

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

TWENTIETH MEETING  
MONDAY, JULY 23, 2012  
10:00 A.M.

REPORTED BY:  
JOHN COTA

APPEARANCESReview Committee Members

Dr. Paul Kimsey, Chairperson (Richmond)

Mr. Paul R. Sedgewick (San Diego)

Mr. Kenton S. Wong (Richmond)

Lieutenant Kevin Davis (Sacramento)

Mr. Dan Jeffries (San Diego)

Mr. Bruce Lyle (San Diego)

Mr. Paul Sedgewick (San Diego)

Ms. Jennifer Shen (San Diego)

Staff

Ms. Natalia Spell, Research Scientist, Food and Drug Laboratory (Richmond)

Mr. David Kiang, Acting Chief, Food and Drug Laboratory (Richmond)

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

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

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

Also Present

Mr. Michael Toms, District Attorney's Lab (Sacramento)

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

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

Ms. Rosalie Dvorak-Remis, Office of Regulations (Sacramento)

Ms. Peggy Campbell, Office of Legal Services (Sacramento)

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1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
2 Clay Larson, Food and Drug Lab Branch.

3 RESEARCH SCIENTIST SPELL: I'm Natalia Spell, Food  
4 and Drug Lab.

5 CHAIRMAN KIMSEY: Okay. If we can go around the  
6 room in Sacramento real quickly.

7 MR. HUCK: Okay. This is Russ Huck with the  
8 Division Office for Food, Drug and Radiation Safety.

9 COMMITTEE MEMBER DAVIS: Kevin Davis, Committee  
10 Member with the CHP.

11 MS. LYONS: Denise Lyons, Solano County Bureau of  
12 Forensic Services.

13 MS. DVORAK-REMIS: Rosalie Dvorak-Remis, Office of  
14 Regulations.

15 MS. CAMPBELL: Peggy Campbell, Office of Legal  
16 Services.

17 MS. TOMS: Michael Toms, Sacramento County  
18 District Attorney's Laboratory of Forensic Services.

19 CHAIRMAN KIMSEY: And we had one other gentleman  
20 here in Richmond. I'm sorry.

21 MR. THANDI: Harby Thandi, Food and Drug  
22 Laboratory Branch.

23 CHAIRMAN KIMSEY: Thank you. And in San Diego?

24 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick,  
25 Committee Member, California Association of Toxicologists.

1           COMMITTEE MEMBER JEFFRIES: Dan Jeffries, the new  
2 representative from the California District Attorneys  
3 Association.

4           CHAIRMAN KIMSEY: Welcome.

5           COMMITTEE MEMBER JEFFRIES: Here now.

6           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
7 That's it?

8           CHAIRMAN KIMSEY: And so that's all in San Diego?

9           COMMITTEE MEMBER JEFFRIES: Yes.

10          CHAIRMAN KIMSEY: Okay. So, I know that we'd  
11 heard from Mr. Slaughter that he was not going to be able to  
12 attend. Had we heard from Bruce Lyle?

13          COMMITTEE MEMBER WONG: He will be here.

14          CHAIRMAN KIMSEY: He will be --

15          COMMITTEE MEMBER WONG: That's what I heard.

16          CHAIRMAN KIMSEY: Okay.

17          ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 He will be here.

19          CHAIRMAN KIMSEY: And I believe that Jennifer was  
20 also going to be available. Well maybe we should give it  
21 another five minutes before we get started to see if,  
22 because there's no point in repeating ourselves for our two  
23 members that aren't here.

24                 So we'll take a five minute break.

25                 (A short off-the-record break was taken.)

1 CHAIRMAN KIMSEY: This is Paul Kimsey again in  
2 Richmond. I guess we'll go ahead and get started.  
3 Actually, the opening remarks --

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
5 Let me find out who's -- have we checked with San Diego to  
6 see who's there?

7 CHAIRMAN KIMSEY: San Diego, has anyone else  
8 shown?

9 COMMITTEE MEMBER JEFFRIES: Yes we do. We have  
10 two new people in San Diego.

11 CHAIRMAN KIMSEY: Ah, wonderful.

12 COMMITTEE MEMBER SHEN: Hello.

13 MR. LYLE: Hello (laughter).

14 CHAIRMAN KIMSEY: Could you identify yourselves  
15 please for our stenographer.

16 MR. LYLE: Bruce Lyle, San Diego.

17 CHAIRMAN KIMSEY: Great.

18 COMMITTEE MEMBER SHEN: Jennifer Shen, Department  
19 of San Diego.

20 CHAIRMAN KIMSEY: Okay.

21 COMMITTEE MEMBER WONG: There we go.

22 CHAIRMAN KIMSEY: So, with regards to the opening  
23 remarks, I don't really have anything new from the  
24 Department. Obviously, we've been dealing with budget  
25 issues. But you've been reading about that in the newspaper

1 so, no inside information there.

2 Any discussion of the agenda? Basically, we have  
3 a discussion opportunity for the Attorney General's opinion  
4 that came out December 27th. And then we continue our  
5 Committee discussion on a draft regulatory work product.

6 And, we're basically scheduled, we can go until  
7 three o'clock. And any questions on the agenda or, at this  
8 point, or should we dive right in?

9 (No response.)

10 Hearing no comments, the, --as we have mentioned,  
11 this was sort of a, a long awaited, I'm not sure how long we  
12 waited, but it seemed awhile with regards to the Attorney  
13 General's opinion concerning the Department's relationship  
14 to the Forensic Alcohol Program.

15 In your packet there's a copy of the Attorney  
16 General's opinion. And basically on page two at the top it  
17 has the two major conclusions.

18 One of the issues that we were waiting for was  
19 some determination on the Department's ability to enforce  
20 compliance with the Forensic Alcohol Program regulations.

21 And the first item there talks about the fact that  
22 the Department can seek mandamus or injunctive relief from a  
23 court to enforce compliance. So that seems pretty straight  
24 forward.

25 And the other item was, in the interim would

1 laboratories or, in this timeframe, would laboratories  
2 continue to have to comply with the regulations.

3 And specifically about a requirement to perform  
4 separate proficiency testing. And that was also upheld by  
5 the Attorney General's letter.

6 Any questions or discussions about the Attorney  
7 General's opinion from any of the Committee members or the  
8 public?

9 When you talk please identify, you know, say your  
10 name and then identify, you know, whether you're a Committee  
11 member or a member of the public. No discussion on the --

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
13 Well, let me say a few things because -- looking back on the  
14 transcripts there were, literally, a dozen or so or more  
15 references to the AG's opinion in the course of the many  
16 meetings of the Review Committee. So I think it probably  
17 deserves some discussion. Let me try to get it started.

18 I think it really answers two questions. Maybe  
19 the most obvious one is the question of how will, how will  
20 the Department enforce the regulations as required by Health  
21 and Safety Code Section 100725?

22 And I see that that question was probably asked a  
23 dozen or more times by various Review Committee members.  
24 And typically towards the end it became almost a rhetorical  
25 question in that it typically occurred during the discussion

1 of ongoing oversight activities by the Department.

2 And those discussions kind of reached a screeching  
3 halt when someone pointed out, somebody asked the question,  
4 well how is the Department ever going to enforce this?

5 So we have a specific legal opinion with regards  
6 to a mechanism that the Department could enforce the  
7 regulations. So the, if we could hit rewind, some of the  
8 discussions that, I say, I think were cut short prematurely  
9 regarding oversight activities could continue.

10 But I think a more careful reading of the AG's  
11 opinion, I think also addresses a different question. A  
12 number of the members have, I say suggested, but actually  
13 stated that, the intent of the, of 16023, the 2004  
14 legislation, was to, was to remove the Department oversight  
15 activities from, remove those activities from the Department  
16 completely, really.

17 And the AG found that except for the specific  
18 licensing authority, their assessment of the, **intent** of the  
19 legislation was that the Department would continue its other  
20 oversight activities. So I think that may be important.

21 And two minor points. The AG cited a section of  
22 the law, Health and Safety Code 100170, paragraph (a)(1).  
23 Which I don't think we've ever discussed before but it  
24 should go into the record. Which apparently provides the  
25 Department with general authority to take all necessary

1 actions to enforce its regulations.

2 So, it probably goes into the discussion. And the  
3 final point is, the AG cited a section of Title 17,  
4 1216.1(c), which grants the Department authority to take  
5 disciplinary action against laboratories for any failure to  
6 meet program standards.

7 And this was the regulation that linked to the  
8 statute, 100725 which requires the Department to enforce the  
9 regulations.

10 So the Committee so far had decided to eliminate  
11 1216.1(c), I think in order based on the AG's opinion, in  
12 order to allow the Department to enforce the statutes. And  
13 the law and the regulations as mandated by the statutes, we  
14 would need to retain the language or some language like that  
15 contained in 1216.1(c).

16 COMMITTEE MEMBER SHEN: This is Jennifer,  
17 Committee Member, in San Diego. I guess my thought is that,  
18 and this has always been a conundrum for us, the way that  
19 the law is written there is, there still appears to be some  
20 sort of oversight by the Department, but it's not really  
21 backed up with anything, which this opinion certainly  
22 addresses. But to me it looks like that this is in the  
23 interim while we are rewriting it, before the new  
24 regulations are adopted the Department still maintains that  
25 oversight.

1           It says on page four, because the Department  
2 regulations **have not yet been revised** in accordance with the  
3 2004 statutes, the existing regulations still include  
4 provisions that purport to enable the Department to grant  
5 and renew licenses. Of course regulations that conflict  
6 blah, blah, blah.

7           And they talked about it. It's because we have  
8 not put forward a revised product that has been approved.  
9 I'm not sure we should write it, write our revisions trying  
10 to keep all the authority necessarily that was in the  
11 original Title 17. But that until we have gotten out  
12 (indiscernible) and we have a new product, we are **bound** by  
13 some of these regulations.

14           CHAIRMAN KIMSEY: Other comments?

15           COMMITTEE MEMBER WONG: I agree with Jennifer. I  
16 mean Senate Bill 1623, it would be absolutely absurd to  
17 think that 1623 was just going to remove licensing and  
18 that's all. That would be absolutely stupid. I mean it's  
19 like, why would you just remove licensing and nothing else?  
20 It doesn't make any sense.

21           And despite Clay's contention that the intention  
22 was to just keep everything status quo, then why have 1623?  
23 The whole idea was that the oversight by the Department of  
24 Public Health was duplicative since the labs were following  
25 17025 either ASCLD or FQS accreditation standards and they

1 were better and over and above the normal CDPH oversight  
2 which really wasn't happening anyway.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
4 Well just one quick responding comment. I, you know, I  
5 would agree that the legislation gave wide authority to the  
6 Committee to write whatever regulations they saw fit. It  
7 also created a process whereby those, any proposed revisions  
8 would be subject to review by Health and Human Services  
9 Agency.

10 I submit that the AG's opinion will have impact  
11 on, should have impact on the Committee and will have impact  
12 or should have impact on the Agency's review of the proposed  
13 regulations.

14 COMMITTEE MEMBER WONG: This is Kenton in  
15 Richmond. I agree. And we are definitely going to have to  
16 deal with that hurdle.

17 But I still contend that if, and I don't know to  
18 quite say this diplomatically, but, CDPH seems bound and  
19 determined to drag us back to the Stone Ages of 25 or 30  
20 years ago with all the regulations and oversight that was of  
21 absolutely no value to what was going on in the Forensic  
22 Alcohol Programs within the state labs and local labs.

23 And 1623 was meant to address that, that  
24 shortcoming and those problems.

25 COMMITTEE MEMBER SHEN: This is Jennifer. I

1 believe that this AG's opinion really is something that  
2 we're going to deal with in the interim as we finish our  
3 product. And we can take a look at it and give it  
4 consideration but I don't think it overrides our overall  
5 purpose with what we've been trying to do all these months,  
6 or years I should say.

7 CHAIRMAN KIMSEY: This is Paul. I would agree. I  
8 mean this, I mean this is certainly something we've been  
9 sort of waiting for about clarifying two specific areas.  
10 But it certainly doesn't negate the work that the Committee  
11 has been doing.

12 And, you know, we can certainly move forward with  
13 the role that the Committee was given based on the  
14 legislation 1623.

15 That, I think, was not affected by the AG's  
16 opinion.

17 COMMITTEE MEMBER SHEN: And this is Jennifer  
18 again. And I also believe that over the last several  
19 meetings that we've made some serious movement towards  
20 compromise and trying to address some of the Department's  
21 concerns while addressing our concerns.

22 So I think we've been moving discussions slightly  
23 anyway. But we just -- we just want to stay away from, you  
24 know, going back to the Stone Age or having duplicative  
25 oversight. I think that's what our goal is here.

1 COMMITTEE MEMBER WONG: I concur.

2 CHAIRMAN KIMSEY: Any other comments from the  
3 Committee?

4 (No response.)

5 Then moving on, the next item on the agenda is our  
6 continued review of our work product.

7 I think it's probably worth sort of reviewing a  
8 little bit. We have a new member, Mr. Dan Jeffries from the  
9 District Attorneys Association, and I'd like to welcome him.

10 And I don't know how much he has been able to find  
11 out about what we have been doing for the previous 19  
12 meetings but I'll start with a sort of a general overview  
13 and the rest of the Committee can certainly chime in with  
14 their version of history.

15 So, the Committee was set up based on AB 1623 as  
16 you've heard us refer to --

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 SB.

19 CHAIRMAN KIMSEY: Excuse me?

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
21 SB.

22 CHAIRMAN KIMSEY: Excuse me, SB, 1623. And we  
23 have basically been going through the regulations that  
24 oversee the Forensic Alcohol Program in the state.

25 And we, as part of the legislation, our Committee

1 once we have a work product, it is reviewed by the Health  
2 and Human Services Agency.

3           We got a draft work product to the Health and  
4 Human Services Agency numbers of months ago and received  
5 back a letter where they had suggested the Committee re-look  
6 at four areas that they felt we should look at again.

7           The Health and Human Services Agency basically has  
8 a, the ability under the legislation to reject, I think I'm  
9 getting this correctly, to reject any particular regulatory  
10 change that we made.

11           Of the large number of areas in the regulations,  
12 there were only these four areas that the Health and Human  
13 Services Agency thought we should re-look at.

14           It was generally around the role of the Department  
15 and we have, we set up a, we basically had some individuals  
16 from the Committee come up with recommended language to  
17 address the issues that Agency had brought up.

18           And that's pretty much what we're going to be  
19 discussing today.

20           Also the legislation of the, it's sort of key that  
21 we talk, mention that our communication with Health and  
22 Human Services Agency previously was a draft product.

23           When we send them, the product, that triggers a 90  
24 day review based on the legislation where they have to get  
25 back to the Committee, or I believe, and please jump in, if

1 Agency does not get back to us then I think, I guess they  
2 just have a 90 day requirement. I'm not sure if they don't  
3 make that 90 days what the consequence is.

4 But so the meeting today, pretty much we're going  
5 to be sort of focussed on going over these four bullets that  
6 the individuals have proposed language for the Committee's  
7 discussion.

8 And at some point either this Committee or a  
9 future meeting when we have a work product to go back to  
10 Agency that process will take place. It will trigger a 90  
11 day review.

12 Once Agency has reviewed our work product again,  
13 or I should say, has reviewed it officially for the purposes  
14 of the legislation, then the product comes back to the  
15 Department for further writing of the regulations.

16 I would anticipate that our Office of Regs will be  
17 involved with that. I think they'll be involved with the  
18 Committee.

19 The American -- the American. The Administrative  
20 Procedures Act, which with regulations have to be in  
21 compliance with here in the state of California, is rather  
22 detailed and specialized. So there will be some looking at  
23 things like clarity and these sorts of areas that come under  
24 the Administrative Procedures Act.

25 And then, and I would advocate that this Committee

1 be very much involved with that process.

2           Anyhow, that's my version of the, of 19 meetings.

3           Anyone want to add anything in particular that I may have  
4 overlooked?

5           COMMITTEE MEMBER DAVIS: Paul?

6           CHAIRMAN KIMSEY: Yes?

7           COMMITTEE MEMBER DAVIS: Kevin in Sacramento. I'm  
8 really sorry. I just got an emergency call I have to attend  
9 to.

10          CHAIRMAN KIMSEY: Okay.

11          COMMITTEE MEMBER DAVIS: I'll try but I may not be  
12 able to come back.

13          CHAIRMAN KIMSEY: That's fine. Thank you for  
14 letting us know.

15          THE REPORTER: Who was that?

16          CHAIRMAN KIMSEY: That was Lieutenant Davis.

17          COMMITTEE MEMBER WONG: Bye Kevin.

18          CHAIRMAN KIMSEY: Good luck.

19          COMMITTEE MEMBER DAVIS: Thanks.

20          CHAIRMAN KIMSEY: So, any other comments about the  
21 history for Mr. Jeffries' benefit?

22          COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries  
23 in San Diego with the CDA. Thank you for the welcome. I  
24 have had a chance to look over the written materials you  
25 sent me. I've also had a chance to, via your website, look

1 over the transcripts of the last couple of meetings so I am  
2 somewhat familiar with the history of the Committee and the  
3 meetings as well as the issues involved with Title 17.

