

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

EIGHTEENTH MEETING
MONDAY, SEPTEMBER 26, 2011
10:00 A.M.

REPORTED BY:
JOHN COTA

APPEARANCESReview Committee Members

Dr. Paul Kimsey, Chairperson (Richmond)

Lieutenant Kevin Davis (Sacramento)

Mr. Paul R. Sedgewick (San Diego)

Mr. Kenton S. Wong (Richmond)

Mr. Torr M. Zielenski (Sacramento)

Mr. Bruce Lyle (San Diego)

Ms. Jennifer Shen (San Diego)

Review Subcommittee Members

Ms. Jennifer Shen (San Diego)

Dr. Paul Kimsey (Richmond)

Staff

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

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

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

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

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

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

Also Present

Mr. Linton Von Beroldingen, Department of Justice (Richmond)

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

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

Mr. Peter Baldrige, Member of the Public (Sacramento)

Ms. Dawn Easciano, Member of the Public (Sacramento)

Mr. Steve Woods, Member of the Public (Sacramento)

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1 CHAIRMAN KIMSEY: Okay. Well again, welcome.
2 This is our eighteenth meeting of The Forensic Alcohol
3 Review Committee.

4 We sent out a packet with some materials. As part
5 of that packet there is an agenda. Any comments on the
6 agenda before we get started?

7 Okay, hearing none, we have some opening remarks.
8 Again, this is Paul Kimsey in Richmond. Just to let you
9 know that we have a new management team here at the
10 Department of Public Health that were appointed in June.

11 Dr. Ron Chapman, a physician, family physician
12 from formerly the Health Officer of Solano County is the new
13 Director of the Department of Public Health.

14 Kathleen Billingsly is the new Chief Deputy for
15 Policy and Programs. She is who I report directly to.

16 And we have a Chief Deputy for Operations which is
17 our administration side of the house. The new Chief Deputy
18 is Daniel Kim, K-I-M.

19 Other departmental business, I don't think there's
20 anything more relevant to this group. Any other comments
21 for opening remarks?

22 (No response)

23 CHAIRMAN KIMSEY: We can move on to the agenda
24 then. We're going to be talking about the subcommittee's
25 proposed revisions to the Forensic Alcohol Committee's Draft

1 Regulatory Work Product.

2 A little bit of background. The Committee sent a
3 letter of December -- the Committee letter was sent April
4 21, 2010. Sending our work product to the Health and Human
5 Services Agency for comment.

6 We received back a letter on December the 15th
7 with comments and suggested areas of, I guess we'd say,
8 additional work.

9 The Committee at our last meeting did set up a
10 subcommittee of Jennifer Shen and myself to look at these
11 four areas of the package and how we might, as a committee,
12 respond to Agency's and Department's concerns about the
13 removal of the Department from certain areas of oversights.

14 The Committee met -- I don't know Jennifer if you
15 can remember the number of times, but I would say, four or
16 five times since our last full Committee meeting hearing.
17 The subcommittee did meet for four or five times which is
18 Jennifer and myself.

19 And we, Jennifer and I went over and you have in
20 your packet from the program the ideas for forensic alcohol
21 analysis regulations.

22 This was proposed by the program within the
23 Department.

24 Jennifer and I discussed this and I think we as a
25 full Committee will discuss it.

1 And then you also have some areas that the
2 subcommittee, Jennifer and I, had some discussions upon
3 which is another document that you have.

4 What I would propose, I mean if anybody wants to
5 sort of add to that history or correct me; feel free to.
6 But what I would also propose is that we as a full committee
7 hear from the program on their document entitled, "The Ideas
8 for Forensic Alcohol Regulations". And then we hear from
9 the subcommittee about their document. And then we have a
10 discussion afterwards about where the Committee wants, the
11 full Committee wants to go.

12 Does that seem like a game plan? Any comments
13 from San Diego or Sacramento?

14 MR. LYLE: Bruce Lyle, that sounds good.

15 CHAIRMAN KIMSEY: Okay. Great. Then I'll have
16 someone from the Department's program. Clay Larson, go
17 ahead and talk the document that they put forward to the
18 subcommittee.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 Yeah. At the last meeting, actually in response to some
21 requests from members at the last meeting for some ideas
22 that would both respond to the concerns shown in the
23 December 15th letter and at the same time enhance the
24 efficiency; and I think the word that was favored at the
25 Committee was, "modernize" the regulations or modernize the

1 program to take advantage of commercial and accreditation
2 organizations in such a way that we could reduce the direct
3 involvement of the Department in the program but still
4 maintain state-level oversight.

5 So in April we put together, we covered the core
6 areas of the current oversight program, proficiency testing,
7 qualification of lab personnel, site inspections, approval
8 of training and then we added, access to records since
9 that's related to the other four.

10 And we came up with some new ideas. Some of them
11 will take quite a bit of work both in crafting regulations
12 and in establishing partnerships.

13 But in the area of proficiency testing we proposed
14 that one idea here is that the Department would no longer be
15 involved in the direct production of PT samples but rather
16 would use commercial proficiency samples.

17 We would continue to evaluate the results. We
18 would actually enhance the requirements a bit in that we
19 would, consistent with our current program we would require
20 the labs that have multiple methods to participate in the
21 proficiency tests for each method.

22 As I say, we would require labs that had an
23 unsatisfactory performance on the proficiency test to
24 provide a written description of the corrective action it
25 takes.

1 The qualification of lab personnel would remain as
2 it is now with the exception, again, that the PT
3 requirements would be performed by a, using a commercial
4 provider.

5 We added site inspections. Currently as a number
6 of members have pointed out or the committees have pointed
7 out extensively in their ISOR, there are site inspections
8 being performed by accreditation bodies such as ASCLD.

9 The thought was that we could partner with ASCLD
10 and utilize their inspections. I think we would have to
11 enhance the inspections.

12 And I think if we do a basic side-by-side
13 comparison of the ASCLD/LAB and the Department's regulations
14 -- although it may be open to debate, I think Jennifer in
15 her comments notes that the clear issue that's not subject
16 to much debate is that ASCLD doesn't cover breath alcohol
17 analysis at all presently.

18 So, we actually have to upgrade, if you will, the
19 ASCLD/LAB inspection program to incorporate that and some
20 other things. And they're listed in the document.

21 And then approval of training. This is probably
22 not as well understood as the others.

23 Every state regulated breath alcohol analysis. In
24 many states, especially the smaller states, the state agency
25 simply does all the training. They do all the certification

1 of personnel.

2 California is quite a bit different in that we
3 distribute that potentially to 40 labs. But the state still
4 maintains oversight by having the authority under the
5 regulations to approve the training programs.

6 So, we would argue that that needs to be continued
7 in order to ensure the competence and consistency of breath
8 alcohol analysis testing in California.

9 And there's in this point in time no accreditation
10 body that covers that. So, the area of training would
11 basically be the same regulatory requirements that currently
12 exist. There doesn't seem to be any opportunity to partner
13 with other people.

14 And then access to records is just a general
15 requirement that, you know in order for the Department to
16 meet the statutory mandate of 100725 to enforce the law on
17 the regulations, still we have to know what people are doing
18 and so there's two sections in the current regulations that
19 describe the Department's access to records and I think
20 those need to be retained.

21 And then we took one more shot at some additional
22 improvements in the regulations that don't directly relate
23 to the December 15th letter but we thought were worth one
24 more look.

25 So that's about it.

1 CHAIRMAN KIMSEY: And those additional ones were
2 laboratory registration, collection and handling of
3 samples --

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 Right.

6 CHAIRMAN KIMSEY: -- collection of sufficient
7 sample volumes, maintenance of equipment in good working
8 order, reviews of written method descriptions, experimental
9 demonstrations of method performance, written descriptions
10 of procedures for the periodic determination of accuracy of
11 breath instruments and preliminary alcohol screening tests
12 and continuous observation of subject prior to breath test.

13 Any questions for Clay at this point? Obviously,
14 we'll get into a broader discussion. But if there's an
15 overwhelming question at this point, we can take a question
16 for Clay.

17 (No response)

18 CHAIRMAN KIMSEY: If not, we can move on to the
19 subcommittee ideas. Jennifer would you mind walking us
20 through that?

21 COMMITTEE MEMBER SHEN: No I wouldn't. So what we
22 spent our time talking about is the requirement -- we want
23 to be able to accommodate the state oversight in a highly
24 efficient fashion.

25 And what we're really trying to get rid of is

1 duplicating our efforts. And we're trying to modernize our
2 approach. That's kind of what we were looking for.

3 So, I can go down the same list. We didn't do our
4 -- our list isn't quite as detailed. But as far as
5 proficiency testing goes we're looking for non-duplication
6 of effort. So I think that Clay is kind of on board with us
7 there.

8 We are looking at conducting our proficiency tests
9 that are provided by an approved provider. And then we
10 would forward our final results to the state. And I think
11 we have a little bit, a different idea on how that would be
12 handled.

13 You know, ASCLD/LAB and the majority of
14 laboratories -- we are focussed on testing the individuals.
15 And so we would have to continue to do that.

16 We want to test the individuals. I think that
17 those test results would be looked at and approved or the
18 laboratory would be given a pass, no pass based upon the --
19 what the requirements of the provider are; not what the
20 requirements of the state are.

21 So there's probably something we need to work out
22 there.

23 As far as qualification of laboratory personnel, I
24 really think I would like to see us go down the route of,
25 you know, the Department provides criteria that need to be

1 imparted to new personnel.

2 So here is a list of lecture topics. Here is an -
3 - and here are the things that the state wants covered. And
4 I think it really is going to be need to be left up to the
5 laboratories themselves, the laboratory management
6 themselves to provide that training.

7 So if we were given some sort of outline and then
8 the laboratories were responsible for imparting that
9 information in a manner that each particular laboratory saw
10 fit that those records would then be available for state
11 review if need be.

12 So, you know, can we take the burden of the work
13 off of state and put it on the laboratories themselves; but
14 we would have to be following, you know, guidelines approved
15 by the state.

16 As far as site inspections, I believe that the
17 accreditation site inspections are all that we really
18 require. They're very thorough.

19 We do need to talk about the breath program. I
20 agree that's a problem. However, ASCLD/LABS is giving
21 certifications in the breath program if you apply as a
22 calibration laboratory which San Diego Police Department is
23 going to be doing.

24 In that case is quite -- the oversight of that is
25 quite expensive and I think would take the place of any need

1 for the Department oversight.

2 So, I guess I'm sort of thinking that we could
3 offer up laboratories that have not gone that route.
4 They've not been accredited in the area of breath
5 calibrations then they may need to have departmental
6 oversight instead. That's something that we talked about.

7 But I think the -- actually the inspections are
8 rather thorough. And I don't know how much more, I don't
9 know how easy it's going to be for the state to try get the
10 ASCLD/LAB inspectors to follow the state's guidelines. I
11 don't know how that would work. It's an option though.

12 In training, I don't really see a problem with the
13 Department keeping oversight of the training program for the
14 breath operators. And I think that's what we've got going
15 on now. I don't see that really as a problem.

16 Access to records, I think our thought was that,
17 you know, our records are accessible to really anyone who
18 wants them. Certainly the state can come in and take a look
19 at those records at any time.

20 We have to produce records for, you know, court
21 cases, public defenders, public records requests et cetera.

22 So, you know, that's something that we can talk about.

23 I don't see us going down the road of laboratory
24 registration, again with the state. I think since all of
25 our laboratories, all our government laboratories are, in

1 fact, accredited I think that that is covered.

2 The thing that Paul and I talked about which I
3 thought was of interest, you know, how can we get this
4 information out to the people who need it? And how can they
5 show us that we are, in fact, doing what the state requires.

6 And so we talked about the website which we can talk about
7 in more detail if you'd like to.

8 But we thought a website that is accessible by the
9 public where the laboratories will sit along with the
10 accreditation status and the accrediting body and something
11 like, you know, proficiency tests, up to date and which
12 analysts in our laboratory are, in fact, approved for
13 testing would be something that might be very helpful.

14 So that would be oversight that the state has in a
15 very simplistic form that the public could access and then
16 we would have to provide the documentation to ensure that
17 the status on the website is accurate.

18 So those are some of the ideas that we were
19 looking at. I guess in my mind one of the most important
20 things we were looking at is that what we put in Title 17 is
21 something we all agree we should follow. And we follow that
22 and nothing else.

23 But I want it clear so that there are no, that
24 parts of it are not subject to interpretation which is some
25 place we've been going in the past and I'd rather not go

1 there again.

2 So what we want to put in there is guidelines that
3 are extremely clear that everybody is on board with and
4 everybody follows and that's all we're required to follow.

5 Those are my thoughts.

6 CHAIRMAN KIMSEY: Thank you. And just real
7 quickly since Jennifer and I represented the subcommittee,
8 I'll make some comments also.

9 What Jennifer expressed is, I agree with the
10 accuracy. As an example in another area when we're talking
11 about inspections and inspectors coming in and inspecting
12 for an organization's purposes and possibly also for
13 government purposes as was mentioned; as an example, the
14 state of California is the, oversees and inspects for the
15 federal Center for Medicaid, Medicare Services Clinical
16 Laboratory Program in California.

17 So our state inspectors go into the clinical
18 laboratories. They look at those laboratories for federal
19 compliance to the federal CLIA requirements and at the same
20 time those same inspectors look at those clinical
21 laboratories for state purposes, for state regulatory
22 compliance since it's not the same programs.

23 So a single inspector looks at federal compliance
24 requirements and also state requirement compliance. And
25 that program seems to work quite well in that context.

1 So obviously it requires, you know, some
2 agreements and like Jennifer was saying that there's, you
3 know, sort of clear understandings of what Title 17 is and
4 what is the federal requirements, you know, for those
5 inspectors so there's no confusion.

6 Now those are state inspectors for governmental
7 purposes but also under the federal program, the federal
8 program for CLIA does have what they call, organizations
9 that they give, "deemed status".

10 In other words, I'm blanking on a name of -- oh,
11 ASCP, the American Society of Clinical Pathologists, a
12 private organization similar to what ASCLD is. They have
13 received, deemed status, from the federal government to
14 inspect for federal purposes.

15 So that inspector is not a federal employee, is
16 not a state employee, it's a ASCP employee. They inspect
17 those laboratories for federal purposes.

18 And so I think what I'm getting around to is I
19 think there's some models or some examples that we can look
20 at for a combined program looking at onsite inspections
21 since a majority or all; and that's sort of a significant
22 issue because I think we have to keep in mind that these
23 regulations are for anyone doing forensic work or forensic
24 alcohol work in California.

25 And we talk about majority sometimes but we have

1 to be careful that what we write into these regulations is
2 going to be, everyone is going to be held to that
3 responsibility.

4 But anyhow, I think there's some opportunity to
5 work with, you know, ASCLD and ASCLD-like organizations for
6 some of this onsite inspections.

7 Usually as we've talked about in the past there's,
8 you know, one percent or two percent where the state
9 actually does the inspections just to sort of, you know,
10 have the ability to sort of keep track of what's going on
11 out there with these organizations; and then also for cause
12 if there's a complaint.

13 Sometimes the state inspection is considered more
14 worthwhile.

15 Let's see, what else from our discussions -- I
16 think the website, we really, I think we both felt that that
17 was a good idea. It would obviously take some doing to get
18 it set up. But it's getting the information out to the
19 public, to the attorneys, the prosecuting attorneys, defense
20 attorneys, everybody involved about the status of a
21 laboratory meeting the requirements and those that, you
22 know, are were not meeting the requirements.

23 We sort of had a list of things that might be on
24 that. But that would require quite a bit of detail. We
25 sort of went to having a lot of things check off boxes to

1 having just a few check off boxes because if you're not in
2 compliance, you're not in compliance to some extent.

3 What else from my thinking -- but I'll just sort
4 of start the discussion a little bit. I perceived that
5 there was some commonality in some of the areas, some of the
6 discussions.

7 Obviously, as we well know with this group, the
8 devil is in the details. And, but anyhow, other comments
9 from the Committee on the Department's program suggestions
10 and the subcommittee ideas? We need to sort of hear from
11 the rest of the Committee a bit.

12 COMMITTEE MEMBER SHEN: You know I'll throw out --
13 this is Jennifer. I have one more comment to throw out
14 there. And one of the things that you're looking at with
15 the website is, what I heard in some of our last few
16 meetings was that the Department felt like that with the
17 Title 17 changes as we had written them that there really
18 was no oversight. So we kind of had written them out of any
19 oversight which we kind of did.

20 And a lot of that is due to the, you know, the
21 current, the current legislation sort of writes them out of
22 oversight.

23 So we have this conundrum where we have
24 Departmental oversight that's sort of mandated but there's
25 no teeth of any kind. So they really can't do anything

1 about us not following our, the mandate.

2 So the website was kind of a way to give oversight
3 to the Department because, you know, if we aren't doing the
4 things that we need to do then that is a mechanism for, I
5 don't want to say punishment, but, it's sort of a mechanism
6 for us to be held accountable for doing the things that we
7 need to do. That's kind of where that website idea came up.

8 CHAIRMAN KIMSEY: Right. And that's correct. And
9 some of these ideas that we've had, I mean, it would be, I
10 mean I'm not an expert, but I would think we might have to
11 get some guidance on whether the Department has the
12 authority to work with an ASCLD-like organization currently
13 for something like onsite inspections.

14 So, I don't want us to feel sort of restrained by
15 that. I think if we think it's a good idea, we ought to
16 sort of get it down and then, you know, see what it might
17 take to implement it.

18 And then if we need to get more authority or some
19 clarification along those lines then we could set about
20 doing that.

21 But other comments from the Committee?

22 (No response)

23 CHAIRMAN KIMSEY: Comments from the public?

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

25 Yeah I, Clay Larson. I wrote down some notes quickly as

1 Jennifer spoke. I wrote four notes and I can read two of
2 them. So I'll go over those.

3 Regarding, there seems to be a disagreement on the
4 proposal that the Department would continue to evaluate the
5 PT. And I think Jennifer said that the labs would be more
6 comfortable, she would be more comfortable with letting the
7 provider evaluate.

8 In fact, under the ASCLD/LAB manufacturing guide,
9 PT manufacturing guidelines, there's a specific requirement
10 that the provider not be doing any evaluation.

11 Having said that, CAPS is a very big company and I
12 guess they couldn't, they would have to include them. So
13 CAPS, of the three, CAPS actually does evaluate PTs.

14 But they evaluate it based on CLIA emergency room
15 toxicological requirements. And it's a plus or minus 25
16 percent. So it's not really applicable.

17 And if you are an ASCLDed member the PT results
18 that submitted are subject to a review by the PRC. But as
19 described in the PRC guidelines, that's a strictly
20 confidential process. So it's not readily open.

21 So I don't see in terms of meeting the
22 Department's expectations and goals with regards to
23 proficiency testing, I don't see how we can avoid CDPH
24 evaluation results. And I don't see why the labs wouldn't
25 want that, actually.

1 COMMITTEE MEMBER SHEN: This is Jennifer. It's
2 not that we don't want it. It's that, you know, --

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 I'm sorry, it's inefficient, yeah --

5 COMMITTEE MEMBER SHEN: -- we're using, no that,
6 it's not even that. But right now what we're doing is we're
7 sending the Department our results. And what we are
8 getting, I believe, is that we are getting, after we do our
9 results and turn them in, we're getting data that shows
10 where we are, where our laboratories results fall within the
11 scope of all the laboratory results.

12 So we can see if we have hit the mark or we have
13 not. And you might be right. I think ultimately it comes
14 down to our own QA sections taking a look at that to see if
15 we are within a legitimate error range of the actual
16 results.

17 But right now what we're doing at the Department's
18 behest is we're sending our results already. So you must be
19 taking a look at them and deciding whether or not you think
20 that they're accurate. Is that something you're already
21 doing?

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 It is something we're already doing. And we would continue
24 to do it. And it would be described in the regulations.

25 COMMITTEE MEMBER SHEN: Oh, what you're doing

1 right now seems perfectly reasonable to me. What I would
2 like to do is stop having my analysts do the other ones.
3 I'd like them only to do the ones that are done by the
4 provider. We send you the results and you can do whatever
5 you're doing to them now.

6 But, you know, we know when we get the results we
7 are very aware already whether or not we have met the mark
8 or not.

9 So I don't have, I don't think there's any issue
10 with sending those to the Department and having the
11 Department also see the same thing we're seeing.

12 I was confused. I thought you wanted to set up a
13 different criteria than what we're already doing.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Okay. It sounds like we're closer together on that than I
16 supposed. The other --

17 CHAIRMAN KIMSEY: Real quickly, on that point,
18 just keep in mind that proficiency testing organizations,
19 you know, will change their programs to some extent.

20 ASCLD may decide at some point to do the
21 evaluations. So when we look at how the regulation is
22 written we need to keep it general enough or keep in mind
23 that outside programs that provide proficiency testing, you
24 know, will change their programs.

25 And I think we want to just talk about is, what is

1 the role of the Department. It sounds like there is some
2 agreement that the Department would have, would be sent
3 those records.

4 And those can come from the laboratory or they can
5 come from the proficiency testing organization. I've seen
6 it done both ways; and that there would be some analysis
7 done by the state.

8 But keep in mind, I guess, the point I'm trying to
9 make is that these private companies are going to change
10 their programs. And rather than having to come back to our
11 regulations we want to have them written such that it allows
12 for that variance.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 The other comment I wanted to, Jennifer made that regarding
15 the possibility of relying on ASCLD/LAB, calibration lab
16 accreditation, with regards to the oversight of breath
17 alcohol analysis.

18 Currently three labs are accredited, Orange
19 County, San Mateo and, I got the third, and Ventura.
20 Ventura was the first one.

21 But I think if you look carefully at the
22 calibration lab requirements, they really only cover a
23 limited subset of what I would call, the periodic
24 determination of accuracy analysis that are required under
25 the regular system.

1 They don't deal at all with any breath testing
2 procedures. They don't deal with training of operators.
3 They don't deal with instrument maintenance. They don't
4 deal with -- I mean, you can go down the list of, under
5 Article 7 and maybe one or two section requirements, this
6 program simply doesn't cover breath alcohol analysis.

7 So I would think it would be foolish to rely on
8 the ASCLD/LAB calibration program. It's currently only
9 includes three of California labs.

10 COMMITTEE MEMBER SHEN: I think, "foolish" is
11 strong. You know, we don't really have, I've got to say, I
12 do not feel like there's a lot of regulation of the breath
13 program as is. And so if, you know, I agree ASCLD/LAB does
14 not provide regulation of the breath program.

15 I do not agree that when you become a breath
16 calibration laboratory that they will not be providing
17 oversight of the breath program.

18 However, what's written into Title 17 now I think
19 even along with our changes provides a structure to have,
20 you know, it provides criteria for a breath program which I
21 think we have left in there in by and large so that we will
22 have that catch all.

23 And I guess I feel like for the blood alcohol, the
24 fluid alcohol analysis that the ASCLD/LAB really provides us
25 everything we need. And we don't even really need Title 17

1 whatsoever.

