

The following is justification for changing, updating, or retaining current verbiage in Title 17, California Code of Regulations, as it pertains to Forensic Alcohol Analysis.

## **Article 1. General.**

1215 Authority: **Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.**

Will be changed to read: *California Health and Safety Code Division 101, part 1, chapter 4, article 2, sections 100700 – 100775.*

- This change will reflect current law. (United States. Senate Bill No. 1623 Chapter 337. Washington, DC: U.S. Government)

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.**

This definition will be maintained in its current form, as it accurately reflects the definition of alcohol.

1215.1 (b) **"Forensic Alcohol Analysis" means the practical application of specialized devices, 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.**

Will be changed to read: *"Forensic Alcohol Analysis" means the use of specialized equipment, instruments, and methods to measure the concentration of alcohol in samples of blood, breath, urine, or tissues of persons involved in traffic accidents or traffic violations.*

- 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 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)

**"Breath Alcohol Analysis" means analysis 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.**

Will be changed to read: *"Breath Alcohol Testing" means analysis 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 alcohol in a person's breath.*

- This definition was changed to more accurately reflect current law and more clearly state what breath alcohol testing means. To that end, the phrase defined here was changed from "Breath Alcohol Analysis" to "Breath Alcohol Testing." The word analysis describes how the test results are achieved, making this revised definition more appropriate. In addition, in 1991, in assembly bill 4318, 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. (United States. Assembly Bill No. 4318. 1989-1990 regular session.) 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)

**"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.**

This definition will be maintained in its current form, as it accurately reflects the definition of concentration.

1215.1 (e)

**"Forensic Alcohol Laboratory" means a place at which specialized apparatus, instruments, and methods are used by trained laboratory personnel to measure the concentration of alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than alcohol analysis.**

Will be changed to read: *“Forensic Alcohol Laboratory” means a place at which specialized equipment, instruments, and methods are used by forensic alcohol supervisors, forensic alcohol analysts, and forensic alcohol analyst trainees 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 forensic alcohol analysis.*

- 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 supervisors, forensic alcohol analysts, and forensic alcohol analyst trainees” to be very specific. In addition, the word “apparatus” was changed to “equipment” and the word “forensic” was added to the phrase alcohol analysis, to provide consistency with other stated definitions.

1215.1 (f)

**"Forensic Alcohol Supervisor" means a person employed by a forensic alcohol laboratory who can be responsible for all aspects of the performance of forensic alcohol analysis and for the supervision of personnel who perform such analysis.**

Will be changed to read: *“Forensic Alcohol Supervisor” means a person employed by a forensic alcohol laboratory who can perform all aspects of forensic alcohol analysis and can supervise personnel who perform such analyses.*

- This definition clarifies the role of a forensic alcohol supervisor (FAS). It clarifies the duties of an FAS to include performing the work, and leaves actual supervision as a possibility and not an assumed duty. This is much more in line with what is actually occurring in laboratories across the state. Many laboratories have all employees achieve the classification of FAS, but do not have those same employees perform any job duties related to supervision. Often the supervision of a section of employees is not provided by an FAS, and often, an FAS is performing the daily tasks of alcohol analysis. This revision should provide clarity to the legal community, which might incorrectly conclude that an FAS is the actual supervisor of the laboratory. The existing definition of an FAS’s duties is unclear, and the designation “supervisor” is not consistent with the typical and common definition of supervision (i.e. providing employee evaluations, etc.)

1215.1 (g)

**"Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the technical procedures of forensic alcohol analysis.**

Will be changed to read: *"Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs methods of forensic alcohol analysis, and who can supervise forensic alcohol analyst trainees.*

- Changing "technical procedures" to "methods" brings this section in line with other sections with regard to consistent verbiage. The addition of supervising duties to this definition provides consistency between this section and the section defining Forensic Alcohol Analyst Trainee (1215.1 (h)).

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.**

Will be changed to read: *"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 methods of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.*

- The phrase "technical procedures" will be replaced with "methods" to provide consistency with verbiage used in other definitions.

