

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. Rosalee Dvorak-Remis, Office of Regulations (Sacramento)

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

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1 RESEARCH SCIENTIST SPELL: Natalia Spell, Food and
2 Drug Lab.

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

5 MR. HUCK: Okay. This is Russ Huck with the
6 Division Office for Food and Drug and Radiation Safety.

7 COMMITTEE MEMBER DAVIS: Kevin Davis, Community
8 Member with the CHP.

9 MS. LYONS: Denise Lyons, Solano County Bureau of
10 Forensic Services.

11 MS. DVORIK/REMIS: Rosalee Dvorik/Remis, Office of
12 Regulations.

13 MS. CAMPBELL: Peggy Campbell, Office of Legal
14 Services.

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

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

19 MR. THANDI: Harby Thandi, Food and Drug
20 Laboratory Branch.

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

22 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick,
23 Committee Member, California Association of Toxicologists.

24 COMMITTEE MEMBER JEFFRIES: Dan Jeffries, the new
25 representative from the California District Attorney's

1 Association.

2 CHAIRMAN KIMSEY: Welcome.

3 COMMITTEE MEMBER JEFFRIES: Here now.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

5 That's it?

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

7 COMMITTEE MEMBER JEFFRIES: Yes.

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

11 COMMITTEE MEMBER WONG: He will be here.

12 CHAIRMAN KIMSEY: He will be --

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

14 CHAIRMAN KIMSEY: Okay.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

16 He will be here.

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

22 So we'll take a five minute break.

23 (A short off-the-record break was taken)

24 CHAIRMAN KIMSEY: This is Paul Kimsey in Richmond.

25 I guess we'll go ahead and get started and -- the,

1 actually, the opening remarks --

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 Let me find out who's -- have we checked with San Diego to
4 see who's there?

5 CHAIRMAN KIMSEY: San Diego, has anyone else
6 shown?

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

9 CHAIRMAN KIMSEY: Ah, wonderful.

10 COMMITTEE MEMBER SHEN: Hello.

11 MR. LYLE: Hello (laughter).

12 CHAIRMAN KIMSEY: Could you identify yourselves
13 please for our stenographer.

14 MR. LYLE: Bruce Lyle, San Diego.

15 CHAIRMAN KIMSEY: Great.

16 COMMITTEE MEMBER SHEN: Jennifer Shen in San
17 Diego.

18 CHAIRMAN KIMSEY: Okay.

19 COMMITTEE MEMBER WONG: There we go.

20 CHAIRMAN KIMSEY: So, with regards to the opening
21 remarks, I don't really have anything new from the
22 Department. Obviously, we've been dealing with budget
23 issues. But you've been reading about that in the
24 newspaper. So, no inside information there.

25 Any discussion of the agenda? Basically, we have

1 a discussion opportunity for the Attorney General's opinion
2 that came out December 27th. And then we continue our
3 Committee discussion on a draft regulatory work product.

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

7 (No response.)

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

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

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

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

23 And the other item was, in the interim would
24 laboratories or, in this timeframe, would laboratories
25 continue to have to comply with the regulations.

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

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

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

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 Well, let me say a few things because -- you know, looking
12 back on the transcripts there were, literally, a dozen or so
13 or more references to the AG's opinion in the course of the
14 many meetings of the Review Committee.

15 So I think it probably deserves some discussion.
16 Let me try to get it started.

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

21 As I say, that question was probably asked a dozen
22 or more times by various Review Committee members. And
23 typically towards the end it became almost a rhetorical
24 question in that it typically occurred during the discussion
25 of ongoing oversight activities by the Department.

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

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

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

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

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

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

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

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

15 COMMITTEE MEMBER SHEN: This is Jennifer in San
16 Diego. I guess my thought is that, and this is all
17 (inaudible) -- was that the way that the law is written
18 there is this, it still appears to be some sort of oversight
19 by the Department, but it's not really backed up with
20 anything (inaudible). But to me it looks like that this is
21 in the interim while we are rewriting it, before the new
22 regulations are adopted the Department still maintains that
23 oversight.

24 It says on page four, because the Department
25 regulations **have not yet been revised** in accordance with the

1 2004 statutes, the existing regulations still include
2 provisions that purport to enable the Department to grand
3 and renew licenses -- of course regulations that conflict
4 blah, blah, blah.

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

11 CHAIRMAN KIMSEY: Other comments?

12 COMMITTEE MEMBER WONG: I agree with Jennifer. I
13 mean Senate Bill 1623 it would be absolutely absurd to think
14 that 1623 was just going to remove licensing and that's all.

15 That would be absolutely stupid. I mean it's
16 like, why would you just remove licensing and nothing else?
17 It doesn't make any sense.

18 And despite Clay's contention that the intention
19 was to just keep everything status quo, then why have 1623?

20 The whole idea was that the oversight by the Department of
21 Public Health was duplicitous since the labs were following
22 17025 either ASCLD or FQS accreditation standards and they
23 were better and over and above the normal CDPH oversight
24 which really wasn't happening anyway.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Well just one quick responding comment. I, you know, I
2 would agree that the legislation gave wide authority to the
3 Committee to write whatever regulations they saw fit. It
4 also corrected a process whereby those, any proposed
5 revisions would be subject to review by Health and Human
6 Services Agency.

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

11 COMMITTEE MEMBER WONG: This is Kenton in
12 Richmond. I agree. And we are definitely going to have to
13 deal with that hurdle.

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

20 And 1623 was meant to address that, that
21 shortcoming and those problems.

22 COMMITTEE MEMBER SHEN: This is Jennifer. I
23 believe that this AG's opinion really is something that
24 we're going to deal with in the interim as we finish our
25 product. And we can take a look at it and give it

1 consideration but I don't think it overrides our overall
2 purpose with what we've been trying to do all these months
3 or years I should say.

4 CHAIRMAN KIMSEY: Oh no. This is Paul. I would
5 agree. I mean this, I mean this is certainly something
6 we've been sort of waiting for about clarifying two specific
7 areas. But it certainly doesn't negate the work that the
8 Committee has been doing.

9 And, you know, we can certainly move forward with
10 the role that the Committee was given based on the
11 legislation 1623.

12 That, I think, was not affected by the AG's
13 opinion.

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

19 I think they've been moving discussions slightly
20 anyway. But we just have to stay away from, you know, going
21 back to the Stone Age or having duplicitous oversight. I
22 think that's what our goal is here.

23 COMMITTEE MEMBER WONG: I concur.

24 CHAIRMAN KIMSEY: Any other comments from the
25 Committee?

1 (No response.)

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

4 I think it's probably worth sort of reviewing a
5 little bit. We have a new member, Mr. Dan Jeffries from the
6 District Attorneys Association. And I'd like to welcome him
7 and I don't know how much he has been able to find out about
8 what we have been doing for the previous 19 meetings.

9 But I'll start with a sort of a general overview
10 and the rest of the Committee can certainly chime in with
11 their version of history.

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

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 SB --

16 CHAIRMAN KIMSEY: Excuse me --

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 SB.

19 CHAIRMAN KIMSEY: -- excuse me, SB, 1623. And we
20 have basically been going through the regulations that
21 oversee the Forensic Alcohol Program in the state.

22 And we, as part of the legislation, our Committee
23 once we have a work product, it is reviewed by the Health
24 and Human Services Agency.

25 We got a draft work product to the Health and

1 Human Services Agency a number of months ago and received
2 back a letter where they suggested the Committee re-look at
3 four areas that they felt we should look at again.

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

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

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

15 And that's pretty much what we're going to be
16 discussing today.

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

20 When we send them, the product, that triggers a 90
21 day review based on the legislation where they have to get
22 back to the Committee or I believe, and please jump in, if
23 Agency does not get back to us then I think, I guess they
24 just have a 90 day requirement.

25 I'm not sure if they don't make that 90 days what

1 the consequences.

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

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

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

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

17 The American - the American, the Administrative
18 Procedures Act which with regulations have to be in
19 compliance with here in the state of California is rather
20 detailed and specialized.

21 And so there will be some looking at things like
22 clarity and these sorts of areas that come under the
23 Administrative Procedures Act.

