has asked us to review this report. I think the report was sent to everyone a week or so ago. The request to us is to review their determination. They recommended that there are 2A carcinogens -- trichloroethylene, that that be linked to multiple myeloma in the SEM, and also antimony be linked to lung cancer.

So I think this is a useful use of the Board, for us to weigh in here. Ninety percent of the work has been done, maybe more. And I'm

looking for a subset who is willing to take a look at this report from PTS and basically weigh in on its conclusions.

We had a carcinogen subcommittee. I only remember two members. I think it was Rose Goldman.

MEMBER FRIEDMAN-JIMENEZ: Rose Goldman and I.

CHAIR MARKOWITZ: Dr. Friedman-Jimenez, I think, was prominent in that effort. Were you part of that?

MEMBER FRIEDMAN-JIMENEZ: I think Marek Mikulski, were you on the group too?

CHAIR MARKOWITZ: I think he was on Parkinson's duty at the time.

In any case, are there any Board members who would like to work on this? I volunteer as one, but are there others?

MEMBER FRIEDMAN-JIMENEZ: Could I ask how long is the report? I don't think I got this report.

CHAIR MARKOWITZ: I'm looking at it on

my phone so I can't tell how many -- oh, seven pages.

MEMBER FRIEDMAN-JIMENEZ: Okay. I'll volunteer.

CHAIR MARKOWITZ: Okay. We have Dr. Friedman-Jimenez. We have Dr. Cloeren. We have enough but if others wish to join, you're welcome. Thank you.

MEMBER BOWMAN: If it would be helpful, I could join.

CHAIR MARKOWITZ: Okay, yes. Now we have Dr. Bowman.

MEMBER BOWMAN: I also don't think I received the report. I looked for it.

CHAIR MARKOWITZ: Okay. I hope I'm not misportraying it as only being seven pages long, but I think that's all it is. In any case, it's finite.

A follow-up on Parkinsonism. We heard that the SEM has been altered and 111 toxic substances have been linked to Parkinsonism. That resulted from Board recommendation. We had

a working group about that a couple of years ago. So I think we discussed receiving that information, which substances are now linked in the SEM, and taking a look at that.

Did I recall that correctly? I'm looking for volunteers who might be willing to do that. We have Dr. Mikulski and Dr. Bowman.

MEMBER BOWMAN: Yes. This definitely falls well within my area of expertise. On the cancer one, because I served on the IARC review with that, I'm happy to continue that because I learned a bit about the process.

CHAIR MARKOWITZ: Okay.

MEMBER BOWMAN: But probably my expertise is better suited with Marek's on the Parkinson's.

CHAIR MARKOWITZ: Okay, great. We talked about hearing loss, re-looking at some hearing loss literature to see whether the minimum number of years used by the program, ten years, to look at the issue of whether consecutive exposure up to ten years was

necessary.

Could it be interrupted and cumulative up to ten years or whatever? And so we thought we should take a look again at that topic for those specific subjects.

Dr. Cloeren?

MEMBER CLOEREN: I think if we're going to be looking at the recent literature on toxic effect and hearing loss, we should also be open to additional agents that are not on the list. I mean, if there is evidence for it.

CHAIR MARKOWITZ: It sounds like a good idea, especially if we have volunteers who are willing to do that.

MEMBER FRIEDMAN-JIMENEZ: This is George Friedman-Jimenez. I will volunteer for this group also.

CHAIR MARKOWITZ: Okay. Thank you.

Dr. Bowman?

MEMBER BOWMAN: The sensorineural component would make sense.

CHAIR MARKOWITZ: And I'll volunteer

to help with that. So we have enough. Again, we're open to additional volunteers should you have a change of mind or a change of heart, whichever.

So public comment. We had a single public commenter yesterday.

I think that the comment on the Santa Susana -- Ms. Splett, in your questions to the Department and you're going to provide certain examples, are you intending to include that?

MEMBER SPLETT: I am.

CHAIR MARKOWITZ: Okay. There was a public comment that came in this morning, a written public comment, which you all should take a look at. It was fairly long, I guess. It had to do with CMCs.

It claimed that many reports are done by relatively few CMCs, that there is not an even distribution across the pool of CMCs. And then there was other discussion about exactly how the CMCs were chosen.

It made me realize, actually, I don't

know if the Board has ever requested any sort of profile of the CMCs and whether the Department has it or the contractor can produce it. So what I'm thinking is: how many are there?

What's their specialties? How many are in occupational medicine? How many orthopedics? How many oncology? How many pulmonary medicine?

