



THE CITY OF SAN DIEGO

September 6, 2013

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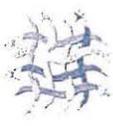
Diana S. Dooley, Secretary
California Health and Human Services Agency
1600 9th Street, Room 460
Sacramento, CA 95814

Dear Ms. Dooley:

We received and discussed Dr. Mark Horton's letter dated December 10, 2010. That letter addressed our request for feedback on the Forensic Alcohol Review Committee's (Committee) summary of recommended revisions to California Code of Regulations, Title 17, Sections 1215-1222.2. The letter contained an evaluation of the summary of revisions proposed by Committee. The letter specifically addresses four areas of concern, as follows:

- 1) The Committee's proposal to remove CDPH evaluation of a laboratory's performance on proficiency tests;
- 2) The Committee's proposal to remove CDPH authority to review, approve, and test the qualifications of persons employed by a laboratory;
- 3) The Committee's proposal to remove CDPH authority to review and approve training programs intended for persons to qualify under the regulations (e.g., breath instrument operator training); and
- 4) The Committee's proposal to remove requirements for a laboratory to provide CDPH with the records of its activities under the regulations, including notification by a laboratory of its intent to perform alcohol analysis.

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The letter stated that, in each of the above listed cases, the Committee is proposing to replace the current CDPH oversight of these activities with self-oversight by the individual laboratories. This would create a situation in which the state would not achieve the statutory mandate of ensuring competence of the laboratories and their employees performing chemical testing in support of California's drinking-and-driving laws, and would, in fact, diminish public safety. While we do not agree with that analysis of the cause and effects in this situation, in an effort to reach compromise and to move this regulation package forward after years of effort, we propose the following changes to the work product:

- 1) Remove CDPH evaluation of a laboratory's performance on proficiency tests.

Along with the removal of licensing authority and the establishment of a review committee, SB 1623 mandated one more important change with respect to proficiency testing. This legislation inserted language that was very specific as to how the proficiency tests should be administered.

SB 1623 states, in part, the following:

- 100702. (a) All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The required proficiency test must be obtained from any ASCLD/LAB approved test provider.*
- (b) Each laboratory shall participate annually in an external proficiency test for alcohol analysis.*
- (c) Each examiner shall successfully complete at least one proficiency test annually.*
- (d) Each laboratory shall have a procedure in writing that describes a review of proficiency test results, and, if applicable, the corrective action taken when proficiency test results are inconsistent with expected test results.*

The pertinent language in this addition is, of course, that "All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing." The language states very clearly that "the required proficiency testing must be obtained from any ASCLD/LAB approved test provider." As CDPH is not an approved provider, this certainly makes the activity of providing proficiency tests unnecessary, or at best redundant. However, stated in the opinion of Attorney General Kamala D. Harris, No. 10-501, issued December 27, 2011, subsequent to new law, the amended statute requires laboratories to comply with Department regulations until updated ones are put in place.

Our original changes to the pertinent section were as follows:

1216.1 (a) (3) ~~Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department; Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702.~~

In order to accommodate the Department's concerns, we submit the following change:

1216.1 (a) (3) Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702. Laboratories shall direct approved providers to submit all external proficiency test results as required by HS 100702 to the Department. The laboratories shall submit, at a minimum, one test per analyst per year. In addition, laboratory staff shall provide the Department any documentation pertaining to corrective actions with respect to proficiency tests.

- 2) Remove CDPH authority to review, approve, and test the qualifications of persons employed by a laboratory.

We recognize the Department's role in ensuring that analysts meet the criteria set forth in Title 17. It is the Committee's opinion that if we provide proof to the Department that analysts conducting alcohol analysis meet the qualifications set forth in the proposed regulations, we will have succeeded in providing the Department with an oversight role. Therefore, we propose to add the following verbiage to Article 2, Section 1216:

- 1216.1 (h) Every laboratory performing forensic alcohol analysis shall provide to the Department the following:*
- (1) A copy of the diploma(s) or transcripts of relevant education for each individual performing forensic alcohol analysis for the laboratory. The relevant education includes proof of a baccalaureate or higher degree in any applied physical or natural science;*
 - (2) A training summary of the topics outlined in 1216.1 (e) (2) with a completion date for each individual performing forensic alcohol analysis for the laboratory;*
 - (3) Copies of qualifying tests to include written and/or practical examinations for each individual performing forensic alcohol analysis for the laboratory;*

- (4) *Proof of completion of a competency test which follows the requirements articulated in 1216.1 (e) (3) for each individual performing forensic alcohol analysis for the laboratory.*
 - (5) *Written notification to the Department alerting it that the individual has successfully completed his or her training prior to beginning casework; and*
 - (6) *Proof of completion of a proficiency test as outlined in 1216.1(a) (3) for each analyst performing forensic alcohol analysis for the laboratory.*
- 3) Remove CDPH authority to review and approve training programs intended for persons to qualify under regulations (e.g., breath instrument operator training).