24 And then, and I would advocate that this Committee
25 be very much involved with that process.

1 Anyhow, that's my version of the, of 19 meetings.
2 Anyone want to add anything in particular that I may have
3 overlooked?

4 COMMITTEE MEMBER DAVIS: Paul?

5 CHAIRMAN KIMSEY: Yes?

6 COMMITTEE MEMBER DAVIS: I just got an emergency
7 call I have to attend to.

8 CHAIRMAN KIMSEY: Okay.

9 COMMITTEE MEMBER DAVIS: I'll try - I may not be
10 able to come back.

11 CHAIRMAN KIMSEY: That's fine. Thank you for
12 letting us know.

13 THE REPORTER: Who was that?

14 CHAIRMAN KIMSEY: That was Lieutenant Davis.

15 COMMITTEE MEMBER WONG: Bye Kevin.

16 CHAIRMAN KIMSEY: Good luck.

17 COMMITTEE MEMBER DAVIS: Thanks.

18 CHAIRMAN KIMSEY: So, any other comments about the
19 history for Mr. Jeffries benefit?

20 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries
21 in San Diego with the CDAA. Thank you for the welcome. I
22 have had a chance to look over the written materials you
23 sent me. I've also had a chance to, via your website, look
24 over the transcripts of the last couple of meetings. So I
25 am somewhat familiar with the history of the Committee and

1 the meetings as well as the issues involved in Title 17.

2 CHAIRMAN KIMSEY: Great. Well thank you very much
3 for your efforts on our behalf. But anything else about the
4 history before we sort of dive into the bullets?

5 (No response.)

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

8 MR. LYLE: That was the easy one. It was on
9 proficiency testing. And two meetings ago we had a lot of
10 verbiage kind of thrown out.

11 If I could put it into one quick down and dirty
12 sentence, laboratories will direct an approved provider to
13 submit all external proficiency test results to the
14 Department at a minimum of one (1) per year.

15 CHAIRMAN KIMSEY: And this replaced, what did this
16 replace?

17 MR. LYLE: I was just looking for that. I
18 couldn't find the - the sample section. Anybody else have
19 some help for me?

20 COMMITTEE MEMBER SHEN: No - I'll look.

21 CHAIRMAN KIMSEY: This is Paul. I think this is
22 obviously very direct. There may be some areas that, under
23 the APA we will need to clarify unless it's already
24 somewhere it strikes me that an approved provider might need
25 to be delineated.

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

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

14 And I think that we discussed that we were going
15 to go proficiency tests for a person and not an instrument.

16 COMMITTEE MEMBER WONG: Right.

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

21 These are the types of issues, I think, that we'll
22 be continuing to discuss at some point when the Office of
23 Regulation gets involved in preparing the package for final
24 submission.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 A couple of comments. I think the regulations are going to
2 need to describe, it's actually been suggested, the
3 terminology, **approved provider**. And I think actually it's
4 appropriate for the Department to approve the provider.

5 I think besides an ASCLD/LAB-approved body, we're
6 going to need a sufficient number of California labs to
7 participate in order to have any kind of statistical basis
8 for evaluating the results.

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

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

19 The laws and regulations governing clinical and
20 workplace drug testing require three PTs per year. So I
21 think two is actually sort of the minimum.

22 Again, the Department must continue to evaluate
23 the performances on proficiency tests. And we need to
24 specify in the regulations the basis for those evaluations.

25 It's the new age of regulations and I believe the

1 AP is going to require that, if, that the regulated entity
2 knows, you know, the criteria that the Department will be
3 employing in order to evaluate those results.

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

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

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

19 COMMITTEE MEMBER SHEN: This is Jennifer. First
20 of all, you know, most of the California laboratories I
21 believe are probably using two tests, correct me if I'm
22 wrong as their providers. So they're approved providers.

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

1 Secondly I would say, that we've gone round and
2 round and round on the methodology versus the analyst. I
3 think that we are pretty clear that we would like to test
4 the analyst. And the methodology can just be the exact same
5 thing on a different instrument.

6 And I think there's (inaudible).

7 CHAIRMAN KIMSEY: So there's --

8 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick in San
9 Diego. Definitions of proficiency tests is exactly that.
10 To test the proficiency, the ability of an analyst
11 (inaudible) to do confirmations on that. But he has to make
12 sure that it's able to do an accurate analysis.

13 And each time the method is run it has quality
14 control samples and standards who test the accuracy of that
15 particular instrument at that method at that time.

16 But proficiency tests by definition are tests on
17 individuals.

18 COMMITTEE MEMBER WONG: Right. This is Kenton.
19 If you look on page nine of the AG's opinion, it's already
20 said that. It's saying in point (c) it says, each examiner
21 shall successfully complete at least one proficiency test
22 annually.

23 So it's not even a point of argument.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 But wait --

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

4 COMMITTEE MEMBER WONG: Right.

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

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

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

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

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

22 But that, they also specifically state that that
23 can be an internal test. The results need not be or not
24 submitted to ASCLD/LAB so I don't want to see those results.

25 They do want to see at least one proficiency test

1 from the **laboratory** each year. And so that philosophy, that
2 approach, the, which measures the quality performance of a
3 **laboratory**.

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

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

10 So it's, you know, if we need to clarify our
11 language a little bit more to make sure that we realize
12 that, that's fine. We're not talking about something the
13 laboratory once a year. That's not even something we're
14 (inaudible) for this set of regulations.

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

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

22 CHAIRMAN KIMSEY: So is there any suggested change
23 to the language that Bruce has proposed that might clarify
24 things or do we want to --

25 COMMITTEE MEMBER WONG: Sure.

1 CHAIRMAN KIMSEY: -- put in, examiner, or, person,
2 whatever we call them.

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

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

14 I don't know that we need to rewrite it all down
15 again if we can cite somewhere, it assumes that's what we're
16 going to be doing.

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

23 And maybe the other six or seven that didn't do
24 the proficiency test were never tested for decades. So this
25 is far in excess and better than what we ever had.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

2 And again, I think a careful reading of the statutes, and
3 you just read them, and I think if you listen carefully to
4 what you read that it creates a clear dichotomy there in
5 that the laboratory PT is described as an **external**
6 proficiency test.

7 That means a test that is produced by some
8 organizations outside the laboratory.

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

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

16 So simply, I mean --

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

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

23 Yeah.

24 COMMITTEE MEMBER SHEN: Okay.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

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

5 CHAIRMAN KIMSEY: Well I don't have a problem with
6 that.

7 CHAIRMAN KIMSEY: Other comments on bullet one?

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

12 So this is an additional section - the laboratory
13 that sent the approved provider that sent the proficiency
14 test to the laboratories from telling the laboratory to ask
15 that, approved provider to send the results, at least one
16 time a year, to the Department.

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

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

22 CHAIRMAN KIMSEY: Okay.

23 COMMITTEE MEMBER SHEN: I guess the - this is
24 Jennifer. I guess the key now would be to figure out where
25 you're going to put that.

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

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

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

8 COMMITTEE MEMBER SHEN: Well, if we can cite 1007
9 and be aware or wherever it is that we add this bullet. I'm
10 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 product
16 we had pulled 1216.1 (e) (4) **out** (inaudible).

17 COMMITTEE MEMBER SHEN: If you look at 3, if you
18 look at (e) 3, it talks about proficiency testing.

19 COMMITTEE MEMBER SHEN: We were (inaudible) or
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 (inaudible) 17. So 1216.1 (e) (3) talks about - I
10 think that's (inaudible) in proficiency testing.

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: Bruce (inaudible) in that
22 spot.

23 CHAIRMAN KIMSEY: I mean that's one of those
24 issues that I think will probably get clarified at some
25 point. I don't know that, do we cite - of course this is

1 our work product so, yes, let's go ahead and cite it.

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

7 CHAIRMAN KIMSEY: Okay.

8 COMMITTEE MEMBER SHEN: To clarify, we're putting
9 this in 1 (c), 1 (6) or (inaudible) - as written. And then
10 cite the Health and Safety Code here at the end.

