

TELECONFERENCE MEETING  
STATE OF CALIFORNIA  
HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH  
FORENSIC ALCOHOL REVIEW COMMITTEE

DEPARTMENT OF PUBLIC HEALTH  
RICHMOND CAMPUS CONFERENCE CENTER  
850 MARINA BAY PARKWAY  
ROOM B-137  
RICHMOND, CALIFORNIA

SEVENTEENTH MEETING  
THURSDAY, JANUARY 27, 2011  
10:00 A.M.

REPORTED BY:  
JOHN COTA

APPEARANCESReview Committee Members

Dr. Paul Kimsey, Chairperson (Richmond)

Lieutenant Kevin Davis (Sacramento)

Mr. Paul R. Sedgewick (San Diego)

Mr. Kenton S. Wong (Richmond)

Mr. Torr M. Zielenski (Sacramento)

Mr. Bruce Lyle (San Diego)

Ms. Jennifer Shen (San Diego)

Review Subcommittee Members

Ms. Jennifer Shen (San Diego)

Dr. Paul Kimsey (Richmond)

Staff

Mr. Robert Haas, Abused Substances Analysis Section  
(Richmond)

Ms. Effie Harris, Abused Substances Analysis Section  
(Richmond)

Mr. Clay Larson, Chief, Abused Substances Analysis Section  
(Richmond)

Ms. Zenaida Zavala, Research Scientist, Food and Drug  
Laboratory (Richmond)

Mr. Harby Thandi, Research Scientist, Food and Drug  
Laboratory (Richmond)

Also Present

Mr. William Chi, Department of Public Health, Office of  
Legal Services (Sacramento)

Mr. Bill Phillips, California Department of Justice, Bureau  
of Forensic Services (Sacramento)

Dr. Kevin Riley, Department of Public Health (Sacramento)

Mr. Russ Huck, Department of Public Health (Sacramento)

Ms. Tamara DuTemple, California Highway Patrol (Sacramento)

Ms. Denise Lyons, Solano County District Attorney's Lab  
(Sacramento)

Ms. Patty Lough, Member of the Public (San Diego)

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1 Russ.

2 THE REPORTER: I do have you down Russ and Tamara,  
3 how do you spell her last name?

4 MS. DUTEMPLE: D-U, capital T, E-M-P-L-E.

5 THE REPORTER: Thank you.

6 MS. DUTEMPLE: You're welcome.

7 CHAIRMAN KIMSEY: And here in Richmond we have --

8 COMMITTEE MEMBER WONG: Kenton Wong.

9 CHAIRMAN KIMSEY: Paul Kimsey.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11 Bob Haas.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

13 Clay Larson.

14 MS. ZEVALA: Zenaida Zevala.

15 CHAIRMAN KIMSEY: Okay, welcome to the seventeenth  
16 meeting of the Forensic Alcohol Review Committee. Thank you  
17 all for your time.

18 This was the day that we could get a quorum.  
19 Laura Tanney is not going to be able to join us today but I  
20 believe everyone else on the Committee has been able to  
21 attend.

22 The agenda that was sent out, my opening comments  
23 would be that stating some of the obvious, but, we have a  
24 new Governor, Jerry Brown.

25 He has appointed Diana Dooley as the Health and

1 Human Services Agency Secretary. That agency has 13  
2 departments which the Department of Public Health which I am  
3 in and the program, the Forensic Alcohol Program is in is  
4 one of the 13.

5 And with regards to changeover, there seems to be  
6 a more methodical, relatively, slow-paced change in  
7 personnel and political appointees.

8 There is still a number of people at Agency from  
9 the previous administration. So there hasn't been a lot of  
10 new appointments at the agency level yet.

11 And we can talk a bit more about, obviously,  
12 Agency's role later on in our meeting.

13 I also have some information which I can bring up  
14 later on the meeting. I mentioned I was going to get some  
15 information from the Governor's budget on the Motor Vehicle  
16 Account and I can report on that later on in the meeting.

17 The only other comment I would say is that, as  
18 most of us know, there was a little bit of a, sort of a dust  
19 up in North Carolina in the late summer, early fall last  
20 year with accrediting crime laboratories.

21 The only reason I mention it is it seems like the  
22 last I read in the paper there in North Carolina in Raleigh,  
23 was that the state has decided to not have a sole or single  
24 accrediting agency for crime labs in North Carolina.

25 So it looks like it's going to be a blend of

1 ASCLAD and also some state oversight. And that's a little  
2 bit relevant to our discussions.

3           Although that's about crime labs in general and  
4 it's not forensic alcohol labs specifically.

5           With those opening comments the other discussion  
6 we can have is the agenda. We're obviously going to talk  
7 about the December 15th letter from the Department of Public  
8 Health on behalf of Agency.

9           We have some work products, the Fiscal Impact  
10 Statement and Statement of Determinations that we'll be  
11 discussing.

12           Is there any other specific agenda item that the  
13 Committee would like to address that I haven't mentioned?  
14 (No response).

15           Hearing none, I'll start the discussion. The  
16 Committee, Jennifer Shen on behalf of the Committee on April  
17 21st sent a letter to Secretary Belshe on behalf of the  
18 Committee.

19           We have a response in our packages that came from  
20 the Department of Public Health on behalf of Agency.

21           That in itself is not unusual that Agency has a  
22 department respond to correspondence on their behalf.

23           And so that letter came out December 15th back to  
24 Ms. Shen and that's in our package.

25           I don't know if, I know Dr. Riley is there in

1 Sacramento. I don't know if he wants to make any comments  
2 on this relationship on behalf of the fact that the  
3 Department has signed this letter on behalf of Agency.

4 DR. RILEY: Thank you Dr. Kimsey. Now Dr. Kimsey  
5 is correct in the idea that agencies will oftentimes ask  
6 their partners to respond on their behalf.

7 This is unusual in that this was done seven months  
8 later. There were a number of conversations with previous  
9 Secretary Kim Belshe about a response and in the end, at the  
10 end of her tenure she was transitioned over on the third of  
11 January.

12 She turned and asked for the Department to respond  
13 back to the Agency.

14 So I want to, first of all, apologize for a seven  
15 month delay in response back to the letter from the  
16 Committee. That's unusual for us as an agency and  
17 organization from the past.

18 But I think everybody has had a chance to review  
19 the letter. My understanding is that the query to Agency  
20 about approval of amendments to regulations or recommended  
21 amendments to the regulations is kind of twofold process.

22 I think that's outlined pretty well in the letter,  
23 the April 21st letter from this end that this letter did not  
24 trigger a response back with a, basically a thumbs up or  
25 thumbs down on various provisions recommended or regulation

1 change.

2 But this letter serves as an opportunity for the  
3 Agency to look at the intent and then it came back on intent  
4 without triggering some of those statutory provisions about  
5 making decisions.

6 CHAIRMAN KIMSEY: And this is Paul Kimsey really  
7 quick in Richmond. And I should have introduced Dr. Riley  
8 better to the Committee. And let me do that real quickly.

9 Dr. Riley is the Chief Deputy in the Department of  
10 Public Health for Policy and Programs. He reports directly  
11 to Dr. Horton, Mark Horton, who is the Director of the  
12 Department of Public Health who is the signature of the  
13 letter.

14 And I, as the state laboratory director, report to  
15 Dr. Riley. So, I'm sorry, I should have introduced or  
16 explained his role prior to having him talk a bit.

17 With regards to --

18 DR. RILEY: Paul --

19 CHAIRMAN KIMSEY: -- yeah, with regards to the  
20 letter I think it's good to have a general discussion. I  
21 think it's fairly straight forward to say that the letter,  
22 that the four bullets there, that, where Agency expressed  
23 and the Department expressed concern about the direction  
24 that the regulations are going, about the reduction, the  
25 continued reduction of the state role in the Forensic

1 Alcohol Oversight Program.

2           And I think the final paragraph or the final  
3 sentence where Dr. Horton in this letter says, recognize the  
4 work of the Committee and encourages the Committee to  
5 continue to work with CDPH on a solution that does not  
6 diminish public health and safety by ensuring independent  
7 state oversight or forensic alcohol analysis.

8           With that I'll just sort of open it up to the rest  
9 of the Committee for their comments.

10           COMMITTEE MEMBER SHEN: This is Jennifer. I guess  
11 I feel compelled to say that I don't believe in any way,  
12 shape or form that this Committee's products would diminish  
13 public health and safety.

14           I actually didn't care for that last sentence. I  
15 think we're working very hard to modernize our things and  
16 the way that we think is best for public safety.

17           Certainly, there are going to be disagreements  
18 about that and I imagine they will be made out to the  
19 Department but I certainly do not feel like we're trying to  
20 diminish public safety.

21           I think we are trying to come up with a product  
22 that will ensure that we get the best modern adaptations.

23           CHAIRMAN KIMSEY: Jennifer you're breaking up a  
24 little bit. I don't know what the speaker situation is like  
25 in San Diego but there were a couple of break ups in your

1 comments.

2 COMMITTEE MEMBER SHEN: Do you want me to say it  
3 all over again?

4 CHAIRMAN KIMSEY: No. I think we got the gist of  
5 it. It's just that, I think for future discussion everyone  
6 should try and get to close to a microphone. It helps our  
7 stenographer with his job.

8 Other comments, other -- (loud static on line).

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
10 I heard that.

11 CHAIRMAN KIMSEY: -- other comments from the  
12 Committee or the public?

13 MS. LOUGH: This is Patty Lough, member of the  
14 public, San Diego. I'd like to commend the Committee for  
15 submitting their recommendations, sort of in line with the  
16 intentions of AB 599 where, you know, the intent was to get  
17 it submitted by December and I'd like to thank the Committee  
18 for meeting that intention that we have even though the  
19 Governor did not sign that bill.

20 CHAIRMAN KIMSEY: If there, are there any other  
21 comments on the letter? If not, I think we need to sort of  
22 have a discussion about what we do next.

23 As I mentioned, we do have a new agency secretary.  
24 And I think, obviously, there is a number of options.

25 One of which is to re-submit this letter or a

1 letter along the same lines to the new agency secretary to  
2 see if there is a different reading of the Committee's  
3 request.

4 And other options that people can --

5 COMMITTEE MEMBER SHEN: This is Jennifer in San  
6 Diego. You know, giving it some thought one of our options  
7 which I don't think is necessarily a bad one is that, you  
8 know, Title 17 is something that the Committee is putting  
9 together.

10 We, as experts in our fields, are putting together  
11 standards and requirements that we feel should be followed.

12 That actually, I mean, I do understand the point of the  
13 letter. And I'm actually not surprised by it.

14 There is a possibility that we could add back in  
15 an oversight by the Department but that oversight would have  
16 to come, oversight of Title 17 as we have written it.

17 And I think that might be our best bet as far as,  
18 you know, we as a Committee decide what provisions to cut,  
19 what the program needs to be like.

20 The Department ensures that we are following those  
21 guidelines. So that is an option for us.

22 I don't, I think that the letter primarily takes  
23 issue with the fact that we have cut any of the state's  
24 oversight out of it.

25 And I think we've done that because of all this

1 past history we have. But if we want to have state  
2 oversight it just has to be very clear in everyone's mind  
3 that that state oversight is over the requirements that we  
4 have written and we approve of.

5 So that might be a compromise that we can make.

6 CHAIRMAN KIMSEY: Okay. Other discussion?

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
8 Yeah, this is Bob Haas from DPH but speaking for the public.  
9 Can you amplify a little bit on that Jennifer. I mean the  
10 PT now is an ASCLD provided PT that's confidential.

11 Are you suggesting that a similar proficiency  
12 testing program be in place, but then would be reviewed by  
13 DPH?

14 COMMITTEE MEMBER SHEN: What I am suggesting,  
15 that's a great example. I mean for us it's inefficient for  
16 us to have to run proficiency tests through ASCLD because  
17 that's what we're required to do and also run another  
18 proficiency test issued by the Department that doesn't meet  
19 the guidelines that we need.

20 So a good compromise may be that we just do the  
21 proficiency test provided by approved providers. You know,  
22 the Department may eventually meet those guidelines. I  
23 don't know.

24 But that the state would then just, the Department  
25 would just ensure that the laboratories have, in fact,

1 completed and passed the proficiency test given by the  
2 approved providers.

3           So the Department would no longer be providing  
4 proficiency tests for us but they would be ensuring that  
5 we've taken the ones that we need to take.

6           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
7 Thank you. I think that's a constructive suggestion.

8           COMMITTEE MEMBER SHEN: So I guess, I think  
9 ultimately that in all of these areas we can come up with  
10 the same kind of concept.

11           You know, that trainees have to have this kind of  
12 educational background that we all decided appropriate. And  
13 the Department ensures, before we start a new employee in  
14 the training program, that they have that background.

15           COMMITTEE MEMBER WONG: This is Kenton Wong from  
16 Richmond. Jennifer I agree. It think in light of the tone  
17 of the letter, I think that our only option is some type of  
18 compromise despite the fact that Senate Bill 1623 basically  
19 wrote out Department of Public Health oversight over  
20 forensic alcohol analysis.

