

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

NINETEENTH MEETING
TUESDAY, NOVEMBER 15, 2011
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)

Mr. Torr M. Zelenski (Sacramento)

Mr. Bruce Lyle (San Diego)

Ms. Jennifer Shen (San Diego)

Review Subcommittee Members

Ms. Jennifer Shen (San Diego)

Dr. Paul Kimsey (Richmond)

Staff

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

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

Mr. Clay Larson, Chief, Abused Substances Analysis Section (Richmond via teleconference from San Diego)

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

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

Also Present

Mr. Dave Koenitzer, Department of Justice (Sacramento)

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

Ms. Rosalee Dvorak-Renis, Office of Regulations (Sacramento)

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

Ms. Tammy Dutemple, California Highway Patrol (Sacramento)

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1 Is there anything else that people would like to
2 mention about the agenda or anything else that we think will
3 be -- any aspect of the agenda?

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 Yeah, I'd like to briefly discuss, I don't know at what
6 point in time, the --

7 THE REPORTER: Who is this?

8 CHAIRMAN KIMSEY: Could you identify yourself,
9 please.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 Clay Larson, member of the public. At some point I'd like
12 to briefly discuss the proficiency test requirements. I
13 have some, after reading the transcripts I have some
14 thoughts. So if you want to do that later in the meeting
15 or --

16 CHAIRMAN KIMSEY: So that was bullet number one?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 Yes.

19 CHAIRMAN KIMSEY: Okay.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Do it now?

22 CHAIRMAN KIMSEY: Well, let's see if there's any
23 other comments on the agenda (no response). Any other areas
24 that we want to add? So Clay, why don't you go ahead and
25 mention your questions about bullet number one.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

2 Yeah, in reading the -- reading from the transcripts, I was
3 struck by the fact that the Committee kind of proceeded with
4 the assumption that the major requirement or the emphasis of
5 the ASCLD/LAB requirements was on analysts proficiency
6 tests. And I don't think that's accurate.

7 And I'm talking now about the Legacy Program and
8 the International Program. They're both reference the PRC
9 supplement which describes the ASCLD/LAB's PT requirements.

10 And ASCLD/LAB requires both analysts' PTs and
11 laboratory PTs. And there's some question whether we PT,
12 proficiency test the laboratory. ASCLD/LAB clearly requires
13 that.

14 And I mentioned this at the last -- the meeting,
15 analysts' PT is listed as an "important" requirement. And
16 the laboratory PT is listed as an "essential" requirement.

17 The PRC summary clearly states that the analysts'
18 PTs can be internal or external. ASCLD/LAB has no interest
19 in seeing those.

20 I mean, they can be generated internally or
21 externally but they are scored internally. And ASCLD/LAB
22 doesn't require laboratories to submit those data, those
23 results.

24 On the other hand, the laboratory PTs must be
25 external and they must be, not only submitted to the

1 laboratory, but they must be submitted, I'm sorry, to
2 ASCLD/LAB, but they must be submitted to ASCLD/LAB by the
3 provider.

4 Basically, all the providers do that and you send
5 them an authorization to submit the results directly to
6 ASCLD/LAB.

7 I would submit that the laboratory PT requirements
8 of ASCLD/LAB more closely capture the kind of data the
9 Department is interested in.

10 So to the extent that the Committee's decision to
11 submit a lot of analysts' PT data was based on an assumption
12 that that was the emphasis of ASCLD/LAB, I think that
13 presumption was wrong.

14 CHAIRMAN KIMSEY: So what are you recommending?

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

16 Well, as I said at the last meeting; I still think we
17 should, I think it's the laboratory PT that we would be
18 interested in. And I think ideally that would cover both
19 instruments. But we had that discussion, it's not necessary
20 to bring that up again.

21 CHAIRMAN KIMSEY: But if I remember correctly, the
22 language that the Committee sort of agreed upon didn't feel
23 that the Department needed that information.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

25 Well, there are two issues here. The language that the

1 Committee agreed upon, although we haven't seen it but we
2 discussed and I --

3 CHAIRMAN KIMSEY: Right.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 -- was that we'd be getting analysts' PT data. So if the
6 lab has five, ten analysts, we'd be getting, apparently,
7 five or ten proficiency tests as opposed to the data -- I'm
8 not sure how they distinguished the two but because some
9 labs, I think, they're both external.

10 Labs that are internal would be changing their
11 operations. But the language that we agreed upon was, the
12 labs would submit the analysts' data. I'm suggesting that's
13 probably overkill and/or underkill.

14 And what we'd be interested in, I think, more
15 appropriate would be the data that represents the lab's best
16 efforts. And I think it should be submitted through the --
17 by the providers.

18 In other words, the labs would simply authorize
19 the provider to give -- to forward the results to the
20 Department.

21 COMMITTEE MEMBER SHEN: This is -- the language
22 proposed was, labs will be responsible to report test
23 results to CDPH who will evaluate these test results and may
24 require written corrective actions of any lab that reported
25 outside acceptable limits.

1 If you recall, we spent an extensive amount of
2 time discussing last time whether or not we thought an
3 analyst should be tested or an instrument should be tested.

4 But I don't believe that we translated that
5 theoretical argument into verbiage for Title 17. So, that's
6 kind of where we are.

7 I still firmly believe, however we do it, that you
8 have to each analyst needs to have a proficiency test.
9 Whether it gets submitted or not submitted, you know, we can
10 talk about that. But the analysts need to each have their
11 own tests every year.

12 CHAIRMAN KIMSEY: Anybody else on the Committee
13 have an interest in changing the language that Jennifer
14 mentioned?

15 COMMITTEE MEMBER SEDGEWICK: This is Paul
16 Sedgewick. I firmly agree with Jennifer.

17 CHAIRMAN KIMSEY: Okay.

18 COMMITTEE MEMBER SHEN: This is Jennifer. We
19 didn't actually, you know, from my own notes from last time,
20 we didn't actually specify down to that detail. And we may
21 want to I suppose because, you know, certainly if you're
22 looking at a laboratory with many, many analysts, you know,
23 Clay is right; there's a lot to submit.

24 And I think that the way that our laboratories
25 handles this is that we, everybody takes a test, everybody

1 has to but only a number of tests were actually submitted
2 for the laboratories.

3 CHAIRMAN KIMSEY: Is it worth, if you're
4 interested in doing that, Jennifer, is it worth having some
5 language that allows that? I mean, do you think the
6 language that you're currently talking about covers that?
7 Or do we need to add something if we're thinking of maybe
8 doing that in the future?

9 COMMITTEE MEMBER SHEN: I think the language we
10 have right now is somewhat vague. And this is just from
11 what I had written down from last time.

12 CHAIRMAN KIMSEY: Sure. And then we haven't, you
13 know, this is a good discussion, don't get me wrong. We
14 haven't, we didn't really have the time to get, you know,
15 draft language out to everybody.

16 But what we did was we obviously had some
17 agreement, you know, on direction. And if we think there's
18 some more specificity that we can add to that language then
19 that's fine at this point.

20 We can also when we actually get the draft
21 language around to people, look at it at that point
22 realizing that we may want to change it.

23 But does someone have some suggested, you know,
24 modified language currently or is this something we just
25 want to track when we actually have the written language in

1 front of us?

2 COMMITTEE MEMBER SHEN: We could do something as
3 simple as -- I mean, I don't know who anyone else feels, but
4 again, I feel very at least strongly that all analysts
5 should be, in fact, taking a proficiency test.

6 We could do something along the lines that all
7 analysts are required to take a proficiency test, X amount
8 of them of which are required to be submitted to the
9 Department for review.

10 We could go that route. I don't know that we want
11 to set it up so that every single person has to have their
12 proficiency test submitted to the state. You know for a
13 smaller lab, not a big deal. For a larger lab, it could be.

14 Or we can just leave it vague. But the vagueness
15 always lends itself to interpretations.

16 CHAIRMAN KIMSEY: No, vague is not good. This may
17 be something that, you know, we come up with, you know, when
18 we get into some of the detail of the actual, you know,
19 either the language we're going to propose or the actual
20 drafting of the regulations.

21 And it seems like Clay's point was, and correct me
22 if I'm wrong Clay, you were more interested in having the
23 state receive some proficiency testing based on the
24 laboratory itself, not the individual?

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Right. That's the current practice. I don't know, it seems
2 to work. I don't know that we need to change it.

3 But again, the Department would like to see, if
4 the lab has two methods, two instrument set ups; there's a
5 continuum of those two methods being very different, those
6 two methods both being GC, maybe in one case a direct
7 injection and head space puts them open to -- GC head space
8 but if they're different instruments and perhaps different
9 experimental parameters and then, you know, the DOJ set up
10 where they have one GC and two head space samplers feeding
11 into the -- what would be identical columns.

12 So if there's a continuum of that -- and I would
13 also suggest besides the, open to interpretation, under the
14 APA requirements, vague regulations run afoul of the clarity
15 issues. That's another issue.

16 CHAIRMAN KIMSEY: No, and that was to my point
17 about, vague is not good. But those kinds of details, we're
18 going to have a number of those issues once we get to that
19 point where the actual regs are being put into compliance
20 with ADA and 17025.

21 I mean, and I'm sure we'll be, as a Committee,
22 discussing those as we go on. So what's the feeling of the
23 group? Do we want and try and work on some language right
24 now that involves proficiency testing with regards to the
25 facility or the laboratory itself? Or do we just propose

1 that that language be included for us to review when we're
2 reviewing all the language?

3 Does someone have some language to suggest, I
4 guess is the way to move the discussion.

5 MR. LYLE: This is Bruce. I think we need to
6 decide whether it's the lab's proficiency or the
7 individual's proficiency. Do we have to decide that first?

8 CHAIRMAN KIMSEY: Well, currently the language
9 really talks about individual proficiency testing. And the
10 issue that Clay is bringing up is more based on the whole
11 facility proficiency testing.

12 And so, we have pretty much agreed last time that
13 the proficiency testing would be, you know, on the
14 individual. And Clay's issue is, currently the Department
15 collects information on the facility and would like to
16 continue to do that.

17 And I guess, I don't know that I've heard any real
18 objections to that. But that is not currently in the
19 language that is in the transcript from September and also
20 in Jennifer's notes.

21 COMMITTEE MEMBER SEDGEWICK: This is Paul
22 Sedgewick in San Diego. From a practical standpoint you
23 cannot proficiency test the laboratory.

24 Because that's ignoring the fact that there's an
25 actual person doing the work. It's far more practical and

1 useful to proficiency test individuals because they're the
2 ones who are doing the work.

3 COMMITTEE MEMBER SHEN: Jennifer, so then it comes
4 down to, which we're all doing anyway, I mean, all of our
5 accredited laboratories are all testing individuals,
6 probably, I would assume. But, it comes down to what it is
7 will be our -- reporting.

8 You know, for instance, our crime scene program,
9 we have a blood splatter proficiency. We ordered three or
10 four of them. We got 20 people taking it. One of them goes
11 in as the one from the laboratory and all the rest of them
12 are kept in our records for auditors.

13 So, I mean, I can see how that would work. It
14 would be, it might be a bit of a burden to take an external
15 proficiency test for everyone, every analyst, and have that
16 turned in through the provider.

17 I don't know. I'm not sure how big other -- that
18 could be a burden.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

20 Excuse me. This is Bob Haas. I'm obviously missing
21 something here. I don't see that there's any controversy.

22 The externally provided proficiency tests are
23 taken by the analysts and the results can or cannot be
24 forwarded to DPH for review as at the same time that they're
25 sent back to the provider for their scoring.

1 Is that right or am I missing something here?

2 COMMITTEE MEMBER SHEN: Actually, you know, I hear
3 -- you're right. Since everybody is taking them anyway,
4 it's not, it wouldn't actually be a burden for us to send
5 those results to the Department. And then we would send our
6 requisite number back to the actual provider.

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
8 Right.

9 COMMITTEE MEMBER SHEN: I guess that's my point.
10 So I could easily, again with my -- I've got 20 analysts
11 taking it, I could send, once the provider -- and you can
12 have a copy of those old -- is that what you're talking
13 about?

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
15 Yeah, that's it. Is, Clay, is that what you're talking
16 about?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 You know, I think the can or cannot creates a clarity issue,
19 a clear clarity issue with regards to reg writing
20 requirements. And all of the --

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Well, whether it's "can" at this point or "must" when the
23 regs get written is not, I mean I'm just trying to search
24 for where there's a difference of opinion here and I'm not
25 finding one.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

2 No, I'm actually beginning to, with some controversy, I'm
3 beginning to feel uncomfortable with the procedure that
4 Jennifer described for her lab.

5 One of the requirements of proficiency testing is
6 samples need to be analyzed exactly as they're analyzed in a
7 regular case sample situation.

8 I submit that if, I'm not saying this lab is a
9 problem, but I submit if that practice that she just
10 described, basically she takes the sample and has 20 people
11 analyze it -- that doesn't conform with my, I would imagine
12 a typical situation, unless, I assume you are too busy to do
13 that, and that there would be a tendency, I would think, on
14 the part of the lab director or the QC officer to look at
15 all 20 results and throw out outliers. I mean if 19 people
16 saw one blood splatter pattern and the other guy saw
17 something completely different; I suspect it's unlikely
18 you'd submit that 20th result.

19 So that there is a little bit of, cherry picking,
20 if you will here. And I think, I don't think that captures
21 the letter, if not the letter the spirit, of the proficiency
22 testing program.

23 So I'm a little uncomfortable with the whole
24 notion that we do kind of a round-robin, democratic process
25 here to achieve results.

1 CHAIRMAN KIMSEY: And I think -- Clay this is
2 Paul. I think Bob's question was though, about the
3 language. We're not talking about any particular practice
4 necessarily. But the language that was discussed, Bob's
5 perception, and mine to some extent too, is it seems to be
6 flexible.

7 And obviously we may have to get to specific
8 language change with, because of the ADA, but, or APA, but,
9 is there something about the language that you would
10 recommend?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 I think the language as Jennifer briefly read it, I actually
13 remember something a little different but I can't find my
14 notes here.

15 But as she briefly read it, it didn't appear to
16 show this was an external proficiency test. It didn't
17 appear to show this was a analyst's result or a lab result.

18 Since the record shows we discussed all this. I
19 think, and you can figure it out now or later, I think
20 probably now is the point in time. We come up with specific
21 requirements.

22 I think it would be disadvantageous for a large
23 lab to submit 20 results to the Department. That, it,
24 because there's a four-letter word that it happens. I'm not
25 going to use that four-letter word.

1 But, and so it, I think if you submit all 20 that
2 there will be, statistically a few more instances where a
3 lab's results were outside acceptable limits. Since the
4 whole lab is being judged by that, I suspect we set pretty
5 high standards.

6 Any error is a flaw requiring corrective action.
7 And the expectations, it's an open -- the lab knows they're
8 being tested. They do their best effort and they're scored
9 accordingly.

10 I think it would be disadvantageous for the lab to
11 have all the analysts complete and submit results. I
12 suspect that wouldn't happen. But when, if it's not going
13 to happen why don't we just demonstrate it's not going to
14 happen?

15 I also think when we discussed this previously,
16 and again, the ASCLD/LAB clearly states that the analyst PT
17 can be internal. The samples, they give some examples.

18 They could be samples that are prepared by the lab
19 or they can be case samples that are re-analyzed.

20 So if we're going to set requirements that an
21 analyst must do an external PT, it's going to be an
22 additional burden, maybe not a major burden, not a problem
23 with San Diego PD since you're already doing it, but some
24 labs this may be a burden. And maybe a change with the way
25 they're doing things and it may not be necessary.

1 I would like to see language that, just that the
2 lab shall submit results through the provider obtained from
3 an approved provider.

4 CHAIRMAN KIMSEY: Well this sounds like, you know,
5 we're getting into some very specific language changes. And
6 since we don't have the language yet in front of us I think,
7 unless someone else wants to propose language, I think we
8 will, you know, when we have language in front of us we can
9 talk more specifically about, you know, word changes and
10 implications of that wording.

11 But right now I think it's my perspective on this
12 meeting that we still have like in bullet number three some
13 overriding issues to discuss with regards to what the role
14 of the Department is going to be in something like training.

15 And I would defer this discussion about the
16 proficiency testing and external versus the facility, versus
17 the individual to when we actually have some language in
18 front of us.

19 COMMITTEE MEMBER SHEN: This is Jennifer. I would
20 agree with that. The last thing I would say about this
21 particular issue is that, what we're doing now is taking of
22 proficiency tests and getting the results back from the
23 provider and then we are forwarding those to the Department.

24 That's the process that's in place currently and
25 that appears to be working. A thing to keep in mind when we

1 write our language.

2 CHAIRMAN KIMSEY: Okay. Other comments from the
3 Committee?

4 MR. LYLE: Bruce Lyle. I agree. We should just
5 wait until we have wording in front of us so we can --

6 CHAIRMAN KIMSEY: Right.

7 MR. LYLE: -- intelligently change it.

8 CHAIRMAN KIMSEY: Okay. Anything else from the
9 Committee? If not, bullet number three is basically, I'll
10 read it. The bullet removes CDP's authority to review and
11 approve training programs intended for persons to qualify
12 under the regulations; example, breath instrument and
13 operator training.

14 As I remember in looking over the transcripts,
15 there was quite a bit of discussion. It would appear to be
16 a certain amount of agreement about the need for a training
17 program for breath instrument operator training.

18 And it was pretty much sort of, I want to say,
19 limited, to that. That there was other parts of training
20 that the Department is currently involved in was not imbued
21 in such a positive perspective.