2 However, because we don't have that catch all with
3 the breath program Title 17 is important in that area in
4 particular.

5 So I don't think anyone is talking about
6 regulating out Title 17 oversight --

7 COMMITTEE MEMBER WONG: No.

8 COMMITTEE MEMBER SHEN: -- of the breath program.

9 COMMITTEE MEMBER WONG: This is Kenton Wong in
10 Richmond. I would like to, first of all, thank Jennifer and
11 Dr. Kimsey for their time in the subcommittee and making a
12 lot of the recommendations and ideas that they've done so
13 far.

14 When I was first reading some of the ideas for the
15 regulations it sounded eerily reminiscent of exactly the way
16 things were in the past. And I'm really uncomfortable with
17 that because the whole reason behind 1623 was, as we stated,
18 to remove Department oversight of the program.

19 But when you read about program, it's almost like
20 a rehash of inspections of labs and proficiency testing and
21 qualification of personnel yada-yada-yada.

22 I still agree with the recommendation from Health
23 and Human Services that we still need to have some type of
24 coordination and cooperation amongst the two groups, the
25 Forensic Alcohol Review Committee and Program so that we can

1 have a minimum amount of obstruction going on with our
2 business in our forensic labs as well as still having the
3 minimal amount of oversight and not having any duplicative-
4 type regulations that were causing a lot of problems and
5 slowing down processes of getting instruments approved and
6 things such as that.

7 I think we really need to be careful about looking
8 at, discussing ASCLD-like labs. And while the preponderance
9 of labs are accredited by ASCLD, not all of them are as was
10 well pointed out in subsection, footnote two. There are
11 other agencies that are required and have accreditation with
12 other bodies.

13 For example, I'm a technical assessor with FQS.
14 And FQS is actually the oldest accrediting body
15 internationally for forensic things.

16 And the way FQS and ASCLD does their business is
17 very, very different.

18 I like the idea that Dr. Kimsey had with the, what
19 was it, the ACS, ASCP --

20 CHAIRMAN KIMSEY: Right.

21 COMMITTEE MEMBER WONG: -- that is a very
22 intriguing model for having some type of inspection done,
23 state inspections to CLIA federal compliance levels.

24 For example, with ASCLD inspectors, ASCLD
25 inspectors are taken and they're sent to other labs,

1 meanwhile their agencies provide their salaries while they
2 go off for two or three days and inspect some other lab.

3 FQS inspectors are different in that you're seen
4 as like a private subcontractor that works for FQS that has
5 no bias or anything. And you take off vacation time and
6 then FQS pays you as a technical assessor to go and do that
7 job.

8 I don't know exactly how it works with the CLIA,
9 ASCP one but there's definitely going to be some logistical
10 issues on how CDPH would work with different type inspectors
11 or different type inspections. But those are issues that
12 we're definitely going to have to look at.

13 CHAIRMAN KIMSEY: A little more on that. If I
14 remember correctly, those are called third-party assessing
15 organizations.

16 It would be like ASCP or ASCLD or FQS and there's
17 usually some relatively specific regulatory language about
18 what it takes to become a third-party accrediting
19 organization that the Department or the Committee would pull
20 together.

21 Again, they're sort of general but you don't want,
22 well maybe, but generally speaking you don't want a single
23 individual, you know, being an accreditor all by himself --

24 COMMITTEE MEMBER WONG: No.

25 CHAIRMAN KIMSEY: -- kind of situation --

1 COMMITTEE MEMBER WONG: It doesn't work that way.

2 CHAIRMAN KIMSEY: -- you want an organization
3 kind of a situation that represents an organization. But
4 anyhow, there's usually some specific language.

5 And again, that takes generally some authority
6 which I'm still not sure this particular program has. But
7 that's something we could work on.

8 COMMITTEE MEMBER SHEN: This is Jennifer. You
9 know one of the things I'm worried about is that this
10 process has gone for years and years and years already. I
11 guess I'm a little worried about setting up a plan or even
12 looking into a plan that's going to necessitate many more
13 years.

14 I mean, I don't see how we'd be able to establish
15 a partnership between the Department and any and all other
16 inspection agencies any time in the near future.

17 And we've got to go a direction that's going to
18 end this process.

19 So I mean, rather than -- that's why I really
20 don't think the partnership thing is, while it's an
21 interesting model, I, you know, it's a, that's a huge
22 undertaking. That's a huge undertaking.

23 And the state is going to want to put its stamp
24 all over these accrediting bodies whomever they may be. And
25 accredit guide and monitors over the processes. I just

1 think we're looking at something that's almost too big to
2 take on.

3 So I wonder instead if, I see ASCLD/LABS that I'm
4 familiar with but there's certainly other accrediting
5 bodies. And I assume that all of them as ASCLD/LAB is doing
6 are going to be going down the road of following the ISO
7 guidelines.

8 COMMITTEE MEMBER WONG: Correct. They're all
9 going 17025.

10 COMMITTEE MEMBER SHEN: So when we are looking at
11 ISO, ISO accreditation or ISO certification, you know, I can
12 see having maybe some guidelines that the inspectors need to
13 take a look at; but the partnership thing, I don't know.

14 I just don't see, I don't see that working anytime
15 soon. So perhaps we're looking at laboratories that are
16 accredited by whoever, don't have to have these particular
17 types of oversight by the Department.

18 So the oversight has been taken over by another
19 body. It does leave you with wondering what we're going to
20 do about those laboratories that aren't accredited. And
21 that's really to me the only rub we have here.

22 You have laboratories doing forensic alcohol work
23 but you don't have any accreditations so therefore they need
24 to have some sort of oversight.

25 But I'm really worried about trying to go down a

1 road that I see no end to.

2 CHAIRMAN KIMSEY: And this is Paul. I think we're
3 all sensitive to the time factor, seeing as how this is our
4 eighteenth meeting.

5 I think if we sort of look at what our timeline
6 currently would be, is we're obviously going to try and get
7 a package, the Commission is going to try to get a package
8 together to send back to Agency that triggered the 90 day
9 review period.

10 And then there will be a decision by Agency and
11 the Department will, you know, start working on writing
12 those regulations. And that still may take some time.

13 I mean, obviously, what we've been told all along
14 that, you know, that's a very time consuming process. And
15 the Department has quite a few regulations that they're
16 working on currently.

17 So I think we ought to sort of keep that timeline
18 in mind. If there's something that we think may take a
19 little bit longer that's fine. I don't know that it has to
20 be all one package.

21 If we really sort of think that a partnership with
22 private, third-party inspectors makes sense for efficiency,
23 you know, a one-time inspection kind of situation; if that,
24 if we think that's a good idea I would hate to not do it
25 because we're not sure of the time factor that it might take

1 to implement.

2 I mean, if it's a good thing to do I think we
3 should, you know, just try and keep it on the table and keep
4 it mind that as we go through the rest of our work of
5 getting these regulations written that that would be
6 something that we'd have to consider. It's only one part
7 of, I think, of our whole package.

8 COMMITTEE MEMBER SHEN: This is Jennifer again.
9 Another thing to consider is that, you know, those
10 accrediting bodies are staffed with people who are, you
11 know, are criminalists; who have experience in this, in, you
12 know, the same experience that we do. And I have to tell
13 you, the Department's take on things and the criminalist's
14 take on things have been different for all these years.

15 I mean, we, you know, there's been a lot of times
16 where we disagree with the Department's regulations and how
17 they're regulating them and in the manner that they're
18 regulating.

19 So, it would be interesting to see if we could get
20 some, you know, an accrediting body to agree with what the
21 Department wants.

22 I mean, there's been kind of a disconnect there
23 for years as far as I can see. I don't know if you agree
24 with that but --

25 COMMITTEE MEMBER WONG: I agree.

1 COMMITTEE MEMBER SHEN: -- it seems like it. So
2 that might be a tough row to hoe to have the Department
3 enforce its views on these accrediting bodies that don't
4 have the same views.

5 CHAIRMAN KIMSEY: Yeah, this is Paul. And I've
6 only heard about that disconnect to some extent.

7 But what I've noticed on the clinical side is
8 that, you know, and pretty soon, I mean, these regulations
9 based on the intent of the 1623, these are going to become
10 our regulations to some extent.

11 So hopefully, and we've done, obviously there's
12 been some major revisions. And so, hopefully, they are a
13 little bit more in line with the industry and the individual
14 criminalists.

15 But also what I've sort of noticed on the clinical
16 side is that when the inspector comes in, I mean they have a
17 checklist and depending upon how they're directed that this
18 is either a sort of a, gotcha kind of inspection or an
19 advisory type of inspection that, you know, something needs
20 to be done. And there's not a lot of discussion about, oh
21 it's, you know, it's these regulations or that regulations.

22 And so, I'm not too concerned about -- these
23 inspectors seem to be able to wear a couple of hats I guess
24 is what I've seen when they're doing their inspections.

25 COMMITTEE MEMBER SHEN: They just can't wear a hat

1 they don't agree with.

2 CHAIRMAN KIMSEY: That's true, unless they're
3 being paid (laughter).

4 COMMITTEE MEMBER WONG: They still can't do that.

5 CHAIRMAN KIMSEY: I know. I was just kidding.

6 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick in San
7 Diego. It strikes me as presumptuous to assume that any of
8 these regulating bodies are even willing to go along with
9 any of this.

10 Has anyone ever talked with any of them? I doubt
11 it. In my experience the board of directors, people I've
12 talked to wouldn't even consider it.

13 CHAIRMAN KIMSEY: Well again, all I know about it
14 is on the clinical side. And when CMS opened up the door to
15 the private sector for these third-party accrediting
16 organizations getting deemed status I believe at least four
17 or five rather large organizations now that, ASCP, CAP that
18 actually inspect these laboratories now; and they see it as
19 a business model.

20 So, it's not so much a philosophical issue for
21 them as, you know, it's a business model.

22 So until we approach them, and I don't think any
23 of us has --

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 No -- let me, we actually did approach them.

1 CHAIRMAN KIMSEY: Aha.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
3 And we provided one of the board of director members, Benny
4 Del Re from Santa Clara. This was a number of years ago.
5 We provided them with a copy of our guidelines for site
6 inspections and our checklist and despite three inquiries
7 from us, we never got any response back.

8 So that doesn't look good. But I'm impressed in
9 reading more about ASCLD/LAB that it is operated as a
10 business.

11 And so I wouldn't assume that ASCLD/LAB would do
12 this free of charge. They would be compensated, I think,
13 for that extra work.

14 So --

15 COMMITTEE MEMBER WONG: ASCLD is for --

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 -- so I'm a little --

18 COMMITTEE MEMBER WONG: -- non-profit.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 -- more optimistic. But in terms of asking them to do it
21 for free, you're right; we've got no responses (laughter).

22 MR. VON BEROLDINGEN: Yes.

23 CHAIRMAN KIMSEY: Identify yourself.

24 MR. VON BEROLDINGEN: Linton Von Beroldingen from
25 the Department of Justice. And I actually wear a couple of

1 hats these days.

2 One of them is associated with our DNA laboratory
3 here in Richmond, about a mile away.

4 And the other one more recently with our blood and
5 breath alcohol programs out of Sacramento.

6 For those of you who don't know me, I've been
7 working in crime labs since 1975. And from 1982 to '89 I
8 was a field criminalist at the regional laboratory in Santa
9 Rosa for the Department of Justice.

10 And during that time I was a forensic alcohol
11 analyst trainee, analyst and then supervisor under the
12 regulations of that period.

13 And did a fair handful of analyses and testified
14 in court in five counties served by that laboratory. That's
15 my major background in the matters that we're discussing
16 today.

17 But I'd like to bring to this discussion a
18 perspective from the DNA side which if you talk to litigants
19 and other clients of forensic service laboratories in the
20 last ten years or so has sort of acquired this name of
21 having the gold standard of reliability for crime lab work;
22 which I'm not necessarily going to buy as an out-and-out
23 truth.

24 But, right now a forensic DNA laboratory that
25 participates in the combined DNA index system has to follow

1 federal law, state law, the quality assurance standards
2 promulgated by the Federal Bureau of Investigation.

3 And it also has to undergo, because of that, an
4 annual audit and every other year it has to be done by
5 external parties.

6 And those audits, I believe are done along the
7 lines we discussed earlier where the auditing teams are
8 generally paid by their own organizations and their own
9 companies' time. And the exchange process is supposed to
10 even that out overall.

11 There are also inspections or audits conducted
12 pursuant to accreditation activities. And currently our DOJ
13 lab system is accredited by ASCLD/LAB under the
14 international standard.

15 And that's something that the major process
16 happens every five years. But you have an annual visit
17 where everything is going to be sort of checked over as
18 well. So it's an annual event.

19 There's also, and again I'm sticking this is the
20 DNA world, we have the U. S. Department of Justice, Office
21 of the Inspector General which is their internal watchdog
22 organization.

23 And they like to do audits of the F.B.I.'s
24 administration of the combined DNA index system. So they
25 come around every once in a while and turn over all the

1 rocks and look at everything.

2 And their last cycle of activities, which are
3 still ongoing, but the culmination of the last cycle a few
4 years ago, was the presentation of a list of 22 or 27
5 findings to the Federal Bureau of Investigation about what
6 they thought needed to be improved in the way they were
7 handling the CODIS system.

8 And one of the outcomes of that was the
9 establishment of an INDIS procedures compliance assessment
10 process within the CODIS unit of the F.B.I.

11 So, I don't know whether we want to go to that
12 multitude of processes in order to ensure that blood and
13 breath alcohol analyses in the state of California are done
14 well and serving the client, criminal justice system and the
15 population of the state well.

16 But I think that there is room for this concept
17 which I expect someone else can back me up on this.

18 As a general principle as I understand it, when
19 you have an accreditation inspection and particularly now
20 under the ISO rules, you are evaluated as a laboratory on
21 the basis of your adherence to your own written technical
22 procedures and other quality assurance documents.

23 So what comes to my mind is that if the
24 Department, and excuse me if I got your name mixed up,
25 because as I said, it's 20 years ago but the Department of

1 Health Services?

2 CHAIRMAN KIMSEY: That's what we used to be --

3 MR. VON BEROLDINGEN: Yeah --

4 CHAIRMAN KIMSEY: -- we're now the Department of
5 Public Health.

6 MR. VON BEROLDINGEN: Okay. If the Department of
7 Public Health has a program within it that has made a review
8 for compliance to state regulations and laws for a
9 laboratory that is in this state and found that that
10 laboratory's protocols provide adherence to those
11 regulations, then I have no doubt that the ASCLD/LAB or
12 other accrediting, accrediting body inspectors will hold
13 that laboratory to what it is written down that it's going
14 to do.

15 And in that way you have a reaching out and
16 affecting the outcome of things. And it should help, I
17 think, to stabilize the activities of the laboratory and
18 keep them in compliance with what they need to comply with.

19 COMMITTEE MEMBER SHEN: This is Jennifer. So I'm
20 going to get this clear. I wasn't sure where you were going
21 until the very end there.

22 If your talk was about something that we talked
23 about, you're right. The ASCLD/LAB inspections, the other
24 inspecting bodies hold the laboratories accountable for what
25 they say they're doing.

1 MR. VON BEROLDINGEN: Yeah, that's the --

2 COMMITTEE MEMBER SHEN: The laboratories have to
3 be doing things that are accepted in the general scientific
4 communities.

5 So if we have included in our processes the needs
6 of the state then the ASCLD/LAB, I'm sorry I keep thinking
7 ASCLD/LAB but the accrediting bodies are going to hold us
8 responsible for what's in those methods.

9 You know, one of the things I would say to you,
10 having been out of it for a while, maybe this is not
11 something you're aware of but by-and-large we feel,
12 criminalists, that the protocols, the procedures, the
13 requirements that we have in the laboratories are well and
14 above, more stringent than what Title 17 lays out for us.

15 So it is not a matter of having this extra
16 oversight that makes us better. We feel like that oversight
17 has been holding us back.

18 So, but again, if your point is that if we have
19 the basic, at least the basics covered in our methods, in
20 our procedures, that we're going to get held accountable to
21 those by our accrediting bodies; I think that that is an
22 excellent point. And that is the way to marry the two
23 oversights I think.

24 MR. VON BEROLDINGEN: Jennifer this is Linton in
25 Richmond. And you said it more briefly than I did.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

2 Well I'm -- this is Clay Larson, comments from the public.
3 My interpretation of your comments, especially in light of
4 the fact that you've noted that the multiple layers of
5 oversight that occur for DNA testing procedures and don't
6 occur for other crime lab procedures at all; but in
7 describing the multiple layers that you were suggesting, I
8 thought, a proposal whereby the Department of Public Health
9 would somehow review and approve written protocols, methods
10 and procedures with the expectation that the ASCLD/LAB or
11 other accrediting body would then site inspect the lab those
12 procedures and therefore through this two-step process we'd
13 have state level oversight.

14 So I think there were two elements there. That's
15 what I understood you to say. I didn't hear Jennifer saying
16 the same thing.

17 I would, I mean that's an interesting model. I
18 would probably add one more element. And although you're
19 confident that the ASCLD/LAB inspectors do inspect to the
20 laboratories' written protocols, it's not well captured in
21 their inspection reports.

22 I've read a number of inspection reports. I read
23 one -- and they're generally not available but they've kind
24 of, there's a few that are around. And during the crime lab
25 task force meetings they provided one from L.A. Sheriff's

1 Department.

2 L.A. Sheriff's Department, I'm sure, does tens of
3 thousands of breath tests a year, I'm sorry, forensic
4 alcohol analysis tests a year. There's no mention, I mean
5 it's a 20 page document, there's no mention of breath
6 alcohol analysis or blood alcohol analysis or any alcohol
7 analysis in the report.

8 So part of the problem is they are balancing 10
9 separate disciplines. And I guess the documents would get
10 very voluminous if they actually described everything they
11 checked.

12 So I would add one more layer there. And I think
13 it's actually captured in the program's proposal is that
14 besides, you know, anecdotal assurances that they accredit
15 to the lab's procedures there would be some sort of written
16 documentation to show that that actually occurred.

17 COMMITTEE MEMBER WONG: Are you talking about like
18 a final finding report?

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 Yeah.

21 COMMITTEE MEMBER WONG: Well, you're absolutely
22 right. I mean they're not going to go through and reiterate
23 everything that they've supposedly gone over and inspected
24 to the standard of ISO.

25 They're only going to discuss the certain findings

1 and recommendations that they are going to make in order for
2 the laboratory to improve or get back in compliance on a
3 certain issue.

4 But other than that everything else has been
5 assumed in the report to have been to the standard and
6 acceptable. So, they're not going to sit there and
7 reiterate all of that because you're right, it would be a 30
8 or 40 page report that would just say that, yeah, the lab is
9 doing exactly what they're saying they're doing to all these
10 different standards.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 And you refer to final findings a suggestion that there may
13 be some intermediate documentation. The ASCLD/LAB site
14 inspection requirements state that those intermediate
15 documents must be destroyed.

16 So it's that kind of language doesn't give me a
17 lot of comfort on the whole process. But it's actually a
18 specific requirement. I can show them to you -- you're
19 furrowing your eyebrows but it required that --

20 COMMITTEE MEMBER WONG: That's why I'm FQS.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 Okay, all right. I don't want to get into a pissing match
23 there (laughter).

24 COMMITTEE MEMBER SHEN: I don't think we want to
25 go there.

1 COMMITTEE MEMBER WONG: Yeah.

2 COMMITTEE MEMBER SHEN: But you know I want to
3 make one more thing very clear. My thought was that, you
4 know, we would have out, we would have guidelines or rules
5 in Title 17 that the laboratories would be required to
6 follow --

7 COMMITTEE MEMBER WONG: Uh-huh.

8 COMMITTEE MEMBER SHEN: -- they would be required
9 to follow that. And those rules would be reflected in our
10 methods and methodologies. I am not interested in going
11 down the road of having some sort of dual write up where we
12 send all of our manuals and methods and everything to the
13 Department to have them, the Department say, hey, this is
14 good and that now, now ASCLD/LAB or another agency can come
15 in and make sure we're being held to that.

16 I'm talking about the fact that we would have
17 Title 17 guidelines reflected in our methods and our
18 accrediting body would hold us to those.

19 So, I don't think it needs a kind of two-tiered
20 approach. I don't think we want to go backwards to having
21 all of our written methods back to the Department for
22 approval.

23 COMMITTEE MEMBER WONG: I absolutely concur.

24 CHAIRMAN KIMSEY: More discussion on the
25 subcommittee ideas and the program proposals?

1 COMMITTEE MEMBER SHEN: Well, maybe what we ought
2 to do is find some, you know, I think ultimately what we're
3 going to have to move forward here is putting together the
4 package to send our annual changes in and maybe we can make
5 a few modifications to it to incorporate some of these.

6 I mean to me the proficiency test is great
7 because, I mean, if we all agree on that. I mean, that's
8 something we could, you know, set forth immediately and
9 we're already in compliance with current legislation if we
10 do it.

11 So we might be able to make some movement there.
12 But I think if you want to move forward we're going to have
13 to see if there's any language you want to adjust and get it
14 out.

15 CHAIRMAN KIMSEY: No, and I would agree. And I
16 think we're close enough on proficiency testing. There
17 seemed to be some good discussion around training. Even the
18 accrediting bodies. The idea of the website.

19 We've been meeting for just about an hour. What
20 we might do is take a bio-break here for, you know, 10 or 15
21 minutes. But everybody be thinking about how we want to
22 spend, you know, the rest of our meeting time.

23 Do we want, you know, start talking specifically
24 about, you know, the language for proficiency testing or,
25 you know, build on some of this discussion this morning

1 which I think has been very good.

2 I think, obviously, from our time frame
3 perspective Jennifer is right. We want to get something
4 back to Agency, you know, pretty much as soon as possible to
5 keep the clock moving here.

6 COMMITTEE MEMBER WONG: Can somebody refresh my
7 memory. The Senate Bill 1623 mandated that the Forensic
8 Alcohol Review Committee meet every like, was it five --

9 CHAIRMAN KIMSEY: Five years.

10 COMMITTEE MEMBER WONG: -- well, we haven't even
11 ended and we are supposed to like meet again, you know
12 (laughter).

13 CHAIRMAN KIMSEY: No, no. We've had 18 meetings
14 in what -- almost six years. So, we're beating the ones
15 that want every five years.

16 So, anyhow, I think what we're trying to, what I
17 want people to be thinking about is how we want to proceed
18 when we come back on, you know, getting some language
19 together. You know, what our time frames might be. Do we
20 spend some time today. What are, you know, how do we want
21 to proceed with -- we've got, you know, this conference call
22 until 3:00 o'clock. You know, you folks all know sort of
23 what our options are.