4 CHAIRMAN KIMSEY: Great. Well thank you very much  
5 for your efforts on our behalf.

6 But anything else about the history before we sort  
7 of dive into the bullets?

8 (No response.)

9 Also in your package, I guess we can start with  
10 bullet number one. Bruce you want to walk us through that?

11 MR. LYLE: That was the easy one. It was on  
12 proficiency testing. And two meetings ago we had a lot of  
13 verbiage kind of thrown out so I sort of put it into one  
14 quick down and dirty sentence: "Laboratories will direct an  
15 approved provider to submit all external proficiency test  
16 results to the Department at a minimum of one (1) per year."

17 CHAIRMAN KIMSEY: And this replaced, what did this  
18 replace?

19 MR. LYLE: I was just looking for that. I  
20 couldn't find the, the actual section. Anybody else have  
21 some help for me?

22 COMMITTEE MEMBER SHEN: No. I'll look.

23 CHAIRMAN KIMSEY: This is Paul. I think this is  
24 obviously very direct. There may be some areas that, under  
25 the APA we will need to clarify. Unless it's already

1 somewhere it strikes me that an approved provider might need  
2 to be delineated.

3 But I think the major issue is, does the Committee  
4 think that one proficiency test a year is sufficient? And  
5 are we talking about proficiency tests? I'm blanking on  
6 this group. Is this by method, by person?

7 COMMITTEE MEMBER SHEN: This is Jennifer. My  
8 memory of this is that we were -- one of the problems the  
9 Department had is that even if you were to switch over to  
10 the -- an outside lab or another agency approved external  
11 proficiency tests, that the Department wasn't -- I think  
12 right now we are sending our results but the Department  
13 wasn't -- wanted to get sort of those directly from the  
14 approved provider so they could have that, you know,  
15 immediately on file.

16 And I think that we discussed that we were going  
17 to go to proficiency testing for a person, not an  
18 instrument.

19 COMMITTEE MEMBER WONG: Right.

20 CHAIRMAN KIMSEY: That's fine. I think these are  
21 things -- I mean obviously if we want to include some  
22 clarifying language now, that's fine. Someone can propose  
23 it.

24 These are the types of issues, I think, that we'll  
25 be continuing to discuss at some point when the Office of

1 Regulation gets involved in preparing the package for final  
2 submission.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
4 A couple of comments. I think the regulations are going to  
5 need to describe, as it's actually been suggested, the  
6 terminology, **approved provider**. And I think actually it's  
7 appropriate for the Department to approve the provider.

8 Besides an ASCLD/LAB-approved body, we're going to  
9 need a sufficient number of California labs to participate  
10 in order to have any kind of statistical basis for  
11 evaluating the results.

12 So we're going to need an appropriate sample  
13 target concentrations to such that we can apply the other  
14 requirements of Title 17 in order to determine the, whether  
15 the results show that the labs' methods continue to meet the  
16 accuracy requirements.

17 And I think we need at least two testing events  
18 per year. That's the current frequency of testing. One  
19 proficiency test per year, reagents degrade, chemical  
20 standards degrade, you know what happens. And so I think a  
21 minimum, I think two is really a minimum.

22 The laws and regulations governing clinical and  
23 workplace drug testing require three PTs per year. So I  
24 think two is actually sort of a minimum.

25 Again, the Department must continue to evaluate

1 the performances on proficiency tests. And we need to  
2 specify in regulations the basis for those evaluations.

3           It's the new age of regulations and I believe the  
4 APA is going to require that, if, that the regulated entity  
5 knows, you know, the criteria that the Department will be  
6 employing in order to evaluate those results.

7           I think laboratories with multiple methods,  
8 methods are separate. And I think if you carefully read the  
9 ASCLD/LAB requirements, it's even clear there that ASCLD/LAB  
10 does only require one submission from a laboratory even if  
11 the lab has multiple methods. But, it is still a laboratory  
12 submission.

13           And two different methods can have, you know,  
14 instruments can have different biases, they can have  
15 mechanical failures, And so it's clearly appropriate to  
16 continue the 30, 40 years standards that we've established  
17 here and have each method tested.

18           And finally, we can cover this later but, it may  
19 actually also be in the same section, that there are  
20 separate PT requirements for the employees of the lab and  
21 that will have to be captured somewhere.

22           COMMITTEE MEMBER SHEN: This is Jennifer. First  
23 of all, you know, most of the California laboratories I  
24 believe are probably using, correct me if I'm wrong, ASCLD  
25 providers. So they're approved providers.

1 I don't think you're going to find a problem with  
2 the approved providers that we're using not being in sign up  
3 laboratories.

4 Secondly I would say, that we've gone round and  
5 round and round on the methodology versus the analyst. I  
6 think that we are pretty clear that we would like to test  
7 the analyst. And the methodology can't just be the exact  
8 same thing on a different instrument. And I think we've  
9 discussed that ad nauseam.

10 CHAIRMAN KIMSEY: So there's --

11 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick in San  
12 Diego. The Definition of proficiency test is exactly that,  
13 to test the proficiency, the ability of an analyst. The  
14 methods that we develop to do confirmations on that. But he  
15 has to make sure that it's able to do an accurate analysis.

16 And then each time a method is run it has quality  
17 control samples and standards to test the accuracy of that  
18 particular instrument at that -- that method at that time.

19 But proficiency tests by definition are tests on  
20 individuals.

21 COMMITTEE MEMBER WONG: Right. This is Kenton.  
22 If you look on page nine of the AG's opinion, it's already  
23 said that. It's saying in point (c) it says, each examiner  
24 shall successfully complete at least one proficiency test  
25 annually. So it's not even a point of argument.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

2 But wait --

3 COMMITTEE MEMBER SHEN: Well and I think -- this  
4 is Jennifer. I think that (inaudible), that we're testing  
5 each analyst once a year.

6 COMMITTEE MEMBER WONG: Right.

7 COMMITTEE MEMBER SHEN: An approved provider. And  
8 then Bruce was stating in his bullet that we would have  
9 those results forwarded to the Department for their records.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
11 Clay Larson. In responding to Mr. Sedgewick's comment. The  
12 Committee sometimes imbues ASCLD/LAB requirements with  
13 almost canonical authority.

14 And the definition of proficiency tests in  
15 ASCLD/LAB is tests to evaluate the competence of analysts,  
16 technical support and the quality performance of a  
17 laboratory.

18 And I would submit that if you look at ASCLD/LAB  
19 requirements, they do make a statement. It's verily saying  
20 this is an important or an essential requirement.

21 But they do have a requirement that analysts  
22 participate in at least one proficiency test in their  
23 discipline. It doesn't necessarily say sub-discipline.

24 But that, they also specifically state that that  
25 can be an internal test. The results need not be -- are not

1 submitted to ASCLD/LAB so they don't see those results.

2 They do want to see at least one proficiency test  
3 from the **laboratory** each year. And so that philosophy, that  
4 approach, the -- which measures the quality performance of a  
5 **laboratory**.

6 So I think that has traditionally been what the  
7 Department has been evaluating. And I think that's  
8 appropriate for us to continue that. Thanks.

9 COMMITTEE MEMBER SHEN: This is Jennifer. Again,  
10 we're not talking about that. We're talking about a  
11 proficiency testing completed by each analyst per year.

12 So it's, you know, if we need to clarify our  
13 language a little bit more to make sure that we realize  
14 that, that's fine. But we are not talking about testing the  
15 laboratory once a year. That's not even something we're  
16 discussing for this, for these regulations.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 And I recognize that. I was just wanted to correct any  
19 misinformation Mr. Sedgewick might have provided in that  
20 there was something inherently individual and personal about  
21 a proficiency test.

22 I'm just suggesting that, in fact, that notion is  
23 inconsistent with the requirements of ASCLD/LAB.

24 CHAIRMAN KIMSEY: So is there any suggested change  
25 to the language that Bruce has proposed that might clarify

1 things or do we want to --

2 COMMITTEE MEMBER WONG: Sure.

3 CHAIRMAN KIMSEY: -- put in, examiner, or, person,  
4 whatever we call them.

5 COMMITTEE MEMBER SHEN: This is Jennifer. Health  
6 and Safety Code Section 100702 provides as follows as was  
7 already pointed out, you know, (c), (a), (b) and (c); (c)  
8 says, each examiner shall successfully complete at least one  
9 proficiency test annually; (b) each laboratory shall  
10 participate annually in an external proficiency test for  
11 alcohol analysis.

12 And we have to follow these guidelines, these  
13 ASCLD/LAB guidelines for proficiency testing. So would it  
14 be appropriate then to note or to cite the safety code in  
15 this bullet and would that take care of our issues?

16 I don't know that we need to rewrite it all down  
17 again if we can cite somewhere that clearly says what we're  
18 going to be doing.

19 COMMITTEE MEMBER WONG: This is Kenton. I agree  
20 Jennifer. I think that's a great idea. And when you look  
21 at that requirement, that's way better than what CDPH had  
22 required years ago because you could have seven or eight  
23 analysts and all they required was one proficiency test from  
24 **the lab.**

25 And maybe the other six or seven that didn't do

1 the proficiency test were never tested for decades. So this  
2 is far in excess and better than what we ever had.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
4 And again, I think a careful reading of the statutes, and  
5 you just read them, and I think if you listen carefully to  
6 what you read that it creates a clear dichotomy there in  
7 that the laboratory PT is described as an **external**  
8 proficiency test. That means a test that is produced by  
9 some organization outside the laboratory.

10 There's no such definition within the, there's no  
11 such specification for the examiner, we assume we know what  
12 examiner means, but the examiner PTs.

13 And typically those are internal PTs. It could be  
14 samples that someone passed around among the analysts of  
15 previously analyzed samples. That's a technique that's  
16 approved by ASCLD/LAB.

17 So simply, I mean --

18 COMMITTEE MEMBER SHEN: So Clay, is your point  
19 that (b) these laboratories shall participate annually in an  
20 external proficiency test and (c) says, each examiner shall  
21 successfully complete at least one proficiency test. And  
22 the word "external" is not repeated? Is that your point?

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
24 Yeah.

25 COMMITTEE MEMBER SHEN: Okay.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
2 And so I think there is a distinction there and it would  
3 have to be clarified in the regulations. Simply referring  
4 to the statute, I think, would not satisfy the clarity  
5 issues of the APA.

6 COMMITTEE MEMBER SHEN: Well I don't have a  
7 problem with that.

8 CHAIRMAN KIMSEY: Other comments on bullet one?

9 MR. LYLE: Yeah the way I - this is Bruce in San  
10 Diego. The way I recall it, it was in addition to, it was a  
11 new bullet or a new subsection under 1216 I think it was,  
12 discussing proficiency testing.

13 So this was an additional section compelling the  
14 laboratory that sent, the approved provider that sent the  
15 proficiency test to the laboratory. So is this compelling  
16 the laboratory to ask that approved provider to send the  
17 results, at least one time a year, to the Department?

18 COMMITTEE MEMBER SHEN: This is Jennifer. I think  
19 that's exactly right. That's what we were doing. We were  
20 adding it to language that already articulated what we were  
21 supposed to be doing.

22 MR. LYLE: Bringing the Department into the loop.

23 CHAIRMAN KIMSEY: Okay.

24 COMMITTEE MEMBER SHEN: So I guess the -- this is  
25 Jennifer. I guess the key now would be to figure out where

1 you're going to put that.

2 CHAIRMAN KIMSEY: So this would be like, (d)? We  
3 have (a), (b), (c), (d).

4 COMMITTEE MEMBER SHEN: (a), (b), (c), (d) under  
5 -- where are you, Paul?

6 CHAIRMAN KIMSEY: Well I was just looking at the  
7 AG's letter on page nine where they talk about 100702. But  
8 that may not be the appropriate spot.

9 COMMITTEE MEMBER SHEN: Well, we can cite 100702  
10 wherever it is that we add this bullet. I'm looking for it.

11 MR. LYLE: Well I was thinking it would be, this  
12 is Bruce in San Diego, under 1216.1(e)(4).

13 CHAIRMAN KIMSEY: Okay.

14 COMMITTEE MEMBER SHEN: So, what we would, we had  
15 in our work product -- this is Jennifer. In our work  
16 product we had pulled 1216.1(e)(4) **out** (inaudible).

17 MR. LYLE: If you look at (3), if you look at  
18 (e)(3), it talks about proficiency testing.

19 COMMITTEE MEMBER SHEN: We were replacing --  
20 excuse me. (Inaudible).

21 COMMITTEE MEMBER WONG: This is Kenton in  
22 Richmond. So should we take Bruce's bullet point and just  
23 add it on to (b), like an addendum, that each laboratory  
24 shall participate annually in an external proficiency test  
25 for alcohol analysis and submit all external proficiency

1 test results to the Department? At a minimum of one per  
2 year?

3 COMMITTEE MEMBER SHEN: Where did you put that?

4 COMMITTEE MEMBER WONG: As an addendum to (b) on  
5 page nine.

6 CHAIRMAN KIMSEY: Yeah, that's the AG's opinion,  
7 there in the actual work product.

8 COMMITTEE MEMBER SHEN: Right. We have to go back  
9 to our -- we have to go back to Title 17. So 1216.1(e)(3)  
10 talks about -- I think that's (inaudible) proficiency test.

11 MR. LYLE: It made over -- over the term.

12 CHAIRMAN KIMSEY: So we add it to 3 or make it, I  
13 guess you're suggestion Bruce was to have it stand on its  
14 own as number 4?

15 MR. LYLE: Yes, that's my suggestion.

16 CHAIRMAN KIMSEY: Okay. Any other comments from  
17 the Committee?

18 COMMITTEE MEMBER SHEN: Do we want to cite the  
19 Health and Safety Code, 100 --

20 CHAIRMAN KIMSEY: 702.

21 COMMITTEE MEMBER SHEN: -- in that spot?

22 CHAIRMAN KIMSEY: I mean, that's one of those  
23 issues that I think will probably get clarified at some  
24 point. I don't know that, do we cite -- of course this is  
25 our work product so, yes, let's go ahead and cite it.

1 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries  
2 in San Diego. It might be a good idea to also throw in the  
3 word, external, when you cite it so it's clear that you're  
4 referring to an external test when you're referring back to  
5 the Health and Safety Code section.

6 CHAIRMAN KIMSEY: Okay.

7 COMMITTEE MEMBER SHEN: To clarify, we're putting  
8 this in 1216(e)(4) (inaudible) as written. And then cite  
9 the Health and Safety Code here at the end.

10 CHAIRMAN KIMSEY: That's what I think we're  
11 agreeing to.

12 COMMITTEE MEMBER SHEN: Well, I mean, we could add  
13 a clarifying statement. The laboratory will direct an  
14 approved provider to submit all external proficiency test  
15 results. To say something in here about, laboratories will  
16 direct an approved provider to submit all external  
17 proficiency or, you know, submit each approved analyst's  
18 external proficiency test here or some such thing. That  
19 every analyst take an external proficiency test. Does that  
20 help?

21 CHAIRMAN KIMSEY: That certainly clarifies it.

22 COMMITTEE MEMBER SHEN: Obviously, I couldn't get  
23 that sentence out. I'm going to need some help on that.

24 COMMITTEE MEMBER WONG: At a minimum of one per  
25 year per examiner or per analyst?

1 MR. LYLE: To extend it with --

2 COMMITTEE MEMBER SHEN: And in effect you submit  
3 all current proficiency tests to the Department at a minimum  
4 of one per year, and that that's per analyst. That sounds  
5 great.

6 Do we want to say something about following  
7 (inaudible)? Are we going to cite it there?

8 MR. LYLE: This is Bruce. The only problem I have  
9 with citing it is how to cite it. I don't think the whole  
10 thing is pursuant to 100702. I think it's more the  
11 laboratories will direct and approve provider to submit all  
12 external proficiency test results, and then comma, as  
13 outlined in Health and Safety Code 100702.

14 COMMITTEE MEMBER WONG: This is Kenton in  
15 Richmond. Maybe a little bit of input from Office of  
16 Regulations in Sacramento. Is it better if we cite a cite  
17 so that it makes things more clear or does Office of  
18 Regulations like to ferret all that out themselves?

19 MS. DVORAK-REMIS: We need you to ferret it out.  
20 And usually you're authority and references are added after  
21 your regulations in a separate note.

22 MR. LYLE: So we can just have a footnote and a  
23 cite?

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
25 Well it's not a footnote. There are authority -- with each

1 section there are notes and authority and reference  
2 citations, could be notes. But they're definitely authority  
3 and reference citations.

4 CHAIRMAN KIMSEY: Rosalie, you broke up a little  
5 bit and we were trying to identify your voice here in  
6 Richmond. Could you repeat your comment please.

7 MS. DVORAK-REMIS: Yes. What we need you to do in  
8 order to review your regs is for you to ferret out each and  
9 every one of the issues that you want to put in your regs.

10 And then secondly, after the regulation there is a  
11 section called, notes. And in the notes there is authority  
12 and reference material that cites statutes that give you the  
13 authority to do what you're doing in that reg.

