

**INITIAL STATEMENT OF REASONS**  
**Revisions to the Regulations Pertaining to Forensic Alcohol Analysis**  
**Title 17, California Code of Regulations**

Under existing law, the State Department of Public Health regulates laboratories engaged in the performance of forensic alcohol analysis by or for law enforcement agencies on blood, urine, tissue, or breath for the purpose of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations. These regulations are detailed in Title 17, Subchapter 1 of Chapter 2 of Division 1.

**BACKGROUND**

Prior to 1969, laboratories performing forensic alcohol analysis were largely unregulated. The forensic community recognized a need for consistency and guidelines to provide the most accurate forensic alcohol testing. In 1969, legislation was passed authorizing the Department of Health Services (DHS) to adopt regulations for the testing of biological samples for alcohol content from persons subject to the implied consent provisions of the Vehicle Code. The new law required DHS to form an Advisory Committee on Alcohol Determination comprised of district attorneys, public defenders, coroners, criminalists, pathologists, and analytical chemists. The committee met in 1970, and the Department's regulations, commonly referred to as Title 17, were put in place in 1971. All laboratories engaged in the performance of forensic alcohol analysis, by or for a law enforcement agency, were now licensed and subject to these regulations. The regulations were last revised in 1986. Only laboratories performing alcohol analysis for law enforcement were required to be licensed. All other laboratories and all other forensic disciplines were, and remain, exempt from state regulation.

The original role of DHS with respect to the regulation of alcohol analysis was to do the following:

- ▶ provide timely reviews of methods submitted by laboratories,
- ▶ to approve new employees to conduct analyses,
- ▶ to conduct regular on-site laboratory inspections,
- ▶ to provide and oversee a proficiency testing program,
- ▶ to conduct regular meetings of the advisory committee,
- ▶ and to license laboratories to perform alcohol analysis.

After 1986, the relationship between DHS and the forensic alcohol laboratories began to deteriorate. In 1991, the Advisory Committee was disbanded by the legislature, effectively shutting off communication between the department and the laboratories. DHS personnel began to stray from the original intent of the regulations, and began mandating numerous additional requirements. Laboratories were forced to comply with these guidelines, or face extreme delays in method review and analyst classification and approval. On-site inspections dwindled, and became almost non-existent. In 1999, the Bureau of State Audits conducted an audit of the DHS' Forensic Alcohol Program (FAP), and released a report titled *Department of Health Services: The Forensic Alcohol Program Needs to Reevaluate its Regulatory Efforts*. This audit was a conducted to follow up on issues identified during a 1998 audit of 19 local forensic laboratories.

The auditors from the Bureau of State Audits summarized the following:

*This report concludes that the Department of Health Services regulatory efforts primarily emphasize reviewing written methods. Although necessary and important, the reviews are not completed promptly and focus on issues that do not improve the lab's analyses. Further, although the Department also conducts periodic site visits and proficiency tests, a greater emphasis on these activities may be more beneficial to labs than method reviews. Finally, the department's requirements for training operators of breath alcohol equipment are unnecessarily restrictive.*

The auditors also noted:

*Furthermore, a professional society within the forensic community accredits laboratory activities; nonetheless, the FAP does not consider the accreditation requirements as meeting the regulations. By relying on the accreditation when appropriate, the FAP may be able to redirect its regulatory efforts to areas that provide more value...the FAP does not consider accreditation when regulating labs under Title 17 and, in effect, may be duplicating requirements to demonstrate compliance with regulations.*

As a result of this audit, as well as the increased reliance of laboratories on the superior standards of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), Senate Bill 1849 was authored to curtail DHS's regulatory role with respect to forensic alcohol programs. That bill was unanimously approved by both the Senate and Assembly. In 2000, Governor Gray Davis vetoed SB 1849 stating that, in spite of the concerns raised by the Bureau of State Audits, he was "confident that the DHS (currently called DPH) can address the issues that have been raised and am directing DHS to make these concerns a high priority." The Governor said he would consider signing a modified version of the bill if DHS did not make significant progress within the next year towards solving the noted problems. Significant progress was not made.

Senate Bill 1623 was chaptered in 2004, an act to amend Section 100425 of, to add Sections 100701, 100702, and 100703 to, to repeal Sections 100710, 100715, 100720, 100730, 100735, 100740, 100745, 100750, 100755, 100760, 100765, and 100770 of, and to repeal and add Section 100700 of, the Health and Safety Code, relating to laboratories. Please see Appendices 1 and 2 for the specific language of what was added and repealed. Senate Bill 1623 was approved and signed into law in August, 2004, with the intent to greatly reduce state oversight of forensic alcohol analysis and to eliminate DHS licensing of laboratories performing such analysis. A newly appointed Forensic Alcohol Review Committee (FARC) comprised of scientific, law enforcement, and legal representatives, was given the authority to evaluate regulations and "determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws."

The FARC was legislatively mandated in August of 2004 with SB 1623, which acted, in part, to add Section 100703 to the Health and Safety Code relating to laboratories. This addition mandates the following:

- (a) *On or before July 1, 2005, the department shall establish a review committee.*
- (b) *The review committee shall have eight members, including one person representing each of the following: (1) Prosecuting Attorneys, (2) Law Enforcement Agencies, (3) Defense Attorneys, (4) Coroners, Pathologists, or Medical Examiners, (5) Criminalists, (6) Toxicologists, (7) Crime Laboratory Directors, and (8) The Department of Health Services.*
- (d) *The review committee shall evaluate Group 8 (commencing with Section 1215) of Subchapter 1 of the Chapter 2 of Division 1 of Title 17 of the California Code of Regulations and determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws.*

A committee was established, and it is of note that its members represent thousands of employees across the spectrum of law enforcement and the forensic science community. The members brought many unique and divergent opinions to the process, and, in the end, put together a work product that was overwhelmingly approved.

The review committee met fifteen times over the past five years to revise Title 17. As the regulations that were being reviewed were last updated in 1986, the committee had several goals when considering revisions. These goals included updating the verbiage within the regulations to meet current APA guidelines, to modernize the scientific techniques and educational requirements, to divest laboratories of redundant oversight and inadequate proficiency testing programs, and to accommodate for a new era of accreditation with the advent of accrediting bodies that are utilized by a vast majority of the alcohol laboratories in California. Each and every change in these regulations have been dissected, discussed, contemplated, and reviewed. As a result, this committee feels that the revisions meet and exceed the goals of both the committee and the legislators.

## REASONS TO UPDATE REGULATIONS

### **Regulations are out of Compliance**

Existing 1986 regulations are not in compliance with the Administrative Procedures Act, and are outdated and inconsistent with California law, current health advisories, and modern instrumentation and technology. Therefore, the regulations needed to be reviewed in their entirety, and re-written where applicable.

### **Technology has Advanced**

In the past 25 years, technology, educational requirements for college degrees, and California law, have all changed and modernized.

The advent of advanced data processing systems and mobile breath instruments has enabled alcohol testing to reach new levels of efficiency and accuracy. Instruments run diagnostics, run calibration checks, and prompt officers to follow the precautionary checklist, all automatically. The introduction of National Institute of Standards and Technology (NIST) traceable dry gas standards has allowed breath testing to become significantly easier to perform, and allows for scientists to check the calibration of their instruments with every single subject breath test,

versus every 10 days with a solution as required by the current Title 17. Data is downloaded, transferred, collated, and compiled, allowing for better and more modern data management. This also facilitates the discovery process, much of which is becoming electronic. Improvement in technology includes the capability for instruments to reject a test when a test parameter is not met. Instruments have become mobile, allowing for roadside breath testing. NIST traceable standards for blood alcohol testing can be purchased, standards with exceptional levels of accuracy and precision, standards that can replace the time consuming and less accurate titrated standards. These standards can be purchased with many different values, allowing for better instrument calibration.

College degrees, course work, class titles, and curriculum have advanced and changed to the point that it is difficult to correlate modern students' coursework with the requirements of the 1986 regulations.

California laws regarding driving under the influence have also changed, creating the need for altered criteria in alcohol testing. While the current regulations center requirements on a 0.10% level, the pertinent legal limit is actually a 0.08%. DUI laws for juvenile and commercial drivers require alcohol programs that check the accuracy of their levels down to a 0.01%. These changes in California law serve to further diminish the relevance of current regulations.

### **The Department of Health Services Has Become Obsolete**

With the advances in technology and the advent of accreditation for crime laboratories, the Department's role in regulating the forensic alcohol program has become largely obsolete, and is generally an exercise in redundancy. Therefore, although the point of some contention with DHS representatives, the changes and updates to these regulations, put forth by the FARC, attempt to remove DHS (currently referred to as the Department of Public Health, and referenced as DPH throughout the rest of this document) oversight where unnecessary, and place that oversight back onto the laboratories that have to answer to their accrediting bodies. As of 2010, every government forensic alcohol laboratory in California is accredited, and must adhere to those very stringent accrediting guidelines. Currently, according to their website, DPH is tasked with four primary activities. These include:

- ▶ proficiency testing,
- ▶ on-site inspections,
- ▶ review and approval of methods and procedures,
- ▶ and coordinating the meetings of the current advisory committee on alcohol determination.

When each is examined below, it is very clear that DPH oversight is not necessary to ensure the competency of forensic alcohol laboratories.

Proficiency testing: 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.” This new regulation vastly changes the way proficiency testing programs in forensic alcohol laboratories are to be handled. The language states very clearly that “the required proficiency testing must be obtained from any ASCLD/LAB approved test provider.” As DHS is not an approved provider, this certainly makes the activity of providing proficiency tests unnecessary, or at best redundant.

On-Site Inspections: Senate Bill 1623 specifically repealed Section 100735 of the Health and Safety Code. This section stated the following:

*100735. Every approved and licensed laboratory shall be periodically inspected by the department. Reports of each inspection shall be prepared on forms furnished by the department and shall be filed with the department.*

With this section no longer existing under current law, DPH is no longer is tasked with inspecting laboratories. This was due in large part to the lack of any consistency in the inspections, which were sporadic at best. DPH was averaging approximately one inspection per laboratory every 10 years.

The auditors from the Bureau of State Audits noted the following:

*Because the FAP invests so much time in reviews, during the past three years, it has visited an average of 4 labs each year. At this rate, it will take the FAP ten years to visit all 42 labs.*

In the past decade, laboratories in California have been relying upon their accrediting bodies for on-site inspections. ASCLD/LAB regulations require an on-site, in-depth inspection of forensic laboratories every five years. In addition, each section within the laboratory is inspected internally on an annual basis. These audits are conducted by scientists that specialize in the area of expertise they are auditing.

The auditors from the Bureau of State Audits recognized this fact and stated the following:

*To be accredited, a lab receives an inspection by a team of analysts from other accredited labs. The inspection team is knowledgeable in the types of work the lab performs. To maintain accreditation, a lab is inspected every five years. Thus, the ASCLD/LAB inspects accredited labs twice as often as the FAP does; as mentioned above, the FAP inspects labs only once every ten years. In addition, practicing forensic analysts conduct the ASCLD/LAB's inspection, while staff chemists-who are not well versed in the daily demands of a forensic lab-make the FAP's site visits.*

It is reasonable to conclude then, that site visits are not under the purview of DPH, and should not be considered a primary activity maintained by DPH personnel.

Review and Approval of Methods and Procedures: Prior to the passage of Senate Bill 1623, DPH spent a considerable amount of time and resources on forensic alcohol method approval. In fact, the detailed approval process of the methods was a very large problem for forensic laboratories, one which was noted in the audit conducted by the State Bureau of Audits in 1999.