1215.1 (i)

**"Method" means the steps used by a trained person to make a measurement of alcohol concentration.**

Will be changed to read: *"Method" means the procedures used by a forensic alcohol supervisor, forensic alcohol analyst, or forensic alcohol analyst trainee, to determine the alcohol concentration in a sample or specimen.*

- 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) **"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.**

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) **"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.**

This definition was repealed as a Rule 100 change.

1215.1 (l) **"Sample" or "Specimen" means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material, taken for the purpose of measuring its alcohol concentration.**

Will be changed to read: *"Sample" or "Specimen" means a representative portion of blood, urine, tissue, or an artificially constituted material, obtained for the purpose of measuring its alcohol concentration. A sample or specimen may also include that portion of an expired breath which is essentially alveolar in composition.*

- This definition has been changed to more accurately define a breath sample or specimen.

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.**

This definition will be maintained in its current form, as it accurately reflects the definition of alveolar.

1215.1 (n) **"Department" means the California State Department of Health and its duly authorized representatives.**

This definition will be maintained to provide clarity to the references to the "Department" noted throughout this document.

1215.1 (o) The addition of the following definition: “*Competency Test*” means the evaluation of a person’s ability to perform work in a discipline prior to the performance of independent casework.

- This was added to define the term that is utilized in the text. (ASCLD/LAB International, an ISO 17025 Program of Accreditation, Terms and Definitions, Page 1)

1215.1 (p) The addition of the following definition: “*Proficiency Test*” means a test to evaluate the continuing competence of analysts, technical support, and the performance of a laboratory; in open tests, the analysts know they are being tested, in blind tests, they do not.

- This was added to define the term that is utilized in the text. (ASCLD/LAB International, an ISO 17025 Program of Accreditation, Terms and Definitions, Page 3)

1215.1 (q) The addition of the following definition: “*Precautionary Checklist*” means a guide to assist in the operation of a breath instrument.

- This was added to define the term that is utilized in the text.

Note: Definitions will need to be renumbered/lettered to reflect deletions and additions to this section.

## **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.**

Repealed due to a Rule 100 change.

Note: Subsequent sections will need to be renumbered/lettered to reflect deletion of (a).

1216 (a) (1) **Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in these regulations for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.**

Will be changed to read: *Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in section 1216.1 for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.*

- This change replaces “these regulations” with a specific site reference to clarify the location of the qualifications.

1216 (a) (1) (A) **A trainee may perform forensic alcohol analysis only under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.**

This subsection will remain as is currently worded, as it accurately reflects current practice in forensic laboratories and is good policy.

1216 (a) (2) **The Department shall not be limited by these regulations in performing functions in administration of the alcohol analysis and licensing program.**

This section will be deleted in its entirety as a Rule 100 change.

1216.1 **Qualifications for Licensing.**

This section will be changed to read: *Qualifications to perform forensic alcohol analysis.*

- This eliminates the reference to “licensing” per a Rule 100 change.

1216.1 (a) **A laboratory meets the qualifications for licensing by:**

This section will be changed to read: *A forensic alcohol laboratory meets the qualifications to perform forensic alcohol analysis by:*

- This eliminates the reference to licensing per a Rule 100 change. The addition of “forensic alcohol” to the laboratory description provides clarity.

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;**

Will be changed to read: *Employing at least one forensic alcohol supervisor or one forensic alcohol analyst.*

- 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 been significantly increased, (1216.1 (f) (1)), bolstering the argument that an FAS is not necessary to perform all of the functions of forensic alcohol analysis. In current practice, the difference between the two classifications is years of experience, not necessarily ability to handle the pertinent tasks.

1216.1 (a) (2)

**Maintaining a quality control program in forensic alcohol analysis procedures;**

Will be changed to read: *Maintaining a quality control program in forensic alcohol analysis procedures as specified in section 1220.3.*

- The addition of the site was to clarify the location in this document of the requirements of an appropriate quality control program.