21           I think somehow we have to compromise and appease  
22 that part of Health and Human Services to have some type of  
23 quasi-oversight if you want to say in some fashion.

24           MS. LOUGH: Patty Lough, San Diego. I believe  
25 that is, that's in force because Health and Safety Code

1 100725 says, the state will enforce it. So that's there.

2 And what the state will enforce that are the  
3 regulations as made up with the FARC.

4 So, I mean, you kind of already have that in  
5 place. There's really no need for the regulations to put  
6 enforcement. That's already in Health and Safety Code.

7 COMMITTEE MEMBER ZIELENSKI: Torr Zielenski from  
8 Sacramento. I agree with Dr. Kimsey that perhaps it's not  
9 that we've heard back from the new director to find out  
10 whether her opinion is sustained as past director and, if  
11 so, perhaps seek language guidance from somebody within the  
12 Department to find out, you know, what language can you  
13 change, what this definition of oversight is.

14 Is that a problem with enabling legislation at the  
15 outset? We're in this modifying Title 17, how much can we  
16 relieve Title 17 with respect changing and altering enabling  
17 legislation which has been sent out previously?

18 We have the ability to change the enabling  
19 legislation and to change potential oversight regulation in  
20 places where it's within the means of the Committee.

21 So what are our, what powers does the Committee  
22 have? Are we simply relegated to assess the terms and  
23 positions in a way which is in Title 17?

24 CHAIRMAN KIMSEY: Mr. Chi do you want to advise  
25 the Committee?

1           COMMITTEE MEMBER CHI: Well I think that might be  
2 problematic in that any legal opinions that come out of the  
3 Department would basically be doing the work of the  
4 Committee in terms of what the, setting parameters of what  
5 the Committee can and cannot do.

6           I think the issue seems to be the Committee needs  
7 to, and the letter from the Department on December, on the  
8 third, on, from the Department on December 15th is that it  
9 lays out the Department's concerns.

10           So I think I agree with Dr. Kimsey too that the  
11 Committee needs to take, probably revisit at our end and  
12 make sure that regulations that in terms of oversight  
13 comports with the intent and the language of the letter.

14           CHAIRMAN KIMSEY: Also to that point, it's my  
15 understanding, you know, that the legislation is legislation  
16 and we can't, I don't think this Committee, I mean, we  
17 can't, I think go back from the legislation or we can't put  
18 back something that has been legislated.

19           Obviously, the regulations that were left are what  
20 we've been working with. So, and I think, if there is a  
21 sentiment that we want to keep some of the governmental or  
22 state department oversight we can, you know, we've talked  
23 about proficiency testing. It sounds like maybe the  
24 Department would need to, sort of, be tracking the  
25 proficiency testing.

1           But if I remember some time back, I'm not exactly  
2 sure which of our 17 meetings but some of the early meetings  
3 we talked about that the way the legislation is written and  
4 some of the discussions we've had, the Department won't even  
5 know, I think currently, who's doing forensic alcohol  
6 testing in the state based on the way, the combination of  
7 the legislation and the way that the Committee had been  
8 thinking about writing these regulations.

9           So I think if the Committee, if we're having the  
10 sentiment that we want to, sort of, re-look at some of that;  
11 this came, I think, because the legislation says, that the  
12 Department will not license or register or any other  
13 terminology. And so it would be very difficult for us to  
14 track proficiency testing, I think.

15           Because if the laboratory, if we don't know the  
16 laboratory is operating and they don't send us any  
17 proficiency testing information they're still off the radar.

18           So --

19           MS. LOUGH: This is Patty Lough. The  
20 documentation we've had over the recent years from the  
21 Department of Public Health has been that the citation of  
22 Health and Safety Code 100725, in those documents it is  
23 maintained that that agency is responsible for enforcing the  
24 regulations.

25           And I have all those copies with me. So, if my

1 understanding that during the 17 meetings that we've been  
2 having on Committee, during that time the Department has  
3 been enforcing the regulations as they've been today.

4           With that said, I don't think the Department is  
5 monitoring all the proficiency testing. They certainly are,  
6 have the ability to do so.

7           I am not aware of any laboratories receiving  
8 onsite inspections which is a major issue that was raised at  
9 the State Board of Audits in the audit that was conducted.

10           So, if we look at what has been happening now with  
11 the Department having full enforcement abilities I think we  
12 just simply go back and look at the Health and Safety Code  
13 which was the most recent changes to the law. And if we  
14 look at Health and Safety Code 100703.(d) it says, the  
15 review committee will determine the regulation. There  
16 doesn't really need to be anything in there about the state  
17 oversight.

18           Health and Safety Code 10075 says, the state will  
19 enforce those regulations. The state can decide how they  
20 want to do that.

21           If they want laboratories to submit information to  
22 them. Laboratories can do that. If they would like to come  
23 inspect laboratories, they can come do that.

24           We do know in the history of the Department that  
25 the average inspections occurred every 10 years and labs

1 could expect an inspection once every 10 years.

2           And that was during previous budgetary times. So  
3 I think if we did give them the two documents and two Health  
4 and Safety Codes, the state can ask for any documentation  
5 they need. They don't need to be involved in the regulation  
6 other than having a representative on the review committee.

7           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
8 Comment from the public. I'm thinking back to one of our  
9 first meetings. We talked about the purpose of regulations.

10           And the purpose of regulations is to clarify and  
11 make specific requirements of, typically of laws, perhaps  
12 court decisions, but typically of laws like the Health and  
13 Safety Code.

14           The fact that we have, the Committee now has  
15 proposed forbiddance to the regulations that would eliminate  
16 the current regulatory authority, for instance, to do site  
17 inspections.

18           The current regulatory authority to require labs  
19 to provide information, provide records to, current  
20 regulatory authority to evaluate proficiency testing. I  
21 suspect that having done that, those are the regulations.  
22 Those regulations are just as binding on the Department as  
23 they are on the laboratories.

24           It would be impossible, I was going to say,  
25 difficult; but impossible, to conduct an oversight and

1 enforcement program in light of the proposed revisions to  
2 the regulations.

3           The reason that we are continuing to do it, we  
4 have done some site inspections. The reason, and we have,  
5 we do still qualify personnel. We conduct a proficiency  
6 testing program. I forget the other bullet.

7           The reason we continue to do those things is  
8 because it's exactly what the regulations, which haven't  
9 been changed yet, prescribe.

10           COMMITTEE MEMBER SHEN: This is Jennifer. I  
11 completely understand what you're saying. And again, my  
12 concern really at the end of all this, what I want, are  
13 updated, modern regulations.

14           And I want it to be very clear what it is that is  
15 and is not expected. We do not want to go back to a time  
16 where there's a lot of interpretation, a lot of external  
17 requirements.

18           So I actually have no problem with the state  
19 having oversight as long as it's, it's narrowly restricted  
20 to what we decide is a legitimate process.

21           So, I understand that we already have a lot of  
22 place that says, the Department will get to, will have  
23 oversight but I equally understand when these have been  
24 written really it takes the Department out of that oversight  
25 role.

1           We've been so frustrated by it in the past and it  
2 hasn't seemed to work well for us.

3           So, I do believe we can come to a compromise as  
4 long as the regulations are written in a manner that we, as  
5 experts, feel is appropriate.

6           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
7 A follow up comment from the public. I think the Committee  
8 is maybe deluding themselves a bit in presuming that we've  
9 re-written the regulations in such a fashion that we have  
10 changed that much at all.

11           With the exception of, I would characterize the  
12 changes, for the most part, as simply, removing every  
13 section in the regulations which clearly ascribed an  
14 oversight role to the Department, we removed that.

15           But in terms of writing regulations that the  
16 Committee now feels more comfortable with, I submit we've  
17 made very few changes.

18           COMMITTEE MEMBER SHEN: I disagree with that.  
19 I don't think that's really --

20           MR. PHILLIPS: This is Bill --

21           COMMITTEE MEMBER SHEN: -- pertinent to our  
22 discussion at the moment.

23           MR. PHILLIPS: Bill Phillips in Sacramento. You  
24 know there's a fundamental difference between the  
25 understanding of what the Department does with regulations

1 and what ASCLD does with your guidelines.

2 And that's a key component of this discussion.  
3 ASCLD lets you do whatever you want with performance, with  
4 accredit, with procedures as long as you can get the right  
5 answer on the proficiency testing.

6 Whereas the Department wants to make sure that the  
7 procedures are written right and then sent out, proficiency  
8 tests to see whether or not it works.

9 And I think we need to get over that. We need to  
10 understand what ASCLD is. There are so many disciplines  
11 within the forensic community that are not regulated and  
12 they do find and they show that on their proficiency testing  
13 that we need to understand what the fundamental difference  
14 is between ASCLD and the Department. And then direct  
15 ourselves in that direction.

16 COMMITTEE MEMBER SHEN: This is Jennifer. I have  
17 to say, I completely disagree with your assessment of what  
18 ASCLD is. It is not a body that allows you to do just  
19 whatever you want.

20 And if you manage to get your proficiency just  
21 right you're all good. It is a very rigorous program that  
22 looks at everything we do, our security of our evidence, our  
23 chain of custody, our procedures, do they make sense, do  
24 they follow scientific guidelines.

25 You know, are you doing what you say you're doing?

1 Is it, you know, is it something that is accepted in the  
2 scientific community? There's a myriad of aspects to our  
3 ASCLD accreditation and to diminish it down to, as long as  
4 you get proficiency tests right, you're good, is just, it's  
5 not accurate.

6 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
7 Jennifer I probably made a misstatement in that. That, you  
8 know, I, my laboratory is ASCLD/ISO accredited.

9 So I know what the procedures are. I know what it  
10 does but what I'm missing is what does the Department do  
11 with our regulations and why do they need to do that when  
12 other disciplines within the forensic community are not  
13 regulated and we seem to be doing fine with those.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
15 Comment from the public. We've asked and answered that  
16 question dozens of times in the 17 meetings.

17 The recent forensic alcohol analysis, the breath  
18 alcohol procedures related from this forensic alcohol  
19 analysis are regulated is because the laws says to regulate  
20 it.

21 So the rubric that somehow this really we should  
22 be answering and we don't need to ask that question anymore.

23 The other point though, I kind of like Bill's  
24 description of the ASCLD/LAB Program.

25 COMMITTEE MEMBER SHEN: (laughter) I'm sure you

1 do.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 But I do think that going back to which that the comment  
4 that you thought was irrelevant regarding how much we've  
5 changed the requirements of the regulations, I think the  
6 issue here is really, and in regs speak, I think the issue  
7 here is really, prescriptive requirements versus performance  
8 requirements.

9 And I think that's actually what Bill was talking  
10 about.

11 I would submit that our regulations after 17  
12 meetings are still very prescriptive.

13 We define the type of standard that you can use,  
14 when that has to be run. We define the QCs and the  
15 concentration ranges of the QCs and the qualifications of  
16 personnel who can interpret an out-of-control result. We  
17 define the way those QC records have to be retained.

18 You guys are familiar with this so these are very  
19 specific requirements. The goal was to make forensic  
20 alcohol analysis testing pretty much uniform throughout, I  
21 mean, uniform throughout the state.

22 Bill asked, why regulate this testing when other  
23 forensic disciplines aren't tested. One of the reasons,  
24 again the main reason, is because the state tells you to do  
25 that because the law tells you to do that.

1           But the other reason is that there are hundreds of  
2 thousands of cases each year.

3           So the state often chooses to regulate activities  
4 that impact lots of folks. Lots of folks unfortunately get  
5 involved with drunk driving situations.

6           But I do think that we have very prescriptive  
7 regulations. And to the extent that there is an oversight  
8 program the oversight would have to evaluate laboratories in  
9 terms of those prescriptive requirements and I submit that  
10 we haven't changed the regulations at all with regards to  
11 that.

12           CHAIRMAN KIMSEY: Other comments? Back to the  
13 letter and I think just to sort of stimulate maybe some more  
14 discussion I'll try and summarize a little bit of what I've  
15 been thinking I've been hearing.

16           I think that maybe the Committee, we're thinking  
17 about re-looking at our package in light of this letter and  
18 the suggestions as pointed out in the bullets to re-think  
19 the relationship of the Department as to the Department's  
20 role to some extent in overseeing, you know, the forensic  
21 alcohol program.

22           And maybe, and this is my own thought just to  
23 throw out in the sense, maybe trying to harmonize the  
24 Department's role with other accrediting organizations  
25 whether it's ASCLD or some other organization.

1           Obviously there's a tremendous workload out there  
2 that maybe the state can partner with and be involved with  
3 to try and have a more efficient oversight of the community.

4           And, you know, as long as I think, you know, the  
5 state has a role and that's going to remain we need to see  
6 that it's an efficient role and isn't duplicative, isn't  
7 onerous; but it adds value to, you know, everything that's  
8 going on with regards to accreditation and oversight.

9           That last little part was my own thought but I  
10 think the Committee is, the summary part is that we're re-  
11 thinking the regulations and the Department's role in light  
12 of this December 15th letter. Is that accurate to say?

13           COMMITTEE MEMBER SHEN: This is Jennifer. I think  
14 that we might have to. And, I mean, I agree with you.

15           If there's going to be any state oversight, you  
16 know there's been so much frustration over the years with  
17 the state oversight. It has not been efficient.