The auditors noted the following in the final report:

*Of the three areas, reviewing labs' written procedures is the FAP's primary emphasis; however, the FAP does not complete its reviews in a timely fashion. At the same time, the labs complain that the reviews' modifications often address editorial aspects of the written procedures and do not improve the labs' overall methods.*

*In addition to creating obstacles through its lengthy approval process, the FAP can present further difficulties for the labs because its modifications to their methods may have little bearing on the quality of their analyses. During a method review, the assigned chemist lists changes in one of two categories: those necessary for compliance with Title 17, and those that are optional, but which the FAP still considers improvements. The following are examples of changes the FAP has required:*

- Modifying titles and word choice.*
- Specifying the source of a chemical.*
- Including an introduction.*
- Paginating a method.*

*Although these items may enhance written clarity, not one is a specific requirement under Title 17. Neither is it clear how these largely editorial changes affect the quality of analysis a lab performs, nor how they differ significantly from what the FAP considers optional modifications, such as altering word choice and correcting spelling and grammar.*

DPH concentrated its efforts on method review, but not on method development, or upon the work product produced by following the methods. Individual analysts were not interviewed, work product was not reviewed, and a concerted effort to stifle change was pervasive. As a result of the audit, and the passage of Senate Bill 1623, DPH altered its regulatory efforts to address these concerns.

In an excerpt from a letter dated January 2005, Status of the Forensic Alcohol Analysis Regulatory Program in 2005, this new oversight policy is laid out.

***Filing of Written Descriptions of Forensic Alcohol Methods:** DHS will no longer require forensic alcohol laboratories to have on file with DHS written descriptions of the methods it uses for forensic alcohol analysis. The laboratories, however, will still be required to maintain detailed, up-to-date written descriptions of each method and to make these available to DHS on request.*

Currently, the forensic alcohol methods being utilized by forensic laboratories are not being approved of, or reviewed by, DPH.

In the last decade, as laboratories have become accredited, this is another area that has been addressed by the accrediting bodies, and again, the criteria by the accrediting bodies is more pertinent, relevant, and stringent than the oversight provided by DPH. Methods are reviewed every five years to ensure that they are scientifically sound, reflect what is actually being done by the analysts, are generally accepted within the scientific community, properly reflect adequate quality assurance and instrument maintenance, are easily available to analysts, are controlled, and are updated when necessary. Analysts are interviewed, and every chemist's work product is reviewed to ensure it meets laboratory, method, and scientific standards. A conduit to new method development and technological advances is readily available, and the process lends itself to ensuring accuracy and allowing modernization at the same time.

Therefore, this is another primary responsibility of DPH that is not relevant, and if enforced, is redundant.

Coordinating Meetings of the Current Advisory Committee on Alcohol Determination: DPH is currently coordinating the FARC meetings, attending them, and advising its members. This is, in fact, a responsibility that is being provided.

With the previous information firmly in mind, the Forensic Alcohol Review Committee members attempted to diminish the redundant oversight of DPH in the regulations, as the goal of the committee, as legislated in SB 1623, is to "evaluate Group 8 (commencing with Section 1215) of Subchapter 1 of the Chapter 2 of Division 1 of Title 17 of the California Code of Regulations and determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws."

## CONCLUSION

As 25 years have passed since the last revision of Title 17, the forensic community finds itself in a new era of technology, education, accreditation, and oversight. We have found that the regulation provided by the Department of Public Health has become obsolete, and that Title 17 is outdated, causing inefficiency in our analytical procedures and keeping laboratories from modernizing to meet the times. In addition, Title 17 is out of compliance with the Administrative Procedures Act. Therefore, the Forensic Alcohol Review Committee proposes

the following amendments to Title 17, Subchapter 1 of Chapter 2 of Division 1 and asserts the following justifications.

## JUSTIFICATIONS

### California Code of Regulations, Title 17, Sections 1215 to 1222.2

#### **Article 1. General Section 1215**

Article 1 cites the authority for the regulations, and provides general definitions for the regulations. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1215:** This section will be changed to reflect current law; Stats 2004, C.337 (SB 1623).

**1215.1 (a)** This definition will be maintained in its current form, as it accurately reflects the definition of alcohol for the purposes of these regulations.

**1215.1 (b)** This definition was changed to clarify the meaning of forensic alcohol analysis and to utilize more common language. To this end, “practical application” was replaced with “use”, and “device” was replaced with “equipment.” In Section 1215.1 (a), alcohol is defined as the unique chemical compound, ethyl alcohol. Therefore, the descriptor “ethyl” was removed from before the word alcohol in this definition to avoid redundancy. Finally, the reference to the operators of the equipment was removed from this definition, (trained laboratory personnel), as the definition should be restricted to the analysis itself. Appropriate personnel to perform these analyses are defined elsewhere.

**1215.1 (c)** The change from “analysis” to “testing” is more consistent with the verbiage used throughout the country. This definition was changed to more accurately reflect current law and more clearly state what breath alcohol testing means. The word “analysis” describes how the test results are achieved which is not suitable in this context, thus making this revised definition more appropriate. The word “sampling” reflects more accurately the limited function of the breath instrument operator in simply obtaining a breath alcohol test result. In 1991, in Assembly Bill 4318<sup>1</sup>, the law was changed to state that the breath test was a reflection of the alcohol concentration in the deep lung air, and was not linked necessarily to the blood level.<sup>2,3,4</sup> In other words, the breath test result is a measure of the breath, and not the blood. The word “ethyl” was again removed from this definition to avoid redundancy.

**1215.1(d)** This definition will be maintained in its current form, as it accurately reflects the definition of concentration.

**1215.1 (e)** This definition was changed to increase its clarity and to provide consistency with other definitions. The “trained laboratory personnel” phrase was replaced with “forensic alcohol analysts” to be very specific. In addition, the word “apparatus” was changed to “equipment” and

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<sup>1</sup> Assembly Bill No. 4318, 1989-1990 regular session

<sup>2</sup> California Senate Bill 1119...

<sup>3</sup> Assembly Bill No. 4318, 1989-1990 regular session

<sup>4</sup> Bransford Decision...

the word “forensic” was added to the phrase alcohol analysis, to provide consistency with other stated definitions. The phrase “other than” was changed to “in addition to” to provide more clarity.

**1215.1 (f)** This definition eliminates the Department’s classifications of forensic alcohol supervisor here and throughout this document. These regulations specify the qualifications required to be an analyst and the guidelines of those analyses. The Department classification of “forensic alcohol supervisor” is ambiguous and inconsistent with the actual practice of supervising employees in the laboratory, i.e., a person who makes work assignments and performs employee evaluations. The revised language provides clarity, especially to the legal community/courts/juries who may incorrectly assume a “forensic alcohol supervisor” is an actual supervisor in the laboratory. The words “can be” were changed to “is” to provide clarity.

**1215.1 (g)** The definition for forensic alcohol analyst is now located in Section 1215.1(f). The requirements for analysts are defined in this document, thus their classification is no longer required to be determined by the Department.

**1215.1 (h)** The Department classification of forensic alcohol analyst trainee has been eliminated here and throughout this document. This classification had been used in administrative hearings by the Department of Motor Vehicles and is no longer appropriate.

**1215.1 (i)** This change specifies who uses the method, and gives a clearer definition as to what a method is. In addition, it provides for consistency of verbiage throughout the definitions.

**1215.1 (j)** This definition will be deleted in its entirety. The words “instrument” and “device” are considered common language, and therefore it is not deemed necessary to define them in this section.

**1215.1(k)** This definition was repealed as a Rule 100 change.<sup>5</sup>

**1215.1 (l)** This definition has been changed to more accurately define a breath sample or specimen.

**1215.1 (m)** This definition will be maintained in its current form, as it accurately reflects the definition of alveolar.

**1215.1 (n)** This definition will be maintained to provide clarity to the references to the “Department” noted throughout this document. The word “Public” was added here and throughout the document to reflect the current title of the Department when applicable.

**1215.1 (o)** This definition was added to define the term that is utilized in the text and distinguish it from a “proficiency” test.<sup>6</sup>

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<sup>5</sup> The Rule 100 change refers to the change in law resulting in the adoption of Health and Safety Code, Section 100700-100775, September, 2008. All references to a Rule 100 change refer to this regulation.

<sup>6</sup> 2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006

**1215.1 (p)** This definition was added to define the term that is utilized in the text and distinguish it from a “competency” test.<sup>7</sup>

**1215.1 (q)** This definition was added to define the term that is utilized in the text.

**1215.1(r)** This abbreviation has been added to define the term that is utilized in the text.

**1215.1(s)** This definition was added to define a term that is utilized in the text and distinguish it from a NIST traceable material.

**1215.1(t)** This definition was added to define a term that is utilized in the text and distinguish it from a NIST Standard Reference Material.

**1215.1(u)** This definition was added to define a term that is utilized in the text and to provide clarity.

## **Article 2. Requirements for Forensic Alcohol Laboratories**

### **Section 1216**

Article 2 cites the regulations a government forensic alcohol laboratory must adhere to in order to be authorized by the Department to conduct forensic alcohol analyses. In addition, this section details the requirements necessary for laboratory personnel to engage in this type of testing. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1216.** This title will remain unchanged.

**1216 (a)** Repealed due to a Rule 100 change.

**1216 (a) (1)** This amendment replaces “these regulations” with a specific site reference to clarify the location of the qualifications. The references to the supervisor and trainee classifications have been removed to be consistent with the changes in this document.

**1216 (a) (1) (A)** This section has been removed in its entirety as the Department classification of trainee and supervisor has been eliminated.

**1216 (a) (2)** This section will be deleted in its entirety as a Rule 100 change.

**1216.1** This section has been amended to eliminate the reference to “licensing” per a Rule 100 change.

**1216.1 (a)** This section has been amended to eliminate the reference to licensing per a Rule 100 change. The addition of “forensic alcohol” to the laboratory description provides clarity.

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<sup>7</sup> 2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006

**1216.1 (a) (1)** This section has been deleted in its entirety. The Department classification of forensic alcohol supervisor has been eliminated. This change reflects a laboratory's ability to operate without a forensic alcohol supervisor. Current practice has many laboratories utilizing forensic alcohol analysts (FAAs) to do all of the alcohol analysis and interpretation, while using supervisors that are not necessarily FASs to supervise the personnel within the unit. The rest of (1) is deleted due to redundancy. It is also important to note that the educational requirements for an FAA have increased, (Section 1216.1(f) (1)), bolstering the argument that an FAS is not necessary to perform all of the functions of forensic alcohol analysis.

**1216.1 (a) (2)** This section was amended to add a cite to clarify the location of the requirements of an appropriate quality control program.

**1216.1 (a) (3)** This section has been amended to include the addition of a cite to clarify the location of the requirements, thereby avoiding redundancy in this document. (Health and Safety Code Section 100702 (a)) The new regulations cited in Health and Safety Code Section 100702 (a) are quite different from the regulations currently laid out in Title 17.