24 So, does that seem like a suggestion? Take a bio-
25 break for --

1 COMMITTEE MEMBER WONG: That's good.

2 CHAIRMAN KIMSEY: -- 15 minutes.

3 COMMITTEE MEMBER SHEN: Sounds good.

4 CHAIRMAN KIMSEY: Okay. Thank you all.

5 (A short break was taken off the record)

6 CHAIRMAN KIMSEY: Do we have Sacramento?

7 COMMITTEE MEMBER DAVIS: We're all back.

8 CHAIRMAN KIMSEY: Great. Do we have San Diego?

9 MR. LYLE: San Diego is here. Can you hear us?

10 CHAIRMAN KIMSEY: Yes we can, loud and clear.

11 Thank you all. So, as mentioned we want to have some
12 discussion about how we want to spend the rest of our time
13 today.

14 Does anyone have, anyone want to start off?

15 COMMITTEE MEMBER SHEN: Well, this is Jennifer.

16 I'll start it off.

17 CHAIRMAN KIMSEY: Sure.

18 COMMITTEE MEMBER SHEN: My thought is that we
19 should take the letter from December 15th and at the bottom
20 of that letter there are bullet points as to how the
21 Department found us lacking.

22 So why don't we address them one by one with the
23 thought that we could do some tweaking of the verbiage in
24 Title 17 and that we could compose, you know, a paragraph
25 that would be inserted into a letter that will accompany our

1 pages.

2 CHAIRMAN KIMSEY: Okay. Other ideas? We'd had a
3 bit of a similar discussion here in the sense that we
4 basically want to trigger the 90 day review by Health and
5 Human Services.

6 And there's obviously, you talked about revisions
7 and summary of revisions. But I think our next -- I mean,
8 I'm assuming that our next letter to Health and Human
9 Services Agency, we want to trigger the 90 day review.

10 And I think your suggestion of going through
11 bullet by bullet here, Jennifer, is a good one.

12 And then we'd have to incorporate those changes in
13 the package. Is that what you were thinking?

14 COMMITTEE MEMBER SHEN: Yes.

15 CHAIRMAN KIMSEY: Okay. So, we can start with the
16 first bullet, remove CDP's evaluation of a laboratory's
17 performance on proficiency tests.

18 And I believe, based on our discussion, that we
19 are talking about having the Department maintain a role in
20 proficiency testing that would be a review of proficiency
21 testing data submitted by the laboratory with the idea of
22 making a determination of passage of acceptability.

23 COMMITTEE MEMBER WONG: Is it they rubber stamp?

24 CHAIRMAN KIMSEY: It shouldn't be that.

25 COMMITTEE MEMBER WONG: Well I mean --

1 CHAIRMAN KIMSEY: Yeah, no, no --

2 COMMITTEE MEMBER WONG: -- but --

3 CHAIRMAN KIMSEY: -- I --

4 COMMITTEE MEMBER WONG: You'd be giving your
5 rubber stamp that we passed and we did our proficiency
6 and --

7 CHAIRMAN KIMSEY: After some analysis though.

8 COMMITTEE MEMBER WONG: -- right, right.

9 RESEARCH SCIENTIST BUTENKA: Statistical analysis.

10 COMMITTEE MEMBER WONG: Right.

11 COMMITTEE MEMBER SHEN: Here's a question I have
12 about that. Since Clay brings up the point that he, that
13 the Department wants us to evaluate each method which by the
14 Department's definition apparently means each instrument;
15 the accrediting bodies require that we test each analyst.

16 So if we were to put together some verbiage where
17 each analyst is tested on a yearly basis and I guess in that
18 process each instrument needs to be utilized; that should
19 accommodate what the Department wants as well as what our
20 accrediting bodies need.

21 COMMITTEE MEMBER WONG: I think that's kind of
22 already met Jennifer because with 17025 if your
23 instrumentation that you're not using and it hasn't been
24 validated and hasn't been calibrated and all that nonsense,
25 then you're not using that instrument at all.

1 I mean, it's actually marked and labelled off,
2 "Instrument Not In Use". So --

3 COMMITTEE MEMBER SHEN: Well, I meant the fact
4 that in my department I have two GCs that are used for
5 alcohol analysis. The same method is used on each
6 instrument but both of those instruments are in use.

7 The Department wants us to conduct proficiency
8 tests using each one of those instruments.

9 RESEARCH SCIENTIST BUTENKA: So what's wrong with
10 this?

11 COMMITTEE MEMBER SHEN: So we just -- and where
12 our accrediting body wants each of our analysts to run a
13 proficiency test to make sure that the analyst knows what he
14 or she is doing.

15 So I don't know and you may know better than I --
16 I don't know that the accrediting bodies by-and-large say
17 that each instrument you have must be tested.

18 COMMITTEE MEMBER WONG: Each instrument just has
19 to be validated. And it has to, if it's in use it has to
20 have been validated and quality checked and calibrated for
21 use.

22 COMMITTEE MEMBER SHEN: Well, okay, so again in
23 our own laboratory our instruments are validated and they're
24 online.

25 Anytime we use them we have to run a two point

1 calibration, we run, you know, we run sanitary controls, we
2 run blanks every single time we run it. But, if I have to
3 test an analyst I don't require that that analyst do the
4 analysis on --

5 COMMITTEE MEMBER WONG: On both instruments.

6 COMMITTEE MEMBER SHEN: -- both instruments, only
7 on one instrument because both instruments -- the set up of
8 the sample and the method used to analyze the sample is the
9 same. They're just two different instruments.

10 COMMITTEE MEMBER WONG: Uh-hmm.

11 COMMITTEE MEMBER SHEN: So the Department, it's my
12 understanding Clay, please correct me if I'm wrong, you want
13 proficiency tests run on each instrument.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Yeah, that's correct. And a couple of points of
16 clarification. I think regarding the requirement that, that
17 you attributed to ASCLD/LAB regarding the requirement that
18 each analyst be tested annually; I think that's a bit of an
19 overstatement actually.

20 I think a careful review of the ASCLD/LAB
21 guidelines suggests that -- describes the annual testing of
22 examiners as an, "important" criteria not a an essential but
23 an important.

24 And it's further clarified in the proficiency
25 testing guidelines. And there they state that individual

1 examiners need to be tested annually in each discipline and
2 at least once every five years in each sub-discipline.

3 So this is splitting hairs but --

4 COMMITTEE MEMBER SHEN: Yes.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 -- but, and in a lab that where the only discipline under,
7 the only sub-discipline under toxicology is forensic alcohol
8 analysis then, you know, it's a moot point.

9 But the other more, maybe, obviously more
10 important point, is that as members of the subcommittee and
11 members of the public have, from the labs have stated in
12 recent meetings; as fully provided by ASCLD/LAB the majority
13 of those proficiency tests are done on samples generated in-
14 house. So they're internal PT samples.

15 And I think when we talk about proficiency testing
16 we're talking about external proficiency testing because you
17 mentioned some of the other QA procedures, the calibration
18 each day, the QC standards, the historical review of the QC
19 standards. Those are all internal programs.

20 Proficiency testing is the one external program
21 that captures certain kinds of errors that would be
22 otherwise very difficult to demonstrate.

23 So if we were to change the procedures and require
24 that the annual proficiency tests, we would set that in
25 regulations; for each analyst was completed using an

1 external proficiency test sample, then I would think that
2 would capture all of the -- probably render unimportant the
3 question of which instrument was used because I would think,
4 you know, at least in the large laboratory with many
5 analysts, both instruments would be covered. And the actual
6 frequency of testing would be increased.

7 But I think it's important to distinguish, and
8 it's not always done in some of the comments from the
9 community members, it's hard to distinguish the external
10 proficiency tests requirements from the internal proficiency
11 test requirements.

12 COMMITTEE MEMBER SHEN: I believe I agree with you
13 completely.

14 COMMITTEE MEMBER WONG: I concur as well.

15 COMMITTEE MEMBER SHEN: So external tests each
16 analyst once a year. We're good?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 Yeah.

19 CHAIRMAN KIMSEY: Okay.

20 COMMITTEE MEMBER WONG: Works for me.

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Wow. We agree.

23 CHAIRMAN KIMSEY: Any dissension among the
24 Committee or is there general agreement?

25 MR. LYLE: This is Bruce Lyle. I have general

1 agreement but I'm not sure that addresses the concerns in
2 the letter about removing the CDPH evaluations. So we'll
3 have to have some kind of wording in there that directs
4 providers to report the tests to the CDPH, the test results.

5 COMMITTEE MEMBER SHEN: Or we don't necessarily
6 have to have the providers --

7 MR. LYLE: Or the labs --

8 COMMITTEE MEMBER SHEN: -- the laboratory on an
9 annual basis must forward those results to the Department.
10 How do you envision that happening?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Well, I mean it might be cleaner to just have the provider
13 do it.

14 COMMITTEE MEMBER SHEN: Yes, that might be harder
15 though. With the, you know, I know we right away can have
16 laboratories provide it without any problem whatsoever.

17 COMMITTEE MEMBER WONG: Hmm.

18 COMMITTEE MEMBER SHEN: It would have to come to
19 the laboratories anyway because the laboratories need to
20 know how it is they did.

21 MR. LYLE: It's Bruce Lyle. And making the
22 laboratory in charge of it or at least responsible for it
23 seems the best way to go because the inspector may not, the
24 evaluator may not really have a dog in that fight.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 Yeah. One more quick comment. I thought someone would
2 mention it and we're not paying for it so that's not -- but
3 for large labs, a number of large labs have 50 people on
4 their, what we used to call, a list of persons qualified to
5 perform forensic alcohol analysis; I suspect that not all 50
6 are actually doing forensic alcohol analysis.

7 So there will be a cost associated with having
8 labs do, obviously, more proficiency tests. Currently labs
9 are doing one -- your lab Jennifer is doing one external
10 proficiency test a year. At least that's what you reported
11 to us.

12 You would now have to do somewhat more than that.
13 You'd have to test enough people not only to cover the
14 typical analysts but to handle back up and the need for, you
15 know, when some analysts are not available.

16 So there might be some cost factors here that --

17 COMMITTEE MEMBER SHEN: I think you misunderstand.
18 We test every analyst every year with an external
19 proficiency test.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Okay, all right.

22 COMMITTEE MEMBER SHEN: And I think that's pretty
23 common.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 I would say --

1 COMMITTEE MEMBER SHEN: And I actually wasn't
2 aware that we are allowed to make our own proficiency tests
3 and tests our analysts with an internal test.

4 I thought it had to be external.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Well, that's specifically provided for in the ASCLD/LAB and
7 I think if you'd check the ASCLD/LAB guidelines you'll see
8 that language.

9 And when it's been discussed in the past the
10 statement has been made that the majority of the tests are
11 done using internal tests.

12 COMMITTEE MEMBER SHEN: Hmm.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 So you, the other thing that ASCLD/LAB provides is that
15 multiple analyst can analyze a single sample, I assume.

16 So that's another wrinkle that we should probably
17 address. And I assume that's something that doesn't occur
18 at San Diego?

19 COMMITTEE MEMBER SHEN: No, it does occur. We get
20 those -- well, actually, I don't actually do them. So, we
21 get the external testing twice a year and I have three, well
22 I only have five analysts, but I used to have three do each
23 one.

24 And I don't, I can't tell you how they're
25 delivered, if each analyst has his or her own little sample

1 or if three of them use one sample. I don't know.

2 Someone else can probably answer that better than
3 I can.

4 MR. VON BEROLDINGEN: This is Linton in Richmond
5 again. And, you know, Clay, I think some of what is
6 excellent in ASCLD/LAB protocols that is directed to the
7 overall lab with a variety of disciplines and some sub-
8 disciplines will collapse to reasonableness when we apply it
9 to forensic alcohol sections and laboratories.

10 But I think it's there because certain types of
11 analyses you really want each person to have exactly the
12 same thing to play with. So it might be a set of
13 photographs or some tire tracks or something like that.

14 And you don't want to have people making their
15 own, they don't give you a rubber tire (laughter).

16 But it makes great sense to me, again, in the
17 context of my more recent experience in this DNA world that,
18 yes, as Jennifer says. Every analyst gets an external once
19 a year. That's right dead on.

20 I'm mulling over the concept of insisting that
21 each instrument itself be proficiency tested in light of the
22 experimental controls that run with every batch and the fact
23 that an instrument has to have undergone at least a site
24 validation to get started to run. And if the instrument
25 undergoes any significant maintenance and perhaps is even

1 moved from one side of the bench to the other you have to do
2 a performance check which is a lesser subset of a site
3 validation.

4 I think the laboratory records for that instrument
5 would stand on their own without actually having to go
6 through making sure that you ran a proficiency test through
7 it.

8 And there's also as, and this is redundant and I
9 apologize, but if it's not being used, under the ISO
10 accreditation standards it's got a big placard on it that
11 say, I am not in use.

12 COMMITTEE MEMBER SHEN: Correct, correct. And I
13 agree with you completely.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 I don't disagree with you either but I don't think it's a
16 significant point because I think if you have five analysts
17 I would imagine the lab would just by chance alone that both
18 instruments would get checked --

19 COMMITTEE MEMBER SHEN: But they might not.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 -- at least once.

22 COMMITTEE MEMBER SHEN: So that's the question.
23 How important is that? I would agree that it's not
24 important. To me, if your instrument has gone through it
25 I'm not going to reiterate what was just said. But it's

1 important that the analysts accept it.

2 COMMITTEE MEMBER WONG: Correct.

3 COMMITTEE MEMBER SHEN: The analyst's time and
4 that person's ability to set up a sample and analyze it
5 using the available equipment.

6 So I can't guarantee you in my labs that the
7 analysts would not use one instrument over the other.

8 So, I mean, if that's a drop dead requirement
9 right there then that's something we have to talk about.

10 COMMITTEE MEMBER WONG: You okay with that?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

12 Well I think it's important, I actually think if you have
13 well written protocols and you have modern automated
14 equipment there's not too much the analyst can do wrong.

15 I think you're actually looking at the instrument.

16 Instruments, you know, gas chromatographs develop leaks --

17 COMMITTEE MEMBER SHEN: Well I have to look at it
18 completely the other way around. Your analyst is where your
19 errors is going to happen. You can't write a sample on an
20 instrument with all of the controls and calibrations and the
21 blanks and everything else we do and not notice that
22 something is wrong with the instrument.

23 COMMITTEE MEMBER SEDGEWICK: This is Paul
24 Sedgewick in San Diego. I think we need to get our
25 terminology straight.

1 Analysts are proficiency tested. Instruments are
2 tested for their accuracy or their or are calibrated. And
3 they're different ball games entirely.

4 COMMITTEE MEMBER SHEN: I agree. I don't think
5 you can proficiency test an instrument.

6 COMMITTEE MEMBER WONG: I agree.

7 MR. LYLE: This is Bruce Lyle. And I think there
8 are in the regulations they are addressed in different
9 sections.

10 COMMITTEE MEMBER SEDGEWICK: Exactly.

11 MR. LYLE: So I think we're just talking about
12 proficiency testing which means just talking about
13 proficiency testing analysts.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 No I -- Clay Larson speaking again. Actually I think the
16 section that we would restore is Section 1220.1 (b) which
17 says, the ability of methods to meet the standard
18 performance set forth in this section shall be evaluated by
19 this department using a laboratory's proficiency test
20 results. And such ability must meet the requirements of the
21 regulations.

22 So the Department typically has described a
23 method, I mean let's take a real artificial case but applies
24 to, at least, Long Beach Police Department.

25 Where a lab is two methods. One is a GC and the

1 other is a wet chemistry diffusion oxidation method.

2 COMMITTEE MEMBER SHEN: All I understand --

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 So we tend to send two sets of samples and we evaluate the
5 ability of the method to meet the standard of the
6 performance requirements. And the method includes the
7 instruments based on the results of the PT and we need two
8 sets of results.

9 You know, maybe the lines become blurred if you
10 have two GCs but they are separate GCs. They're separate
11 columns. Columns can degrade. Columns can, depending on
12 anything the analyst does, columns can degrade to the extent
13 that they integrate peak areas differently and so --

14 RESEARCH SCIENTIST BUTENKA: Different area count,
15 I notice that.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 I think it's appropriate to somehow make a -- I'm surprised
18 it would just happen automatically. I guess everybody has a
19 favorite instrument.

20 Somehow we would just ask the labs to, I guess we
21 have to do this in regulation, to make sure that among those
22 multiple proficiency tests -- and by the way, we would also,
23 the full description of the proposal as we sent in the new
24 ideas was that labs would subscribe to the full suite of
25 proficiency test samples.

1 So CAPS actually sends three samples a year.
2 That's actually very typical of the CLIA requirements, a
3 number of the environmental health lab regulatory
4 requirements include three proficiency tests a year.

5 CTS only does two. But the expectation would be
6 labs would subscribe to the full, would subscribe to both
7 proficiency tests.

8 So, some are, if it was CTS some are in the
9 beginning of the year and in the end of the year there would
10 be a proficiency test that the Department could evaluate to
11 determine that the lab's methods are capable of meeting the
12 standard performance requirements set forth in the
13 regulations.

14 COMMITTEE MEMBER SHEN: This is Jennifer again. I
15 think, you know, we need to hear from other committee
16 members on this. I just have a real problem -- the only
17 reason we get both CTS proficiency tests is because we had
18 five analysts that need to be tested. And that works well
19 for us.

20 I really disagree with the need to proficiency
21 test our instruments. I totally get it if you have
22 completely different types of methods like wet chemistry
23 versus a GC.

24 So I don't want to write something into our
25 requirements that require us to do something like

1 proficiency test an instrument because, again, the
2 instruments are set up so that you have to have a myriad of
3 things pass before you can use the results.

4 COMMITTEE MEMBER WONG: Right.

5 COMMITTEE MEMBER SHEN: So every single time we
6 run a sample, every single time, that instrument is being
7 checked --

8 COMMITTEE MEMBER WONG: Yep.

9 COMMITTEE MEMBER SHEN: -- to make sure it worked.

10 COMMITTEE MEMBER WONG: Yep.

11 COMMITTEE MEMBER SHEN: -- we're proficiency
12 testing the analyst. And to do a full suite of tests that
13 makes no sense to me unless you're requiring each and every
14 analyst to be tested more than once a year.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

16 Well I -- want to say something? Go ahead.

17 RESEARCH SCIENTIST BUTENKA: I work --

18 CHAIRMAN KIMSEY: Identify yourself.

19 RESEARCH SCIENTIST BUTENKA: Natallia Butenka. I
20 work in the lab. And recently I was asked by my boss, Clay
21 Larson, to perform so-called uncertainty budgeting which
22 means I have to calculate what is the error of analyst
23 possibly? What is the error of other sample, possibly?
24 What is the error of this diluted dispenser?

25 And come to conclusion what is a common error?

1 So, from my knowledge of statistics I can say,
2 that different instruments they have different uncertainty
3 budgeting.

4 And it could possibly happen that the instrument
5 which is a borderline performance combined with a not-very-
6 well performance of analyst could give you, actually, a
7 pretty big error.

8 So I disagree with you in terms of science and in
9 terms of statistics and in terms of experience I have.

10 And I possess very extensive experience in terms
11 of, like, let's say, ISOR, in terms of working in the lab,
12 working in a pharmacy, pharmaceutical laboratory which has
13 so much more stricter requirements than this. It's
14 unbelievable.

15 So I could say that it would make sense for me to,
16 at least, do the analyst perform on both instruments and at
17 least compare, maybe internally. Just to make sure.

18 CHAIRMAN KIMSEY: But in the example that you
19 give, they would fail that proficiency test, wouldn't they?

20 RESEARCH SCIENTIST BUTENKA: Probably. But again,
21 the question now arise, as I understand, how the ASCLD/LAB
22 evaluate, if this results, if standard, if substandard, if
23 it's beyond this 95 percent of probabilities the results
24 supposed to be compared to peer group mean or it's not.

25 I have no knowledge how they evaluate it. And

1 also I have to say that, from my understanding, ASCLD/LAB
2 authorized on a very, very basic level of -- like a plain
3 set of rules to many, many tests, and not very specific
4 generally to, let's say, analysis of alcohol.

5 And I evaluate some statistical data and I came to
6 conclusion, hey, this data are not normally distributed.
7 Now what? How we going to do it? How we going to evaluate
8 this particular result?

9 Does it fall within the standard deviation? If
10 the standard deviation concept even not applied here? How
11 we going to do it?

12 Like, if it's the Department who is overseeing
13 these results and even if we are not sending in proficiency
14 testing but we have accepted them from ASCLD/LAB I can do
15 statistics and I can say for sure, hey, this lab has a
16 problem. It's beyond 95 percent.

17 Using the statistical model I think it fits
18 normally, I don't think it fits normally and I acquire some
19 difference model and I evaluated according to this model.

20 I can say which is substandard. The question is,
21 can the ASCLD/LAB do the same job specifically related to
22 alcohol, forensic alcohol analysis or not. And if not, then
23 what is the point of testing?

24 CHAIRMAN KIMSEY: Well I think also the question
25 for the Committee is, are we proficiency testing individuals

1 or instruments? It sounds like we've heard from --

2 COMMITTEE MEMBER SHEN: And you should keep in
3 mind also that the new accreditation guidelines mandate an
4 uncertainty measurement budget. And so we are, all of those
5 things that you were talking about, all laboratories are
6 mandated to do and we're mandated to report out that
7 uncertainty measurement budget. And, again, if you are
8 running on an instrument where you have a calibration curve
9 but all the other standard controls, blanks, et cetera that
10 we have mandated every single time and you have to have your
11 two samples, your sample run twice. And it has to be within
12 a certain percentage of each other; you are going to know if
13 something is wrong with your instrument.

14 And if you're running an instrument that's very
15 borderline and failing on a somewhat regular basis then
16 that's not an instrument you should be running. But that's
17 something I would expect the laboratory personnel to be
18 handling.

19 And that you wouldn't wait until you got a
20 proficiency test to figure that out.

21 RESEARCH SCIENTIST BUTENKA: Well some problems
22 arise just right when you do proficiency testing, at least
23 from my experience. Then what do you do?

24 I mean, the total to ensure that there is no
25 problem from my understanding would be just to test it, just

1 both instruments. Just provide the results for both
2 instruments and that's it.

3 It's just one sample more if you have two
4 instruments.

5 I mean I agree, it's pretty arguable but if you
6 say, strictly from the point of view of statistics and
7 chance that something can fail just in the same vein when
8 you're doing this samples; if I were a lab analyst I would
9 just do it on both instruments. Just set it up
10 simultaneously. Just like what we do when we are tested by
11 other outside providers.

12 If we have two instruments that's what --

13 COMMITTEE MEMBER SHEN: You know what, I have a
14 question.

15 RESEARCH SCIENTIST BUTENKA: -- I do.

16 COMMITTEE MEMBER SHEN: So do you run all your
17 samples on both instruments?

18 RESEARCH SCIENTIST BUTENKA: Well, so far we have
19 only one instrument for one method and another instrument
20 for another method. They are principally different, head
21 space and direct injection GC but I'm saying to you, if I
22 had two instruments which are the same method; yes, they
23 have QC, yes you kind of make sure that they don't fail but
24 I would still do it on both instruments because your QCs are
25 not your completely is the same as your blood samples, so to

1 speak. They are different matrix.