18           It has not been in step with what we the  
19 laboratories think it should be.

20           So if there is going to be some partnership  
21 between accrediting bodies and the state it needs to be in a  
22 manner that isn't duplication of effort.

23           And I think the proficiency tests is a great  
24 example of that. I am still (indiscernible) to why the  
25 state feels that it needs to be involved in issuing

1 proficiency tests.

2 I completely understand why it would want to  
3 ensure that they're being done but this is something that  
4 we've been trying to move on and we're getting a lot of push  
5 back on that.

6 I don't know why we should do proficiency tests  
7 that are not up to what is in the law as standards.

8 You know, so this kind of thing creates a tension.

9 I'm guess I'm not seeing that let's work this out has come  
10 up with a very efficient process is that we've always done  
11 it this way and we're going to continue because the law says  
12 we can.

13 But just because the law says you can does not  
14 mean it's being done in the most efficient way possible.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 Comment from the public. I think the proficiency tests is a  
17 good example. And I think we should probably have a candid  
18 discussion about it, a more thorough discussion.

19 You seem to emphasize the efficiency role. A  
20 large lab analyzes thousands of blood samples a year, ten of  
21 thousands for a very large center.

22 So I assume you, it sounds like your primary  
23 argument is that it is very inconvenient and costly for the  
24 laboratory to analyze, you know, several, one to two extra  
25 proficiency test samples a year. That's your primary

1 argument?

2 COMMITTEE MEMBER SHEN: Yeah, that's, I mean that  
3 isn't my primary argument actually because I understand that  
4 it doesn't take much time. But what we're doing is we're  
5 engaging ourselves in analysis that does nothing for us.

6 It does not meet what we need to meet as far as  
7 what the law says. It doesn't do anything for us as far as  
8 our accreditation. It's just an extra thing we have to do  
9 to appease an oversight body.

10 And to me, I want to get rid of those things. I  
11 don't want to do extra things that make no sense. And I  
12 don't really care if they take an hour or one day.

13 To me there is no point in doing those things. So  
14 if we can come up with a relationship that's efficient and  
15 meaningful and that everything we has straight meaning then  
16 it's worth it. If we can't, then it isn't.

17 MR. LYLE: Bruce Lyle. And my understanding was  
18 the inefficiency was not necessarily having to, you know,  
19 take the time in the lab to do the actual analysis on the  
20 proficiency tests but to await results from the base and to,  
21 you know, the lag time that that took.

22 And I thought that that was part of the genesis of  
23 Senate Bill 1323 was to try to streamline that.

24 COMMITTEE MEMBER SHEN: This is Jennifer. It's  
25 not probably all that efficient for the state to be

1 expending monetary funds creating proficiency tests that do  
2 not meet the requirements of the law.

3           So, I mean, you can look at the efficiency from  
4 many, many different levels. Perhaps that money could be  
5 better spent by the Department doing something that is more  
6 meaningful than issuing a proficiency test that is not what  
7 we need it to be.

8           COMMITTEE MEMBER CHI: This is William Chi in  
9 Sacramento. I think it might be instructive to look at the  
10 December 15th letter. In the second page there's a  
11 paragraph that I think the essence of the letter really laid  
12 out in that last sentence of the second paragraph where it  
13 says, the substitution of the ASCLD/LAB requirements for the  
14 current program would not achieve the statutory mandate of  
15 ensuring the competence laboratories and their employees  
16 performing chemical testing in support of California's  
17 drinking-and-driving laws.

18           I don't see any letters about proficiency testing  
19 but I think that last sentence in that paragraph really lays  
20 out Agency and the Department's concerns and, perhaps, that  
21 we can come up with the language or regulations that would  
22 address that.

23           And I think that would appease Agency's concerns.

24           COMMITTEE MEMBER SHEN: Yes, this is Jennifer.

25 You know, this might be as easy as adding one extra, instead

1 of going back and re-writing a lot of this, it may be as  
2 easy as adding in a little section that outlines what, in  
3 fact, that oversight would be.

4 I would hesitate to just blanket oversight again  
5 where the Department can ask for all sorts of things that  
6 they are no longer getting. But we may be able to just put  
7 in a little something that says, you know, the Department  
8 will have oversight of these things and have the ability to  
9 ask for this that and the other thing to ensure that the  
10 laboratories are complying with these regulations.

11 COMMITTEE MEMBER WONG: This is --

12 COMMITTEE MEMBER CHI: That might work as long as  
13 the, I think it might be instructive to also have this  
14 harmonize the Department's and would allow, you know, to  
15 focus more, what's more of a concern on the Department's  
16 concern on how the (indiscernible) and working with the  
17 Committee to come up with language that might be acceptable  
18 to both the Committee as well as Agency.

19 COMMITTEE MEMBER WONG: This is Kenton. I agree  
20 with everyone in what we've been saying. But the bottom  
21 line is that the Health and Safety Code on 100725 talks  
22 about enforcement by the Department and the Department has  
23 been stripped of that because basically it always used to be  
24 stripping of your laboratory license and that is not an  
25 issue anymore.

1           So why we can work toward cooperating and having  
2 some type of blend between whatever it is in trying to work  
3 things out and meet some kind of compromise, ultimately the  
4 enforcement still is going to be the issue.

5           I mean, it says that they still have the  
6 requirement to enforce the laws and regulations but they  
7 don't have any power to enforce that. So what's going to  
8 happen?

9           COMMITTEE MEMBER CHI: Well let me just take, let  
10 me just clarify that. The Department was, the Department's  
11 licensing and the licensing power was taken away but the  
12 language on the Department's ability to enforce the  
13 regulations was not stripped.

14           So I think when you inquired about that point that  
15 the statute still has a role, the statutes of the language  
16 for (indiscernible) to play in this is that the licensing  
17 power has been taken away.

18           COMMITTEE MEMBER WONG: Which means, what can  
19 Department do? Suppose a laboratory goes rogue and doesn't  
20 do these things and follow things, what is the Department  
21 going to do?

22           How are they going to physically enforce that?  
23 How are they going to make the lab comply?

24           COMMITTEE MEMBER CHI: I think that's something  
25 that can be laid out by the Committee in the regulatory

1 language and still have that enabling statutory authority  
2 based on the enforcement powers that the statute lost and  
3 the Legislature lost the language.

4 I think that's the issue that the Committee has to  
5 deal with. And that's, I think that's the intent of the  
6 December 15th letter is to have the Committee work with the  
7 Department in coming up with language that's satisfactory  
8 and achieves the statutory mandate of the Department having  
9 a role and enforcement power or an enforcement role still in  
10 the whole program.

11 COMMITTEE MEMBER ZIELENSKI: Torr Zielenski. What  
12 troubles me is that where nobody really knows what this  
13 letter means.

14 We're all sitting here reading this thing and  
15 trying to interpret, you read one sentence, you read the  
16 previous sentence and it said, while we agree that voluntary  
17 accreditation programs are important, ASCLD/LAB guidelines  
18 do not establish specific laboratory performance or  
19 procedure standards for blood alcohol analysis, nor mention  
20 breath alcohol analysis.

21 What do they want us to do with respect to that?  
22 Then it gets into a next sentence that was just mentioned  
23 here. And, you know, we read that paragraph and the  
24 sentences there and we're trying to interpret what it is  
25 that this letter means.

1           First of all, what is the import and significance  
2 of this letter? Is this binding? In other words, I don't  
3 know who this person is that responds this way and simply  
4 notifies everything that we've done and then basically  
5 (indiscernible) everything we've done and basically says,  
6 you know, (indiscernible) is not up to snuff.

7           We interpret it and we can't figure out what it is  
8 that he's talking about. Is there somebody that can assist  
9 the Committee from that Agency to be more specific about  
10 exactly what it is that their concerns are.

11           It appears cryptic. It appears vague. We're  
12 trying to interpret. If we take action we're speculating  
13 that that's going to, you know, suffice for them later on.

14           So, and this is important because I remember it's  
15 something we talked about very early on. And we remember we  
16 never got an answer to that and, you know, what is the,  
17 what, you know, what is the function (indiscernible) it  
18 seems like it was to (indiscernible) Title 17 requirements,  
19 assess those things and determine whether or not they're  
20 updated and make sure they're modernized.

21           And there's also this issue about getting the  
22 Department out on worker sites which is (indiscernible) part  
23 of the enabling legislation.

24           This paragraph here seems to be addressing  
25 something that we may not be able to remedy. And --

1 COMMITTEE MEMBER SHEN: This is Jennifer in San  
2 Diego --

3 COMMITTEE MEMBER ZIELENSKI: And so how can we --

4 COMMITTEE MEMBER SHEN: -- I'm sorry, we are  
5 having such a hard time understanding you. I know you're  
6 making great points but we're missing them.

7 Can you get closer to the microphones?

8 CHAIRMAN KIMSEY: Uh-oh, the microphone just went  
9 off.

10 MR. SEDGEWICK: Whomever that was we could hear  
11 him real well.

12 CHAIRMAN KIMSEY: Yeah, that's Paul. Okay.

13 COMMITTEE MEMBER ZIELENSKI: How's that?

14 CHAIRMAN KIMSEY: Okay, that's better. I'm not  
15 sure for San Diego but we can --

16 COMMITTEE MEMBER ZIELENSKI: The overall point  
17 that I'm making is that we sit here with letter and we are  
18 trying to interpret what the letter means.

19 To me the letter is vague. It's cryptic. It  
20 doesn't, you know, why can't the response even state  
21 specifically, here is the problem with what it is that you  
22 submitted to us?

23 This is how they should be remedied. And to  
24 assist us in the process of making this legislation work. I  
25 don't know whether or not there is anything this, that this

1 Committee can do that's going to suffice for the Department  
2 with respect to this.

3           So this whole thing really seems vague and it  
4 almost seems, to a certain extent, illusory. And if not,  
5 can't we get some assistance from them specifically as to  
6 what they want us to do in terms of the language that there  
7 having a problem with; to come forward and do this in a  
8 timely fashion so we're not spending 17 meetings addressing  
9 issues that we had five years ago.

10           And then still now with counsel here, legal  
11 counsel, everybody is speculating about what this letter  
12 means.

13           One, we don't even know whether or not the new  
14 governor and the new director would interpret it in the same  
15 way.

16           And, you know, what if they're new, my guess is,  
17 again I'm speculating but my guess is we might get a similar  
18 opinion but what if somebody else looked at this and says,  
19 no, we don't agree with that at all? Then this whole thing  
20 would be moot.

21           So that seems to me it might be a threshold issue.

22           Secondly, maybe we could send this thing back with  
23 the idea that if somebody could interpret what we've  
24 submitted, evaluate it, determine whether or not it's  
25 sufficient or if it's deficient.

1           If it's deficient, tell us why it's deficient and  
2 see what we can do with it, otherwise we're just looking  
3 for --

4           It's like a needle in a haystack. We're looking  
5 for a needle in the haystack, speculating about what they  
6 want.

7           And I'm not sure that we're on the same page. It  
8 would assist us if we were on the same page. It would  
9 certainly help us to focus our analysis in this, in terms of  
10 doing what we're doing if we knew exactly what we needed to  
11 do.

12           That's just my point. And, again, you know, this  
13 is all science. It seems to me that Title 17 an aspect of  
14 it but the Department seems to be having a problem  
15 potentially with some of the science aspect in the preceding  
16 sentence but also with enforcement and oversight.

17           And it seems to be kind of looking at those  
18 concerns. So, you know, it appears that we're all a bit  
19 confused.

20           If there's anybody that has a very clear mind set  
21 about what this letter means and specifically how to remedy  
22 the deficiency in terms of what we've submitted then, you  
23 know, I'd like to hear it and so we could flesh it out and  
24 figure out why that's not what we should do.

25           If not, I'm looking for some guidance from

1 somebody outside of this Committee to assist us in being  
2 able to perform our function because it seems to me the  
3 people that hold the power and the leverage have submitted a  
4 response to us that to me is vague and cryptic and difficult  
5 to discern, at least in my mind.

6 COMMITTEE MEMBER SHEN: This is Jennifer. Those  
7 are excellent points and I would also say that the letter is  
8 inaccurate as well.

9 There are statements in this letter that are not  
10 accurate and perhaps there needs to be some education for  
11 those people who are reviewing our product.

12 CHAIRMAN KIMSEY: Well this is Paul in Richmond.  
13 Obviously, there's some lack of specificity in the letter  
14 but I think the four bullets pretty clearly talk about where  
15 the Department and Agency thought that the regulations were  
16 problematic.

17 In other words it talked about the fact that  
18 they're proposing to remove more of the Department's  
19 oversight on, in the past what was done by the legislation.

20 So, and that, we have had numerous discussions  
21 over the 17 meetings on what the Department oversight should  
22 be. And we've had numbers of votes. And, you know, it's  
23 been pretty, the Committee has been quite clear that they  
24 have wanted to remove further the Department's oversight.