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

13 COMMITTEE MEMBER SHEN: Well, I mean, we could add
14 clarifying statements. So, laboratories will direct an
15 approved provider (inaudible) test results to say something
16 in here about - laboratories will direct an approved
17 provider to permit all (inaudible) proficiency or, you know,
18 this is it, keeps (inaudible) analysts external proficiency
19 testing here or some such thing. (inaudible) that every
20 analyst (inaudible) external proficiency test. Does that
21 help?

22 CHAIRMAN KIMSEY: That certainly clarifies it.

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

25 COMMITTEE MEMBER WONG: At a minimum of one per

1 year per examiner or per analyst?

2 MR. LYLE: (inaudible) extension of (inaudible)

3 COMMITTEE MEMBER SHEN: In effect (inaudible) send
4 all current proficiency tests to the Department at a minimum
5 of one per year as a background, that sounds great.

6 Do we want to say something about solving
7 (inaudible)? Or are we going to say that they're --

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 providers 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. DVORIK/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 there are definitely
3 authority and reference citations.

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

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

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

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

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

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

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

7 Some link that would increase the clarity by citing the
8 statutes.

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

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

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

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

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

25 I would add an earlier comment I made though. And

1 it relates to this particular citation that we're talking
2 about here. Is that, besides making available these data to
3 the Department, whatever they may be, the expectation, at
4 least from the part of the program is, that the Department
5 will take those data and make some kind of finding.

6 The regulation right now doesn't describe that at
7 all. And it might be confusing and if we're citing 100702
8 regarding the laboratory's participation the literal reading
9 of the statutes simply says that the labs shall participate
10 in a proficiency test, external proficiency test.

11 It doesn't necessarily require that the labs have
12 any particular performance on that test. They could fail
13 it, pass it, I guess.

14 So, although the more reason that the regulations
15 should clarify what exactly the Department, I think that
16 we'll need to clarify, what exactly the Department is going
17 to do with those results.

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

24 COMMITTEE MEMBER WONG: Recently it was done for
25 licensing. This is Kenton in Richmond. But since you guys

1 aren't in charge of licensing it wasn't required. But we
2 were recommended to add this back in to satisfy Health and
3 Human Services.

4 So, we're again at that kind of impasse of what
5 the goal here is in some ways to satisfy Health and Human
6 Services but then also satisfy 16.3.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 Actually I think you're mistaken Kenton. The purpose of
9 proficiency tests was set forth under Article 6 and it
10 requires that the Department utilize the PT results to
11 determine and establish that the laboratory's methods
12 continue to meet the accuracy, the standards of performance
13 requirements set forth in the regulation.

14 So, it wasn't specifically a licensing thing.

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

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

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

24 COMMITTEE MEMBER WONG: No. I agree.

25 RESEARCH SCIENTIST SPELL: Well, I can add -

1 Natalia Spell. Licensing in my opinion is a part of
2 oversight, right? So you can remove the license but you
3 still can provide certain oversights like examining the
4 proficiency testing and see how it, quote, statistically.

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

11 COMMITTEE MEMBER WONG: I agree.

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

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

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

22 COMMITTEE MEMBER SHEN: This is Jennifer again.
23 You know, we've gone around and around about this too. And
24 you know, this is a quandary. We are an accredited
25 laboratory. We cannot (inaudible) fail all our proficiency

1 tests on a yearly basis and not have 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 doesn't pass the proficiency test.

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

9 THE REPORTER: So what was the lab part of, if
10 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 but if we have proficiency tests and we
24 just don't pass them, as you just said, year after year
25 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 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 at
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 them with that information and then
9 if our analyst doesn't pass a proficiency test we have to,
10 you know, we have to address that. We have to address that
11 to ASCLD/LABS for us for our laboratories.

12 And once I know why that is and what we did. So,
13 we're already giving 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 that needs to be
18 clear 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 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 the, you focussed the conversation
4 here on analysts' proficiency tests; there's no requirement
5 that the laboratory submit, for consideration to ASCLD/LAB
6 or to the Proficiency Review Committee, any analyst's PT
7 data.

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

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

17 So, I think it's irrelevant.

18 COMMITTEE MEMBER SHEN: You know (inaudible) here.

19 But I don't think that's true. I think that, I think, you
20 know, is anyone else that can help me with this? I believe
21 that the, that the proficiency tests are, our accrediting
22 agencies and a tribute to them on making that task.

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, now this being duplicitous perhaps (inaudible) is a

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

6 The Department knows that we have taken steps to
7 address it. For those laboratories who are not accredited
8 then 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 FQS and each analyst has to
12 pass their proficiencies which are reported to the
13 accrediting body and checked and if there's a problem, our
14 individual laboratory or your local labs are going to be
15 much more concerned even before, way before, the CDPH is
16 ever concerned about that.

17 So, it would just be another example of
18 duplicitous 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 in
22 the 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, proficiency testing program, is
4 that in their bylaws it is completely confidential. So the
5 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 an ASCLD/LAB'S procedures which are 100 percent
9 confidential.

10 COMMITTEE MEMBER WONG: They're 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 it.

14 And they can drag all of that into court. So it's
15 not confidential.

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

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

25 And the program here is proposing changes that

1 will allow the Department to enforce the regulations.

2 CHAIRMAN KIMSEY: This is Paul --

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

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

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

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

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

23 The state adopted statutes which asked the
24 Department and other states have similar programs, asked the
25 Department to provide an oversight of the chemical testing

1 in support of the drunk driving laws.

2 So that's, certainly the Legislature when they
3 passed that was aware that things could be introduced in a
4 court.

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

8 COMMITTEE MEMBER JEFFRIES: I think that, this is
9 Dan Jeffries again. I think it's much higher than that,
10 probably 99 percent of (inaudible) do not go to trial.

11 At least in Los Angeles County we're seeing fewer
12 than one percent of the DUI cases go to trial.

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

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

1 I think the intent of the law is, as I say, to
2 provide a more proactive program that makes it less likely
3 and/or prevents that from happening.

4 CHAIRMAN KIMSEY: This is Paul real quick. I
5 think this has been a good discussion and we're sort of
6 going around, this also brings back memories for a lot of
7 us.

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

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

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

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

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

1 COMMITTEE MEMBER SHEN: This is Jennifer. I
2 think, you know, I guess the point that and I guess the
3 point that the Department is going to be looking at these
4 and they, and someone sees there something that has not been
5 addressed that the Department would want assurances that it
6 has been addressed.

7 So, I do get that. And I can see that that would
8 be something that would possibly be reasonable. I just, I
9 don't want to do things, I don't want to duplicate efforts.
10 And I don't think the Department would want to duplicate
11 efforts, for instance, re-analyzing all the stats on the
12 proficiency tests.

13 I don't see that there's any point to that. So, I
14 mean, I wouldn't be opposed to some sort of language in here
15 that indicates at least provide the Department with some
16 information that we have handled the 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 it could be, the Department
23 will see how we address it and two, the Department can rest
24 assured that, in fact, it was noted and addressed.

25 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.

3 I don't think that's particularly 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, how we define a
14 negative result and who made that determination? And that
15 would apply to the gamut of labs out there 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 he's either getting the right
21 results or 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 negative or adverse result or whatever term you use, seemed
2 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 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. But I
22 think at the end of the day what we're looking at is, we
23 have (inaudible) writers who, this is, you know, these
24 companies, this is what they do for a living. They are
25 giving up tests. They're analyzing the data and they're

1 providing that data to us telling us how our analysts do in
2 comparison to everybody else that has taken the 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 follow some of the accepted ranges.

6 So, and we have to address that. As an accredited
7 laboratory we have to address those failures. So there will
8 be (inaudible) in front of those. And we can forward them
9 so that the Department can see that.

10 CHAIRMAN KIMSEY: So maybe the failure is I think
11 the word that has sort of caused the stumbling block.
12 Maybe, the Department will be notified of corrective actions
13 for 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 have, as
22 well versed in this as I should be, but the PT, I don't
23 believe and I think you ask for something that most letters
24 are reviewed I think, I don't believe they give you a
25 pass/fail. They just - I think they give you the data and

1 you look at it, your quality assurance manager or whoever is
2 in charge of proficiency test, 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 So, I think that's a definition of an internal proficiency
9 test. 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. And another thing,
14 it's not going to be very straight forward. We don't get
15 something after CPS that says, you failed.