14 COMMITTEE MEMBER SHEN: This is Jennifer. I guess  
15 the confusion is that we know we have the authority to do it  
16 but do we want to point -- as someone is reading through it  
17 specifically, as I know my analysts do all the time, they  
18 pull it out and they look for a specific thing. We want to  
19 give them, we want to give them guidance right then and  
20 there as they're looking at this particular issue.

21 So we're not looking at, necessarily, showing what  
22 has, what has given us the authority but adding clarity and  
23 direction to someone who is looking something up. Does that  
24 make sense?

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Well, you know, generally, the APA frowns on a simple  
2 replication of the statute. Their argument would be that  
3 that would be unnecessary since we've got the statutes you  
4 don't - but, so, maybe there would need to be some link that  
5 may have, you may think you've, perhaps we've established  
6 that. Some link that would increase the clarity by citing  
7 the statutes.

8 But that there will be a separate citation of the  
9 authority and reference. So besides the authority to write  
10 regulations the regulations need to refer to a particular  
11 statutory section that the reg writer is making, is  
12 clarifying and making specific.

13 COMMITTEE MEMBER SHEN: This is Jennifer. So I  
14 think you just agreed with me then. You did agree?

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 It had to happen (laughter).

17 COMMITTEE MEMBER SHEN: So we could put it in  
18 here?

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
20 Eventually. Yeah. We make the finding that it makes things  
21 clearer. That it will be subject to review by others. But  
22 if you guys make the finding and it makes things clearer  
23 then that would be justification.

24 I would add an earlier comment I made though. And  
25 it relates to this particular citation that we're talking

1 about here. Is that, besides making available these data to  
2 the Department, whatever they may be, the expectation, at  
3 least from the part of the program is, that the Department  
4 will take those data and make some kind of finding.

5           The regulation right now doesn't describe that at  
6 all. And it might be confusing, if we're citing 100702  
7 regarding the laboratory's participation, the literal  
8 reading of the statutes simply says that the labs shall  
9 participate in a proficiency test, an external proficiency  
10 test. It doesn't necessarily require that the labs have any  
11 particular performance on that test. They could fail it,  
12 pass it, I guess.

13           So, all the more reason that the regulations  
14 should clarify what exactly the Department -- I think that  
15 we need to clarify what exactly the Department is going to  
16 do with those results.

17           RESEARCH SCIENTIST SPELL: Natalia Spell. I agree  
18 with Clay Larson. Stating simply that laboratories will  
19 direct an approved provider to submit all external  
20 proficiency test results to the Department without the  
21 purpose of why it's done, to me it's a little bit  
22 meaningless.

23           COMMITTEE MEMBER WONG: Recently it was done for  
24 licensing. This is Kenton in Richmond. But since you guys  
25 aren't in charge of licensing it wasn't required. But we

1 were recommended to add this back in to satisfy Health and  
2 Human Services.

3           So, we're again at that kind of impasse of what  
4 the goal here is in some ways to satisfy Health and Human  
5 Services but then also satisfy 1623.

6           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
7 Actually I think you're mistaken, Kenton. The purpose of  
8 proficiency testing was set forth under Article 6 and it  
9 requires that the Department utilize the PT results to  
10 determine and establish that the laboratory's methods  
11 continue to meet the accuracy, the standards of performance  
12 requirements set forth in the regulations. So, it wasn't  
13 specifically a licensing thing.

14           COMMITTEE MEMBER WONG: Well, which then went  
15 towards licensing.

16           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
17 And now will go towards the possibility of writ of mandamus,  
18 we're learning a little Latin here, and/or injunctive relief  
19 apparently.

20           So, we've substituted, and I want to get out of  
21 that trap of saying, well we ruled out licensing therefore  
22 this all goes away. I don't think that's correct.

23           COMMITTEE MEMBER WONG: No. I agree.

24           RESEARCH SCIENTIST SPELL: Well, I can add --  
25 Natalia Spell. Licensing, in my opinion is a part of

1 oversight, right? So you can remove the license but you  
2 still can provide certain oversights like examining this  
3 proficiency testing and see how it, quote, statistically.

4           And if it's apparently post, beyond any  
5 statistical possible error, you can say, yeah, there is  
6 something wrong here. Especially if it happening  
7 consistently, one year, another year, another year. So,  
8 that's my opinion constitutes oversight without licensing,  
9 right?

10           COMMITTEE MEMBER WONG: I agree.

11           CHAIRMAN KIMSEY: Yeah. So, what's the feeling of  
12 the Committee? Do we want to make some -- I mean right now  
13 the Department apparently doesn't seem to be directed to do  
14 anything with this information.

15           So, it does seem unusual that the Department would  
16 collect information and if they did know that people were  
17 not passing that they would not do anything with it.

18           But currently I guess they're, it's unclear what  
19 the Committee wants the Department to do with the  
20 information, if anything.

21           COMMITTEE MEMBER SHEN: This is Jennifer again.  
22 You know, we've gone around and around about this too. And  
23 you know, this is a little bit of a quandary. We are an  
24 accredited laboratory. We cannot just universally fail all  
25 our proficiency tests on a yearly basis and not have

1 repercussions.

2           So I think that the Department wants to be in the  
3 loop as to how our analysts are doing. And, I don't know  
4 what the Department can do above and beyond what we are  
5 already going to have to go through if we have analysts that  
6 don't pass the proficiency test.

7           CHAIRMAN KIMSEY: So that's arguing that the  
8 Department would not --

9           THE REPORTER: What was the last part? She said,  
10 if they don't something.

11           RESEARCH SCIENTIST SPELL: I think that was --

12           THE REPORTER: If they don't pass proficiency? Is  
13 that what she said?

14           CHAIRMAN KIMSEY: Yeah, probably.

15           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 Is San Diego still there?

17           COMMITTEE MEMBER SHEN: Yes.

18           CHAIRMAN KIMSEY: Oh, okay. It's just that the  
19 last part of your sentence broke up.

20           COMMITTEE MEMBER SHEN: I said, we, I'm not sure  
21 what the Department is going to be able to do above and --  
22 you know, I guess I feel like, you know, the Department is  
23 sort of holding out that if we -- if we have proficiency  
24 tests and we just don't pass them, as you just said, year  
25 after year after year, there's a problem.

1 I mean, you have to have, give some recognition to  
2 the fact that these are accredited laboratories and there  
3 are consequences of not passing proficiency tests.

4 So we can tackle what we want to do but it needs  
5 to be very clear that we are not just trying to get away  
6 with failing all our proficiency tests and having no one do  
7 anything about it.

8 CHAIRMAN KIMSEY: No, no, I didn't mean to imply  
9 that. This is Paul. I'm just curious is that -- I mean  
10 right now the Department, and maybe this is what we want,  
11 but the Department is not going to be doing anything with  
12 this information except collecting it.

13 MR. LYLE: This is Bruce from San Diego. What  
14 would the Department like to do with it?

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 Well, I think we would continue the current program. We  
17 look at the results, compile statistics based on the  
18 performances of other California labs and make a reasonable  
19 statistically valid determination of what constitutes an  
20 outlier result. And when those occur we ask the lab to  
21 provide a written clarification.

22 To some cases if there's changes in the method,  
23 experimental data that demonstrates that the method with the  
24 corrections is capable of meeting the standard performance  
25 requirements.

1           COMMITTEE MEMBER SHEN: This is Jennifer. You  
2 know, and I don't think that's an unreasonable request  
3 except for the fact that as we talk about it, we don't want  
4 to be specific with it and we're already there.

5           My understanding that once that, that these  
6 proficiency tests results already go through the process of,  
7 they collect the data, they, you know, they determine the  
8 outliers, they provide all that information. And then if  
9 our analyst doesn't pass a proficiency test we have to, you  
10 know, we have to address that. We have to address that to  
11 ASCLD/LABS for us, for our laboratory.

12           And once I know why that is and what we did. So,  
13 we're already doing those things. So, perhaps what we need  
14 to do is, I don't know that it's worthwhile for the  
15 Department to spend time and money reanalyzing all the data  
16 that's already been analyzed.

17           You'll have it. And maybe all we need to do here  
18 is to provide, if in fact an analyst falls out, falls  
19 outside what is acceptable or there is an outlier, that you  
20 will get in addition a copy of the written response that the  
21 laboratories have to do now to address that problem.

22           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 You know. A couple of comments on the continued reference  
24 to ASCLD/LAB. Number one, there is no requirement in the  
25 regulations that any lab ever be accredited by ASCLD/LAB, by

1 any accreditation organization. There are certainly some  
2 labs that aren't accredited.

3 But regarding, you focussed the conversation here  
4 on analysts' proficiency tests; there's no requirement that  
5 the laboratory submit, for consideration to ASCLD/LAB or to  
6 the Proficiency Review Committee, any analyst's PT data.

7 Moreover, ASCLD/LABS has got the very user-  
8 friendly definition of a successful performance. And it  
9 says basically, you get expected results or failing to get  
10 expected results you take corrective action in accordance  
11 with the lab's quality assurance policies.

12 So, there's no absolute requirement that --  
13 there's no reason to believe that ASCLD/LAB, for those labs  
14 that are accredited by ASCLD/LAB, is ever going to see  
15 analysts' PT data. It's never submitted.

16 So, I think it's irrelevant.

17 COMMITTEE MEMBER SHEN: You know, I need my  
18 (indiscernible) right here but I don't think that's true. I  
19 think that, I think, you know, is there anyone else that can  
20 help me with this? I believe that the, that the proficiency  
21 tests are -- that our accrediting agencies (indiscernible)  
22 to them when we do not pass.

23 Yeah. I'm not 100 percent sure about that but I'm  
24 pretty sure because we have to then address them. So,  
25 again, about them being duplicative, perhaps when there is a

1 result that is an outlier or is considered a non-pass that  
2 the laboratories, if in fact the laboratory is accredited by  
3 a body that makes them address it and come up with a written  
4 response and a plan to fix it, then we just simply pass  
5 forward that information to the Department. The Department  
6 knows that we have taken steps to address it.

7 For those laboratories who are not accredited then  
8 I would agree, you would, the Department would need to  
9 follow up with them in some fashion.

10 COMMITTEE MEMBER WONG: I agree, Jennifer, because  
11 our lab is accredited by FQS and each analyst has to pass  
12 their proficiencies, which are reported to the accrediting  
13 body and checked. And if there's a problem, our individual  
14 laboratory or your local labs are going to be much more  
15 concerned even before, way before, the CDPH is ever  
16 concerned about that.

17 So, it would just be another example of  
18 duplicative nature like it was in the past.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
20 You know, I don't, I'm not familiar, I must say, with FQS's  
21 requirements. They don't seem to publish them. I look on  
22 their website, it seems to be -- but ASCLD/LAB, Jennifer  
23 invited a comment from her colleagues, I would be interested  
24 to hear a response regarding any, any possibility that what  
25 I said was incorrect.

1           But the other, I mean I'm not sure this is  
2 important, but the other feature of ASCLD/LAB'S  
3 accreditation, I'm sorry, the proficiency testing program,  
4 is that in their bylaws it is completely confidential. So  
5 the records aren't made public.

6           So there's a real distinction between a  
7 governmental oversight process in which everything is public  
8 and ASCLD/LAB'S procedures which are 100 percent  
9 confidential.

10           COMMITTEE MEMBER WONG: They are not 100 percent  
11 confidential. This is Kenton in Richmond. Any defense  
12 attorney can ask for examiner or analysts' proficiency tests  
13 for the last five years if they want and they can drag all  
14 of that into court. So it's not confidential.

15           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 The Department may not have the luxury of doing those kinds  
17 of requests. I mean that kind of harkens back to the issue  
18 that the courts are going to, we waver on whether the courts  
19 are going to enforce these regulations or whether ASCLD/LAB  
20 is going to enforce them.

21           I think there are problems. The current program  
22 has a department. And the statute remains, 100725 has a  
23 department which enforces the regulations.

24           And the program here is proposing changes that  
25 will allow the Department to enforce the regulations.

1 CHAIRMAN KIMSEY: This is Paul --

2 COMMITTEE MEMBER JEFFRIES: Dan Jeffries from CDAA  
3 down in San Diego. I would note that it's sort of that all  
4 the Title 17 regulations are in some way self-enforcing.  
5 That is, any non-compliance with Title 17 will be argued up  
6 and down the state.

7 If you have a requirement in Title 17 that lab  
8 directors wear green coats and there's a non-compliance with  
9 that, every defense attorney in the state will be arguing  
10 that in every DUI filed in the state.

11 Whether the state takes any action on that or not,  
12 it will become relevant and will become known to everyone  
13 throughout the state.

14 So whatever regulations are adopted will be  
15 enforced simply because they will be argued in court in  
16 criminal cases in terms of both admissibility and the weight  
17 given to it by a jury.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 And those mechanisms have existed for, you know, since the  
20 state in 1969 adopted a program besides the cauldron of the  
21 courtroom I think you're referring to.

22 The state adopted statutes which asked the  
23 Department, and other states have similar programs, asked  
24 the Department to provide an oversight of the chemical  
25 testing in support of the drunk driving laws.

1           So certainly the Legislature when they passed that  
2 was aware that things could be introduced in a court.

3           You know, the other issue is that, I've heard  
4 various estimates, perhaps you could provide me one. Eighty  
5 to 90 plus percent of DUI cases never go to trial.

6           COMMITTEE MEMBER JEFFRIES: I think that, this is  
7 Dan Jeffries again. I think it's much higher than that,  
8 probably 99 percent of them do not go to trial. At least in  
9 Los Angeles County we're seeing fewer than one percent of  
10 the DUI cases go to trial.

11           Besides, if you know that a laboratory is not  
12 complying with Title 17, if you know that none of their  
13 methods are tested, that there's no proficiency exam, that  
14 no one is accredited at all, we would expect that the one  
15 percent would go up significantly. A lot more people would  
16 bring things to trial because they would be able to have  
17 something to argue about why the science is wrong.

18           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 And I submit the Legislature in passing, you know, a law  
20 which is retained that requires the Department to enforce  
21 the Department's regulations and the law; anticipated a more  
22 proactive approach, not simply waiting until a scofflaw lab  
23 had made enough mistakes so everyone became aware of it.

24           I think the intent of the law is, as I say, to  
25 provide a more proactive program that makes it less likely

1 and/or prevents that from happening.

2 CHAIRMAN KIMSEY: This is Paul real quick. I  
3 think this has been a good discussion and we're sort of  
4 going around. It's also bringing back memories for a lot of  
5 us.

6 I think it's pretty clear that currently, unless a  
7 Committee member wants to propose some additional language  
8 that -- I've heard a lot of people on the Committee make  
9 comments that they don't want the Department's role to be  
10 duplicative.

11 And, as I remember also, previously the idea was  
12 is that the Department pretty much wanted to see directly  
13 from the providers proficiency testing results which would  
14 be the same thing that the laboratory would see.

15 And I think, pretty much, the Committee's  
16 perspective has been that that would be sort of the limit of  
17 the Department's role. That we would not be redoing or  
18 reduplicating what the external proficiency testing provider  
19 had done.

20 So, I mean, I understand the arguments. I'm just  
21 sort of trying to move the discussion along.

22 Is there anyone on the Committee that wants to  
23 propose an additional role for the Department besides what  
24 this bullet discussion has already outlined?

25 COMMITTEE MEMBER SHEN: This is Jennifer. You

1 know. I think -- I mean, I get the point that -- and I get  
2 the point that the Department is going to be looking at  
3 these and they, and someone sees that there is something  
4 that has not been passed that the Department would want  
5 assurances that it has been addressed.

6 So, I do get that and I can see that that would be  
7 something that would possibly be reasonable. I just, I  
8 don't want to do things, I don't want to duplicate efforts.

9 And I don't think the Department would want to duplicate  
10 efforts, for instance, re-analyzing all the stats on the  
11 proficiency tests. I don't see that there's any point to  
12 that.

13 So, I mean, I wouldn't be opposed to some sort of  
14 language in here that indicated that we provided the  
15 Department with some information that we have handled the  
16 problem.

17 CHAIRMAN KIMSEY: So the correction, the  
18 Department would be notified of a corrective action or --

19 COMMITTEE MEMBER WONG: Resolution.

20 CHAIRMAN KIMSEY: -- a resolution to the --

21 COMMITTEE MEMBER SHEN: Yes, to the problem.

22 Which is actually twofold. One, they can see, the  
23 Department could see how we address it and two, the  
24 Department can rest assured that, in fact, it was noted and  
25 addressed. So it's not left for the Department to wonder if

1 we, you know, noticed we didn't pass something and if we did  
2 anything about it. I don't think that's particularly  
3 unreasonable.

4 CHAIRMAN KIMSEY: So it sounds like maybe an  
5 additional sentence? The Department would be notified of  
6 corrective actions based on negative proficiency test  
7 results or --

8 COMMITTEE MEMBER SHEN: Well that's, you know,  
9 that's what I think. I don't know about anyone else thinks.  
10 But I would be willing to go that road.