2 You never know what kind of effect could the
3 matrix have on analysis on this particular day. So, to be
4 strict maybe I'm too nerdy, but I would run it on both
5 instruments.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 To answer Jennifer's questions. When we qualify PT samples
8 we analyze them. But the head space and direct injection
9 instruments to see if there's any --

10 RESEARCH SCIENTIST BUTENKA: Well, but she's
11 talking about when you have different methods as apparently
12 we have to do. But if we have the same method and two
13 different instruments, I would still do it.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 You know, I think the question as you pose it Dr. Kimsey is,
16 the notion of proficiency testing an instrument sounds
17 inherently problematic.

18 But the language that we're trying to capture here
19 in the regulations which I would submit that we're now
20 striking completely, actually we're not, we're not striking
21 it, we're just striking the Department.

22 Is the idea that the Department would evaluate the
23 ability of methods to meet the standard of performance based
24 on PT results?

25 So, the shorthand notation you can call that the

1 proficiency tests of the instrument and kind of wonder what
2 instrument proficiency means.

3 But the language of the regulations simply say we
4 use the laboratory's data to evaluate the methods.

5 And also --

6 COMMITTEE MEMBER SHEN: Okay. So and once you do
7 zero one, point 1 (b), the only change that was made was
8 that the ability of methods to meet the standards of
9 performance set forth in this section shall be evaluated by,
10 and it used to say the Department, and now it says, a
11 forensic alcohol analyst using a laboratory proficiency test
12 results and such ability must meet the requirements of these
13 regulations. That's what we're talking about here right
14 now, right?

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 That definitely is, yes.

17 COMMITTEE MEMBER SHEN: Okay. So it would occur
18 to me then, if we were going to have the Department have
19 oversight of the proficiency tests that perhaps this would
20 be where we would insert that information.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 I agree.

23 COMMITTEE MEMBER SHEN: I think that we wouldn't
24 want to just put it back the way it was because then that
25 can be subject to interpretation. Do we want to say,

1 evaluated by the Department upon the laboratory, that, you
2 know, upon submission of, you know, proficiency test results
3 to the Department on such-and-so, you know, on a yearly
4 basis or whatever. We probably want to say something that
5 would indicate exactly how that evaluation is going to
6 occur.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 Okay. I agree --

9 RESEARCH SCIENTIST BUTENKA: Can we be more
10 specific?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 -- I agree. If the OR people are there I think they would
13 concur that, generally in a given section don't want to put
14 too many different requirements and too many different
15 descriptors. So it's probably going to be several
16 subsections to actually capture all that.

17 COMMITTEE MEMBER SHEN: Generally it's only one
18 subsection. And so let's talk about what exactly you want
19 in there. I mean, we're not, obviously, coming to agreement
20 on the instrument issue.

21 I mean, I still just, we have two points of view.
22 Does anyone else have a point of view? I still think that
23 each analyst needs to be tested every year.

24 CHAIRMAN KIMSEY: Right. And I think we need to
25 sort of get some feeling from the Committee. I mean, this

1 has all been a very good discussion but, and the Committee
2 sort of needs to be the one to decide.

3 COMMITTEE MEMBER SHEN: Yes.

4 CHAIRMAN KIMSEY: And I've heard from Jennifer.
5 I've heard, I think Kenton has been nodding his agreement to
6 Jennifer's interpretation. Other folks?

7 COMMITTEE MEMBER SEDGEWICK: This is Paul
8 Sedgewick. I agree with Jennifer.

9 CHAIRMAN KIMSEY: And Bruce?

10 MR. LYLE: I've said it before, I thought that
11 proficiency testing was testing the analysts.

12 CHAIRMAN KIMSEY: Lieutenant Davis

13 COMMITTEE MEMBER DAVIS: This is Kevin. You know,
14 my lack of comment is not a lack of caring. It's just I
15 don't fully, you know, have the understanding that you guys
16 have of what proficiency testing involves or, you know, the
17 devices that are being tested and how they're tested.

18 But the --

19 COMMITTEE MEMBER WONG: You know, that's okay.

20 COMMITTEE MEMBER DAVIS: -- logic behind what
21 Jennifer says makes sense to me.

22 CHAIRMAN KIMSEY: That's fine.

23 COMMITTEE MEMBER WONG: That's okay.

24 CHAIRMAN KIMSEY: Is there any other Committee
25 member that I -- I don't know that Torr is here online or

1 Laura.

2 MR. LYLE: Laura is not here.

3 CHAIRMAN KIMSEY: Right, okay. So I think the
4 consensus of the Committee then is that proficiency testing
5 applies to individuals, pretty much along the lines of what
6 Jennifer has been discussing.

7 Do we have some specific language? Do we want to
8 get into that level of detail?

9 MR. LYLE: Bruce Lyle. I have some to propose.
10 It says, labs will be responsible to report test results to
11 CDPH and they evaluate these test results and they require
12 written corrective action of any laboratory that reported
13 outside acceptable limits.

14 COMMITTEE MEMBER SHEN: This would be a
15 subsection?

16 MR. LYLE: Yes.

17 COMMITTEE MEMBER WONG: This is Kenton. I think
18 as long as we get all the information out there, like Clay
19 said, they may direct us to break it down into subsections.
20 But that's okay. I mean, as long as we get the information
21 that they need to satisfy them.

22 COMMITTEE MEMBER SHEN: I can't remember -- did we
23 lay out anywhere in Title 17, the new version, that these
24 need to be external tests? Do we need to have a subsection
25 that says, each analyst needs to be tested once a year by an

1 external proficiency test?

2 RESEARCH SCIENTIST BUTENKA: I don't see it.

3 COMMITTEE MEMBER SHEN: Because if that isn't laid
4 out somewhere we probably need to add that.

5 COMMITTEE MEMBER WONG: Yeah. We might have to go
6 back and add, "external", the word, external because, if I
7 recall, it didn't specifically say that.

8 COMMITTEE MEMBER SHEN: Okay.

9 RESEARCH SCIENTIST BUTENKA: I think ISO has
10 internal requirement tests done by them. ISO requires
11 internal testing.

12 CHAIRMAN KIMSEY: Any other comments on the
13 language suggested? Member Bruce?

14 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
15 Well I, it seems that -- this is Bob Haas from the program.
16 We still haven't resolved whether we keep the language,
17 whether we're testing methods, analysts or instruments.

18 And it's not for me to say but, my opinion is that
19 if you're testing a method that's based on the SOP, the SOP
20 will describe the instrumentation.

21 And if the instrumentation is identical and well
22 calibrated I would think that you wouldn't need to test each
23 instrument. And I don't know how big the biggest lab is.

24 Does it have ten GCs? Does that mean they have to
25 do ten different, each analyst has to do it on ten different

1 instruments?

2 So, there's a practical limit to this. But I like
3 the language, the original language that tests a method
4 because that's your standard operating procedure.

5 And in those SOPs there's always the
6 instrumentation described. It may say, you know, an agilent
7 GC or equivalent.

8 COMMITTEE MEMBER WONG: Right.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 I certainly could live with that as long as it's the method
11 that's being tested.

12 COMMITTEE MEMBER WONG: I concur.

13 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
14 Is there still debate about method, analysts, instrument or
15 not?

16 RESEARCH SCIENTIST BUTENKA: Well, I have a
17 question to Jennifer. Do you require, in your lab, do so-
18 called intermediate precision which actually involves study
19 of analyst to analyst, instrument to instrument -- when you
20 start your new methods, when you just start the methods?

21 Do you have the --

22 COMMITTEE MEMBER SHEN: You know, I'm having --

23 RESEARCH SCIENTIST BUTENKA: -- study
24 performance --

25 COMMITTEE MEMBER SHEN: -- I can barely hear you.

1 I didn't catch that at all.

2 RESEARCH SCIENTIST BUTENKA: -- well I'm, what I'm
3 asking, when you just introduce the method, and let's say
4 you have 10 instruments, let's say you have, it's a big lab
5 and you have 10 instruments --

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 Let me interrupt for one quickly -- there's one lab with
8 three instruments, other than that it's maybe two labs,
9 maybe L.A. has got three now, I've forgotten.

10 But one or two labs has three instruments, other
11 than that the maximum is two. So --

12 RESEARCH SCIENTIST BUTENKA: Yeah, even if it's --

13 COMMITTEE MEMBER SHEN: Yeah, we have two.

14 RESEARCH SCIENTIST BUTENKA: -- okay. So if you
15 have two instruments, when you just first introduce the
16 method for GC; let's say head space GC and you have two
17 instruments and you have several analysts working, do you
18 perform any study or do you require to perform any study so-
19 called intermediate, precision, procedure validation part of
20 the method where you actually describe what is the error
21 involved when you to analyst-to-analyst study and
22 instrument-to-instrument.

23 And if you do, is it somewhere documented in your
24 written procedure?

25 COMMITTEE MEMBER SHEN: Well, I mean, I think this

1 is probably getting beyond the discussions that we need to
2 have here. I certainly do, we certainly, I'm certainly
3 happy to discuss all of those things with you, probably at a
4 different time.

5 But I think discussing our very fine detail of how
6 we handle our instruments is probably not appropriate for
7 here. And we do, absolutely, quite a bit of testing on
8 those instruments before they go online.

9 And we do quite a bit of testing every time we run
10 a sample and we are required and we will be required to
11 report an uncertainty measurement.

12 I think that's something that is coming for all
13 laboratories soon. So that is something that we also are
14 involved in.

15 But if you want to talk further about that and how
16 we're doing that, I'm happy to do so at a different time.

17 CHAIRMAN KIMSEY: And sort of back to Dr. Haas's
18 question. Are we sort of agreed that this is method and
19 individual that proficiency testing is testing and not
20 instruments? Was that your point? Your question?

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Yeah, that was my question.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
24 Well then I would --

25 RESEARCH SCIENTIST BUTENKA: Well if they do it, I

1 would agree that, really, it's a person testing. If they do
2 intermediate procedure, they will establish the budget and
3 everything, then, yeah, of course, it makes sense. You
4 don't test instrument. You test the analyst.

5 If they don't then it's kind of question. That's
6 all.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 Yeah, and it also occurs to me that there's a, regarding the
9 question, it's a little bit like Jello, trying to pin it to
10 a wall. The definition of method, I think Jennifer agreed
11 that if you had a methods involving three different
12 principles, liquid diffusion oxidation method and a GC
13 method, those would be separate methods, I guess, subject to
14 separate proficiency tests in order to enable the Department
15 to evaluate the ability of the method.

16 But, and at the other extreme, there are labs that
17 have a single written document. Therefore you might call
18 that a method description using two, as much as is possible
19 to manufacture two identical instruments, two identical
20 instruments, and I gather that there's a sentiment here,
21 although I don't particularly agree with it, that that would
22 be a single method.

23 There's an intermediate step. There are labs with
24 an old GC and a new GC, separate written documents and
25 sometimes somewhat different procedural requirements in

1 terms of how you set up the, a run.

2 Just throwing it out there, would that be two
3 methods or a single method?

4 COMMITTEE MEMBER SHEN: You're asking me?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Actually you do all the talking, you can get seven other
7 members there, six other members there that could respond.

8 COMMITTEE MEMBER SHEN: All right. I'll stop
9 talking.

10 COMMITTEE MEMBER DAVIS: This is Kevin. I have no
11 idea on that one.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 Better take it Jennifer (laughter).

14 COMMITTEE MEMBER SHEN: Well, I guess my thought
15 is that if you have two, if you have two instruments that do
16 the same thing, they are the same brand, they are within the
17 same decade of each other and you operate them in the same
18 manner, then that is one method.

19 I would agree that both of them have to go through
20 extensive testing before they go online but I would consider
21 that to be one method.

22 Where I would consider two different, if they were
23 using an FTIR and a GCMS, those are completely different
24 methods and you would have to test your samples using each
25 of those methods.

1 So, to me, this is kind of semantics, you know.
2 You're right if you've got, you know, you've got an
3 instrument that's so old you have to do something
4 drastically different to it to run your samples, then maybe
5 that would be something you would have to look at as far as
6 the different methods.

7 But basically, in my opinion, if it's the same
8 type of instrument doing the same work in the same way, it
9 is one method.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

11 Well, and then let me throw in one more last thing, the
12 practical experiences of the Department since we've been
13 doing proficiency tests for 30 years we actually are the
14 obvious experts here.

15 We've certainly seen the case that labs with
16 multiple methods have had satisfactory results on one
17 instrument, if you will, and unsatisfactory results on
18 another instrument.

19 I don't recall whether it was the same operator
20 but I suspect in some cases it was the same operators. So
21 our practical history, the results we've seen from our
22 history here is that even though they're one method, it's
23 possible to have a method produce unsatisfactory results;
24 and instrument, if you will, under one method and have the
25 other produce acceptable results.

1 So we've seen that, probably the typicals. It's
2 unusual for a lab with two instruments to have
3 unsatisfactory on both instruments.

4 COMMITTEE MEMBER WONG: I agree with Jennifer that
5 even if there are different instruments but they're the same
6 principle, you're going to know from your QA, your QC, your
7 day-to-day running of that instrument whether there's going
8 to be a problem.

9 And the bottom line here is the Department wants
10 to know whether we can get the right answer. That's the
11 bottom line.

12 I don't care how you cut it, it still comes up
13 Snickers. We have to come up with the right answer. And it
14 doesn't make a difference. I mean that's, that's where the
15 rubber meets the road.

16 You guys want to know, can you guys get the right
17 answer?

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 And I say, our practical experience has been labs where the
20 rubber met the road, labs in the past have produced the
21 right answer on one instrument and the wrong answer on
22 another instrument. That's happened.

23 COMMITTEE MEMBER WONG: Well that's --

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
25 Well that's seriously problematic because both instruments

1 are in routine use. And, you know, that argues, I think,
2 for testing --

3 RESEARCH SCIENTIST BUTENKA: How much was the lab
4 or analyst --

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
6 -- instruments as part of this --

7 RESEARCH SCIENTIST BUTENKA: -- I think it's a --

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
9 -- I don't know, I don't know that history --

10 COMMITTEE MEMBER SHEN: And that laboratory has to
11 go through some sort of --

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 -- myself. But that's serious --

14 COMMITTEE MEMBER SHEN: -- fixing.

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

17 COMMITTEE MEMBER SHEN: -- that's fairly unlikely
18 with the type of QA we run on these instruments.

19 COMMITTEE MEMBER WONG: I agree.

20 RESEARCH SCIENTIST BUTENKA: Yeah.

21 COMMITTEE MEMBER SHEN: I just don't, I don't
22 think that we want to write these regulations for an extreme
23 example which I think that is.

24 COMMITTEE MEMBER SEDGEWICK: This is Paul
25 Sedgewick. It doesn't really matter whether it's one

1 instrument. If two different instruments are giving two
2 answers, it's an instrument problem not a methodology
3 problem.

4 MR. LYLE: Bruce Lyle. But it's the bottom line
5 in the language that I was proposing. The second half of it
6 gives the Department the ability to look at those results
7 and if there is something out of the ordinary that isn't
8 right then they can ask for corrective action.

9 So it doesn't matter whether it's the method, the
10 instrument or the person messing up; what they need to do
11 is, what they'll do is they will identify that incorrect
12 answer results and then get back to the laboratory that's
13 providing that and require some kind of corrective action
14 whether it's corrective action fixing the machine,
15 retraining the analyst or redoing the method.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 However, if the Department doesn't see results from
18 instrument A, it always gets results from instrument B, at
19 least during one annual cycle, there's no way the Department
20 will be able to evaluate --

21 RESEARCH SCIENTIST BUTENKA: Instrument B.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 -- and request corrective action for instrument B.

24 COMMITTEE MEMBER SHEN: Well, the bottom line is,
25 when you do an analysis you have to run whatever instrument

1 you pick, the quality assurance or controls, everything else
2 has to be in, and if they're not, that's a problem.

3 And when we do proficiency tests if there's any
4 soot on an instrument and we're going to run it and we're
5 going to give you the results.

6 COMMITTEE MEMBER WONG: Correct.

7 COMMITTEE MEMBER SHEN: And if there's a
8 problem --

9 COMMITTEE MEMBER WONG: You're going to know it.

10 COMMITTEE MEMBER SHEN: -- you'll get it.

11 CHAIRMAN KIMSEY: I think the consensus of the
12 Committee is that we're talking about methods and employees
13 not instruments. Is that pretty much what I'm hearing for
14 proficiency testing?

15 We're talking about the analyst and the method,
16 not the instrument.

17 COMMITTEE MEMBER SHEN: Yes.

18 COMMITTEE MEMBER WONG: Well, I think everybody --

19 RESEARCH SCIENTIST BUTENKA: Uh-hmm.

20 COMMITTEE MEMBER WONG: -- is talking about
21 employees and analysts but Clay is talking about
22 instruments.

23 CHAIRMAN KIMSEY: No, I know. I'm just saying,
24 but the Committee, the members of the Committee. And I
25 understand Clay's perspective but the Committee, the

1 consensus seems to be, not, siding with doing proficiency
2 testing on each instrument which is what Clay is proposing.

3 COMMITTEE MEMBER WONG: Correct.

4 CHAIRMAN KIMSEY: I'm just trying to sort of move
5 us along with regard to the --

6 COMMITTEE MEMBER WONG: Yes.

7 CHAIRMAN KIMSEY: -- language that Bruce has
8 proposed. And if we can, obviously, we're coming up on the
9 lunch hour. But it would be nice if we could sort of agree
10 on bullet number one and the language and resolve this
11 discussion before we break.

12 So, is there any other suggestions or additions to
13 Bruce's language suggestion?

14 COMMITTEE MEMBER WONG: No.

15 COMMITTEE MEMBER SHEN: So we want to put under
16 that particular section, the subsection of the discussion
17 that we need to test the analyst per year with an external
18 proficiency test and then another one that says something on
19 the lines of, the last we are responsible to report test
20 results to CDPH who will evaluate the test results and may
21 require written corrective action of any labs that are
22 reported outside the acceptable limits.

23 COMMITTEE MEMBER WONG: Yes.

24 COMMITTEE MEMBER SHEN: But if you put, if we
25 write that down in two subsections, will that accommodate

1 this?

2 RESEARCH SCIENTIST BUTENKA: Could it be possible
3 at least indicate what instruments you use for proficiency
4 testing?

5 MR. LYLE: It's not in the regulations.

6 COMMITTEE MEMBER SHEN: No.

7 RESEARCH SCIENTIST BUTENKA: Okay. But I mean
8 practically.

9 MR. LYLE: We're talking about the regulations.

10 RESEARCH SCIENTIST BUTENKA: Ah, okay.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Well, we're also considering changing the regulations. And
13 so you don't need to be hamstrung by them. I mean, unless
14 you want to be. But you don't need to be.

15 COMMITTEE MEMBER WONG: We don't want to be.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 So then we --

18 COMMITTEE MEMBER SHEN: This is Jen, we don't want
19 to be.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 So then we can go ahead and include a requirement that we
22 would identify -- for instance, that lab that does a Widmark
23 method and a GC method, do we get --

24 RESEARCH SCIENTIST BUTENKA: Yeah, we need to know
25 what methods they use, right?

1 COMMITTEE MEMBER SHEN: We're --

2 RESEARCH SCIENTIST BUTENKA: We need to know what
3 do you, what method do you use for precision --

4 COMMITTEE MEMBER WONG: You're going to --

5 RESEARCH SCIENTIST BUTENKA: -- testing.

6 COMMITTEE MEMBER WONG: -- you're going to have
7 to do external proficiencies for each one of those methods.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 Right.

10 RESEARCH SCIENTIST BUTENKA: Yeah.

11 COMMITTEE MEMBER WONG: That's understood.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 And the methods would be identified in the reports?

14 COMMITTEE MEMBER WONG: Yeah. You're going to
15 know that you're getting the Widmarking. You're going to
16 know you're getting the GC.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 But that's not in the regulations as Bruce Lyle will point
19 out.

20 RESEARCH SCIENTIST BUTENKA: Yeah, it's not.

21 COMMITTEE MEMBER SHEN: And I think --

22 COMMITTEE MEMBER WONG: For each --

23 COMMITTEE MEMBER SHEN: -- that's okay.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Also --

1 COMMITTEE MEMBER SHEN: I think, as of my opinion,
2 this is enough.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 Lots of words get thrown out here, mainly for effect, I
5 suspect. You mentioned that two instruments that were
6 manufactured within the same decade; are you suggesting that
7 the regulations should incorporate a manufacturing date? Or
8 was that just, were you just --

9 COMMITTEE MEMBER WONG: No.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
11 -- throwing out words?

12 COMMITTEE MEMBER WONG: I'm speaking for Jennifer,
13 no.

14 COMMITTEE MEMBER SHEN: I was just --

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 So it was --

17 COMMITTEE MEMBER SHEN: -- no, no.

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 -- she was kidding, all right.

20 COMMITTEE MEMBER SHEN: I know. You can't see my
21 face or you would know that I was kidding. I'm sorry.

22 CHAIRMAN KIMSEY: Any other suggestions to Bruce
23 Lyle's language?

24 (No response)

25 CHAIRMAN KIMSEY: Okay. How long do we want to

1 take for lunch? Thirty minutes?

2 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

3 Thirty minutes.

4 COMMITTEE MEMBER WONG: Do they have to go --

5 CHAIRMAN KIMSEY: Do you guys have to go out and

6 about down there in San Diego or --

7 COMMITTEE MEMBER SHEN: We're not really sure

8 (laughter).

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

10 Forty-five minutes.

11 CHAIRMAN KIMSEY: Want to make it 45 minutes? Be

12 back at one.

13 COMMITTEE MEMBER SHEN: Back at one.

14 COMMITTEE MEMBER WONG: Does that work?

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

16 Back at one.

17 CHAIRMAN KIMSEY: Okay. Thank you all.

18 (A lunch break was taken off the record.)

19

20

21

22

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25

1 continue.

2 We were just talking here that we have one bullet
3 down and three to go. And the first bullet only took us an
4 hour.

5 COMMITTEE MEMBER SHEN: And that was the easy
6 bullet.

7 CHAIRMAN KIMSEY: I was going to say that my
8 perspective was, that was the easy bullet (laughter). But
9 moving on to bullet number two, it says, remove CDPH
10 authority to review, approve and test the qualifications of
11 persons employed by a laboratory.

12 And we, the subcommittee had talked a bit about
13 training. I don't know that we had gotten into
14 qualifications. It's in my book.

15 COMMITTEE MEMBER SHEN: Well we have the
16 qualifications set out in our proposed Title 17, correct?

17 CHAIRMAN KIMSEY: Right. And we seem to have some
18 agreement on training with regards that, you know, the
19 Department could put out some criteria and guidelines for
20 training that would need to be followed.

21 COMMITTEE MEMBER SHEN: Right. What we talked
22 about was, I think, maybe where we are going to want to go
23 here is that the, you know, when we have a new person on
24 board at the laboratory that that person has to submit a
25 transcript or certificate or proof of graduation in a

1 particular degree that would be appropriate for what we have
2 laid out in Title 17.