1216.1 (a) (3)

**Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department;**

Will be changed to read: *Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702.*

- The addition of the site was included to clarify the location of the requirements, thereby avoiding redundancy in this document. (Health and Safety Code Section 100702 (a))

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. (California Association of

Criminalists Lab Directory *and* List of Licensed Forensic Alcohol Analysis Laboratories) 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) to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines, for which the provider has been approved. (American Society of Crime Laboratory Directors Laboratory Accreditation Board, Proficiency Review Program, pages 9-11) 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.
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. (American Society of Crime Laboratory Directors Laboratory Accreditation Board, Proficiency Review Program, page 10 of 23)

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. (Reporting Results of Laboratories' Annual Participation in Proficiency Testing, California Department of Public Health, September 23, 2008) 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. It should be noted that the test samples provided in the Department's proficiency testing program are severely limited in scope and design. The Department sends out one set containing four test samples to each laboratory, for each instrument that is to be tested. Therefore, laboratories with only one instrument receive only one set of samples. There is no requirement mandating the all analysts actively performing alcohol analysis be tested, only the instruments. In addition, historically, no more than two sources containing alcohol have been used to prepare any one set of tests. Therefore, an analyst performing the Department's tests would be alerted should their results indicate three or more different concentrations of alcohol among the four test samples. Perhaps the Department could continue to provide this program for the few laboratories that would still derive some benefit from it.

1216.1 (a) (4)

**Passing such on-site inspections as the Department may require;**

Removed due to change in statute.

- 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 the majority of laboratories in California are accredited, (California Association of Criminalists Lab Directory), 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, titled, in part, "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), the following conclusion appeared:

“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) **Showing ability to meet the requirements set forth in these regulations.**

Removed as vague and redundant.

1216.1 (b) **These qualifications shall be maintained at all times by each licensed laboratory.**

Removed due to change in statute.

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.**

Removed due to change in statute.

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.**

Removed due to relevancy.

- With the removal of the requirement that a laboratory must employ a forensic alcohol supervisor, the discussion in (d) is not relevant.

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.**

Removed due to relevancy.

- With the removal of the requirement a laboratory must employ a forensic alcohol supervisor, the discussion in (d) (1) is not relevant.

1216.1 (e)

**A forensic alcohol supervisor is a person who meets the following qualifications:**

This subsection will be left intact; it is merely a lead-in to the following requirements.

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;**

Will be changed to read: *Possesses a baccalaureate or higher degree in any applied physical or natural science.*

- Removed “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)

**Has two years of experience in performing forensic alcohol analysis, such experience 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, in lieu of such two years of experience, satisfactorily completes a training course approved by the Department, such training course to include at minimum the following schedule of subjects:**

Will be changed to read: *Has two years of experience in performing forensic alcohol analysis, to include experience in the 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, in lieu of such two years of experience, satisfactorily completes a training course at the laboratory of employment, or approved by appropriate laboratory personnel, such training course to include, at a minimum, the following schedule of subjects:*

- The phrase “approved by the department” was replaced with “at the laboratory of employment, or approved by the laboratory of employment”. This clarifies that the individuals must be qualified by their specific Forensic Alcohol Laboratories., “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.

1216.1 (e) (2) (A) **Value and purpose of forensic alcohol analysis, including breath alcohol analysis;**

Will be changed to read: *Value and purpose of forensic alcohol analysis;*

- The phrase “including breath alcohol analysis” was removed as redundant. The term Forensic Alcohol Analysis is defined in 1215.1 (b), and includes a reference to breath alcohol analysis.

1216.1 (e) (2) (B) **Physiological action of alcohol;**

This subsection will be retained in its current form as it accurately depicts an appropriate topic for instruction of an FAS.

1216.1 (e) (2) (C) **Pharmacology and toxicology of alcohol;**

This subsection will be retained in its current form as it accurately depicts an appropriate topic for instruction of an FAS.