16 (inaudible) that was a failure so we're going to
17 report that. It's not that clear cut.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 So, 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: You know --

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 quite as well but the actual process
3 of the proficiency tests program itself in my opinion is
4 much, much better.

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

9 COMMITTEE MEMBER SHEN: No. 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 So 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 sufficient, having access to
24 what the provider submits to, sends back to the laboratory.
25 Is that 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
18 lab 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, in training
5 (inaudible) 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 have
6 accomplished 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, unless they
11 (inaudible) we're contacting the approved provider.

12 The approved provider is, they're a conduit of
13 results of an approved provider to the Department, that will
14 not accomplish getting corrective actions to the Department.

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

19 COMMITTEE MEMBER SHEN: Correct.

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

23 CHAIRMAN KIMSEY: Or not.

24 COMMITTEE MEMBER WONG: Or not.

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

1 COMMITTEE MEMBER WONG: Well - so that's, whatever
2 it is we just need to make sure that it's all transparent.

3 COMMITTEE MEMBER SHEN: Yes I agree.

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

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

13 RESEARCH SCIENTIST SPELL: Criteria.

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

21 RESEARCH SCIENTIST SPELL: I agree.

22 CHAIRMAN KIMSEY: Well that's getting back to what
23 the Department currently does which is my impression that
24 the Committee was moving away from.

25 COMMITTEE MEMBER SHEN: Well, this is Jennifer.

1 We, I mean I think that if we're going to go that route the
2 corrective action has to be we can supply a copy of the
3 corrective actions to the Department at that time that we
4 have already taken.

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

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

18 So - I'm not sure we want to put the Department in
19 a position where they will now determine that in addition to
20 what we've already done the Department will now do something
21 else.

22 COMMITTEE MEMBER WONG: I agree.

23 CHAIRMAN KIMSEY: But there is an interest in
24 having the Department in the loop sort of knowing that a
25 corrective action has taken place.

1 COMMITTEE MEMBER WONG: Correct. I agree with
2 that.

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

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

10 COMMITTEE MEMBER SHEN: This is Jennifer. Are we
11 thinking of, the laboratories, what I have right now, the
12 laboratories will direct approved providers to submit an
13 external proficiency test results as required by (inaudible)
14 100702 to the Department at a minimum of one per year per
15 analyst, any corrective actions - documentation?

16 Corrective action --

17 MR. LYLE: That should be, taken.

18 COMMITTEE MEMBER SHEN: -- taken, including
19 documentation of any corrective actions taken?

20 COMMITTEE MEMBER WONG: That's all transparent.

21 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries
22 in San Diego. If the language in 100702 refers to
23 corrective actions taken so we just mirror that language.

24 COMMITTEE MEMBER WONG: It sounds good Jennifer.

25 CHAIRMAN KIMSEY: Any other comments from the

1 Committee?

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

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

11 (No response.)

12 Any other suggestions to the language? Any
13 questions on the language?

14 MS. LYONS: This is Denise Lyons. I had one
15 comment about the last language that Jennifer read. And the
16 way it was worded it seemed to imply, and I think this was
17 Clay's concern, that the corrective action come from the
18 provider the way it's written. And corrective action
19 documentation would indeed come from the laboratory.

20 And I think I'm trying to combine that into one
21 sentence makes it unclear who will be providing the
22 documentation for the corrective action.

23 COMMITTEE MEMBER SHEN: Perhaps we need two
24 sentences then. In addition the laboratory, the (inaudible)
25 the laboratories, the laboratories will forward any

1 documentation of corrective actions taken?

2 CHAIRMAN KIMSEY: That's pretty clear.

3 COMMITTEE MEMBER WONG: Uh-hmm.

4 COMMITTEE MEMBER SHEN: That be better?

5 COMMITTEE MEMBER WONG: Uh-hmm.

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

9 CHAIRMAN KIMSEY: Okay. Other comments before we
10 vote?

11 COMMITTEE MEMBER SHEN: You want me to read this
12 again?

13 COMMITTEE MEMBER WONG: Read it one more time.

14 COMMITTEE MEMBER SHEN: Okay. Good.

15 CHAIRMAN KIMSEY: Sure as requested, have it read
16 one more time please.

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

24 COMMITTEE MEMBER WONG: Cool.

25 CHAIRMAN KIMSEY: Okay, any Committee member

1 dissatisfied with the language?

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

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

12 I just want to go on record with that.

13 CHAIRMAN KIMSEY: Okay.

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

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

21 How do we make a conclusion whether they passed or
22 failed?

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

24 RESEARCH SCIENTIST SPELL: Well, who makes these
25 conclusions then?

1 CHAIRMAN KIMSEY: It's the providers and the
2 laboratory.

3 RESEARCH SCIENTIST SPELL: Providers --

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 No, not the providers --

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

7 CHAIRMAN KIMSEY: -- well the --

8 RESEARCH SCIENTIST SPELL: -- no, providers don't
9 do it.

10 CHAIRMAN KIMSEY: -- the accrediting organization.

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

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

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

23 CHAIRMAN KIMSEY: No, that's been explained
24 before. The Committee is not interested in having the
25 Department go through their proficiency testing program.

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

4 COMMITTEE MEMBER SHEN: Well that's --

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

8 CHAIRMAN KIMSEY: It's not the Department's
9 concern.

10 RESEARCH SCIENTIST SPELL: Okay.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Well it may be but it's - well, it's the Committees
13 responsibility.

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

19 (No response.)

20 Okay. Let's move on to bullets two and four. I
21 believe those were yours Jennifer.

22 COMMITTEE MEMBER SHEN: Paul, are we going to vote
23 on that?

24 CHAIRMAN KIMSEY: Do we need to?

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

1 CHAIRMAN KIMSEY: I think the Committee has pretty
2 much approved it. So --

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

4 CHAIRMAN KIMSEY: -- okay.

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

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

14 CHAIRMAN KIMSEY: Okay.

15 COMMITTEE MEMBER SHEN: Because I found four
16 easier than two (laughter).

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

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

24 And you suggested, 1216 (a), every laboratory
25 performing forensic alcohol analysis will have on record

1 with the Department the following: a statement of intent to
2 perform or stop performing alcohol analysis to include
3 notification for breath and fluid analysis specifically,
4 two, the laboratory's address as well as the name, address
5 and phone number of the laboratory's point of contact,
6 three, a list of laboratory personnel qualified to do
7 forensic alcohol analysis and/or a list of instruments used
8 by the laboratory personnel for alcohol analysis.

9 Comments?

10 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries.

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

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

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

24 But that was some of the ideas around the
25 Department just knowing who in the state was going to be

1 doing this type of work.

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

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

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

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

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

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

24 There are a number of activities that a lab
25 performs besides analysis of blood, urine and tissue samples

1 the labs are also tasked under the regulations with certain
2 responsibilities involving breath alcohol analysis that
3 involve training the instrument operator and then
4 maintaining it and determining the accuracy of the
5 instrument.

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

9 COMMITTEE MEMBER SHEN: This is Jennifer
10 (inaudible) breath and fluid analysis specifically in the
11 language.

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

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

17 Notification of intent then, all right,
18 notification of initiation or discontinuation of alcohol
19 analysis to include identification of breath and fluid
20 analysis specifically.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 Yeah, okay. But regarding breath alcohol analysis I just
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 talk to the training component we'll talk the fact that labs
6 under the current regulations and even as proposed by at
7 least the Committee members so far would have a role in
8 approving that training procedures.

9 So, we need to know what instrument they are
10 using. You know, I think, my list for the notification form
11 include the name of the laboratory, mailing address,
12 telephone or fax numbers, full names of the persons, we also
13 now, and I think it's appropriate to require that, not a
14 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 won't be required, and we haven't talked
4 about training, but to submit written descriptions of any
5 training program conducted by 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
14 that it was my intent to provide the full names of the
15 analysts. I think the point that contacts might be, I mean,
16 the laboratory's point of contact could be to clarify to
17 indicate the person who is in charge of the regulations, the
18 person 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'm
8 liking to change the word, intent, to have a statement.