Proficiency testing is an integral part of an effective quality assurance program. It is one of many measures used by laboratories to monitor performance and to identify areas where improvement may be needed. It verifies that technical procedures are valid, and that the quality of the work product is maintained at a high level. Therefore, crime laboratories take proficiency testing very seriously, and have stringent criterion for employing a proficiency testing program. It is important to note, therefore, that the Department's proficiency testing program is not currently sufficient to meet accreditation requirements mandatory for accredited crime laboratories. Currently, 27 of 39 laboratories (approximately 70%) approved by the Department to perform forensic alcohol analysis are accredited.<sup>8</sup> These laboratories are accredited through the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). Under this system, laboratories are held to rigorous standards both to receive and maintain an accredited status. An integral part of this process is a defined and mandatory proficiency testing program. In order to provide proficiency tests, a company must comply with regulations mandated by the accrediting body. An approved proficiency test provider is an individual, organization, or company which has applied for and obtained approval from ASCLD/LAB (or other accrediting body as approved by the legislature) to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines, for which the provider has been approved.<sup>9</sup> The Department is not recognized as an approved proficiency test provider. Proficiency tests themselves must adhere to strict guidelines. These include, in part, the following:

The company must provide or make available to each test subscriber a summary report within 90 calendar days after the due date. The summary report shall include the following:

1. Compiled results from all participants.

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<sup>8</sup> California Association of Criminalists Lab Director, and List of Licensed Forensic Alcohol Analysis Laboratories

<sup>9</sup> "Proficiency Review Program" American Society of Crime Laboratory Directors, Ver. 2.1, 2008, pages 9-11

2. Description of the test design, test objective, and details of its manufacture.
3. Results of pre-distribution laboratories confirming the manufacturer's specifications (expected/target results) or a statement that the results of the pre-distribution testing confirmed the expected results.
4. Results of all reporting subscribers identified only by a unique code.
5. A brief summary and/or analysis of all of the results plus any additional comments provided by the subscribers.<sup>10</sup>

The Department proficiency tests do not adhere to these guidelines. This puts accredited laboratories in a difficult position. Although the Department requires that approved forensic alcohol testing laboratories participate in a proficiency testing program, the Department will not allow that program to be comprised of only approved providers. The Department still mandates that laboratories participate in the Department provided proficiency testing at least once a year.<sup>11</sup> Since this participation does not fulfill accreditation requirements, laboratories are forced to participate in a substandard program along with the accredited program. This is not efficient, and adds nothing to the qualifications of a laboratory. It therefore seems redundant, and a waste of state resources, for the Department to supply an unnecessary program.

**1216.1 (a) (4)** Since 2005 the Department has discontinued on-site inspections following the change in the Health and Safety code.

This section was removed as it was the intent of the legislature to diminish the oversight of the Department. It should be noted that the inspections conducted by the Department are not done on a regular or frequent basis. Laboratories can, and do, go many years without an inspection conducted by the Department. As all government forensic laboratories in California are accredited<sup>12</sup>, this function would appear to be redundant, as ASCLD/LAB, the accrediting body used by the majority of crime laboratories in California, requires annual audits of all accredited areas, as well as reaccreditation inspections every 5 years. In addition, for those laboratories that are not accredited, their work product must pass scrutiny on all adjudicated cases through the court system. In the 1999 audit of the Department of Health Services by the California State Auditor's Office<sup>13</sup>, the following conclusion appeared:

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<sup>10</sup> American Society of Crime Laboratory Directors Laboratory Accreditation Board, Proficiency Review Program, page 10 of 23

<sup>11</sup> Reporting Results of Laboratories' Annual Participation in Proficiency Testing, California Department of Public Health, September 23, 2008

<sup>12</sup> California Association of Criminalists Lab Directory

<sup>13</sup> "The Forensic Alcohol Program Needs to Reevaluate Its Regulatory Efforts," conducted by the California State Auditor's Office, Report 97025.1". Sacramento: Bureau of State Audits, August 1999

“To be accredited, a lab receives an inspection by a team of analysts from other accredited laboratories. The inspection team is knowledgeable in the types of work the lab performs. To maintain the accreditation, a lab is inspected every 5 years. Thus, the ASCLD/LAB inspects accredited laboratories twice as often as the FAP (Department) does; as mentioned above, the FAP only inspects laboratories once every 10 years. In addition, practicing forensic analysts conduct the ASCLD/LAB’s inspections, while staff chemists—who are not well versed in the daily demands of a forensic lab—make the FAP’s site visits.”

It would seem apparent that for accredited laboratories, the Department’s oversight in this area is not only unnecessary, but possibly substandard.”

**1216.1 (a) (5)** This section was removed as vague and redundant.

**1216.1 (b)** This section was removed due to change in statute regarding licensing, and the general statement is unnecessary because there is no language that allows a lab to deviate from the qualifications at any time.

**1216.1 (c)** This section was removed due to change in statute.

**1216.1 (d)** This section was removed due to elimination of licensing and forensic alcohol supervisor classification.

**1216.1 (d) (1)** This section was removed due to a lack of relevance.

**1216.1 (e)** This section was amended to remove the word supervisor as the supervisor classification has been eliminated.

**1216.1 (e) (1)** This section was amended to remove “or an equivalent” to further clarify the section. The phrase “in any applied physical or natural science” was added to allow employers broader discretion over educational requirements. In addition, “applied” assumes hands-on experience vs. theoretical experience, a desirable trait. The current regulations are too limiting in today’s educational environment. Finally, the reference to the Department will be removed as it no longer should have oversight in this area.

**1216.1 (e) (2)** This section was amended to replace the phrase “approved by the department” with “at the laboratory of employment.” This clarifies that an individual must be qualified by his or her specific Forensic Alcohol Laboratory. “Approved by the Department” was removed, in part, as it was the intention of the legislature to give individual laboratories oversight in this area. In addition, as the expectations of the course training are outlined in the following sections, it appears to be redundant that the Department approves what is already spelled out. Giving the laboratories control of the approval of courses appropriate for training forensic alcohol analysts, allows for local agency control of when, where, and by whom these courses will be offered. The word “ethyl” was eliminated to be consistent with rest of document and type of alcohol has already been defined.

**1216.1 (e) (2) (A)** This section was amended to remove the phrase “including breath alcohol analysis” as it is redundant. The term Forensic Alcohol Analysis is defined in Section 1215.1 (b), and includes a reference to breath alcohol analysis.

**1216.1 (e) (2) (B)** This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

**1216.1 (e) (2) (C)** This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

**1216.1 (e) (2) (D)** This section was amended to include the word “forensic” for clarity and consistency.

**1216.1 (e) (2) (E)** This section was amended to replace the word “analysis” with “testing” to more accurately reflect the training topic. This also reflects the change in the definition of “Breath Alcohol Testing” noted in Section 1215.1 (c).

**1216.1 (e) (2) (F)** This section was amended to add the word “forensic” for clarity and consistency. “Analyst” replaces “student” for clarity.

**1216.1 (e) (2) (G)** This section was amended to add the word “forensic” for clarity and consistency.

**1216.1 (e) (2) (H)** This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

**1216.1 (e) (2) (I)** This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

**1216.1 (e) (2) (J)** This section was amended to remove the words “these regulations” and the title and phrase “Sections 1215 to 1222.1 inclusive” were added to clarify the section.

**1216.1(e) (3)** This section was amended for clarity. Completion of “competency” tests rather than “proficiency” tests is a more accurate term in this context. The addition of the definition of competency tests under Section 1215.1(o) will aid in the clarity of this section. The references to “the Department” were removed to accommodate the intent of the legislature, i.e., that ASCLD/LAB guidelines will be used. The proficiency tests issued by the Department do not meet the standards that are required by current accreditation bodies. Please refer to justification Section 1216.1(a) (3).

It is of note that in the 1999 audit report contained the following conclusion:<sup>14</sup>

“To obtain accreditation, a laboratory must demonstrate that it meets established standards for management, operations, personnel, procedures, equipment, facilities,

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<sup>14</sup> “The Forensic Alcohol Program Needs to Reevaluate Its Regulatory Efforts,” conducted by the California State Auditor’s Office, Report 97025.1”. Sacramento: Bureau of State Audits, August 1999

security, and health and safety procedures. The program also requires labs to implement proficiency testing, continuing education, and other programs that improve their staff members' overall skills and services. Currently, California has at least 16 accredited forensic laboratories. However the FAP (Department) does not consider accreditation when regulating labs under Title 17, and, in effect, may be duplicating efforts to demonstrate compliance with the regulations.”

The number of accredited laboratories is now 41; this includes the 70% of laboratories in California that are currently authorized by the Department to perform forensic alcohol analysis.<sup>15</sup>

The reference to passing examinations prescribed by the Department is no longer necessary, as the laboratory of employment has requirements that will be the determining factor in deciding whether a person is deemed competent in forensic alcohol analysis. This is referred to in the following Section 1216.1 (e) (4). It is also pertinent to note that the testing by accredited laboratories, whether by written or practical examinations, is likely to be more current and relevant to today's technological advances. The Department has not updated its written examination in over two decades.<sup>16</sup>

**1216.1 (e) (4)** This section is redundant and is deleted in its entirety. The information is already required in a previous section.

**1216.1 (e) (5)** This section was amended for clarity.

**1216.1 (f)** This section has been eliminated because the analyst qualifications are now located in Section 1216.1(e).

**1216.1 (f) (1)** This section has been eliminated because the analyst academic requirements are now located in Section 1216.1(e)1.

**1216.1 (f) (2)** This section has been eliminated because the analyst training requirements are now located in Section 1216.1(e) 2.

**1216.1 (f) (3)** This section will be deleted in its entirety. This element is covered in a general in Section 1216.1(e) (2). The forensic alcohol laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. This is also covered in Section 1216.1(e) (4). Running 25 samples with known results serves only as practice for an analyst, and does not show competence. In most instances, the laboratory program will have much more stringent training requirements than the Department. The competency test requirement outlined in Section 1216.1 (e) (3) is a true test of an analyst's competency, as the answers to the test are unknown to the analyst.

It should also be noted that some forensic alcohol laboratories perform only breath testing. These laboratories are not able to easily satisfy the requirement for staff to complete a minimum

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<sup>15</sup> California Association of Criminalists Lab Director, and List of Licensed Forensic Alcohol Analysis Laboratories

<sup>16</sup> Department of Health Services Food and Drug Laboratory, Proficiency Test and Written Examination, LAB 529, Rev. 9/87

of 25 analyses of alcohol concentration in blood samples. Therefore, the removal of the specificity of “blood samples” in this section is also appropriate.

**1216.1 (f) (4)** This section has been eliminated as the analyst proficiency testing is now in Section 1216.1(e)(3).

**1216.1 (f) (5)** This section has been eliminated as the analyst employment requirements are now located under Section 1216.1(e)(4).

**1216.1 (f) (6)** This section will be amended to clarify the “grandfather clause.”

**1216.1 (g)** This section was removed as the trainee classification has been eliminated thus this section is no longer applicable.

**1216.1 (g) (1)** This section was removed as the trainee classification has been eliminated thus this section is no longer applicable.

**1216.1 (g) (2)** This section was removed as the trainee classification has been eliminated thus this section is no longer applicable.

### **Article 3. Licensing Procedures**

#### **Section 1217**

Article 3 will be removed in its entirety as a Rule 100 change and the elimination of licensing. References to the maintenance of proficiency test records and analyst training records are redundant as they are included in Article 8.

### **Article 4. Training of Personnel**

#### **Section 1218**

This section will be removed in its entirety. This section discusses appropriate training programs; programs that are deemed suitable by the Department. As we have removed the oversight of training programs from the Department, enhanced the requirements of the analyst, and have given such oversight to the employing laboratory entities, as noted in Sections 1216.1 (e) (4) and 1216.1 (f) (4), this section becomes irrelevant. In addition, the training curriculum required is spelled out in Section 1216.1 (e) (2) A-I. This would appear to make this section redundant as well.