25 So, to that extent I think the letter has some

1 clarity. Obviously, you know, we did the Department or the  
2 letter does not go, you know, particular regulations section  
3 by section but it certainly does give us an idea of, you  
4 know, the removal of the Department's oversight is, was, is  
5 by this letter problematic.

6 DR. RILEY: Dr. Kimsey, this is Kevin Riley. I  
7 would personally like to hear a little bit more specificity  
8 on the concern that there were inaccuracies in the letter.

9 And if that is the case I think that that's very  
10 important for the Committee to hear if there was something  
11 misperceived by the Agency, Department and portrayed in this  
12 letter that is inaccurate, I very much want to hear it, the  
13 specificity there.

14 COMMITTEE MEMBER SHEN: Hi, this is Jennifer. The  
15 inaccuracy that jumps out at me is that, let me read it  
16 here, while we agree that voluntary accreditation programs  
17 are important ASCLD/LAB guidelines do not establish  
18 specific laboratory performance or procedure standards for  
19 blood alcohol analysis.

20 That is inaccurate. I do agree that our present  
21 alcohol program, unless you are accredited as an calibration  
22 laboratory there are, the ASCLD/LAB does not currently  
23 accredit breath alcohol but it certainly does toxicology  
24 would certainly include blood alcohol and our labs --

25 My own experience, our labs inspection that we

1 had, the, our inspector was quite knowledgeable in the area  
2 of forensic alcohol analysis and he had some issues that he  
3 wanted us to address but it made our program much, much  
4 better.

5 So to say that it is not covered is an inaccuracy.

6 DR. RILEY: Well I believe the language says,  
7 guidelines do not establish specific laboratory performance  
8 or procedures standards for blood alcohol analysis. Is that  
9 accurate or not?

10 COMMITTEE MEMBER SHEN: I guess I --

11 DR. RILEY: The guidelines?

12 COMMITTEE MEMBER SHEN: -- I feel like we're sort  
13 of pressing words. I mean, our, we have to have procedures.  
14 They have to be legitimate procedures. They have to be  
15 scientifically acceptable.

16 And we have to ensure that the things that we're  
17 doing, ensure that we are giving accurate results.

18 So, I mean, do they say, you have to do it this  
19 way, that way, the other way? No. But they look at our  
20 procedure in general and it must meet general, scientific  
21 principles.

22 It has to be generally accepted in the community  
23 and you have to ensure with blanks and linearities and  
24 controls, calibrators et cetera that the results that you  
25 are giving are accurate.

1 DR. RILEY: So the substitution for the ASCLD  
2 guideline standards as they extent right now, the conclusion  
3 in this letter is that they do not achieve the mandates of  
4 ensuring competence in the laboratories.

5 And, again, I hate to parse the words but I do  
6 want to have a very clear understanding of why there is a  
7 concern that or if there is a difference in opinion that  
8 those requirements, if they are placed into regulation to  
9 replace the existing regulatory framework, it looks like the  
10 Agency and the Department feel that that's not meeting the  
11 statutory requirement around competence of laboratory  
12 testing.

13 And I just want to get a feel for that, about our  
14 justifications and arguments around that. That was almost  
15 as clear, I can, sorry --

16 I hope you hear what I'm saying that I heard  
17 William say the (indiscernible) substitution of the  
18 requirements for the current program would not achieve the  
19 statutory mandate, ensuring competence in the laboratories  
20 and the employees that are performing the testing.

21 If there's just a base disagreement on that  
22 conclusion I want to parse it down to what the difference  
23 between the two are.

24 MS. LOUGH: This is Patty Lough --

25 DR. RILEY: And --

1 MS. LOUGH: Patty Lough in San Diego. You're  
2 questioning competent laboratory testing, these regulations  
3 while the justifications (indiscernible) many times  
4 ASCLD/LAB guidelines, these regulations as written by this  
5 Committee are the regulations that were determined to  
6 provide competent laboratory testing regardless of what  
7 agency someone is accredited with.

8 There is a discussion talking about that it's in  
9 compliance which also includes ISO standards which is pretty  
10 big.

11 But these regulations on their own worked out by  
12 the Committee to be those that are necessary to establish  
13 competent laboratory testing. It really has no, makes no  
14 difference whether a lab is accredited or not because there  
15 are private laboratories doing forensic alcohol work for law  
16 enforcement agencies that are not accredited by anyone.

17 So it's just that the majority doing work are also  
18 accredited. And there are redundancies. And that's  
19 probably why it's mentioned over and over again.

20 But the scientific methods that are established  
21 that are in here by this Committee do provide competent  
22 laboratory testing to provide good results for the state of  
23 California.

24 So it really isn't even an issue whether or not  
25 ASCLD/LAB tells everyone what their procedures are going to

1 be. The procedure is as written by this Committee.

2 And I don't think anybody here is going to argue  
3 that the highest level standards have not been included in  
4 these regulations.

5 DR. RILEY: I apologize. I have just one more  
6 question. In the proposed regulations by reference or that  
7 language is put in.

8 And, again, I read this to say that the  
9 substitution of the ASCLD program for the current, existing  
10 regulatory program does not present the same protections,  
11 the same assurance of competence.

12 And now I hear that the regulations, the proposed  
13 regulations have that specificity of procedure is not or by,  
14 is not adopting the ASCLD --

15 MS. LOUGH: Right.

16 DR. RILEY: -- program. So I'm just wanting to  
17 make sure I understand.

18 MS. LOUGH: Patty Lough again, San Diego. You  
19 know that is something that has been argued from the time  
20 this Committee started meeting when I was a member of the  
21 Committee.

22 There seems to be a misunderstanding that the  
23 Committee was saying, we're just going to have everybody  
24 follow ASCLD/LAB guidelines for how you do your work.

25 The only place that it specifies that you must

1 follow ASCLD/LAB guidelines is in proficiency testing which  
2 is clearly spelled out in the Health and Safety Code which  
3 is why precisely the state proficiency testing program is  
4 out of compliance. They are not approved providers.

5           Everything else in here, it also follows the  
6 ASCLD/LAB guidelines because the majority of labs are  
7 accredited.

8           So we want it to be able to meet those  
9 requirements. That has nothing to do with whether you're  
10 accredited or not. It does not require that you be  
11 accredited even to trying to improve providers does not  
12 require that you be accredited ever with ASCLD/LABS.

13           So I think that's been a misinterpretation from  
14 the beginning.

15           COMMITTEE MEMBER SHEN: This is Jennifer. I think  
16 this letter is all about oversight. I do not get the  
17 impression that this letter is questioning our scientific  
18 accuracy or legitimacy of the requirements in Title 17.

19           It's questioning who's going to make sure we're  
20 doing them?

21           MR. PHILLIPS: This is Bill Phillips. The  
22 sentence where it says that we are substituting ASCLD/LAB  
23 for the current program --

24           CHAIRMAN KIMSEY: Bill, can you get closer to a  
25 microphone please?

1           MR. PHILLIPS: Sure. The sentence in that last  
2 paragraph, in that long paragraph on the second page that  
3 states, the substitution of ASCLD/LAB requirements for the  
4 current program would not achieve the statutory mandate;  
5 what does that have to do with what we have written here?

6           We're not substituting the ASCLD/LAB guidelines  
7 requirements for the current program. We've written and  
8 changed the current regulation and recommended that they be  
9 changed and adopted.

10           I don't understand the point there.

11           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
12 Comment from the --

13           COMMITTEE MEMBER SHEN: I agree.

14           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
15 Comment from the --

16           COMMITTEE MEMBER SHEN: I agree.

17           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 Comment from the public. I think the letter was responding  
19 to, and you might want to refresh your memory by looking at  
20 it, Jennifer Shen's letter, and although the Agency hasn't  
21 seen the statement of reasons, in both cases the letter and  
22 the statement of reasons frequently, dozens of times, tout  
23 ASCLD/LAB oversight as a reason why some former departmental  
24 oversight is no longer needed.

25           So I think it's, I don't think you can back away

1 from that now. The Committee clearly in its comments, in  
2 the letter in the ISOR have expressed a tremendous amount of  
3 reliance on the ASCLD/LAB program.

4 COMMITTEE MEMBER SHEN: This is Jennifer. Again,  
5 though, we're coming down to oversight. Oversight of the  
6 program. And so I agree.

7 We are not substituting ASCLD/LAB requirements for  
8 what was in Title 17. We took Title 17 requirements and we  
9 updated them, modernized them. We certainly did substitute  
10 what we needed to on the proficiency test section.

11 But these requirements stand alone. And it still,  
12 it comes back down to, this is why I thought the letter was  
13 not really on point particularly, except for the bullets.

14 And the bullets show us, the problem is the  
15 Department doesn't want to have that oversight removed  
16 entirely.

17 And there's no doubt about it, we pretty much  
18 write all that out. In Title 17 you write out all of the  
19 Department oversight and I'm not going to argue that. We  
20 certainly do.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
22 And parsing that letter again and risking the criticism for  
23 doing that. It says, the substitution of the ASCLD/LAB  
24 requirements for the current program. It doesn't say, for  
25 the current regulations. No one is suggesting that you're

1 substituting the involuntary guidelines that don't cover all  
2 labs for the Department's regulations. It refers to the  
3 program. So it's still talking about the oversight  
4 activities that are bulleted in page one of the letter.

5 CHAIRMAN KIMSEY: More comments on the letter?

6 MR. LYLE: Bruce Lyle. I'm sort of with Torr on  
7 my lack of enthusiasm for the letter. What it really  
8 doesn't do for me is that it doesn't really tell me what,  
9 you know, it doesn't spell out in plain kind of language  
10 what is wanted or that they, that the Department, what they  
11 want to do about it. What they want us to do about it or  
12 what they really, really think.

13 I mean, it's kind of, it just seems like it's  
14 hinted at that they're not, that the Department doesn't like  
15 the idea of having total removal of this. But nowhere does  
16 it say, we disagree with that. It just sort of balances and  
17 pushes one against the other, the ASCLD versus the  
18 Department of Health, the Department of Public Health  
19 oversight.

20 So I'm, and I don't know what their, what weight  
21 this letter holds. Does it mean that we have to progress  
22 (indiscernible) forward? Does it put a total halt to it?  
23 Is that what it's saying to me? I don't really know what it  
24 means.

25 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

1 Comment from the public. You all will certainly recall  
2 that the purpose of sending this to Agency was to try to get  
3 some informal clarification of and some feedback about the  
4 direction of the Committee.

5 And now you've gotten that. And albeit it may not  
6 be, you know, the crystal ball that everybody expected but  
7 don't forget that this is more-or-less and off-the-record,  
8 you know, or it's really on the record but it was an  
9 informal attempt by the Committee to not trigger the 90 day  
10 review by Agency but to still get, you know, a review of the  
11 proposed revisions.

12 So, and I think that this, that the letter of  
13 December 15th achieves that and clearly doesn't satisfy most  
14 of you but it was not intended, you're asking, what is the  
15 weight of this?

16 And I don't know the answer to that. I'm not Mark  
17 Horton. And I'm certainly not Diane Dooley but this is  
18 provided, I think some, from the discussion it certainly has  
19 provided at least some direction.

20 MR. PHILLIPS: This is Bill Phillips in  
21 Sacramento. The one thing I think I got from the letter was  
22 it was like a bogey man letter. It was going to scare you  
23 away from doing anything further.

24 And what I would go back to this, the Agency and  
25 say, okay, now we want you to go through point by point each

1 section and explain why you will not accept this particular  
2 section.

3 That's what I think ought to be done. And at this  
4 point, you know, we're left with no explanation that  
5 satisfies us and yet, I still think there are changes that  
6 we've made that will modernize the regulation.

7 We don't see any agency stepping up to the plate  
8 and describing each point, why they rejected it. I think  
9 that's important to do.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11 Well I --

12 MR. PHILLIPS: And the --

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

14 -- no, go ahead.

15 MR. PHILLIPS: I would certainly agree but 1623  
16 says that that is what triggers the 90 day review. And if  
17 the Committee chooses to go that route then I think that's  
18 the Committee's decision.

19 CHAIRMAN KIMSEY: This is Paul in Richmond. I  
20 would agree with, I think it might have been Jennifer Shen,  
21 that made the comment that, I don't think Agency is  
22 disagreeing with the science that the Committee is putting  
23 forth.

24 It really is sort of at the political issue level  
25 or policy level of what is the state's role in oversight of

1 this community? I think, you know, I think they recognize,  
2 I mean this is my personal opinion, they recognize the  
3 authority and the expertise of the Committee with regards to  
4 this specific scientific issues.

5           They're not, you know, obviously not going to be  
6 forensic laboratory, you know, specialists at Agency. I  
7 think they recognize our role for that but they're basically  
8 responding at the policy level which is, you know, state  
9 oversight versus not-state oversight of this particular  
10 laboratory program, laboratory endeavor.

11           So I think that basically they are making the  
12 argument that there needs to be more state involvement in  
13 this oversight.

14           COMMITTEE MEMBER SHEN: This is Jennifer. I  
15 obviously agree with that. That's what I think as well.  
16 And I think as a Committee our plan, what we need to do is  
17 determine what do, what do we want to do at this point?