Our original changes to the pertinent section were as follows:

Article 4. Training of Personnel

Article deleted in its entirety.

**Article 7. Requirements for Breath Alcohol Analysis
Section 1221 (pertinent sections only)**

1221.4 Standards of Procedure

- 1221.4 (a) (3) *Breath alcohol ~~analysis~~ testing shall be performed only with instruments for which the operators have received training, such training to include at minimum the following schedule of subjects:*
- 1221.4 (a) (3) (A) *Theory of operation;*
 - 1221.4 (a) (3) (B) *Detailed procedure of operation;*
 - 1221.4 (a) (3) (C) *Practical experience;*
 - 1221.4 (a) (3) (D) *Precautionary checklist;*
 - 1221.4 (a) (3) (E) *Written and/or practical examination.*

- 1221.4 (a) (4) ~~The tTraining curriculum in the procedures of breath alcohol analysis testing shall be developed by under the supervision of persons who qualify as forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees in a licensed forensic alcohol laboratory.~~
- 1221.4 (a) (4) (A) ~~After approval as set forth in Section 1218, the forensic alcohol laboratory is responsible for the training and qualifying of its instructors.~~
- 1221.4 (a) (5) ~~An operator shall be a forensic alcohol supervisor, forensic alcohol analyst, forensic alcohol analyst trainee or a person who has completed successfully the training described under Section 1221.4 (a)(3) and (a)(4), and who may be called upon to operate a breath testing instrument in the performance of his/her duties.~~

We propose changing those recommendations to the following. These changes will serve to flesh out the requirements for the breath testing program and to provide the Department with a clear understanding of what is to be included in the breath operator training program.

We propose to reinsert Article 4 with the following amendments:

Article 4. Training of Personnel

1218. *Training Program Review.*
Any organization, laboratory, institution, school, or college conducting a course of instruction for persons to qualify under Section 1221.4 (a) (3) shall provide the following to the Department to demonstrate compliance with Title 17.
- 1218.1 *For training described under section 1221.4 (a) (3); the laboratory shall provide the following:*
- 1218.1 (a) *A complete outline of the training which meets the requirements of Section 1221.4;*
- 1218.1 (b) *A copy of the written examination together with the correct answers;*
- 1218.1 (c) *A written description of the practical examination;*
- 1218.1 (d) *A list of qualified instructors; and*

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1218.1 (e) A description of the qualifications of instructors for the training, which at a minimum shall mean persons that meet the requirements described under Section 1221.4 (a) (4) (A).

1218.2 Additional Requirements:

1218.2 (a) At the discretion of the forensic alcohol laboratory, any phase or portion of a training program shall be subject to alteration in an effort to update the program as technological advances are made or if a portion has been judged inappropriate. The changes will be subject to Department notification as outlined in 1218.1 (a) through 1218.1 (c).

1218.2 (b) If the Department believes that the laboratory's training program does not comply with these regulations, the Department shall notify the laboratory in writing within 30 days with its specific concerns. The laboratory management will respond to the Department in writing within 30 days. If the laboratory's management elects to address the Department's concerns, it will notify the Department of those changes within 30 days of receipt of the Department's written notification.

Note: Authority cited: Sections 100170, 100275, 100703, 131050, 131051, and 131200, Health and Safety Code. Reference: Sections, 100703, 100725 Health and Safety Code.

In addition, we propose the following changes to Article 7:

Article 7. Requirements for Breath Alcohol Analysis

1221.4 Standards of Procedure

1221.4 (a) Procedures for breath alcohol testing shall meet the following standards:

1221.4 (a) (3) Breath alcohol testing shall be performed only with procedures for which the operators have received training, such training to include at a minimum the following schedule of subjects:

- 1221.4 (a) (3) (A) *Theory of Operation:*
- i. *Value and purpose of forensic alcohol testing;*
 - ii. *General processes of absorption, distribution, and elimination of alcohol;*
 - iii. *Theory of breath alcohol analysis;*
 - iv. *Discussion of the required 15 minute wait period, and*
 - v. *Methods of breath alcohol testing*
- 1221.4 (a) (3) (B) *Detailed Procedure of Operation:*
- i. *Procedures of analysis for the specific breath alcohol testing instrument used by the agency.*
- 1221.4 (a) (3) (C) *Precautionary Checklist:*
- i. *Description of, and adherence to, the Precautionary Checklist.*
- 1221.4 (a) (3) (D) *Practical Experience:*
- i. *The Precautionary Checklist shall be incorporated into the testing sequence.*
 - ii. *Each instrument screen prompt shall be discussed and reviewed by the instructor.*
 - iii. *The operation of the breath instrument shall be demonstrated by the instructor.*
 - iv. *The instructor shall observe the trainee(s) perform a test on the instrument while he or she acknowledges each step of the Precautionary Checklist.*
- 1221.4 (a) (3) (E) *At the completion of the training session, each breath instrument operator trainee will be required to successfully complete a written examination and to achieve a passing score of a minimum of 80%.*
- 1221.4 (a) (3) (F) *Prior to the completion of the training session, each breath instrument operator trainee will be required to successfully complete a breath test, accurately following the Precautionary Checklist as outlined in 1221.4 (a) (3) (D) iii.*
- 1221.4 (a) (3) (G) *Upon successful completion of the training session, and successful completion of both the written and practical examinations, the trainee will be issued a certificate. The certificate will indicate the operator's name, ID/Badge #, agency, and include the instructor's name.*

- 1221.4 (a) (4) *Training curriculum in the procedures of breath alcohol testing shall be developed by forensic alcohol analysts. Department notification of the proposed curriculum will follow Section 1218.1.*
- 1221.4 (a) (4) (A) *The instructors will be, at a minimum, certified breath instrument operators with 2 years of practical experience, or, a Forensic Alcohol Analyst who has successfully completed the breath instrument training and has at least 6 months of practical experience with the instrument. Training in the Theory of Operation, pursuant to 1221.4 (a) (3) (A) shall be coordinated by a Forensic Alcohol Analyst.*
- 1221.4 (a) (4) (B) *The breath instrument operator trainees will receive, at a minimum, 4 hours of instructional training by a certified breath instrument operator.*
- 1221.4 (a) (4) (C) *If a breath instrument operator trainee has already undergone training to operate an approved breath testing instrument, the trainee may receive instruction as above excluding the portion covering 1221.4 (a) (3) (A).*
- 1221.4 (a) (5) *An operator shall be a forensic alcohol analyst or a person who has successfully completed the training described under Section 1221.4 (a) (3) and 1221.4 (a) (4), and who may be called upon to operate a breath testing instrument in the performance of his or her duties.*

Note: Authority cited: Sections 100170, 100275, 100703, 131050, 131051, and 131200, Health and Safety Code. Reference: Sections, 100703, 100725 Health and Safety Code.

- 4) Remove requirements for a laboratory to provide CDPH with records of its activities under the regulations, including notification by a laboratory of its intent to perform forensic alcohol analysis.

To provide oversight, the committee agrees that the Department will need to have knowledge of the activities of the laboratory and its staff. Therefore we propose to add the following language:

- 1216 (a) *Every laboratory performing forensic alcohol analysis shall provide the Department the following:*
- (1) *A statement of intent to perform or stop performing alcohol analysis, that shall include fluid analysis, breath analysis, or both;*
 - (2) *The laboratory's current address, as well as the name, address, and phone number of the laboratory's point of contact;*

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- (3) *A list of current laboratory personnel qualified to do forensic alcohol analysis; and*
- (4) *A list of current instruments used by laboratory personnel for alcohol analysis.*

Having met as a committee several additional times over the last two years, we feel that we understand and have addressed your concerns. I will reiterate that each of these changes in the regulations have been dissected, discussed, contemplated, and reviewed. As a result, this committee feels that the revisions that we are submitting to you meet and exceed the goals of both the committee and the legislators. It is also noteworthy that these changes were voted on and passed unanimously by the committee's members.

On behalf of the Forensic Alcohol Review Committee, thank you for your time.



Jennifer Shen
FAR Committee CACLD Representative

Mr. Dan Jeffries	CA District Attorney's Association
Lieutenant Kevin Davis	California Highway Patrol
Mr. Mark Slaughter	California Public Defender's Association
Mr. Bruce Lyle	California State Coroner's Association
Mr. Kenton S. Wong	California Association of Criminalists
Ms. Jennifer Harmon	California Association of Toxicologists
Dr. Paul Kimsey	California Department of Public Health

Cc: Dr. Ron Chapman, MD, MPH
Director and State Health Officer
California Department of Public Health

JLS/lw

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