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 the right to exclude,
13 yeah. I'm kidding. Would 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, I don't know, I
25 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 points 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 we'll
14 find that's the way it is.

15 COMMITTEE MEMBER SEDGEWICK: This is Paul
16 Sedgewick and 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 the laboratory and tell
19 them, we want or what you want.

20 COMMITTEE MEMBER WONG: Do we need address twice?

21 COMMITTEE MEMBER SHEN: Probably not if you're
22 point of contact is at the laboratory.

23 COMMITTEE MEMBER WONG: Right.

24 COMMITTEE MEMBER SHEN: So I'll take the second
25 address out?

1 COMMITTEE MEMBER WONG: Uh-hmm.

2 COMMITTEE MEMBER SHEN: (Inaudible) with phone
3 number only?

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

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

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

13 COMMITTEE MEMBER WONG: I agree.

14 CHAIRMAN KIMSEY: Other suggested changes?

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

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

1 COMMITTEE MEMBER WONG: Uh-hmm.

2 COMMITTEE MEMBER SHEN: Does that work?

3 COMMITTEE MEMBER WONG: Uh-hmm.

4 RESEARCH SCIENTIST SPELL: Right.

5 COMMITTEE MEMBER JEFFRIES: Dan Jeffries. That's

6 perfect. I think.

7 CHAIRMAN KIMSEY: Other comments?

8 (No response.)

9 Sort of general agreement?

10 COMMITTEE MEMBER SHEN: Yes.

11 MR. LYLE: Yes.

12 COMMITTEE MEMBER JEFFRIES: Yes.

13 CHAIRMAN KIMSEY: Okay.

14 UNIDENTIFIED SPEAKER: I would like a seven to
15 zero vote in favor (laughter).

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

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

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

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

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

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

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

17 COMMITTEE MEMBER SHEN: This is Jennifer. I can
18 already see that in six we need to put something leaning to
19 the (inaudible) annual, I think.

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

22 COMMITTEE MEMBER SHEN: We, you know, we need,
23 that had a (inaudible) analyst performing alcohol analysis
24 for the laboratory. But somehow we put in there for each
25 analyst per year. I think. Although we did say that

1 elsewhere, so maybe not.

2 CHAIRMAN KIMSEY: Other comments?

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

9 COMMITTEE MEMBER WONG: Yes.

10 COMMITTEE MEMBER JEFFRIES: Thank you.

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

14 COMMITTEE MEMBER SHEN: That sounds good.

15 CHAIRMAN KIMSEY: Okay.

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

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

24 Currently that's something the Department
25 qualifies individuals. And I would submit that if you look

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

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

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

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

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

1 the testing.

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

6 COMMITTEE MEMBER SHEN: This is Jennifer. That's
7 exactly what it does. That's what we've been assessing for
8 years now with lots of laboratories as they are doing now.

9 But laboratories are responsible for training
10 their employees and putting them through very rigorous
11 training programs. And lots and lots of laboratories
12 (inaudible) to that.

13 Not the Department being informed of what we're
14 doing but we want the Department to ensure that we're
15 following the guidelines that we are currently writing.

16 So to me this is a compromise where, you know, we
17 were writing these guidelines and we're writing these,
18 writing what need to do, what we all agree that needs to do
19 educationally-wise, topically what we need to discuss and
20 train on and that 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 got
24 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 (inaudible) at this point the
7 Department is going to be looking at that (inaudible)
8 ensuring that the person that we have proffered is in fact
9 qualified based on what's in Title 17.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

11 And I would just, okay, I just heard again, I don't think
12 necessarily, I don't think it satisfies, I don't think it
13 attempts to satisfy the concern of the bullet was, the
14 concern was the fact that the existing regulations without
15 this language removes CDPH's authority to review, approve
16 and test the qualifications of persons employed by a
17 laboratory.

18 CHAIRMAN KIMSEY: Other comments from the
19 Committee?

20 (No response.)

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

25 Any other comments in general on bullet two as

1 we're calling it?

2 (No response.)

3 Okay.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

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

6 UNIDENTIFIED SPEAKER: Yes, seven zero gothic.

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

8 UNIDENTIFIED SPEAKER: This is just a comment.

9 But I think (inaudible) unanimous decision by the Committee
10 to go forward with that one.

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

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

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

22 (Ayes.)

23 Any nays?

24 (No response.)

25 Bullet number four, which is the one we discussed

1 just previously. All in favor?

2 COMMITTEE MEMBER WONG: Aye.

3 (Ayes.)

4 Any nays?

5 (No response.)

6 Bullet number one. All in favor?

7 (Ayes.)

8 Any nays

9 (No response.)

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

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

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

20 COMMITTEE MEMBER SHEN: I (inaudible) park.

21 CHAIRMAN KIMSEY: I'm sorry?

22 COMMITTEE MEMBER SHEN: This is --

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

24 COMMITTEE MEMBER SHEN: This is Jennifer. I need
25 to go move my car.

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

3 COMMITTEE MEMBER SHEN: Yeah, I would like maybe
4 15 minutes.

5 CHAIRMAN KIMSEY: Okay. Why don't we get started
6 at five, well, let's make it 10 minutes after noon. So at
7 12:10.

8 MR. LYLE: Thank you Paul.

9 CHAIRMAN KIMSEY: Thank you. We're taking a
10 break.

11 (A recess was taken off the record.)

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

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

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

24 1218.1 Additional Requirements. At the discretion
25 of the Department, any phase or portion of a training

1 program shall be subject to alteration in an effort to
2 update the program as technological advances are made or if
3 a portion has been judged inappropriate.

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

11 Comments from the Committee? Kenton you -

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

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

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

24 COMMITTEE MEMBER JEFFRIES: Correct.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Okay.

2 COMMITTEE MEMBER SHEN: This is Jennifer. You
3 know, I think there might, we might not want to add this
4 back in verbatim. And I think that this can be, this can
5 lead us down the road of doing of a lot of things that we're
6 trying not to do anymore.

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

11 COMMITTEE MEMBER SHEN: Correct. And (inaudible)
12 training.

13 COMMITTEE MEMBER WONG: Uh-hmm.

14 COMMITTEE MEMBER SHEN: And the other three
15 points, they certainly, they certainly try to raise the
16 compromised position, at least in my mind.

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

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

1 COMMITTEE MEMBER SHEN: This is Jennifer. I agree
2 with that. I think maybe you want to take a look at this
3 and talk about providing information to keep the Department
4 in the loop and informed and letting the Department ensure
5 that we're following what's in Title 17.

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

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

13 COMMITTEE MEMBER WONG: Right. So either just
14 notification or informing?

15 COMMITTEE MEMBER SHEN: Yeah. We kind of model it
16 if you really think that that is a good idea. We kind of
17 model it after one of the, I think that bullet. Bullet
18 number one, three and two are same sort of concept as bullet
19 number one.

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

24 COMMITTEE MEMBER SHEN: For breath alcohol
25 analysis?

1 CHAIRMAN KIMSEY: Right.

2 COMMITTEE MEMBER SHEN: No way. Let me know, this
3 is coming back to me. And that was our issue I think, is
4 that, is that there isn't going to, well (inaudible) in
5 general build their training programs. And they need to
6 build it following the guidelines of Title 17 and then need
7 to ensure that the Department is kept apprised of what we're
8 doing.

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

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

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

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

1 And though I'll withdraw my comments since it does
2 seem like someone needs to be doing it if the Department
3 isn't. It does seem that it needs to be done by someone.

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

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

12 MR. LYLE: Well I'm --

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 -- do that.

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

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

22 And our accrediting bodies ensure that we have a
23 training program and that we're following that training
24 program. And that people that we have onboard have gone
25 through that training program and that were properly

1 (inaudible) proficiency test competency tests et cetera.

2 That's what they are ensuring. But as far as the
3 makeup of the training programs itself, you know, the
4 laboratories are responsible for putting that together.

5 So in this way the breath alcohol program isn't
6 any different except for the breath alcohol program
7 currently has this extra level of approval that isn't really
8 seen in our other sections, in (a) for instance.