18           Do we want to finish up our process here and  
19 submit it and make them come back to us point-by-point and  
20 tell us that they won't accept it because there isn't enough  
21 oversight which, you know, is fine with me. But we need to  
22 know that it's probably going to come back that way.

23           Or do we want to attempt to outline what we think  
24 is an appropriate role of oversight for the state and submit  
25 it that way?

1 I think we just have to have a, we have to decide  
2 which way we want to go. And I'm happy to go either way but  
3 I firmly believe that we send it in as is, it's going to get  
4 popped right back at us.

5 COMMITTEE MEMBER WONG: Yeah.

6 MR. LYLE: Bruce Lyle. I agree with that. So I  
7 think what we probably need to do is to figure out what  
8 language we need and where it needs to go to include it,  
9 even though it's probably in the law but to include it in  
10 the regulation where the Public Health Department fits in.

11 COMMITTEE MEMBER SHEN: This is Jennifer. We can  
12 do that by addressing those particular points that are  
13 brought out in the letter I suppose.

14 And I think that we might be able to come up with  
15 some clarity on what is and isn't appropriate and make some  
16 strides towards having a more (indiscernible) and the  
17 accrediting bodies.

18 CHAIRMAN KIMSEY: Other comments from the  
19 Committee on the direction that we seem to be heading? Or  
20 at least the discussion.

21 MR. LYLE: Bruce Lyle. Paul do you happen to know  
22 what any of that language looks like in North Carolina and  
23 how that all washed out, the agreement between the state and  
24 private labs?

25 CHAIRMAN KIMSEY: No. The news article, typical

1 of a lot of news articles didn't get into that level of  
2 detail. And I haven't had a chance to, you know, follow up  
3 with anybody in North Carolina.

4 No. So I don't know specifically.

5 MR. LYLE: Okay, so it's probably too soon to  
6 steal from them anyway.

7 CHAIRMAN KIMSEY: Well and I think this news  
8 article is just, dated January 19th. So it is relatively  
9 recent. I think they had some commissions and some  
10 investigations of the issues back in the late summer or  
11 early fall and they've just, you know, come out with their  
12 recommendations.

13 And so, I'm sure there are folks in North  
14 Carolina that we can follow up with to get the specifics.

15 MR. LYLE: Bruce Lyle. Thank you.

16 COMMITTEE MEMBER ZIELENSKI: Dr. Kimsey. Torr  
17 Zielenski here. Are you aware of, either personally or any  
18 other means, that you might be able to find, or is there,  
19 let me ask you this, is there a single relationship that you  
20 observed in any other state agency with respect to private  
21 industry where there's been the integration of language  
22 dealing with oversight by the state with respect to private  
23 industry going both ways.

24 That might assist us to be able to determine what  
25 the Department wants. And then my other fact that that

1 appears to be what the Agency wants which is to have some  
2 type of oversight and direction.

3           And yet, we're assuming that. And we're inferring  
4 that from the document. It's not crystal clear. They  
5 didn't spell it out (indiscernible).

6           But I think it, and I agree, I think that's really  
7 what they're talking about here. And if there is a means of  
8 figuring out exactly what type of language that may have  
9 been used in other examples where you have this  
10 participation of both private and public involvement, that  
11 might help with assistance in telling what language they're  
12 expecting or what they would want.

13           I wish there was some, you know, agency or, you  
14 know, as opposed to communicating to them via a letter with  
15 the assistance if we actually had somebody there that knows  
16 exactly what it is that they want and need to assist us.

17           They say, here, this is what, this a problem that  
18 we see, that we anticipate. Specifically, and the ones that  
19 you proposed; we could take a look at that and then move  
20 forward.

21           But right now this, the whole document that we  
22 submitted is something that is subject to scrutiny and  
23 revision and we don't exactly know where to focus on  
24 interest and we're still even, with what we got now,  
25 speculating as to what it is that the Agency might be

1 wanting of us.

2 CHAIRMAN KIMSEY: I don't know of any particular  
3 model that comes to mind. I am familiar with a lot of  
4 laboratory oversight and on the environmental laboratory  
5 side and on the clinical laboratory side.

6 You know, I can't think of a specific model. I  
7 think this really gets to, again, the issue of the policy  
8 of, you know, government oversight or not and complying with  
9 the law.

10 I mean, obviously, I think, you know, what the  
11 Agency might want or the Department might want or any one of  
12 us might want, I mean, we're sort of dealing with laws and  
13 regulations. I think to take the letter at face value  
14 without trying to read a whole lot into it that if we go  
15 back, if the Committee goes back and looks at where we have  
16 removed the state's role in the regulations and have a  
17 discussion on, do we still want to have that removed or is  
18 there a role for the state oversight?

19 I think, and it's been discussed, I think that  
20 could be, I don't know that we can get it done today, but,  
21 you know, I think that's the direction that the letter is  
22 recommending that we go.

23 And, you know, so no, I don't know of any  
24 particular model that anyone has in mind.

25 Whether North Carolina or some other, you know,

1 state agency or federal agency has a blend of, you know,  
2 private and public oversight; I mean, the clinical  
3 laboratories, it's basically a federal requirements under  
4 CLIA, under CMS, the Clinical Laboratory Improvement  
5 Amendments.

6           They have organizations that have deem status that  
7 can do the inspections. And they are a private  
8 organization. College of American Pathologists follows the  
9 federal regulations. They are a private organization. They  
10 charge. They come in and they inspect your laboratory to  
11 those federal standards.

12           You know, but there's, you know, I don't think  
13 anybody had any particular model in mind that I'm aware of,  
14 of when this letter was written.

15           COMMITTEE MEMBER CHI: This is William Chi in  
16 Sacramento. I apologize, being a lawyer I kind of read  
17 things literally. And on the second page of the letter it  
18 says that, the last paragraph, recognize and applaud the  
19 work of the Committee and encourage the Committee to  
20 continue to work with CDPH on a solution that does not  
21 diminish public health and safety.

22           So, it seems to me that the (indiscernible) order  
23 is, maybe, to work with CDPH program to come up with a  
24 solution that would, that would address the concerns that  
25 are laid out in the letter.

1           So, it seems to me at this point that rather than  
2 going back to Agency and ask for point-by-point concern  
3 which they're not legally mandated to come back with any  
4 reply; that the Committee might be better served to try to  
5 work with current CDPH staff and come up with a solution  
6 that might address Agency concerns.

7           COMMITTEE MEMBER WONG: This is Kenton in  
8 Richmond. You know since we have members of CDPH staff  
9 here, can the Committee work with them to get input as to  
10 what might be a minimum threshold level of an efficient  
11 level of oversight that wouldn't be onerous or obstructive  
12 and work to some compromise in amending some minimal level  
13 of oversight that would appease everyone?

14           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
15 Well, as a representative of the Food and Drug Laboratory I  
16 certainly would agree with that. And we would be happy to  
17 do that.

18           I think that William didn't read the last clause  
19 of that final sentence which says, ensuring independent  
20 state oversight of forensic alcohol analysis. So it doesn't  
21 seem to me ambiguous at all that this letter is, promotes  
22 that idea.

23           And certainly, the Food and Drug Laboratory Branch  
24 is more than happy to discuss what Kenton is recommending.

25           COMMITTEE MEMBER SHEN: This is Jennifer. I

1 agree. That last paragraph to me was pretty crystal clear  
2 on, and I guess that for me, what I would like to see; I  
3 know that the people that I represent would like to see, is,  
4 again, I don't have any problem with oversight but oversight  
5 is going to be in this case because of the lack of any  
6 enforcement, really that the Department has, it's going to  
7 be oversight not enforcement.

8           And it has to be oversight of the regulations as  
9 they're written. And what we do not want to have happen is  
10 that, you know, the oversight would be, well let me see what  
11 the background of your person is.

12           And even though the background does fall within  
13 Title 17 as written, that the Department decides, oh, that  
14 person has to have this and this and this also. But we're  
15 not going to let you have that person do any analysis until  
16 they've met these other things.

17           And that's really, for my understanding, what's  
18 been going on over the last 20 years. It's extra stuff. It  
19 isn't what's in Title 17. It's extra things that we are  
20 being held accountable for. And that is what I don't want  
21 to see.

22           I'm perfectly happy having the state take a look  
23 at what we're doing, send in our proficiency test and make  
24 sure we're doing them. But don't come back at me and say, I  
25 don't want you to use that proficiency test provider even

1 though it's perfectly legitimate. You have to do this and  
2 this and this also.

3 Do you understand what I mean?

4 COMMITTEE MEMBER CHI: Well with all due respect,  
5 the legal reality of the situation is that the Committee  
6 made them up with language that it deems appropriate. But  
7 the statute also placed the approval, particularly, squarely  
8 on the shoulders of Agency which the language, I think there  
9 had a line somewhere that, Agency may disapprove of any  
10 provisions that the Committee may submit.

11 So I think it probably is more efficient for the  
12 Committee to work with the intent of the letter of December  
13 15th to better than, try to work with the Department to come  
14 up with language that would appease Agency rather than, I  
15 think, you know, for passing (indiscernible), the Committee  
16 is talking about what it wants to do but I think Agency is  
17 making it clear that the Department also has a role to play  
18 in this process.

19 And the statute clearly gives Agency that power.

20 COMMITTEE MEMBER SHEN: I don't disagree.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
22 Comment from the public actually in response to what  
23 Jennifer said. I think it would be very helpful, there's a  
24 lot of urban legend out there regarding allegations that the  
25 Department's evaluations of the regulations are at times

1 arbitrary and capricious.

2           You gave an example of not accepting results from  
3 an approved proficiency test provider, I'm sure that never  
4 happened.

5           So I think it would be helpful especially if we do  
6 go on and have the conversation about how we might want to  
7 change these regulations and we clearly define what  
8 oversight means and whatever oversight Agency is involved,  
9 what they can and cannot do. It would be helpful to have  
10 real-world examples that could be checked rather than urban  
11 legends that on retelling kind of lost all sense of reality.

12           MS. LOUGH: This is Patty Lough in San Diego.  
13 Since everybody is pretty much in agreement that the  
14 regulations as written cover the good science that and  
15 everything that has been thought, carefully thought out in  
16 these regulations; is it possible just to add one more  
17 article to it and simply state in that article whatever is  
18 agreed upon and either, you know, maybe through a  
19 subcommittee and then back to Committee, something simple  
20 about documents will be made available at any time to the  
21 enforcement agency or laboratories will be open to  
22 inspection at any time to enforcement agency thereby leaving  
23 the enforcement agency itself not specified because that can  
24 be changed in the Health and Safety Code at any time that  
25 there's any changes to how the state operates.

1           But just something in there that shows that the,  
2 you know, as a separate article without saying how they're  
3 going to do that because that should be left really with the  
4 agency that has that enforcement responsibility. But just a  
5 note in there that so the lab can know that the laboratories  
6 are going to be following these regulations and having an  
7 open book, an open laboratory policy certainly for the state  
8 to come in and check at any time.

9           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
10 Clay, member of the public. So let me just understand. So  
11 your proposal is, we've gone ahead and removed or repealed  
12 all those sections that describe the authority of the  
13 Department to do site inspections, to request records, to do  
14 proficiency tests, to interpret the results of proficiency  
15 tests, et cetera, et cetera.

16           Your proposal is now to somehow recapture all  
17 those and put them in a different place, under a separate  
18 article?

19           MS. LOUGH: Patty Lough. No. Not at all. It  
20 should stand as it is because it also includes in there the  
21 regulations now, the revisions include how long documents  
22 will be kept and all that. We've already discussed that.

23           So, you know, I don't think anybody disagrees on  
24 how the paperwork is done, how the science is done, that's  
25 all, you know, in agreement.

1           The question now is oversight. Why not simply add  
2 an article that is one sentence long that says, laboratories  
3 will make available to the enforcement agency any documents  
4 that they request and have the lab available to inspection  
5 at any time.

6           And then the agency, your agency for instance,  
7 Clay, that was the enforcement agency, you can decide among  
8 yourselves how often would we like to review their  
9 documents, do inspections, things like that.

10           But the regulations stand alone separately. They  
11 are determined by the Forensic Alcohol Review Committee. It  
12 isn't the, your office doesn't come back and say, okay, we  
13 want you to do this way or that way. That is done in  
14 Committee. That's really clear. And that has been done.

15           And you have a representative on the Committee for  
16 your input. So I'm just saying that a one sentence  
17 something, an article on or about oversight or enforcement;  
18 you can refer it back to the Health and Safety Code 100725  
19 just so that it's clear. So you know who the agency is that  
20 is going to enforce and that could be changed. They have  
21 nothing to do with the regulations because they're two  
22 separate things.

23           You have regulations on how to do the work and  
24 then this, a little one liner.

25           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Comment from the public. I'm not sure the one liner is  
2 going to capture the four bullets.

3 Those four bullets were captured in many lines of  
4 regulations. I also caution you to be careful what you ask  
5 for.

6 The regulations are intended to limit the  
7 Department just as much as they are intended to limit the  
8 regulated public.

9 If we simply have a one, Carte Blanche clause, one  
10 article, that says, the Department can basically do whatever  
11 it wants to, I think, in effect, it would say the Department  
12 can basically do whatever it wants to do in terms of  
13 oversight as long as it's based on their interpretation of  
14 the rest of these regulations.