11 COMMITTEE MEMBER WONG: Clay.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
13 Well I, so, it's not clear to me how we define a negative  
14 result and who made that determination? And that would  
15 apply to the gamut of labs out there, the labs that are  
16 accredited, not accredited, accredited by FQS, accredited by  
17 ASCLD/LAB. I'm not sure what -- given the fact that  
18 ASCLD/LAB defines a, it doesn't require a successful  
19 performance and defines a successful performance, in the  
20 case of the analysts, as either getting the right results or  
21 saying, I'm sorry.

22 So I'm not sure what, I mean, I don't want to go  
23 back to the Caveman times but I'm not sure what -- it seems  
24 as you articulated, I realize I was not, you weren't  
25 necessarily drafting regulatory language, that the notion of

1 a negative or adverse result or whatever term you used,  
2 seemed a little fuzzy.

3 CHAIRMAN KIMSEY: Well I just wrote down here real  
4 quickly a sentence, the Department will be notified of  
5 corrective action for each PT failure?

6 COMMITTEE MEMBER SHEN: Well we're going to have a  
7 problem with identifying what failure is.

8 RESEARCH SCIENTIST SPELL: Exactly. Because it  
9 seems that ASCLD/LAB and Department have slightly, I mean,  
10 to say from statistical point of view, not slightly but  
11 significantly different criteria for passing and not passing  
12 the test.

13 We currently have plus/minus percent, five percent  
14 while dealing with the data from CDS provider and CAP  
15 provider, the data from California Lab I noticed that they  
16 only mark outlier if this is beyond three sigma, which is  
17 quite a big range.

18 So, there is certain conflict in idea where are  
19 the criteria of the failure -- of the lab?

20 COMMITTEE MEMBER SHEN: Well maybe we don't do  
21 that then. Maybe we shouldn't have access then. I mean, I  
22 think at the end of the day what we're looking at is we have  
23 approved providers who, this is, you know, these companies,  
24 this is what they do for a living. They are giving us  
25 tests, they're analyzing the data and they're providing that

1 data to us telling us how our analysts do in comparison to  
2 everybody else that has taken those tests.

3 So that work is already done. I think it's fairly  
4 clear when you have an outlier, fairly clear when you don't  
5 fall within the accepted range.

6 So, and we have to address that. As an accredited  
7 laboratory we have to address those failures. So there will  
8 be paperwork on of those and we can forward them so that the  
9 Department can see that.

10 CHAIRMAN KIMSEY: So maybe "failure" is I think  
11 the word that has sort of caused the stumbling block. Maybe  
12 the Department will be notified of corrective actions for  
13 each proficiency testing --

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
15 Boo-boo (laughter).

16 RESEARCH SCIENTIST SPELL: What is defined as a  
17 boo-boo?

18 COMMITTEE MEMBER SHEN: Yeah, that is the problem  
19 right there.

20 RESEARCH SCIENTIST SPELL: Yeah, exactly.

21 COMMITTEE MEMBER SHEN: So and I, again I -- I am  
22 not as well-versed in this as I should be. But the PT, I  
23 don't believe -- CPS is something that most laboratories  
24 use, I think. I don't believe they give you a pass/fail.  
25 They just -- I think they give you the data and you look at

1 it, your quality assurance manager or whoever is in charge  
2 of proficiency tests, takes a look at the results.

3 RESEARCH SCIENTIST SPELL: It's internal  
4 proficiency test results --

5 COMMITTEE MEMBER SHEN: -- acceptable range. So  
6 I --

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
8 I think that's a definition of an internal proficiency test.  
9 In other words, each of the 40 labs' QA manager would  
10 assigned under the regulations, assigned responsibility to  
11 determine whether that performance was, you know, met the  
12 standards of performance requirements in that field.

13 COMMITTEE MEMBER SHEN: Right. I'm just saying,  
14 it's not going to be very straight forward. We don't get  
15 something back from CPS that says, you failed. Okay, that  
16 was a failure so we're going to report that. It's not that,  
17 not that clear cut.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 And I'm saying, under the current regulations, under the  
20 current program, you get a letter back from CDPH that says,  
21 you failed or you passed. So, we're replacing that with --

22 COMMITTEE MEMBER SHEN: Well --

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
24 -- something arguably much fuzzier.

25 COMMITTEE MEMBER SHEN: Well, we're replacing it

1 with a proficiency test process that's much better. You may  
2 not like the reporting. The actual process of the  
3 proficiency test program itself in my opinion is much, much  
4 better.

5 RESEARCH SCIENTIST SPELL: Excuse me, Jennifer,  
6 it's Natalia Spell. Can you clarify actually, what is the  
7 reason that you believe that it is better? Do you have any  
8 factual material to prove it?

9 COMMITTEE MEMBER SHEN: Well actually, you know,  
10 we've gone around and around on this and I don't want to get  
11 into it because it's long and lengthy but, you know, I do.  
12 And our justifications, if you read the justifications for  
13 the changes, there's a lot of information in there that  
14 would, that would answer that question.

15 But I don't think that's an appropriate  
16 conversation to have here but if you look at the  
17 justification of the work product and specifically in  
18 reference to proficiency tests, you will see why it is that  
19 I think that.

20 CHAIRMAN KIMSEY: So back to, maybe or maybe not  
21 having a second sentence. This is Paul. Would there be any  
22 benefit if the Department was notified of a corrective  
23 action or does the Department having access to what the  
24 provider submits to, sends back to the laboratory, is that  
25 sufficient?

1 COMMITTEE MEMBER WONG: Well it already says that  
2 we're going to be submitting all external proficiency test  
3 results.

4 CHAIRMAN KIMSEY: Right.

5 COMMITTEE MEMBER WONG: So --

6 CHAIRMAN KIMSEY: We could say, including  
7 corrective action.

8 COMMITTEE MEMBER WONG: I don't even think you  
9 need to say that because it's saying, **all** external  
10 proficiency test results.

11 CHAIRMAN KIMSEY: Okay.

12 COMMITTEE MEMBER WONG: You guys are getting  
13 everything.

14 CHAIRMAN KIMSEY: Well it's going from the  
15 provider to the lab.

16 COMMITTEE MEMBER WONG: Right.

17 CHAIRMAN KIMSEY: I don't know about from the lab  
18 to the provider.

19 COMMITTEE MEMBER WONG: It's going to be **all**  
20 external test results, not just certain ones. You're going  
21 to get them all.

22 CHAIRMAN KIMSEY: Okay.

23 COMMITTEE MEMBER SHEN: Do you think that means  
24 that if we have a corrective action then that is encompassed  
25 in that statement?

1 COMMITTEE MEMBER WONG: **All** test results, right?

2 COMMITTEE MEMBER SHEN: So, if we have a test  
3 result and something happened and they didn't go well and so  
4 there was some sort of corrective action taken, retraining,  
5 retesting, you know, doing whatever it is we've decided  
6 needs to be done, do you believe that what we have written  
7 there will cover sending the Department those corrective  
8 actions steps?

9 COMMITTEE MEMBER WONG: That's the way I read it.  
10 I mean, that whatever external proficiency test results the  
11 laboratories subscribe to and perform, that those results  
12 will eventually get forwarded to the Department.

13 CHAIRMAN KIMSEY: I sort of saw that as one  
14 direction. But, that anything that the approved provider  
15 sent to the laboratory, the Department would get a copy of.

16 It's not clear to me necessarily that what the  
17 laboratory sends back to the provider in the way of a  
18 corrective action would come to the Department.

19 COMMITTEE MEMBER SHEN: I would tend to agree with  
20 that.

21 COMMITTEE MEMBER WONG: Uh-hmm.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 Moreover, the laboratory would not be submitting any reports  
24 of corrective action to the PT provider. We disagree with,  
25 apparently in some cases might submit something through the,

1 to the PRC, Proficiency Review Committee, if it's an  
2 ASCLD/LAB. I don't know what FQS does but -- so it wouldn't  
3 be the provider that's getting the report of corrective  
4 action.

5 COMMITTEE MEMBER SHEN: So, we probably could  
6 accomplish that by just adding, including any corrective  
7 action taken if necessary or something.

8 CHAIRMAN KIMSEY: So, to submit all external  
9 proficiency test results including corrective actions to the  
10 Department.

11 COMMITTEE MEMBER WONG: I think that's fair.

12 CHAIRMAN KIMSEY: But I guess the question that  
13 Clay is raising is do the laboratories routinely send back  
14 to their approved providers corrective action steps? I  
15 mean, does the provider care if they're not giving up, sort  
16 of a pass/fail criteria and that's up to the quality  
17 assurance individual in the laboratory. Does the external  
18 provider, is there a requirement through ASCLD/LAB or the  
19 other accrediting groups that their corrective action take  
20 place or is it just more informational?

21 COMMITTEE MEMBER SEDGEWICK: This is Paul  
22 Sedgewick in San Diego. Proficiency Review Committee is  
23 required to receive that information and they look it over  
24 and they require remedial action.

25 CHAIRMAN KIMSEY: That's for ASCLD. How about the

1 other groups? Do you know?

2 COMMITTEE MEMBER WONG: We have to do the same.

3 CHAIRMAN KIMSEY: The same.

4 COMMITTEE MEMBER SHEN: This is Jennifer. I don't  
5 think, and again I, I don't think that we provide anything  
6 back to the approved provider. Our response, the approved  
7 provider sends our results to our accrediting body.

8 COMMITTEE MEMBER WONG: Right.

9 COMMITTEE MEMBER SHEN: And we have to respond to  
10 our accrediting body. I don't think that, unless they have  
11 some sort of clarifying question, that we're contacting the  
12 approved provider.

13 The approved provider, if they're the direct  
14 conduit of results from an approved provider to the  
15 Department, that will not accomplish getting corrective  
16 actions to the Department.

17 COMMITTEE MEMBER WONG: Okay. So. This is Kenton  
18 in Richmond. The bottom line for this bullet that Lyle has  
19 drafted, that Bruce has drafted, is just transparency,  
20 right?

21 COMMITTEE MEMBER SHEN: Correct.

22 COMMITTEE MEMBER WONG: We want to have  
23 transparency to the Department so that they can see that  
24 everything is up to snuff.

25 CHAIRMAN KIMSEY: Or not.

1 COMMITTEE MEMBER WONG: Or not.

2 MR. LYLE: Bruce, yeah that's --

3 COMMITTEE MEMBER WONG: Well. So that's, whatever  
4 it is we just need to make sure that it's all transparent.

5 COMMITTEE MEMBER SHEN: Yes I agree.

6 MR. LYLE: That's correct. And if the Department,  
7 this is Bruce again. If the Department needs, it does seem  
8 to sort of hang there without addressing what the Department  
9 does with that information.

10 And it seems like the Department is getting all  
11 this information from the provider and then, and I think I  
12 heard Clay say that they have a different -- or somebody  
13 said that the Department has a different threshold or -- you  
14 know, what their threshold for a boo-boo is --

15 RESEARCH SCIENTIST SPELL: Criteria.

16 MR. LYLE: -- is different than what ASCLD or  
17 somebody else may be. So why don't they compile all this  
18 information and why don't we say that they can compile it,  
19 study it and analyze it, the test results. And if they  
20 recognize an aberration or an outlier or a boo-boo or  
21 whatever we want to call it, they can request that  
22 corrective action from the laboratory.

23 RESEARCH SCIENTIST SPELL: I agree.

24 CHAIRMAN KIMSEY: Well that's getting back to what  
25 the Department currently does, which it's my impression that

1 the Committee was moving away from.

2 COMMITTEE MEMBER SHEN: This is Jennifer. We, I  
3 mean I think that if we're going to go that route the  
4 corrective action has to be we can supply a copy of the  
5 corrective action to the Department at that time that we  
6 have already taken.

7 The bottom line is, there isn't going to be a  
8 situation, it's not likely that there is going to be a  
9 situation where the laboratories have a (indiscernible)  
10 scope of error unless there is some sort of, some sort of  
11 aberration, something strange happens like, for instance, in  
12 the -- for our own proficiency tests we transported them  
13 some, what, at one point and all of the, all the volatiles  
14 evaporated so everybody got negative results. And barring  
15 something strange going on.

16 You know, the labs are pretty tight requirements.  
17 So, what I don't want to do is where we started. I don't  
18 want to recreate a process and have the Department do  
19 something that we're already doing.

20 So, I'm not sure we want to put the Department in  
21 a position where they will now determine that in addition to  
22 what we've already done the Department is going to have to  
23 do something else.

24 COMMITTEE MEMBER WONG: I agree.

25 CHAIRMAN KIMSEY: But there is an interest in

1 having the Department in the loop sort of knowing that a  
2 corrective action has taken place.

3 COMMITTEE MEMBER WONG: Correct. I agree with  
4 that.

5 COMMITTEE MEMBER SHEN: Maybe we should go back to  
6 that then; including any corrective actions that have taken  
7 place and just call it a day.

8 CHAIRMAN KIMSEY: So, laboratories will direct an  
9 approved provider to submit all external proficiency test  
10 results including corrective actions to the Department at a  
11 minimum of one per year per analyst.

12 COMMITTEE MEMBER SHEN: This is Jennifer. I'm  
13 taking notes. The laboratories, what I have right now is  
14 the laboratories will direct approved providers to submit an  
15 external proficiency test result as required by H&S 100702  
16 to the Department at a minimum of one per year per analyst,  
17 any corrective actions -- documentation? Corrective  
18 action --

19 MR. LYLE: That should be, taken.

20 COMMITTEE MEMBER SHEN: -- taken. Including  
21 documentation of any corrective actions taken?

22 COMMITTEE MEMBER WONG: That's all transparent.

23 COMMITTEE MEMBER JEFFRIES: Dan Jeffries in San  
24 Diego. The language in 100702 refers to corrective actions  
25 taken so we can just mirror that language.

1 COMMITTEE MEMBER WONG: It sounds good, Jennifer.

2 CHAIRMAN KIMSEY: Any other comments from the  
3 Committee?

4 COMMITTEE MEMBER SHEN: Hi, this is Jennifer.  
5 Bruce pointed out to me that I put, laboratories will direct  
6 approved providers to submit **an** external proficiency test  
7 results. And I, he pointed out that some of those could be  
8 all. That it will be **all** external proficiency test results  
9 as required, blah, blah, blah, at a minimum of one per  
10 analyst per year.

11 CHAIRMAN KIMSEY: Okay. So, do we want to vote on  
12 this as a Committee?

13 (No response.)

14 Any other suggestions to the language? Any  
15 questions on the language?

16 MS. LYONS: This is Denise Lyons. I had one  
17 comment about the last language that Jennifer read. And the  
18 way it was worded it seemed to imply, and I think this was  
19 Clay's concern, that the corrective action come from the  
20 provider, the way it's written. And the corrective action  
21 documentation would indeed come from the laboratory. And I  
22 think trying to combine that into one sentence makes it  
23 unclear who will be providing the documentation for the  
24 corrective action.

25 COMMITTEE MEMBER SHEN: Perhaps we need two

1 sentences then. In addition, the laboratory, -- I don't  
2 want to say the laboratories. The laboratory will forward  
3 any documentation of corrective actions taken?

4 CHAIRMAN KIMSEY: That's pretty clear.

5 COMMITTEE MEMBER WONG: Uh-hmm.

6 COMMITTEE MEMBER SHEN: That be better?

7 COMMITTEE MEMBER WONG: Uh-hmm.

8 COMMITTEE MEMBER SHEN: So it will be two separate  
9 sentences. Are we going to, can we say the laboratory will  
10 send. I guess we can.

11 CHAIRMAN KIMSEY: Okay. Other comments before we  
12 vote?

13 COMMITTEE MEMBER SHEN: You want me to read this  
14 again?

15 COMMITTEE MEMBER WONG: Read it one more time.

16 COMMITTEE MEMBER SHEN: Okay. Good.

17 CHAIRMAN KIMSEY: Sure as requested, have it read  
18 one more time please.

19 COMMITTEE MEMBER SHEN: I need one more second,  
20 hang on. Okay. The laboratories will direct approved  
21 providers to submit all external proficiency test results as  
22 required by H&S 100702 to the Department at a minimum of one  
23 per analyst per year. In addition, the laboratory will send  
24 to the Department any documentation, documentation of any  
25 corrective actions taken.

1 COMMITTEE MEMBER WONG: Cool.

2 CHAIRMAN KIMSEY: Okay, any Committee member  
3 dissatisfied with the language?

4 COMMITTEE MEMBER SEDGEWICK: This is Paul  
5 Sedgewick. I've made this comment before. And I just want  
6 to go on record as saying, I'm philosophically opposed to  
7 requiring laboratories to do anything that has no  
8 consequences.

9 The Department of Health is, by statute, not  
10 allowed to pull their license because they don't have  
11 licenses. They don't anything that they can do that I'm  
12 aware of that gives any result or any consequence to what  
13 these people are being required to do.

14 I just want to go on record with that.

15 CHAIRMAN KIMSEY: Okay.

16 RESEARCH SCIENTIST SPELL: Yeah, I'm still not,  
17 I'm still not clear about criteria. Does it mean that each  
18 lab specifically sets criteria for itself, pass or fail?

19 There is no clarity from either the provider or  
20 ASCLD/LAB director, they pass, fail? So, do they set  
21 criteria themselves? So -- or what? Do they do their  
22 statistical data treatment? Each lab by itself?