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

14 CHAIRMAN KIMSEY: Hmm.

15 COMMITTEE MEMBER WONG: Hmm.

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

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

1 And, under the regulations there are only two
2 training, it used to be three, but now there's only two
3 training programs provided.

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

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

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

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

1 But, this sort of self-regulating mechanism
2 doesn't work at all in that instance.

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

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

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

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

25 COMMITTEE MEMBER WONG: Uh-hmm.

1 COMMITTEE MEMBER SHEN: -- and that information is
2 all applied to the Department. And so the level of
3 oversight that would be applied, the Department looks at
4 what was provided and determines whether or not that, in
5 fact, follows what is laid out in Title 17.

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

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

17 And that's just kind of where we are. We have to
18 figure out what to do in there.

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

22 COMMITTEE MEMBER SHEN: Yes.

23 COMMITTEE MEMBER JEFFRIES: This is Dan Jeffries.
24 I guess showing my ignorance, it would strike me that you
25 could also interpret this to say that, UCLA has to submit a

1 list of their instructors which are going to get someone who
2 qualifies because they have a bachelor's degree in a
3 physical science from UCLA.

4 I don't think that's what you intend to do. But
5 the way it's worded it would require that or could be argued
6 to require it.

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

17 So, that could be easily corrected.

18 COMMITTEE MEMBER SHEN: Well, again. We're in a
19 philosophical difference here. I mean, between what the
20 Department wants and what the Committee has supported. So I
21 think that's the discussion we need to have.

22 I mean this was brought up as a bullet point that
23 this, I think, a point of concern that we've removed
24 authority to review and approve training programs.

25 So again, fall back position, we're going to look

1 at Title 17. We're going to do what it says. And we're
2 going to show the Department that we've done that.

3 You know, what (inaudible). We can go around and
4 around on this but it really comes down to which direction
5 does the Committee want to go?

6 COMMITTEE MEMBER WONG: I agree with you Jennifer
7 that we have to compromise because Health and Human Services
8 already said that they're not going to accept that this
9 draft that we have.

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

13 And if we need to have a citation for persons to
14 qualify under these regulations for either analyst or breath
15 operators then we can cite that for those two groups.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Well --

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

22 COMMITTEE MEMBER WONG: Right.

23 COMMITTEE MEMBER SHEN: How do we do that?

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Let me just ask, incredulously but, so the letter indicated

1 a concern over the removal of the Department's authority to
2 review and approve. So, our compromise, as you put it, is
3 to strike the role of the Department in approving the
4 training but have some, I mean this is a little bit like the
5 proficiency testing role.

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

10 Is that the proposal? I'm not, is that the
11 compromise, as you're suggesting?

12 COMMITTEE MEMBER SHEN: Well, yes it is, actually.
13 I think that the Department has had quite a bit of input
14 into how we're writing these regulations and how, what is or
15 is not important.

16 So, I guess, I'm thinking that when we're finished
17 with the work product (inaudible) it's approved, the
18 laboratories are going to be held responsible for following
19 what we as a Committee, with great input from the
20 Department, have decided is necessary.

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

1 If we're not, I mean, then, now we're in the same
2 position as everything else, it's just that, if the
3 laboratories is doing something the Department want us to do
4 or doesn't agree with then, you know, we really (inaudible)
5 position of again, we're probably just an interaction,
6 taking interaction. I don't know the Department, you guys
7 just don't like these things doesn't have a lot they can do.

8 But I, you know, if our goal is to follow what we
9 laid out in Title 17. And it's our goal to let you see that
10 we're doing that.

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

16 But I think it seems for the most part that it's
17 self enforcement.

18 COMMITTEE MEMBER WONG: Uh-hmm.

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

25 If the Committee specifically strikes the

1 language, the Department for approval, I'm not sure what
2 your standing would be to go court and saying, we don't
3 approve of this. You could argue that the regulations don't
4 ask you to approve it.

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

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

13 We, although, the program has proposed actually
14 adding a specific minimum number of hours of instruction.
15 It wasn't accepted by the Committee.

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

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

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

1 in Title 17 as we envision it.

2 So, you know, I suppose, if we look at that and it
3 looks like you could give all the instruction that's
4 necessary in 20 minutes, then maybe we need to alter that
5 versus giving oversight in an area we don't want to.

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

12 COMMITTEE MEMBER SHEN: Again, I think Kenton
13 (inaudible) what we need to do, to separate it out and
14 (inaudible) breath instrument users versus the analysts, the
15 forensic alcohol analysts. We should separate that section
16 out a little bit so that it addresses them both.

17 And then cite the appropriate sections in Title
18 17.

19 COMMITTEE MEMBER WONG: Uh-hmm.

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

25 Or has that been burdensome within the part of the

1 laboratories to submit the information?

2 COMMITTEE MEMBER SHEN: No, somebody else may be
3 more able to answer that than I am.

4 CHAIRMAN KIMSEY: I mean, my concern is just that,
5 you know, if there's no other entity really approving the
6 training then we really do need to be sure that Title 17 is
7 quite reflective of what we feel that training needs to be.

8 COMMITTEE MEMBER SHEN: I would agree.

9 MR. TOMS: This is Mike Toms from Sacramento from
10 the public. Something that need separated out are whether
11 or not you're training a brand new officer to utilize the
12 instrumentation or you're just training an officer on new
13 instrumentation.

14 They would need a four hour course on alcohol
15 physiology to utilize a new instrument.

16 So that's some of the things that can be
17 problematic that you're going require of this long training
18 for just showing someone how to go through four steps.

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

1 I said, I know you guys have already had that but
2 we have to follow the spirit of the law in certifying you
3 for use in this county.

4 So, it was, yeah, I know what you're talking
5 about.

6 MR. TOMS: And I get lead training officers on new
7 instruments but it shouldn't require a full training if
8 they've already had all of the other stuff for, it just
9 shouldn't require that. It's, we have a lot of officers
10 that come into our county as well and it's the same thing.

11 COMMITTEE MEMBER WONG: Yeah.

12 MR. TOMS: The people that go to a new instrument,
13 upgrade our Draeger instrumentation, basically it's the same
14 instrument with a different look but likely we would be
15 required to provide every officer in our county brand new
16 training. And I don't think that's appropriate.

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

1 So he's going to be now operating a different
2 instrument. I would agree that it doesn't make any sense to
3 send the officer through the whole thing again.

4 CHAIRMAN KIMSEY: But that's currently happening?

5 COMMITTEE MEMBER WONG: It is. It's considered to
6 be quite onerous because you get these guys lateralling
7 around --

8 CHAIRMAN KIMSEY: Sure.

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

11 CHAIRMAN KIMSEY: Uh-hmm. And we've already
12 approved that officer training somewhere? Did we make any
13 changes to the, having a baseline course versus a new --

14 COMMITTEE MEMBER WONG: That's why.

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

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

24 COMMITTEE MEMBER SHEN: What I'm saying is sort of
25 something but I'm having trouble finding, I'm having trouble

1 finding that particular area. So, I mean, I think for our
2 analysts in our laboratories we have pretty specific, we
3 need to cover X amount of topics such as X amount of things
4 as proficiency tests such as, maybe we can make the officer
5 training if it is, if the Department feels like it could be,
6 I think, we could follow what's in Title 17 and (inaudible)
7 credibly training, then maybe we pump that area up a little
8 bit. I'm just having trouble looking. If you look at it.

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

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

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

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 (Hand signalling three).

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

1 COMMITTEE MEMBER SHEN: This is Jennifer. I think
2 before we do that we have to decide how we're going to
3 proceed. We have, I think again, we might need to address
4 that philosophical difference. We've got to figure out
5 which way we're going to go.

6 And then, but I don't think we can work on
7 language until we have a, a somewhat clear plan as to what
8 that language is trying to encompass.

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

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

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

23 COMMITTEE MEMBER SHEN: This is Jennifer. I guess
24 I don't necessarily disagree as long as, I would like to see
25 it be very specific. So, if we're going to go that route

1 there will be very specific things to provide for approval
2 because what tends to happen in my experience is that a
3 specific topic becomes very broad.