15 I think that's moving farther away from the goal  
16 that you seem to have stated in the beginning.

17 MS. LOUGH: Yeah, Patty Lough, again. Yeah,  
18 basically I'm saying that the laboratories will make  
19 available documents and for inspection by the state.

20 I mean, it's already there. We already talked  
21 about it being public record, information that you can  
22 obtain at any time.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
24 Clay again. So you believe that addresses all those four  
25 bullets?

1 MS. LOUGH: What the four bullets are arguing is  
2 removing all the language about enforcement and oversight  
3 and it's sticking to the meat of the document which is, how  
4 does alcohol get analyzed in a laboratory.

5 I mean that was even in a discussion on removing  
6 the different titles of alcohol analysts and supervisors and  
7 trainees and basically what we were trying to say is, people  
8 who just do this work must have this background.

9 And we're trying to kind of get away from all  
10 those other things that are in there.

11 COMMITTEE MEMBER SHEN: And, again, we ran into  
12 the issue, of course, of oversight versus enforcement. So  
13 the Department certainly has the ability to come in and do a  
14 tour and look at our manuals and methods and, but, you know,  
15 the way everything has been currently there really is no  
16 enforcement.

17 COMMITTEE MEMBER WONG: Correct.

18 MS. LOUGH: Does, this is Patty Lough. Does the  
19 Department have some idea of language that they would like  
20 to propose that the Committee can look at since the  
21 Committee has already determined what the regulations will  
22 be. Do you have something in mind already that you'd like  
23 to see?

24 CHAIRMAN KIMSEY: This is Paul Kimsey. Not to my  
25 knowledge. This may also get to the issue of oversight and

1 enforcement, the definitions. I mean, if the Department  
2 sees something wrong, let's say grossly wrong, so we know  
3 about it; if we don't take any enforcement I mean what is  
4 the point? Sort of like the tree falling in the woods.

5 COMMITTEE MEMBER SHEN: -- Kenton's point.

6 MS. LOUGH: Yes, this is Patty Lough. And I have  
7 a question about that. Something grossly wrong. Okay, one  
8 thing we know is that the law says that your proficiency  
9 testing must follow ASCLD/LAB guidelines.

10 Now in the last meeting we had a little discussion  
11 that there was one laboratory that was not doing that. And  
12 that was I don't know how many months ago we had.

13 And that's a gross thing. That's pretty big. And  
14 the proficiency test is what tells you if your work product  
15 is good.

16 So with that in mind, what happened with that  
17 laboratory? Did something happen with that lab? You know,  
18 that's, that is the law. So there is something right there  
19 that has happened and has happened recently. What kind of  
20 enforcement action was taken?

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
22 I can answer that. The enforcement action was, and let me  
23 update because each year we request labs, we ask labs to  
24 submit their results.

25 And this year I believe there were five or six

1 labs which I don't know that they didn't, and I should have  
2 maybe clarified, I don't know that the labs didn't  
3 participate in a proficiency test by an approved provider.  
4 But they didn't provide us the results.

5           So this year it was five or six labs that didn't  
6 do that, including a number of ASCLD/LAB accredited labs.

7           But our response was --

8           MS. LOUGH: So --

9           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
10 -- to send them a letter saying that, by not providing those  
11 proficiency results, we are not able to satisfy the  
12 requirements of the regulations and in a particular section  
13 it says that, one of our roles is to evaluate those  
14 proficiency tests to make sure that the labs and its methods  
15 are still competent.

16           So for those labs we, last year we were unable to  
17 fulfill that role as defined in the regulations.

18           MS. LOUGH: Well, okay. This is Patty Lough  
19 again. So you weren't able to enforce that role and yet you  
20 are the enforcement and oversight agency currently.

21 Correct?

22           So, I mean, this is has nothing to do with these  
23 regulations that we've been writing for 17 meetings.

24           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
25 You're right. The current regulations are still in force.

1 Nothing you've done has changed any of the regulations,  
2 that's correct.

3 The current regulations are still in force. I  
4 mean, we haven't changed the regulations.

5 MS. LOUGH: Oh, okay. Patty Lough again. I have  
6 a question for Torr because you represent the defense. In  
7 this meeting, there are several laboratories that may be out  
8 of compliance with the Health and Safety Code.

9 COMMITTEE MEMBER ZIELENSKI: Yes.

10 MS. LOUGH: But what does that mean to you,  
11 representative of that establishment?

12 MR. PHILLIPS: Patty I don't believe Torr heard  
13 you. This is Bill Phillips. Patty is asking you a  
14 question.

15 COMMITTEE MEMBER ZIELENSKI: Oh, I'm sorry Patty.

16 MS. LOUGH: Yes. Torr, this is Patty Lough here  
17 in San Diego. And the reason I'm asking this question is  
18 because we know that the B, Y cases are the ones that are  
19 probably really vigorously handled in the courtroom setting  
20 which is where a lot of our oversight occurs.

21 So now as a member of this Committee we've just  
22 been told that there are laboratories that are not following  
23 the proficiency test guidelines as prescribed by the Health  
24 and Safety Code.

25 How does the defense bar which you represent, how

1 would they respond to that kind of information. The state  
2 is currently in charge of oversight and enforcement of the  
3 alcohol program and we know that there are laboratories that  
4 are not complying with proficiency testing. And it's  
5 proficiency testing that assures us that our work product is  
6 correct, accurate and correct.

7           COMMITTEE MEMBER ZIELENSKI: If the defense bar  
8 became aware of a lab that was actually functioning or  
9 accounting was doing the evaluation they would go after and  
10 challenge the lab's findings and probably use many of the  
11 criteria established in Title 17 and experts supporting the  
12 validity of that finds, you really destroy the lab.

13           And once that happens, the lab would probably then  
14 lose all of its credibility and have to (indiscernible) an  
15 expert because they would realize that they had a problem  
16 with accreditation and a problem with reliability and that  
17 type of thing.

18           So, but in terms of Sacramento, we're not, there  
19 are, every once in a while problems prop up and we become  
20 aware of it. And obviously when that happens then the DA  
21 gets involved in those to try and rectify the problem by  
22 removing the people that are not performing in a competent  
23 fashion.

24           But if it gets out, if word gets out through  
25 examination of a lab or personnel from a lab are doing

1 things that are not scientific in the lab well then they  
2 will be challenged and it can be very devastating to a lab.

3 MR. PHILLIPS: Patty, this is Bill Phillips again.  
4 I think, not only beyond just not submitting their  
5 proficiency results, but I understand there are laboratories  
6 in the state that are not submitting their changes to their  
7 procedures to the Department as well.

8 So the chaos is beginning because they don't  
9 understand that they were to submit their, you know, the  
10 Department hasn't made it clear to agencies or the way the  
11 letter was written concerning whether they had to submit  
12 procedures to them is not clear.

13 So, therefore, they're not submitting the revised  
14 procedures to the Agency or, excuse me, to the Department.

15 MS. LOUGH: Yeah, this is Patty Lough. I have a  
16 memo I'm kind of looking for here. It was 2005 or 2006. I  
17 believe the Department sent an advisory out saying, you no  
18 longer have to submit your methods on file.

19 And I believe in Committee we were told that as of  
20 2005 they were no longer performing any inspections of  
21 laboratories (indiscernible) they have done some.

22 But I think you don't have to submit your methods  
23 anymore. It's, again, it's an advisory which means  
24 hopefully everybody got the advisory but you still, you know  
25 you're dealing with the regulations and advisories may or

1 may not make it to everybody in the program.

2 CHAIRMAN KIMSEY: This is Paul Kimsey in Richmond.  
3 We're coming up on the lunch hour, possibly. I don't want  
4 to, does anyone want to make a comment on or to sort of  
5 conclude this last discussion?

6 COMMITTEE MEMBER SHEN: This is Jennifer. You  
7 know, I guess, I actually have to leave but I guess my  
8 thought is that we need to think about what oversight we are  
9 comfortable with I suppose.

10 I think that's something we need to take a look  
11 at. I am a little worried about giving Kirk lunch. I don't  
12 want to do that because it's never good in any situation.

13 COMMITTEE MEMBER WONG: Correct.

14 COMMITTEE MEMBER SHEN: But, you know, I think we  
15 need to have some discussions. I do not want to see us go  
16 down another 17 meetings of parsing out every single word in  
17 our regulations. So there must be a way for us to put that  
18 in here in a relatively straightforward manner. And I think  
19 that's something that we probably should look to.

20 CHAIRMAN KIMSEY: And Jennifer, what is your  
21 timeframe? When do you have to leave? Because we don't  
22 have to stop at noon. I mean, I'm just pointing out the  
23 timeframes and, obviously, we have this, this set up here  
24 until four o'clock.

25 But, you know, if you can, we can take one-half

1 hour lunch if you can be involved at that point. We can all  
2 think about next steps. If we take one-half hour lunch we  
3 can think about what we want to, how we want to progress  
4 with either the rest of the day or to direct a group to do  
5 something or ask the Department to do something.

6 But what is your timeframe?

7 COMMITTEE MEMBER SHEN: I have to be back to my  
8 laboratory at 12:30. So I can give you another half an hour  
9 and then I got to get going.

10 CHAIRMAN KIMSEY: Okay.

11 COMMITTEE MEMBER SHEN: And if I'm, I'm sorry  
12 about that. I wish I didn't have to.

13 CHAIRMAN KIMSEY: No, no, that's okay. We all  
14 have our day jobs as we say.

15 COMMITTEE MEMBER WONG: Can we take a five minute  
16 bio-break?

17 CHAIRMAN KIMSEY: Yeah, we had a couple of  
18 requests here in Richmond for a five minute bio-break. Why  
19 don't we make it 10 minutes. I think when we come back why  
20 don't we try, have some discussion on how we want to, you  
21 know, use the rest of the day and Jennifer's time.

22 Hopefully she can hang in there until, you know,  
23 12:25 or so. And so, why don't we reconvene at 10 minutes  
24 after 12.

25 COMMITTEE MEMBER SHEN: Okay.

1 CHAIRMAN KIMSEY: Thank you.

2 (OFF THE RECORD FOR 10 MINUTES)

3 CHAIRMAN KIMSEY: This is Paul Kimsey in Richmond.  
4 Our 10 minutes are up. Do we have Sacramento on line still?

5 MR. PHILLIPS: Sacramento is on line. A few  
6 people had to leave but we're back on line.

7 CHAIRMAN KIMSEY: Okay, that's fine. And I heard  
8 San Diego. So we're officially reconvening for the purposes  
9 of our stenographer.

10 So did anyone have a brilliant idea in the midst  
11 of their bio-break or sidebar discussions?

12 COMMITTEE MEMBER SHEN: This is Jennifer.

13 CHAIRMAN KIMSEY: Yes.

14 COMMITTEE MEMBER SHEN: And yes, I did have an  
15 idea. I don't know if it's brilliant or not. But, one of  
16 the things we could do is provide targeted oversight.

17 So, I think that we can all agree that's a very  
18 excellent tool for determining whether or not a laboratory  
19 is performing properly is, in fact, the proficiency test.

20 So what if we were to put in language that very  
21 clearly drew or laid out the fact that the Department is  
22 responsible for oversight of our proficiency tests?

23 It seems that a laboratory would have to submit  
24 their proficiency tests to the Department for a review, if  
25 in fact, and I realize there's no real enforcement, but,

1 from conversations we've had before the break, if, in fact,  
2 the laboratory is not complying with that, we are not  
3 allowing the Department either to have that oversight or the  
4 laboratory is, in fact, not passing the proficiency test.

5 The Department, as you have done this last year,  
6 apparently, can issue that letter that you are out of  
7 compliance because of this, that and the other thing.

8 And as our defense representative so eloquently  
9 pointed out, that if that letter is sent to the laboratory  
10 it does become discoverable and that will, in fact, point  
11 the enforcement against the laboratory for not following  
12 policies.

13 So instead of trying to go back and put in  
14 oversight here and oversight there, let's give oversight in  
15 the area that is most appropriate and probably the easiest  
16 which is that the Department would oversee our proficiency  
17 testing ensuring laboratories are, in fact, following the  
18 guidelines and getting correct results. So that would be my  
19 idea.

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
21 This is Bob Haas. I have a question about that reflecting  
22 my naivete. As I understand the, at least the ASCLD/LAB  
23 proficiency test results are confidential.

24 And there's no way that the Department could  
25 evaluate those results in a transparent manner. Is that

1 wrong?

2 MR. SEDGEWICK: This is Paul Sedgewick. I was on  
3 the ASCLD/LAB Proficiency Review Committee for toxicology  
4 and alcohol for (indiscernible) retirement.  
5 And it is true that ASCLD/LAB can operate these  
6 (indiscernible). However, there's nothing to say that the  
7 laboratory itself cannot release those results and send them  
8 to the Department.

9 COMMITTEE MEMBER WONG: Voluntarily.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
11 Well then, this is a very, I think a pretty constructive  
12 suggestion.