### **Article 5. Collection and Handling of Samples**

#### **Section 1219**

This section outlines the regulations for collecting the samples utilized in forensic alcohol testing. The title of this article will be changed to more accurately reflect the kinds of samples

being collected utilizing these particular regulations. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1219** This section was amended to remove the phrase “in a manner approved by the Department”. We feel that oversight of these issues by the Department is redundant, as the protocol for appropriate handling is outlined in the following sections. For those issues not specifically outlined in Section 1219.1, the laboratory’s protocols will address these particulars (chain of custody logs, labeling, security etc.) as each laboratory entity sees fit, while fulfilling the requirements outlined in Section 1219. The court system provides for the ultimate oversight of proper collection and handling, as these issues are challenged in most driving under the influence cases.

**1219.1** This section will remain as written.

**1219.1 (a)** This section was amended to reflect a change in the Vehicle Code cite.<sup>17</sup>

**1219.1 (b)** This section will be removed in its entirety. This section is vague, and puts the onus on the technician drawing the blood to determine what amount is sufficient, versus on the analyst with the knowledge to support that decision making process. The analyst will be required to determine whether the sample collected is sufficient to perform duplicate analyses.

**1219.1 (c)** These changes were incorporated to update the section as to suitable disinfectants. In May 2002, a letter issued by the Department stated the “Aqueous merthiolate or other mercury containing compounds should not be used to clean the skin as these compounds are now known to cause cancer or reproductive toxicity.” (Larson, Clay. “Collection of Blood Samples for Forensic Alcohol Analysis, Suitable Aqueous Disinfectants”)

**1219.1 (d)** This section was amended for clarification, and make it grammatically correct.

**1219.1 (e)** This will remain as written as it reflects current accepted practice.

**1219.1 (e) (1)** This will remain as written as it reflects current accepted practice.

**1219.1 (e) (2)** This will remain as written as it reflects current accepted practice.

**1219.1 (f)** The section will be amended to change the word “insure” to “ensure” for grammatical correctness.

**1219.1 (f) (1)** This section was amended to reflect current practices. Current practices recommend the addition of a preservative irrespective of refrigeration. Current practice also is to store blood specimens in a refrigerated environment.

**1219.1 (f) (2)** This section will remain as written as it reflects current accepted practice.

**1219.1 (g)** This section will remain as written as it reflects current accepted practice.

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<sup>17</sup> California Law “Vehicle Code Section 23152-23229”

**1219.1 (g) (1)** This section has been amended to replace “coroner” with “medical examiner.” Different jurisdictions may use a coroner system while others use a medical examiner system. The term “coroner” in this sense may be incorrect. The term “medical examiner” is more accurate and will apply to either system. Also the treatment of medical examiner cases is sufficiently different and has been renumbered to reflect this.

**1219.1 (g) (2)** This section has been amended to create a more accurate representation of current practices.

**1219.2** This section will remain as written.

**1219.2 (a)** This section has been amended to clarify what an appropriate sample collection is, removing the ambiguity of “an approved” sample. It also clarifies that the protocol in this section refers to a living individual, as these procedures are not utilized when dealing with urine collection from a deceased person.

**1219.2 (b)** This section will remain as written as it reflects current accepted practice.

**1219.2 (c)** This section will remain as written as it reflects current accepted practice.

**1219 (c) (1)** This section has been amended to include “or coroner/medical examiner’s office” to create a more accurate representation of current practices. The change of “by” to “on” provides consistency with prior language contained in Section 1219.1 (g) (2).

**1219.3** Section 1219.3 will more appropriately be relocated to the Breath Alcohol Testing as section 1221.1(b) (3).

## **Article 6. Methods of Forensic Alcohol Analysis**

### **Section 1220**

This section outlines the regulations for conducting the analysis of the samples. It includes discussions on sample handling, testing procedures, standards, controls, and quality assurance. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1220 (a)** This section will remain as written.

**1220 (b)** This section is amended as a Rule 100 change, and reflects the intent of the legislature to remove Department oversight in this area. In addition, it should be noted that all methods are available for review by anyone in the public or private arena through the California Public Records Act.<sup>18</sup>

**1220 (b) (1)** This section has been amended to address the important factor that the analyst has immediate access to methods he/she is using. This is a criterion addressed in Section 5.4 (Test

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<sup>18</sup> California First Amendment Coalition – Government Code Section 6250-6270

and Calibration Methods and Method Validation) of ISO 17025 Program of Accreditation, currently utilized by ASCLD/LAB-International. All accredited crime laboratories will be following the ISO guidelines within the next 5 years. As stated previously, the Department has access to any and all methods through the California Public Records Act, causing the inclusion of a reference to availability to be unnecessary.

**1220 (b) (2)** This section will remain as written. This section is fairly general in its requirement for available methods to include calibration and quality control procedures. This section can stand on its own as currently written, because it provides general guidelines that are fleshed out in great detail in the requirements of the accrediting bodies utilized by most crime laboratories. The ASCLD/LAB accrediting guidelines far exceed the requirements set forth in this document.<sup>19</sup> For those laboratories that are not accredited, this guideline is appropriate.

**1220.1** This section will remain as written.

**1220.1 (a)** This section will remain as written, as it is merely an introduction to the following requirements.

**1220.1(a) (1)** This section was amended to replace “0.10 grams per 100 milliliters” to “0.08 grams per 100 milliliters” to reflect the change in state legal limit.<sup>20</sup>

**1220.1 (a) (2)** This section has been amended to provide clarity as the phrase “adequate and appropriate” are vague.

**1220.1 (a) (3)** This section will remain as written with the more correct replacement of “shall” as it reflects current accepted practice.

**1220.1 (a) (4)** The word “a” was added to be grammatically correct. The rest of the section will remain as written as it reflects current accepted practice.

**1220.1 (a) (5)** This section will remain as written as it reflects current accepted practice.

**1220.1 (b)** This section was amended to remove the reference to “Department” and replace it with “a forensic alcohol analyst” to give oversight of the proficiency program to the individual laboratories. This serves to clarify who must make the determination that a method is meeting requirements, and brings this section in line with the intent of the legislature. All of the California government laboratories, state, county, and city, are accredited, largely replacing the need for the Department to have any oversight of the proficiency testing program.<sup>21</sup> Accredited laboratories have mandated quality assurance programs, with quality assurance managers that are tasked with implementing, running, and overseeing a proficiency test program. The laboratory must follow accreditation proficiency testing requirements, and is held accountable through the Proficiency Review Program, (PRP), applicable to both the ASCLD/LAB Legacy accreditation

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<sup>19</sup> General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories

<sup>20</sup> Vehicle Code Section 23152 (b)

<sup>21</sup> California Association of Criminalists Lab Directory September 19, 2008

program as well as the ASCLD/LAB-International accreditation program. To retain accredited status for a full five year term, a laboratory must continue to meet the standards under which it was accredited. One of the means by which ASCLD/LAB monitors compliance is by reviewing proficiency testing reports submitted by approved test providers. The PRP outlines the roles and responsibilities of the Proficiency Review Committees (PRC), approved test providers, the ASCLD/LAB Proficiency Test Program Manager, and others in carrying out the elements of the proficiency review process. This program provides the oversight need to ensure methods are functioning according to required specifications.<sup>22</sup> As also discussed previously, the proficiency tests issued by the Department do not meet the standards that are required by current accreditation bodies. Please refer to justification section 1216.1 (a) (3). The requirements are set forth in these regulations in a manner sufficient to accommodate those laboratories that are not currently accredited. Please refer to sections 1216.1 (e) (3) and 1216.1 (f) (3).

**1220.2** This section will remain as written.

**1220.2 (a)** This section will remain as written, as it is merely an introduction to the following requirements.

**1220.2 (a) (1)** This section will be amended. The word “method” will be changed to “instrument” for clarification, and to describe actual practice.

**1220.2 (a) (1) (A)** This section was revised to allow the use of two different types of solutions, those prepared according to the 1986 regulations, and those that can be commercially purchased. The use of purchased solutions saves many hours of analyst time and provides better quality solutions. The complete justification for this change is located under Section 1220.2 (a) (1) (C).

**1220.2 (a) (1) (B)** This section will be amended to add National Institute of Standards and Technology (NIST) traceable standards as an option for secondary standards.

Accurate calibration of instruments used in forensic alcohol testing is critical, as the results directly affect criminal prosecutions. For the past 30 years, CA laboratories have been required by regulation to prepare their own secondary alcohol standards using a direct oxidimetric method. These secondary standards were then utilized to check the calibration of the instruments. Commercially prepared secondary standards and NIST Standard Reference Materials (SRMs) are now widely available at critical concentration levels. In this revision laboratories are given the opportunity to continue to prepare secondary standards themselves or take advantage of the availability of commercially prepared NIST traceable secondary standards. See the justification outlined for section 1220.2 (a) (1) (A).

The word “direct” was added to emphasize the fact that alcohol is added directly to the oxidizing media in the method for the quantitative determination of the alcohol present in the aqueous alcohol solutions. The United States National Bureau of Standards no longer exists and has been replaced by the National Institute of Standards and Technology.

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<sup>22</sup> “Proficiency Review Program” American Society of Crime Laboratory Directors, Version 2.1, 2008

**1220.2 (a) (1) (C)** This additional requirement was added as a final verification and most accurate test of the secondary standards that will be used to check the calibration of the instrument for testing. NIST SRM solutions are designed to provide consistency and reliability for use in all countries and for all methods.

Currently, laboratories make their own secondary standards using a direct oxidimetric method. These secondary standards are then utilized to check the calibration of the instruments used for forensic alcohol analysis. This process has inherent difficulties, as the process is fraught with the possibility for human error. This error rate is exacerbated by the fact that laboratories do not have to perform this method on a regular basis, and often a different analyst does the work each time. The regulations currently allow for a 5% error rate in the preparation of these solutions. In contrast, the NIST ethanol-water SRMs have an established error rate of less than 1.2% for all concentration levels.<sup>23</sup> The concentration of the SRMs have been tailored to legally relevant percentages (0.02%, 0.04%, 0.08%, 0.10%, 0.2% and 0.3 %.) The ethanol-water SRMs are prepared gravimetrically, and the concentrations of ethanol in water are confirmed at NIST by using gas chromatography with flame ionization (GC-FID) detection. The National Metrology Laboratory (CSIR-NML) in Pretoria, South Africa, provides measurements for each of the concentrations of ethanol in water using a titrimetric method. The National Analytical Reference Laboratory (NARL) in Sydney, Australia, provides measurements using an exact isotope dilution-gas chromatography. The certified concentrations of ethanol in water of the SRMs are based upon a combination of the gravimetry (NIST), GC-FID (NML), and the NARL measurements. The product produced by NIST is clearly of a higher quality, and is much more accurate than any of the secondary standards the state, city, or private laboratories currently produce.

A review of accredited laboratories in all 50 states indicates that the restriction of using titrated secondary standards for calibration purposes is mandated only in California. Although other states have laboratories that use the direct oxidation procedure to titrate secondary standards, this is a matter of choice, not state mandate. It would appear that California's requirement is overly restrictive, and does not necessarily produce the best product.<sup>24</sup>

**1220.2 (a) (2)** This section was amended as the original language is vague as to when the blank and secondary standard can be analyzed in a given day, and does not address situations where multiple instruments are in use. This revision is more specific regarding the time frame when the blank and standard samples must be run in the day. Further the revisions require blank and secondary sample analysis be performed on each instrument used for analysis.