22 And so there was a bit of a dichotomy that there
23 did seem to be a general feeling that training for operator
24 breath instrument, operator training needed to have some
25 sort of standardization review and approval.

1 But that was not true of other aspects of
2 training. Now, my attempt there was to try and summarize
3 from my memory and what I read in the transcript.

4 Anyone else have a perspective on what the
5 discussion was in late September?

6 COMMITTEE MEMBER SHEN: I have in my notes that
7 bullet three needs more discussion.

8 CHAIRMAN KIMSEY: Yes (laughter). And in looking
9 at the transcript yesterday and last night I mean there
10 really did seem to be a general, I mean there was quite a
11 bit of discussion about the fact that the CHP struggles a
12 little bit when they move around having to go through, you
13 know, that some training again.

14 There was a recognition of that. I think there
15 was some perspective that that just may be a reality. That
16 there didn't seem to be a way around that but that, I think,
17 everyone still felt that that training was important and
18 that there be some sort of standardized review and approval
19 of that training which could be maybe a consolidated.

20 I mean, obviously, there's a certain number of
21 instruments. I think Kenton mentioned that there's, you
22 know, some basic, you know, physiology of alcohol
23 consumption that could be sort of standardized.

24 And, but I didn't, it was my, I didn't hear any
25 people really feeling that the breath instrument operator

1 training was not necessary.

2 So, anyone want to sort of build on that
3 discussion?

4 COMMITTEE MEMBER SHEN: I felt we had sort of
5 gotten to where we agreed that laboratories had to have
6 their own protocols because even though the basic technology
7 can be the same in several types of instruments, even
8 instruments that are the same are set up differently and are
9 run differently.

10 So, officers need to be trained on those specific
11 instruments.

12 CHAIRMAN KIMSEY: Right. And I think there was
13 some feeling that there, yes, that each laboratory might
14 have some specifics with regards to their own, you know,
15 situations and locations but there was quite a bit of this
16 information that could be sort of standardized.

17 I mean, obviously, you know, the physiology of
18 alcohol consumption and some of the bases for how these
19 machines operate is not going to change.

20 But, you know, the protocols and that sort of
21 stuff may be, you know, county specific. But I think there
22 was some interest in having sort of a larger
23 standardization. And maybe I'm wrong.

24 COMMITTEE MEMBER SHEN: You know, I'm just going
25 to throw this out there again. I mean, do we need to train

1 our breath operators in anything other than how to operate
2 the instruments?

3 COMMITTEE MEMBER SEDGEWICK: This is Paul
4 Sedgewick. The whole purpose of Title 17, originally at
5 least, was to train and standardize analytic procedures.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 I think, this is Clay Larson speaking. I think the simple
8 answer to that question is the current regulations
9 specifically require that.

10 And I don't know, actually, I think it's
11 remarkable that you look at California's regulations
12 regarding training that they, as I said before, they have a
13 number of unique characteristics.

14 One, it's left up to the individual laboratories
15 with approval of training procedures by the Department where
16 other states into, take direct control.

17 But a number of states have in their regulations a
18 requirement that a specific number of hours of training.
19 And we see with New York, New York went from 40 to 32 and so
20 they cut it down.

21 And, they all include, the proposal -- there's
22 physiology, there's the principle of operations, so, I mean,
23 there seems to be nationally a reluctance to treat this just
24 as a black box that requires a button. And that there's an
25 expectation, you know, it may be similar to the fact that do

1 you need to have a BS in chemistry or a baccalaureate degree
2 in an applied physical science or natural science to make
3 injections into a GC.

4 The answer could be, no. And it's probably no
5 when the GC is working perfectly and the samples don't
6 present any problems and things are routine.

7 It's probably, yes, when those circumstances don't
8 hold. And I suspect that the same argument probably is made
9 in other states for breath testing operator training.

10 COMMITTEE MEMBER SHEN: I would say that the
11 scientific degrees with the criminalists are necessary by
12 and large, that methodology, you need them to send it --

13 As far as the officer goes, an officer who is
14 running an instrument, he or she needs to be trained in how
15 to use that instrument and what the state laws are.

16 I mean, for, after a waiting period et cetera. I
17 don't know how important it is or how much of it stays in an
18 officer's training about, you know, the physiology of
19 alcohol in particular.

20 It doesn't mean that we can't offer it if we want
21 to. But, should we not be concentrating specifically in
22 legislation on training the officer and what he or she needs
23 to be trained in.

24 This really takes down to very individual
25 methodologies for the laboratories.

1 CHAIRMAN KIMSEY: And so, would you propose then
2 Jennifer that, what would the role that the Department be in
3 that? Just that the training would be, there would be a
4 training program that would be available on inspection or --

5 COMMITTEE MEMBER SHEN: Yeah. I think, that's
6 where I'd like to see a lot of this go. Because we have the
7 accreditation already and because we document everything and
8 have all of this stuff available, there needs to be a
9 training program because the officers need to be trained.
10 The operator needs to be trained. And that needs to be, it
11 needs to be laboratory specific. And it needs to be well
12 documented.

13 And, you know, if we follow, if we put in Title 17
14 the instructions to train the officers on these particular
15 things that are meaningful, the laboratories will be
16 responsible for providing that training.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 Comment from the public. Jennifer was quick to use the A
19 word, the accreditation word. I think the discussion last
20 time showed, unless someone presents new information, I
21 think we have to conclude that the current accrediting
22 bodies provide nothing in the way of oversight,
23 accreditation of breath alcohol analysis. I would add, I
24 would include the breath calibration -- accreditation
25 offered by ASCLD/LAB.

1 COMMITTEE MEMBER SHEN: My point being that
2 accredited laboratories operate in a manner in which we have
3 to document what we're doing. We have methods. We have
4 procedures. We give testing and all of that stuff is
5 documented.

6 So, you would be required to have that training
7 program documented and in our manuals and at our facilities
8 for review.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 Well, this is Bob Haas, comment from the public. Number
11 one, the purpose of Title 17 as I understand it is to ensure
12 the competence of the laboratories and their testing
13 procedures.

14 And Clay is absolutely right with regard to
15 addressing the breath alcohol operators. I personally
16 believe that the more instruction that's given, particularly
17 to officers in the field, the better they are able to
18 administer these tests, and particular, to ensure that these
19 cases don't end up in court in a controversial testing
20 environment.

21 Regarding that, Clay is also correct in saying
22 that the accrediting body doesn't really refer to breath
23 testing per se. And also, what Jennifer, you're suggesting
24 puts the entire burden, the entire Department's burden on an
25 audit procedure rather than having defined parameters for a

1 testing program before, a priori, that can be, that's
2 constructed here and sent out for review.

3 Now that can be generic. It doesn't have to be
4 specific to every single procedure and every single
5 instrument that's done, that's used. However, to have the
6 Department in order to carry out it's mandate, have to audit
7 all of the laboratories and all of the training manuals I
8 think is very burdensome and really puts the cart before the
9 horse.

10 COMMITTEE MEMBER SHEN: I agree with you. And I
11 do really, I guess I was really just sort of trying out some
12 ideas. I don't have any problem with how we're doing things
13 right now. We have a training program and it's tailored to
14 our needs and the Department reviews it.

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
16 Exactly. And I too am happy with that. And I've sat down
17 with CHP to go over when they modernize their instruments
18 and they revised their training manual.

19 And Clay went through this them and everything
20 works fine. So, again, this seems to me an already solved
21 problem, at least partially.

22 COMMITTEE MEMBER SHEN: Yeah, I agree. My only
23 thought was, do we want to -- because we had the long
24 discussion about, you know, whether or not we want to have
25 something that is very general and then have some specific

1 training as well. Do we, in fact, need the very general
2 training if what we really care about, I mean, really, nuts
3 and bolts, we care about the officers being able to operate
4 those instruments and doing them correctly and following the
5 regulations that are set out for them.

6 I mean, don't get me wrong. I think training is
7 wonderful. And I didn't say, I wouldn't in no way
8 anticipate that we would stop training officers in these
9 other things. But do we want to have that regulated or do
10 we want to have the operation of the instrument regulated?

11 And I frankly don't really care one way or the
12 other. I was sort of throwing it out there as a thought.

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 Well thanks. Are there any other thoughts on that?

15 COMMITTEE MEMBER WONG: This is Kenton in
16 Richmond. You know, I've trained thousands of officers on
17 the Intoxilizer and the Drayger and it's really not an
18 issue. I mean, you know, I always explain to them, I'm not
19 here to make you a physiologist. I'm not here to give you a
20 degree in biology. But, you know, you've got to hang with
21 me for the first half an hour, 40 minutes. And we've got to
22 go over physiology. We've got to over the alveolar air so
23 that you understand what's happening in the test and you
24 know what to look for; whether someone is trying to short
25 blow or -- and they're cool with it.

1 I mean, it works. And I totally concede to them.
2 I say, you know, that the important parts are going to be
3 the last couple of hours of the class for training because
4 it's specifically on this Drayger instrument or this
5 Intoxilizer and you've got to get the nuts and bolts on
6 that.

7 But before we get there you've got to go over this
8 general part. And so, it's sort of really not an issue.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 So what is the issue then? If this is put into regulations,
11 it doesn't sound to me like that's an issue at all.

12 CHAIRMAN KIMSEY: Well, isn't it being put back?
13 I mean, isn't Article 4 that was removed, isn't this covered
14 in Article 4? As I remember reading the transcript I think
15 it was -- it was whether or not there was, it was in more
16 than one place.

17 And it seemed like some it had been summarized in
18 Article 4.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 Clay? You're our memory on this.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 That is correct. It is Article 4. And, yeah that would be
23 -- restore the language of Article 4. 1218 and 1218.2
24 actually.

25 CHAIRMAN KIMSEY: And this though would be limited

1 to the breath instrument operator training. I think there
2 was the other training was felt to be requirements would be
3 that the laboratory would keep that and that would be more
4 of an audit review that would determine a problem with
5 training. Is that correct?

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 Well the program wouldn't agree with that. I think that was
8 the sentiment of the committee.

9 CHAIRMAN KIMSEY: Yeah, that is what I was
10 referring to.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
12 I didn't hear that. What was said?

13 CHAIRMAN KIMSEY: That the sentiment of the
14 Committee from the previous discussion, which can change
15 (laughter), was that, the breath alcohol training seemed to
16 be necessary, the Department's role in that.

17 But that the other training, that the approval of
18 the other that the Department did for other types of
19 training was burdensome and would not go forward.

20 That the training would be the responsibility of
21 the individual laboratory. Am I reflecting that correctly?

22 COMMITTEE MEMBER SHEN: This is Jennifer. Yes you
23 are. And, you know, and we kind of went off on a little
24 tangent on the breath operator training. But I think a lot
25 of what we were expressing, I believe, was the approval and

1 the training of alcohol analysts themselves.

2 So I don't know that anyone was really
3 particularly having difficulty with oversight of the
4 operator, breath operator training. It's the, having our
5 analysts have to meet a certain set of guidelines outside of
6 what the laboratory is looking for that we were discussing.

7 CHAIRMAN KIMSEY: Okay.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 Let me just very quickly. Resubmit the argument just so
10 we're all clear on why I think -- approach this from a
11 slightly different way, why I think the other major training
12 components which the Department has approved over the years
13 and only one agency, DOJ, ever offered that training.

14 Was the training that allowed a supervisor, that
15 doesn't have two years experience, the requirements for a
16 forensic alcohol supervisor are that they have a
17 baccalaureate or higher degree in chemistry or biochemistry
18 and that they have had two years of experience, under the
19 current regulations, have had two years of experience
20 performing forensic alcohol analysis.

21 The proposals, a couple of changes, one would
22 change the word "supervisor" to "analyst" but we retained
23 that two years experience requirement.

24 I think the way it is written now it would
25 actually be more honest and cleaner to simply eliminate the

1 requirement for any experience.

2 This would be consistent with ASCLD/LAB.

3 ASCLD/LAB doesn't require an analyst to have any experience.

4 Because as it sits now we say that an analyst must have two
5 years or in lieu of two years, the Department, his own
6 employing lab will train him.

7 So, I mean, there are no requirements for the
8 hours of instruction or much details as to what the
9 instruction would contain. I submit that labs that are busy
10 or are just following the ASCLD/LAB guidelines could make
11 that a very brief and meaningless training. But more to the
12 point, we're writing a regulation that basically requires
13 the lab to do whatever it wants to do.

14 I think at some point when we go down the road of
15 developing and promulgating these regulations and I think,
16 an APA question will be, what is the necessity of such a
17 regulation? Some labs will do an excellent job of training
18 an inexperienced employee and make sure that he is
19 absolutely up to snuff, other labs probably won't do a very
20 good, as good a job.

21 But putting language in regulations that says, you
22 know, train good, is -- but can you guys figure out what
23 that means -- is meaningless.

24 I would say the cleaner way to deal with that is
25 simply eliminate the requirements that analysts have any

1 experience at all.

2 CHAIRMAN KIMSEY: And so the other training that
3 you're talking about Clay is not the Department's training,
4 it's the Department of Justice's training?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Yeah. The existing regulations state that a forensic
7 alcohol supervisor shall have two years of experience
8 performing alcohol analysis and that experience includes --
9 components, but basically in lieu of that an individual can
10 take a, take special supervisor training which has been
11 approved by the Department.

12 Historically, the only lab, the only program that
13 we ever approved was the DOJ course which is still offered
14 but very, very infrequently. It's a five day course, very
15 exhaustive. It was reviewed, approved by the Department.

16 You know, historically, the reason that that
17 existed, I think the language in this -- back in the early
18 '70s when the regulations were written, there were sort of
19 starting, sort of running from basically a standing start.
20 That there was probably a paucity of people with two years
21 experience because forensic alcohol was a new, a sexy new
22 activity.

23 And so, it probably had more applicability then
24 than it does now. Now I suspect there are people around
25 that have had the experience.

1 But, I think the current reg requirements under
2 the 1216 definition of an analyst is pretty meaningless.

3 CHAIRMAN KIMSEY: It's pretty meaningless, you
4 say?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Yes. Requiring two years experience. Or in lieu of that,
7 experience training.

8 COMMITTEE MEMBER SHEN: Well, I mean, let's keep
9 in mind when you read what we are -- you know, we are
10 proposing is that you have the degree in science and you
11 have two years experience, of analytical experience and
12 experience interpreting and correlating, demeanor, behavior
13 of persons who have ingested amounts of alcohol, blah, blah,
14 blah or can train, or satisfactorily complete the training
15 course.

16 And this training course has to include all of
17 these things that we have, that were outlined and are still
18 outlined.

19 So I have a, I mean, I guess I take a slight
20 offense at the fact that we're just going to throw someone
21 out there because we're way too busy to train them and, you
22 know, what, give them 30 seconds on each of these
23 categories. That's not going to happen.

24 And we need to be able to prove, and we have, in
25 fact, provided training for this analyst, the same analyst.

1 And what that person was trained in and how we trained it
2 and trained him and we also have to have records of what it
3 is that we required; whether that's written tests or mid-
4 course, I know for our department we have an extensive
5 training program to include new course in a courtroom with
6 attorneys and judges.

7 So we outlined what is necessary in the proposed
8 regulations and we have to prove that we meet that. You
9 just can't pretend.

10 CHAIRMAN KIMSEY: Any other comments on this from
11 any Committee members? It sounds like, you know, there some
12 agreement with regards to having, reinstating some aspects
13 of Article 4 that talks about breath instrument operator
14 training.

15 And we can work on some language that reflects
16 that. It's still seems like I haven't heard any Committee
17 members articulate a reason to keep the Department involved
18 in the approval of other training programs. Is that a fair
19 summary?

20 MR. LYLE: Yes. Bruce. Yes, a fair summary.

21 CHAIRMAN KIMSEY: Is there anything else on bullet
22 number three with regards to training that we want to
23 discuss (no response).

24 The bullet number four from what I could remember,
25 and of course this was later in the day and the transcripts

1 are wonderful by the way, but somehow didn't always trigger
2 my memory.

3 I wasn't sure that we had a discussion -- we did
4 talk about, bullet number four, remove requirements for a
5 laboratory to provide CDPH with records of its activities
6 under the regulations including notification by laboratory
7 of its intent to perform forensic alcohol analysis.

8 I think there were general agreement that the
9 Department should have access to those records. And we
10 talked a little bit about access.

11 But I couldn't see or remember that we talked
12 about this idea of a notification of the laboratory's intent
13 to sort of get into the business or be in the business.

14 And this obviously gets very difficult because
15 obviously based on the legislative language we are not
16 licensing or certifying any of those types of processes.
17 And so there was some question in, you know, how would the
18 Department know who is doing this work?

19 I know that the subcommittee, which was Jennifer
20 and myself, talked a little bit about a website that the
21 Department would maintain of people, of laboratories that
22 were doing this work with some sort of meeting of the
23 standards of Title 17.

24 And there was some discussion on whether that
25 should be a long list of things or just a very short list of

1 things.

2 But, so I'm just throwing it out to the group.
3 How do we feel about this issue of the Department being
4 notified that a laboratory is going to be doing forensic
5 alcohol analysis?

6 COMMITTEE MEMBER SHEN: This is Jennifer. I don't
7 think that you can ask the state to regulate a program in
8 any way, shape or form if the state doesn't know that the
9 laboratory is performing alcohol analysis.

10 So, I mean, it seems to me that somehow not going
11 down the road of licensing because we're not doing that, but
12 somehow the Department needs to at least know when a
13 laboratory is going to start providing that service.