13 COMMITTEE MEMBER WONG: Powerful.

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
15 I wanted to throw out before I lose it, during the break  
16 we, it had been mentioned earlier that there was a lack of  
17 clarity about laboratory, about FDLB sending letters to the  
18 regulated laboratories regarding, you know, who changes in  
19 personnel or methods and procedures.

20 And, indeed, we did that for a long time but were  
21 directed a number of years ago to stop doing that by our  
22 management.

23 And that's the reason that that hasn't been fully  
24 clear but we're happy to begin that again.

25 And, in fact, Clay tells me that with regard to

1 some of those aspects that those letters have been sent out  
2 annually to all of the 40 labs.

3           So, again, if that's, if that helps make that  
4 situation clearer that's easily corrected.

5           COMMITTEE MEMBER SHEN: This is Jennifer. I  
6 suppose, this is not where you were going with that, but, I  
7 suppose, we would still, as laboratories, would need to talk  
8 about continuing to provide the Department with personnel  
9 that we have trained that are going to be doing alcohol  
10 analysis because if you're going to be following up on the  
11 proficiency tests, you probably will need to know who it is  
12 that's doing that.

13           And one of the things that we have to do with our  
14 ASCLD is that we have to test all of the analysts. Every  
15 analyst must complete a proficiency test --

16           COMMITTEE MEMBER WONG: Annually --

17           COMMITTEE MEMBER SHEN: -- not a section or an  
18 instrument.

19           COMMITTEE MEMBER WONG: Right.

20           COMMITTEE MEMBER SHEN: So I think because of that  
21 and because of the way the regulations would not be written  
22 you would still need to keep track of who it is that  
23 performing the analysis.

24           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
25 Right.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
2 Comment from the public. The proficiency tests is a good  
3 example. It's only one of them. But it certainly is a good  
4 example. The devil is often in the details.

5 Obviously, if we were going to, if the lab was  
6 going to require laboratories to report results and  
7 ASCLD/LAB proficiency test it's probably best to state that  
8 in the regulation.

9 But there are some differences in the ASCLD/LAB  
10 requirements, at least as interpreted by the laboratory  
11 community and the Department's requirements.

12 The Department is required to evaluate each  
13 method. And since if a lab has a GC method that uses a  
14 Perkin/Elmer and a completely different GC method that uses,  
15 I mean a different GC method that uses an adjunct GC, we  
16 call that two methods.

17 And we require the labs to participate, they have  
18 two proficiency tests. One for each method.

19 In looking at the ASCLD/LAB results we're getting  
20 back, it, for a time, initially, the labs kind of followed  
21 that, but, more and more we're seeing that a lab that may  
22 have three methods submits only or at least reports to us  
23 but submits results for only one of the methods.

24 In the past, labs since, all the approved  
25 providers provide at least two tests a year. CAPS has three

1 but at least two tests a year.

2 In the past where labs tended to participate in  
3 both tests which I think is good, this year we're noticing  
4 that many labs elected, probably for cost savings perhaps,  
5 elected to participate in only one test.

6 So in writing regulations I think this is much  
7 more than a one liner. I think you'd have to capture what,  
8 get an agreement on, on what the requirements are and  
9 capture those in regulation.

10 COMMITTEE MEMBER SHEN: This is Jennifer. I don't  
11 disagree with that. I think, as I have only two more  
12 minutes, I would like to leave the Committee with this  
13 concept sowed.

14 The concept of giving oversight to the Department  
15 over the proficiency testing. And the devil really is in  
16 the details. I get that. We have to kind of figure out, I  
17 mean, and maybe a compromise is that you have to for the  
18 state, that you do need to have each method that's tested,  
19 that's fine.

20 You know, for our accreditation we have to have  
21 each analyst tested. So if we can come up with a  
22 combination thereof and, you know, kind of flesh that out,  
23 but if that is the main oversight then we can flesh that out  
24 so it captures what is needed.

25 But, I guess, the concept is, would this, would

1 this accommodate what the Department is looking for in a  
2 manner that we can all live with?

3 I mean, I would feel very comfortable about it. I  
4 think it's a great compromise.

5 And so, I guess I would like you all to think  
6 about, is that something we could do? Is that a way we  
7 might want to go?

8 CHAIRMAN KIMSEY: Jennifer, this is Paul. It  
9 sounds like, yes, that we're, you know, coming to some sort  
10 of a happy, not happy, but some sort of agreement.

11 But to let you go, first of all, thank you very  
12 much for your time and your input. It's, obviously, been  
13 very key to the meeting.

14 Would you be able to, if we, to get to the point  
15 later on in our meeting today, at some point, and we set up  
16 a subcommittee; would you be able to help, you know, follow  
17 through on some specifics along these kinds of discussions?

18 COMMITTEE MEMBER SHEN: Absolutely.

19 CHAIRMAN KIMSEY: Okay.

20 COMMITTEE MEMBER WONG: This is Kenton from  
21 Richmond. I really agree with Jennifer. I think that's a  
22 great idea about the targeted type of oversight.

23 However, I also agree with Mr. Chi that looking at  
24 the four bullet points, it's going to have to cover, it's  
25 pretty clear that it's going to have to cover those four

1 bullet points, whatever we do. To appease Agency, Health  
2 and Human Services in working with CDPH for a compromise on  
3 each one of those bullet points.

4 COMMITTEE MEMBER SHEN: This is Jennifer. I guess  
5 my thought is that, by giving, because, by giving oversight  
6 of the proficiency testing, that does an over-arching sort  
7 of oversight that would accommodate what the Department is  
8 looking for without having to specifically go into certain  
9 details.

10 I think the proficiency test is something that is  
11 very important. You know, I don't know, it seems like we're  
12 going to have trouble if we try to outline just certain  
13 points; if there's oversight in this area, that area and  
14 this area, so my concept would be that we would not address  
15 them individually as bullet points.

16 We would simply give this one big, large thing.  
17 It would give them oversight of this one particular thing  
18 and that would accommodate the needs of the Department in  
19 its entirety.

20 So that is a thought. And I am running out the  
21 door. Thank you all for listening to me. And good luck  
22 with that --

23 COMMITTEE MEMBER WONG: Bye Jennifer.

24 CHAIRMAN KIMSEY: Thank you.

25 COMMITTEE MEMBER WONG: I think that will totally

1 work as long as it accommodates the four bullet points  
2 because that's pretty clear like I said that they want that  
3 to be met.

4 CHAIRMAN KIMSEY: Continuing the discussion. I  
5 didn't mean to jump in there with the whole idea of the  
6 subcommittee, but if we do set up a subcommittee I think we  
7 need to spend some time as a group, and maybe we need to  
8 take a, you know, a lunch break at some point, obviously.

9 And come back or it's up to the group if we want  
10 to just, sort of, push through for another period of time  
11 and recess or whatever.

12 But I think it would be helpful if it looks like  
13 we do set up subcommittee that we continue some discussion  
14 about giving them some guidance on just the type of  
15 discussion we had about proficiency testing, are there other  
16 areas or not; and where do we not want, maybe something to  
17 happen.

18 So, well first off, what is everybody's feeling  
19 about lunch? Do --

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
21 Let's have it. I'm hungry (laughter).

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 Torr has to leave at two.

24 COMMITTEE MEMBER CHI: Dr. Kimsey.

25 CHAIRMAN KIMSEY: Yes.

1 COMMITTEE MEMBER CHI: This is William Chi. I'm  
2 not going to be available in the afternoon because I've got  
3 a reading to go to.

4 CHAIRMAN KIMSEY: Okay. We're hearing here in  
5 Richmond that, you know, really, we can't go much past two  
6 o'clock at the latest for, everybody, you know other,  
7 similar sorts of reasons.

8 And so, we can take a half hour for lunch, come  
9 back at one and continue on for another hour. Does that  
10 seem reasonable to people or what are some other ideas?

11 COMMITTEE MEMBER WONG: Speak up.

12 CHAIRMAN KIMSEY: I guess, not hearing any other  
13 ideas, I guess we can, you know, let's reconvene at one  
14 o'clock. Hopefully, people will have had some lunch in the  
15 meantime.

16 (Off The Record for Lunch)

17 CHAIRMAN KIMSEY: Yes, this is Paul Kimsey in  
18 Richmond. It looks like Sacramento has their --

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
20 Russ is there.

21 CHAIRMAN KIMSEY: -- Russ, if you can hear us --

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
23 -- and so is --

24 CHAIRMAN KIMSEY: -- can you turn on the mic.

25 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

1 -- and Torr.

2 CHAIRMAN KIMSEY: We can't hear you.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 How does that work?

5 CHAIRMAN KIMSEY: I think you need to point it at

6 us Russ.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

8 Pulls his hand back --

9 CHAIRMAN KIMSEY: That's it, put your glasses on  
10 (laughter).

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

12 All right, call I, T.

13 MR. HUCK: Can you hear us?

14 ALL IN RICHMOND: Yay, you did it, yay.

15 COMMITTEE MEMBER WONG: You did it.

16 CHAIRMAN KIMSEY: Do we have San Diego on the  
17 line? It looks like we're waiting for San Diego.

18 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

19 And, who is the woman now? Is it, I don't know, I can  
20 barely see her.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

22 That's not the officer, right?

23 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

24 I don't know. She came in half way through the morning.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Oh, okay.

2 THE REPORTER: Now you know this is all going to  
3 be on the record.

4 CHAIRMAN KIMSEY: Yeah, let's go ahead and pause  
5 until we get San Diego.

6 (Off the Record)

7 CHAIRMAN KIMSEY: I hope everyone had an enjoyable  
8 lunch and break. I'll try and summarize, sort of, how we  
9 ended up. There seems to be some agreement on re-looking at  
10 some of the oversight, enforcement aspects of the role of  
11 the Department.

12 I think we're going down the road of setting up a  
13 subcommittee. And if I remember correctly that has to be,  
14 it can be no more than two people, if I remember correctly.

15 And Jennifer has volunteered. And I think since I  
16 represent the Department it's appropriate for me to be  
17 volunteered and we've had some very good discussion on  
18 proficiency testing, a little bit more discussion on  
19 personnel.

20 I think we can spend some time this afternoon for  
21 the Committee to get some more discussion on some of the  
22 other bullet points to give the subcommittee some guidance  
23 on the feeling of the larger Committee with regards to some  
24 additional changes that might be made as they relate to  
25 those four bullet points.

1           Does that seem like a fairly good overview of  
2 where we left off?

3           MR. LYLE: Bruce Lyle in San Diego. Yeah, I  
4 agree.

5           CHAIRMAN KIMSEY: Okay. Then I'll open it up for,  
6 you know, the full Committee and the public to make some  
7 more comments related to a subcommittee and the aspects of  
8 these four bullets.

9           MR. LYLE: Bruce Lyle. It appears to me that the  
10 first bullet is the proficiency testing is sort of the major  
11 over-arching point in, and a real robust kind of issue.

12           The other three are, they either kind of fold  
13 under the proficiency testing or they're not as, I mean they  
14 don't seem to be as important or they wouldn't be as  
15 important to the Department.

16           So I'm not really sure if, I mean I think in the  
17 spirit of compromise, you know, I think that probably just  
18 sticking with the proficiency testing as one of the, as the  
19 one oversight area would probably be a good start.

20           CHAIRMAN KIMSEY: Okay. Thank you. Other  
21 comments? The last bullet, you know, the requirements that  
22 the Department receive records of activities under the  
23 regulations; I guess this gets to the idea of the Department  
24 knowing, to some extent, who is doing proficiency, I mean,  
25 is doing, I'll call it testing in the state. Does that --

1           MR. LYLE: Yeah, that's kind of what, this is  
2 Bruce Lyle again. That's the way I took it. And then  
3 that's the one that seems to be kind of folded under the  
4 proficiency testing and what Jennifer was talking about  
5 earlier.

6           That it seems like that one is kind of folded in  
7 there. So that one is, appears to be covered by what she  
8 was talking about.

9           And then the two middle, you know, seemed to have  
10 and I don't know if that's the right way to say it, but they  
11 have a lesser importance.

12           And maybe the Department could give those as a  
13 compromise.

14           CHAIRMAN KIMSEY: Those would be the  
15 qualifications issues for the employees and then the  
16 training programs.

17           MR. LYLE: Right.

18           CHAIRMAN KIMSEY: Okay.

19           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
20 Comment from the public. I would say all four bullets  
21 pretty much describe a normal regulatory program.

22           PT performance measures, I mean, open PTs which  
23 the ASCLD/LAB commercially approved PTs are open, it's known  
24 they monitor the very best work the lab can do.

25           I mean, it's a PT. They know they're, you know,

1 they're going to be judged on this. And it's, so it's not  
2 always necessarily the typical or average work. It  
3 represents the very best work.

4           The other three components are, I say, all typical  
5 components of any kind of lab oversight program and I would  
6 strongly disagree with the notion that one is more  
7 important. That one is over-arching. And that one, really,  
8 is related to the others.

9           They're related only in that they, the goal of all  
10 four is to ensure the competence of the laboratories.

11           My response would be to do some horse trading  
12 here. It doesn't make much sense.

13           COMMITTEE MEMBER DAVIS: This is Kevin in  
14 Sacramento. Just for my own clarification, when we're  
15 talking about proficiency testing are we talking about  
16 individual lab employees or labs as a whole? Or both?