23 How do we make a conclusion whether they passed or  
24 failed?

25 CHAIRMAN KIMSEY: Well, the Department doesn't.

1 RESEARCH SCIENTIST SPELL: Well, who makes these  
2 conclusions then?

3 CHAIRMAN KIMSEY: It's the providers and the  
4 laboratory.

5 RESEARCH SCIENTIST SPELL: Providers --

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
7 No, not the providers --

8 RESEARCH SCIENTIST SPELL: -- no, it's not --

9 CHAIRMAN KIMSEY: -- well the --

10 RESEARCH SCIENTIST SPELL: -- no, providers don't  
11 do it.

12 CHAIRMAN KIMSEY: -- the accrediting organization.

13 RESEARCH SCIENTIST SPELL: But as I stated, the  
14 accrediting organization, we don't know their criteria  
15 actually. It might be very broad.

16 And then, if it is much broader than what we have  
17 now plus/minus five percent, I couldn't see why the step to  
18 moving towards ASCLD/LAB accreditation is better than what  
19 it was before when the Department had oversight.

20 If you have narrow criteria, you stand up against  
21 more, I mean better standards. If you have broader  
22 criteria, which is as I told the provider mark outlier as  
23 three sigma, which is extremely broad, then you stand up to  
24 very vague and very, I would say, worse, criteria.

25 CHAIRMAN KIMSEY: No, that's been explained

1 before. The Committee is not interested in having the  
2 Department go through their proficiency testing program.

3 RESEARCH SCIENTIST SPELL: And what kind of  
4 oversight could be, we talking about? If we don't know  
5 their criteria --

6 COMMITTEE MEMBER SHEN: Well that's --

7 RESEARCH SCIENTIST SPELL: -- we cannot make any  
8 conclusions. What is their performance? Is it substandard?  
9 Is it better than other statewide labs? Is it worse?

10 CHAIRMAN KIMSEY: It's not the Department's  
11 concern.

12 RESEARCH SCIENTIST SPELL: Okay.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
14 Well it may be but it's - well, it's the Committee's  
15 responsibility.

16 CHAIRMAN KIMSEY: Right. It's the Committee's  
17 responsibility. So back to the, this, the two sentences.  
18 Thank you Paul for your comment about the general idea of  
19 the Department's role. Any other comments from the  
20 Committee?

21 (No response.)

22 Okay. Let's move on to bullets two and four. I  
23 believe those were yours, Jennifer.

24 COMMITTEE MEMBER SHEN: Paul, are we going to vote  
25 on that?

1 CHAIRMAN KIMSEY: Do we need to?

2 COMMITTEE MEMBER SHEN: I don't know, do we?

3 CHAIRMAN KIMSEY: I think the Committee has pretty  
4 much approved it. So --

5 COMMITTEE MEMBER SHEN: Okay, it works for me.

6 CHAIRMAN KIMSEY: Okay.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
8 One process point. In presenting bullets two and four they  
9 are actually presented, we provided the email that Jennifer  
10 sent and it says, two and four but actually they're  
11 presented as four and two.

12 So, if we want to go in the order that was  
13 contained in the letter we should go to the second bullet,  
14 which is two, and then come back to the first bullet which  
15 is four.

16 CHAIRMAN KIMSEY: Okay.

17 COMMITTEE MEMBER SHEN: Because I found four  
18 easier than two (laughter).

19 CHAIRMAN KIMSEY: Well let's take the one at the  
20 top of the page which is four first then, since that's  
21 easier.

22 It says, remove the requirements for a laboratory  
23 to provide CDPH with records of its activities under the  
24 regulations including notification by a laboratory of its  
25 intent to perform forensic alcohol analysis.

1           And you suggested, 1216(a), every laboratory  
2 performing forensic alcohol analysis will have on record  
3 with the Department the following: a statement of intent to  
4 perform or stop performing alcohol analysis to include  
5 notification for breath and fluid analysis specifically;  
6 two, the laboratory's address as well as the name, address  
7 and phone number of the laboratory's point of contact;  
8 three, a list of laboratory personnel qualified to do  
9 forensic alcohol analysis; and four, a list of instruments  
10 used by the laboratory personnel for alcohol analysis.

11           Comments?

12           COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries.

13           Just a question on one. Why is there a need to tell you of  
14 the intent to stop or start performing alcohol testing? Is  
15 there something that you'll do in response to either of  
16 those notifications?

17           CHAIRMAN KIMSEY: Some of the, this is Paul. Some  
18 of the back and forth has been, since we're not licensing  
19 and we do still have responsibility for the regulations, the  
20 Department; that the Committee had some discussions back and  
21 forth about, how would we know who was doing this work?

22           And so that is part of the background on the  
23 intent to perform. That the Department be notified that an  
24 entity was going to do this type of work. I'm not sure so  
25 much about the stop performing part.

1           But that was some of the ideas around the  
2 Department just knowing who in the state was going to be  
3 doing this type of work.

4           COMMITTEE MEMBER JEFFRIES: Dan Jeffries again. I  
5 guess my concern is the statement of intent makes it sound  
6 like there's some question as to whether it's going to be  
7 allowed to go forward or not. That that is what the lab  
8 intends to do provided they receive approval from Sacramento  
9 they're going to do it.

10           It seems like they're going to go forward and it's  
11 really just that you want to know when they started testing  
12 and when you stop testing.

13           CHAIRMAN KIMSEY: That's a good point. You  
14 suggest a different word? Wording?

15           COMMITTEE MEMBER JEFFRIES: I think something  
16 along the lines of notification of initiation of alcohol  
17 analysis or discontinuation of alcohol analysis.

18           If what we're really looking for is just that the  
19 Department be notified.

20           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
21 Clay Larson. Actually I think, I kind of suspect that  
22 taking four of the, that there was probably some  
23 intelligence in the, in the ordering that was in the  
24 original letter. And taking four before two and three  
25 probably is a disadvantage for this discussion.

1           There are a number of activities that a lab  
2 performs. Besides analysis of blood, urine and tissue  
3 samples the labs are also tasked under the regulations with  
4 certain responsibilities involving breath alcohol analysis  
5 that involve training the instrument operator and then  
6 maintaining and determining the accuracy of the instrument.

7           So I think that the notification requirements  
8 would have to include a description of those activities.  
9 That's it.

10           COMMITTEE MEMBER SHEN: This is Jennifer. The  
11 notification for breath and fluid analysis specifically is  
12 in the language.

13           CHAIRMAN KIMSEY: I'm sorry Jennifer. Can you get  
14 a little closer to the mic. You're pretty soft.

15           COMMITTEE MEMBER SHEN: To include a statement for  
16 breath and fluid analysis specifically is in the language  
17 right now. Does that not cover what we need to?

18           Notification of intent then -- notification of  
19 initiation or discontinuation of alcohol analysis to include  
20 notification for breath and fluid analysis specifically.

21           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
22 Yeah, okay. But regarding breath alcohol analysis, I do see  
23 it's, although that term fluid analysis would have to be  
24 defined. It's nowhere defined in -- and a gas is a fluid in  
25 terms of, if you remember your basic physics, so, it's a

1 little bit -- I don't think that the language necessarily  
2 captures it but I think that was your intent.

3 I think there is a lot missing here if we talked  
4 about breath alcohol analysis that involves -- and when we  
5 get to talk to the training component we'll talk the fact  
6 that labs under the current regulations and even as proposed  
7 by at least the Committee so far would have a role in  
8 approving that training procedure so, we need to know what  
9 instrument they are using.

10 You know, I think, my list for the notification  
11 form included the name of the laboratory, mailing address,  
12 telephone and fax numbers, full names of the person. We  
13 also now, and I think it's appropriate to require that, not  
14 a contact person but the labs identify someone at the  
15 laboratory who is responsible for the activities of the  
16 laboratory under the regulations.

17 We need a description of the activities to be  
18 performed by the laboratory. We'll need the name of the  
19 test provider the lab intends to use.

20 I think we should continue to require a copy of  
21 the written descriptions of methods for forensic alcohol  
22 analysis. We currently require labs to submit experimental  
23 data demonstrating, I assume, similar to something they may  
24 submit to their accrediting body for those labs that are  
25 accredited. But experimental data sometimes called,

1 validation data, which describes the capabilities of the  
2 method.

3           They will be required, and we haven't talked about  
4 training, but to submit written descriptions of any training  
5 program conducted by the laboratory.

6           We'll need the full names of each person  
7 performing or intending to perform forensic alcohol  
8 analysis. And this will all be signed by the, currently by  
9 the person responsible and the owner/administrator.

10           So I think we're going to need to -- just like any  
11 normal regulatory program we're going to need to capture  
12 those, all those items of information.

13           COMMITTEE MEMBER SHEN: Well, I can assure you it  
14 was my intent to provide the full names of the analysts. I  
15 think the point of contact might be, I mean, the  
16 laboratory's point of contact could be clarified to indicate  
17 the person who is in charge of the regulations, the person  
18 -- regulations that, that should be a verbiage change.

19           But instruments used by laboratory personnel are  
20 already included in this report here.

21           CHAIRMAN KIMSEY: Any interest to, any Committee  
22 member to add to the, this list of four that Jennifer has  
23 proposed?

24           MR. LYLE: Bruce in San Diego. It seems like it's  
25 duplicating efforts if we go on and list all the training

1 and all the other things that are already listed for the  
2 accrediting body.

3 CHAIRMAN KIMSEY: Okay. We sort of got, did we  
4 sort of agree that notification rather than intent to  
5 perform or stop performing alcohol analysis? So a statement  
6 of notification to perform alcohol analysis?

7 COMMITTEE MEMBER SHEN: That's fine with me. I  
8 can just change the word "intent" to "notification."

9 CHAIRMAN KIMSEY: Pretty much. It's a little  
10 English in there, but, yeah.

11 This issue of fluid analysis --

12 COMMITTEE MEMBER SHEN: And I'd like to exclude  
13 gas. I'm kidding. Do we want to clarify the point of  
14 contact?

15 CHAIRMAN KIMSEY: Yeah. What seems appropriate?  
16 I mean, I have a lot of regulatory oversight and sometimes  
17 I'm called the responsible official. What else am I called?

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 You really want to know (laughter)?

20 CHAIRMAN KIMSEY: Yeah.

21 COMMITTEE MEMBER WONG: Don't go there.

22 CHAIRMAN KIMSEY: What's the language sort of in  
23 the forensic laboratory?

24 COMMITTEE MEMBER SHEN: I mean, well, I don't  
25 know, I don't know what to put there.

1 COMMITTEE MEMBER WONG: Big Kahuna.

2 RESEARCH SCIENTIST SPELL: Or someone  
3 responsible --

4 COMMITTEE MEMBER SHEN: Or just the appropriate  
5 point of contact but then might wonder what, appropriate,  
6 was.

7 CHAIRMAN KIMSEY: I'm sometimes called an  
8 institutional official.

9 COMMITTEE MEMBER SHEN: Yikes.

10 CHAIRMAN KIMSEY: Well point of contact, that  
11 certainly gets to somebody in the laboratory of some  
12 significance.

13 COMMITTEE MEMBER SHEN: I would agree, maybe it's  
14 fine just the way it is.

15 COMMITTEE MEMBER SEDGEWICK: This is Paul  
16 Sedgewick. I agree with that too because you might be  
17 wanting to contact different people for different purposes.

18 And all you really need is to get to the laboratory and  
19 tell them who you want or what you want.

20 COMMITTEE MEMBER WONG: Do we need "address"  
21 twice?

22 COMMITTEE MEMBER SHEN: Probably not if your point  
23 of contact is at the laboratory.

24 COMMITTEE MEMBER WONG: Right.

25 COMMITTEE MEMBER SHEN: So I'll take the second

1 "address" out?

2 COMMITTEE MEMBER WONG: Uh-hmm.

3 COMMITTEE MEMBER SHEN: Name and phone number  
4 only?

5 CHAIRMAN KIMSEY: Do we want to modernize and have  
6 an email address.

7 COMMITTEE MEMBER SHEN: I was wondering about  
8 that. Do you want to put a fax number in there?

9 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. It  
10 certainly seems that if you have someone's name and phone  
11 number and you needed their fax or email you could always  
12 call them so adding unnecessary language doesn't seem to  
13 help.

14 COMMITTEE MEMBER WONG: I agree.

15 CHAIRMAN KIMSEY: Other suggested changes?

16 COMMITTEE MEMBER JEFFRIES: Dan Jeffries again.  
17 If we just go back, the way we have this first sentence  
18 worded number one is really confusing now because we have a  
19 statement of notification to perform or stop performing  
20 alcohol analysis to include notification. And we're using  
21 notification twice with different meanings in the same  
22 sentence.

23 COMMITTEE MEMBER SHEN: This is Jennifer. I think  
24 I have a statement of what I went with, notification of  
25 initiation for discontinuance of alcohol analysis to include

1 breath and fluid analysis specifically.

2 COMMITTEE MEMBER WONG: Uh-hmm.

3 COMMITTEE MEMBER SHEN: Does that work?

4 COMMITTEE MEMBER WONG: Uh-hmm.

5 RESEARCH SCIENTIST SPELL: Right.

6 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. That's  
7 perfect with me.

8 CHAIRMAN KIMSEY: Other comments?

9 (No response.)

10 Sort of general agreement?

11 COMMITTEE MEMBER SHEN: Yes.

12 MR. LYLE: Yes.

13 COMMITTEE MEMBER JEFFRIES: Yes.

14 CHAIRMAN KIMSEY: Okay.

15 UNIDENTIFIED SPEAKER: Sounds like a 7-0 vote in  
16 favor (laughter).

17 CHAIRMAN KIMSEY: Bullet number two. Remove CDPH  
18 authority to review, approve and test the qualifications of  
19 persons employed by a laboratory. 1216(h), every laboratory  
20 performing forensic alcohol analysis will have on record  
21 with the Department the following:

22 (1) A copy of the diplomas or transcripts of  
23 relevant education for each individual performing forensic  
24 alcohol analysis for the laboratory. The relevant education  
25 includes proof of a baccalaureate or higher degree in any

1 applied physical or natural science.

2 (2) A training summary of the topics outlined in  
3 1216.1(e)(2) with a completion date for each individual  
4 performing forensic alcohol analysis for the laboratory.

5 (3) Copies of qualifying tests to include written  
6 and/or practical examinations for each individual performing  
7 forensic alcohol analysis for the laboratory.

8 (4) Proof of completion of a competency test  
9 which follows the requirements articulated in 1216.1(e)(3)  
10 for each individual performing forensic alcohol analysis for  
11 the laboratory.

12 (5) Written notification to the Department  
13 alerting it that the individual has successfully completed  
14 his or her training and is beginning casework and,

15 (6) Proof of completion of a proficiency test as  
16 outlined in 1216.1(a)(3) for each analyst performing  
17 forensic alcohol analysis for the laboratory.

18 COMMITTEE MEMBER SHEN: This is Jennifer. I can  
19 already see that in six we need to put something making sure  
20 that that's an annual thing at this point.

21 CHAIRMAN KIMSEY: Okay, perfect. An annual  
22 proficiency test?

23 COMMITTEE MEMBER SHEN: We, you know, we need -- I  
24 have for each analyst performing alcohol analysis for the  
25 laboratory. But somehow we need to put in there for each

1 analyst per year. I think -- although we did say that  
2 elsewhere so maybe not.

3 CHAIRMAN KIMSEY: Other comments?

4 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. As to  
5 One, this is just a question of the history of the previous  
6 discussion of the Committee. Is there a general consensus  
7 that all alcohol analysis has to be conducted by people with  
8 bachelor's or higher in either physical or natural science.  
9 Is that pretty clear to everyone?

10 COMMITTEE MEMBER WONG: Yes.

11 COMMITTEE MEMBER JEFFRIES: Thank you.

12 CHAIRMAN KIMSEY: So, if we put on number six to  
13 Jennifer's point, proof of completion of an annual  
14 proficiency test as outlined?

15 COMMITTEE MEMBER SHEN: That sounds good.

16 CHAIRMAN KIMSEY: Okay.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 Comment from Clay Larson, comment from the public. I think  
19 this is an important section. The general purpose of the  
20 Title 17 regulations is to ensure the competence of the  
21 laboratories and employees to prepare, analyze and report  
22 the results of tests to comply with applicable laws.

23 So I think this is kind of central to the, to the  
24 purpose of the regulations.

25 Currently that's something -- the Department

1 qualifies individuals. And I would submit that if you look  
2 through the six outlined items here that there's references  
3 to suggest that each of the 40 labs would be independently  
4 making their own assessment and they would be kind of  
5 submitting -- and it might be a subtle difference but  
6 submitting their evidence of the individual's qualifications  
7 to the Department, more as a notification.

8           So it would -- the intent here, I think, is to  
9 eliminate really any authority on the part of the Department  
10 to review, approve and test the qualifications of the  
11 persons employed by the laboratories.

12           So in essence it doesn't address at all the  
13 concerns shown in the letter.

14           I would submit again that I think the proficiency  
15 tests which is -- and I would say, also say a written  
16 examination. I think a written examination is important  
17 because it tests the knowledge of the individual, of the  
18 candidate's knowledge of both the regulations and the  
19 laboratory's method and of course the proficiency test.