14 CHAIRMAN KIMSEY: I would tend to agree that we
15 ought to know what the universe is to some extent. Does
16 anyone have, I mean, obviously, we've gone -- we know we're
17 not licensing. We're not certifying. We're not any of that
18 sort of process.

19 So, what are some other ideas? I mean, obviously,
20 maintaining a website was one. But is there anything, any
21 other ideas?

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
23 This is Bob Haas. Maintaining the website as my
24 recollection was simply to inform the public of what, you
25 know, what resources there were for forensic alcohol testing

1 in the state.

2 I would suggest that there be mandatory
3 notification of any laboratory that either plans to continue
4 or plans to start forensic alcohol testing; be required to
5 just inform the Department of their intent.

6 And then they can follow the whatever other
7 regulations are in place for training programs, proficiency
8 testing et cetera.

9 But, yeah, I agree with you completely Jennifer.
10 I think it's absolutely essential for some state agency to
11 know who is doing forensic testing, and in this case,
12 alcohol testing. But forensic testing in general.

13 COMMITTEE MEMBER SHEN: Paul and I talked a lot
14 about the website. And, you know, an example I had is that,
15 you know, you can pull up a specific police department
16 laboratory and then there would be an indication if this
17 laboratory is accredited, yes or no. What is the
18 accrediting body? Are they current in their proficiency
19 tests and is the lab in good standing?

20 You're right. That's something for notification.
21 We're sort of thinking notification for public and for the
22 defense community. But there's no reason that couldn't
23 serve a dual purpose of that notification is required for
24 this website which would also serve to notify the
25 Department.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
2 Well right, right. I mean, all I'm saying is a letter of
3 intent, let's say a new lab comes, you know, either in-state
4 or not, wants to perform testing. A letter of intent to the
5 Department and then the requirements that you just described
6 would be included on a website that would be publicly
7 accessible.

8 I think that's terrific.

9 CHAIRMAN KIMSEY: Ah, something --

10 COMMITTEE MEMBER SHEN: We --

11 CHAIRMAN KIMSEY: -- something, you know. This is
12 Paul real quick in Richmond. Something that Bob mentioned
13 triggered a thought. In a larger sense does the Department
14 of Justice do forensic laboratories register or are they
15 licensed or does the Department of Justice have a list of
16 forensic, laboratories doing forensic science broadly?

17 In other words, I'm thinking that this could be a
18 partnership. That if the Department of Justice sort of
19 knows who's out there doing forensic work in general, maybe
20 they could have a box on -- I mean, obviously, I don't
21 assume all forensic labs do all the forensic types of
22 analyses. Maybe next to DNA there could be a box saying,
23 alcohol, forensic alcohol.

24 I mean, is this something that's already being
25 collected I guess in the system?

1 MR. KOENITZER: This is Dave from DOJ. And, no,
2 it's not. We take care of our own ten laboratories. But we
3 don't really get into other laboratories in this state's
4 business.

5 That's their realm of doing possibilities. But on
6 the site of that website we do run a website for DAs and law
7 enforcement for results and things like that. So if we
8 wanted to do something like that I think the DAs would be
9 the ones to, if somebody tried to start a laboratory that
10 wasn't following Title 17 they would be the ones that would
11 be the front line for us to see it before we would.

12 If somebody chose not to follow a regulation that
13 they need to register.

14 CHAIRMAN KIMSEY: And so this is a, is this a, I'm
15 sorry, I'm just not familiar with the Department of
16 Justice's system. But is this DAs, is this an organization
17 under DOJ or is this a private organization or run by the
18 counties or what's the --

19 MR. KOENITZER: The district attorneys are their
20 own entities. Dave again, from the Department of Justice so
21 the reporter knows.

22 But we do offer, as part of our services for our
23 ten laboratories, that we offer a website for the district
24 attorneys within our realm and law enforcement to get
25 results for all our criminalists, takes our blood alcohol

1 and our breath alcohol so that they can take those results
2 to our court.

3 So I was just thinking if you wanted to do
4 something a little more secure as far as trying to regulate
5 a new laboratory trying to come in not inform you that the
6 DAs would probably going to be your front line to notice
7 that somebody is trying to do that.

8 If they ever want to -- the blood alcohol case in
9 court they should be the ones that are trying to make sure
10 that everything is following your regulations.

11 COMMITTEE MEMBER SHEN: This is Jennifer --

12 MR. KOENITZER: That way --

13 COMMITTEE MEMBER SHEN: -- the bottom line is that
14 we can't, it's not reasonable to think that we can operate
15 without the proper approvals without somebody noticing.

16 Because alcohol is highly contentious at all times
17 in court, it seems. And it's not reasonable to expect that
18 there is going to be a laboratory is going to be able to do
19 work and not follow these guidelines and nobody is going to
20 notice.

21 CHAIRMAN KIMSEY: Right. And I would agree. I'm
22 just trying to, I was just had a train of thought that, you
23 know, we're talking about a website that, you know, that if
24 someone would have responsibility for that would acknowledge
25 that an entity is complying with Title 17 to some extent

1 which obviously would be up for discussion.

2 But it doesn't sound like that there is an entity,
3 I mean, this district attorneys site sounds interesting but
4 I, I guess, we would have to think more about, I mean
5 obviously if the Department has responsibility for the
6 regulations, responsibility for Title 17, you know, it seems
7 like, you know, a website in the Department that could, you
8 know, that would be accessible that would reflect compliance
9 to the extent the Committee wants us to have information on
10 that website, might be a more clean-cut solution.

11 I mean obviously --

12 COMMITTEE MEMBER SHEN: I would agree. I think it
13 would have to be the Department run.

14 MR. LYLE: Bruce from San Diego. The attorney
15 general may have something on crime labs or laboratories --
16 but I think they would be the only ones.

17 It sounds like if we're talking about oversight
18 and that the Department has oversight or, I don't know, we
19 can't really come up with a good word for it. But --

20 CHAIRMAN KIMSEY: Responsibility (laughter).

21 MR. LYLE: -- yeah. You say a responsibility --

22 COMMITTEE MEMBER SHEN: Interest.

23 MR. LYLE: -- interest. That they should, the
24 Department should be at least have their hands in on what
25 gets uploaded onto that website.

1 And I, after breaking last, in September, just
2 mulling it over, I thought a website was probably the best
3 way to go.

4 And that language into the regulations that compel
5 labs that are doing forensic alcohol testing or considering
6 it that they do, that we compel them to send a notification
7 to the Department.

8 COMMITTEE MEMBER SHEN: And this is Jennifer. And
9 not to rain on my own brainchild but one of the things that
10 we need to worry about, I think, is that, you know, one of
11 the reasons we are rid of the licensing is that we did not
12 want -- well, actually I'm not going to go there.

13 But what we could set ourselves up for here is
14 that the Department could choose to say we're not in good
15 standing or -- but the standing that we would need on this
16 website depends on its interpretation of what it thinks it
17 needs.

18 So, I mean, if it was up to me, in order to go
19 this route, it would have to be exceptionally clear what it
20 is that does or does not net you a yes or a no on that
21 website.

22 CHAIRMAN KIMSEY: No. I would agree. And I think
23 the regulations would have to be quite specific. I mean
24 that's the point of them to some extent.

25 And, you know, and then you and I Jennifer, we

1 talked about, we went both ways (laughter) in the sense that
2 the discussion we had, you know, 20 different things. And
3 then we got down to two things or whatever.

4 So, I think if there's, it sounds like there's
5 general agreement that this website would reflect, you know,
6 a laboratory's standing. I guess what we need to talk more
7 about is what criteria do we want the Department to use.

8 And you mentioned a few of them Jennifer. You
9 know, is the laboratory accredited? Is it up on its
10 proficiency testing? You know, so, I think we can move on
11 to, you know, the idea, what would that website reflect
12 specifically that the Department would -- we have to
13 understand that the Department would have to have some
14 ability to make a determination.

15 So, any thoughts on what we want reflected? Do
16 you have that list in front of you, again, Jennifer that you
17 mentioned?

18 COMMITTEE MEMBER SHEN: Great. I do. And, you
19 know, the laboratory's name, whether or not the laboratory
20 is accredited, what the accrediting body was and is the
21 laboratory current in the proficiency tests? And then the
22 last one we had talked about, is the laboratory in good
23 standing?

24 That one is fraught with difficulties.

25 CHAIRMAN KIMSEY: Well, the regulation could say,

1 you know, "good standing" means x, y and z. I mean --

2 COMMITTEE MEMBER SHEN: That's what it, that is
3 what would have to happen.

4 CHAIRMAN KIMSEY: Right.

5 COMMITTEE MEMBER SHEN: I mean, and then, you
6 know, then you were talking about perhaps, you know, if the
7 operator manual is current and -- approved and that kind of
8 stuff.

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
10 Comment from the public, Clay Larson. I'm just thinking
11 about those items that you just described. It's not clear
12 to me that it would be appropriate to list accreditations
13 since nothing in the regulations requires a lab to be
14 accredited.

15 And the Department is not in a position to, I
16 mean, you said, name the accrediting body to determine
17 whether we have no regulations, no directions to determine
18 whether those are appropriate accrediting bodies.

19 So I would think that information is, probably
20 wouldn't go on the website. The statement that the lab was
21 current in, I'm not sure exactly what that means. Current
22 in proficiency tests.

23 So if a lab fails a proficiency, it wouldn't be
24 current? Is that the --

25 COMMITTEE MEMBER SHEN: Well, and this is, I mean,

1 this is just some options we wrote down. This is certainly
2 nothing that we are propering as the way we should go.

3 I think Paul and I considered the fact that the
4 website would be of use to the public and to the defense
5 attorneys. Therefore, the accreditation status might be of
6 interest.

7 But as far as, you know, as far as proficiency
8 tests go in my mind, however we set it up, that we do the
9 first test and the Department gets a copy of that. That has
10 to be done on a yearly basis.

11 However, if we decide, so if we have met that
12 criteria then, yes, it would be current.

13 If you want to call it something else, that's fine
14 with me. These are just sort of things that we're thinking
15 about having on that website that somebody could look up.

16 And it does give the Department a little bit, it
17 gives where the Department currently doesn't seem to have
18 any oversight abilities of any kind based on the existing
19 regulations, any teeth. This kind of gives the Department
20 an ability to hold laboratories accountable.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 Comment from the public. Back to proficiency testing, I
23 thought you kind of glossed over the issue. When we
24 discussed proficiency testing the Department would -- we
25 kind of all agree now all -- maybe we're not totally clear

1 on the exact details, but in some fashion labs would be
2 submitting proficiency tests results to the Department on an
3 annual basis.

4 The Department would make a determination of
5 whether those results, in the current language, whether
6 those results show that the lab's methods are, meet the
7 standard performance requirements set forth in the
8 regulations.

9 So, given enough time I suspect at some point in
10 time, sometime or another a lab will submit results. The
11 Department would evaluate those results and make a
12 determination that they didn't meet the standard of
13 performance.

14 The question is, if that eventuality, if that
15 occurred would you then use the language, they weren't
16 current?

17 COMMITTEE MEMBER SHEN: We can use whatever
18 language that we all decide would be appropriate.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 I think also, this is Bob Haas again. And I, if Rosalee
21 could comment on this perhaps. I think if that eventuality
22 occurred Clay, that there should be described in detail into
23 the regulations the procedure for corrective action.

24 That could, and I'm not suggesting what that'll be
25 at this time. But, if, you know, if results are out of

1 compliance, quote/unquote, then there will be a procedure
2 for the Department and the laboratory to provide corrective
3 action to, or the individual laboratory to provide
4 corrective action in order to bring them into compliance.

5 And you're right, if the website is as I'm hearing
6 it now would be, would have to say, until that corrective
7 action had been implemented that is was not current.

8 But I see this as a, you know, first of all, rare,
9 but, you know, not unheard of, but also, temporary. And
10 that's the advantage of a website. Is that it's a living
11 document in a real sense and that, you know, within a period
12 of days to weeks, you know, the compliance issue can be
13 resolved.

14 But that also, again, I want to emphasize, has to
15 be described and detailed carefully in regulations. So that
16 everybody knows that there's a level playing field here.

17 Rosalee do you have a comment on that?

18 MS. DVORAK-RENIS: Nothing except that I agree
19 with what you said Bob (laughter).

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
21 Well, thank you.

22 MS. DVORAK-RENIS: You need to be just, it would
23 need to be described in regulations.

24 CHAIRMAN KIMSEY: And I appreciate that. And I'd
25 like to sort of, sort of, come back up out of the weeds a

1 little bit. And I, only to the extent that we've talked
2 about the name of the organization.

3 I don't know if that would include an address.
4 We've talked about accrediting, accredited, yes or no.

5 We've talked about accrediting body. We've talked
6 about the proficiency testing being up to date, current,
7 whatever, would be important.

8 And then we had this general category of, good
9 standing. I'd sort of like to talk about things at a higher
10 level knowing that we'll have some detail to work out.

11 But, what else might be on this website that the
12 Department would have some knowledge of or control over? I
13 mean, I happen to think, I don't know, do we ever get
14 letters of complaint or about laboratories?

15 I mean, that could be, you know, good, in good,
16 that might be reflected about, good standing. Although
17 you've got to be careful. You know, letters of complaint
18 have to be investigated to be shown to be, you know, viable
19 or whatever or true.

20 But anyhow, sort of at a higher level besides the
21 proficiency testing, accrediting, accredited, name -- any
22 other suggestions to what could be on the website?

23 COMMITTEE MEMBER SEDGEWICK: This is Paul
24 Sedgewick. I may be an interesting minority here speaking
25 just for myself, we can skirt a lot of these problems by

1 simply limiting the website to the name of the laboratory,
2 maybe an address, certainly contact information.

3 And that would serve the purpose of its needs, in
4 my personal opinion. Anything else, they would contact the
5 laboratory for.

6 COMMITTEE MEMBER SHEN: And you would get on that
7 list by sending your letter of intent. The Department would
8 put you on that list when had you let them know or they do
9 know that you're doing alcohol analysis.

10 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick. Yes,
11 precisely. On top of which --

12 COMMITTEE MEMBER SHEN: I like it.

13 COMMITTEE MEMBER SEDGEWICK: -- it's solves the
14 problem of --

15 COMMITTEE MEMBER SHEN: Checking --

16 COMMITTEE MEMBER SEDGEWICK: -- whether that
17 information provided to the website, is accurate. Because
18 someone should be doing that, if it's going to be put on the
19 website.

20 CHAIRMAN KIMSEY: Well that's certainly the
21 minimalist approach (laughter). I mean, I know of one point
22 when Jennifer and I were talking we were, we had a real --

23 COMMITTEE MEMBER SHEN: I think we got down to one
24 thing only.

25 CHAIRMAN KIMSEY: -- right. But at some point we

1 were like (laughter) at in the 30s so -- any other thoughts
2 on what could or should not be on the website?

3 I mean, I guess there's some agreement that there
4 should be a website. And it just sort of gets down to, you
5 know, what should be on it.

6 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
7 This is Bob Haas and speaking from the public point of
8 view. What do the other Committee members think about
9 Paul's suggestion?

10 I'll make my comments first. Having a list with
11 no information is like yelp.com having no reviews
12 (laughter).

13 I thought that the purpose of having this was to
14 inform the public and the legal community of the resources,
15 not to just simply provide a list.

16 I mean, everybody knows that, you know, the county
17 of San Diego and San Francisco and Contra Costa have
18 laboratories that test for, that test alcohol.

19 Anybody else, any Committee members have an
20 opinion?

21 COMMITTEE MEMBER SHEN: Well, this is Jennifer.
22 And, you know, I kind of go back and forth as Paul knows. I
23 don't want to set ourselves up in a situation, that, you
24 know, of writing that -- my department, I don't want to set
25 myself up in a situation where there is a disagreement

1 between myself and our representative at the Department as
2 to what is or is not acceptable about a regulation that
3 built in some sort of -- on the website.

4 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
5 What was that? This is Bob Haas again. I would say, you
6 know, that if all that this site would have is a list of
7 available laboratories then we should just scrub the whole
8 idea.

9 I mean, anybody can contact CDPH and get a list of
10 laboratories if they're all on record here.

11 COMMITTEE MEMBER SHEN: Well, that is true. And
12 which would take us back to bullet four to just requiring
13 some sort of notification of the Department that a
14 laboratory has intent to do that kind of work.

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
16 Exactly.

17 CHAIRMAN KIMSEY: That's not serving the public
18 very much.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 You're right.

21 CHAIRMAN KIMSEY: But --

22 COMMITTEE MEMBER SHEN: Well no, it isn't. This
23 is not necessarily what we're trying to do with the
24 regulations, other than provide -- obviously, provide those
25 excellent and analytical results.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
2 True.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 I thought that was -- we're not trying to serve the
5 public --

6 COMMITTEE MEMBER SHEN: Other than --

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 -- let me write that down. You know, the one
9 discretionary activity that we seem to be putting back is
10 the approval breath instrument operator training procedures.

11 So, as far as the notification and/or a website or
12 a list, I think it would be appropriate to, the Department,
13 to and we will do anyway we're asked, but to be able
14 memorialize our approval of if a lab uses provided training
15 for a given instrument.

16 CHAIRMAN KIMSEY: It just occurred to me that
17 another way to look at this website, if it's going to
18 reflect public information that the Department has about an
19 entity which is already discoverable in public; there could
20 be a lot of information on the website, potentially.

21 I mean, because obviously the website would be
22 reflecting public documentation. And so, whatever we
23 collect or have knowledge of, in an official capacity, is
24 public information.