3 And then, my thought was that we would have an
4 outline of the topics that need to be covered in training
5 and about the laboratory staff is responsible for providing
6 that training.

7 However, it befits that the Department would have
8 access to the training records to ensure that an analyst has
9 the background through training in all of the areas that are
10 important.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Which bullet are we talking about?

13 RESEARCH SCIENTIST BUTENKA: Number three, I
14 guess.

15 CHAIRMAN KIMSEY: Number two.

16 RESEARCH SCIENTIST BUTENKA: No, I think it's
17 number three, three is --

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
19 What --

20 CHAIRMAN KIMSEY: Well we were talking about
21 qualifications, bullet number two --

22 RESEARCH SCIENTIST BUTENKA: Ah, qualifications --

23 CHAIRMAN KIMSEY: -- training came up as a result.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Okay. So we're talking about both of them?

1 CHAIRMAN KIMSEY: If you'd like.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 I don't know -- one at a time --

4 MR. LYLE: They're talking about qualifications.

5 COMMITTEE MEMBER SHEN: Oh, I'm sorry. I was sort
6 of, I was sort of combining the two. I apologize.

7 CHAIRMAN KIMSEY: No, no. That's okay. We were
8 just acknowledging that. And they do fit together to some
9 extent.

10 But back to sort of the qualifications issue.
11 What role do we see for the Department with regards to that?

12 COMMITTEE MEMBER SHEN: Well what are, in fact,
13 the qualifications currently? I mean, with what we have
14 written in Title 17 now the qualifications are certainly,
15 educational, correct?

16 COMMITTEE MEMBER WONG: Uh-hmm.

17 CHAIRMAN KIMSEY: Correct.

18 COMMITTEE MEMBER SHEN: So we'll start with that.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 Well, the other qualification is two years experience, will
21 now be, two years of experience performing forensic alcohol
22 analysis.

23 COMMITTEE MEMBER SHEN: The issue that the author
24 of the letter took was the elaborate, the changes in Title
25 17 was that we removed CDPH, the CDPH's authority to review,

1 approve and test the qualifications of persons employed by a
2 laboratory.

3 There was no questioning of what we determined
4 qualifications would be. Just that the Department didn't
5 have any oversight of them.

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

7 Okay, I'm --

8 COMMITTEE MEMBER SHEN: Put aside an argument
9 about what the qualifications should be and look to how the
10 CDPH has oversight of the qualifications that we've already
11 decided were appropriate in our rewrite of Title 17.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

13 Well, I think we would just continue the current, the
14 current procedure is labs submit something called a, page B.

15 There would be some equivalent of that which lists the
16 education, training and experience of the individual. And
17 we would review that.

18 And then, since it's a specific requirement of the
19 regulations those individuals would have to take a
20 proficiency test and a written examination -- the
21 regulations actually refer to those activities as being
22 submitted by the Department.

23 So the Department actually, under the current
24 program, it would actually administer those tests but under
25 the proposal and the program's new ideas those tests would

1 be conducted by, an actual test would be performed by some
2 approved proficiency testing entity.

3 COMMITTEE MEMBER SHEN: Okay. So, for educational
4 requirements we're looking at submission of degree or
5 submission of transcripts? Does anyone feel one way or the
6 other on that?

7 Because now all we have for education is, a
8 Baccalaureate or higher degree in any applied physical or
9 natural science, period. So, how does the Department want
10 proof of that degree?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Well, you say the labs always require that the individuals
13 have a transcript. So just go ahead and submit copies of
14 those transcripts.

15 COMMITTEE MEMBER SHEN: All right.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 And then the regulations require that they have two years of
18 experience performing forensic alcohol analysis.

19 MR. LYLE: This is Bruce Lyle. And this is in
20 order to be an analyst? They have to have two years of
21 experience analyzing?

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 Or in lieu of that two years experience, they've completed a
24 training course. Those are the regulations that you guys
25 wrote.

1 COMMITTEE MEMBER SHEN: A training course approved
2 by the laboratory. This training course to include the
3 minimum of the following schedule of subjects.

4 So again, I don't, I would rather we didn't go
5 down the road of arguing what it is to pass in our newly
6 listed Title 17. Let's talk about the oversight.

7 If we want to address the oversight, how would we
8 do that?

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
10 And that's what we're talking about. In order to restore
11 that Department's authority to review, approve and test the
12 qualifications then the lab, the Department would be
13 involved in a review and approval of the educational,
14 training and experience qualifications to the individual and
15 in addition would submit a proficiency test and written
16 examination.

17 That's how you would restore the removed CDPH
18 authority to review, approve and test the qualifications of
19 persons employed by the laboratory.

20 COMMITTEE MEMBER SHEN: I personally would like to
21 see the written tests go away.

22 RESEARCH SCIENTIST BUTENKA: Why?

23 COMMITTEE MEMBER SHEN: Because it's very
24 outdated. Either that, or it needs to be much modernized.

25 CHAIRMAN KIMSEY: Is this a test that the

1 Department puts out?

2 COMMITTEE MEMBER SHEN: Yes.

3 COMMITTEE MEMBER SEDGEWICK: This is Paul
4 Sedgewick. It strikes me as though it's really tough to put
5 a written test and check a person's analytic ability.

6 I don't think that's ever going to work.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 Well, it's a written test and a proficiency test.

9 COMMITTEE MEMBER SHEN: Well, I'm on board with a
10 proficiency test, absolutely.

11 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick, me
12 too.

13 CHAIRMAN KIMSEY: What is the written test?

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 The written exam tests the individual's, I mean, for an
16 analyst it simply tests the individual's knowledge of Title
17 17, the requirements for QC, his knowledge of what the
18 method, what the lab's individual methods actually require.

19 RESEARCH SCIENTIST BUTENKA: Just the knowledge of
20 those things.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 So it tests the knowledge of those areas.

23 COMMITTEE MEMBER SHEN: I guess what I would like
24 to see in this particular bullet, I, you know, we can talk
25 about the authority to review and approve and as far as

1 testing the qualifications of persons, I think that that
2 should be handled by the proficiency tests.

3 I would like to see the written test go away --
4 completely. I just don't, I don't, and this is just my
5 opinion from -- and the opinion of my analysts, that it's
6 just, it doesn't really do anything for us.

7 So if there is, say, a correct background
8 educationally and the correct amount of experience or
9 someone has gone through an approved training program and
10 that person passes a proficiency and/or competency test, I
11 think we have competency tests outlined in Title 17, then I
12 think that would be enough.

13 RESEARCH SCIENTIST BUTENKA: Could it be possible
14 you provide your training course so I can see how much it's
15 more modern compared to our outdated test?

16 CHAIRMAN KIMSEY: Well I think right now we're
17 talking about the written test though.

18 RESEARCH SCIENTIST BUTENKA: Yeah, written test.
19 Because they say they have their internal training
20 procedure. Is it possible, at least, to see that training
21 procedure? Do they have some kind of requirements to know
22 what is in the method? What do they have there?

23 At least this information, I think, would be,
24 would be, I mean, beneficial to know to make some kind of
25 idea.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
2 I guess more to the point, does your training procedure
3 include a written exam?

4 RESEARCH SCIENTIST BUTENKA: Yeah.

5 COMMITTEE MEMBER SHEN: Well, I think where we're
6 at here is we're trying to talk about what we want in Title
7 17. And it's my opinion that the correct educational
8 background, a proof of a, you know, of lecture series that
9 includes all the topics of relevance and a proficiency test
10 should be enough to meet our state oversight.

11 But individual laboratories choose to do with
12 their written tests or not do, it would be, you know, part
13 of their own training program.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 So you want to keep that, you don't want to divulge what,
16 it's confidential information then? I don't want to --

17 COMMITTEE MEMBER SHEN: What I want to avoid here
18 is I don't want to make this about San Diego Police
19 Department. So I'm extremely comfortable with the way we
20 operate our system. I am extremely comfortable with our
21 laboratories and how we work.

22 So I have absolutely no problems with that. And
23 if you want to have any of these conversations at another
24 time, I'm absolutely happy to do that.

25 But here we're talking about regulations for the

1 entire state. And I don't think it's important what it is
2 that I do in my laboratory.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 Well I would just argue that it's not uncommon when,
5 especially when an agency is approving the qualifications of
6 someone that involves some, you know, some knowledge,
7 technical knowledge and knowledge of the law and the
8 regulations here; it's not uncommon to have a an exam.

9 COMMITTEE MEMBER SHEN: You know, I agree.

10 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

11 And so, the Department was simply, and you know, the
12 Committee can just vote and determine, I don't want to argue
13 this all day either --

14 COMMITTEE MEMBER WONG: Right.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

16 -- could just vote and determine that even though it's
17 common for some reason, I think you would state those in
18 the, you know, in the initial statement of reasons, for some
19 reason it, because of the special characteristics of this
20 group, it's not necessary.

21 COMMITTEE MEMBER SHEN: It's not that it's not
22 necessary. It's that it should be -- I think though what we
23 want, or at least what I should state what I want, is I want
24 the laboratory management to have a little more oversight on
25 how they train their people and whether that's through a

1 course or written exams or, you know, certain types of tests
2 or correlations studies along with all the lecture material
3 and, you know, I want the laboratory to take ownership of
4 their training because, you know, we're the ones that have
5 to defend what we're doing in court. And we're the ones
6 that have to ensure our people are ready to go.

7 And I would like the Title 17 to have the minimum
8 that we have to have. And I would wager that most
9 laboratories go well above and beyond that.

10 And I don't want to be forced into a written
11 examination. It doesn't address my needs for my section.
12 So, you know, you can, I suppose a good alternative would be
13 that the training program must include these areas of
14 lecturing and in addition to that at the end of the training
15 program there needs to be a written test so that the
16 laboratory management can determine.

17 So if you feel a written examination is very
18 important, I just don't want it to be one size fits all.

19 CHAIRMAN KIMSEY: And this is Paul. And not that
20 I'm advocating a written exam but would there be any
21 advantage to a common exam, you know, sort of for, it would
22 be across the state, and if it, it might be able to made at
23 least more convenient if it was online.

24 You know that's, a lot of that is done now where
25 you pretty much know by the end of the 15, 20, 30 minute,

1 whatever, period of time that the exam --

2 RESEARCH SCIENTIST BUTENKA: You know, we can
3 design that --

4 CHAIRMAN KIMSEY: -- takes that, you know, you
5 know whether you've passed or not. You can print out a
6 certificate. I don't know. I think there's some, I guess
7 the point I'm trying to make is that there's some easier
8 ways now of doing exams and is there any advantage to having
9 a -- if there is going to be a written exam, of having a
10 common statewide exam.

11 COMMITTEE MEMBER SHEN: It depends on who that
12 exam is written by I suppose.

13 CHAIRMAN KIMSEY: Well, the Committee could, you
14 know, we're supposed at least every five years.

15 COMMITTEE MEMBER WONG: We're already to the
16 second round (laughter).

17 RESEARCH SCIENTIST ZABALA: Can I make a comment?

18 CHAIRMAN KIMSEY: Sure.

19 RESEARCH SCIENTIST ZABALA: Okay.

20 CHAIRMAN KIMSEY: Yes, state your name please.

21 RESEARCH SCIENTIST ZABALA: Zenaida Zabala.

22 Regarding these exams, the Department's exams. It's just,
23 these are written exams of how much the analyst know of the
24 regulations in relation to what they do in the laboratory.

25 RESEARCH SCIENTIST BUTENKA: That's true. And

1 most of the methods are set up --

2 RESEARCH SCIENTIST ZABALA: And that's just my
3 comment.

4 RESEARCH SCIENTIST BUTENKA: -- to accommodate the
5 regulations, historically. So in this sense, this exam
6 makes perfect sense. It doesn't test how they are good,
7 according to their manager to perform the work. It tests
8 how they are good to perform work according to regulation.

9 And as I looked at the method, they are feed the
10 regulation, historically. So, so far the situation is like
11 this, they do feed the regulation.

12 CHAIRMAN KIMSEY: Excuse me just a moment. I can
13 see some more people have joined us in Sacramento. Could
14 you identify yourselves?

15 COMMITTEE MEMBER ZIELENSKI: Yes, Torr Zielenski,
16 California Public Defenders Association.

17 CHAIRMAN KIMSEY: Oh, hi Torr.

18 COMMITTEE MEMBER ZIELENSKI: How are you?

19 CHAIRMAN KIMSEY: Good.

20 COMMITTEE MEMBER ZIELENSKI: Good.

21 CHAIRMAN KIMSEY: And I think somebody came back
22 from OLS or --

23 MS. DVORAK-REMIS: Office of Regs --

24 CHAIRMAN KIMSEY: Office of Regs.

25 MS. DVORAK-REMIS: -- Rosalee Dvorak-Remis.

1 CHAIRMAN KIMSEY: Oh yes, hi Rosalee. It's a
2 little fuzzy up there on our lens here --

3 RESEARCH SCIENTIST BUTENKA: It's blurry.

4 CHAIRMAN KIMSEY: -- anyhow, back to the question
5 of the exam. What's the feeling of the Committee members on
6 the necessity --

7 MR. LYLE: Bruce Lyle. I wouldn't be opposed to
8 the Forensic Alcohol Review Committee meeting regularly to
9 draft a written test. It just seems like it should people
10 that are, that actually work in the field and do, do the
11 actual jobs.

12 Because it seems like the people that are applying
13 for these jobs and that are either applicants or they're
14 perspective analysts, that they've gone through a lot of
15 testing as far as written testing --

16 RESEARCH SCIENTIST BUTENKA: Poor guys.

17 MR. LYLE: -- already.

18 CHAIRMAN KIMSEY: Other perspectives, comments?

19 COMMITTEE MEMBER WONG: This is Kenton. I'm not
20 actually sure if we, if the goal here is to actually restore
21 the authority of the Department to review and approve and
22 test the qualifications of persons.

23 I mean, according to 17025 and ISO regs, you have
24 to have your individuals go through their training and
25 their --

1 RESEARCH SCIENTIST BUTENKA: Aha, it's not much --

2 COMMITTEE MEMBER WONG: -- their what-not that's
3 required. And then the laboratory certifies them for work
4 within that discipline. And I'm not exactly sure that, I
5 mean, because the Department already doesn't have the
6 authority to really review, approve and test qualifications
7 anymore.

8 So I'm not exactly sure what this is all about.

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
10 Comment from the public. I do think, I'm glad we're kind
11 of getting off the discussion of the merit and value of a
12 written examination because I don't think -- I think the
13 issue here, and probably the issue with all of these
14 bulletin points is whether we have a system or we have
15 independent, external, state-level overview or whether we'll
16 rely on a kind of, self-review.

17 And the Committee has, in revising the regulations
18 has consistently fallen on the side of allowing independent
19 self-oversight. And I think the letter from, the December
20 15th letter was in response to that.

21 So again, the Committee can vote down what, you
22 know, a given proposal and we'll see what happens.

23 COMMITTEE MEMBER SHEN: Well, you know, the
24 captain is right. You know, what we're sort of kind of
25 doing here is trying to come to a sort of a middle ground

1 but we obviously wrote Title 17 in a manner to keep that
2 oversight from happening.

3 So, you know, I'd be willing to discuss a, some
4 options so that you as a Department have some idea of what
5 our analysts have gone through.

6 So I do think providing a transcript, providing
7 proof of someone --

8 COMMITTEE MEMBER WONG: Right.

9 COMMITTEE MEMBER SHEN: -- has had two years
10 experience or providing documentation from a laboratory
11 director or manager that this person has finished a training
12 program that encompasses these things --

13 COMMITTEE MEMBER WONG: Right.

14 COMMITTEE MEMBER SHEN: -- that should be it.

15 That's the kind of oversight I'm looking for --

16 COMMITTEE MEMBER WONG: That's, I agree --

17 COMMITTEE MEMBER SHEN: -- not for you to do any
18 evaluations or anything else. It's just that, you know, I
19 as a lab director have not submitted to you a person's
20 transcripts, their experience. And if they finished this
21 training I'm signing it. If they finish this training
22 that's covering these topics and this person is ready to go.

23 And that you now know that that person has
24 accomplished those things.

25 And so it's the oversight, that is what I

1 personally would be looking for here.

2 COMMITTEE MEMBER SEDGEWICK: This is Paul
3 Sedgewick in San Diego. I totally agree with Jennifer and
4 the comments that we're really not in the position to
5 restore repealed regulations. That's not what we're doing.

6 COMMITTEE MEMBER WONG: Nope.

7 COMMITTEE MEMBER SEDGEWICK: And speaking as an
8 ex-ASCLD/LAB inspector, there's more than one way to skin a
9 cat. And there is no way to write a test that's going to
10 cover everything.

11 As long as people are trained, the testing is
12 documented and, if need be, provided to Clay's group I agree
13 with Jennifer, that should be sufficient.

14 CHAIRMAN KIMSEY: Okay. This is Paul Kimsey in
15 Richmond. And so, I guess when it comes to the test,
16 Kenton, Paul Sedgewick and Jennifer are pretty much, no, to
17 the idea of a written exam.

18 I mean, I'm sort of equivocal. I mean, I don't
19 feel strongly at this point. I think Bruce was sort of
20 leaning towards possibly not an exam but thought that we,
21 maybe the Committee could be writing the questions. Is that
22 correct Bruce? What your --

23 MR. LYLE: That's correct.

24 CHAIRMAN KIMSEY: -- and I don't know, Torr, what
25 is your perspective? I know you came in a little late but

1 do you have sufficient information to sort of -- talk about
2 a test idea?

3 COMMITTEE MEMBER ZIELENSKI: Yes. I think perhaps
4 I need to hear more -- to come in kind of late.

5 CHAIRMAN KIMSEY: Sure. Well, I guess I can try
6 and summarize real quick. I mean, of the December 15th
7 letter, we're working on bullet number two which talked
8 about the Department's authority with regards to reviewing,
9 approving and testing the qualifications of persons employed
10 by a laboratory.

11 There seems to be a consensus that the
12 documentation, transcripts, these sorts of issues, the
13 Department would be aware of.

14 We currently do an exam. And the necessity of
15 that exam is sort of what's under discussion. I think
16 there's some feeling that the exam is not, obviously maybe
17 not necessary.

18 My perspective a little bit is that, you know, a
19 statewide exam with uniformity might have some merit if it
20 was updated and this Committee could see to that.

21 But you've heard sort of the arguments, I believe
22 on the other side with regards to the not having a
23 necessity.

24 But you have some questions of the Committee to
25 help decide your thoughts?

1 COMMITTEE MEMBER ZIELENSKI: So the question is
2 whether, the question is whether or not to allow the
3 credentials and/or any examination to be conducted
4 internally via the private labs as opposed to having state
5 oversight of those, of the examination and/or the
6 credentialing process?

7 The question is, is what after is supposedly going
8 to be state or Department oversight of these requirements?
9 Is that right?

10 CHAIRMAN KIMSEY: Yes, overall. And I think the
11 issue that is most controversial is the actual written exam.

12 COMMITTEE MEMBER ZIELENSKI: As to whether or not
13 it will be internally handled?

14 CHAIRMAN KIMSEY: Internal to the laboratory or
15 something that the Department was involved with.

16 COMMITTEE MEMBER ZIELENSKI: I'm all for oversight
17 from the Department.

18 COMMITTEE MEMBER WONG: Well, Torr, in the past
19 the laboratory and analysts were given a test by the state
20 in order for that person to be provided a state licensure as
21 either a forensic alcohol analyst or an alcohol supervisor.

22 But those designations and licensures don't exist
23 anymore in regulation.

24 So there's no reason to actually provide a test
25 because the state isn't giving licensures or granting

1 licensures to any individuals to do those things anymore.

2 So, what we're talking about here is, if there's
3 no state licensure that's actually being deemed and blessed
4 upon an individual then I think the happy medium that we're
5 talking about here is for us to provide the documentation
6 and transcripts that the person has the sufficient education
7 and training and certification of the laboratory for that
8 forensic discipline to do the work.

9 And I don't really think the Department has the
10 authority to really approve of that per se because it's not
11 a regulation anymore. There's no licensures being given.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

13 Let me just --

14 COMMITTEE MEMBER ZIELENSKI: Well that --

15 RESEARCH SCIENTIST BUTENKA: Is that what we
16 discuss the --

17 COMMITTEE MEMBER ZIELENSKI: That appears to be
18 the conflict that we're having here as to whether or not
19 there's, you know, is it going to be Department oversight
20 and/or whether or not this is all going to be privatized and
21 handled internally.

22 My view on this stuff is that, to the extent that
23 we're not statutorily precluded, clear and conclusively,
24 from having state oversight, I prefer to have checks and
25 balances.

1 And if that means having somebody from the
2 Department get involved in this thing and certifying things
3 I'm inclined to look at it from that perspective.

4 And that appears to be consistent with Dr.
5 Kimsey's position. Is that correct?

6 CHAIRMAN KIMSEY: Well -- I, I, sort of a little
7 bit like Lieutenant Davis. I mean, if -- I'm not familiar
8 with the exam. I'm was never licensed. And I've not worked
9 in a forensic laboratory. I just know that if we are
10 talking about an exam and whether it's for licensure or not,
11 I'm not sure it is, but just maybe for an approval which is
12 a slippery slope, I understand.

13 But if there's, you know, if there's an exam that
14 we're going to talk about I just know in other areas that a
15 standardized exam across the state has more meaning if
16 you're moving from one laboratory to the next.

17 But, again, if the individual laboratories are
18 doing their own testing, you know, that may be sufficient.

19 So I really am in the middle of the road here on
20 whether or not the Department should be involved with the
21 test.

22 I know that, obviously a lot of tests could be
23 modernized. This Committee could have, you know, approval
24 of the test. It could be done online.

25 It wouldn't necessarily be a burden. At least it

1 could be tried to be made as not much of a burden.

2 But I defer to other people, actually, in these
3 laboratories as to the necessity. I just see advantages of
4 a statewide exam.

5 COMMITTEE MEMBER DAVIS: This is Kevin. Just a
6 question. Are there any standardized or statewide exams for
7 other disciplines like DNA or firearms or things like that?

8 COMMITTEE MEMBER WONG: There are certification
9 exams in the different forensic disciplines. And then
10 there's also a general criminalistic exam which is a
11 national board certification by the American Board of
12 Criminalistics.

13 CHAIRMAN KIMSEY: And on the clinical side there's
14 over 30 different certifications and exams and licensures.

15 COMMITTEE MEMBER WONG: Right. I also have my
16 licensure as a clinical toxicologist as well with the state.
17 So there's a bunch of different exams you can take.

18 COMMITTEE MEMBER DAVIS: So, so then --

19 COMMITTEE MEMBER SHEN: Really, those exams are
20 not, those are the exams that are not required.

21 COMMITTEE MEMBER WONG: No, they're not.

22 COMMITTEE MEMBER SHEN: So, and I just want to
23 point out here that what, we're not talking about the state,
24 I mean, in my concept, it's not that we're talking about the
25 state not having an oversight.