1216.1 (e) (2) (D) **Laboratory methods of alcohol analysis;**

Will be changed to read: *Laboratory methods of forensic alcohol analysis.*

- The word “forensic” was added for clarity and consistency.

1216.1 (e) (2) (E) **Instruments and procedures for breath alcohol analysis;**

Will be changed to read: *Instruments and procedures for breath alcohol testing;*

- The word “analysis” was replaced with “testing” to more accurately reflect the training topic. This also reflects the change in the definition of “Breath Alcohol Testing” noted in 1215.1 (c).

1216.1 (e) (2) (F) **Practical laboratory demonstration of the student's ability to perform alcohol analysis;**

Will be changed to read: *Practical laboratory demonstration of the student's ability to perform forensic alcohol analysis;*

- The word “forensic” was added for clarity and consistency.

1216.1 (e) (2) (G) **Interpretation of results of alcohol analysis, including correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of alcohol;**

Will be changed to read: *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;*

- The word “forensic” was added for clarity and consistency.

1216.1 (e) (2) (H) **Court testimony;**

This subsection will be retained in its current form as it accurately depicts an appropriate topic for instruction of an FAS.

1216.1 (e) (2) (I) **Court decisions regarding chemical tests of alcohol to determine alcohol influence; and**

This subsection will be retained in its current form as it accurately depicts an appropriate topic for instruction of an FAS.

1216.1 (e) (2) (J) **Requirements of these regulations;**

Will be changed to read: *Requirements of Title 17 of the California Code of Regulations, sections 1215 to 1222.1 inclusive;*

- The words “these” were removed and the phrase “*sections 1215 to 1222.1 inclusive*” were added to clarify the section.

1216.1 (e) (3) **Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;**

Will be changed to read: *At a minimum, successfully complete an external competency test comprised of at least four 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.*

- The addition of the definition of competency tests under 1215.1 (o) will aid in the clarity of this section. The reference to “external” ensures that the laboratory will receive such testing samples from a source other than its own employees. The references to “the Department” were removed to accommodate the intent of the legislature. In addition, 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 conducted by the California State Auditor’s Office (Report 97025.1”. Sacramento: Bureau of State Audits, August 1999), the report contained the following conclusion:

“To obtain accreditation, a laboratory must demonstrate that it meets established standards for management, operations, personnel, procedures, equipment, facilities, 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 that are currently authorized by the Department to perform forensic alcohol analysis. (California Association of Criminalists Lab Directory and List of Licensed Forensic Alcohol Analysis Laboratories)

- 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 (Department of Health Services Food and Drug Laboratory, Proficiency Test and Written Examination, LAB 529 (Rev. 9/87))

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

This section was changed to read: *Meets the requirements of the laboratory of employment;*

- Individual laboratory management is responsible for its employees and for determining whether they are capable of performing these analyses. Allowing the laboratory oversight of its employees is in line with the intent of the legislature.

1216.1 (e) (5) **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.**

Will be changed to read: *Or in lieu of (1) and (2) above, 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, or was qualified by the Department of Health Services as a Forensic Alcohol Supervisor on or before (date to be inserted for the expected filing of the public notice with OAL.)*

- This will serve to clarify this section.

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

- This subsection will remain as it is written. It merely is a lead-in to the following listed requirements.

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;**

Will be changed to read: *Possess a baccalaureate or higher degree in any of the applied physical or natural sciences.*

- The applicable sciences should include chemistry and biology courses that are desired by crime laboratory management for their scientists. In addition, this allows broader latitude for the employers to hire personnel that fit their particular needs. This is particularly relevant for smaller laboratories where staff may be required to perform analyses in several disciplines. This does eliminate persons with degrees in the social or behavioral sciences, as well as those with several technical disciplines (math, statistics, and computer science), as is allowed under current regulations. This change is reasonable, as the requirement of an applied physical or natural sciences would ensure that the applicant has an appropriate scientific background without locking him or her into a defined number of chemistry hours that are subject to interpretation by the Department.
- Additional issues: since these guidelines were written in the 1970s, the verbiage is outdated and restrictive. With the advancement in instrumental technology, much of what is required in a quantitative class is not applicable. Modern applied sciences cover instrumentation that is much more pertinent to today's testing needs.