25 MR. LYLE: Bruce in San Diego. So we, so the

1 Department can go ahead and do a website now without any
2 regulations around it and just make public whatever they
3 make public anyway, public records.

4 And, yeah, from what Paul Sedgewick says and Bob,
5 it sounds like we don't really need the website. What we
6 need to focus on writing right now are or deciding on, is
7 how. What the regulation needs to say.

8 And if the regulation doesn't need to talk about
9 what the Department is going to put on a website then we
10 should just skip over that.

11 CHAIRMAN KIMSEY: Right and I that just sort of
12 rolls back to the idea of the notification of the Department
13 that you're going to be doing business as a forensic alcohol
14 laboratory.

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
16 Which is what we, which is what the bullet is all about.
17 So I would agree with you Bruce that, right. We can do,
18 DPH, we can do whatever we want outside of regulation. And
19 all that we need to discuss here is the notification issue
20 which is the issue.

21 COMMITTEE MEMBER SHEN: All right, well.

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
23 That was easy.

24 COMMITTEE MEMBER SHEN: What kind of language are
25 you anticipating?

1 CHAIRMAN KIMSEY: So, this notification would it
2 be a one-time only? I think we were agreeing that there
3 would be some notification. I'm making that assumption. I
4 mean you can correct me but I'm going somewhere with this.

5 So if there is a notification, is this a one-time
6 only or is it annually or is it, I mean, when you start
7 talking about notification annually it does strike me like,
8 a little more like the L word or the C word, licensing and
9 certification type stuff.

10 But then if it's a one-time only and they're out
11 of business, how does that help us?

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

13 Well, you --

14 CHAIRMAN KIMSEY: Do you --

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

16 Excuse me, this is Bob Haas again. I think this ties, in
17 and please you guys jump in and beat me up on this if you
18 like, it ties into the staff changes, the training issue and
19 all of that.

20 What is noted, and again, and Paul hit the nail on
21 the head. What is the essence of notification? Just we,
22 some corporation is going to or some public laboratory is
23 about to proceed and endeavor to this kind of testing -- but
24 does notification include things like personnel changes and
25 the training of those, of the staff members as well.

1 I'm just throwing that out as a, you know, red
2 herring maybe and would like to discuss that further.

3 COMMITTEE MEMBER SHEN: This is Jennifer. And
4 Paul and I talked about this pretty extensively as well.

5 That we need to, and I think as far as
6 notification of a laboratory, probably notifying one time
7 that the laboratory is going down this road. And then
8 notifying if the laboratory stops, would be reasonable.

9 But I know that Paul and I discussed notification
10 to the Department of analysts that we were going to have
11 doing the alcohol, doing the alcohol work and whether that
12 would be sending in the names and I think probably discussed
13 a memo generated by the laboratory indicating that this
14 person has this degree and the head person stated in this
15 training and these competency tests et cetera and has been
16 find out by our department for alcohol analysis and sending
17 that to the Department so that it has records of those
18 analysts that are, in fact, providing that service. This is
19 something that we thought would be reasonable.

20 CHAIRMAN KIMSEY: Yes, we did have that
21 discussion. This is Paul in Richmond.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 Comment from the public. Jennifer, I think it was probably
24 an oversight that you -- but one of the elements was the
25 external proficiency testing.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

2 Right. Well, that's --

3 COMMITTEE MEMBER SHEN: Paul and I --

4 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

5 -- as I understood from Jennifer from last time. I think
6 that that's, and from Kenton as well, that that's sort of
7 standard practice that new staff, after training, take an
8 external proficiency test and that would also be part of
9 their personnel record.

10 COMMITTEE MEMBER SHEN: Correct. But I was not
11 giving you the absolute most complete list of things we
12 might put on that memo. It's the notification of the
13 Department, to the Department that this person with this
14 training, these tests and this experience and this
15 educational background is now cleared by the laboratory to
16 do testing.

17 CHAIRMAN KIMSEY: Well that's, you know, that's an
18 option. I lost my train of thought. Oh, real quickly. Is
19 the Committee may remember those that have been around,
20 early on we talked about this issue. And, you know, we're
21 not going to be licensing, certification is licensing,
22 smacks of licensing.

23 I'm just curious, and I don't mean to put Ms.
24 Campbell on the spot but do you think that notification of
25 the Department that an entity is going to be doing alcohol

1 analysis in the state, that notification is compatible with
2 1623?

3 MS. CAMPBELL: I think it is.

4 CHAIRMAN KIMSEY: Okay. I mean, that's fine. We
5 can say --

6 MS. CAMPBELL: And I think there does have to
7 be --

8 CHAIRMAN KIMSEY: Yeah --

9 MS. CAMPBELL: There does have to be some kind of
10 notice to the Department that a lab is operating. So I
11 don't think it smacks of licensing.

12 CHAIRMAN KIMSEY: Okay. No, that makes sense. I
13 just -- and we can obviously dwell on it some more. But if
14 right off, if it didn't feel comfortable to you then we
15 shouldn't be, you know, talking about it.

16 I'm sorry if I interrupted. There was discussion
17 on, you know, one time that we're going to do business and
18 then a time that we're not going to do business in the
19 state.

20 So we're sort of avoiding the, you know, annual or
21 periodic notification.

22 COMMITTEE MEMBER SHEN: This is Jennifer. Bob's
23 point was that he felt, I think, that he felt that there
24 should be some notification of --

25 MS. BUTENKA: Change --

1 COMMITTEE MEMBER SHEN: -- abstain of the
2 training, et cetera. So my thought on the memo that would
3 be provided when we got a new staff person up and ready to
4 go would, I guess sort of be included in that notification
5 process.

6 MR. LYLE: Right. That's, you're exactly right.
7 It just that it kind of, you know, we've been discussing
8 these four bullets as if they're not inter-related at all.
9 And, in fact, they, to my mind, they are.

10 And so, likewise, when staff retires or leaves the
11 job, that sort of notification is probably useful as well.
12 Just in a bookkeeping sense for DPH.

13 CHAIRMAN KIMSEY: Is there some evidence that this
14 could be sort of a standardized form that, you know, I don't
15 know.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Comment from the public. I mean, I think I can address that
18 question. There is a section in the current regulations,
19 1217.2 which requires the labs to submit, something called a
20 report of change. And there's a report of change form.

21 MS. BUTENKA: Right.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 It used to talk about changes of address --

24 COMMITTEE MEMBER WONG: It already exists.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 -- changes in personnel, additions of new methods and
2 procedures and deletion of old methods and procedures. So I
3 just certainly, we already have statutes, regulations to
4 cover that. And we have a form and so, the form now, I
5 think, should be incorporated into the regulations.

6 I think that would be a good starting point to
7 discuss this.

8 Let me go back to one other point though. When we
9 talk about the, I shouldn't be picking at these things but,
10 when we talk about a memo being issued by the lab and you
11 kind of went through -- the bullet that we addressed under
12 the qualification of laboratory personnel, bullet two and
13 which we're still addressing; was in response to the
14 December 15th letter's concern about the removal of DPH
15 authority to review, approve and test the qualifications of
16 persons employed by a laboratory.

17 So, if we put back an approval mechanism regarding
18 personnel if that's the goal, I mean, most responsive to the
19 bullet point; then it's a little more than a memo from the
20 lab. I'm not sure you capture the interchange here, exactly
21 when you refer to a memo from the lab informing the
22 Department of the lab's approval at some -- points of
23 unpleasanties down the road, we'll just have then now.

24 CHAIRMAN KIMSEY: I'm sorry Clay, that didn't come
25 through. I didn't track what you were saying. I mean, I

1 think under bullet number two that the Committee had made it
2 pretty clear that they didn't want the Department testing
3 the qualifications. That the laboratories themselves wanted
4 to do that. Is that what you're saying?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

6 No. I think what, the decision was, the testing the
7 qualifications involves several things.

8 It involves review of education and experience.
9 That's pretty straightforward. And we made education less,
10 pretty simple.

11 But a review of an external proficiency test and a
12 written examination, to date the Committee is, it hasn't
13 really wanted -- hasn't embraced the written examination,
14 I'll go as far to say that they, I think, by submitting
15 those proficiency test results and allowing the Department
16 to review, we'd be reviewing at least the analytical
17 qualifications of the nominated individual.

18 CHAIRMAN KIMSEY: That's a statement.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

20 That's my understanding of where we are going with bullet
21 two.

22 CHAIRMAN KIMSEY: Okay. On bullet number four,
23 this notification we talked about it, you know, I mean I'm
24 sure, I guess I was still on bullet two, Clay, when you went
25 over to bullet -- I mean bullet four when you went over to

1 bullet two.

2 And we're going to have to take a break here in
3 about five minutes I think.

4 Any other, any other issues around notification?
5 There seems to be a general acceptance. And when we talk
6 about, you know, getting some language reflecting our
7 thoughts today we can sort of throw that in there.

8 But, are there any objections to this notification
9 idea from the Committee?

10 MR. LYLE: Bruce in San Diego. No, I don't have
11 any objections to it. I like the initial notification and
12 then notifying that you're, that the lab is disbanding or
13 quitting the practice of forensic alcohol testing.

14 And then some form of updates of who is, who are
15 the analysts.

16 COMMITTEE MEMBER SHEN: This is Jennifer. I
17 agree.

18 CHAIRMAN KIMSEY: Any other comments about bullet
19 four?

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Comment from the public. And again, besides who the
22 analysts are, so that you also include to the extent that we
23 have retained some approval, oversight of breath testing,
24 what instruments are being, the lab is offering training
25 for?

1 CHAIRMAN KIMSEY: I'm sorry Clay. Maybe you need
2 to closer to a microphone. Did you want to include in the
3 notification that they're doing breath alcohol analysis?

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 Well, to the extent that a lab is offering training of
6 operators performing breath alcohol analysis. And to the
7 extent that the Department will retain some role in
8 approving that training.

9 COMMITTEE MEMBER SHEN: We're on four --

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 We're on four but we're talking about the information that
12 would be included. I think Bob Haas was right on point.

13 We're talking about the information, potentially
14 it's all related. We're talking about the information that
15 would, logically would be included in the form.

16 And Bruce mentioned qualification of personnel and
17 changes in personnel. I would submit that to the extent
18 that we're going to retain a role in the approval of breath
19 instrument operator training procedures it would be
20 appropriate to let us know what instruments they're going to
21 use.

22 CHAIRMAN KIMSEY: So you're recommending that this
23 notification include the fact that the entity is going to do
24 breath alcohol analysis.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Well, the entity, first of all a laboratory, and I don't
2 want to get into the place entity issue right now, but that
3 the laboratory doesn't necessarily do breath alcohol
4 analysis except for the fact that they train operators to
5 perform breath alcohol analysis but --

6 CHAIRMAN KIMSEY: Right.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 -- an activity for which the Department may retain a role,
9 it would be appropriate to describe that activity or any
10 changes in that activity in these notification forms.

11 COMMITTEE MEMBER SHEN: This is Jennifer. And
12 although I agree, all of these bullet points are somewhat
13 interchangeable, the bullet point that we're talking about
14 now specifically stresses requirements provide the
15 Department with records of its activities including
16 notification of its intent to perform alcohol analysis.

17 Bullet two talks about reviewing and approving
18 qualifications. So as far as bullet four goes I would agree
19 with Bruce that we want to initially notify the Department
20 that we're doing the work.

21 I think it's reasonable to say we're doing blood
22 and/or breath alcohol; notify the Department when we are no
23 longer doing the work. And there should be some sort of
24 regular updates in place as to what analyst we have that
25 work.

1 CHAIRMAN KIMSEY: Okay.

2 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
3 Yeah. This is Bob Haas again. I would just like to add
4 that beyond the analysis I think it's really important that
5 laboratory management also be tracked, if you will, through
6 a notification process.

7 COMMITTEE MEMBER SHEN: And what do you mean
8 exactly by that.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 Well, I mean like who's running the lab not just, I guess
11 what I hear analysts I'm thinking about the bench chemists
12 there or, you know, the breath instrument operators.

13 But the management of the laboratory, the
14 supervisors as well as the managers. You know, in other
15 words, the staff of the laboratory from top to bottom.

16 Not to the bottom, bottom. Not to the dishwashers
17 (laughter). I think you know what I mean.

18 And again, this all has to be specifically spelled
19 out, unfortunately or fortunately. But it does.

20 COMMITTEE MEMBER SHEN: And I assume that you want
21 that sort of information for communication purposes.

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
23 Exactly. For contact information. Exactly.

24 COMMITTEE MEMBER SHEN: Now that makes sense to
25 me.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
2 Thank you.

3 CHAIRMAN KIMSEY: Any other comments from the
4 Committee? It is 11:30. I would propose that we take a
5 bio-break for 15 minutes. And while we're on the break be
6 thinking about, I mean we obviously have, I mean, obviously
7 we'll take lunch if we need to.

8 But we have the afternoon. A couple of other
9 things. I think if there's more about the bullets we want
10 to discuss, that's fine.

11 But I think we're to the point where we're going
12 to have to be talking about getting some language reflecting
13 our discussions.

14 And how do we go about doing that. Because I
15 think our next step would be to be have language sent out in
16 advance of a meeting and have a meeting, agree on the
17 language, pull apart the language and get some, you know,
18 agree on that language.

19 And then we would be talking about sending
20 another, a package to Agency which would contain our
21 revisions that would trigger the 90 day review. I think
22 we're getting to that level of completion here.

23 So think about that on the break. And if I don't
24 here any objections we'll start back up at 11:45.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Actually, let's be sure on the consensus. Because 11:45 if
2 we do break for lunch that will put us close to lunch. Is
3 it the sense that we're going to, we'd better wrap this up
4 somehow between 11:45 and, I don't know some, probably a
5 short period of time, and then, and not come back after
6 lunch? Is that what you said?

7 CHAIRMAN KIMSEY: That's an option if the
8 Committee wants to. I'm just thinking that we could, we'll
9 have at least 15 or 45 minutes of discussion. We could
10 break for lunch at 12:30 or --

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Okay.

13 CHAIRMAN KIMSEY: -- 1:00, it's up to the
14 committee. But, so -- any other comments?

15 MR. LYLE: It sounds like a good plan Paul.

16 CHAIRMAN KIMSEY: Okay. Let's --

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 I like it too.

19 CHAIRMAN KIMSEY: -- we'll be back at 11:45.
20 Thank you all.

21 (A brief break was taken off the record)

22 CHAIRMAN KIMSEY: So, any brilliant ideas on how
23 to spend the rest of our day?

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
25 Yeah. I have a brilliant idea (laughter).

1 CHAIRMAN KIMSEY: Well, let's hear from the
2 Committee first.

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
4 Oh, I'm sorry.

5 CHAIRMAN KIMSEY: That's okay. Anyone on the
6 Committee that, we, turns out I'm a technology --

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
8 I knew it.

9 CHAIRMAN KIMSEY: -- genius. Anyone on the
10 Committee have some ideas. Obviously I had talked about,
11 you know, we don't have language in front of us.

12 I think, I personally think it may be difficult to
13 craft language in this environment without saying something
14 in black and white. At least it's harder for me.

15 And so, anyhow, we need some suggestions on how to
16 go about getting some language written up, a time frame.
17 You know, we do have if we want to go back and visit any
18 bullets, we do have this time from now until 3:00 set aside
19 for the Committee. Any suggestions --

20 COMMITTEE MEMBER SHEN: This is Jennifer. I think
21 we should take a crack at, maybe not crafting the language,
22 but since the language will have to be crafted by someone.
23 That person ought to have some guidelines.

24 So maybe we could try to at least craft the
25 elements of the language.

1 CHAIRMAN KIMSEY: Okay.

2 COMMITTEE MEMBER WONG: I agree.

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
4 Well actually, this is Bob Haas. That's exactly what I was
5 going to suggest. So it must be that geniuses all think
6 alike (laughter).

7 COMMITTEE MEMBER SHEN: I've never met anyone who
8 thinks I'm a genius.

9 CHAIRMAN KIMSEY: And so, okay, we can spend some
10 time with that. It looks, then we're definitely -- what's
11 the group's feeling? Do we want to take an hour for lunch?
12 You know, basically starting and come back at -- now, there
13 are some restrictions, I think there were some issues about
14 getting back into the building in San Diego? Or where you
15 have to go for lunch. What is the issue, what is the issue
16 there?

17 COMMITTEE MEMBER SEDGEWICK: This is Paul
18 Sedgewick. I think we solved that problem.

19 COMMITTEE MEMBER WONG: Good.

20 CHAIRMAN KIMSEY: Well, good. So, if we were to
21 take an hour for lunch starting at noon, be back at one.
22 And we'll actually go through and see what we can do about
23 working on the language specifically for each of the four
24 bullets.

25 Maybe getting some parameters, setting up

1 parameters about what we really all think we have agreed to.

2 I'll go back and get some, you know, I have a copy
3 of the transcript here. And I know Jennifer had taken some
4 notes too about some language. And I have a little bit.

5 So we can build on that this afternoon.

6 Also this afternoon I think we want to talk a
7 little bit, I mentioned a little bit before the break about
8 sort of where the process may be going.

9 We're getting close enough to where we want to
10 have some understanding of what the process will be with the
11 submission of what, I guess, we're going to call the
12 revisions.