And then what's the distribution of reports in a given time period? So you take a given 12-month period, how many are done by what discipline? How do they break down in terms of the individual CMCs? Are there a relatively small number of CMCs who are doing a lot of reports?

There's nothing wrong with that, but it would be interesting to know, particularly if you move ahead and look at the quality assessment process with that. So just basic data, distribution data on the CMCs and the reports.

My question, Mr. Vance, is that kind of information that the program and the

Department already has? If not, is that something that we can reasonably expect the contractor to produce?

MR. VANCE: I would think that would be something that we could reasonably produce.

CHAIR MARKOWITZ: Okay. Thank you.

Aside from what I just mentioned about the distribution of disciplines, the numbers, the reports, the distribution of who's doing the reports, is someone willing to write up an information request and send it around? Are there any other aspects of this off the top of your heads that you think would be useful?

MEMBER BOWMAN: Potentially the length of service to get a sense for the turnover.

CHAIR MARKOWITZ: Dr. Cloeren?

MEMBER CLOEREN: Would it make any sense to also look at the proportion of denials versus approvals?

CHAIR MARKOWITZ: They don't deny.

MEMBER CLOEREN: I know they don't, but the decisions to deny are produced that may

have hinged on the causation analysis. I know there are other factors that are at play.

CHAIR MARKOWITZ: Also the condition, actually, what condition the issue is about.

Dr. Van Dyke?

MEMBER VAN DYKE: Given we go around the country and look at all these different sites, it would be nice to know the particular site too, especially in light of hearing that there's an increase of claims from CANEL.

CHAIR MARKOWITZ: Yes, right. I mean, this is subject to how the program and how the contractor keep the data, but we can certainly ask for these things.

I'll send around a draft. You may think of some other useful ones. We're not asking for a lot of work here. This is a basic profile of CMCs and the reports that they write that would give us a better sense of the activity.

Okay. So nothing further on that topic. I don't have anything else on my list

here.

Dr. Bowman?

MEMBER BOWMAN: I just recalled when we were going through this that we mentioned yesterday a request for an update on the report of the case distribution by disease category.

CHAIR MARKOWITZ: Right.

MEMBER BOWMAN: I don't know if that needs to be a written request.

CHAIR MARKOWITZ: So Ms. Rhoads makes an action list from the discussion of our last day and a half. That will be on the action list. I'm sure she caught that.

Mr. Key?

MEMBER KEY: Yes. Ms. Carrie yesterday sent the Board members responses to the 926 questions. And in opening those, from my side there are some questions that I have.

Who do I submit these questions to? Do I submit them to Carrie? Do I submit them to Ryan, Mr. Dan, who?

CHAIR MARKOWITZ: These are follow-up

questions regarding the SEM?

MEMBER KEY: Yes.

MS. RHOADS: They can be sent to you as the Chair. And then we can decide where to send them after that.

CHAIR MARKOWITZ: Okay. You can send them to me. I personally was hoping it was a different answer.

MEMBER BOWMAN: Gail, aren't you preparing the summary of questions? Wouldn't those be just part of that?

CHAIR MARKOWITZ: They'll make their way around to the other Board members.

MEMBER BOWMAN: Yes, okay.

MEMBER SPLETT: If you want to send them to me, I'll route them to everybody.

CHAIR MARKOWITZ: Yes.

MEMBER SPLETT: Unless you want them, Dr. Markowitz, directly.

CHAIR MARKOWITZ: You can send them to me and CC everybody else. How about that?

This is November. We'll meet again in

roughly May. Right now the Board is scheduled to end its existence, I think, in December of 2024 unless Congress changes the date, extends it. I think that is part of legislation. Maybe a decision will be made by the end of December, but who knows. It's Congress. So we'll see. We'll just continue our work.

This particular Board term is over in July of 2024. So we should try in the meeting to the extent we can to close out on certain issues that we can come to a conclusion about or otherwise pass it along to the next Board that serves.

Does anybody see any need for a telephone meeting before our next in-person meeting in six months? I haven't heard of anything that would require a vote.

As usual, there will be a very careful deliberative process about where we meet next. We'll see where that is. I'm trying to shoot for a place where we can get a pretty good tour. That's a little bit of a challenge at the labs.

That's why in general we haven't been to the labs. We'll work with Greg Lewis and see what we can use.

Are there any other issues, comments, closing thoughts? Okay.

Mr. Jansen, I think you officially adjourn the meeting.

MR. JANSEN: Thanks, everyone. The meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 10:36 a.m.)