**1220.2 (a) (2) (A)** This section is deleted in its entirety. Applicable information has been incorporated more clearly into section 1220.2(a)(2)

**1220.2 (a) (3)** This section will remain as written.

**1220.2 (a) (3) (A)** This section will remain as written.

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<sup>23</sup> National Institute of Standards and Technology, Certificate of Analysis, Standard Ref. Material 1828b

<sup>24</sup> List of United States Accredited Laboratories, contacted by San Diego Police Department Personnel, September 2008

**1220.2 (a) (4)** This section will remain as written.

**1220.2 (a) (5)** This section will be deleted in its entirety as redundant and unnecessary.

**1220.3** This section will remain as written.

**1220.3 (a)** This section will remain as written as it serves to introduce the following requirements.

**1220.3 (a) (1)** This section will be amended. The alcohol concentration range will be changed to reflect current law.<sup>25</sup>

**1220.3 (a) (2)** This section will be amended. Based upon the precision provided with the current forensic alcohol methods, and the importance of the quantitative forensic alcohol results, it would appear that laboratories should employ three significant figures (i.e. three decimal places) here.

**1220.3 (a) (3)** This section will remain as written.

**1220.3 (a) (3) (A)** This section will be amended. The 0.01 will be changed to read 0.010 to reflect the change already noted in Section 1220.3 (a) (2).

**1220.3 (a) (3) (B)** The 0.01 in the preceding sections will be changed to read 0.010 to reflect the change already noted in Section 1220.3 (a) (2).

It should be noted that if three decimal places are used, the +/- range for a sample would be 0.020%. If, however, the truncated two decimal place range is used, then the total range of acceptable three decimal place results are effectively increased to 0.029%. This is nearly 50% greater than the 0.02 % range implied by the +/- 0.01 grams % limits. This analysis shows that the acceptable results required by current regulations can only be accurately applied by using all three significant figures.

**1220.3 (a) (4)** This section revision is more specific and provides clarity, and a greater frequency, as to when a quality control reference material is to be analyzed. This additional mandate will demonstrate a higher degree of confidence that the instrument remained in calibration throughout the entire analysis of all samples. The term "set" has been included in the definitions section for clarity.

**1220.3 (a) (5)** This section has been amended to reflect the deletion of the forensic alcohol supervisor classification.

This will correspond with the changes made to Section 1216.1 (a) (1). With the increased educational requirements for a forensic alcohol analyst, a forensic alcohol supervisor classification is no longer required.

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<sup>25</sup> Vehicle Code Section 23152 (b)

**1220.3 (a) (6)** This section will remain as written, as it reflects current and accepted practice.

**1220.4** This section will remain as written, as it reflects current and accepted practice.

**1220.4 (a)** This section will remain as written, as it reflects current and accepted practice.

**1220.4 (a) (1)** The phrase: “or grams per 210 liters of breath” was added to the section to address the change in law regarding the partition ratio. In 1991, Assembly Bill 4318 changed the law to state that the breath test was a reflection of the alcohol concentration in the deep lung air, and was not linked necessarily to the blood level. In other words, the breath test result is a measure of the breath, and not the blood.<sup>26</sup> The word “liquid” was changed to “blood” to be consistent with the CA Vehicle Code.

**1220.4 (b)** No change was made to this section. It remains current.

**1220.4 (c)** This section was amended to remove the word “blood” to make this section inclusive of all sample types as is appropriate. The word “may” has been retained in this section as well as in Section 1220.4(d). Different laboratories may be able to satisfy greater reliability of analysis at lower levels. Also as technical advances occur, more laboratories may have a greater capacity to test for smaller levels, and this language would apply.

**1220.4 (d)** This section was amended to remove the word “blood” from the phrase “blood alcohol” to make this section inclusive of all sample types as is appropriate.

**1220.4 (e)** No change was made to this section. It remains current.

**1220.4 (f)** In 1991, Assembly Bill 4318 changed the law to state that the breath test was a reflection of the alcohol concentration in the deep lung air, and was not linked necessarily to the blood level. In other words, the breath test result is a measure of the breath, and not the blood.<sup>27</sup> This section was amended to reflect the change in the law.

**1220.4 (g)** This sentence was restructured to be more grammatically correct.

## **Article 7. Requirements for Breath Alcohol Analysis**

### **Section 1221**

This section outlines the regulations for breath alcohol testing. The word analysis has been replaced with “testing” in this title and in the following sections to be consistent with the definition section and the remainder of the document. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1221** This section was amended to exchange the word analysis with testing, to provide consistency with the definition section.

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<sup>26</sup> Assembly Bill No. 4318, 1989-1990 regular session

<sup>27</sup> Assembly Bill No. 4318, 1989-1990 regular session

**1221.1** No change was made to this section.

**1221.1 (a)** This section was amended to clarify what must meet requirements. The US Department of Transportation uses the word “units”, the Health and Safety code uses the word “devices.” The change here should serve to clarify this difference. In addition, the Health and Safety Code Section was added to lead the reader to the specific requirements.

**1221.1 (b)** This section was amended to change “analysis” to “testing” for consistency; reference to licensing deleted as a Rule 100 change; and references to forensic alcohol supervisors and analyst trainees were deleted for consistency.

**1221.1 (b) (1)** This section was amended to change “analysis” to “testing” for consistency; reference to licensing deleted as a Rule 100 change; and references to forensic alcohol supervisors and analyst trainees were deleted for consistency.

**1221.1 (b) (2)** This section was amended to change “analysis” to “testing” for consistency throughout the document.

**1221.1(b) (3)** The original section 1219.3 has been relocated to this section where it is more relevant. The first sentence has been deleted as redundant because the information is already listed in the definitions section. The second sentence was deleted as it does not accurately reflect modern technology. Currently, most instrumentation will not necessarily measure and report a quantity of breath sample; rather, the instruments are set to require a minimum volume of breath in the chamber prior to proceeding with testing. The “continuous observation” is vague and lacks specificity as to how that will be accomplished. The new wording clearly requires that no test will be performed in less than 15 minutes after as subject eats, smokes, etc.

**1221.2 and 1221.3** Sections 1221.2 through 1221.3(a) were removed in their entirety as redundant. The specifications set out here are outlined in Health and Safety Code Section 100701, referenced in Section 1221.1 (a).

**1221.4** No change was made to this section.

**1221.4 (a)** This section was amended to change “analysis” to “testing” for consistency throughout the document.

**1221.4 (a) (1)** This section was amended to change the word blood to breath, and the phrase “grams per 100 milliliters” to 210 liters of breath. This will be consistent with Assembly Bill 4318.

**1221.4 (a) (2)** This section was amended to specify what types of reference samples are appropriate for checking the accuracy of the instrument.

**1221.4 (a) (2) (A)** This section was amended in the following ways for the following reasons.

It should be noted that if three decimal places are used, the +/- range for a sample would be 0.020%. If, however, the truncated two decimal place range is used, then the total range of

acceptable three decimal place results are effectively increased to 0.029%. This is nearly 50% greater than the 0.02 % range implied by the +/- 0.01 grams % limits. The acceptable results required by current regulations can only be accurately applied by using all three significant figures. Therefore, the 0.01 grams % precision limit was changed to 0.010 grams %.

The addition of dry-gas standards was added to reflect current and accepted practice. Many laboratories are using NIST traceable dry-gas standards to perform accuracy checks on a regular basis.

The range of 0.08 to 0.25 grams % was inserted to more accurately reflect meaningful alcohol levels. In particular, the 0.08 % reflects current state law.<sup>28</sup>

**1221.4 (a) (2) (A) 1** This section was amended as instruments are now available with the ability to automatically perform accuracy checks. The change from the entity of a laboratory to an analyst is more specific as to who will make the determination of accuracy.

**1221.4 (a) (2) (B)** No change was made to this section.

**1221.4 (a) (3)** This section was amended to change “analysis” to “testing” for consistency throughout the document.

**1221.4 (a) (3) (A)** This section will remain as written as it accurately reflects current and accepted practice.

**1221.4 (a) (3) (B)** This section will remain as written as it accurately reflects current and accepted practice.

**1221.4 (a) (3) (C)** This section will remain as written as it accurately reflects current and accepted practice.

**1221.4 (a) (3) (D)** This section will remain as written as it accurately reflects current and accepted practice.

**1221.4 (a) (3) (E)** This section was amended as both a written and practical examination are now required to ensure the operator has sufficient information and experience to perform a test.

**1221.4 (a) (4)** This section was amended as the phrase “under the supervision of” is vague. The development of the training curriculum has been clearly defined as a responsibility of the forensic alcohol analyst. The word “analysis” was changed to “testing” to conform to the rest of this document, and to the definitions listed in Section 1215. The phrase “of persons who qualify as” was removed as redundant and increase the clarity of the section. The supervisor and trainee classification were eliminated to be consistent with the other sections of this document. The term “licensed” was removed as a Rule 100 change. The word “laboratory” was removed to allow for off-site training, which is very relevant in today’s environment.

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<sup>28</sup> Vehicle Code Section 23152 (b)

**1221.4 (a) (4) (A)** This section is now obsolete as Section 1218 has been removed in its entirety. Section 1218 discussed appropriate training programs; programs that were deemed suitable by the Department. As we have removed the oversight of training programs from the Department, and have given such oversight to the employing laboratory entities, as noted in 1216.1 (e) (4) and 1216.1 (f) (4), this section becomes irrelevant. In addition, the training curriculum required is spelled out in 1216.1 (e) (2) A-I. This would appear to make this section redundant as well. The changes cited here have already given oversight to the forensic alcohol analyst, so section 1221.4 (a)(4)(A) becomes redundant as well.

**1221.4 (a) (5)** This section was amended to replace the word “his” with “his or her.” Supervisor and trainee classifications have been removed to be consistent throughout the document. The reference to (a) (4) was added for clarity.

**1221.4 (a) (6)** This section was amended to add the words “a manual” into the section just prior to “determination of accuracy.” This insertion is to address the current technology offered by many breath programs that includes automatic calibration checks. Many instruments are set up to perform calibration checks as needed, prompted by the software program using guidelines determined by laboratory personnel. Therefore, it is feasible that in many programs, the operator will be the person administering the breath test. In one breath program, a calibration check is performed automatically before and after every subject test. In actuality then, the “calibration check” is being done by the instrument at the prompting of the officer. If the instrument is receiving additional service, and a calibration check is part of that service, and is essentially a “manual calibration check”, then that operator will be recorded as having performed that check.

**1221.4 (a) (6) (A)** The word “licensed” was removed because of the Rule 100 change.

**1221.4 (b)** This section was added here to finish the discussion of required records. It was removed from Section 1222.2 and put here as it is a more appropriate location.

**1221.5** This section was amended. The word “analytical” was removed as unnecessary. The word “analysis” was changed to “testing” for consistency throughout the document.

## **Article 8. Records**

### **Section 1222**

This section outlines the regulations with respect to the type of documentation necessary for forensic alcohol testing laboratories to generate and maintain. The following are the justifications for the suggested amendments, repeals, and re-writes.

**1222** This section has been amended. The reference to “law enforcement agencies” has been deleted. These regulations are not intended to regulate the law enforcement community. The phrase “Such records shall be available for inspection by the Department on request” will be removed as a Rule 100 change. In addition, as discussed previously, any and all such records would be available to the Department through the California Public Records Act upon request.<sup>29</sup> It is therefore not necessary to include that here. Also, as previously noted, most laboratories in

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<sup>29</sup> California First Amendment Coalition – Government Code Section 6250-6270

California are accredited, and as such, have stringent requirements placed upon their manuals, records, logs, etc. Department oversight here would be redundant.