13 And, any other items or suggestions about the
14 afternoon?

15 MR. LYLE: Well how about, this is Bruce in San
16 Diego. As an alternative, how about if we just work through
17 lunch and then -- it doesn't seem like it's going to take
18 more than an hour to --

19 CHAIRMAN KIMSEY: That's fine with me. How does
20 the rest of the Committee feel?

21 COMMITTEE MEMBER SHEN: I'm good with that.

22 CHAIRMAN KIMSEY: Okay. Any objections? Well
23 then, why don't we, I'm not hearing anybody screaming or
24 fainting, why don't we start with bullet number one.

25 I know you had some language, Jennifer, you want

1 to read that to us again?

2 COMMITTEE MEMBER SHEN: Right. And I think I just
3 wrote this down from our last meeting. I don't have any
4 real ownership over this.

5 Labs will report test results to CDPH who will
6 evaluate these test results and may require written
7 corrective actions of any lab that reported outside
8 acceptable limits.

9 All right, and I think there's a myriad of
10 problems with that already.

11 CHAIRMAN KIMSEY: And I guess the purpose of what,
12 you know, we agreed to was to have CDPH, you know, back
13 involved in evaluating proficiency testings from the
14 laboratories. And that was sort of the intent.

15 And this is where we were talking earlier about
16 internal proficiency testing versus or individual
17 proficiency testing versus, you know, facility or laboratory
18 proficiency tests.

19 COMMITTEE MEMBER SHEN: Well to me it seems like
20 the first thing we need to decide is if we want to
21 articulate whether or not these are internal or external
22 tests.

23 If we're looking for elements this is what we
24 might want to include in this language. That might be our
25 first one.

1 CHAIRMAN KIMSEY: Okay.

2 MR. LYLE: This is Bruce. And it seems like what
3 we're after is external you reported out. Wrong?

4 COMMITTEE MEMBER SHEN: I would agree with that.

5 CHAIRMAN KIMSEY: Yeah. And these external tests,
6 actually -- I mean, do we want to say something about who or
7 what sort of organization does, provides them. I mean, or,
8 I mean are these commercial or they --

9 MR. LYLE: I think in the regulations -- already,
10 what we've already come up with, have we defined what
11 external tests are?

12 COMMITTEE MEMBER SHEN: I believe we have to have
13 an approved provider based on -- so, I guess so, we would
14 have to have an external proficiency test provided by an
15 approved proficiency, accredited -- obviously, there's too
16 many providers in there. But you have to have an approved
17 provider giving the laboratories external tests that the
18 laboratories then submit to the Department.

19 You have to have those elements in there.

20 CHAIRMAN KIMSEY: Right. Any other information we
21 want in that?

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 Well one comment, I mean, Jennifer is right. There are
24 several bridge points here that, several forks in the road.

25 Another would be whether the labs submit the PT

1 results or the providers submit the results, that's an
2 option.

3 Also there would be an issue with regarding the
4 timing. In other words, there is a schedule for these
5 proficiency tests with the labs --

6 CHAIRMAN KIMSEY: I think you need to get closer
7 to mic again, Clay.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 Yeah, I -- issue number one is whether the lab will simply
10 submit the results or whether they would direct their
11 provider to submit the results to the Department.

12 The other question, this question is answered but
13 assuming the lab, if we decide the labs would be submitting
14 themselves is there some sort of timing requirement? In
15 other words, if they take a test in, CTS offers one early in
16 the year, February. To submit those results within some
17 time frame?

18 I guess you'd want to avoid, not that anyone would
19 do this but you'd probably want to avoid a situation where a
20 lab, they subscribe to several PT results and simply, you
21 know, wait and see how its results compared with others
22 because eventually the provider will provide a summary.

23 And then at the end of the year submits the ones
24 that they like best.

25 CHAIRMAN KIMSEY: Well I think that the timing

1 issue is resolved is if we have the provider provide the
2 Department the results; if the laboratory authorizes the
3 provider to provide it to the Department then we don't have
4 to worry about time frames or people cherry picking.

5 COMMITTEE MEMBER WONG: Well typically when you
6 have a proficiency test, there's a deadline date anyway that
7 you have to abide by. So, whether whatever external
8 proficiency test provider, they're going to say, you must
9 provide results by x date. That's in stone.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 I'm not sure that's germane because if the question here is,
12 when would the Department receive it, would the labs be
13 required to submit those to the Department?

14 Clearly the provider, and again, if it's the
15 providers who provide the information to the Department then
16 it is taken care of. But, is that where we're going?

17 MR. LYLE: Bruce. Well, the purpose of providing
18 it to the Department isn't so the Department can say, you're
19 right they were proficient or they weren't. I thought the
20 reason was for them to collect that data.

21 So, if the proficiency tester, the external proof
22 provider that is saying, yes, you did pass or no you didn't.
23 Just that, yes I did pass.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Okay, well several points. Back to his point because it

1 doesn't seem to be sinking in. Under the rules that
2 ASCLD/LAB manufacturing practices that ASCLD/LAB set up, the
3 provider is not permitted to evaluate the results.

4 Also I think this whole issue is responsive to the
5 first bullet obviously. And the concern expressed in the
6 12/15 letter that the regulations were removing CDPH
7 evaluations of a laboratory's performance on proficiency
8 tests.

9 I think evaluation I would interpret that and I
10 thought that's where we're going, would be would include a
11 evaluation of the data and a determination of whether the
12 data reflects the method is meeting the standard performance
13 requirements in the regulations.

14 CHAIRMAN KIMSEY: Yeah, so I think there's two
15 roads here. One is that the Department does the evaluation
16 and determines whether a laboratory has passed, an external
17 provider, proficiency testing provider or the Department is,
18 has, is the repository of information where the laboratory
19 can point to an external, having passed an external
20 proficiency test.

21 In other words, you know, cherry picking would be
22 allowed but at some point somewhere you did pass proficiency
23 testing versus sending or having information provided to the
24 Department that the Department would evaluate and then agree
25 or tell the laboratories that they had passed.

1 Is that sort of the dichotomy that I'm hearing?

2 COMMITTEE MEMBER SHEN: This is Jennifer. Here
3 is, what do you think about language that the laboratories
4 will submit results of external proficiency tests from an
5 approved provider to the Department on yearly basis?

6 CHAIRMAN KIMSEY: And so that would take the
7 Department out of evaluating. They would --

8 COMMITTEE MEMBER SHEN: Well the Department --

9 CHAIRMAN KIMSEY: -- they --

10 COMMITTEE MEMBER SHEN: -- is welcome to evaluate
11 the results as they get them. But the thing is that the
12 external providers provide the information from which any
13 kind of evaluation takes place.

14 Currently, what happens is that information comes
15 back to the laboratories and they, with the information
16 provided it's clear the quality assurance measure can
17 clearly see whether or not our results follow then
18 acceptable limits.

19 And Clay is right that external providers don't
20 tell us if we passed or not. They just provide us all the
21 information and it's up to our own, our own quality
22 assurance standards as to whether or not we came into
23 compliance.

24 And what's happening currently is they are now
25 forwarding those results, I believe, on a yearly basis to

1 the Department.

2 So this is the process that is in place right now.

3 It seems to be working. Once that information gets to the
4 Department an additional review is done. That is certainly
5 an option.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

7 And I would suggest that it's the option that is implied in
8 the bullet, in the word, evaluate, is in the bullet.

9 CHAIRMAN KIMSEY: Well then I would agree that
10 Jennifer's language seems to cover that.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

12 Well, it doesn't directly address the issue of cherry
13 picking. I'll --

14 COMMITTEE MEMBER SHEN: I guess, I whatever, we
15 don't really get to do that. I mean we send out our
16 proficiency tests, they come back and if we, we have not
17 come into compliance on one of those proficiency tests have
18 all sorts of answers to do for that. We don't get to just
19 pretend like we never did it.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

21 Well, but I'm not sure you have any answering under the plan
22 you proposed. I mean, unless you submit it you might not
23 have any answering to do to the Department.

24 COMMITTEE MEMBER SHEN: Well --

25 MR. LYLE: -- the answering in court --

1 COMMITTEE MEMBER SHEN: -- and to our accrediting
2 body --

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 I think the issue here is, when we're talking about the
5 issue here is responding to this bullet. And the intent, I
6 believe, of the bullet is to retrieve some departmental
7 oversight in the form of evaluation of a laboratory PT.

8 COMMITTEE MEMBER SHEN: Well and I do believe that
9 if present those proficiency tests, the laboratories submit
10 them you'll have the opportunity to do that evaluation.

11 In my mind this is all the, I mean, again, we have
12 to test, our laboratory, every single analyst --

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 Uh-hmm.

15 COMMITTEE MEMBER SHEN: -- where much earlier it
16 was, you know, that might be burdensome and let's just have,
17 you know, -- person are testing, you just have one person
18 put forward those results to the Department.

19 It's not really all that different in my mind.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 I thought I made the point that ASCLD/LAB is absolutely
22 disinterested in seeing the, seeing the individual analysts'
23 PT results.

24 Perhaps every five years they'll return and
25 perhaps look at an audit. So, I think we're talking about

1 the performance that labs you submit to, that you would
2 direct either to -- lab PRCs. I would think that the clean
3 way to do it is simply ask ASCLD/LAB providers to just also
4 submit these results to the Department.

5 COMMITTEE MEMBER WONG: Clay, could you say that
6 again.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 I think the clean way to avoid the issues of, I don't think
9 it's cherry picking but to a simple, straightforward way
10 would be to whatever results you selected to be submitted to
11 ASCLD/LAB in this case, you would direct those results to be
12 submitted, also submitted to the Department.

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 I thought, this is Bob Haas. I thought that was already
15 agreed upon before we took the break.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 It was a rough break.

18 COMMITTEE MEMBER SHEN: What we agreed upon is
19 that the proficiency tests results need to be forwarded to
20 the Department.

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Right. That, and that would be done at the same time that
23 you're submitting them to the provider, to the test
24 provider. Correct?

25 COMMITTEE MEMBER SHEN: No. I don't think that

1 we're talking about that. I think what Clay is saying is
2 that we would provide, that he would like to see us, but I
3 believe he would like to see us do is that we provide our
4 results, we take the test and the results are forwarded to
5 the providers; they do whatever they do with it and send
6 that information out to the Department, first to the
7 laboratory, to the laboratory to forward to the Department.

8 What's happening now is we get the, quote/unquote
9 results back and this is what you got and this is what
10 everybody else got. And what we're doing now is we are
11 forwarding that to the Department for, I don't know if you
12 evaluate or just store data at this point.

13 So, that again, that process is in place right
14 now. What Clay would like to see is that the results don't
15 come back to the laboratory, they go directly to the
16 Department.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Yeah then, I misunderstood what we were discussing this
19 morning.

20 CHAIRMAN KIMSEY: I didn't understand that it was
21 one or the other. I thought that when the proficiency
22 testing provider provided the laboratories with their
23 results they would also be providing the Department with
24 their results.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 I think that's correct. And at the same time they provide,
2 in this case, ASCLD/LAB PRC with the results. All one
3 seamless process.

4 CHAIRMAN KIMSEY: So I don't know if there is
5 anything new here. But it sounds like when the lab orders a
6 proficiency test they tell the proficiency testing provider
7 that they want the results and they also want a copy of the
8 results to go to the Department. That seemed to be the
9 cleanest -- I'm getting one --

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
11 Well, Kenton is saying, okay, I think.

12 CHAIRMAN KIMSEY: At least he's not --

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 -- why don't you say something?

15 COMMITTEE MEMBER WONG: I thought that's what
16 we're talking about.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 -- I thought that, yeah, me too. That's what I understood
19 this morning's discussion was all about.

20 COMMITTEE MEMBER SHEN: That is just not what is
21 happening currently. What is happening currently is the
22 laboratories are providing our results to the Department on
23 a yearly basis.

24 So, if we don't want to do that any longer and we
25 want to switch it we would, that is something we'd have to

1 change. And I don't really care one way or the other.

2 But that's, that is what is happening now is the
3 laboratories are seeing those results back and the
4 laboratories forward that stuff to the Department.

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

6 Well, in addition what's happening now is the Department
7 also prepares its own proficiency tests samples to send out.

8 So that --

9 COMMITTEE MEMBER SHEN: Correct.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11 -- if that's going to go away I think, and Clay correct me
12 if I'm wrong, I think what we would like to see is those
13 external proficiency test results come directly to the
14 Department as they go back to you.

15 And that's what I thought we were, what this
16 morning discussion was about. Clay, is that correct? Am I
17 missing something here?

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

19 No, that's correct. I agree.

20 COMMITTEE MEMBER WONG: So, what are we arguing
21 about?

22 CHAIRMAN KIMSEY: So, I mean, is there, as Bob
23 just described does anyone on the Committee have a problem
24 with that even though it's something we're not doing
25 currently, as was pointed out.

1 That basically we're going to craft some language
2 that would have the laboratories tell the proficiency
3 testing, approved proficiency testing providers to provide
4 the results to the Department at the same time they provide
5 the results back to the laboratory.

6 COMMITTEE MEMBER SHEN: I do believe that some
7 checking should be done on that to make sure that that is
8 something we can do.

9 Just because --

10 CHAIRMAN KIMSEY: Okay.

11 COMMITTEE MEMBER SHEN: -- we order it to be so
12 doesn't mean --

13 CHAIRMAN KIMSEY: Sure --

14 COMMITTEE MEMBER SHEN: -- it will --

15 CHAIRMAN KIMSEY: -- sure --

16 COMMITTEE MEMBER SHEN: -- be that easy. So I
17 think we need to check with the CTS and others to make sure
18 that that's not an issue. I don't think it will be but we
19 should at least check with them.

20 CHAIRMAN KIMSEY: Yeah, we can check with that.
21 Any, I do sort of, we obviously don't have specific language
22 in front of us. But we certainly have the parameters set.

23 Is there any more of the discussion about the
24 parameters on bullet number one?

25 COMMITTEE MEMBER SHEN: Could we, if we outlined

1 the fact that it has to be an approved provider, an external
2 test and the results have to be provided to the Department
3 on a yearly basis, I think we're mostly there.

4 I think where we, we haven't really outlined
5 whether, how many tests need to be forwarded to the
6 Department on a yearly basis.

7 I mean, because the laboratories will continue, I
8 would imagine by and large testing all of their analysts.
9 And I think the way we do it is we get in two batches of
10 tests a year.

11 CHAIRMAN KIMSEY: And is there, let's see, I
12 guess, I had a thought that, well, how about just all the
13 proficiency tests that are done. I mean, is that too much
14 for the Department? Or is that too much data or not
15 helpful?

16 I mean, rather than sort of say, I guess, we could
17 say, one proficiency test a year or two or -- what is the
18 current requirement?

19 COMMITTEE MEMBER SHEN: Well ultimately as for
20 proficiency sake it's going to be easier if we have buy in
21 from the approved providers to send information directly to
22 the Department. It's going to be easier, probably, to have
23 them send whatever gets sent to them.

24 CHAIRMAN KIMSEY: Right.

25 COMMITTEE MEMBER SHEN: I'm trying to figure out

1 which ones you do and do not.

2 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

3 And that would include whenever that's done. For instance

4 --

5 COMMITTEE MEMBER SHEN: Whenever it's done.

6 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

7 -- yeah, whenever you hire new staff, train new staff and
8 they take the external proficiency test, that would also --
9 yeah, whenever it's done.

10 COMMITTEE MEMBER SHEN: So then it comes down to
11 whether or not, if there should be any regulation on as to
12 how many the Department needs to receive on a yearly basis.

13 Because it could, I mean we're currently, you
14 know, currently again, I believe we're sending two results a
15 year into our CPS proficiency tests. That we are testing
16 each analyst.

17 There's going to be no requirement it doesn't seem
18 like that each analyst has to have an external proficiency
19 for the Department's desires, then is one a year enough for
20 the Department? Three a year?

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

22 Well, I'm frankly, this is Bob Haas again. I'm unfamiliar
23 with -- Kenton would you, how many tests a year, external
24 proficiency tests does you lab do?

25 COMMITTEE MEMBER WONG: Well we have different

1 providers. We have like two or three different proficiency
2 tests --

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
4 Right, but like CAP --

5 COMMITTEE MEMBER WONG: -- but I think currently,
6 I think currently all we send is the one from our lab to you
7 people, to the Department.

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
9 And not the others.

10 COMMITTEE MEMBER WONG: No.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
12 Well, Clay, I would think that we would want to evaluate,
13 get and evaluate all of them since we're not doing our own
14 proficiency testing.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 I agree. To correct Kenton. We also receive, we receive
17 the lab's results from the external providers -- they've
18 been good about submitting them. So we get both of those.

19 You know, currently we're looking at at least two
20 testing events a year. We have our PT which would be phased
21 out and we have the external providers.

22 So, and the CTS only provides two tests a year.
23 So we're not talking ten.

24 CAPS provides three.

25 So I think the simple language which was to just

1 simply submit a lab's performances in all forensic alcohol
2 proficiency tests.

3 COMMITTEE MEMBER WONG: Yeah, I would concur with
4 that.

5 CHAIRMAN KIMSEY: What's the feeling from the
6 Committee?

7 COMMITTEE MEMBER WONG: I think that's the easiest
8 and the cleanest way to do it because if you just, if it's
9 always set in motion so that the proficiency test provider
10 knows that they always have to forward the results to the
11 Department then that always gets done. Instead of, well
12 sometimes we all want this one but sometimes we want that
13 one. It's just going to be too confusing.

14 So just make it all, you know, all across the
15 board.

16 COMMITTEE MEMBER SHEN: This is Jennifer. And I
17 don't have any problem with that except for the fact that I
18 just want to make sure that if a laboratory has five
19 employees, let's say, and they send in one test a year, that
20 is fine.