1 It's kind of like the proficiency tests, we're
2 going to do, we're going to hire people with the right
3 degree.

4 We're going to make sure that they follow Title 17
5 as far as their experience goes. We're going to make sure
6 that they get a training program that, I would assume most
7 laboratories have written examinations as well as like a --
8 course, and a, a proficiency tests, competency tests as well
9 as the lectures et cetera. That those training programs
10 follow the outline that is laid out in Title 17.

11 The Department would then get proof of those
12 things occurring. So that to me is the check and balance
13 right there.

14 I don't think the Department has to write the
15 examination --

16 COMMITTEE MEMBER WONG: No.

17 COMMITTEE MEMBER SHEN: -- in order to make the
18 training program legitimate. The Department needs to know
19 that there is one and what's being taught and the analysts
20 have completed it.

21 So that to me is where we want to be as far as a
22 moderate approach that will take both points of view into
23 account.

24 CHAIRMAN KIMSEY: Does that help you Torr?

25 COMMITTEE MEMBER ZIELENSKI: It does. The problem

1 is that leaves up to each laboratory without any objective
2 criteria being laid across the line; each lab setting their
3 own criteria and then indicating that that is sufficient as
4 opposed to there being some across-the-board, universal
5 measures that would establish that the qualifications
6 across-the-board with every lab that's engaged in this type
7 of testing.

8 And we'll worry about, you know, certainly I
9 suspect that most of the labs out there are responsible
10 labs. But what about the labs that are not responsible that
11 are certified that, you know, a particular individual to be
12 able to connect the testing when it turns out that it, in
13 fact, may not be reliable and therefore not having an
14 across-the-board standardization process you run into the
15 potential of rogue labs or those types of things occurring
16 even though, I think, the probability is that, that doesn't
17 happen -- that most people are going to attempt to be
18 responsible.

19 But I like the idea of in this area of there being
20 some across-the-board standardized testing that
21 authenticates and verifies the legitimacy of whatever the
22 labs certify.

23 And it seems to me that's the protection that, a
24 means of protecting basically against the minority of the
25 labs that may not do what they're supposed to do.

1 COMMITTEE MEMBER SHEN: But don't forget that
2 right now laboratories are using their discretion in their
3 training programs.

4 All the Department is doing really is issuing a
5 proficiency test which they would still be getting that
6 result and issuing a written examination that is very
7 focussed on certain things that probably aren't going to be
8 all that apropos any longer anyway.

9 So, I mean, I'm not against written examinations.
10 I think they are fine and certainly I think that
11 laboratories ought to have that as part of their repertoire.

12 I am concerned about a report or a testing issue
13 that is fully Department driven I guess. So, I mean, if we
14 feel, if everybody feels that the state needs to have some
15 sort of written examination out there, then I agree that
16 people like us should be writing it. And then that can be
17 used.

18 But I think going with what we have now I'm ready
19 to go away from the written examination that is currently
20 being offered.

21 CHAIRMAN KIMSEY: And how many questions is the
22 current examination?

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
24 Thirty maybe.

25 CHAIRMAN KIMSEY: About 30 I hear.

1 COMMITTEE MEMBER ZIELENSKI: I mean, if the
2 examination is going to be something that is required then
3 why not have the examination be something that has universal
4 objectives analysis in their interpretation.

5 I mean, our own crime lab here in Sacramento has
6 some issues in it, with it, in various aspects.

7 So, you know, with the volume of cases that come
8 through on DUIs it's important, I think, across-the-board
9 that we have those types of checks and balances overall.

10 CHAIRMAN KIMSEY: Would this Committee want to
11 have responsibility or at least contribute to that exam? To
12 make it maybe more relevant to the circumstances?

13 RESEARCH SCIENTIST BUTENKA: More modern, so to
14 speak.

15 MR. LYLE: Bruce Lyle, I would.

16 COMMITTEE MEMBER DAVIS: This is Kevin, I would
17 not (laughter).

18 COMMITTEE MEMBER SHEN: Yeah. We're having
19 trouble getting our own work done here (laughter).

20 COMMITTEE MEMBER SEDGEWICK: Paul Sedgewick. And
21 maybe we need to decide whether we want an exam before we
22 decide who is going to write it.

23 COMMITTEE MEMBER SHEN: I would like to offer up
24 the concept of the laboratories having to follow the
25 guidelines set forth in Title 17. And if we want to put in

1 those that that would include a written examination, that
2 would be fine and get away from the Department-authorized
3 one.

4 That is my opinion.

5 CHAIRMAN KIMSEY: And so, your idea of the exam
6 would be, it would be by each individual laboratory. Is
7 that correct Jennifer?

8 COMMITTEE MEMBER SHEN: Yes. And again, you know,
9 if we want to have a part of the oversight, the training
10 program is the, the completion of the training program with
11 its elements, there needs to be some sort of indication to
12 the Department that an analyst completed a training program
13 covering these topics to include a mid court, a written
14 examination and proficiency test and competency test or
15 whatever it is the laboratory decides.

16 And then that documentation would go to the
17 Department.

18 COMMITTEE MEMBER WONG: And Torr, that's something
19 that all the labs are doing anyway in accordance with their
20 accreditation standards.

21 COMMITTEE MEMBER SHEN: Yes.

22 CHAIRMAN KIMSEY: Well, any other discussion? I
23 think we may end up having to have a vote here. I mean, not
24 that that's the end of the world. But, any other discussion
25 before we go around with the Committee and have a vote?

1 RESEARCH SCIENTIST BUTENKA: May I suggest
2 something?

3 CHAIRMAN KIMSEY: Can you state your name.

4 RESEARCH SCIENTIST BUTENKA: Natallia Butenka.
5 I'm not very, I haven't been here for many years, but I
6 would love to hear from my colleagues, what is it like,
7 mistakes in this written exams?

8 Are there really that egregious or something wrong
9 with them? Then we may come to conclusion that maybe we do
10 need to have written examination to test knowledge of the
11 people who are supposedly approved by their training program
12 before they come to us.

13 And if they do have this kind of error, I catch, I
14 caught personally only several of them but, to me it's kind
15 of like unacceptable.

16 For example, they don't know what is a unit. They
17 don't know that it should be area count instead of, for
18 example, just ratio.

19 They sometimes they make typos on the results.
20 I'm talking about the submission of proficiency testing
21 results when they actually identify the area count and they
22 give us the idea that they understand the whole process, how
23 they arrived at this particular results, quantitatively.

24 And if people who are presumably approved by the
25 training of their lab go and make these kinds of mistakes,

1 for me, this is the argument for exam rather than against
2 exam.

3 CHAIRMAN KIMSEY: Do we have any other --

4 RESEARCH SCIENTIST BUTENKA: Yeah, maybe people
5 have no experience --

6 CHAIRMAN KIMSEY: -- information on the number of
7 people who have taken and failed or --

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 Well, we provide them one opportunity to correct or clarify
10 the response. And the overwhelming majority -- I mean, the
11 most common failure is a failure on the PT and then that's,
12 they have to take it again. And they have to --

13 Probably the, we do a kind of a one-time basis,
14 you know, methods have become, unlike the old days, the
15 methods have become very black box-like.

16 The instrument spews out a concentration. And in
17 some cases, and so, we actually ask the candidates, for this
18 one time at least, it's probably something under ISO you
19 should do infrequently at least, to utilizing the raw data
20 and the calibration data to reproduce the -- by this data
21 analysis software.

22 And sometimes that's probably the area that gets
23 the most. As a challenge they, the data aren't internally
24 consistent, they don't, these instruments spew out eight
25 significant figures and they don't get the numbers right.

1 So typically it's not a major error. Sometimes
2 they make quite a few errors and that's a little surprising.

3 But we give them one --

4 RESEARCH SCIENTIST BUTENKA: Yeah, to me this
5 is --

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 -- opportunity to correct or clarify. And it's rare when
8 we've -- after one opportunity we sometimes give them a
9 second, at some point we halt it and say, why don't you take
10 it again. But that's a very rare occurrence.

11 It hasn't happened in recent years. So, those are
12 the questions. There are other questions regarding the
13 Title 17 requirements, to know what the appropriate, what
14 the interval for the QC is. Sometimes they don't get that
15 correctly.

16 The requirement that the QC is a separate
17 independent solution. They don't always -- I mean --

18 RESEARCH SCIENTIST BUTENKA: Oh yeah, they make
19 this mistake.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 -- there's a variety of errors. And on a one-time basis
22 it's, the Department has always been, the belief, I'm
23 disappointed that people find this unmodern and outmoded.

24 And if you have better questions I've never gotten
25 one from any lab. But if you have --

1 RESEARCH SCIENTIST BUTENKA: Yeah, we'll be happy
2 to hear from you guys here.

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
4 -- well, I will be and she doesn't count, so -- (laughter).

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 We'll be happy to get that information. That would be
7 great.

8 CHAIRMAN KIMSEY: Any other comments or questions
9 before we take a vote?

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
11 I just want to make sure we haven't -- talked about the, as
12 part of this, we talked about education, transcripts,
13 training or experience, but the external PT, is that also,
14 that's what, that's the practical exam, if you will, at the
15 end of the qualification of personnel? Yes?

16 COMMITTEE MEMBER SHEN: You know, I'm sorry. You
17 cut out a little bit on that. I didn't get all --

18 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
19 An external PT is sort of the final exam for new staff or --

20 COMMITTEE MEMBER SHEN: Yes.

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Okay.

23 COMMITTEE MEMBER SHEN: I think we called it a
24 competency test and --

25 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

1 Oh, okay.

2 COMMITTEE MEMBER SHEN: -- some pretty
3 significant, let's see, at a minimum successfully complete a
4 competency test comprised of at least four samples that must
5 have different predetermined values range from zero to .25
6 percent alcohol concentrations, have values unknown to the
7 test taker and be analyzed using water choice forensic
8 alcohol method. Results must fall within plus or minus five
9 percent of the known value.

10 So actually it's quite a bit of verbiage about
11 that final test.

12 COMMITTEE MEMBER WONG: Uh-hmm.

13 CHAIRMAN KIMSEY: Okay.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 I find all that verbiage, it doesn't establish whether
16 that's an external or an internal test.

17 COMMITTEE MEMBER SHEN: Well we've already talked
18 about the fact that our proficiency tests are going to be
19 external.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 But now we're talking about competency tests.

22 COMMITTEE MEMBER SHEN: If you want to add, you
23 know, I think the competency tests are a little bit
24 different because your trainer is making those.

25 So you can, I have absolutely no problem with the

1 competency test, with all of these guidelines being internal
2 and then the last step would be an external proficiency
3 test.

4 COMMITTEE MEMBER WONG: Right.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 Well, you said the last step. Would that occur before the
7 individual began analysis or some time down the road during
8 the next year?

9 COMMITTEE MEMBER SHEN: No. As I said, a last
10 step of the training would be an external proficiency test.
11 I think that's completely reasonable.

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 All right.

14 COMMITTEE MEMBER WONG: Thank you.

15 CHAIRMAN KIMSEY: So, back to my trying to sort of
16 phrase the question that we're going to vote on with regards
17 to testing. I guess the question is, should the Department
18 have a statewide or a common test to be given statewide for
19 determining qualifications of personnel employed by a
20 laboratory? Is that phrasing the question correctly?

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 I'm nodding yes.

23 CHAIRMAN KIMSEY: Okay. I guess we'll go down
24 the --

25 COMMITTEE MEMBER DAVIS: This is Kevin real quick.

1 Just to try and --

2 CHAIRMAN KIMSEY: Yes.

3 COMMITTEE MEMBER DAVIS: -- understand better.

4 I'm sorry you have to slow down for me.

5 CHAIRMAN KIMSEY: That's okay.

6 COMMITTEE MEMBER DAVIS: We're talking about a
7 written, for example 30 question test, in addition to the
8 proficiency testing we discussed earlier, right?

9 CHAIRMAN KIMSEY: Correct.

10 COMMITTEE MEMBER DAVIS: Okay.

11 RESEARCH SCIENTIST BUTENKA: Multiple choice --

12 CHAIRMAN KIMSEY: So, based on the phrasing of
13 that question, Lieutenant Davis you want to give us your
14 vote?

15 COMMITTEE MEMBER DAVIS: I went with what Jennifer
16 said. I think there should be testing but given all the
17 checks and balances in place with providing the
18 qualifications, the experience, the practical and
19 proficiency -- I think the labs should be allowed to conduct
20 their own written exam catered to their own local issues and
21 instrumentation and court issues, all those sorts of things.

22 CHAIRMAN KIMSEY: So that's a no?

23 COMMITTEE MEMBER DAVIS: Correct.

24 CHAIRMAN KIMSEY: Okay. And Torr?

25 COMMITTEE MEMBER ZIELENSKI: Yes.

1 CHAIRMAN KIMSEY: Yes. Bruce?

2 MR. LYLE: No.

3 CHAIRMAN KIMSEY: Kenton?

4 COMMITTEE MEMBER WONG: I'm ambivalent. I don't
5 think it really matters whether the state has an exam which
6 is not a big deal anyway or whether the lab has their own
7 internal exam.

8 CHAIRMAN KIMSEY: So, that's an ambivalent
9 (laughter). It's going to make the counting easier.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
11 That's an abstention (laughter).

12 CHAIRMAN KIMSEY: Abstention I guess. Paul
13 Sedgewick?

14 COMMITTEE MEMBER SEDGEWICK: No.

15 CHAIRMAN KIMSEY: Jennifer?

16 COMMITTEE MEMBER SHEN: No.

17 CHAIRMAN KIMSEY: And I'm sort of an ambivalent.
18 Oh dear (laughter). But that still gives us four nos. I am
19 ambivalent and --

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Two ambivalents --

22 CHAIRMAN KIMSEY: I'll vote yes. So we have, let
23 the record show that we have two nos, four nos, two yeses
24 and an undecided or ambivalent.

25 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

1 So we don't have a majority vote. Or we have a majority of
2 the members.

3 CHAIRMAN KIMSEY: Yeah, we have four to two.

4 COMMITTEE MEMBER WONG: We're only missing Laura,
5 right?

6 CHAIRMAN KIMSEY: Right. So, it's a no. So
7 anything else on this bullet? Do we have some language?

8 MR. LYLE: I drafted some language, this is Bruce.

9 CHAIRMAN KIMSEY: Great.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
11 Excuse me, this is Bob Haas. Linton, are you now a
12 Committee member in place of Bill Phillips?

13 MR. VON BEROLDINGEN: I don't understand my
14 status.

15 CHAIRMAN KIMSEY: He was just representing the
16 Department of Justice.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Okay.

19 MR. VON BEROLDINGEN: Yeah, I'm public today.

20 COMMITTEE MEMBER WONG: Okay.

21 CHAIRMAN KIMSEY: I'm sorry, Brian, excuse me,
22 Bruce. You had some language?

23 MR. LYLE: Yes. Are you ready?

24 CHAIRMAN KIMSEY: Yes.

25 MR. LYLE: Okay. I have it in two sections. The

1 first section, laboratories will submit to CDPH proof of a
2 prospective analyst's education, through transcripts in
3 parenthesis, experience, proof of completion of a training
4 program and an external proficiency test.

5 And my second subsection says, CDPH will evaluate
6 the prospective analyst materials in order to establish or
7 ensure competency.

8 CHAIRMAN KIMSEY: Okay.

9 COMMITTEE MEMBER SHEN: This is Jennifer. We're
10 probably going to have to add something, well no, never
11 mind. I take that back.

12 Although we're probably going to have to add a
13 bullet about, or a subsection about an external proficiency
14 test -- under training because that's something that we all
15 agree should be done, so that needs to be added in, so I
16 don't think we have it --

17 COMMITTEE MEMBER WONG: Yes.

18 CHAIRMAN KIMSEY: Okay. Any other comments about
19 the language that Bruce proposed?

20 MR. BALDRIDGE: Paul, this is Pete Baldrige in
21 Sacramento.

22 CHAIRMAN KIMSEY: Yes.

23 MR. BALDRIDGE: So, is it clear what standards
24 we're going to be evaluating this information against?

25 CHAIRMAN KIMSEY: It sounds like it's a review of

1 the submitted documentation to see that it's all there and
2 all corrected, but --

3 MR. BALDRIDGE: So is that going to be the
4 standard, that this documentation is all there?

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 A response --

7 COMMITTEE MEMBER SHEN: I would say, yes.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 -- I think if you carefully looked at all the regulations
10 written by the Committee -- and we discussed this briefly in
11 the past but I, it bears repeating. And I think O.O.R.,
12 once they get involved, all these regulations are going to
13 require rewriting in order to meet APA requirements.

14 Peter is right. You can't simply state that the
15 Department shall, shall evaluate. There's going to have to
16 be standards.

17 I believe that's exceeds the competency of this
18 Committee to write that. So I assume that we're simply
19 going to have to write that and hopefully or with the intent
20 to capturing the will of the Committee.

21 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
22 Well I, this is Bob Haas. I think it was already mentioned
23 this morning that or this afternoon that the requirements
24 are already for a baccalaureate degree and --

25 COMMITTEE MEMBER WONG: Uh-hmm.

1 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

2 -- in physical science --

3 COMMITTEE MEMBER WONG: Uh-hmm.

4 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

5 -- natural or physical science --

6 COMMITTEE MEMBER WONG: Uh-hmm.

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

8 -- so that's really just, that's the standard, the minimum
9 standard.

10 COMMITTEE MEMBER WONG: Uh-hmm.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

12 There are already minimum standards in the regulations.

13 MR. BALDRIDGE: So they're going to submit the
14 information to the Department and the Department is going to
15 make sure that this person --

16 COMMITTEE MEMBER WONG: Yes.

17 MR. BALDRIDGE: -- has a degree.

18 THE REPORTER: Who is speaking?

19 COMMITTEE MEMBER WONG: That's correct.

20 CHAIRMAN KIMSEY: That's Pete Baldrige. And if
21 they've finished their training program.

22 MR. BALDRIDGE: So I would suggest, okay, well
23 then, I would suggest that that be put into the regs so that
24 you don't have to have this additional reg writing.

25 COMMITTEE MEMBER SHEN: Okay, so what we would

1 have at the end of that, a Baccalaureate or higher degree,
2 blah, blah, blah and proof of degree will be submitted to
3 the Department, sort of sentence right in there?

4 MR. BALDRIDGE: If that's the criteria you want to
5 use. I'm just saying that if you leave it open-ended then
6 it raises the potential for issues to arise when the
7 Department goes applying whatever standard it's going to
8 apply.

9 But if you spell it out in the regulations then
10 there isn't any question what the Department is going to do
11 and the public is going to know what the Department is going
12 to do.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 And I suspect you face those issues earlier than that. You
15 faced some during the regulation promulgation process.

16 And you haven't addressed the issue of how we
17 score the external PT. How do we decide what's an
18 acceptable result?

19 I suspect, I mean that's going to be need to be
20 spelled out in the regulations. I think that's --

21 COMMITTEE MEMBER SHEN: How are you doing that
22 now?

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
24 Well I wouldn't, we can describe that. We basically use a
25 nomogram that's based on the five percent but it includes

1 statistically, I believe, valid -- we may have to publish
2 the whole table of acceptable results depending on the, I
3 hope we can avoid that but, we may have to publish a whole
4 table of acceptable results based on the peer group mean or
5 based on the analytical expected value.

6 COMMITTEE MEMBER SHEN: And you do realize that
7 work has already been done by the proficiency provider.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 Now as I said before, and I'm, let me say, I may have been
10 talking too fast. The provider, in this case, one case, CTS
11 and the second one is escaping my memory now; does not
12 provide, in order to be ASCLD approved they don't provide
13 any evaluation of the result.

14 If you want to check that, go ahead. I mean I
15 appreciate you doing that. But that's certainly the case.

16 So --

17 COMMITTEE MEMBER SHEN: But what they don't tell
18 you if you passed or failed. It doesn't mean they don't do
19 analysis on the data.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 But the Department is going to have to tell you whether you
22 passed or failed. They --

23 COMMITTEE MEMBER SHEN: Well I understand that.
24 I'm telling you that the provider does not tell you whether
25 you passed or failed. It tells, it will give you your

1 results and what the known results were and in many cases
2 what every other laboratory, what their results were. That
3 you can make an assessment of how your laboratory did.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 And the procedures for making that assessment in this case
6 since the Department will be doing that, need to be spelled
7 out in the regulations.

8 COMMITTEE MEMBER SHEN: Well --

9 RESEARCH SCIENTIST BUTENKA: Yeah, it has to be
10 transparent.

11 COMMITTEE MEMBER SHEN: -- again, you're doing it
12 now. You're mandating that we send these things into to
13 you. So you must be doing, and that's not written down
14 anywhere on the regulations, and yet you're having us do it
15 and you're evaluating them.

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 Yeah. This may come as a surprise to you, you haven't been
18 with the Committee that long, but there are aspects of the
19 current regulations that don't meet current APA
20 requirements.

21 COMMITTEE MEMBER SHEN: You know it, having spent
22 many, many, many hours rewriting every single one of these
23 regulations, I am completely aware of that. That's why we
24 had to rewrite the entire thing.

25 I'm just saying, you're using some criteria right

1 now to analyze the data that we are sending you so perhaps
2 that is the type of analysis you'll be doing in the future
3 when we're sending you --

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 It will be. I am saying, I believe that will need to be
6 spelled out in regulation.

7 RESEARCH SCIENTIST BUTENKA: Maybe it was one
8 sentence.

9 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
10 But that's our problem. I mean, I think it's our problem.

11 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
12 Eventually.

13 CHAIRMAN KIMSEY: So, any other comments on bullet
14 number two? We have language with --

15 COMMITTEE MEMBER SHEN: We have language.

16 CHAIRMAN KIMSEY: Are we ready to move on to
17 bullet number three? This is to remove CDPH authority to
18 review and approve training programs intended for persons to
19 qualify under the regulations.

20 COMMITTEE MEMBER SHEN: This is, well, this is
21 more of the same, kind of.

22 CHAIRMAN KIMSEY: We talked about earlier in the
23 morning, the Department setting up some criteria for the
24 training, maybe an outline, guidelines, review -- what do we
25 want to, what sort of authority do we want the Department to

1 have about training programs?

2 COMMITTEE MEMBER SHEN: Well, Title 17 lays out
3 the written, and as proposed, what the areas of training
4 need to be.

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
6 Well, this is Bob Haas. The table that program provided I
7 think focuses here on the breath testing, pretty much
8 exclusively.

9 So I think that you're right Jennifer. We covered
10 a lot of this in this previous bullet in the qualifications
11 of personnel.

12 But the training, as we all agree, for breath
13 testing has not been explored.

14 COMMITTEE MEMBER SHEN: You know an option here is
15 that, you know, our laboratories and I'm sure many others
16 are as well, are engaging in breath testing proficiency
17 tests.

18 We really can go down the same road for our breath
19 tests I suppose. And so --

20 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
21 So, what you're suggesting is that, basically, we combine
22 these two to be educational requirements, the same or
23 similar educational requirements, training and an external
24 proficiency test for breath test operators as well?