**1222.1** No change is required.

**1222.1 (a)** This section was amended. The phrase “is licensed to perform” will be removed and replaced with “performs”. This is a Rule 100 change.

**1222.1 (a) (1)** This section was amended to be more grammatically correct and accurately reflect whose records are required in the laboratory.

**1222.1 (a) (2)** This section will be removed because the trainee classification has been deleted.

**1222.1 (a) (3)** This section will remain as written as it accurately reflects current and accepted practice.

**1222.1 (a) (4)** This section will remain as written as it accurately reflects current and accepted practice.

**1222.1 (a) (5)** This section will remain as written as it accurately reflects current and accepted practice.

**1222.1 (a) (6)** This section was amended. The phrase “maintenance and/or calibration” was added to further clarify what records need to be maintained for three years. In addition, this recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed *by* or *for* law enforcement agencies. Therefore, the phrase “as a laboratory may perform for law enforcement agencies,” is not needed and should be deleted. The term “breath” was removed to clarify that records should be maintained for all types of tests.

**1222.1 (a) (7)** This section was amended to provide clarity to the requirements. In addition, this recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed *by* or *for* law enforcement agencies. Therefore the phrase “for law enforcement agencies,” is not needed and should be deleted.

**1222.2** Section 1222.2 will be deleted in its entirety as redundant.

## FISCAL IMPACT STATEMENT

(a) Fiscal Effect on Local Government

The committee has made the initial determination that there may be minor absorbable increased costs to local governments due to the amended Title 17 requirements that each analyst performing Forensic Alcohol Analysis be proficiency tested annually (whereas in the past, the laboratory engaged in Forensic Alcohol Analysis merely had to submit a single laboratory proficiency test that allowed for all individual analysts to be renewed). These costs may also be related to the costs associated with subscription fees charged by a proficiency test provider for the proficiency test samples and the analytical/statistical service they provide.

(b) Fiscal Effect on State Government

The committee has determined that the proposed amended regulations may result in significant cost savings to the State since the California State Department of Public Health would no longer be responsible for:

- 1) Providing the semi-quarterly alcohol proficiency test samples along with subsequent statistical analysis of proficiency test results to laboratories engaging in Forensic Alcohol Analysis.
- 2) Conducting inspections of laboratories engaged in Forensic Alcohol Analysis for compliance due to the enactment of SB 1623.

(c) Fiscal Effect on Federal Funding of State Programs

The committee has made the initial determination that the proposed regulations would not have any significant adverse economic impact directly affecting businesses, including the ability of California business to compete with businesses in other states since the California State Department of Public Health's Forensic Alcohol Program was entirely a state-funded agency program that received no Federal funding.

(d) All cost impacts, known to the Department at the time of the notice of amended Title 17 regulations was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur reasonable compliance with the proposed amendments. The committee has made an initial determination that there may be a small but undetermined economic impact on some small businesses. Specifically, those private labs that do not meet ASCLD-equivalent standards and are unable to do so may suffer some economic loss.

(e) Other nondiscretionary costs or savings including revenue changes imposed on State or Local Governments: None known.

## STATEMENTS OF DETERMINATION

### Alternatives Considered

The committee has made the initial determination that no reasonable alternatives considered by the committee or that have otherwise been identified and brought to the attention of the committee, would be more effective and less burdensome to affected private persons than the legislative action. Reverting to the status quo, which is the only other alternative, will result in the same problems the legislation was intended to correct.

### Local Mandate Determination

The committee has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with 17500) Division 4 of the Government Code.

### Economic Impact

The committee has made the initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The committee has determined that the proposed regulations would not significantly affect the following:

- (1) The creation or elimination of jobs in California,
- (2) The creation of new businesses in California,
- (3) The expansion of new businesses in California.

### Effect on Small Businesses

The committee has made an initial determination that there may be a small but indeterminate economic impact on some small businesses. Specifically, those private labs that do not meet ASCLD standards and are unable to do so, may suffer some economic loss.

### Effect on Housing Costs

The committee has made the initial determination that the proposed regulations will have no effect on housing costs.

### Cost Impact

The committee has made an initial determination that the proposed regulations will have no cost impact.

## PROPOSED TEXT

### Article 1. General

1215 Authority: ~~Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.~~ California Health and Safety Code Division 101, part 1, chapter 4, article 2, sections 100700 – 100775.

### 1215.1 Definitions

- 1215.1 (a) "Alcohol" means the unique chemical compound, ethyl alcohol, with the exception that reference in these regulations to compounds to be avoided as skin antiseptics includes the generic class of organic compounds known as alcohols.
- 1215.1 (b) "Forensic Alcohol Analysis" means the ~~practical application~~ use of specialized ~~devices~~ equipment, instruments, and methods ~~by trained laboratory personnel~~ to measure the concentration of ethyl alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.
- 1215.1 (c) "Breath Alcohol Analysis Testing" means ~~analysis the sampling of a sample of a person's expired breath, using a breath testing instrument. designed for this purpose, in order to determine the concentration of ethyl alcohol in the person's blood.~~ analysis the sampling of a sample of a person's expired breath, using a breath testing instrument.
- 1215.1(d) "Concentration" means the weight amount of alcohol contained in a unit volume of liquid or a unit volume of gas under specified conditions of temperature and pressure; in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit weight of specimen.
- 1215.1 (e) "Forensic Alcohol Laboratory" means a place at which specialized ~~apparatus~~ equipment, instruments, and methods are used by ~~trained laboratory personnel~~ forensic alcohol analysts to measure the concentration of alcohol in samples of blood, breath, urine, or tissues of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities ~~other than~~ in addition to forensic alcohol analysis.
- 1215.1 (f) "Forensic Alcohol ~~Supervisor~~ Analyst" means a person employed by a forensic alcohol laboratory who ~~can be~~ is responsible for all aspects of the performance of forensic alcohol analysis. ~~and for the supervision of personnel who perform such analysis.~~ \_\_\_\_\_

- 1215.1 (g) ~~"Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the technical procedures of forensic alcohol analysis.~~
- 1215.1 (h) ~~"Forensic Alcohol Analyst Trainee" means a person employed by a forensic alcohol laboratory for the purpose of receiving comprehensive practical experience and instruction in the technical procedures of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.~~
- 1215.1 (i) "Method" means the steps procedures used by a ~~trained person~~ forensic alcohol analyst to ~~make a measurement of~~ determine the alcohol concentration in a sample or specimen.
- 1215.1 (j) ~~"Instrument" or "Device" means any item or combination of items of equipment used to make a measurement of alcohol concentration; simple and complex devices are included in this meaning.~~
- 1215.1 (k) ~~"License" means a document issued by the State Department of Health to a laboratory to perform the tests referred to in the Health and Safety Code, Sections 436.51 and 436.52.~~
- 1215.1 (l) "Sample" or "Specimen" means a representative portion of ~~breath, blood, urine, or tissue, or~~ of an artificially constituted material, or a portion of expired breath which is essentially alveolar in composition taken obtained for the purpose of measuring its alcohol concentration.
- 1215.1 (m) "Alveolar" refers to the smallest air sacs in the lungs and to that portion of the expired breath which is in equilibrium with respect to alcohol with the immediately adjacent pulmonary blood.
- 1215.1 (n) "Department" means the California State Department of Public Health and its duly authorized representatives.
- 1215.1 (o) "Competency Test" means the evaluation of a person's ability to perform work in forensic alcohol analysis prior to the performance of independent casework.
- 1215.1 (p) "Proficiency Test" means a test to evaluate the continuing competence of analysts, technical support, and the performance of a laboratory.
- 1215.1 (q) "Precautionary Checklist" means a guide to assist in the operation of a breath instrument.

- 1215.1(r)                    “NIST” is an abbreviation for the National Institute of Science and Technology.
- 1215.1(s)                    “NIST Standard Reference Material (SRM)” is a controlled reference material that meets NIST specific certification criteria, and is issued with a certificate of analysis that details its characteristics and provides information on its appropriate uses.
- 1215.1(t)                    “NIST Traceable” means that the properties of a reference material/standard are authenticated by a documented series of comparisons to a NIST standard reference material and the values are certified by the manufacturer.
- 1215.1(u)                    “Set” means a group of samples analyzed in a continuous time span.

## Article 2. Requirements for Forensic Alcohol Laboratories

### 1216. Authorization Requirement

- 1216 (a)                    ~~Every laboratory performing forensic alcohol analysis shall have a valid license issued in accordance with the provisions of these regulations.~~  
Every laboratory performing forensic alcohol analysis shall provide the Department the following:
- (1) A statement of intent to perform or stop performing alcohol analysis, to 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;
  - (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.
- 1216 (a) (1)                    ~~Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in these regulations~~ Section 1216.1 for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.
- 1216 (a) (1) (A)                    ~~A trainee may perform forensic alcohol analysis only under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.~~
- 1216 (a) (2)                    ~~The Department shall not be limited by these regulations in performing functions in administration of the alcohol analysis and licensing program.~~
- 1216.1                    ~~Qualifications for Licensing~~ to perform forensic alcohol analysis.

- 1216.1 (a) A laboratory meets the qualifications ~~for licensing~~ to perform forensic alcohol analysis by:
- 1216.1 (a) (1) ~~Employing at least one forensic alcohol supervisor. If forensic alcohol analysis is performed by persons other than forensic alcohol supervisors, such persons shall meet the qualifications set forth in these regulations for forensic alcohol analysts or forensic alcohol analyst trainees;~~
- 1216.1 (a) (2) Maintaining a quality control program in forensic alcohol analysis procedures as specified in Section 1220.3;
- 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. 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.
- 1216.1 (a) (4) ~~Passing such on-site inspections as the Department may require;~~
- 1216.1 (a) (5) ~~Showing ability to meet the requirements set forth in these regulations. —~~
- 1216.1 (b) ~~These qualifications shall be maintained at all times by each licensed laboratory.~~
- 1216.1 (c) ~~The Department may deny a license or renewal thereof, or take disciplinary action against a licensee, for failure to maintain ——— these qualifications in a manner which meets the Department's standards for approval.~~
- 1216.1 (d) ~~Whenever a licensed laboratory employing only one forensic alcohol supervisor loses that person, the Department may upon petition of the laboratory extend the license for a period not exceeding 90 days during which time the laboratory shall hire another forensic alcohol supervisor.~~
- 1216.1 (d) (1) ~~Such an extension shall be contingent on the laboratory's having in its employ at least one forensic alcohol analyst and upon the laboratory's successfully demonstrating to the Department continued competence in forensic alcohol analysis through such proficiency tests, examinations, and on-site inspections as the Department may require.~~

- 1216.1 (e) A forensic alcohol ~~supervisor~~ analyst is a person who meets the following qualifications:
- 1216.1 (e) (1) Possesses a baccalaureate or higher degree, ~~or an equivalent, in chemistry, biochemistry, or other appropriate discipline as determined by the Department;~~ in any applied physical or natural science.
- 1216.1 (e) (2) Has two years of analytical experience, and experience in interpreting and correlating performing forensic alcohol analysis, such experienced to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol, or ; or, in lieu of such two years of such experience, satisfactorily completes a training course approved by the Department; laboratory of employment. sSuch training course to include at minimum the following schedule of subjects:
- 1216.1 (e) (2) (A) Value and purpose of forensic alcohol analysis, ~~including breath alcohol analysis;~~
- 1216.1 (e) (2) (B) Physiological action of alcohol;
- 1216.1 (e) (2) (C) Pharmacology and toxicology of alcohol;
- 1216.1 (e) (2) (D) Laboratory methods of forensic alcohol analysis;
- 1216.1 (e) (2) (E) Instruments and procedures for breath alcohol analysis testing;
- 1216.1 (e) (2) (F) Practical laboratory demonstration of the ~~student's~~ analyst's ability to perform forensic alcohol analysis;
- 1216.1 (e) (2) (G) Interpretation of results of alcohol analysis, including correlation of forensic alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of alcohol;
- 1216.1 (e) (2) (H) Court testimony;
- 1216.1 (e) (2) (I) Court decisions regarding chemical tests of alcohol to determine alcohol influence; and
- 1216.1 (e) (2) (J) Requirements of ~~these regulations~~ Title 17 of the California Code of Regulations, Sections 1215 to 1222.1 inclusive;
- 1216.1(e)(3) At a minimum, Ssuccessfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully

passes examinations prescribed by the Department; complete a competency test comprised of at least 4 samples that must:

- (A) Have differing, predetermined values;
- (B) Range from 0 to 0.25 percent alcohol concentration;
- (C) Have values unknown to the test taker;
- (D) And be analyzed utilizing the laboratory's forensic alcohol method.
- (E) Results must fall within plus or minus 5% of the known value.