21 There is no expectation that there would be at
22 least x amount of proficiency tests, external proficiency
23 tests a year for a department.

24 COMMITTEE MEMBER WONG: Right. And we can say
25 that in the wording. We can say, at least one external

1 proficiency test per analyst per year.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 I just thought of --

4 COMMITTEE MEMBER SHEN: That's an element.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

6 There's no parameters.

7 COMMITTEE MEMBER SHEN: I understand that. It's

8 possible that a department could only send out the results

9 for one --

10 MR. LYLE: A lab.

11 COMMITTEE MEMBER SHEN: -- one lab, for, excuse

12 me, for a laboratory to only send in one external

13 proficiency test.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

15 That would only be possible if they only subscribed to one,

16 external proficiency.

17 If we write the language that says, whatever you

18 subscribe to send us the results. If you only subscribe to

19 one that's correct --

20 COMMITTEE MEMBER SHEN: That works for me. I just

21 want to put in at least one. I think that's an element we

22 want to have in there then.

23 COMMITTEE MEMBER WONG: Fine.

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

25 Well, I don't think that's going to really fly when the reg

1 writing starts because all the labs do proficiency tests.

2 So, I like Kenton's suggestion better that they
3 just, all of them, go, and that will be in fact, at least
4 one. And because the providers provide either two or three.
5 It'll be two or three.

6 COMMITTEE MEMBER SHEN: If the laboratory --

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

8 So --

9 COMMITTEE MEMBER SHEN: -- chooses to take part in
10 two or three. That's my only point.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

12 Well the thing is --

13 COMMITTEE MEMBER SHEN: -- we can't do anything --

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

15 -- if the --

16 COMMITTEE MEMBER SHEN: -- for our laboratory,
17 we're going to do the same amount we've always done. So
18 there is a possibility that a laboratory would choose to
19 participate in only external proficiency test a year, I
20 think.

21 And if that's fine then that's fine. We don't
22 have to put anything in the language. If it isn't going to
23 be fine, if you are grow to expect two or three or more
24 external proficiency tests --

25 COMMITTEE MEMBER WONG: No.

1 COMMITTEE MEMBER SHEN: -- a year from a
2 laboratory, if it's not spelled out in the regulations we
3 can't ask the laboratories to do more than at least once.

4 COMMITTEE MEMBER WONG: Agreed.

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
6 Okay. I agree too. So how about this as just to throw
7 out, is that external proficiency test results shall be
8 forwarded to CDPH and that this will be a minimum of one per
9 year. Something like that?

10 COMMITTEE MEMBER SHEN: That sounds good to me.
11 I'm writing that down.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 Okay.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 And that's --

16 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
17 Remember that's from the public not from the Committee.

18 COMMITTEE MEMBER SHEN: Well, -- shall be
19 forwarded, well, provided -- we are not going to write the
20 language -- until we check with our proficiency test
21 providers.

22 CHAIRMAN KIMSEY: Right.

23 COMMITTEE MEMBER SHEN: We're looking --

24 COMMITTEE MEMBER WONG: Right.

25 COMMITTEE MEMBER SHEN: -- at -- least 20 years --

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
2 Right.

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
4 Clay, are you aware of other states that have this sort of
5 mechanism. Because the providers are national. So if
6 they're providing it to other state departments then
7 presumably the problem that Jennifer mentions is not going
8 to occur.

9 COMMITTEE MEMBER SHEN: And I have no expectations
10 that will be a problem.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
12 Yeah, I don't either.

13 COMMITTEE MEMBER SHEN: We've got to let them
14 know.

15 CHAIRMAN KIMSEY: Sure.

16 COMMITTEE MEMBER SHEN: Anything --

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Yeah, they may want more money.

19 COMMITTEE MEMBER SHEN: Uh-hmm.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Giving I-Pads to the workers so I --

22 COMMITTEE MEMBER SHEN: Federal grant money
23 (laughter).

24 CHAIRMAN KIMSEY: Any other comments on bullet one
25 (no response)? Before we go on to bullet two, we obviously

1 have our transcript but how do we anticipate getting some
2 language to review?

3 I mean, obviously we've talked about, you know,
4 various sentence structures here on bullet one but, do we
5 have volunteers or are we going to assign this? Are we
6 going to have a subcommittee?

7 What's, who's going to actually bang out the
8 actual language that will be sent around?

9 COMMITTEE MEMBER WONG: This is Kenton. I don't
10 even think the language is that important. I mean, we can
11 set down a bare bones structure in language that we think is
12 acceptable. But I think by the time it gets to the people
13 that really write the regs, I think it's all going to be
14 rewritten despite what we think anyway.

15 So, I think that the spirit and content and
16 rationale of what we're doing and why we're doing it is more
17 important than the actual verbiage. Yes.

18 CHAIRMAN KIMSEY: I would agree. But who's going
19 to, I mean, how do we -- who's going to be responsible for
20 coming up with the verbiage or the language? I mean, I
21 understand that there'll be some specifics about, you know,
22 17025 and APA, ADA or whatever, APA compliance and that sort
23 of thing that we'll have to maybe interact with in the
24 future.

25 But, is this something we're going to want the

1 Department to do to come up with the language, suggested
2 language? Or are we going to have volunteers per bullet?
3 Or are we going to have a subcommittee? What's the --

4 MR. LYLE: Bruce. I'll do the --

5 COMMITTEE MEMBER WONG: Thanks Bruce.

6 CHAIRMAN KIMSEY: Bruce, you're going to do bullet
7 one?

8 MR. LYLE: Sure.

9 CHAIRMAN KIMSEY: Great. A volunteer. So, moving
10 on to bullet two. CDPH authority to review, approve and
11 test the qualifications of persons employed by a laboratory.

12 COMMITTEE MEMBER SHEN: We need to go to a
13 different bullet (laughter).

14 CHAIRMAN KIMSEY: When it's more fresh in our
15 minds?

16 COMMITTEE MEMBER SHEN: Well I think, I mean, I
17 think, yeah --

18 COMMITTEE MEMBER WONG: You bullet picker
19 (laughter).

20 CHAIRMAN KIMSEY: Well, bullet number four should
21 be fresh in our minds. Requirements for a laboratory to
22 provide CDPH with records of its activities under the
23 regulations including notification of a laboratory, of its
24 intent to perform forensic alcohol analysis.

25 And there I believe we were thinking that, if you

1 looked at Article 4 and sort of put it back in the package,
2 that that, and I don't have Article 4 in front of me --

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
4 You will in a minute.

5 CHAIRMAN KIMSEY: -- great.

6 COMMITTEE MEMBER WONG: It pretty much already
7 exists in regs already.

8 CHAIRMAN KIMSEY: Okay.

9 COMMITTEE MEMBER WONG: So --

10 CHAIRMAN KIMSEY: So --

11 COMMITTEE MEMBER WONG: -- there's the change in
12 forms and change in address and change in personnel and all
13 those things kind of already exist already.

14 CHAIRMAN KIMSEY: Okay. So, do we feel
15 comfortable at least looking, at putting back in Article 4
16 and reviewing it for bullet number four?

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Well --

19 COMMITTEE MEMBER SHEN: Well ah, yes.

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
21 Yeah --

22 CHAIRMAN KIMSEY: Okay.

23 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
24 -- in the draft that I have in front of me, this is Bob
25 Haas again. Article 4 was completely struck.

1 So --

2 COMMITTEE MEMBER SHEN: Right.

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

4 -- so this will just need to be reinstated and then --

5 CHAIRMAN KIMSEY: And then reviewed.

6 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

7 -- and then reviewed.

8 COMMITTEE MEMBER SHEN: This is Jennifer. I do
9 not agree with that.

10 CHAIRMAN KIMSEY: Oh, okay.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

12 Okay. So tell us what you like --

13 COMMITTEE MEMBER SHEN: Well --

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

15 -- and don't like.

16 COMMITTEE MEMBER SHEN: -- you know, we talked
17 about adding one line back in as I recall. And just a
18 second I got to -- pull out, we wanted to make sure that the
19 Department had access to records.

20 But, I'm looking at Article 4 and Article 4 to me
21 is training programs. Unless I'm looking at something
22 wrong, here's it's training program approval.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

24 Again, it's Clay Larson --

25 COMMITTEE MEMBER SHEN: Am I looking at the wrong

1 thing?

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 You're looking at the exact right thing.

4 COMMITTEE MEMBER SHEN: Okay.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

6 -- the issue here is the approval of the training programs
7 used to train operators of breath instruments.

8 CHAIRMAN KIMSEY: I thought we were on --

9 COMMITTEE MEMBER SHEN: We're on bullet four,
10 aren't we?

11 CHAIRMAN KIMSEY: -- bullet four.

12 COMMITTEE MEMBER SHEN: Yes.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

14 Okay, I'm sorry.

15 COMMITTEE MEMBER SHEN: So as far bullet four --

16 CHAIRMAN KIMSEY: Records --

17 COMMITTEE MEMBER SHEN: -- Article 4 back in,
18 perhaps --

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

20 Yeah. No, no. Forget what I said. It's, you're
21 absolutely right. It's the training. It's bullet two.

22 CHAIRMAN KIMSEY: Okay.

23 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

24 Which we're not talking about.

25 CHAIRMAN KIMSEY: On bullet four then, the

1 requirements for a laboratory to provide CDPH with records
2 of its activities under the regulations including
3 notification of a laboratory of its intent to perform.

4 And we agreed on the notification.

5 Are they -- what else do we want to say about that
6 bullet?

7 COMMITTEE MEMBER SHEN: We had talked about
8 putting in, and I, personally, I'm over -- here, we had
9 talked about putting in one extra line that, we -- put in
10 one extra line saying that the records were available to the
11 Department for review.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 That's under Section 1222.2.

14 COMMITTEE MEMBER SHEN: Is that the line we put
15 in?

16 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
17 Clay, repeat that please.

18 CHAIRMAN KIMSEY: 1222 --

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 It's under Section 12, twenty, one, two, two, two -- three
21 twos. It currently reads, forensic alcohol laboratories
22 shall maintain records which clearly represent their
23 activities which are covered by these regulations.

24 And then the next sentence which was previously
25 struck, such records shall be available for inspection to

1 the Department on request.

2 COMMITTEE MEMBER SHEN: Yes.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 And the decision was to restore that. That didn't take care
5 of the notification issue but that took care of the
6 available, it partially took care of, I believe, partially
7 took care of the availability of records issue.

8 COMMITTEE MEMBER SHEN: Right. And that's what we
9 had talked about for bullet four the last time. Is that we
10 all agreed to put that sentence back in.

11 CHAIRMAN KIMSEY: Okay.

12 COMMITTEE MEMBER SHEN: And that means our records
13 are available for inspection which they were anyway.

14 COMMITTEE MEMBER WONG: Yeah. Right.

15 COMMITTEE MEMBER SHEN: So, you're right. That
16 doesn't take care of the --

17 CHAIRMAN KIMSEY: Notification. Do we have a
18 volunteer. I think we've talked about notification enough.
19 Is somebody willing to craft some language?

20 COMMITTEE MEMBER SHEN: Yeah. I'd be willing to
21 do that. But I think we need to lay out those elements a
22 little bit more.

23 CHAIRMAN KIMSEY: Okay. As I remember it, we were
24 talking about notification to perform forensic alcohol
25 analysis in the state. I guess we would need, they would

1 have to provide an address and a name and a contact person.

2 Whether or not, I think we also talked about
3 whether or not they were doing breath instrument operator
4 training.

5 COMMITTEE MEMBER SHEN: I don't think we want to
6 add that in here.

7 CHAIRMAN KIMSEY: Okay.

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
9 It looks like it would be another article?

10 COMMITTEE MEMBER SHEN: Yes.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
12 Yes?

13 COMMITTEE MEMBER SHEN: Well, that's what -- yeah.
14 That's why I think we solved some of our problems writing
15 in that sentence. But I do believe this delete requires
16 another paragraph or something.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Well it doesn't seem to fall under, records, which is
19 Article 8. So, I would think that it would be --

20 COMMITTEE MEMBER SHEN: This might be a --

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 -- a different article.

23 COMMITTEE MEMBER SHEN: -- sure.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Article 4 is training --

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

2 What's that Clay?

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 There was a suggestion here that maybe Article 4 would be
5 appropriate. But Article 4 is titled, Training, and I don't
6 think that would be an appropriate section.

7 CHAIRMAN KIMSEY: It may need --

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

9 Well I --

10 CHAIRMAN KIMSEY: -- it may need to be its own
11 section or, own article.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

13 Yeah. I think so. Because, at least from, I'm kind of
14 thumbing through it now and I don't see an --

15 COMMITTEE MEMBER SHEN: I don't --

16 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

17 -- appropriate place to put it.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

19 I think previously it was in Article 3 which was called,
20 licensing procedures, the name has to be changed.

21 But there is a section, there's a couple of
22 sections under Article 3, maybe most pertinent is 1217.2.
23 It talks about application forms.

24 So basically, if it was rewritten to cover this,
25 it would require labs to, I think, capturing the same

1 language using forms furnished by the Department. They
2 would specify the information which was contained on the
3 form.

4 The laboratory would notify the Department of its
5 intent to perform forensic alcohol analysis. And we would
6 --

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
8 Yeah. Clay, you're absolutely right. It just requires
9 deleting the references to licensing, a lot of deleting.
10 But that would be an appropriate, it seems an appropriate
11 place to insert it.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 The "lot of deleting" comment got a lot of head shaking
14 here.

15 COMMITTEE MEMBER SHEN: Well, we --

16 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
17 Well it could also go into Article 2 for that matter. I
18 don't see, I don't know, I mean, I'm not a regulator writer,
19 regulation writer, but in the requirements for forensic
20 alcohol laboratories just having a requirement to notify the
21 Department.

22 CHAIRMAN KIMSEY: I mean, where it goes may be
23 beyond our capability, but --

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

1 CHAIRMAN KIMSEY: -- what it says --

2 COMMITTEE MEMBER SHEN: Well we --

3 CHAIRMAN KIMSEY: -- is probably what we should
4 concentrate on.

5 COMMITTEE MEMBER SHEN: Yeah. And we should
6 attempt to figure out where we want to stick it actually. I
7 actually agree that Article 2 would be a good place to put
8 it.

9 We went to a lot of effort to delete Articles 3
10 and 4. So I'm kind of hesitant to just throw them back in
11 there again (laughter).

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 I hear you.

14 COMMITTEE MEMBER SHEN: Article 2, I mean, that
15 certainly could be a requirement under, you know -- even the
16 first one, authorization requirement, you can call that
17 something completely different but we could put in the
18 verbiage right there, 1215 (a) which currently does not
19 exist.

20 Call it, notification requirements, for instance.

21 CHAIRMAN KIMSEY: Right. And so, what do we want
22 the Department to be notified of?

23 COMMITTEE MEMBER SHEN: Well, I think we all agree
24 that we want to be, that we should notify the Department
25 that we are actually doing alcohol analysis.

1 CHAIRMAN KIMSEY: Right.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 -- as analysis --

4 COMMITTEE MEMBER SHEN: Blood alcohol -- And I
5 think we talked about the fact that I think it's appropriate
6 to notify the Department when we are no longer doing alcohol
7 analysis.

8 MS. BUTENKA: I've never seen it before.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 Jennifer, you said, basically, in 1216 (a)?

11 COMMITTEE MEMBER SHEN: Yes.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 Yeah. I like that too.

14 COMMITTEE MEMBER SHEN: So we'll call it,
15 notification requirements and we'll notify the Department.
16 Do we want to put in there that we have to -- do we want to
17 put in there that we notify the Department of A, B and C or
18 do we want to put in there that we notify the Department
19 using a Department-specified form?

20 CHAIRMAN KIMSEY: Well, the form could contain A,
21 B and C or whatever. I mean, I mean, obviously, I guess we
22 would need a name and address and a contact or -- what are
23 we, what does the Department need?

24 COMMITTEE MEMBER SHEN: Name, address and contact
25 person --

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
2 I think you'd also have a list of personnel and I believe
3 you'd have skipped over it, but, regarding the approval of
4 breath instrument operator training programs. I think that
5 if that's an activity the Department is still going to
6 exercise some approval; have a listing of lab's proposed --
7 breath instrument alcohol operator training program.

8 COMMITTEE MEMBER SHEN: This is Jennifer. I, you
9 know, I think that we're, that's something we're going to
10 have to discuss. But I think for this particular element
11 we're looking at this notification.

12 So it may be that we want to notify here that
13 we're, that a laboratory is -- fluid and breath analysis. I
14 don't know.

15 But, I think to try to get the forensic, the
16 operator training manual on this portion is not, not going
17 to fit properly.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 You're not going to --

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
21 This is Bob Haas. I agree with you Jennifer. I think that
22 we have an entire article here on training of personnel that
23 that's would be appropriate place for the breath instrument
24 operator.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 I think if the Department is going to retain a role in
2 approving breath instrument operator training they're going
3 to have to know which, what labs are performing breath
4 instrument operator training.

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
6 Well yeah. You're right. Absolutely, Clay. And I think
7 in terms of notification that, yes, the Department should be
8 notified of laboratories doing breath instrument analysis.