20           I think both are important. I think it's  
21 important to keep in mind that none of the current  
22 laboratory accreditation programs qualify, do anything  
23 regarding qualifying individuals, nothing. So, as a  
24 consequence I think it's important to retain the current  
25 state-level oversight of the approval of the qualifications

1 of laboratory personnel in order to ensure the competence of  
2 the testing.

3           And I don't think these six -- I think these six  
4 subsections, if you read them carefully, actually transfer  
5 that responsibility to each of the individual, each of the  
6 40 individual laboratories.

7           COMMITTEE MEMBER SHEN: This is Jennifer. That's  
8 exactly what it does. And that's what we've been discussing  
9 for years is that lots of laboratories, as they are really  
10 now, is that laboratories are responsible for training their  
11 employees and putting them through very rigorous training  
12 programs. We want to have the laboratories apprised of  
13 that. Have the Department be informed of what we're doing.  
14 We want the Department to ensure that we're following the  
15 guidelines that we are currently writing.

16           So to me this is a compromise where, you know, we  
17 -- we're writing these guidelines and we're writing these,  
18 writing what we need to do, what we all agree that needs to  
19 do educationally-wise, topically what we need to discuss and  
20 train on and then we're providing the Department proof that  
21 we've done those things.

22           So, you are correct. This is much more a, the  
23 laboratories figure how they're going to do it. But we've  
24 got to follow what's in Title 17 and we've got to hit all  
25 those topics. And we've got to show the Department that we

1 have, in fact, hired someone who has the correct educational  
2 background, put that person through a training program that  
3 encompasses everything that's stated in Title 17 and provide  
4 proof of passing competency tests which are more rigorous  
5 and a proficiency testing program on an annual basis.

6 So I would envision at this point the Department  
7 is going to be looking at that (inaudible) and ensuring that  
8 the person that we have proffered is in fact qualified based  
9 on what's in Title 17.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
11 And I would just submit again, I don't think necessarily, I  
12 don't think it satisfies, I don't think it attempts to  
13 satisfy. The concern of the bullet was, the concern was the  
14 fact that the existing regulations without this language  
15 removes CDPH's authority to review, approve and test the  
16 qualifications of persons employed by a laboratory.

17 CHAIRMAN KIMSEY: Other comments from the  
18 Committee?

19 (No response.)

20 Any additional language changes? I think the only  
21 one we have so far is the annual proficiency test in item  
22 number six. Otherwise I think we're going, that's the only  
23 addition I've heard so far that I remember.

24 Any other comments in general on bullet two as  
25 we're calling it?

1 (No response.)

2 Okay.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 It's getting close to noon, do you --

5 UNIDENTIFIED SPEAKER: Yes, 7-0 passing.

6 CHAIRMAN KIMSEY: I'm sorry, excuse me?

7 UNIDENTIFIED SPEAKER: Just a comment that I think  
8 that's an unanimous decision by the Committee to go forward  
9 with that one.

10 CHAIRMAN KIMSEY: Yeah, it's a consensus,  
11 unanimous, yeah.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
13 I think we should put -- I think it's -- we could ask Peggy  
14 but I think -- well actually we should, I think it was a  
15 mistake not to vote on any of these. I think that was an  
16 error on the part of the Chair. (Laughter.)

17 CHAIRMAN KIMSEY: So, let's back up then and --  
18 well, let's not necessarily back up. We're currently on  
19 bullet number two, which we've just discussed. All in favor  
20 on bullet number two? Aye?

21 (Ayes.)

22 Any nays?

23 (No response.)

24 Bullet number four, which is the one we discussed  
25 just previously. All in favor?

1 (Ayes.)

2 Any nays?

3 (No response.)

4 Bullet number one. All in favor?

5 (Ayes.)

6 Any nays?

7 (No response.)

8 Okay. It is ten minutes to noon. I would  
9 recommend -- well, the Committee can, we can decide what we  
10 want to do. What I would recommend is that we continue  
11 working. Let's get into Article 4 or the bullet number  
12 three, Kenton's piece ,and see how that progresses.

13 I know there is some difficulty I believe in San  
14 Diego getting in and out of that area, you know, for lunch  
15 type of a thing.

16 Do people need a bio-break? Do we want to break  
17 for 10 minutes? Come back at noon?

18 COMMITTEE MEMBER SHEN: I do, I have to move my  
19 car.

20 CHAIRMAN KIMSEY: I'm sorry?

21 COMMITTEE MEMBER WONG: She has to move her car.

22 COMMITTEE MEMBER SHEN: This is Jennifer. I need  
23 to go move my car.

24 CHAIRMAN KIMSEY: Oh, you do need to go out and  
25 move your car.

1 COMMITTEE MEMBER SHEN: Yes. I would like maybe  
2 15 minutes.

3 CHAIRMAN KIMSEY: Okay. Why don't we get started  
4 at five, well, let's make it ten minutes after noon. So at  
5 12:10.

6 MR. LYLE: Thank you Paul.

7 CHAIRMAN KIMSEY: Thank you. We're taking a  
8 break.

9 (A break was taken off the record.)

10 CHAIRMAN KIMSEY: Let's see. Moving on to bullet  
11 point three. It says, remove CDPH authority to review and  
12 approve training programs intended for a person to qualify  
13 under the regulations.

14 Example, breath instrument operator training.  
15 Therefore, add back in Article 4, Training of Personnel.

16 1218. Training Program Approval. Any organization,  
17 laboratory, institution, school or college conducting a  
18 course of instruction for persons to qualify under these  
19 regulations shall submit a course summary and list of  
20 instructors and their qualifications to the Department for  
21 approval.

22 1218.1. Additional Requirements. At the  
23 discretion of the Department, any phase or portion of a  
24 training program shall be subject to alteration in an effort  
25 to update the program as technological advances are made or

1 if a portion has been judged inappropriate.

2 1218.2. Contracts. The Department may contract  
3 with persons it deems qualified to administer such practical  
4 tests and oral examinations as may be required under these  
5 regulations. This section shall not be construed to  
6 authorize the delegation of any discretionary functions  
7 conferred on the Department by law, including but not  
8 limited to, the evaluation of tests and examinations.

9 Comments from the Committee? Kenton you --

10 COMMITTEE MEMBER WONG: This was just taken  
11 verbatim from originally that which was stricken. And based  
12 on Health and Human Services' recommendations, this was to  
13 be added back in.

14 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. Just  
15 to, since I'm new to this, does this not give the Department  
16 back some approval over a lot of things that the Department  
17 wasn't approving?

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 When you say, wasn't approving, I assume you mean, you're  
20 saying that, future perfect tense, wouldn't be approving  
21 under the revisions originally proposed.

22 COMMITTEE MEMBER JEFFRIES: Correct.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
24 Okay.

25 COMMITTEE MEMBER SHEN: This is Jennifer. You

1 know, I think we might, we might not want to add this back  
2 in verbatim. And I think that this can be, this can lead us  
3 down the road of doing a lot of things that we're trying not  
4 to do anymore.

5 COMMITTEE MEMBER WONG: I agree. We were kind of  
6 in a position of compromising. We had made ground on all  
7 the revisions that we had. But I guess it was these four  
8 sticking points that came back in the letter.

9 COMMITTEE MEMBER SHEN: Correct. Have we done  
10 adjustments for (indiscernible)?

11 COMMITTEE MEMBER WONG: Uh-hmm.

12 COMMITTEE MEMBER SHEN: And then the other three  
13 points. They certainly, they certainly tried to reach a  
14 compromise position, at least in my mind.

15 Where it seems on this one we're just going back  
16 to what we had versus trying to reach a compromised  
17 position.

18 MR. LYLE: So I guess being consistent with the  
19 actions earlier, for instance, under 1218 it would seem like  
20 submitting the course summaries and list of instructors and  
21 qualifications to the Department is one thing. But then  
22 adding these four approvals will get you back down that road  
23 of what if the Department doesn't approve.

24 COMMITTEE MEMBER SHEN: This is Jennifer. I agree  
25 with that. I think maybe you want to take a look at this

1 and talk about providing information to keep the Department  
2 in the loop and informed and letting the Department ensure  
3 that we're following what's in Title 17.

4 So I think the laboratories have to ensure that we  
5 are, in fact, following Title 17 and we have to provide  
6 proof of that to the Department to address those issues.

7 But I agree, I don't necessarily want to, to open  
8 that door where we're losing that, losing that control and  
9 we're going down the roads of, probably, duplicate actions  
10 again.

11 COMMITTEE MEMBER WONG: Right. So either just  
12 notification or informing?

13 COMMITTEE MEMBER SHEN: Yeah. We can kind of  
14 model it if the Committee thinks that that is a good idea.  
15 We kind of model it after one of the, I think our bullet,  
16 bullet number one. Three and two are same sort of concept  
17 as bullet number one.

18 CHAIRMAN KIMSEY: This is Paul. Are there  
19 organizations that approve training programs currently? I  
20 mean, other than the Department? I mean is that something  
21 ASCLD or one of your accrediting groups does?

22 COMMITTEE MEMBER SHEN: For breath alcohol  
23 analysis?

24 CHAIRMAN KIMSEY: Right.

25 COMMITTEE MEMBER SHEN: No. This is coming back

1 to me. And that was our issue I think, is that, is that  
2 there isn't going to -- well laboratories in general build  
3 their training programs. And they need to build it  
4 following the guidelines of Title 17 and they need to ensure  
5 that the Department is kept apprised of what we're doing.

6 I think that's probably the road we need to go  
7 down. But you're right, there isn't another body that's  
8 going to approve that for us.

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
10 Two points. I think it's interesting when you continue to  
11 refer to Title 17 as guidelines. I mean, equivalent to the  
12 guidelines in the completely voluntary ASCLD/LAB program.

13 But you use the word, duplicates. So I think  
14 Dr. Kimsey's question was that kind of, that language there  
15 presupposed that this is duplicating the efforts of some  
16 other external body. The approval process, approval of  
17 breath instrument operator training procedures.

18 COMMITTEE MEMBER JEFFRIES: Well, Dan Jeffries.  
19 Since I'm the one that started this discussion; I wasn't  
20 aware of that. It does seem like there needs to be someone  
21 that is involved in approving this type of courses and  
22 instruction.

23 And so I'll withdraw my comments since it does  
24 seem like someone needs to be doing it if the Department  
25 isn't. It does seem like it needs to be done by someone.

1 COMMITTEE MEMBER SEDGEWICK: This is Paul  
2 Sedgewick in San Diego. ASCLD/LAB inspectors don't prior  
3 approve training but they do review the training in their  
4 inspections and decide whether it is appropriate.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
6 Since ASCLD/LAB has **no standards** for breath alcohol  
7 analysis, I would submit that the inspectors are incompetent  
8 to --

9 MR. LYLE: Well I'm --

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
11 -- to do that.

12 COMMITTEE MEMBER SEDGEWICK: -- I'm speaking of  
13 all the other training not just breath.

14 COMMITTEE MEMBER SHEN: I think the point is, this  
15 is Jennifer. The point is that our accrediting bodies, at  
16 least just speaking for ours, don't come in and approve our  
17 training programs. When a laboratory puts together a  
18 training program it has to meet certain criteria.

19 And our accrediting bodies ensure that we have a  
20 training program and that we're following that training  
21 program. And that people that we have on board have gone  
22 through that training program and that were properly tested  
23 with proficiency test competency tests et cetera. That's  
24 what they are ensuring.

25 But as far as the makeup of the training programs

1 itself, you know, the laboratories are responsible for  
2 putting that together.

3           So -- and to say that the breath alcohol program  
4 isn't any different except for the breath alcohol program  
5 currently has this extra level of approval, that isn't  
6 really seen in our other sections, in (a) for instance.

7           MS. LYONS: Denise Lyons from the public. I think  
8 -- it seems to me that we're blurring the line between  
9 training as opposed to internal training of the forensic  
10 laboratory employees and external training that we're  
11 providing for law enforcement agencies for the breath  
12 program.

13           CHAIRMAN KIMSEY: Hmm.

14           COMMITTEE MEMBER WONG: Hmm.

15           COMMITTEE MEMBER JEFFRIES: Dan Jeffries. I  
16 agree. I'm a little confused now that you bring that up.  
17 Is this talking about for training of law enforcement  
18 officers to operate breath testing equipment or is this  
19 talking about the technicians within the laboratories do  
20 their own testing?

21           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
22 Well, I mean, I would, I think I can -- we should probably  
23 hear from people on the Committee more than me. But it  
24 covers all training.

25           Under the regulations there are only two training.

1 It used to be three but now there are only two training  
2 programs provided.

3 One was, one is the breath instrument operator  
4 training. The other was, training that would permit  
5 forensic alcohol personnel who lacked two years experience,  
6 it would be another avenue for qualifying those individuals  
7 who in lieu of two years -- in lieu of those two years  
8 experience, you complete a training course.

9 Currently, that training also must be approved by  
10 the Department. And I would submit, as I said before, this  
11 will only take a second, that the, absent that external  
12 approval or some external approval, the way the current  
13 regulations are written, this is talking about internal  
14 training again just for a moment, that the regulations are  
15 written, they now state that a laboratory will design,  
16 implement and then provide training to the forensic alcohol  
17 analyst staff without any external review.

18 And I submit that at some point in the process  
19 somebody will recognize that basically we're telling the  
20 labs to do whatever they want to do.

21 And that kind of regulation, I think, through the  
22 process will be recognized as unnecessary. I mean, labs  
23 will either do a good job or they won't do a good job.

24 But, this sort of self-regulating mechanism  
25 doesn't work at all.

1           The other form of training is, as you say, the  
2 training of breath instrument operators to use, administer  
3 breath testing instruments to obtain results which are then  
4 admitted at trial.

5           COMMITTEE MEMBER SHEN: Well I, this is Jennifer.  
6 I think the goal is to provide training that follows what  
7 is laid out in Title 17. We're pretty specific in Title 17  
8 about the areas that need to be covered. And this could be  
9 a way of telling the Department that we, in fact, cover  
10 those areas in our training programs.

11           MR. LYLE: This is Bruce in San Diego. It was  
12 originally deleted or removed all of Article 4 was because  
13 the oversight was given to employing laboratories in the  
14 earlier sections. And it wasn't just breath analysis, there  
15 was all kinds (inaudible). As I remember it was all  
16 (inaudible).

17           COMMITTEE MEMBER SHEN: This is Jennifer. So  
18 again, I guess what we're looking at doing -- you know,  
19 there's a difference in philosophy, there's no doubt about  
20 it -- is coming to the compromised position of the  
21 laboratories are in charge of that training. They're in  
22 charge of ensuring it and also ready to go --

23           COMMITTEE MEMBER WONG: Uh-hmm.

24           COMMITTEE MEMBER SHEN: -- and that information is  
25 all applied to the Department. And so the level of

1 oversight that would be applied, the Department looks at  
2 what was provided and determines whether or not that, in  
3 fact, follows what is laid out in Title 17.

4 But the Department wouldn't be responsible for  
5 generating, creating and giving the training programs.

6 So that's really kind of where we are. We either  
7 have to move one way or the other. We can go back to the  
8 way it was or we can go forward. And if we as a Committee  
9 decide to go forward sort of cutting the Department out in  
10 its entirety, which is a compromised position of following  
11 what's written, ensuring that the laboratories have  
12 responsibility and providing that information to the  
13 Department so the Department can see that we are, in fact,  
14 doing what we're supposed to be doing.

15 And that's just kind of where we are. We have to  
16 figure out what to do from there.

17 CHAIRMAN KIMSEY: And so the yardstick that would  
18 be the training requirements that are in Title 17 that you  
19 referred to.

20 COMMITTEE MEMBER SHEN: Yes.

21 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries.  
22 I guess showing my ignorance, it would strike me that you  
23 could also interpret this to say that, UCLA has to submit a  
24 list of their instructors if you are going to get someone  
25 who qualifies because they have a bachelor's degree in a

1 physical science from UCLA. I don't think that's what you  
2 intend to do. But the way it's worded it would require that  
3 or it could be argued to require it.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
5 Well that could be easily solved by simply listing the, be a  
6 little less general, any organization that, for instance if  
7 you're talking about -- and breath instrument operator  
8 training is described elsewhere under Article 7. But you  
9 could simply correct that by saying, any organization blah,  
10 blah, blah that is providing training to qualify under  
11 either, there are two kinds of training again, the analyst  
12 training and there's a reference under 1216 for that or the  
13 operator training in 1221-something.

14 So that could be easily corrected.

15 COMMITTEE MEMBER SHEN: Again we're at a  
16 philosophical difference here. I mean, between what the  
17 Department wants and what the Committee has purported to  
18 want. So I think that's the discussion we need to have.

19 I mean this was brought up as a bullet point that  
20 this is, I think, a point of concern that we've removed  
21 authority to review and approve training programs.

22 So again, fall back position. We're going to look  
23 at Title 17, we're going to do what it says and we're going  
24 to show the Department that we've done that.

25 You know, what is it -- We can go around and

1 around on this but it really comes down to which direction  
2 does the Committee want to go?