1216.1 (e) (4) ~~Demonstrates the ability to adhere to the provisions of these regulations; or (in lieu of (1) and (2) above)~~

1216.1 (e) ~~(5)~~ (4) ~~Either is a person who, prior to January 1, 1971, qualified as director of a clinical laboratory operating under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol supervisor. The qualification requirements set forth in subdivisions (e) (1), (e) (2), and (e) (3) shall not apply to any of the following persons:~~

- (A) A person who, prior to January 1, 1971, qualified as a director of a clinical laboratory operating under the provision of the California Business and Professions Code.
- (B) A person who, was employed in the activities of a forensic alcohol supervisor for a period of one year prior to January 1, 1971, or
- (C) A person who was qualified by the Department as a forensic alcohol supervisor prior to January 1, 1971, or,
- (D) A person who was qualified by the Department as a forensic alcohol analyst prior to January 1, 1971.

1216.1 (f) ~~A forensic alcohol analyst is a person who meets the following qualifications:~~

1216.1 (f) (1) ~~Successfully completes at least 60 semester hours, or their equivalent in quarter hours, of college level courses, including 8 hours of general chemistry and 3 hours of quantitative analysis;~~

1216.1 (f) (2) ~~Successfully completes a training period in alcohol analysis on forensic or clinical specimens in a forensic alcohol laboratory or in a clinical laboratory;~~

- 1216.1 (f) (3) ~~Performs during the training period a minimum of 25 analyses~~ of alcohol concentration in blood samples, at least half of which contain alcohol;
- 1216.1 (f) (4) ~~Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;~~
- 1216.1 (f) (5) ~~Demonstrates ability to adhere to the provisions of these regulations; or (in lieu of (1), (2), and (3) above)~~
- 1216.1 (f) (6) Either is a person who, prior to January 1, 1971, was a clinical laboratory technologist licensed under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol analyst.
- 1216.1 (g) ~~A forensic alcohol analyst trainee is a person who meets the following qualifications:~~
- 1216.1 (g) (1) ~~Meets the educational qualification set forth as (1) for a forensic alcohol analyst;~~
- 1216.1 (g) (2) ~~Is employed by a licensed forensic alcohol laboratory.~~
- 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.

Article 3. Licensing Procedures:

1217 Forensic Alcohol Laboratory License.

~~1217 (a) Upon receipt of a completed application which shows ability to meet the requirements set forth in these regulations,—and upon payment of any required fee, the Department shall submit such proficiency test samples and perform such examinations as are required for that laboratory to complete the qualifications.~~

~~1217 (b) Upon the laboratory's successfully completing all the qualifications, the Department shall issue to the applicant laboratory a forensic alcohol laboratory license.~~

1217.1 Renewal of Licenses.

~~1217.1 (a) Licenses under these regulations shall be renewed as required by the Department as long as the activity requiring authorization continues. Renewal shall be contingent upon the laboratory continuing in the qualifications set forth in these regulations.~~

~~1217.1 (a) (1) A forensic alcohol laboratory license shall be valid from January 1 to December 31 of a calendar year. Applications for renewal and applicable fees shall be submitted to the Department on or before October 1 of each year.~~

~~1217.1 (a) (2) Failure to apply for renewal shall result in forfeiture after a period of three months from the day on which the application for renewal should have been submitted, with the exception that the Department may grant a temporary extension under special circumstances.~~

~~1217.1 (a) (3) An application for renewal shall not list as a forensic alcohol analyst trainee any person who fails to comply with the requirements of Section 1216.1 (f) (4) within a period of one year after he was first listed with the Department as a trainee. The Department may extend this period for a justifiable reason, such as illness.~~

1217.2 Application Forms.

~~Application for a license and renewal thereof shall be made on forms furnished by the Department. The applicant shall set forth all pertinent information called for by the form.~~

~~1217.3 Report of Change or Discontinuance.~~

- ~~1217.3 (a)~~ A person responsible for the operation of a forensic alcohol laboratory shall report to the Department in writing within 30 days any change in qualified personnel who may be performing forensic alcohol analysis, change of ownership, change of address or change or discontinuance of an activity authorized under these regulations.
- ~~1217.3 (b)~~ Such reports shall be made on forms furnished by the Department and shall set forth all pertinent information called for by the form.
- ~~1217.3 (c)~~ Persons who formerly qualified as forensic alcohol supervisors or forensic alcohol analysts in another laboratory may be required to demonstrate again their ability to meet the requirement of Section 1216.1 (c) (3) or 1216.1 (f) (4) using the method, apparatus and facilities of the forensic alcohol laboratory which newly lists them in such a Report of Change or Discontinuance.
- ~~1217.4~~ License Implications.  
Licenses issued under these regulations shall not imply approval of anything carried out by a laboratory other than what is specified on the document.
- ~~1217.5~~ Licensing Records.  
Forensic Alcohol Laboratory Licenses shall become part of permanent records available to the courts for legal proceedings or to the Department.
- ~~1217.6~~ Inspection and Additional Requirements.
- ~~1217.6 (a)~~ Display of Licenses. Licenses issued under these regulations shall be displayed on request to representatives of the Department.
- ~~1217.6 (b)~~ Access to Premises. The Department may enter at all reasonable times upon any laboratory for the purpose of determining whether or not there is compliance with the provisions of these regulations.
- ~~1217.7~~ Surveys and Proficiency Tests.
- ~~1217.7 (a)~~ Laboratories having been licensed or applying for licensing as forensic alcohol laboratories shall be subject to on-site surveys by representatives of the Department, the results of which must meet the requirements of these regulations, and shall accept periodic evaluation samples, perform analyses and report the results of such analyses to the Department.
- ~~1217.7 (b)~~ These analytical results shall be used by the Department to evaluate the accuracy of the forensic alcohol analyses performed by the laboratory, and the results must meet the requirements of these regulations.

~~1217.8 Fees and Other Procedures.  
The annual application fee for a Forensic Alcohol Laboratory License or its renewal shall be one hundred dollars (\$100). A laboratory operated by the state, city or county or other public organization shall be exempt from the annual application fee requirement. Other procedures in the administration of these regulations shall be carried out as set forth in Chapter 5 (commencing with section 436.50) of Part 1 of Division 1 of the Health and Safety Code. Such other procedures include suspension or revocation of license, denial of license, and disciplinary action.~~

#### Article 4. Training of Personnel

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

~~1218.1 Additional Requirements.  
At the discretion of the Department, 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.~~

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

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
- 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 shall respond to the Department in writing within 30 days.

Article 5. Collection and Handling of Blood, Urine, and Tissue Samples Vote: 7 yes; 1 no

- 1219                    Samples taken for forensic alcohol analysis ~~and breath alcohol analysis~~ shall be collected and handled in a manner ~~approved by the Department.~~ in which the identity and integrity of the samples shall be maintained through collection to analysis and reporting.
- 1219.1                Blood Collection and Retention
- 1219.1 (a)            Blood samples shall be collected by venipuncture from living individuals as soon as feasible after an alleged offense and processed in compliance with CVC Section 23158. ~~only by persons authorized by Section 13354 of the Vehicle Code.~~
- 1219.1 (b)            ~~Sufficient blood shall be collected to permit duplicate determinations.~~
- 1219.1 (c)            Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. ~~Aqueous benzalkonium chloride (zephiran), aqueous merthiolate or other suitable aqueous disinfectant shall be used.~~ Examples of suitable aqueous disinfectants include: aqueous povidine-iodine (Betadine) or aqueous benzalkonium chloride (zephiran chloride.)

- 1219.1 (d) Blood samples from living individuals shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned with or kept in alcohol or other volatile organic solvents.
- 1219.1 (e) The blood sample shall be deposited into a clean, dry container which is closed with an inert stopper.
- 1219.1 (e) (1) Alcohol or other volatile organic solvent shall not be used to clean the container.
- 1219.1 (e) (2) The blood shall be mixed with an anticoagulant and a preservative.
- 1219.1 (f) When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to ~~insure~~ ensure an uncontaminated sample shall be employed, such as:
- 1219.1 (f) (1) Samples shall be obtained prior to the start of any embalming procedure. Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid. ~~Coroner's samples do not need a preservative added if stored under refrigeration.~~
- 1219.1 (f) (2) Care shall be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion ~~therefrom~~. The sample shall be taken from a major vein or the heart.
- 1219.1 (g) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.
- 1219.1 (g) (1) In coroner's/ medical examiner cases, ~~blood~~ samples shall be retained for at least 90 days after date of collection.
- 1219.1 (g) (2) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic ~~alcohol~~ laboratory, ~~or~~ law enforcement agency, or coroner/medical examiner's office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried on the original sample container.
- 1219.2 Urine Collection and Retention
- 1219.2 (a) ~~The only approved~~ A urine sample from a living individual shall be a sample collected no sooner than twenty minutes after first voiding the bladder.