9 CHAIRMAN KIMSEY: Is it just the two --

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
11 But, but --

12 CHAIRMAN KIMSEY: -- categories then --

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 -- the training portion of that belongs in its own article
15 in the training.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 I agree. But we're talking about the notification
18 requirements and I think --

19 CHAIRMAN KIMSEY: Either that, or we assume that
20 everyone is doing that's doing forensic alcohol analysis is
21 doing breath. Either that --

22 MS. BUTENKA: Can we assume it?

23 CHAIRMAN KIMSEY: -- or we say it's fluid or
24 breath or fluid, breath and whatever.

25 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

1 Is that indeed the case? I don't know the answer.

2 MS. BUTENKA: No it's not.

3 COMMITTEE MEMBER SHEN: I think it's reasonable to
4 notify the Department that we will be, the types of analyses
5 that we are doing as far as, very basically, fluid analysis,
6 breath analysis or some other things?

7 Tissue analysis or what?

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

9 But, don't some jurisdictions do just fluid and contract
10 out? Or do just breath and contract out the blood analysis?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 There's not much activity in the coroner's lab to do breath
13 analysis (laughter).

14 COMMITTEE MEMBER WONG: Hee, ha, ha.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

16 Well, yeah, yeah, there are labs --

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

18 Is that the coroner's breath they're analyzing (laughter)?

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 Yeah, right. There are labs that -- let me just, correct
21 Jennifer, labs -- or at least, my understanding, labs don't
22 do breath alcohol analysis.

23 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

24 He's right.

25 CHAIRMAN KIMSEY: It's just training.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
2 They provide training. So I don't think you're just, I
3 think in reference to them doing fluid and breath analysis
4 would be under the clarity issues because then they never do
5 breath analysis.

6 So, they do do training. And I think that would
7 be by notification of their intent to do training if this is
8 a new lab. Or a change in that training if this is an
9 existing lab.

10 It would include, I think, the name of the
11 instrument, that is about all you'd need.

12 COMMITTEE MEMBER SHEN: The laboratories, well you
13 know, we're talking a lot of semantics here but the
14 laboratories that provide a course for breath programs,
15 training -- all in the breath program.

16 So, I think it's important to note that a
17 laboratory will be supporting a breath program as well as
18 providing a fluid program.

19 So you can, you know, parse those words any way
20 you want. I think you know where I'm going with that.

21 But I think for this particular element that's all
22 we need, -- the laboratory is doing the work or the back of
23 the laboratory it stops, the name, the address, the contact
24 person and what type of analyses will be -- by that
25 department.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
2 Well, the labs that currently are providing training in
3 instrument A decides to switch to instrument B, how would
4 the Department be informed of that?

5 COMMITTEE MEMBER SHEN: I don't know. Currently,
6 they're not being informed of it.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 No, currently they're required to submit reports of change.
9 And I believe they're following the regulations, in the law
10 they are required.

11 I think for scofflaw labs, but if the labs are
12 following the law -- yeah they are.

13 COMMITTEE MEMBER SHEN: Are you talking about
14 changing to a completely different type of analyses or just
15 an instrument, like a new breath instrument.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 A new breath instrument. They'll do training on it. Any
18 change in the training --

19 COMMITTEE MEMBER SHEN: A new type of breath. So
20 if you have a 50 of one type of instrument and you get a
21 51st, that's not what you're talking about.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 No.

24 COMMITTEE MEMBER SHEN: Okay. Again, I don't know
25 that this is the place to house, go into a lot of detail

1 other than the fact that the Department needs to be notified
2 that an alcohol, that a laboratory is providing this type of
3 analyses.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 I think it would be incomplete without a statement of what
6 instrument they were providing training for.

7 You don't have to have an inventory of the number
8 of instruments. They don't have to inform the Department if
9 they went from 50 to 51.

10 But if they went from -- changed the training in
11 any substantive way or they changed instruments --

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 Clay, this is Bob. I have a suggestion. Why don't you
14 draft the notification language and submit it to the
15 Committee for comment.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Okay.

18 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
19 Is that acceptable?

20 CHAIRMAN KIMSEY: Well, I think Jennifer had
21 mentioned she would be willing to write it. I mean, whoever
22 writes it I think needs to understand sort of the parameters
23 that we're agreeing on.

24 And we haven't quite gotten to agreement yet with
25 regards to what's going to be in the notification.

1 And the issue seems to be about, you know, breath,
2 I mean we think agreed to include breath alcohol analysis.
3 I think Clay would like to have the instrument described.
4 Is that correct Clay?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Yes, listed. I don't know describing it. But, listed, yes.
7 I mean, it's got to be an instrument that's on the
8 conforming products list; enough information to identify
9 that. And then follow up with the details of the training
10 would be a separate submission but basically the instrument
11 used.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 Jennifer, do you have a comment?

14 COMMITTEE MEMBER SHEN: Now, so we're looking at
15 notifying that a department is providing the work but the
16 contact person, an address, a list of persons involved in
17 the analysis, what kind of analyses we'll be providing or
18 supporting and what instruments will be being used.

19 CHAIRMAN KIMSEY: Comments on that list?

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 I actually don't anticipate we'll be getting instruments for
22 fluid analysis.

23 CHAIRMAN KIMSEY: Well, the bullet mentions
24 forensic alcohol analysis.

25 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

1 Which would include breath analysis.

2 COMMITTEE MEMBER SHEN: Only a list of the breath
3 instruments?

4 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
5 Is that what I'm, that sounds like what I'm hearing from
6 Clay. Is that correct?

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 Well, I mean, you certainly have approval authority. So
9 we'll currently -- put back to authority for breath
10 instrument operator training.

11 We have apparently decided we don't want to give
12 the Department any approval authority over methods, over
13 the training of forensic alcohol analysts.

14 If you decide to do that then the instruments used
15 become more germane but I'm just thinking of these areas
16 we're putting back here.

17 And one of the areas we're putting back is
18 approval of training procedures. So, training procedures
19 are related to specific breath instruments.

20 COMMITTEE MEMBER SHEN: This is Jennifer. I, is
21 there anywhere in here that, since you all know this section
22 better than I, that discusses the fact that you must use
23 instruments that are on the approved, conforming list?

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 There is currently and I would argue that the revisions

1 provided by the Committee don't really state that any
2 longer.

3 But in the current regulations there is.

4 COMMITTEE MEMBER SHEN: And we took that out?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

6 It's not in the section.

7 COMMITTEE MEMBER SHEN: Because if it says in here
8 that we have to use instruments that are on the, on this
9 particular list, then that should cover it as far as I'm
10 concerned.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 But you're not going to be providing training for all 118
13 instruments. I assume you're not. I don't want -- so, I
14 assume you're not going to be providing training for all 120
15 instruments on the CPL.

16 So, we, the department, interested in the
17 instrument or instruments that the lab will be providing
18 training to operators in their area.

19 COMMITTEE MEMBER SHEN: I understand that but for
20 this particular portion, we are talking about notifying the
21 Department that a laboratory is going to be performing or
22 going to be involved in forensic alcohol analysis.

23 And I think it should be very short and to the
24 point. I think that trying to incorporate in whether we do
25 or do not give the Department oversight of the operator

1 training for the breath instruments is not relevant to this
2 particular point that we're trying to do right now.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 I'm going to argue that it's completely relevant. If we get
5 a notification from Acme Labs, new laboratory, that they
6 intend to provide training for AlcoSensor 4, we will fully
7 anticipate that we will receive with that package or
8 something in the very near future a summary of that
9 training.

10 If they indicate that they are not going to do any
11 breath instrument operator training we won't expect any
12 summary of training.

13 I actually don't see there's a lot of liability
14 for the labs here. It's just that, it's just an activity
15 which the Department will apparently retain some oversight
16 role.

17 And that activity should be captured, where it's
18 possible, in the notification.

19 CHAIRMAN KIMSEY: And this is Paul. How does the
20 rest of the Committee feel? It really comes down to, do we
21 want to have under notification an inclusion of the breath
22 alcohol analysis instrument or not?

23 And we've obviously heard from Jennifer and Clay.
24 And I appreciate their perspectives but how does the rest
25 of the Committee feel?

1 MR. KOENITZER: This is Dave from the public side
2 over here in Sacramento. I think what Clay is looking for
3 is more or less a flag so that you'd know something is going
4 on. Other than that I don't know that you'd need to put in
5 the notification.

6 I think, isn't that what you're looking at Clay?
7 Is you want some sort of a flag so that you guys know to
8 look for an updated procedure for training of officers?

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
10 I think that's correct, yeah. We'll not make a decision
11 based on that -- yeah.

12 COMMITTEE MEMBER SEDGEWICK: This is Paul
13 Sedgewick in San Diego. My major question, my concern here
14 is, what is the Department going to do with all of this
15 information?

16 Talking about approval, what point?

17 CHAIRMAN KIMSEY: Well, I think the notification,
18 you know, is really just notification. I don't know that
19 the Department is not going to be approving anything, at
20 least based on notification.

21 It's just sort of letting the Department know who
22 is out there and a little bit about what they're doing.

23 Further on down the road we are talking about, you
24 know, the breath instrument operator training issue. But
25 that, right now this is just about the notification and

1 what's going to be contained in that.

2 I don't know, if it's helpful to the Department to
3 know about the instrument, I'm not sure that's an overly
4 burdensome thing for the laboratories.

5 But, you know, that's obviously the bureaucratic
6 perspective.

7 COMMITTEE MEMBER SEDGEWICK: This is Paul
8 Sedgewick again. The Department is asking for notification
9 but my question now is, is the same. What are they going to
10 do with this?

11 CHAIRMAN KIMSEY: Well, we'll know who's operating
12 a laboratory.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 I'd rather hear from the other Committee members. I'm
15 probably doing more talking than I should. This presumes
16 that the bullets that we haven't gotten to we skipped over.
17 But the training bullet with respect to breath test
18 operations -- if the decision there is made that falls on
19 the side of giving the Department an oversight and approval
20 role regarding breath instrument operator training.

21 If that doesn't happen then I would agree that
22 there's no need to provide information. So maybe we should
23 take these in order.

24 CHAIRMAN KIMSEY: I mean, Paul, this is Paul in
25 Richmond. Are you concerned that we shouldn't be doing the

1 notification?

2 COMMITTEE MEMBER SEDGEWICK: I think if, there's
3 certainly no harm in telling the Department who is doing the
4 work. But my question is, what is the Department going to
5 do with that information? Why do they want that
6 information?

7 CHAIRMAN KIMSEY: I guess just to know who is
8 performing forensic alcohol analysis in the state. I mean,
9 is there something that you think the Department is going to
10 do with the information that you're concerned about? Or --

11 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick, and
12 no, there's not.

13 CHAIRMAN KIMSEY: So, did I hear earlier Jennifer
14 that you had volunteered to write the language for bullet
15 number four?

16 COMMITTEE MEMBER SHEN: Yes you heard that.

17 CHAIRMAN KIMSEY: So I don't know that we got you
18 the final perspective from the Committee on including
19 whether or not to include the specific instrument in that
20 notification if the entity is going to do forensic alcohol
21 analysis.

22 COMMITTEE MEMBER SHEN: Well, it's my opinion that
23 this should be fairly brief and it's just a notification of
24 the status of the laboratory, really.

25 CHAIRMAN KIMSEY: Okay.

1 COMMITTEE MEMBER SHEN: So I can write it without,
2 I don't think it's appropriate to include here a list of
3 breath instruments in this particular -- I mean, we could, I
4 suppose, say, that a list of instruments shall be provided
5 to the Department or something like that.

6 But I just don't think that's what this particular
7 thing is about. We want to notify --

8 CHAIRMAN KIMSEY: Right.

9 COMMITTEE MEMBER SHEN: -- the Department. So the
10 Department is not operating in a vacuum. The Department
11 knows who is, in fact, providing the service.

12 Please, be pretty brief. That's my feeling. So I
13 can write that in a pretty brief format and we can, you
14 know, hash that next time.

15 CHAIRMAN KIMSEY: Why don't we do that. Why don't
16 you go ahead and write it up. You obviously aren't going to
17 forget this discussion. And we can talk, we can all think
18 about it a little bit.

19 And we might see how some of these other bullets
20 may play into, maybe in a more appropriate place or
21 something for this type of information.

22 But go ahead with, as you described. Any other
23 comments about bullet number four?

24 So, it's a quarter to one and we have two bullets
25 to go. Any feeling about whether we want to tackle bullet

1 number two which is, authority over persons -- bullets two
2 and three. I'm sorry, what did I say? Oh, two and three.

3 And three is, authority to review and approve
4 training programs which we're pretty much limiting to breath
5 instrument operator training.

6 I think that one, since we talked about that one
7 today a bit more, it's probably a little more fresh in our
8 minds.

9 And, so, CDPH authority to review and approve
10 training programs intended for persons to qualify under the
11 regulations, breath instrument operator training. Do we
12 have a volunteer to shepherd this language along?

13 COMMITTEE MEMBER WONG: I'll do it.

14 CHAIRMAN KIMSEY: Okay, Kenton has volunteered.
15 Now, was there a particular article that this, this was, is
16 this our famous Article 4 yet? Or is that -- no, that was
17 training which is the one above.

18 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
19 No, this is training.

20 CHAIRMAN KIMSEY: No, this is training. Okay.
21 So, Article 4 was training I believe. So if we have, and
22 we, I think it was the consensus of the Committee that the
23 training approval would be limited to the breath instrument
24 operator training.

25 COMMITTEE MEMBER WONG: Uh-hmm.

1 CHAIRMAN KIMSEY: So, I don't know, we can
2 certainly give Kenton that direction and he can look at
3 Article 4 and come back to us. Or we can have any further
4 discussion.

5 COMMITTEE MEMBER SHEN: This is Jennifer. My
6 question is, if we're going to limit it to the breath
7 operator training, is there somewhere in the regs portion
8 that we could put that instead of reinserting Article 4?

9 CHAIRMAN KIMSEY: Possibly. That's sort of a, you
10 know, a reg writing decision. Maybe if we just had
11 language, I mean, obviously we don't have to call, I mean,
12 if it comes out of Article 4 we can call it whatever we
13 want.

14 But I was just thinking that Kenton might look at
15 Article 4 and find language that would help come up with
16 something specific for breath instrument operator training.

17 And then if it's under, we might incorporate it as
18 a section or a sub-article under, you know, the breath
19 alcohol analysis -- instrument, excuse me, yeah, breath
20 alcohol.

21 But anything sort of, any sort of direction we
22 want to give Kenton with, it seems fairly straight forward
23 unless there's some, unless Kenton has some questions or a
24 Committee member wants to add in something more specific.

25 COMMITTEE MEMBER WONG: Well, the Department had

1 in the past already been approving of what was taught in the
2 four hour course to the officers on specific
3 instrumentation.

4 So, it's --

5 CHAIRMAN KIMSEY: It's pretty straight forward, I
6 think, yeah.

7 COMMITTEE MEMBER WONG: Yeah.

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
9 You just have to maintain that.

10 CHAIRMAN KIMSEY: And then we can obviously
11 discuss it again when we have some written language.

12 Any other comments though on bullet number three?

13 COMMITTEE MEMBER SHEN: No, I guess not. It looks
14 like the, well, I guess so, it looks like the, what needs to
15 be taught and included are already outlined in here.

16 So it's just a matter of, probably, of inserting
17 somewhere a line that says, you know, that this curriculum
18 shall be presented to the Department for approval or some
19 such thing, if we even want to go that way.

20 CHAIRMAN KIMSEY: No, I would agree. I think the
21 language may be there. It just may be that we're going to
22 put it somewhere else. But, you --

23 COMMITTEE MEMBER WONG: Right.

24 CHAIRMAN KIMSEY: -- know, that's something we can
25 talk about in our next meeting, our 20th meeting.

1 So, do you feel comfortable with that Kenton --

2 COMMITTEE MEMBER WONG: Uh-hmm.

3 CHAIRMAN KIMSEY: -- at this point?

4 COMMITTEE MEMBER WONG: Uh-hmm.

5 CHAIRMAN KIMSEY: Okay. So, on to bullet number
6 two. CDPH authority to review, approve and test the
7 qualifications of persons employed by a laboratory. And as
8 I remember this was going to be more of a reporting function
9 that the laboratories would report to the Department the
10 staff that they had.

11 And the, there's some information on what their
12 qualifications are, I believe. Do we have somebody who
13 wants to shepherd this bullet along from the Committee?

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Comment from the public. I wasn't as sure, I wouldn't, I
16 don't know if I agree with your characterization that this
17 would be a reporting function.

18 I think the discussion to date has been, been on
19 point in response to the bullet that refers to the concern
20 aired regarding removing the Department's authority to
21 review and approve.

22 So I'm not sure that we came out of that with the
23 conclusion that the labs can simply report. And I don't
24 know, I don't know that we -- we certainly had a vote on the
25 written examination and there was not a majority of the

1 Committee didn't favor that. But, on the issue of the
2 Department's evaluation of a proficiency test, so that would
3 be, I wouldn't, I don't think that would be a reporting
4 activity.

5 COMMITTEE MEMBER SHEN: This is Jennifer. I
6 wouldn't mind doing this one either if no one else wants to
7 do it. I think we're looking at providing information about
8 the staff, who is or isn't, who is, in fact, doing the,
9 doing the work, what kind of qualifications that person has
10 to probably, I would assume, to include the education and
11 the type of training that person has gone through, the type
12 of internal, external proficiency tests et cetera.

13 And written examinations, mid course, whatever it
14 is that we decide. So we would be providing to the
15 Department a, I said memo, you know, to be a reporting
16 format of some kind, that this person has these
17 qualifications, has completed these things and in addition
18 to that, we would be providing to the Department through our
19 proficiency testing program, an external proficiency test
20 for the Department to review.

21 So I think we would meet this bullet by allowing
22 the Department to do the evaluation of the proficiency tests
23 and providing the Department a listing of the qualifications
24 of that person.