3 COMMITTEE MEMBER WONG: I agree with you,  
4 Jennifer, that we have to compromise because Health and  
5 Human Services already said that they are not going to  
6 accept this draft that we have.

7 So, we have to just either inform or notify or  
8 something and have that compromise and strike off, for  
9 approval, at the end of 1218.

10 And if we need to have a citation for persons to  
11 qualify under these regulations who are either analysts or  
12 breath operators then we can cite that for those two groups.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
14 Well --

15 COMMITTEE MEMBER SHEN: That's the only way I  
16 would like to go. To me, that's the best position for us is  
17 to leave our Committee's intentions intact but involve the  
18 Department in a -- they need to be put in the loop  
19 essentially.

20 COMMITTEE MEMBER WONG: Right.

21 COMMITTEE MEMBER SHEN: How do we do that?

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 Let me just ask, incredulously but, so the letter indicated  
24 a concern over the removal of the Department's authority to  
25 review and approve. So, our compromise, as you put it, is

1 to strike the role of the Department in approving the  
2 training but have some, I mean this is a little bit like the  
3 proficiency testing role.

4           So, you're simply going to provide the Department  
5 with some information but, and we'll see how it goes from  
6 that, but to leave unstated in the regulations what the  
7 Department does with that information.

8           Is that the proposal? I'm not, is that the  
9 compromise that you're suggesting?

10           COMMITTEE MEMBER SHEN: Well yes it is, actually.

11 I think that the Department has had quite a bit of input  
12 into how we're writing these regulations and how, what is or  
13 is not important.

14           So, I guess I'm thinking that when we are finished  
15 with the work product, if ever, and it's approved, the  
16 laboratories are going to be held responsible for following  
17 what we as a Committee, with great input from the  
18 Department, have decided is necessary.

19           So, by providing, by following the Title 17,  
20 what's laid out in Title 17 and by providing the Department  
21 that information as to how we're following those rules, then  
22 the Department can **see** that in fact we are doing what we  
23 need to do as laboratories.

24           If we're not then we're in the same position as  
25 everything else. If the laboratories are doing something

1 the Department doesn't want us to do or doesn't agree with  
2 then, you know, we really (inaudible) position of again,  
3 we're probably just an interaction, seeking interaction. I  
4 don't know the Department because it's not liking things,  
5 doesn't have a lot they can do.

6 But I, you know, it's our goal is to follow what  
7 we laid out in Title 17 and it's our goal to let you see  
8 that we're doing that.

9 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. I think  
10 following up on the Attorney General's opinion, if something  
11 is not complied with the Department can always go to court  
12 and either through several different mechanisms to enforce  
13 them if they wanted to.

14 But I think it seems like for the most part that  
15 it's self-enforcement.

16 COMMITTEE MEMBER WONG: Uh-hmm.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
18 I mean I, I'm not sure, I think the AG's opinion regarding  
19 the ability to seek an injunctive relief, a writ of  
20 mandamus, was based on language in the regulations that put  
21 a, described a particular responsibility or role of the  
22 Department.

23 If the Committee specifically strikes the  
24 language, the Department for approval, I'm not sure what  
25 your standing would be to go court and saying, we don't

1 approve of this. You could argue that the regulations don't  
2 ask you to approve it.

3 I want to also note that every state regulates  
4 this stuff. So California -- I mean it'll be an  
5 interesting, this could be an interesting adventure that the  
6 Committee is launching off. Because, as I say, every state  
7 regulates this stuff.

8 Typically states provide much more detailed  
9 descriptions of the course content and especially the number  
10 of hours of instruction.

11 Although the program has proposed actually adding  
12 a specific minimum number of hours of instruction it wasn't  
13 accepted by the Committee.

14 So again, it's conceivable that a program could  
15 decide a 20 minute discussion of breath instruments is  
16 sufficient to impart the instrument operator with sufficient  
17 knowledge to go forth and gather data.

18 But I think this will be interesting. I think  
19 it'll put California at odds with the other states.

20 COMMITTEE MEMBER SHEN: Well, this is Jennifer. I  
21 guess my thought would be, and I'd have to pull that back  
22 out and look at it again. I think it would be difficult to  
23 cover what we said we're going to cover in 20 minutes as  
24 outlined in Title 17 as we envision it.

25 So, you know, I suppose, if we look at that and it

1 looks like you could give all the instruction that's  
2 necessary in 20 minutes, then maybe we need to alter that  
3 versus giving oversight in an area we don't want to.

4 CHAIRMAN KIMSEY: Do we want to reference that?  
5 Is it -- this is Paul. We're talking about, you know, the  
6 training that's in Title 17. Right now it looks like we're  
7 assuming that is the training that would be outlined. I  
8 mean, do we need to reference that training in this --

9 COMMITTEE MEMBER SHEN: Again, I think Kenton  
10 (inaudible) what we need to do. To separate it out and  
11 specify the breath instrument users versus the analysts, the  
12 forensic alcohol analysts. We should separate that section  
13 out a little bit so that it addresses them both and then  
14 cite the appropriate sections in Title 17.

15 COMMITTEE MEMBER WONG: Uh-hmm.

16 CHAIRMAN KIMSEY: How is the training approval  
17 been with the Department's program up until this point? I  
18 mean, have we made modifications or suggested, I mean, have  
19 we taken action on any of the training programs or felt them  
20 to be inadequate?

21 Or has that been burdensome within the part of the  
22 laboratories to submit the information?

23 COMMITTEE MEMBER SHEN: Somebody else might be  
24 more able to answer that than I am.

25 CHAIRMAN KIMSEY: My concern is just that, you

1 know, if there's no other entity really approving the  
2 training then we really do need to be sure that Title 17 is  
3 quite reflective of what we feel that training needs to be.

4 COMMITTEE MEMBER SHEN: I would agree.

5 MR. TOMS: This is Mike Toms from Sacramento from  
6 the public. Some things that need separated out are whether  
7 or not you're training a brand new officer to utilize the  
8 instrumentation or you're just training an officer on new  
9 instrumentation.

10 They would need a four-hour course on alcohol  
11 physiology to utilize a new instrument.

12 So that's some of the things that can be  
13 problematic that you're going require this long training for  
14 just showing somebody how to go through four steps.

15 COMMITTEE MEMBER WONG: This is Kenton in  
16 Richmond. I hear you Mike. I know exactly what you're  
17 talking about because I used to work in San Mateo County.  
18 And CHP officers would come in from CHP-SF or CHP Santa  
19 Clara and we were training them on the same instrument. And  
20 it was tough but they had to go through the same four hour  
21 training course that I provided to them.

22 And I told them that. I said, I know you guys  
23 have already had that but we have to follow the spirit of  
24 the law in certifying you for use in this county.

25 So, it was, yeah, I know what you're talking

1 about.

2 MR. TOMS: And I get re-training officers on new  
3 instruments but it shouldn't require a full training if  
4 they've already had all of the other stuff before, it just  
5 shouldn't require that. We have a lot of officers that come  
6 into our county as well and it's the same thing.

7 COMMITTEE MEMBER WONG: Yeah.

8 MR. TOMS: If wa want to go to a new instrument,  
9 upgrade our Draeger instrumentation, basically it's the same  
10 instrument with a different look. But likely we would be  
11 required to provide every officer in our county brand new  
12 training and I don't think that's appropriate.

13 COMMITTEE MEMBER SHEN: This is Jennifer. We'll  
14 have to take a look at how it's written now. But I  
15 wouldn't, you know, in order to be a breath testing officer  
16 you have to have an amount of training. I think that once  
17 you have what you had, the initial baseline training for the  
18 (inaudible) et cetera, that you wouldn't have to take that  
19 again with a change of instrumentation. Because that  
20 officer has already had that particular type of training to  
21 be a breath instrument operator.

22 So he's just going to be now operating a different  
23 instrument. I would agree that it would not make any sense  
24 to send the officer through the whole entire thing again.

25 CHAIRMAN KIMSEY: But that's currently happening?

1 COMMITTEE MEMBER WONG: It is. It's considered to  
2 be quite onerous because you get these guys lateralling  
3 around --

4 CHAIRMAN KIMSEY: Sure.

5 COMMITTEE MEMBER WONG: -- and it's like, my God  
6 I've been through all of this already.

7 CHAIRMAN KIMSEY: And we've already approved that  
8 officer training somewhere? Did we make any changes to the,  
9 having a baseline course versus a new --

10 COMMITTEE MEMBER WONG: That's why.

11 CHAIRMAN KIMSEY: -- instrument? That sounds like  
12 something we should try and address. But I was sort of  
13 interpreting this Article 4 here as more about personnel in  
14 the laboratory.

15 And I think Jennifer you were, I think I may have  
16 heard you agree about having some sort of oversight on the  
17 training. If it wasn't the Department you think we can make  
18 Title 17 specific enough that it doesn't need to be a  
19 Departmental approval?

20 COMMITTEE MEMBER SHEN: Well that's what I was  
21 sort of hoping but I'm having trouble finding, I'm having  
22 trouble finding that particular area. So, I mean, I think  
23 for our analysts in the laboratory we have pretty specific,  
24 we need to cover X amount of topics, you have to do X amount  
25 of things, and take proficiency tests, et cetera.

1           Maybe we can make the officer training -- if it  
2 is, if the Department feels like it could be, I think, we  
3 could follow what's in Title 17 and (inaudible) training,  
4 then maybe we can bump that area up a little bit. I'm just  
5 having trouble locating it to look at it.

6           CHAIRMAN KIMSEY: Well, what's the feeling of the  
7 group? We've identified a couple of issues. One is to  
8 split out the officer training versus from the analyst's  
9 training. And obviously make some changes under the officer  
10 training seems appropriate.

11           And then I think we're still sort of discussing  
12 the role of the Department with regards to the analyst's  
13 training with regards to approval or, you know, courses in  
14 summary.

15           Some of this sounds like to me like we may need  
16 some time. I mean we've got lunch on our horizon. We have  
17 this set-up until four. So I think --

18           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 (Hand signalling three). Three.

20           CHAIRMAN KIMSEY: -- oh, three, excuse me. Until  
21 three. Maybe we need a little more time to have someone  
22 work on some more language with regards to the training  
23 issue.

24           COMMITTEE MEMBER SHEN: This is Jennifer. I think  
25 before we do that we have to decide how we're going to

1 proceed. We have, I think again, we might need to address  
2 that philosophical difference. We've got to figure out  
3 which way we're going to go.

4           And then -- because I don't think we can work on  
5 language until we have a somewhat clear plan as to what that  
6 language is going to encompass.

7           CHAIRMAN KIMSEY: Yeah, I would agree. And I've  
8 expressed, my only concern is that if, you know, some of  
9 what of what we have talked about where the Department's  
10 role has been where there has been another entity doing it  
11 that notification might be sufficient.

12           My concern here is that if there isn't another  
13 entity, then who? And if the Department, if we get some  
14 good language and some good Title 17 outlines maybe the  
15 Department's role in approval wouldn't be considered  
16 obviously duplicative and maybe, you know, not as onerous or  
17 whatever.

18           So, but I tend to think that there should be some  
19 oversight and approval of a training program. I don't know,  
20 that's just my thoughts at this point.

21           COMMITTEE MEMBER SHEN: This is Jennifer. I guess  
22 I don't necessarily disagree as long as, I would like to see  
23 it be very specific. So, if we're going to go that route  
24 there would be very specific things to provide for approval  
25 because what tends to happen in my experience is that a

1 specific topic becomes very broad.

2           So, for instance, if we were going to supply an  
3 outline for training for our breath instrument operators,  
4 that would not mean that we would be giving approval on the  
5 methodology that is being used by the people who are doing  
6 the training.

7           And that the training, it wouldn't, for instance,  
8 be including everything for our trainers necessarily. We  
9 wouldn't be providing the type of outline we're using for  
10 our trainees. Does that make sense? I'd like to see it  
11 very specific.

12           And if it's very specific I think that that would  
13 be something that would be a reasonable compromise.

14           CHAIRMAN KIMSEY: Well and it also occurs to me  
15 that maybe we need to have some sort of model training  
16 programs. I mean, is there some advantage to having a  
17 training curriculum on-line that is sort of standard or are  
18 things different enough in each of the laboratories that it  
19 needs to be so unique to each laboratory?

20           I'm just trying to think of a way to sort of make  
21 this more efficient and accessible to the laboratories.

22           COMMITTEE MEMBER SHEN: Well, I guess if we, if we  
23 articulate clearly in Title 17 what needs to be covered for  
24 a breath instrument operator then the Department will be in  
25 the position of approving a training outline that

1 encompasses those things.

2           If we were to submit a training outline and it  
3 were to -- unless it's clearly outlined in Title 17 that we  
4 would need to be training them in, then the Department would  
5 have some sort of ability to then say, hey, you know what,  
6 you're missing this and this needs to be added to your  
7 training outline. I mean, I can kind of envision something  
8 like that.

9           COMMITTEE MEMBER WONG: Uh-hmm.

10           COMMITTEE MEMBER SHEN: But that would probably  
11 mean that Title 17 the way it's written now might need to be  
12 -- I'm sorry, I fluffed up a little bit.

13           COMMITTEE MEMBER WONG: Uh-hmm.

14           COMMITTEE MEMBER JEFFRIES: This is Dan. A follow  
15 up on what Jennifer was saying. Perhaps if you get rid of  
16 the concept of approval and instead substitute like a  
17 demonstrating compliance approval. So that you put the  
18 language in there saying you're submitting them to the  
19 Department demonstrating compliance with all these  
20 regulations.

21           Then you can take whatever you need and put them  
22 in as regulations and come back to it.

23           In other words, what I'm suggesting was something  
24 along the lines of 1218 reading, training approval, or I  
25 mean I'm sorry, training program. Any laboratory conducting

1 a course of instruction for persons to qualify under these  
2 regulations shall submit a course summary demonstrating  
3 compliance with these regulations and submit a list of  
4 instructors and their qualifications to the Department.

5 That way, if there's non-compliance, if the things  
6 that are submitted are not in compliance with the  
7 regulations the Department can actually do something.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
9 I actually don't see any difference in the wordsmithing  
10 effort. I don't think it produces any difference.

11 The Department's current approval process has been  
12 based on compliance with the requirements in the  
13 regulations.

14 COMMITTEE MEMBER JEFFRIES: Well I guess what I  
15 was getting at is do you want to be in a place where you  
16 submit it to the Department and the Department says yes or  
17 no, or do you want to be in a place where you submit to the  
18 Department and if the Department doesn't think it's in  
19 compliance then the Department can take some action.

20 Who has the responsibility for taking some action  
21 if they're not in compliance?

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
23 Well, I mean, you're talking about if the lab submits  
24 training procedures that aren't in compliance we would then  
25 seek an injunctive relief?

1           Our process, I think, now would be to write back  
2 to the lab and say, you know, this program does not appear  
3 to comply with the requirements of the regulations because  
4 of A, B, C and D.

5           COMMITTEE MEMBER JEFFRIES: Yeah, I guess you do  
6 get to the same place. You get to the point where if you  
7 get a lab trying to submit a 20 minute training program  
8 you're going to say, that's not in compliance with these  
9 regulations.

10           So, it really comes back to the same thing, the  
11 Department saying it's not in compliance with the  
12 regulations.

13           COMMITTEE MEMBER SHEN: Well, since the  
14 regulations are very clear then it should be, it should be,  
15 number one, rare that you get something that's out of  
16 compliance.

17           COMMITTEE MEMBER WONG: Uh-hmm.

18           COMMITTEE MEMBER SHEN: And extremely easy for you  
19 to articulate why the program is out of compliance and very  
20 easy for the laboratory to agree to that.

21           You don't want to go down the road of having  
22 lengthy discussions where the Department and the  
23 laboratories are at odds with what is or is not in  
24 compliance.

25           COMMITTEE MEMBER WONG: Uh-hmm.

1 COMMITTEE MEMBER SHEN: We want to make sure that  
2 we don't make these so broad or open to interpretation that  
3 we are going to have some battles. We don't want the  
4 battles anymore.

5 I guess it looks to me like we may be going down  
6 the road of articulating extremely clearly what it is that  
7 we would provide to the Department and what the Department  
8 would have oversight of.

9 It sounds to me the Department, if itself, that we  
10 were not in compliance with Title 17, would respond back,  
11 you know, in written form.

12 CHAIRMAN KIMSEY: So it sounds like we need to  
13 sort of look at Title, what's actually written in Title 17.  
14 I don't have my copy here.

15 COMMITTEE MEMBER SHEN: At 161.4, I think.

16 COMMITTEE MEMBER WONG: What did she say?

17 CHAIRMAN KIMSEY: 1261.4.

18 COMMITTEE MEMBER SHEN: 1221.4(a)(3)(e) both a  
19 written and practical examination are now required to ensure  
20 the operator has sufficient information. This is kind of  
21 the area we need to be in.

22 CHAIRMAN KIMSEY: Were you saying, what was the  
23 number again that you had Jennifer?

24 COMMITTEE MEMBER SHEN: 1221.4.

25 CHAIRMAN KIMSEY: 1221.4.

1 COMMITTEE MEMBER SHEN: And (a)(3)(e) was written  
2 and -- written and practical examination. We (inaudible)  
3 written and/or against the written and practical.