17           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
18 Well I think that that needs to be decided. I would  
19 suggest that maybe we start with the first bullet and  
20 actually go back into the revised, the revisions and try to  
21 come up with acceptable language that satisfies all parties.

22           And to facilitate that, with regard to proficiency  
23 testing, there's five different citations in the current  
24 regulations that relate to that.

25           And we could just go to the first one and, you

1 know, start throwing out some modifications that, and see  
2 how that works.

3 I think if we tried to like, generally, you know,  
4 in the next two hours, try to solve the whole problem, it's  
5 not going to work perhaps.

6 DR. RILEY: This is Kevin and I agree and I think  
7 we only have 45 minutes. I was just curious so I know we're  
8 all talking about the same thing here.

9 I didn't want to get down to the weeds of it at  
10 this point.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
12 Okay. Well that's --

13 DR. RILEY: How was it done previously?

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
15 -- fine too.

16 DR. RILEY: Was it individuals?

17 MR. HUCK: No, it was the laboratory, okay.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 Well I would say, Clay, member of the public. I would say  
20 the third bullet described the proficiency testing of  
21 individuals.

22 You know, under the California regulations every  
23 forensic alcohol analyst has to, at least, once, take an  
24 external proficiency test. In this case, conducted by the  
25 Department.

1           In the case of the ASCLD/LAB guidelines, there's  
2 never been a requirement that analysts ever take an external  
3 proficiency test.

4           So there's some fundamental differences between  
5 the ASCLD/LAB requirements and accreditation requirements in  
6 general in the Department.

7           And so, to simply answer your question, is the,  
8 among other things, the qualifications of individuals would  
9 capture the individual PTs.

10           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11        But we've heard this morning that each individual, in fact,  
12 does have to be qualified annually.

13           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

14        But that's a nuance. And that is with ASCLD/LAB guidelines  
15 is, can be handled and typically is handled by internal  
16 proficiency samples.

17           Either samples prepared by the lab or samples that  
18 are simply retested by the analysts and passed around. So,  
19 it's something different between an external proficiency  
20 test, you get one shot; it's reviewed by some external body.

21        You know you have to pass that proficiency test that day.

22           And in the internal proficiency test that's  
23 referred to in the ASCLD/LAB guidelines and the ASCLD/LAB  
24 guidelines defines successful performance on a proficiency  
25 test as either getting the expected result or taking

1 corrective action in, consistent with lab policy.

2           So if lab policy says, you get a bad result you  
3 just say, I'm sorry and, there's no, anyway --

4           I'm sure that doesn't happen but, so, there are  
5 some differences there.

6           FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
7 Well, right. And we all agree that there are differences.  
8 And I think that that's a good place to begin discussing  
9 this.

10           CHAIRMAN KIMSEY: Other comments? I think it was  
11 helpful for me to hear the suggestion that we look at our  
12 current package and where we have sections dealing with  
13 proficiency testing or the qualifications of personnel or  
14 training or there's records that as the subcommittee,  
15 Jennifer and I, would be looking at each of those sections  
16 and would come back to the Committee with recommendations  
17 for a more specific and much more broad discussion.

18           And maybe with some recommendations. But that we  
19 would identify those parts of the regulations that sort of  
20 cross, they're affected by these four bullets and review  
21 them with the idea of suggesting modifications to the full  
22 Committee at a later meeting.

23           MR. LYLE: Bruce Lyle. I agree with that  
24 wholeheartedly.

25           CHAIRMAN KIMSEY: Other sort of direction though

1 for Jennifer and myself? Feelings about any aspects of any  
2 parts of these bullets that would give us some food for  
3 thought?

4 MR. LYLE: Well, yeah the only, Bruce Lyle again.  
5 The only direction that I have and what I was trying to get  
6 at is that if something has to fall by the wayside that it  
7 would be the two middle and not the proficiency testing.

8 That would be the one issue that we have to  
9 concentrate on.

10 CHAIRMAN KIMSEY: Okay.

11 COMMITTEE MEMBER WONG: This is Kenton. I don't  
12 believe that Health and Human Services is going to allow for  
13 any of the four to be gone by the wayside.

14 I think that in Health and Human Services eyes  
15 they're all important and critical to the successful  
16 revision of Title 17.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
18 Yeah, a comment from the public. I would agree with  
19 Kenton. I don't know how you can excise the qualifications  
20 or training of the analysts from their performance on  
21 proficiency tests.

22 MR. LYLE: This is Bruce Lyle. Obviously they're  
23 all part of a, you know, of a well-qualified, you know, good  
24 analysts but I think the oversight issue is not really  
25 whether, I mean I think the regulations approach the

1 qualifications and they approach the training.

2           It's the oversight that I'm not really sure that  
3 the Department needs to have on those things. I think  
4 that's where a lot of the heartburn comes from.

5           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
6 Comment from the public. Sometimes you have to read these  
7 carefully. And I'm sure the subcommittee will.

8           The reference to review and approve of training  
9 program and they actually give a specific example, is maybe  
10 the most, I mean that can include training programs for  
11 analysts working in the lab.

12           But, probably the most important aspect of the  
13 program is as indicated in the EG and parenthesis is the  
14 breath instrument operator training.

15           And that's actually the basis by which the  
16 Department kind of maintains state-level oversight of breath  
17 alcohol analysis.

18           If all the labs are required to train officers  
19 with the training program that's approved by the Department.

20           The Department indirectly achieves, you know, a level of  
21 oversight of that training.

22           So that's really got nothing to do with, I mean if  
23 a lab may be competent at proficiency tests but that won't  
24 necessarily indicate that they're doing a competent job at  
25 training police officers to perform testing on breath

1 instruments.

2 CHAIRMAN KIMSEY: Other comments or directions in  
3 the subcommittee?

4 COMMITTEE MEMBER WONG: This is Kenton in  
5 Richmond. I agree with Clay. And with regard to breath  
6 instrument operator training, it shouldn't be that big of a  
7 deal because like I used to be in San Mateo and our methods  
8 for our four course for operator certification training was  
9 approved by you guys and I'm sure they still have those.  
10 And it shouldn't be that big of a deal.

11 I mean they were approved methods for a four hour  
12 course and they should still be able to go back to those and  
13 repeat those.

14 And I'm sure they're still doing that anyway.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 We were --

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:  
18 The assurance, I mean the point for CDPH is that, I mean  
19 that may, that's great in San Mateo but we want uniform  
20 standards for the state.

21 COMMITTEE MEMBER WONG: Correct.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 Response from the public. And the other thing to keep in  
24 mind is the breath instruments keep changing. So the new  
25 instruments are introduced. So new training procedures are

1 needed to be written and perhaps that's the bulk of our  
2 current review process is, I guess as a result of a recent  
3 OTS grant there's been four or five, five or six labs that h  
4 have recently gotten new instruments.

5 And so we're asked to and we are reviewing those  
6 training procedures.

7 CHAIRMAN KIMSEY: This part of the discussion  
8 seems to be winding down which was actually our, sort of our  
9 first agenda item.

10 I think this is, I don't mean to be cynical, this  
11 has been very helpful and I think we made a lot of progress,  
12 don't get me wrong.

13 We did have on the agenda to talk about the fiscal  
14 impact and the Statement of Determinations. And I was also  
15 going to give some comments on the budget for the Motor  
16 Vehicle Account because that was requested from our last  
17 meeting.

18 Why don't I let you know what I have found out  
19 about the Motor Vehicle Account and I will send, I have a  
20 paragraph here that I will be speaking from and I will send  
21 this paragraph with the links and the numbers and the budget  
22 numbers and all this kind of thing to the full Committee  
23 later on today or we'll get it in the full Committee maybe  
24 later on today or tomorrow.

25 Basically, the CDPH, Motor Vehicle Account

1 appropriations shown in the Governor's budget, there's the  
2 very long address.

3           There's two accounts. One for 1.253 million and  
4 one for 302 thousand. So the total according to the  
5 Governor's budget is 1.55 million dollars.

6           This is very general, very high level discussion  
7 of the budget. It's public information. You can see it  
8 online. I'll be sending out the URL.

9           To get a further breakdown of that, if the  
10 Committee wants it, we would probably need to go to the  
11 Department of Finance and make some requests.

12           But, anyhow, that's the general Motor Vehicle  
13 Account amounts coming to the Department. It comes in two  
14 lumps. But it totals 1.55 million dollars.

15           Any questions or comments?

16           With regards to reviewing the fiscal impact  
17 estimate and the Statement of Determinations, what's the  
18 feeling of the Committee. Do we want to, you know, Kenton  
19 Wong and Bruce Lyle have prepared these. Do we want to take  
20 some time and make some comments? Do we want to, you know,  
21 postpone this to another meeting? Or what's the feeling of  
22 the group?

23           Bruce or Kenton, do you have any feelings? Do you  
24 want to go ahead and, you know, give us an overview of what  
25 you've prepared?

1           COMMITTEE MEMBER WONG: Kenton. I just basically  
2 followed some other examples of, I'm kind of taking a shot  
3 in the dark. I really, to be blunt, I really didn't know  
4 what I was doing.

5           I think there was one comment that on paragraph A  
6 that I really didn't need the last sentence. But, since  
7 everybody is already doing proficiency testing anyway that  
8 the last sentence in that, these costs may be related, that  
9 that sentence is moot.

10           CHAIRMAN KIMSEY: Okay. Other comments on the  
11 fiscal impact estimate? Okay, Bruce, you want to walk us  
12 through the Statement of Determinations?

13           MR. LYLE: Okay. This is Bruce Lyle in San Diego.  
14 Unlike Kenton I knew exactly what I was doing when I did  
15 this (laughter).

16           COMMITTEE MEMBER WONG: I'm glad one of us did.

17           MR. LYLE: No. I hope you know I was kidding. I  
18 was in the same boat as Kenton. I borrowed liberally from  
19 other sources to figure out what the components were and  
20 really, I mean, you could just read for yourself.

21           These were the five or six, one, two, three, four,  
22 five, these were the six headings that were in each one of  
23 the statements of determinations that I saw.

24           And I read a number of them and they all contained  
25 these particular things. Some of the language was boiler

1 plate, the effect on housing costs and the effect on small  
2 businesses; that was pretty much boiler plate except for  
3 that last sentence on, and the effect on small businesses,  
4 specifically those private labs that do not meet ASCLD  
5 standards.

6 And a lot of this obviously is going to change  
7 depending on what we determine to be, you know, who is going  
8 have the oversight.

9 COMMITTEE MEMBER WONG: Correct.

10 MR. LYLE: So those words are going to have to  
11 change.

12 CHAIRMAN KIMSEY: Okay, thank you Bruce.  
13 Comments, questions?

14 MR. PHILLIPS: This is Bill Phillips in  
15 Sacramento. The Fiscal Impact Statement on state  
16 government, that may have to change as a result of whatever  
17 you may change in the regulations concerning proficiency  
18 testing.

19 COMMITTEE MEMBER WONG: Right.

20 MR. LYLE: And the mention of the Motor Vehicle  
21 Account that funds the Department to do those kind of tests  
22 might be appropriate.

23 CHAIRMAN KIMSEY: Okay. Any other comments on the  
24 two documents? Okay. The Statement of Reasons which we  
25 were also on the agenda to review, I believe Jennifer would

1 be walking us through that.

2 But I'll certainly entertain any comments if  
3 someone wants to make a comment on the Statement of Reasons  
4 but Jennifer is obviously not on the line anymore.

5 Okay. Well it's 1:30. I think things are winding  
6 down. Is there something I have, on the agenda that I have  
7 missed that we want to go back to or --

8 If there, I would, Jennifer and I will get  
9 together as a subcommittee. I can't really anticipate when  
10 we might have a work product for everybody to review. I  
11 think, I'm thinking there's not much point for us to meet  
12 until we have that work product and that we would, I think  
13 we'll, you know, try and do it as quickly as possible.

14 I think this has been a very good meeting and  
15 there's talk of compromise and working together, that sort  
16 of thing.

17 So, I'm an inherently optimistic person. I would  
18 like to say March but we'll just see where that goes with  
19 both of our schedules.

20 Any comments about the format of the meeting or,  
21 obviously, a little technical difficulty this morning. That  
22 doesn't usually happen to that extent.

23 But it looks like we'll probably try and have  
24 another meeting when we have a work product which will be in  
25 March or April.

1           Other comments or ideas? If not, if I don't hear,  
2 I'm not hearing any objections, we will close this meeting  
3 at 1:32. And I want to thank you all, again, for your time  
4 and commitment to this process.

5           (Thereupon, the California Department of  
6 Public Health, Forensic Alcohol Review  
7 Committee meeting adjourned at 1:32 p.m.)

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## CERTIFICATE OF REPORTER

I, John Cota, an Electronic Reporter, do hereby certify that I am a disinterested person herein; that I recorded the foregoing California Department of Public Health, Forensic Alcohol Review Committee meeting, that it was thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said meeting, nor in any way interested in the outcome of said matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of February, 2011.

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JOHN COTA