25 CHAIRMAN KIMSEY: And so, you were not expecting

1 then, you know, a review and approval from the Department.

2 COMMITTEE MEMBER SHEN: Well, if we want to say
3 that the evaluation of the proficiency test is review and
4 approval then that works for me.

5 CHAIRMAN KIMSEY: Okay.

6 COMMITTEE MEMBER SHEN: But I think what I would
7 like to get away from is submitting someone's transcripts or
8 written examinations et cetera for the Department to review
9 then evaluate and decide whether that person is someone we
10 can employ doing that type of work.

11 I would like to provide the Department the
12 information that outlines what that person has in his or her
13 background and what they've done as far as training and then
14 give the Department the option or obviously the ability to
15 evaluate a proficiency test.

16 CHAIRMAN KIMSEY: And then the laboratory would be
17 responsible for, I guess, maintaining the records of things
18 like transcripts or whatever that showed those
19 qualifications.

20 COMMITTEE MEMBER SHEN: Correct. And in Title 17
21 it does, it will outline, I think, in educational
22 requirements.

23 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
24 Yeah, this is Bob Haas. Thanks for bringing that up
25 because I'm now equipped with the draft here. And you're

1 absolutely right, Jennifer that Article 2, 1216.1 starting
2 with about .1 (e) does have these requirements.

3 And it's, and it already includes the practical
4 laboratory demonstration of the analyst's ability to perform
5 forensic alcohol analysis.

6 So -- and then 1216.1 (e) (3) is also successfully
7 complete a competency test comprised of at least four
8 samples et cetera.

9 So, this is already there. At least, from my reading
10 of it.

11 COMMITTEE MEMBER SHEN: So it would be, I guess my
12 thought would then be that we are required to follow Title
13 17. So the analysts have to complete all of those
14 requirements. And then the laboratory would have to have
15 documentation to show that that, in fact, occurred.

16 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
17 Exactly.

18 CHAIRMAN KIMSEY: Any comments from the Committee
19 on the direction Jennifer wants to go?

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 I trying to think about how all this works out in terms of
22 details. So we're going to require a lab to obtain an
23 external proficiency test for a, for the candidate and
24 usually nominated for forensic alcohol analyst.

25 Would that be the same proficiency test because,

1 I'll ask the question, would that be the same proficiency
2 test that the other 15 people in the lab are also analyzing?

3 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

4 Well, Clay, this is Bob again. In 1216.1 (e) (3) it's the,
5 the text currently reads, competency test. And that could
6 easily be changed to external proficiency test.

7 That would satisfy, I think, what you're bringing
8 up. I, reading between the lines of what you just said, and
9 correct me if I'm wrong, is that, you know, staff member, a
10 new staff member or, you know, or any staff member takes the
11 same test as ten other analysts in the lab and then they,
12 you know, confirm that they got it correct. And that
13 satisfies the requirement.

14 I don't think that any legitimate lab would really
15 go that route but you want to prevent the possibility of
16 occurrence. Am I reading this wrong?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

18 I think from the previous discussions and I think the
19 transcripts will capture this; we had discussions that the
20 competency tests which currently under ASCLD/LAB guidelines
21 can be an internal test.

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

23 Exactly. And I'm suggesting that it go to the external one
24 which I think we already agreed was acceptable.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 And let's make sure the Committee agrees with that. In
2 other words, in addition to this there would be an
3 additional test that would be an external test? Is that
4 correct? Is that --

5 COMMITTEE MEMBER SHEN: Under 1216.1 (a) (3) it
6 says, meeting the proficiency test and requirements
7 specified in Health and Safety Code Section 100702.

8 It does specify an external test.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 There we go.

11 CHAIRMAN KIMSEY: Okay.

12 COMMITTEE MEMBER SHEN: We're stuck in the wrong
13 spot here, so --

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 It actually doesn't, it depends on how you read it. I
16 actually think that's the Health and Safety Code. And in
17 general statutes are written with less detail with the
18 expectation that regulations would clarify and make specific
19 those statutes.

20 But that statute, requires two things are -- it
21 refers to a laboratory proficiency test and it refers to an
22 annual proficiency test taken by examiners once we decide
23 what examiners means but --

24 So, it doesn't appear, and ASCLD and it also
25 references the ASCLD/LAB proficiency testing guidelines.

1 And ASCLD clearly permits competency tests to be, and even
2 be annual proficiency tests to be internal tests.

3 So, you can't rely totally on either the Health
4 and Safety, I don't believe, the Health and Safety Code or
5 ASCLD/LAB definitions -- I think that you're going to have
6 to write.

7 CHAIRMAN KIMSEY: So the issue is, what type of
8 proficiency tests that the person doing breath instrument
9 operator training was going to be required to have.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 I'm not talking about breath instrument operator training at
12 all. We're talking about qualifications of individuals now
13 at one level, just analysts.

14 CHAIRMAN KIMSEY: Oh, okay. So whether or not
15 those will be internal or external proficiency tests.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Right.

18 COMMITTEE MEMBER SEDGEWICK: This is Paul
19 Sedgewick. If we're talking about qualifying trainees, if
20 you call them qualified samples or anything except
21 proficiency samples or competency test, but at the end of
22 those training there always has to be some kind of an
23 essentially final, final exam which is a qualifying
24 competency test.

25 And it doesn't really matter whether external or

1 internal.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
3 No, I think it was, Clay Larson again. I think it matters
4 to the Department, and you're correct. Under ASCLD/LAB
5 there's no requirement that in order for a person to do, to
6 conduct analysis in the lab to ever be, ever tested by an
7 external entity. There's absolutely no requirement under
8 ASCLD/LAB.

9 Again, in regards to individuals. The Department
10 though had a requirement that in order to be approved by the
11 Department to perform forensic alcohol analysis and the only
12 way you can perform forensic alcohol analysis is by having
13 that approval. That individual, at least on a one-time
14 basis would have to complete an external proficiency test by
15 an independent organization -- in the state, Department of
16 Public Health and demonstrate appropriate accuracy,
17 precision in the analysis of those test samples.

18 That's what we have now to respond to the bullet.
19 -- certainly not what we have with the proposed revisions
20 proposed by the Committee and we're responding to the bullet
21 to address some concern about that.

22 COMMITTEE MEMBER SHEN: If we were to add under, I
23 finally got to where I needed to be here, 1216.1 (e) (3),
24 and a man must successfully complete a competency test
25 comprised of at least four samples that must A, B, C, D and

1 E, we certainly could -- I have absolutely no issue
2 whatsoever with having an analyst complete an external
3 proficiency test prior to going, prior to doing case work.

4 CHAIRMAN KIMSEY: Yeah, that seems to be on
5 100702. It says, guidelines for proficiency test and
6 testing of laboratory examiners, written procedures. B, it
7 says, each laboratory shall, oh, but it's the laboratory,
8 it's not the individual.

9 COMMITTEE MEMBER SHEN: I think you kind of have
10 that. I mean, I think that we want to have our analysts --
11 prior to being --

12 CHAIRMAN KIMSEY: Sure. It makes sense.

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 Are we back to modifying 1216.1 (e) (3) to include an
15 external proficiency test? Is that what I'm hearing?

16 COMMITTEE MEMBER SHEN: If that, I mean, if that
17 solves our other problems then I think that we could add
18 another sentence in there pretty easily.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 Yeah, because as Paul just pointed out 100702 just refers
21 to the laboratory not to the individuals and to the
22 individual analyst.

23 COMMITTEE MEMBER SHEN: We would add one extra
24 line in there about in addition, the analyst would complete
25 one external proficiency test.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

2 Well, now I'm confused because I, and I'm not an expert at
3 this but 100702 (c) then says, each examiner shall
4 successfully complete at least one proficiency test
5 annually.

6 Now it, true it doesn't say that that's an
7 external proficiency test but, again, in terms of
8 interpreting 1216.1 (a) (3) with meeting the proficiency
9 testing requirements in H & S Code 100702 we could interpret
10 that that each examiner as they're calling the analysts,
11 have to participate in an external proficiency test.

12 There's an ambiguity there it seems to me in the
13 statute.

14 COMMITTEE MEMBER SHEN: I actually think that
15 it's, I don't see that ambiguity there but I think our issue
16 in this particular instance, I believe, is that looking for
17 a way for the Department to evaluate a new analyst.

18 So we would want to ensure, I think, that an
19 analyst completes an external proficiency test prior to
20 doing case work.

21 If we simply follow things as written in 100 in
22 the, you know, the statute as written then we could have
23 analyst that was trained, started to work and at some point
24 during that year -- external proficiency test. But not
25 necessarily one prior to starting case work. I guess it

1 comes down to whether or not we want to make that
2 distinction.

3 CHAIRMAN KIMSEY: I think we do. I think you want
4 to have an external proficiency test before you're doing
5 case work. It makes sense to me. You just want to know
6 that these people are qualified.

7 COMMITTEE MEMBER SHEN: I agree. And if that
8 proficiency test is sent to the Department then the
9 Department has a method for evaluating the new analyst.

10 CHAIRMAN KIMSEY: Correct.

11 COMMITTEE MEMBER SHEN: I think, again, it takes
12 us back to adding a line or two into 1216.1 (e) (3).

13 CHAIRMAN KIMSEY: Okay. Well, we also agree on
14 the direction depending on where it goes that we may get
15 some additional guidance or some suggestions. Any other
16 comments or discussion on bullet number two?

17 COMMITTEE MEMBER SHEN: Well, since I'm writing
18 that, that I'm -- we're going to go, we'll go with the
19 assumption that we're going to add some verbiage in
20 somewhere that an external proficiency test is required
21 prior to case work.

22 CHAIRMAN KIMSEY: Okay.

23 COMMITTEE MEMBER SHEN: And so that you can go
24 back to what we talked about for bullet two that, it's a
25 reporting function largely with the Department doing the

1 evaluation based upon that proficiency test.

2 CHAIRMAN KIMSEY: Okay. Any other comments from
3 the Committee on bullet number two? So I have written in my
4 notes here that Bruce Lyle was going to work on the language
5 for bullet one. Jennifer bullet two. Kenton bullet three.

6 And Jennifer again on bullet four.

7 COMMITTEE MEMBER SHEN: That's -- double it.

8 CHAIRMAN KIMSEY: I don't hear any (laughter), any
9 takers. Obviously, we're the week before Thanksgiving.
10 What's realistic for you all. I mean I think obviously we
11 would collect the language and get it back out to the
12 Committee -- obviously I think the Committee needs, you
13 know, a couple of weeks to look at it before we have another
14 meeting to review it.

15 So, it's in my mind I don't see how we're doing
16 this before the holidays. So we're looking at maybe, does
17 mid January or early February -- for a meeting that would
18 mean that we would probably want to have your language by
19 the first of the year.

20 COMMITTEE MEMBER SHEN: I don't, I mean, it
21 shouldn't take long to write those bullets. I think January
22 versus early February.

23 CHAIRMAN KIMSEY: Okay. Well if you folks can get
24 us your language pretty much as soon as possible then we can
25 look at the middle of January for another meeting.

1 And we'll send out a notice, you know, to try and
2 get everybody's calendar coordinated for maybe the second
3 through the third week of January sometime, shooting for the
4 middle of January.

5 But if you can get your language to the Department
6 and I would go ahead and send it to -- that's a good
7 question. Everybody has, I guess, Bob Haas's or Clay's
8 email or my email address or sent it to all three of us.
9 But what email address is everyone have access to most
10 easily?

11 COMMITTEE MEMBER SHEN: I have all of those.

12 CHAIRMAN KIMSEY: Well why don't you send it to
13 Dr. Haas as the, as the lab chief. Of course, he's retiring
14 here. Why don't you send it to me (laughter). I'm not
15 retiring anytime soon. Not that I don't want to.

16 So, yeah, Paul, it's paul.kimsey@CDPH.ca.gov, and
17 you might cc anyone, someone like Clay or any other email
18 address you have in the Department, just so nothing gets
19 lost.

20 I would anticipate then that we'll have a meeting
21 in January. We'll sort of finalize the language. That
22 would mean that we would, the Committee would be ready to
23 send another package to Agency that would trigger the 90 day
24 review.

25 And that package, we can talk about it then. But

1 I would think that it might be, the package that we sent
2 first with a cover talking about these, you know, additions
3 and letting them know that it's going to trigger the 90 day
4 review, something along those lines.

5 But anyhow package would probably, you know, go
6 from the Committee to Agency sometime by the end of January
7 it sounds, it seems like. That's good news (laughter).

8 COMMITTEE MEMBER SHEN: Yeah --we had a letter
9 addressing the changes that we've made to accommodate, at
10 least in our minds, the questions.

11 CHAIRMAN KIMSEY: Okay. Other comments or
12 questions from the group before we sign off for this, our
13 19th meeting?

14 MS. BUTENKA: I have a question.

15 CHAIRMAN KIMSEY: You want to identify yourself.

16 MS. BUTENKA: Natalie Butenka. Just out of
17 curiosity, bullet number two, you saying that it's not only
18 reporting, it's also evaluation procedure. What happen if
19 we evaluate the results of proficiency testing and we come
20 to conclusion that they beyond their acceptable limits?

21 COMMITTEE MEMBER SHEN: We have a problem.

22 MS. BUTENKA: Yeah I know but, but what would be
23 the concrete action of the Department as you understand it.

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
25 This is Bob Haas. I think that we are, this is related to

1 the A.G. opinion that is currently being worked on by the
2 Department of Justice.

3 And this has to do with enforceability. And it
4 actually has to do a lot with what Paul Sedgewick was saying
5 earlier. You know, what is notification, what's approval?

6 This is not really answerable now. But I think
7 certainly when the regulations are being written and are, a
8 need to be APA compliant that these, that sort of issue will
9 need to be addressed comprehensively.

10 CHAIRMAN KIMSEY: Other comments?

11 COMMITTEE MEMBER SHEN: Yeah, that is a good
12 point. You know, we're not going to be able to not address
13 that.

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

15 You're absolutely right, we're not. And, in fact, ever
16 since the licensing was demolished six years ago there's
17 been ambiguity about what are the, what is enforceable.

18 This hasn't really been an issue because the
19 laboratories have been compliant and understand that, and
20 Jennifer you've made this point many, many times over, that
21 it's in your own interests to be accurate.

22 So, corrective action is part of every
23 laboratory's, you know, standard operating procedures.

24 So, this, and if you will, the, just the notion
25 that the Department doesn't think that the, in this case

1 let's say, a result, a test result is, quote, unquote,
2 accurate enough, is, you know, demands, you know, corrective
3 action at the individual laboratory level. And that's where
4 it's been. And historically and it hasn't, it hasn't raised
5 its, you know, its ugly head as to what, hammer if you will,
6 the Department has to enforce these sorts of things.

7 But, you're right. It's going to have to be
8 addressed. And it will certainly be addressed during the
9 reg writing procedure. And we'll, and the Committee will be
10 actively involved in those issues when they come up.

11 And I have to reiterate that the reg writing
12 process is going to be long and arduous and is going to have
13 to clarify things of this sort and will be done with the
14 full, you know, full input of the Committee as well.

15 CHAIRMAN KIMSEY: Do we know, I know Clay was
16 tracking the A.G. Report. Anything new on where it is?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 I know the results for October came out and there were no
19 new opinions. No, I haven't, no, I don't know.

20 CHAIRMAN KIMSEY: Okay.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 I look every month.

23 CHAIRMAN KIMSEY: Right.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 I would note though that Natalia's question was not totally

1 theoretical. Since 2005 we've had individuals fail PTs and
2 the results for individuals is that they need to take
3 corrective action and apply again.

4 And we've had labs with unsatisfactory performance
5 with those PTs. So it's not totally theoretical. It's
6 happened in the past.

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
8 Right. And it's worked out well. In, you know, with the
9 give and take of the Department. Correct Clay?

10 COMMITTEE MEMBER SHEN: It's not outlined right
11 now exactly what happens is it? If you don't pass
12 something?

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 I think the regulations are probably remiss in that they do
15 state that the Department shall evaluate the PT results and
16 determine whether the lab's methods continue to meet the
17 standard performance set forth in regulations. And we've
18 done those evaluations and found in some cases that they
19 haven't we have added, we have asked the labs to provide a
20 response.

21 That response typically is identification of the
22 source of the error and correction. If it's not just that,
23 if it's a systematic error, then a demonstration of some
24 data, validation data that shows the method at least has the
25 capabilities at least of satisfying the requirements of the

1 regulations.

2 But I think that should be spelled out in the
3 regulations, I think. The regulations are old and I think
4 that times have changed. So whoever has that section should
5 write something in there and take a stab at writing what the
6 Department's response should, would be if this were, the
7 results were found to be not demonstrate that the lab's
8 methods were appropriately accurate and precise.

9 COMMITTEE MEMBER SHEN: -- personally me.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11 I think that we've been hopeful to get some guidance from
12 the attorney general on this. But Clay is absolutely right.

13 There's no way these regulations will go to the Office of
14 Administrative Law without that question resolved.

15 COMMITTEE MEMBER SHEN: Well, I'll take a stab at
16 it.

17 CHAIRMAN KIMSEY: Okay.

18 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

19 Thank you. We appreciate that.

20 CHAIRMAN KIMSEY: Any other comments? If not, I'd
21 like to thank you all for your time and your patience and
22 professionalism. And we'll be in touch. Thank you.

23 (Thereupon, the California Department of
24 Public Health, Forensic Alcohol Review
25 Committee meeting adjourned at 1:15 p.m.)

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 30th day of November, 2011.

JOHN COTA