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;**

Will be changed to read: *Successfully completes training in forensic alcohol analysis on forensic specimens in a forensic alcohol laboratory;*

- This change will clarify training to refer to the forensic alcohol discipline versus a clinical discipline.

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;**

This section will be deleted in its entirety.

- This element is covered in a general sense in 1216.1 (f) (2). The forensic laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. This is also covered in section 1216.1 (f) (5). 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 1216.1 (f) (4) is a true test of an analyst's competency, as the answers to the test are unknown to the laboratory and 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 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)

**Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;**

Will be changed to read: *At a minimum, successfully complete an external competency test comprised of at least four 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.*

- The addition of the definition of competency tests under 1215.1 (o) will aid in the clarity of this section. The term proficiency test is not really accurate here, as it is the competency of the analyst to start casework that is at issue. Please see the definitions for "Competency Test" and "Proficiency Test" in 1215.1(o) and (p) of these proposed requirements. The reference to "external" ensures that the laboratory will receive such testing samples from a source other than its own employees. The references to "the Department" were removed to accommodate the intent of the legislature.
- The reference to passing examinations prescribed by the Department is no longer necessary, as the laboratory of employment will have 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 (f) (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 (Department of Health Services Food and Drug Laboratory, Proficiency Test and Written Examination, LAB 529 (Rev. 9/87)).

1216.1 (f) (5)

**Demonstrates ability to adhere to the provisions of these regulations; or (in lieu of (1), (2), and (3) above)**

This section will be removed in its entirety and replaced with the following: *Meets the requirements of the laboratory of employment;*

- This section was removed as it is ambiguous and redundant.
- The laboratory is the entity responsible for its employees and for determining whether they are capable of performing these analyses. Allowing the laboratory oversight of its employees is in line with the intent of the legislature. In addition, the accredited laboratory has much more stringent and up to date, and therefore more relevant, requirements of its employees' training than does the Department.

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.**

Will be changed to read: *In lieu of (1), (2), and (3) above, 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, or was qualified by the Department of Health Services as a Forensic Alcohol Analyst on or before (date to be inserted for the expected filing of the public notice with OAL.)*

- This will serve to clarify this section.

1216.1 (g)

**A forensic alcohol analyst trainee is a person who meets the following qualifications:**

- This section will remain as it is written. It merely is a lead-in to the following listed requirements.

1216.1 (g) (1)

**Meets the educational qualification set forth as (1) for a forensic alcohol analyst;**

This will be changed to read: *Meets the educational qualification set forth in (f) (1) for a forensic alcohol analyst;*

- These minor changes will serve to clarify this section while avoiding redundancy.

1216.1 (g) (2) **Is employed by a licensed forensic alcohol laboratory.**

Remove the word “licensed” from this section.

- This is a Rule 100 change.

### **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 (e) (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 3 will be removed in its entirety as a Rule 100 change.

#### **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.**

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, 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.

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

1219

**Samples taken for forensic alcohol analysis and breath alcohol analysis shall be collected and handled in a manner approved by the Department. The identity and integrity of the samples shall be maintained through collection to analysis and reporting.**

This section will be changed to read: *Samples taken for forensic alcohol analysis and breath alcohol testing shall be collected and handled in a manner in which the identity and integrity of the samples shall be maintained through collection to analysis and reporting.*

- The word analysis after “breath alcohol” was changed to testing to provide consistency with the rest of the document. The phrase “in a manner approved by the Department” was removed. 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 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 1219. The court system provides for the ultimate oversight of proper collection and handling, as these issues are challenged in most DUI cases.

1219.1 **Blood Collection and Retention**

This subsection will remain as written.