25 COMMITTEE MEMBER SHEN: Well, I mean, here, as I'm

1 getting ready to completely contradict everything we've said
2 all morning long, the proficiency test is all about the
3 instruments for breath and it has nothing to do with the
4 analysts in particular.

5 So, I mean, and I realize that's kind of
6 contradictory.

7 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
8 What, what --

9 COMMITTEE MEMBER SHEN: We're not really set up to
10 give proficiency tests to all the officers that may use our,
11 use our instruments. So we're running those tests, let's
12 see, our analysts are running those tests on the
13 instruments.

14 So it's not, yeah, I really don't have anything to
15 say about that except for testing the instruments in those
16 cases.

17 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
18 Okay. Well, I just see this as a different section than,
19 that defines that.

20 CHAIRMAN KIMSEY: Right. It just talks about
21 breath instruments.

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
23 Exactly, yeah.

24 COMMITTEE MEMBER SHEN: Well so, your regulation
25 may come down to the fact, I mean, really the regulation of

1 these systems, let's say you have a quality assurance
2 program in place for your instruments and you test it to
3 make sure it works.

4 So, you know, laboratories are already doing those
5 things they're just not really spelled out particularly in
6 Title 17.

7 And I'm not interested in more regulation
8 particularly. But those are things that laboratories have
9 to do in order to show that their instruments are working
10 properly.

11 And those instruments are attacked in court
12 extensively. So, we can't be anything but vigilant in
13 making sure that we have proven that they all, those
14 instruments work.

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 But the, this is Clay Larson. The third prong in that
17 support of the admissibility, of the admission of breath
18 alcohol results is that the operator was competent and
19 that's handled through breath instrument operator training.

20 COMMITTEE MEMBER WONG: Right.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 And every --

23 COMMITTEE MEMBER SHEN: Correct.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 -- state regulates that training, every single state in the

1 Union. And the proposal under the current revised
2 regulations is simply allow the 40 individual labs to come
3 up with, I think they use the word, outline, for that
4 training. And things get very vague.

5 But there's certainly no state level oversight of
6 whatever training the individual labs provide. And I would
7 submit that would put California at odds with every other
8 state.

9 CHAIRMAN KIMSEY: Does every other state do the
10 same thing?

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
12 Well it --

13 CHAIRMAN KIMSEY: The same type of training
14 requirement or --

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 -- they use different models. Some states, a state agency,
17 especially the smaller states, simply does all the training
18 itself. It's not handled by individual laboratories.

19 So the models vary. California is kind of unique
20 in that the laboratories have to do the training.

21 But under the current regulations and today, that
22 training is, there's two elements. That training is
23 reviewed and approved by the Department and the Department
24 requires that qualified individuals, analysts or trainees or
25 supervisors supervise the training.

1 So through an indirect process the state maintains
2 a degree of oversight. And it's something that has
3 continued to this day.

4 We've approved an L.A. Sheriff's Department
5 procedure last week, or two weeks ago.

6 So I think the intent of this bullet is to suggest
7 that the Committee consider restoring that which is
8 primarily Article 3.

9 Article 3 simply states that the Department shall
10 approve any training offered to individuals to qualify under
11 the regulations.

12 So I think it's a simple matter of restoring that
13 article.

14 COMMITTEE MEMBER WONG: This is Kenton. I don't
15 have a problem with that at all. I mean in the past the
16 Department had approved of a four hour training course set
17 to cover various topics for operator breath instrument
18 training for those officers and then that consisted of a
19 written exam as well as a practical exam on use of the
20 instrument.

21 And I don't have any problem with that.

22 CHAIRMAN KIMSEY: Other comments from the
23 Committee?

24 MR. LYLE: This is Bruce. Was that POST that gave
25 that test on the, or the instructions and the testing on the

1 breath equipment?

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

3 I don't believe there are any police officer training
4 standards for, or standards of training for breath testing.

5 I mean, it wasn't POST. I'm not aware of that.

6 COMMITTEE MEMBER WONG: It wasn't.

7 COMMITTEE MEMBER SHEN: Well laboratories are
8 responsible for writing their own written examinations.

9 COMMITTEE MEMBER DAVIS: This is Kevin. Having
10 been through that training and every single time I've been
11 through it in several different counties. The person giving
12 the exam was usually the person from the lab.

13 COMMITTEE MEMBER WONG: Correct.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Correct, that's correct.

16 COMMITTEE MEMBER DAVIS: But having also been
17 through a POST Academy, we also had similar training during
18 my academy. Now I don't POST mandated or just something
19 that we did on top of POST.

20 But I do know we had breath machine training in my
21 academy.

22 MR. LYLE: I'm pretty sure it's a training domain
23 but I'm not 100 percent on that.

24 COMMITTEE MEMBER DAVIS: It'd be easy to find out.
25 I just don't know right now.

1 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
2 Sergeant Davis, was DOJ involved with that POST-sponsored
3 training?

4 COMMITTEE MEMBER DAVIS: No it didn't. I don't
5 recall who did it. I just know that when I was at the
6 academy, back then I think it was Toxicology 3000 or 5000.
7 We had to receive, I think, an hour or two of training on
8 it.

9 But one frustration I've always had is that for
10 the CHP because we go between different counties all the
11 time we have to have the same training in every county we
12 work in which is --

13 COMMITTEE MEMBER WONG: Right.

14 COMMITTEE MEMBER DAVIS: -- per facility. So if
15 I'm working in L.A. County and they use, you know, say a
16 DataMaster and I return to Sacramento County using the same
17 device I have to be retrained. I can't use it until I
18 receive training again.

19 So if you restore that requirement that would be
20 one consideration that it be, you know, a statewide
21 standardized training not lab by lab.

22 COMMITTEE MEMBER SHEN: Well the problem that you
23 have is that different laboratories use different types of
24 equipment.

25 COMMITTEE MEMBER WONG: Uh-hmm.

1 COMMITTEE MEMBER SHEN: So for the San Diego
2 Police Department, you know, our training is specific to our
3 instruments.

4 COMMITTEE MEMBER DAVIS: Right. But let's say you
5 guys use the FST or the F5 and Ventura County uses the same
6 device I don't think officers should do the same training
7 again.

8 COMMITTEE MEMBER SHEN: Yeah. I --

9 COMMITTEE MEMBER DAVIS: That's all I'm saying, by
10 device not by counties per se but --

11 COMMITTEE MEMBER SHEN: Yeah. The problem we run
12 into, you know, the Sheriff's Department and the P.D. use
13 two different type instruments. So, you know, it's, it'll
14 be tough to, it would take some coordination to get all the
15 laboratories to get one type of instrument to come up with
16 one type of test that everybody agrees on.

17 We do things a little differently even if we use
18 the same instrument as another agency, the way we have ours
19 set up is a little bit different.

20 So, you know, you're really, I think it's
21 unfortunate, you're just kind of stuck with that. It would
22 be tough to take that away.

23 COMMITTEE MEMBER DAVIS: Well, aren't we talking
24 now about reinstating it. I thought we did take it away
25 with the current proposed regs.

1 COMMITTEE MEMBER SHEN: I'm sorry. It would be
2 hard to take away the requirement that if we had a test that
3 you would have to take it in whatever county you were in.

4 COMMITTEE MEMBER DAVIS: Oh, okay.

5 COMMITTEE MEMBER SHEN: That's what I meant. You
6 know, I guess I don't really have problems with the fact
7 that there has to be a mandatory training program and that
8 an officer must take that training prior to using the
9 instrument.

10 How much oversight we need on that I don't know.

11 MR. VON BEROLDINGEN: This is Linton from the
12 public side, since I've been quiet for so long. I think
13 it's essential that there should be a statewide curriculum
14 for this training.

15 And I think the individual laboratories whose
16 service areas will encompass either a city, a county or
17 multiple counties and particular brands or types of breath
18 test instruments should have the latitude to design the
19 local implementation of that curriculum to suit their local
20 needs.

21 But the fundamental principles in the particular
22 areas of concern for the training ought to be equivalent
23 across the state. And I can't see it being much of any
24 other way really.

25 COMMITTEE MEMBER DAVIS: This is Kevin, I would

1 agree.

2 COMMITTEE MEMBER SHEN: Well, I think that, I
3 mean, the basic concept of how alcohol is in your breath and
4 the basic concept of, you know, some of the things that we
5 learned in our training programs are the same but it really,
6 a good portion of the points of training these officers is
7 that they use the instrument correctly, to make sure they
8 wait long enough and they, you know, know what the Trompetta
9 is and that for each individual instrument that they know
10 how to operate it efficiently and what kinds of things are
11 going to interfere et cetera.

12 Those are, to me, you know, I don't do this on a
13 regular basis, but to me, the officer needs to know the ins
14 and outs of the instrument his agency is using.

15 I don't know how you turn that into a statewide
16 examination.

17 COMMITTEE MEMBER DAVIS: This is Kevin. All I
18 meant was, I mean, I don't how many there are out there, I
19 would guess there's, I mean, what are there, maybe five
20 different devices being used in the state? Seven at the
21 most.

22 COMMITTEE MEMBER SHEN: You know, I don't know.

23 COMMITTEE MEMBER DAVIS: Clay do you know?

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 I think that's a good guess, five to seven, you know.

1 COMMITTEE MEMBER DAVIS: So what I mean is, rather
2 than 58 different testing or training programs about five or
3 seven or how many devices there are.

4 RESEARCH SCIENTIST BUTENKA: Yeah.

5 COMMITTEE MEMBER DAVIS: That's all I was
6 suggesting.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
8 You know, unfortunately, the newer devices provide a great
9 deal of, they have e-prompts and they provide a great deal
10 of flexibility. So you can, you know, you can ask different
11 questions in terms of operator and subject information.

12 And there's differences in the way the final data
13 are uploaded. And so, unfortunately, with the 5000 it was,
14 there was only one way to operate it.

15 With some of the newer equipment there actually, I
16 mean we see methods submitted for the same instrument and
17 they're, at least some of the detailed procedural steps are
18 different even though the instruments are the same.

19 MR. VON BEROLDINGEN: So this is Linton. And
20 Jennifer I just want to clarify that I'm not suggesting that
21 there should be statewide detailed instructions for
22 conducting a breath test, that was not the point.

23 But I think there are those things that are
24 essential to organizing training that could be readily and
25 easily listed. And those things could comprise the level of

1 oversight that's necessary to ensure that the appropriate
2 subjects are covered in the training.

3 And that's all that I meant by that.

4 COMMITTEE MEMBER SHEN: Well I think that's
5 actually a good point. You know, we're talking about
6 training that's already listed in here for the analysts. I
7 mean, I don't think we've ever gone down the road of talking
8 about, you know, these five topics need to be covered with
9 an officer using the breath instrument, these five very
10 basic topics.

11 And then in addition to that, the officer needs
12 specific training for this specific instrument. I suppose
13 we could go down the same road as we are with our analysts
14 here, you know, outlining what those topics are.

15 You know, at a minimum the training program will
16 cover A, B, C and D --

17 COMMITTEE MEMBER WONG: Sure.

18 COMMITTEE MEMBER SHEN: -- and then specific
19 training.

20 COMMITTEE MEMBER WONG: Right.

21 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
22 In response to Linton's comment. I would say that there is
23 a fundamental difference between a state agency or some body
24 issuing best practices or guidelines and then letting 40
25 individual laboratories interpret those as they will.

1 And actually having a program which is provided
2 under the current regulations which requires the Department
3 to review and approve the actual training procedures, some
4 reasons for the training procedures.

5 So there's a fundamental difference there. We've
6 got to agree that there is a difference and you can agree to
7 disagree and which is necessary, which is more important;
8 but I submit the third bullet here is talking about a
9 concern over the elimination of that statement of oversight.

10 CHAIRMAN KIMSEY: So this is Paul. Where are we
11 with this discussion? We've got about, we've got less than
12 an hour left. Has anybody seen a consensus developing here?

13 COMMITTEE MEMBER SHEN: It seems to me that where
14 we are is we either put the stuff back in we took out or we
15 go another way.

16 CHAIRMAN KIMSEY: That's referring to --

17 COMMITTEE MEMBER SHEN: I'm unclear as to where
18 we, you know, what the consensus is.

19 CHAIRMAN KIMSEY: -- and, yeah. So I was unclear
20 too. So we're thinking, one option is putting Article 3
21 back or doing something different. So I guess we're down to
22 two options. What would we do differently than what is in
23 Article 3? Does anyone have that Article 3 in front of
24 them?

25 COMMITTEE MEMBER WONG: Well, right now, I mean,

1 under the old regs, under Article 3 I guess, in the past,
2 the Department had approved of a prescribed topics that the
3 officers had to be trained on in general for any breath
4 instrument, right?

5 CHAIRMAN KIMSEY: Uh-hmm.

6 COMMITTEE MEMBER WONG: When it was a DataMaster,
7 was an Intoxilyzer, was a Draeger, and then, each individual
8 laboratory of those 40 would have to tailor their use and
9 practical of those various instruments for whatever county
10 or jurisdiction they had under.

11 So, I don't see that as being any different than
12 now. I totally sympathize with Kevin that sometimes the
13 officers have to do retraining but it's somehow the general
14 knowledge part, that doesn't change.

15 But it's just going to be the specific part for
16 the various instruments from maybe one county to the next
17 city line or whatever that might change. Maybe it's somehow
18 a blend of that might help.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

20 I think, this is Bob Haas. I think that's the rare
21 occurrence here because CHP serves, you know, the entire
22 state. But, and Clay jump in if I be wrong about this but,
23 each sort of training manual from whether it's DOJ or CHP
24 comes to us where it's reviewed to, for, and approved.

25 And I think that's what we have now and I guess

1 the question then becomes, is that what we want to continue
2 for the breath tests operators?

3 And going back to the very beginning of this it
4 was like two aspects to this was the instrument evaluation
5 and as well as the operator evaluation.

6 I don't know but Clay help me out here, but I
7 don't know that there's a, you know, this is like a black
8 and whites situation.

9 I think Linton is right that general guidelines
10 are a great idea. But I'm not sure that if everything is,
11 in order to have consistency across the state that whether
12 review of each individual protocol or training manual as
13 what I've seen is necessary or desirable.

14 COMMITTEE MEMBER SHEN: That's right.

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
16 Do you have a comment on that?

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 I'm momentarily stung by the fact that I mis-spoke. It's
19 actually Article 4.

20 COMMITTEE MEMBER SHEN: We were just figuring that
21 out.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 Well, okay. I apologize for sending you on -- anyway,
24 there's only one section and a couple of subsections but
25 it's 1218 training program approval and it requires that any

1 organization offering any training to qualify individuals
2 under the regulation tests to submit to the Department a
3 summary of that training and wait for Departmental approval.

4 And I've actually lost track of your question.

5 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

6 Well that was it. You know, they submit a summary of the
7 training and --

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

9 Right.

10 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

11 -- and we review it.

12 COMMITTEE MEMBER WONG: What if it was a split a
13 split like the general topics and principles of alcohol, its
14 absorption, it's all of this kind of stuff; that would be
15 the first part that maybe you guys could promulgate, that no
16 matter where you are in the state, this first part is always
17 going to be the same.

18 And then, the last 25 percent is going to be for
19 the DataMaster or for the Draeger, specific to that county
20 and that may help to alleviate some of the problems that CHP
21 is having and still satisfy everybody's training and
22 oversight.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

24 Well, and we mentioned the possibility of improving on the
25 current training. But I think the nub of the question here

1 is whether, however you get the training, obviously if the
2 Department writes it it's pretty, we'd probably approve it,
3 but however we get --

4 COMMITTEE MEMBER WONG: No they won't.

5 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
6 -- yeah. We change our minds, right? However we get the
7 training are we going to include a component, a requirement
8 that the Department review and approve the training that
9 will then be administered by the laboratories?

10 I mean, I think that's the critical issue.

11 COMMITTEE MEMBER SHEN: Well if you look at
12 Article 4, you know, we removed the section. And we all
13 voted to remove the section. This section discusses
14 appropriate training programs, programs that are deemed
15 suitable by the Department.

16 As we have removed the oversight of training
17 programs from the Department, enhance the requirements of
18 the analysts and have given such oversight to the employing
19 laboratory entities, this section becomes irrelevant.

20 So we already, we took it all out. And we took it
21 out for the reasons that we, this basically is talking about
22 our analysts that we required more education on the analysts
23 and we are giving oversight of the training to the
24 laboratories.

25 So if we're talking about restoring oversight of

1 that, of the training to the Department, I would like to see
2 that we would talk about only doing it in the, in the area
3 of the breath operator training.

4 COMMITTEE MEMBER WONG: Right.

5 COMMITTEE MEMBER SHEN: And my personal opinion is
6 that, you know, and I'm sorry, I'm sorry for those of you
7 that have to take training over and over again, but that
8 that training, it has to be agency specific.

9 But even if you were to take some training that
10 was, you know, was appropriate for the entire state you
11 would still have to take the training for every individual
12 agency that you were training for anyway.

13 MR. VON BEROLDINGEN: This is Linton --

14 COMMITTEE MEMBER SHEN: So I think it would be a
15 little tougher to, you know -- so then we'd have to divide
16 out our training into people who have already had some of it
17 but not the other of it and, you know, it's all one class
18 and then you have to go, I think instruments are different
19 enough even if they're the same instruments.

20 Because of the way they are set up that the agency
21 has to be responsible for writing the tests and the agency
22 has to be responsible for training anyone who uses those
23 instruments.

24 MR. VON BEROLDINGEN: Kevin, this is Linton.

25 COMMITTEE MEMBER DAVIS: Yes.

1 MR. VON BEROLDINGEN: Part of my background that I
2 didn't tell you was two tours with the Oregon State Police
3 as a sworn officer working in the laboratory.

4 And part of that meant that three times a year I
5 got to go out and punch holes in paper. And the point of
6 that is that there are aspects of training that are
7 repetitive for all of us in various professions and so
8 forth.

9 But and, I sympathize also with the frustration of
10 having to rethink exactly what it is you're going to do
11 because you crossed the county line. That's got to be a
12 little bit of a difficulty.

13 But I do think that there's a place for statewide
14 consistency in operator training because the operator
15 generally is a peace officer of the state. And it just
16 makes sense to me.

17 COMMITTEE MEMBER DAVIS: Thank you. And again,
18 this is Kevin. I realize that as statewide, we're kind of
19 in the minority with that issue. But by all means, if it
20 needs to be lab-specific training, that's fine. We've dealt
21 with that for years and we can continue to do so.

22 And it's not so much the training that we mind,
23 what's frustrating is when we transfer to a new area, you
24 know, the training is only offered every so often. So the
25 frustration is that has happened to me twice in my career.

1 I go to a new area that's using the exact same
2 device as the area I came from but I can't use that device
3 for X amount of months, so, until I get that training or
4 until it's offered.

5 I don't mind the training class itself. I have no
6 problem with that. And if anything it's actually a
7 refresher. It's just for four to six months every DUI
8 arrest I have to call someone else to rubber mat to come do
9 it for me who has had the class when I know just as much
10 about the machine as they do.

11 But I realize there's really no easy solution for
12 that so if we need to reinstate the current practice of 40
13 different training classes then, so be it.

14 CHAIRMAN KIMSEY: This is Paul --

15 COMMITTEE MEMBER SHEN: Yes they'll be super
16 trained --

17 CHAIRMAN KIMSEY: -- this is, yeah, this is Paul
18 in Richmond. There was a suggestion, and I defer to the
19 people that have to go through this, but that there might be
20 two parts to an exam. One that would be sort of a statewide
21 exam that was applicable to any type of instrument and then
22 the local exam would be very instrument specific.

23 Does that make sense or --

24 COMMITTEE MEMBER SHEN: You would still have the
25 exact same problem. You're still going to have to wait four

1 to six months to get the training on his specific
2 instruments --

3 COMMITTEE MEMBER WONG: Yeah, it's still not --

4 CHAIRMAN KIMSEY: Sure.

5 COMMITTEE MEMBER SHEN: -- but no officer is
6 allowed to use our instruments without the training on it
7 that we get. And I assume that's the way it is everywhere.

8 COMMITTEE MEMBER WONG: Yeah.

9 COMMITTEE MEMBER SHEN: So even --

10 COMMITTEE MEMBER WONG: Yeah.

11 COMMITTEE MEMBER SHEN: -- even though you
12 wouldn't need as much training, the problem will be the
13 same.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Actually, I'd like to comment on something Jennifer said
16 earlier. The December 15th letter gives us a, it says, e.g.
17 it gives an example of breath instrument operator training
18 and it indicated some willingness to, it might be okay to
19 approve that but she didn't want to cover any other kind of
20 training.

21 The other major kind of training is the training
22 currently offered to forensic alcohol supervisors. The
23 language of the current regulations which is still in
24 existence says, that you have to have two years of
25 experience or in lieu of that two years experience you

1 complete a training course that's approved pursuant to
2 Section 1218 which is requires Departmental approval.

3 We made another, the Committee has made a number
4 of changes. One is we've eliminated the name, supervisor,
5 but we simply renamed that forensic alcohol analyst.

6 Under the current regulations every lab is
7 required to have someone with significant, with two years of
8 experience. I don't know how significant that is.

9 Under the new regulations we actually permit
10 individuals to head up a lab, I guess, with no experience.
11 So I think, and that can happen because we provided the
12 opportunity for the labs to provide some kind of training.

13 Historically, the only approved supervisor
14 training has been one offered by the Department of Justice.

15 It's a five day course. It's fairly extensive. It's been
16 reviewed and approved by the Department.

17 Under the revised regulations presuming that we
18 have no requirement that the Department review or approve
19 the training offered by individual laboratory to sort of
20 boot strap some individual into an analyst classification
21 when that person lacks two years of experience.

22 Without any oversight I submit that could be a
23 five minute training course. The labs are given some
24 general categories that they have to cover but I'm assuming
25 it won't be a five minute course but --

1 COMMITTEE MEMBER SHEN: That's slightly offensive.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
3 --but it, and it would never happen in the best labs but,
4 you know, Ronald Reagan said, trust but verify. That's the
5 only thing he ever said that I agreed with (laughter).

6 But I, so I think the spirit of the third bullet
7 there is that the Department would have an oversight and
8 review and approval function for any training offered to
9 qualified individuals under the regulations.

10 COMMITTEE MEMBER SHEN: I thought we had moved
11 beyond speaking about the analysts and we were talking about
12 the operators of the instruments, of the breath equipment.

13 I find the thought that you even proper that these
14 laboratories are going to be doing five minutes of training
15 for alcohol analysts, when, in fact, you know perfectly well
16 that we are talking about having to have discussions in
17 every one of these areas plus the competency tests, plus the
18 proficiency tests; I would say that would be a hell of a
19 five minutes.

20 So, we've already moved beyond that. We are now
21 talking about specifically the breath operator training.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 Well I would submit, I'm sorry if I offended you -- five
24 minutes, I'm sure has never happened.

25 But the training we're talking about here is not,

1 is specific training that covers those individuals that
2 haven't had two years experience.