- 1219.2 (b) The specimen shall be deposited in a clean, dry container which also contains a preservative.
- 1219.2 (c) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.
- 1219 (c) (1) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic ~~alcohol~~ laboratory, ~~or~~ law enforcement agency, or coroner/medical examiner's office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried ~~by~~ on the original sample container.
- ~~1219.3 A breath sample shall be expired breath which is essentially alveolar in composition. The quantity of the breath sample shall be established by direct volumetric measurement. The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.~~
- Article 6. Methods of Forensic Alcohol Analysis Vote: 7 yes, 1 no
- 1220 (a) All laboratory methods used for forensic alcohol analysis shall be subject to standards set forth in this Article.
- 1220 (b) Each ~~licensed~~ forensic alcohol laboratory shall have ~~on file with the Department~~ detailed, up to-date written descriptions of each method it uses for forensic alcohol analysis.
- 1220 (b) (1) Such descriptions shall be immediately available to the person performing an analysis ~~and shall be available for inspection by the Department on request.~~
- 1220 (b) (2) Each such description shall include the calibration procedures and the quality control program for the method.
- 1220.1 Standards of Performance
- 1220.1 (a) Methods for forensic alcohol analysis shall meet the following standards of performance:
- 1220.1(a)(1) The method shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus

or minus 5 percent of the value; these limits shall be applied to alcohol concentrations which are ~~0.10~~ 0.08 grams per 100 milliliters or higher;

- 1220.1 (a) (2) ~~The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate f~~For traffic law enforcement purposes the method shall be specific for the analysis of ethyl alcohol.
- 1220.1 (a) (3) The method ~~should~~ shall be free from interference from anticoagulants and preservatives added to the sample;
- 1220.1 (a) (4) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ~~ethyl~~ alcohol by a qualitative test;
- 1220.1 (a) (5) The method shall give a test result which is always less than 0.01 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.
- 1220.1 (b) The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by ~~the Department~~ a forensic alcohol analyst using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.
- 1220.2 Standards of Procedure
- 1220.2 (a) Methods for forensic alcohol analysis shall meet the following standards of procedure:
- 1220.2 (a) (1) The ~~method~~ instrument(s) shall be calibrated with standards which are water solutions of alcohol.
- 1220.2 (a) (1) (A) Such alcohol solutions are secondary standards which, for the purposes of these regulations, applies to prepared or purchased solutions.
- 1220.2 (a) (1) (B) Each forensic alcohol laboratory shall purchase (NIST) traceable secondary alcohol standards, or prepare a secondary alcohol standard establish the concentration of each lot of secondary alcohol standards it uses, whether prepared or acquired, by an using a direct oxidimetric method which employs a primary standard, such as ~~United States National Bureau of Standards~~ the NIST potassium dichromate.
- 1220.2 (a) (1) (C) The forensic alcohol laboratory personnel shall verify the concentration of any new secondary standard used in the method by analyzing the new secondary standard concurrently with a NIST standard reference material.
- 1220.2 (a) (2) ~~The procedure shall include blank and secondary alcohol standard samples at least once each day that samples are subjected to forensic alcohol~~

~~analysis.~~ A blank and secondary standard shall be analyzed concurrently or prior to analysis of subject samples on each day of analysis and on any instrument used.

1220.2 (a) (2) (A) ~~The blank and secondary alcohol standard samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.~~

1220.2 (a) (3) The procedure shall also include analysis of quality control reference samples as described in Section 1220.3 and shall include at least duplicate analyses of samples for forensic alcohol analysis.

1220.2 (a) (3) (A) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.

1220.2 (a) (4) Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis;

1220.2 (a) (5) ~~All instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision.~~

1220.3 Quality Control Program

1220.3 (a) Methods for forensic alcohol analysis shall be performed in accordance with the following quality control program:

1220.3 (a) (1) For each method of forensic alcohol analysis it performs, each forensic alcohol laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which it shall analyze along with each set of samples; the alcohol concentration in the reference material shall be between ~~0.10~~ 0.08 and 0.20 grams per 100 milliliters of liquid;

1220.3 (a) (2) For each lot of quality control reference material, the laboratory shall determine a mean value of at least 20 replicate analyses to three decimal places, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis;

1220.3 (a) (3) Acceptable limits of variation for the method shall be set as follows:

1220.3 (a) (3) (A) The lower limit shall be calculated by subtracting, from the mean value, 0.010 grams per 100 milliliters;

1220.3 (a) (3) (B) The higher limit shall be calculated by adding, to the mean value, 0.010 grams per 100 milliliters;

- 1220.3 (a) (4) At least one sample of the quality control reference material shall be analyzed at the beginning and end of ~~with~~ each set of samples analyzed for the purpose of forensic alcohol analysis;
- 1220.3 (a) (5) Whenever analysis of the quality control reference material is outside the acceptable limits, the method shall be regarded to be in error, and a forensic alcohol ~~supervisor~~ analyst shall take remedial action to investigate and correct the source of error;
- 1220.3 (a) (6) Until such time as the error has been corrected, as shown by return of the analysis of the quality control reference material to values within the acceptable limits, no samples shall be analyzed for the purpose of forensic alcohol analysis.
- 1220.4 Expression of Analytical Results
- 1220.4 (a) With the exception of tissue analysis, all analytical results shall be expressed in terms of the alcohol concentration in blood, based on the number of grams of alcohol per 100 milliliters of blood.
- 1220.4 (a) (1) The symbols, grams %, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of blood liquid, or grams per 210 liters of breath.
- 1220.4 (b) Analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present.
- 1220.4 (c) ~~Blood~~ Alcohol concentrations less than 0.01% in living subjects may be reported as negative.
- 1220.4 (d) ~~Blood~~ Alcohol concentrations less than 0.02% on post-mortem ~~blood~~ samples may be reported as negative.
- 1220.4 (e) A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 1.3 milliliters of blood is equivalent to the amount of alcohol in 1 milliliter of urine.
- 1220.4 (f) ~~A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood.~~ Analytical results for breath shall be based on the number of grams of alcohol per 210 liters of breath.
- 1220.4 (g) ~~Tissue analysis~~ Analytical results for tissue analysis shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.

Article 7. Requirements for Breath Alcohol Analysis Testing

1221. General  
Breath alcohol analysis testing shall be performed in accordance with standards set forth in this Article.
- 1221.1 Authorized Procedures
- 1221.1 (a) Breath alcohol analysis testing shall be performed only with instruments and ~~related~~ accessories calibrating units/devices which meet the ~~standards of performance set forth in these regulations~~ requirements specified in Health and Safety Code Section 100701.
- 1221.1 (b) Such instruments may be used for the analysis testing of breath samples in places other than ~~licensed~~ forensic alcohol laboratories and by persons other than ~~forensic alcohol supervisors,~~ forensic alcohol analysts and ~~forensic alcohol analyst trainees~~ only if such places and persons are under the direct jurisdiction of a governmental agency or ~~licensed~~ forensic alcohol laboratory.
- 1221.1 (b) (1) Breath alcohol analysis testing by persons other than ~~forensic alcohol supervisors,~~ forensic alcohol analysts and ~~forensic alcohol analyst trainees~~ shall be restricted to the immediate analysis testing of breath samples collected by direct expiration by the subject into the instrument in which the measurement of alcohol concentration is performed.
- 1221.1 (b) (2) Except for the requirements of Section 1220.4, such immediate analysis testing shall not be subject to the requirements of Article 6.
- ~~1219.3~~ 1221.1(b)(3) ~~A breath sample shall be expired breath which is essentially alveolar in composition. The quantity of the breath sample shall be established by direct volumetric measurement. The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.~~
- ~~1221.2.~~ Standard of Performance.
- ~~1221.2 (a)~~ ~~Instruments for breath alcohol analysis shall meet the following standard:~~
- ~~1221.2 (a) (1)~~ ~~The instrument and any related accessories shall be capable of conforming to the "Model Specifications for Evidential Breath Testing Devices" of the National Highway Traffic Safety Administration of the U.S. Department of Transportation, which were published in the Federal Register, Vol. 49,~~

No. 242, Pages 48854-48872, December 14, 1984, and are hereby adopted and incorporated.

- ~~1221.2 (b)~~ ~~The ability of instruments and any related accessories to conform to the standard of performance set forth in this section shall be tested by the U.S. Department of Transportation.~~
- ~~1221.3.~~ ~~Approved Instruments.~~
- ~~1221.3 (a)~~ ~~Only such types and models of instruments and related accessories as are named in the "Conforming Products List" published in the Federal Register by the National Highway Traffic and Safety Administration of the U.S. Department of Transportation shall be used for breath alcohol analysis in this State.~~
- 1221.4 Standards of Procedure
- 1221.4 (a) Procedures for breath alcohol analysis testing shall meet the following standards:
- 1221.4 (a) (1) For each person tested, breath alcohol analysis testing shall include analysis of 2 separate breath samples which result in determinations of ~~blood~~ breath alcohol concentrations which do not differ from each other by more than 0.02 grams-per-~~100 milliliters~~ 210 liters of breath.
- 1221.4 (a) (2) ~~The accuracy of instruments shall be determined. The instruments shall be checked for accuracy with reference samples which are known water solutions or dry-gasses of alcohol.~~
- 1221.4 (a) (2) (A) Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.010 grams % of the true value; these limits shall be applied to alcohol water concentrations and/or dry-gas standards reference samples of alcohol from ~~0.10~~ 0.08 to ~~0.30~~ 0.25 grams %. The reference sample shall be provided by a forensic alcohol laboratory.
- 1221.4 (a) (2) (A) 1 Such analysis shall be performed automatically on applicable instruments, or manually by an operator as defined in Section 1221.4 (a)(5), and the results shall be used by a forensic alcohol ~~laboratory~~ analyst to determine if the instrument continues to meet the accuracy set forth in Section 1221.4 (a)(2)(A).
- 1221.4 (a) (2) (B) For the purposes of such determinations of accuracy, "periodic" means either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner.

- 1221.4 (a) (3) Breath alcohol ~~analysis testing~~ shall be performed only with ~~instruments~~ procedures 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:
- 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) ~~Practical experience;~~ Precautionary checklist:
- i. Description of, and adherence to, the Precautionary Checklist.
- 1221.4 (a) (3) (D) ~~Precautionary checklist;~~ 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) ~~Written and/or practical examination.~~ 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) The Training curriculum in the procedures of breath alcohol analysis testing shall be developed by ~~under the supervision of persons who qualify as forensic alcohol supervisors~~ a forensic alcohol analyst. ~~s or forensic alcohol analyst trainees in a licensed forensic alcohol laboratory.~~ Department notification of the proposed curriculum will follow Section 1218.1.
- 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.~~ The instructors will be, at 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 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 1221.4 (a)(4), and who may be called upon to operate a breath testing instrument in the performance of his/her duties.
- 1221.4 (a) (6) Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of ~~the~~ any person performing ~~the~~ a manual determination of accuracy.
- 1221.4 (a) (6) (A) Records shall be kept for each instrument at a ~~licensed~~ forensic alcohol laboratory showing compliance with this Section.
- 1221.4 (b) A precautionary checklist shall be available at the location of each instrument.
- 1221.5. Expression of ~~Analytical~~ Results.  
  
Results of breath alcohol ~~analysis~~ testing shall be expressed as set forth in Section 1220.4.

Article 8. Records

1222. General

Forensic alcohol laboratories ~~and law enforcement agencies~~ shall maintain records which clearly represent their activities which are covered by these regulations. ~~Such records shall be available for inspection by the Department on request.~~

1222.1 Forensic Alcohol Laboratory Records.

1222.1 (a) Each laboratory which ~~is licensed to perform~~ forensic alcohol analysis shall keep the following records for a period of at least three years:

1222.1 (a) (1) An up-to-date record of persons in its employ who are qualified as ~~forensic alcohol supervisors and forensic alcohol analysts~~; the record shall include qualifications of each such person, including but not limited to the records of education, experience, training.

1222.1 (a) (2) ~~A list of persons in its employ who are forensic alcohol analyst trainees, the date on which each such person began his training period and the number and results of analyses performed during the training period;~~

1222.1 (a) (3) Records of samples analyzed by that laboratory under these regulations, their results and the identity of persons performing the analyses;

1222.1 (a) (4) Records of the quality control program;

1222.1 (a) (5) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;

1222.1 (a) (6) Records of ~~such~~ determinations of accuracy, maintenance, and/or calibration of ~~breath~~ testing instruments as a laboratory may perform ~~for law enforcement agencies~~;

1222.1 (a) (7) Records of ~~such~~ the training as a laboratory may provide provided to persons who operate breath testing instruments ~~for law enforcement agencies~~.

~~1222.2 Breath Alcohol Analysis Records.~~

~~1222.2 (a) Each agency shall keep the following records for breath~~

~~1222.2 (a) (1) Records of instrument determinations of accuracy;~~

- ~~1222.2 (a) (2) Records of analyses performed, results and identities of the persons performing analyses;~~
- ~~1222.2 (a) (3) At the location of each instrument, the precautionary checklist to be used by operators of then instrument.~~

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