1219.1 (a) **Blood samples shall be collected by venipuncture from living individuals as soon as feasible after an alleged offense and only by persons authorized by Section 13354 of the Vehicle Code.**

This section will be changed to read: *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.*

- This reflects a change in the Vehicle Code cite. (California Law “Vehicle Code Section 23152-23229”)

1219.1 (b) **Sufficient blood shall be collected to permit duplicate determinations.**

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.

Note: All following section designations will need to be updated to reflect the removal of (b).

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.**

This section will read: *Alcohol or other volatile organic disinfectants shall not be used to clean skin where a specimen is to be collected. Examples of suitable aqueous disinfectants include: aqueous povidine-iodine (Betadine) or aqueous benzalkonium chloride (zephiran chloride.)*

- 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) **Blood samples 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 or kept in alcohol or other volatile organic solvent.**

The word “with” was added to this section after “...not be cleaned” and an “s” was added to the word solvent so that the last sentence will read:  
*Reusable equipment, if used, shall not be cleaned with or kept in alcohol or other volatile organic solvents.*

- These changes serve to clarify the section, and make it grammatically correct.

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.**

This subsection will remain as written as it reflects current accepted practice.

1219.1 (f) **When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to insure an uncontaminated sample shall be employed, such as:**

The word “insure” will be changed to “ensure” for grammatical correctness.

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.**

The phrase “Coroner’s samples do not need a preservative added if stored under refrigeration” will be removed.

- Current practice recommends the addition of a preservative irrespective of refrigeration. Current practice also is to store blood specimens in a refrigerated environment.

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.**

This subsection will remain as written as it reflects current accepted practice.

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.**

This subsection will remain as written as it reflects current accepted practice.

1219.1 (g) (1) **In coroner's cases, blood samples shall be retained for at least 90 days after date of collection.**

This subsection will remain as written as it reflects current accepted practice.

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 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.**

The phrase “or coroner/medical examiner’s office” will be added in this section so that the section reads, in part: *Whenever a sample is requested by the defendant for analysis and sufficient sample remains, the forensic laboratory, law enforcement agency, or coroner/medical examiner’s office in possession...*

- This inclusion created a more accurate representation of current practices.

1219.2 **Urine Collection and Retention**

1219.2 (a) **The only approved urine sample shall be a sample collected no sooner than twenty minutes after first voiding the bladder.**

This section will be changed to read: *A urine sample from a living individual will be collected no sooner than twenty minutes after first voiding the bladder.*

- This change clarifies the section to state 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) **The specimen shall be deposited in a clean, dry container which also contains a preservative.**

This subsection will remain as written as it reflects current accepted practice.

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.**

This subsection will remain as written as it reflects current accepted practice.

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 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 the original sample container.**

The phrase “or coroner/medical examiner’s office” will be added in this section so that the section reads, in part: *Whenever a sample is requested by the defendant for analysis and sufficient sample remains, the forensic laboratory, law enforcement agency, or coroner/medical examiner’s office in possession...* The word “by” in the last sentence will be changed to “on” so that the sentence reads, in part: *...the identifying information carried on the original sample container.*

- The inclusion of the coroner/medical examiner’s office will create a more accurate representation of current practices. The change of “by” to “on” provides consistency with prior language contained in 1219.1 (g) (2).

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.**

The phrase “The quantity of the breath sample shall be established by direct volumetric measurement” will be removed.

- This phrase 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.

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

1220 (a) **All laboratory methods used for forensic alcohol analysis shall be subject to standards set forth in this Article.**

This subsection will remain as written.

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.**

The phrases “licensed”, and “on file with the department” will be removed so that the section will read: *Each forensic alcohol laboratory shall have detailed, up-to-date written descriptions of each method it uses for forensic alcohol analysis.*

- This is 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. (California First Amendment Coalition – Government Code Section 6250-6270)

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.**

The phrase “and shall be available for inspection by the Department on request” will be removed. The section will read: *Such descriptions shall be immediately available to the person performing an analysis.*

- This section will now 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 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)

**Each such description shall include the calibration procedures and the quality control program for the method.**

This subsection 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. (General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories) For those laboratories that are not accredited, this guideline is appropriate.