4 So, for instance, if we were going to supply an
5 outline training for breath instrument operators, that would
6 not mean that we would be giving approval on the
7 methodologies that is being used by the people who are doing
8 the training and that the training, it wouldn't, for
9 instance, to be including everything in for our trainers
10 necessarily.

11 We would be providing the type of outline we're
12 using for our trainees. Does that make sense? I'd like to
13 see it very specific.

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

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

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

24 COMMITTEE MEMBER SHEN: Well, I guess if we, if we
25 articulate clearly in Title 17 what needs to be covered for

1 breath instrument operator then the Department will be in
2 the position of a training outline that encompasses those
3 things.

4 (inaudible) a training outline and it work through
5 (inaudible) certainly outlined in Title 17 that was
6 (inaudible) training them in, then the Department would have
7 some sort of ability to say, hey, you know what you're
8 missing this and this needs to be added to your training
9 outline.

10 I mean, I can kind of envision something like
11 that.

12 COMMITTEE MEMBER WONG: Uh-hmm.

13 COMMITTEE MEMBER SHEN: But that would probably
14 mean that this Title 17 the way it's written now
15 (inaudible), I'm sorry, fluffed up a little bit.

16 COMMITTEE MEMBER WONG: Uh-hmm.

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

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

1 In other words, what I'm suggesting is something
2 along the lines of 1218 reading, training approval, or I
3 mean I'm sorry, training program. Any laboratory conducting
4 a course of instruction for persons to qualify under these
5 regulations shall submit a course summary demonstrating
6 compliance with these regulations and submit a list of
7 instructors and their qualifications to the Department.

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

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 I actually don't see any difference in the wordsmithing
13 effort. I really don't think it produces any difference.

14 The Department's current and longstanding approval
15 process has been based on compliance with the requirements
16 of the regulations.

17 COMMITTEE MEMBER JEFFRIES: Well I guess what I
18 was getting at is do you want to be in a place where you
19 submit it to the Department and the Department says yes or
20 no or do you want it submitted to the Department and if the
21 Department doesn't think it (inaudible) then the Department
22 can take some action.

23 Who has the responsibility to take some action if
24 they're not in compliance?

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Well, I mean, you're talking about if the lab submits
2 training procedures that aren't in compliance we would then
3 seek an injunctive relief?

4 I mean, our process, I think, now would be to
5 write back to the lab and say, you know, this program does
6 not appear to comply with the requirements and regulations
7 because of A, B, C and D.

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

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

15 COMMITTEE MEMBER SHEN: Well, since the
16 regulations are very clear then it should be, it should be,
17 number one rare that we get something that's out of
18 compliance --

19 COMMITTEE MEMBER WONG: Uh-hmm.

20 COMMITTEE MEMBER SHEN: -- and extremely
21 (inaudible) or articulate why that program is out of
22 compliance and very easy for the laboratory to agree to
23 that.

24 We don't want to go down the road of having
25 lengthy (inaudible) where the Department and the

1 laboratories are at odds with what is or is not science.

2 COMMITTEE MEMBER WONG: Uh-hmm.

3 COMMITTEE MEMBER SHEN: -- we want to make sure
4 that we don't think these so broad or over-simplification
5 that we're going to have some battles. We don't want the
6 battles anymore.

7 It looks to me like we're maybe going down the
8 road of articulating extremely clearly what it is that we
9 would provide to the Department and what the Department
10 would have oversight of.

11 It sounds to me like the Department is itself that
12 we were not in compliance with Title 17, (inaudible) back,
13 you know, the written form.

14 CHAIRMAN KIMSEY: So it sounds like we need to
15 sort of look at Title, what's actually written in Title 17.

16 I don't have my copy here.

17 COMMITTEE MEMBER SHEN: (inaudible) the ones,
18 point four, I think.

19 COMMITTEE MEMBER WONG: What did she say?

20 CHAIRMAN KIMSEY: 1261.4.

21 COMMITTEE MEMBER SHEN: 1204 (a) (3) (e) both are
22 written, a practical examination are now required to ensure
23 the operator has sufficient information. This is the kind
24 of area we need to be in.

25 CHAIRMAN KIMSEY: Were you saying, what was the

1 number again that you had Jennifer?

2 COMMITTEE MEMBER SHEN: 1221.4 --

3 CHAIRMAN KIMSEY: 1221.4 --

4 COMMITTEE MEMBER SHEN: And (a) (3) (e) was
5 written in, written and practical examination. We took
6 (inaudible) and/or (inaudible) the written and practical.

7 CHAIRMAN KIMSEY: All right. Standards or
8 procedure. Procedures for breath alcohol analysis shall
9 meet the following.

10 COMMITTEE MEMBER SHEN: By the time you get to (e)
11 I think we're looking at, (e) is a procrastinatory check list
12 and I think after that we're looking at training, I think.

13 RESEARCH SCIENTIST SPELL: And practical.

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

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

22 Training in the procedures of breath alcohol shall
23 be under the supervision of persons who qualify.

24 COMMITTEE MEMBER SHEN: I believe we made some
25 changes to that.

1 CHAIRMAN KIMSEY: Right.

2 COMMITTEE MEMBER SHEN: We went to written and
3 practical. And then we took the training curriculum to be
4 developed by a forensic alcohol analyst.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 You know, I would add a couple of things to that actually.
7 I would add, any periodic determination of accuracy
8 activities performed by the operator.

9 It's not always the case but in some cases
10 laboratories have the individual operator do the periodic
11 tests, every 10 days or into two subjects.

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

13 It's also common to provide, many labs it's not a
14 requirement, but many labs include some of the legal aspects
15 of breath testing since this, I mean, issues like
16 observation for the 15 minutes and things like that, they're
17 a bit little in flux in that it could, they can be changing
18 case law which addresses that.

19 So they may be valid. And many states do that to
20 include in the training any relevant, any discussion of some
21 of the legal aspects of breath testing.

22 COMMITTEE MEMBER SHEN: Well it does appear that
23 the, what we're going to outline here is fairly (inaudible).

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Fairly what?

1 COMMITTEE MEMBER WONG: Broad.

2 COMMITTEE MEMBER SHEN: (inaudible).

3 CHAIRMAN KIMSEY: That's why I was wondering if
4 there was sort of a model curriculum that could be, you
5 know, online or something that would talk a little bit more
6 about specifics and timeframes.

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

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

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

20 So we, you know, we could put together based
21 probably on some of the better labs' efforts a model
22 training program.

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

1 probably, unfortunately, have to be in the regulations.

2 And many states do that. Many states describe the
3 training program, they include that as an appendices in the,
4 to the regulations in a summary of training.

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

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 But that's --

9 CHAIRMAN KIMSEY: Yeah you just --

10 COMMITTEE MEMBER SHEN: Well --

11 CHAIRMAN KIMSEY: -- go ahead.

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

15 (inaudible) go down the road of having the
16 Department (inaudible) specific about what we have to do
17 with training on because with the, you know, the advent of
18 technology and moving forward and ask to acknowledge all
19 this other stuff I want it broad enough that we hit topics
20 and not specifics.

21 If we're going to put in the regulations they need
22 to be topics thus we have to reference the alcohol analyst.

23 We have, you know, four or five or six topics that must be
24 covered.

25 COMMITTEE MEMBER WONG: Jennifer, this is Kenton

1 in Richmond. I think that'll work if it's really, really
2 watered down for the breath alcohol operators because
3 there's just no way they need all the scientific background
4 part that an analyst needs.

5 That's just not going to fly for them.

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

10 COMMITTEE MEMBER WONG: Understood --

11 COMMITTEE MEMBER SHEN: -- where we lay out topics
12 that must be covered we could stick to topics that are
13 appropriate here and just lay them out.

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

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

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

24 COMMITTEE MEMBER SHEN: Well, what I mean by that
25 is, we talked about, let's see, what an analyst needs to

1 have. We're in 1216 and, you know, you have to have this
2 degree and you have to have this much experience and then,
3 let's see, there has to be a training course that includes
4 **at a minimum** the following schedule of subjects.