3 The training doesn't, not even discuss the
4 analysis of samples. So I assume, separate from that, the
5 lab would be providing training that enabled the individual
6 to complete his proficiency test.

7 But those are two separate kinds of training.

8 RESEARCH SCIENTIST BUTENKA: What Clay is talking,
9 he's talking that this is under the same bullet. And it
10 says, e.g. breath instrument operator training.

11 I mean, logically it suggests that it's all kind
12 of training. It's not limited to only breath operator, if
13 you read this bullet.

14 CHAIRMAN KIMSEY: Maybe we're into the afternoon
15 blues here.

16 COMMITTEE MEMBER SHEN: Well, I prefer stagnated.
17 So I don't feel like we're making any progress.

18 CHAIRMAN KIMSEY: Right.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 This is Bob Haas. I'd like to see just maybe we'd go back
21 to just the breath operator training because we seem to
22 be --

23 CHAIRMAN KIMSEY: Making progress --

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
25 -- making more progress with that than with the entire

1 bullet.

2 Am I correct to just summarize that this is two-
3 fold, the approval of instruments as well as operator
4 approval and that within the operator training would be a
5 general principle statewide curriculum.

6 And then instrument-specific training and then the
7 question is, what is the role of the state in that, in the
8 last one, in the instrument-specific training?

9 COMMITTEE MEMBER SHEN: Well if that, if we did
10 all that, that would be adding quite a bit to the
11 regulations.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
13 Well you're right but --

14 COMMITTEE MEMBER SHEN: I don't know, I don't --

15 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
16 -- Jennifer you had --

17 COMMITTEE MEMBER SHEN: -- if I still -- I'm
18 sorry, go ahead.

19 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
20 -- I mean, in your memo I think you already -- well it says
21 here, and I'm quoting here but I'm not quoting from your
22 memo, but, the, we discussed that the breath program is the
23 one area where we really need some oversight.

24 So that's somewhere in your memo I think. And
25 that's --

1 COMMITTEE MEMBER SHEN: Yeah and I do feel that
2 way. I was just going to say, I'm not really sure that I
3 feel like where we're lacking is in the breath instrument
4 operator training.

5 You know, it's just seems to me that everything
6 else is so spelled out every which way but Sunday. And for
7 the blood and the breath really isn't. I mean there isn't
8 really anything about proficiency testing. There really
9 isn't much about a quality assurance program.

10 I mean, the things that we do have in there are
11 rapidly becoming outdated because the instruments are able
12 to do so much more than they were.

13 So I don't know that we want to spend a lot of
14 time trying to have oversight of how we train our officers
15 on the instruments. Maybe we want to focus our efforts more
16 on the program in its entirety although, you know, that's
17 sort of daunting.

18 I'm actually cursing myself for putting that in
19 there at all but -- I think they are two different elements
20 here.

21 CHAIRMAN KIMSEY: So, we had been talking a little
22 bit about Article 4. And the, does that have it broken up
23 into two separate, the two separate parts that you were
24 referring to Jennifer? Let's see.

25 COMMITTEE MEMBER SHEN: I just meant that the

1 concept of the breath alcohol program in its entirety is
2 different than the small subset of how we're training our
3 officers on the instruments.

4 CHAIRMAN KIMSEY: Right. So that's the local
5 training versus the, what might be considered, statewide
6 training.

7 COMMITTEE MEMBER SHEN: Well, I don't mean
8 statewide training. I mean we have a (inaudible) alcohol
9 program and we have a breath alcohol program. There's a lot
10 of oversight in ASCLD and other agencies, other accrediting
11 bodies for the fluids --

12 CHAIRMAN KIMSEY: Right.

13 COMMITTEE MEMBER SHEN: -- there's not much
14 oversight on --

15 CHAIRMAN KIMSEY: On breath.

16 COMMITTEE MEMBER SHEN: -- on the breath. And you
17 know to give laboratories credit, including my own, we do a
18 lot of our own oversight. We do, we try to run it as though
19 it were accredited.

20 And so, I actually feel like we're doing
21 everything we need to. But if you look at laboratories
22 statewide I don't know that everyone is doing those same
23 things.

24 So the breath element of the overall program it
25 does not appear to be, you know, there's not a lot of

1 oversight there.

2 There does appear to be oversight in how we train
3 our officers. Although we took that out.

4 To me that's not really as relevant as a program
5 in its entirety. And I don't mean to give that anything --
6 I'm not really all that interested in talking statewide
7 criteria necessarily for each individual program.

8 It just occurred to me that we don't all that
9 oversight in our breath program.

10 MR. LYLE: Bruce Lyle. I think probably what
11 we're looking at is the, I think since it works pretty well
12 with the labs training the officers in the field with people
13 that use the machines, that works pretty well.

14 But that maybe the point of oversight for the
15 Department we should be focussing on is just overseeing the
16 laboratories and how they behave, instead of overseeing the
17 officers in the field.

18 That seems a little bit wrong.

19 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
20 Comment from the public. No one is suggesting that we
21 oversee the officers in the field. And there are some legal
22 issues and questions there.

23 We're talking about the oversight of operator
24 training. I appreciate the fact that you said things are
25 going well. I would suggest that we have to consider at

1 least the possibility that the 30 years of oversight and
2 approval of the operator training have contributed to things
3 going well.

4 CHAIRMAN KIMSEY: So that speaks to reinstating
5 Article 4.

6 COMMITTEE MEMBER SHEN: Well, again, if we're
7 going to talk about reinstating, you know, I would want us
8 to be very, very myopically focussed on the operator
9 training for the breath instrument only.

10 CHAIRMAN KIMSEY: Okay.

11 MR. LYLE: Yeah, because the way Article 4 is
12 written it doesn't say anything about breath analysis. It
13 just talks in general. And those things are, they were
14 stricken because they didn't apply anymore.

15 But it could be made specific to the breath
16 analysis.

17 CHAIRMAN KIMSEY: Okay. Well we have 30 minutes
18 left. I don't know that we're close here on the third
19 bullet. So let me, just sort of a recommendation, that we
20 at least have some further discussion on the fourth bullet
21 which is, I believe, records. And what we might do,
22 depending on how far we get on records, we might come back
23 to bullet number three.

24 But then also we might have bullet number three be
25 where we start at our next meeting and we all will have had

1 a bit of more time by then to look at Article 4 and maybe
2 make some suggestions based on that.

3 Does that seem acceptable to everybody, that we
4 sort of move on to have a brief discussion of bullet number
5 four which deals with records and the Department's role.

6 And then, if we have more time, come back to
7 bullet number three? Any objections?

8 MR. LYLE: You have some good nods in San Diego,
9 all three are.

10 CHAIRMAN KIMSEY: Okay. So bullet number four
11 reads, remove requirements for a laboratory to provide CDPH
12 with records of its activities under the regulations,
13 including notification by a laboratory of its intent to
14 perform forensic alcohol analysis.

15 And, anybody want to start off the issue about the
16 records? The subcommittee did have some discussion about
17 records under training and that the Department, you know,
18 the Department having access to records, you know, might be
19 appropriate.

20 RESEARCH SCIENTIST BUTENKA: Just to make sure
21 it's not five minutes thing, right?

22 COMMITTEE MEMBER SHEN: Well having access to the
23 records and having them submitted and approved are two
24 different things. So I don't think anyone was ever talking
25 about the fact that the Department couldn't access the

1 records.

2 Again, like I stated many hours ago --

3 CHAIRMAN KIMSEY: Sure.

4 COMMITTEE MEMBER SHEN: -- you know, we have to
5 supply our records to all sorts of people for all sorts of
6 reasons.

7 CHAIRMAN KIMSEY: And I think that's a good point.

8 I think the issue is whether the Department has to ask or
9 it says here, they are provided. In other words, it's --

10 MR. LYLE: This is Bruce Lyle. I don't see any
11 problem with, you know, adding something in there to
12 automatically have them forwarded to the Department for you
13 guys.

14 CHAIRMAN KIMSEY: How much --

15 MR. LYLE: You know, depending on what those
16 records are.

17 CHAIRMAN KIMSEY: -- how much of a burden on the
18 labs is the provision of records under the old regulations
19 or the current regulations I should say?

20 COMMITTEE MEMBER SHEN: Well, it depends on what
21 the purpose of that is. I mean, we don't want to go down
22 the road that providing our annuals, only to have them, have
23 asked to be pulled if they're not appropriate.

24 So, you know, we're not interested in having those
25 things reviewed and critiqued at this point. We've moved

1 away from that.

2 So, I mean, clearly, particularly the accredited
3 laboratories, you have to have all of that, you have to have
4 manuals. And you have to have policies and procedures. And
5 you have to follow them. And we have to have proofs that
6 we've testified and proof that we were observed and proof
7 that we've been trained and proof that we're education and
8 we have proof of proficiency tests and competency tests and
9 all those things.

10 So we have loads of records that show that we are
11 able to do what we say we're able to do.

12 So, if there is a particular issue or if the
13 Department wants to send someone to take a look at those
14 records for whatever reason, we, you know, the Department
15 already has the ability to access those records.

16 I'm loathe to set up a situation where every time
17 we make a change or issue a new copy or do something else
18 that we, it's incumbent upon us to forward all of that stuff
19 to the Department.

20 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
21 Comment from the public. You know, I think what we're
22 talking about here is a fairly little micro surgery. There
23 were several sections of the regulations, I'm looking at
24 one, 1222, three twos, which is a general statement that
25 requires labs to maintain records of their activities under

1 the regulations.

2 And the current regulations read, such records
3 shall be available for inspection by the Department. And
4 after some discussion the Committee voted to strike that
5 language.

6 And it occurred two other places and I can find it
7 here in a minute. So, I think this could be, this bullet
8 could be addressed simply by restoring the language that
9 says, such records shall be available for inspection by the
10 Department upon request.

11 CHAIRMAN KIMSEY: And so that would not be
12 providing the records. It would just, unless it was a
13 request.

14 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
15 Unless we, yeah -- receive them --

16 RESEARCH SCIENTIST BUTENKA: Uh-hmm.

17 CHAIRMAN KIMSEY: So it's not an automatic, send
18 all your paperwork.

19 COMMITTEE MEMBER SHEN: Well, what we changed it
20 to is that, forensic alcohol laboratories shall maintain
21 records which clearly represent their activities which are
22 covered by these regulations.

23 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
24 That's not a change at all. That's the existing language,
25 right.

1 RESEARCH SCIENTIST BUTENKA: Uh-hmm.

2 COMMITTEE MEMBER SHEN: Well it is a change since
3 we took out, and law enforcement agencies.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 Okay.

6 COMMITTEE MEMBER SHEN: So we took out, and law
7 enforcement agencies. And we took out, such records shall
8 be available for inspection by the Department on request.

9 So, I mean, your issue is that we took out that
10 sentence but at the end of the day, you have the ability to
11 take a look at those records. And we have to have them on
12 file.

13 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
14 Yeah. The Department is, you give us kind of an omnipotence
15 that I don't feel. The Department is limited by the
16 regulations as the labs are.

17 If the regulations don't make the records
18 available it would be difficult for me as a state employee
19 to, you know, just ask a favor, I guess, to ask for those
20 records.

21 If they are readily available then I see no reason
22 for striking and the similar language in a couple of other
23 places.

24 CHAIRMAN KIMSEY: So, Jennifer are you talking
25 about availability through like a Public Records Act Request

1 or --

2 COMMITTEE MEMBER SHEN: Well, I mean, that's how
3 you could get them easily. But, you know, I can see your
4 point. I could see why you might feel that wouldn't have
5 ready access to them.

6 We would certainly have nothing to hide
7 whatsoever. So if you wanted to see them you're certainly
8 welcome to. And I could see why you would feel that it
9 might be tough if we took that out.

10 So, I mean, from my own perspective, I guess, I'm
11 willing to consider leaving that in if that doesn't mean
12 that we have to send you everything all the time.

13 CHAIRMAN KIMSEY: Other comments from the
14 Committee? I mean, do you make a request for records very
15 frequently?

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 We may ask, issues may come up. I'm trying to think of a
18 recent example where a lab, we learned that a lab changed
19 its, changed some of the equipment they used in breath
20 testing and we requested copies of the lab's new training
21 procedures, things like that.

22 No, it's not rare. I don't want to read that stuff.

23 CHAIRMAN KIMSEY: So, any other comments about the
24 suggestion of adding back that language that authorizes the
25 Department to request --

1 MR. LYLE: This is Bruce. I don't see any sort of
2 reason why it can't be put back in there. It seems to me, I
3 don't run a lab, but it seems to me that that would be the
4 least daunting way to do it as opposed to sending your
5 records, sending records to you guys everything that you do
6 and every change you make just to have them available.

7 And then to put it in there to make the Department
8 feel that it's at least addressed and mandated that if they
9 ask you have to give them up.

10 COMMITTEE MEMBER SHEN: Well and I think you're
11 probably only need to put it in one spot --

12 MR. LYLE: Yeah.

13 COMMITTEE MEMBER SHEN: -- all right, you know,
14 we took it out apparently in two or three places?

15 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
16 You know I'm trying to find --

17 COMMITTEE MEMBER SHEN: But it seems to me that if
18 it's under 1222, under general, forensic alcohol
19 laboratories shall maintain records which clearly represents
20 their activities which are covered by these regulations.

21 Those records shall be available for inspection by
22 the Department on request. That would handle any kind of
23 record you're interested in.

24 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
25 Yeah, I'm trying to think where else it occurs. I mean,

1 there's another section that currently provides --

2 COMMITTEE MEMBER SHEN: In 1220 (b), (1).

3 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

4 -- that currently, I'm sorry, what?

5 COMMITTEE MEMBER SHEN: It's 1220 (b), (1).

6 MR. LYLE: Regarding method.

7 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

8 Yeah, we could --

9 RESEARCH SCIENTIST BUTENKA: Yeah regarding the
10 method.

11 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

12 I see no problem in putting that back in.

13 MR. LYLE: Well, it's redundant if you put it in
14 the general section.

15 CHAIRMAN KIMSEY: Yeah, I think if that's our
16 intent we can, the people that'll end up writing the
17 specific regulations, you know, will --

18 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:

19 Well these are the specific regulations, right?

20 CHAIRMAN KIMSEY: -- have to deal with that.

21 COMMITTEE MEMBER WONG: It just has to be
22 available on request.

23 CHAIRMAN KIMSEY: Right.

24 COMMITTEE MEMBER WONG: That's cool.

25 CHAIRMAN KIMSEY: Yeah, right.

1 COMMITTEE MEMBER WONG: Any records.

2 CHAIRMAN KIMSEY: Any concerns about that --

3 RESEARCH SCIENTIST BUTENKA: -- methods would be
4 under procedures --

5 CHAIRMAN KIMSEY: -- reintroduction of that
6 language or that intent to have records available on request
7 to the Department?

8 COMMITTEE MEMBER WONG: That's fine. That's not
9 unreasonable.

10 RESEARCH SCIENTIST BUTENKA: It could be even, it
11 could be --

12 COMMITTEE MEMBER WONG: Take a vote.

13 RESEARCH SCIENTIST BUTENKA: -- it could be even
14 out of spec investigation.

15 CHAIRMAN KIMSEY: If no one has an objection I
16 think we might go ahead and move back to bullet number
17 three. We've got 20 minutes left.

18 COMMITTEE MEMBER SHEN: I just one, so if we, so
19 my understanding after that was that we would consider
20 putting in, back into the one place only, under general,
21 1222 the sentence at the end that was taken out. And that
22 will cover everything.

23 CHAIRMAN KIMSEY: Correct.

24 COMMITTEE MEMBER SHEN: Okay. And that that would
25 address, and hopefully in the Department's mind, bullet

1 number four.

2 CHAIRMAN KIMSEY: Yes. The only caveat being, you
3 know, if the regs writers, you know, our Office of
4 Regulations says, it has to be in multiple places. I mean,
5 but I think the intent (cell phone ringing) --

6 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
7 I think it's a phone going off.

8 CHAIRMAN KIMSEY: -- of the Committee is is that
9 records would be made available to the Department from the
10 laboratories.

11 RESEARCH SCIENTIST BUTENKA: No, mine is on
12 vibration.

13 CHAIRMAN KIMSEY: But I agree, I think it's
14 probably only necessary in one spot. I don't write regs
15 everyday so --

16 RESEARCH SCIENTIST BUTENKA: -- 12220 (a) --

17 CHAIRMAN KIMSEY: So back to question number --

18 RESEARCH SCIENTIST BUTENKA: -- I think it's on
19 the back --

20 CHAIRMAN KIMSEY: -- bullet number three on the
21 training. We were talking about breath instrument operator
22 training. We were talking about Article four. I thought
23 there might be some need to, as a Committee, have us review
24 that some more before we could come to any sort of
25 recommendation.

1 But if anyone has something that they want to
2 recommend with regards to the Department's oversight in that
3 area, feel free to make a recommendation.

4 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
5 Actually we'll return briefly to the -- I found one other
6 section here. I'm sorry to take this backwards but I don't,
7 I may not get another chance to discuss this.

8 Under Section 1217.6 there's a section of the
9 regulations that refers to, and it occurs somewhere else,
10 but this is good enough, access to premises, the Department
11 may enter at all reasonable times upon any laboratory for
12 the purposes of determining whether or not there is
13 compliance with the provisions of these regulations.

14 So --

15 COMMITTEE MEMBER SHEN: So 1217.6?

16 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
17 -- 1217.6 (b) --

18 COMMITTEE MEMBER SHEN: Well -- I mean that whole
19 Article 3 is out. So I would be uninclined to put in a
20 sentence or two under Article 3 that we have removed it its
21 complete entirety.

22 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
23 So you think you'd want to move it somewhere else?

24 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
25 No.

1 COMMITTEE MEMBER SHEN: No.

2 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
3 No? Well, I think the interest in the 12/15 letter was to
4 provide a process where there's transparency. If there's
5 reluctance to do that then duly noted.

6 COMMITTEE MEMBER SHEN: I'm just reluctant to put
7 in an Article back in that we took out, in its entirety.

8 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
9 And I indicated you could place it somewhere else.

10 COMMITTEE MEMBER SHEN: Exactly, and better access
11 to the laboratories for this section?

12 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
13 Yeah.

14 COMMITTEE MEMBER SHEN: I mean, I think that that,
15 a whole new section we would need to have versus just
16 saying, okay, and slopping it in somewhere else.

17 ABUSED SUBSTANCES ANALYSIS SECTION CHIEF LARSON:
18 So we could have a discussion.

19 MR. LYLE: Well I think since --

20 COMMITTEE MEMBER SHEN: That's not real --

21 MR. LYLE: -- if Dr. Horton didn't have any issues
22 with it --

23 CHAIRMAN KIMSEY: You know, let's go back to
24 bullet --

25 MR. LYLE: -- we shouldn't have any either.

1 COMMITTEE MEMBER SHEN: I agree.

2 CHAIRMAN KIMSEY: -- three. So back to article, I
3 mean, bullet three, Article 4. Are we sort of, do we need
4 more time to read it over before we have more discussion?

5 I would imagine that we will, obviously, get the
6 minutes from this meeting and it looks like we're going to
7 have another meeting, you know -- probably in a relatively
8 short period of time, I would think to sort of go over, to
9 review what we've agreed to, at least with the bullets one
10 and two and at least part of four.

11 And, but what's the feeling of the group with
12 regards to bullet number three for right now?

13 MR. LYLE: This is Bruce. I agree with you Paul.

14 CHAIRMAN KIMSEY: Okay. I also assume since we're
15 all concerned about time that we would maybe want to try and
16 get together on a relatively quick turn around.

17 Peoples' schedules being what they are, once you
18 get into the holidays it's a mess. So we might send out a
19 note tomorrow trying to get people's calendar times for
20 something before Thanksgiving, so mid November.

21 I think we have, it seems to me that we have some
22 pretty good language for bullets one and two and we'll get
23 that out. People can review it and probably even four.

24 And then I guess the homework assignment is for us
25 all to think about how we can come to some agreement on

1 bullet number three with regards to the Department's
2 oversight or responsibility with regards to training.

3 I'm afraid it's training overall which is more
4 controversial. But specifically I guess there's been some
5 tendency towards agreement with the breath instrument
6 operator training.

7 Other comments? Things people want to add?

8 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

9 I guess I'm a little bit confused. This is Bob Haas from
10 the public. Some of the training issues for fluid testing,
11 I think, have been discussed in the second bullet in the
12 qualifications of personnel.

13 So, is a very to me, a very blurry line between
14 points two and three with regard to the training for that.

15 I would suggest that we just kind of separate
16 those two issues and deal with the training for breath
17 alcohol testing separately from -- and try to coalesce the
18 training for fluid testing into the qualifications for
19 personnel.

20 Does that make any sense --

21 COMMITTEE MEMBER WONG: Uh-hmm.

22 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

23 -- to you guys?

24 COMMITTEE MEMBER WONG: Uh-hmm.

25 MR. LYLE: This is Bruce. I think that's the way

1 we were going.

2 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

3 Yeah, I thought so too.

4 CHAIRMAN KIMSEY: I'm sorry if I said something
5 that --

6 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

7 No, you did say something --

8 COMMITTEE MEMBER SHEN: You confused us Paul.

9 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:
10 -- you said --

11 CHAIRMAN KIMSEY: Right.

12 FOOD AND DRUG LABORATORY BRANCH ACTING CHIEF HAAS:

13 -- it's all the training.

14 CHAIRMAN KIMSEY: (laughter) -- well, there did
15 seem to be some feeling that not all of the training, you
16 know, should be under the Department's oversight. I mean, I
17 agree with the qualifications of the people but I remember
18 some frustration being expressed, which I was trying to
19 reflect, about some other of the training other than breath
20 instrument operator training and the qualification training.

21 So maybe that, maybe I just misunderstood. But I
22 was trying to reflect a comment that I, or I thought I had
23 heard earlier.

24 COMMITTEE MEMBER SHEN: But, we sort of worked
25 through number, I agree with number two and number three are

1 very similar. And we kind of worked that through number two
2 in elements that are associated with it from three, handling
3 the analysts. So what's left, I believe, is to how we want
4 to handle the breath operators, the training of the breath
5 operators.

6 So I think we'd already kind of gotten ourselves
7 where we wanted to be as far as training of the analysts.

8 CHAIRMAN KIMSEY: Good, good. No, then I stand
9 corrected.

10 COMMITTEE MEMBER SHEN: But that's just my
11 interpretation.

12 CHAIRMAN KIMSEY: No, that's fine. Other
13 comments, things, duties, announcements?

14 (No response)

15 CHAIRMAN KIMSEY: Then I want to thank everybody
16 for their time, again, this afternoon, this morning and this
17 afternoon.

18 And we'll get out a notice trying to get people's
19 schedules coordinated for a meeting sometime in the middle
20 of November and before Thanksgiving.

21 If there's nothing else, thank you very much.

22 (Thereupon, the California Department of
23 Public Health, Forensic Alcohol Review
24 Committee meeting adjourned at 2:48 p.m.)

25 --oOo--

CERTIFICATE OF REPORTER

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

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

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

JOHN COTA