4 CHAIRMAN KIMSEY: All right. Standards or  
5 procedure. Procedures for breath alcohol analysis shall  
6 meet the following.

7 COMMITTEE MEMBER SHEN: By the time you get to (e)  
8 I think we're looking at, (e) is a precautionary checklist  
9 and I think after that we're looking at training, I think.

10 RESEARCH SCIENTIST SPELL: And practical.

11 CHAIRMAN KIMSEY: Yeah, written or practical  
12 examination is (e). Have received, okay. 1221.4 (3) reads,  
13 breath alcohol analysis shall be performed only with  
14 instruments for which the operators have received training.

15 Such training to include at minimum the following schedule  
16 of subjects: A through E, theory of operation, detailed  
17 procedure of operation, practical experience, precautionary  
18 checklist, written or practical examination.

19 Training in the procedures of breath alcohol shall  
20 be under the supervision of persons who qualify.

21 COMMITTEE MEMBER SHEN: I believe we made some  
22 changes to that.

23 CHAIRMAN KIMSEY: Right.

24 COMMITTEE MEMBER SHEN: We went to written and  
25 practical. And then we took the training curriculum to be

1 developed by a forensic alcohol analyst.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 You know, I would add a couple of things to that actually.

4 I would add, any periodic determination of accuracy

5 activities performed by the operator.

6 It's not always the case but in some cases

7 laboratories have the individual operator do the periodic

8 tests, every 10 days or 150 subjects.

9 So the operator needs to know how to do that.

10 It's also common to provide written -- many labs

11 -- it's not a requirement but many labs include some of the

12 legal aspects of breath testing since this -- I mean, issues

13 like observation for the 15 minutes and things like that.

14 They're a bit, a little in flux in that it could, there can

15 be changing case law which addresses that.

16 So they may be valid. And many states do that to

17 include in the training any relevant, any discussion of some

18 of the legal aspects of breath testing.

19 COMMITTEE MEMBER SHEN: Well it does appear that

20 the, what we'll outline here is fairly broad.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

22 Fairly what?

23 COMMITTEE MEMBER WONG: Broad.

24 COMMITTEE MEMBER SHEN: (inaudible).

25 CHAIRMAN KIMSEY: That's why I was wondering if

1 there was sort of a model curriculum that could be, you  
2 know, on-line or something that would talk a little bit more  
3 about specifics and timeframes.

4 I mean, I don't know, you can almost get through  
5 this in 20 minutes if you had to. I just worry that it's  
6 not specific enough.

7 What is our approval, training approval programs  
8 look like. I mean, how detailed are they? What do you  
9 approve? Is it timeframes or just --

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
11 No, we're not permitted under the regulations to require any  
12 specific timeframe. But we, you know, staff have looked at  
13 hundreds in some cases, I mean, the older guys, of training  
14 programs. So, under the theory of operation there should be  
15 instrument theory but also the physiological how alcohol is  
16 eliminated in the body and the role of respiration.

17 So, you know, we could put together based probably  
18 on some of the better labs' efforts a model, a model  
19 training program.

20 In terms of the regulations, I think it would have  
21 to be, that model training program I don't believe would,  
22 I'm not sure, but it could refer to a website. It would  
23 probably, unfortunately, have to be in the regulations.

24 And many states do that. Many states describe the  
25 training program, they include that as an appendices to the,

1 to the regulations, a summary of the training.

2 RESEARCH SCIENTIST SPELL: Yeah, we're not using  
3 that at all, lab courses --

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
5 But that's --

6 CHAIRMAN KIMSEY: Yeah you just --

7 COMMITTEE MEMBER SHEN: Well --

8 CHAIRMAN KIMSEY: Go ahead.

9 COMMITTEE MEMBER SHEN: This is Jennifer. Could  
10 we sort of mirror what we do for the analyst? I mean,  
11 earlier in Title 17 that's laid out with topics.

12 What you really don't want to do is go down the  
13 road of having the Department be too super-specific about  
14 what we have to do this training on. Because with the, you  
15 know, the advent of technology and moving forward and all  
16 this other stuff I want it broad enough that we hit topics  
17 and not specifics.

18 If we're going to put in the regulations they need  
19 to be topics like we have for our forensic alcohol analyst.  
20 We have, you know, four or five or six topics that must be  
21 covered.

22 COMMITTEE MEMBER WONG: Jennifer, this is Kenton  
23 in Richmond. I think that'll work if it's really, really  
24 watered down for the breath alcohol operators because  
25 there's just no way they need all the scientific background

1 part that an analyst needs. That's just not going to fly  
2 for them.

3 COMMITTEE MEMBER SHEN: Well, I totally agree.  
4 And I didn't mean we would use the same topics. I just  
5 meant that we could use that, kind of that structure. The  
6 structure we had earlier in Title 17 --

7 COMMITTEE MEMBER WONG: Understood.

8 COMMITTEE MEMBER SHEN: -- where we lay out topics  
9 that must be covered. We could stick to topics that are  
10 appropriate here and just lay them out.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
12 You know, I think under the APA, under the requirements for  
13 writing regulations you can have proscriptive or  
14 prescriptive.

15 You can have prescriptive regulations or you can  
16 have performance-based regulations. But, in general, the  
17 role, I'm not -- in general, the role of regulations is to  
18 clarify and make specific the requirements.

19 So I think, I think it's going to be difficult to  
20 satisfy Jennifer's goal here of writing **general** regulations.

21 COMMITTEE MEMBER SHEN: Well, what I mean by that  
22 is, we talked about what, let's see, what an analyst needs  
23 to have. We're in 1216 and, you know, you have to have this  
24 degree and you have to have this much experience and then,  
25 let's see, there has to be a training course that includes

1 **at a minimum** the following schedule of subjects.

2           Which is how Title 17 has been written in the  
3 past. So (indiscernible) forensic alcohol analysis,  
4 physiological action of alcohol, pharmacology and toxicology  
5 of alcohol, et cetera. That's what I mean.

6           To lay out topics as is seen in 1216 for our  
7 breath operators.

8           CHAIRMAN KIMSEY: And then if we had that level of  
9 detail that we all agreed upon, the Department's role would  
10 be one of approving the fact that it's all there or  
11 accepting that's what submitted --

12           COMMITTEE MEMBER SHEN: Well that's what I would  
13 envision. If we write that section, 1218, like we did 1216,  
14 that the Department's role would be to look at a training  
15 outline and ensure the topics covered in the training  
16 outline cover everything that's outlined in Title 17.

17           And that would be pretty much it. Not telling the  
18 laboratory how to cover it, not telling the laboratory the  
19 details of the topics but that the topics are in fact  
20 covered.

21           MR. LYLE: This is Bruce in San Diego. So it  
22 sounds like we would leave in 1218 and take out point one  
23 and point two.

24           COMMITTEE MEMBER SHEN: In concert with that we  
25 would have to --

1 MR. LYLE: Tighten up the regulations.

2 COMMITTEE MEMBER SHEN: Yes We would have to  
3 expand the regulations under 1218, wherever that was, (e).

4 MR. LYLE: I --

5 COMMITTEE MEMBER SHEN: -- 1221 --

6 MR. LYLE: -- right --

7 COMMITTEE MEMBER SHEN: So that would be my  
8 suggestion. We're going, if we're going to go back and do  
9 some more work I would suggest the work that is done is that  
10 that section is sort of modelled after 1216 as far as  
11 discussing what the training ought to include.

12 CHAIRMAN KIMSEY: Okay. It is 1:00 and we have  
13 not had lunch. We can take some volunteers. I guess we can  
14 have two individuals that can work, I believe that's  
15 correct, as a subcommittee of the Committee. Two members of  
16 the Committee to work on some training, personnel training  
17 guidelines similar to 1216 for the purposes of 1218 and  
18 report back to the group at our next meeting.

19 COMMITTEE MEMBER SHEN: I guess I'm wondering how  
20 the Committee feels about that. I mean, that's an idea but  
21 it's not necessarily one we need to follow.

22 MR. LYLE: It seems like the best alternative.

23 COMMITTEE MEMBER WONG: I agree.

24 CHAIRMAN KIMSEY: Yeah, Kenton agreed here but  
25 there might have been some coverage on the microphone there.

1 Do we have volunteers?

2 (No response.)

3 Not having been involved in the training program I  
4 probably would not, mine would not be of any benefit.

5 COMMITTEE MEMBER SHEN: You know, I feel the same  
6 way. It's really not my bailiwick so it's probably better  
7 for someone else to do it. Jennifer.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
9 Was it anybody's bailiwick on the Committee, on the Review  
10 Committee? Maybe that's the problem.

11 CHAIRMAN KIMSEY: I think Kenton had some, didn't  
12 you do some training?

13 COMMITTEE MEMBER WONG: I've trained officers in  
14 the past. But like I said, we just went with that brief  
15 general kind of thing.

16 COMMITTEE MEMBER SHEN: I nominate Kenton.

17 COMMITTEE MEMBER WONG: Accepted.

18 COMMITTEE MEMBER SHEN: Oh, yay.

19 COMMITTEE MEMBER WONG: But I'm going to need some  
20 help on fleshing out the generalness on what was originally  
21 approved in Title 17 for breath operators.

22 COMMITTEE MEMBER SHEN: I can help you do that.  
23 If no one else wants to volunteer I will help you do that as  
24 long as you provide all the brainpower.

25 CHAIRMAN KIMSEY: Well and also, we might have, do

1 we have some of model curriculums that we thought were good  
2 that might be helpful to the subcommittee? Things that we  
3 thought should have been covered?

4 COMMITTEE MEMBER WONG: Then we'll have the best?

5 CHAIRMAN KIMSEY: The best of the best.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

7 Yeah, we can send -- I mean, they're all approved so they're  
8 all great (laughter).

9 COMMITTEE MEMBER WONG: But which one do you like  
10 Clay?

11 COMMITTEE MEMBER SHEN: Mine.

12 COMMITTEE MEMBER WONG: Because that's what really  
13 matters.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

15 As I say, we got through, I think San Diego still owes us  
16 some revisions but -- other labs, yeah, I can provide you --

17 COMMITTEE MEMBER WONG: Okay. Send it my way  
18 then.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

20 And I'm going to assume that this is kind of a Public  
21 Records Act request and -- okay.

22 Sure, I don't believe the particularly involved  
23 labs would have any, I'll let them know that we're doing it.

24 CHAIRMAN KIMSEY: Or you might strike out.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 No, that's too much trouble.

2 CHAIRMAN KIMSEY: If you get permission that would  
3 probably be sufficient.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
5 We strike out social security numbers.

6 CHAIRMAN KIMSEY: So, how much, I guess we can  
7 just wait to hear from the subcommittee about timeframe when  
8 they would like us to review, to meet again.

9 COMMITTEE MEMBER SHEN: So, our goal then is to  
10 satisfy Title 17 where it discusses the training for  
11 operators, mirror the structure of the training for the  
12 analysts earlier in Title 17. Is that correct?

13 COMMITTEE MEMBER WONG: At the 1221.4. To model  
14 1216.

15 COMMITTEE MEMBER SHEN: Is that what we agree?

16 COMMITTEE MEMBER WONG: Yes.

17 COMMITTEE MEMBER SHEN: Okay.

18 CHAIRMAN KIMSEY: Yes.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
20 Let me make sure, I mean, because I think the goal, I mean,  
21 I think Jennifer put it well before when she said, there's a  
22 philosophical question here.

23 And no matter how well you write the regulations  
24 there still is always the possibility that one person  
25 writing, another person looking at it might disagree on

1 whether the, you know, one or another aspects demonstrates  
2 compliance with the regulations.

3           So I still think you've got to go back to the  
4 basic question of whether the regulations are going to refer  
5 to either approval role or a determination of compliance  
6 role, to the extent that that makes any difference, on the  
7 part of the Department or whether this is like the  
8 proficiency data, something that's just filed with the  
9 Department without stating what particular role the  
10 Department will have and do with that supplied information.

11           COMMITTEE MEMBER SHEN: Yeah, I think we discussed  
12 this already that it appears, at least possibly for the  
13 moment, that we're going to give the Department an approval  
14 role in the training --

15           ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
16 Okay.

17           COMMITTEE MEMBER SHEN: -- program outline. So,  
18 what we talked about is that it would have to be extremely  
19 specific. And so what I would like to see as the  
20 Department's role is determining whether or not the  
21 laboratories' outlines comply with what Title 17 says  
22 specifically.

23           And not interpretations of Title 17 or additional  
24 things that the Department might like but only what Title 17  
25 says.

1 COMMITTEE MEMBER WONG: So it's very black and  
2 white.

3 COMMITTEE MEMBER SHEN: Very black and white.

4 COMMITTEE MEMBER WONG: I agree.

5 COMMITTEE MEMBER SHEN: It will not be the  
6 Department's role to determine if we did exactly what the  
7 Department might want us, wanted on theories of operations  
8 but did we in fact cover it.

9 So I guess that's our role to come up with  
10 language that's clear and black and white. Because we do  
11 not want to get into a situation where the Department  
12 (indiscernible) where we can't come to an agreement as to  
13 what is or is not required.

14 COMMITTEE MEMBER WONG: Right. We want no  
15 ambiguity.

16 COMMITTEE MEMBER SHEN: Correct.

17 CHAIRMAN KIMSEY: Okay. What would your projected  
18 timeframe be, do you think? We're in the middle of July at  
19 the moment.

20 COMMITTEE MEMBER SHEN: I'm back in town for  
21 several months so I'm open Kenton to whatever you want to  
22 do.

23 COMMITTEE MEMBER WONG: I just got back from  
24 vacation so I'm around too.

25 CHAIRMAN KIMSEY: A month, two months?

1 COMMITTEE MEMBER SHEN: Try for a month.

2 COMMITTEE MEMBER WONG: Let's shoot for a month.

3 CHAIRMAN KIMSEY: Okay. And, any other direction  
4 to the subcommittee or any clarification before we talk  
5 about some other issues?

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
7 You know, one question regarding, because I do all the  
8 scheduling. Regarding the one month timeframe, because of  
9 Bagley-Keene the notification has to go out 10 days ahead.  
10 And making reservation of, making sure that place in San  
11 Diego, for instance, is available takes a couple of days.

12 So, it would be helpful to know within two weeks  
13 to whether we're going to, I mean, I need to know within two  
14 weeks whether we're going to make an August, in this case  
15 late August, mid-August, date for the next meeting.

16 So I --

17 COMMITTEE MEMBER SHEN: I think I can do that.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
19 All right. So I will assume, I will go ahead and schedule  
20 that and I'll assume hearing nothing else that we're on for  
21 a meeting next month.

22 COMMITTEE MEMBER WONG: And that will also assume  
23 that you can shoot us --

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
25 Sure.

1 COMMITTEE MEMBER WONG: -- some of those things as  
2 soon as possible as well.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:  
4 Okay.

5 COMMITTEE MEMBER WONG: Fabulous.

6 CHAIRMAN KIMSEY: Okay, then, sort of moving,  
7 thinking forward here a little bit, we have our meeting in  
8 late August. We approve and have further discussion and  
9 approve some language.

10 At some point here we're getting, the Committee as  
11 a whole is getting to the point of submitting a package to  
12 Agency that would trigger the 90 day review.

13 And so, and then that, we get that determination  
14 from Agency and then the --

15 COMMITTEE MEMBER SHEN: Let's --

16 CHAIRMAN KIMSEY: Yes.

17 COMMITTEE MEMBER SHEN: I have a question.

18 CHAIRMAN KIMSEY: Uh-huh.

19 COMMITTEE MEMBER SHEN: Jennifer. So should I be  
20 updating, should I be updating the work product and the  
21 justification et cetera as we go along to reflect these  
22 changes that we just made?

23 CHAIRMAN KIMSEY: You know, that's a good  
24 question. I was thinking that there might be some ease and  
25 some clarity if you didn't change the previous draft work

1 product maybe. But I was just thinking that the next letter  
2 that went to Agency would talk about these four particular  
3 bullets.

4 COMMITTEE MEMBER WONG: And how we've addressed  
5 them.

6 CHAIRMAN KIMSEY: And how we've addressed them --

7 COMMITTEE MEMBER SHEN: Okay.

8 CHAIRMAN KIMSEY: -- with the new language.

9 COMMITTEE MEMBER SHEN: I like that.

10 CHAIRMAN KIMSEY: And, you know, maybe on the  
11 next, maybe on the work product that would be blacked out or  
12 something so there's no confusion again.

13 But, and refer to that letter. But that's sort of  
14 for the Committee to decide. I was just thinking that might  
15 make review and make the understanding of what we've done to  
16 Agency more clear.

17 COMMITTEE MEMBER WONG: I agree.

18 COMMITTEE MEMBER SHEN: Yeah, I agree totally. So  
19 that's something, you know, we should put off for right now  
20 until we come back with --

21 CHAIRMAN KIMSEY: Yes.

22 COMMITTEE MEMBER SHEN: Okay. So I don't have to  
23 worry about doing anything then.

24 CHAIRMAN KIMSEY: Not along those lines.

25 COMMITTEE MEMBER SHEN: Okay.



## 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 3rd day of September, 2012.

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JOHN COTA