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

9 To lay out topics as is seen in 1216 for our
10 breath operators.

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

15 COMMITTEE MEMBER SHEN: Well this is the way I
16 would envision it, you can write that section 1218 like we
17 did with 1216 that the Department's role would be to look at
18 a training outline and ensure the topics covered in the
19 training outline cover everything that's outlined in Title
20 17.

21 And that would pretty much be (inaudible) not
22 telling the laboratories how to cover it, not telling the
23 laboratory the details of the topics so that the topics are
24 in fact covered.

25 MR. LYLE: This is Bruce in San Diego. So it

1 sounds like we would leave in 1218 and take out point one
2 and point two.

3 COMMITTEE MEMBER SHEN: (inaudible) with that we
4 would have to --

5 MR. LYLE: Tighten up the regulations.

6 COMMITTEE MEMBER SHEN: -- tighten up, yeah, we
7 would have to expand the regulations under 1218, wherever
8 that was, (e).

9 MR. LYLE: I --

10 COMMITTEE MEMBER SHEN: -- 1221 --

11 MR. LYLE: -- right --

12 COMMITTEE MEMBER SHEN: -- so that would be my
13 position. We're going, if we're going to go back and do
14 some more work I would suggest the work that is done but
15 that section is sort of modelled after 1216 part of our
16 discussion what the training ought to include.

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

24 COMMITTEE MEMBER SHEN: I guess I'm wondering how
25 the Committee feels about that. I mean, that's an idea but

1 it's not necessarily one we need to follow.

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

3 COMMITTEE MEMBER WONG: I agree.

4 CHAIRMAN KIMSEY: Yeah, Kenton agreed here, there
5 might have been some coverage on the microphone here.

6 Do we have volunteers?

7 (No response.)

8 Not having been involved in the training programs
9 it probably would not, mine would not be of any benefit.

10 COMMITTEE MEMBER SHEN: You know, I feel the same
11 way. It's really not my bailiwick so you probably
12 (inaudible) Jennifer.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 Was it anybody's bailiwick on the Committee, on the Review
15 Committee? Maybe that's the problem.

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

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

21 COMMITTEE MEMBER SHEN: I nominate Kenton.

22 COMMITTEE MEMBER WONG: Accepted.

23 COMMITTEE MEMBER SHEN: Oh, yay.

24 COMMITTEE MEMBER WONG: But I'm going to need some
25 help on fleshing out the generalness on what was originally

1 approved in Title 17 for breath operators.

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

5 CHAIRMAN KIMSEY: Well and also, we might have, do
6 we have sort of model curriculums that we thought were good
7 that might be helpful to the subcommittee? Things that we
8 thought should be covered?

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

10 CHAIRMAN KIMSEY: The best of the best.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Yeah, we can send (inaudible). I mean they're all approved.
13 So they're all great (laughter).

14 COMMITTEE MEMBER WONG: But which ones would you
15 like Clay? Because that's what really matters.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Like I say, when we got through, I think San Diego still
18 owes some revisions but - other labs, yeah, I can provide
19 the --

20 COMMITTEE MEMBER WONG: Okay. Send it my way
21 then.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 And I'm going to assume that this is kind of Public Records
24 Act request and -- okay.

25 Sure, I don't believe the particularly involved

1 labs would have any, I'll let them know that we're doing it.

2 CHAIRMAN KIMSEY: Or you might strike out.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 Not (inaudible).

5 CHAIRMAN KIMSEY: If you get permission that would
6 be probably sufficient.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

8 Strike out social security numbers.

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

12 COMMITTEE MEMBER SHEN: So, our goal then is to
13 satisfy Title 17 where it discusses the training for
14 operators, mirror (inaudible) fracture of the training for
15 the analysts earlier in Title 17. Is that correct?

16 COMMITTEE MEMBER WONG: At the 1221.4. To model
17 1216.

18 COMMITTEE MEMBER SHEN: Is that what we agree?

19 COMMITTEE MEMBER WONG: Yeah.

20 COMMITTEE MEMBER SHEN: Okay.

21 CHAIRMAN KIMSEY: Yep.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

23 Let me make sure, I mean, because I think the goal, I mean,
24 I think Jennifer put it well before when she said, there's a
25 philosophical question here.

1 And no matter how well you write the regulations
2 there still is always a possibility that one person writing,
3 another person looking at it might disagree on whether the,
4 you know, one or another aspects demonstrates compliance
5 with the regulations.

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

14 COMMITTEE MEMBER SHEN: Yeah, I think we discussed
15 this already that it appears (inaudible) for the moment,
16 that we're going to give the Department an approval role in
17 the training --

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 Okay.

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

1 And not interpretations of Title 17 or additional
2 things that the Department might like but only what Title 17
3 says.

4 COMMITTEE MEMBER WONG: So it's very black and
5 white.

6 COMMITTEE MEMBER SHEN: Very black and white.

7 COMMITTEE MEMBER WONG: I agree.

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

12 So I guess that's our role to come up with
13 language that's clear and black and white because we do not
14 want to get into a situation where the Department is taking
15 our laboratories they believe can't come to an agreement of
16 what is or is not required.

17 COMMITTEE MEMBER WONG: Right. We want no
18 ambiguity.

19 COMMITTEE MEMBER SHEN: Correct.

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

23 COMMITTEE MEMBER SHEN: I'm back in town for
24 several months so I'm open Kenton to whatever you want to
25 do.

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

3 CHAIRMAN KIMSEY: A month, two months?

4 COMMITTEE MEMBER SHEN: Try for a month.

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

6 CHAIRMAN KIMSEY: Okay. And, any other direction
7 to the subcommittee or any clarification before we talk
8 about some other issues?

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

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

19 So I --

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

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

25 COMMITTEE MEMBER WONG: And that will also assume

1 that you can shoot us --

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 Sure.

4 COMMITTEE MEMBER WONG: -- some of those things as
5 soon as possible as well.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

7 Okay.

8 COMMITTEE MEMBER WONG: Fabulous.

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

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

16 And so, and then that, we get that determination
17 from Agency and then the --

18 COMMITTEE MEMBER SHEN: Let's --

19 CHAIRMAN KIMSEY: -- yeah.

20 COMMITTEE MEMBER SHEN: -- I have a question.

21 CHAIRMAN KIMSEY: Uh-huh.

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

1 CHAIRMAN KIMSEY: You know, that's a good
2 question. I was thinking that there might be some ease and
3 some clarity if you didn't change the previous draft work
4 product maybe. But I was just thinking that the next letter
5 that went to Agency would talk about these four particular
6 bullets.

7 COMMITTEE MEMBER WONG: And how we've addressed
8 them.

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

10 COMMITTEE MEMBER SHEN: Okay.

11 CHAIRMAN KIMSEY: -- with the new language.

12 COMMITTEE MEMBER SHEN: I like that.

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

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

20 COMMITTEE MEMBER WONG: I agree.

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

24 CHAIRMAN KIMSEY: Yes.

25 COMMITTEE MEMBER SHEN: -- okay. So I don't have

1 to worry about doing anything then.

2 CHAIRMAN KIMSEY: Not along those lines.

3 COMMITTEE MEMBER SHEN: Okay.

4 CHAIRMAN KIMSEY: Okay. What's the feeling of the
5 group? We can, unless there is, we could just call it quits
6 for the day or we can come back in an hour or 45 minutes.
7 I'm not sure what we'd be coming back for at this point,
8 but. It's up to the Committee.

9 COMMITTEE MEMBER SHEN: I think we made some good
10 progress. And I think we're at a great stopping spot here.

11 COMMITTEE MEMBER WONG: I think it's been a
12 productive day.

13 CHAIRMAN KIMSEY: Okay. Okay I think that's some
14 general consensus that we will go ahead and call it quits
15 for today. Any other comments or suggestions or ideas
16 before we, before we sign off?

17 (No response.)

18 Okay. Hearing nothing, I want to thank you all
19 very much for your time. I think we made some progress
20 today. And we'll be in touch, hopefully we'll meet again in
21 about 30 days. Thank you.

22 (Thereupon, the California Department of
23 Public Health, Forensic Alcohol Review
24 Committee meeting adjourned at 1:14 p.m.)

25

CERTIFICATE OF REPORTER

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of August, 2012.

JOHN COTA