1220.1

**Standards of Performance**

1220.1 (a)

**Methods for forensic alcohol analysis shall meet the following standards of performance:**

This subsection will remain as written, as it is merely an introduction to the following requirements.

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 grams per 100 milliliters or higher;**

The “0.10 grams per 100 milliliters” was changed to read “0.08 grams per 100 milliliters” to reflect the change in state legal limit. (Vehicle Code Section 23152 (b))

1220.1 (a) (2)

**The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement.**

This subsection will remain as written as it reflects current accepted practice, with the exception of the deletion of the word “ethyl” as it has been previously defined.

1220.1 (a) (3)

**The method should be free from interference from anticoagulants and preservatives added to the sample;**

This subsection will remain as written as it reflects current accepted practice.

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 qualitative test;**

This subsection will remain as written as it reflects current accepted practice, with the exception of the deletion of the word “ethyl” as it has been previously defined.

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.**

This subsection will remain as written as it reflects current accepted practice.

1220.1 (b)

**The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by the Department using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.**

This section will be changed to read: *The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by a forensic alcohol supervisor or a forensic alcohol analyst using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.*

- The reference to Department was removed and replaced with an FAS or an FAA 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 state laboratories, 16 of 17 county laboratories, and all relevant city laboratories are accredited, largely replacing the need for the Department to have any oversight of the proficiency testing

program. (California Association of Criminalists Lab Directory September 19, 2008) 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 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. (“Proficiency Review Program.” American Society of Crime Laboratory Directors. Version 2.1. 2008) 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 **Standards of Procedure.**

1220.2 (a) **Methods for forensic alcohol analysis shall meet the following standards of procedure:**

This subsection will remain as written, as it is merely an introduction to the following requirements.

1220.2 (a) (1) **The method shall be calibrated with standards which are water solutions of alcohol.**

The word “method” will be changed to “instrument” to clarify this subsection, and to describe actual practice.

1220.2 (a) (1) (A) **Such alcohol solutions are secondary standards.**

This will be changed to read: *Such alcohol solutions are secondary standards, or are tertiary standards, having concentrations which have been established using a purchased secondary standard.*

- Currently, laboratories are making their own secondary standards using a direct oxidimetric method, which employs a primary standard, potassium dichromate. These secondary standards are then utilized to calibrate 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. It appears that the Department currently allows for a 5% error rate, one that is necessary for laboratories in order to perform this type of work. In contrast, the NIST ethanol-water Standard Reference Materials (SRMs) have an established error rate of less than 1.2% for all concentration levels. (National Institute of Standards and Technology. Certificate of Analysis, Standard Ref. Material 1828b) 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 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, CSIR-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 are producing on a regular basis.
- It could be argued that using a tertiary standard (a standard that has a concentration established using a secondary standard) could introduce a higher error rate. Indeed, introducing multiple levels of indirect analysis would increase the likelihood of error. However, if a purchased NIST SRM is utilized, with the low error rate of less than 1.2%, any additional uncertainty of measurement added to the overall error rate would still be lower than the error rate already approved by the Department of 5%. It would not be appropriate to utilize a prepared secondary standard with a 5% error rate to establish a concentration of a tertiary standard, because that would be multiple levels of analyses, and could generate a higher error rate than should be acceptable. To accommodate this possibility, the tertiary standards must have their values established by purchased SRMs.

- It is important to note that a review of accredited laboratories in all 50 states indicates that the restriction of using titrated secondary standards for calibration purposes is restricted to 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. (List of United States Accredited Laboratories, contacted by San Diego Police Department Personnel)

1220.2 (a) (1) (B)

**Each forensic alcohol laboratory shall establish the concentration of each lot of secondary alcohol standards it uses, whether prepared or acquired, by an oxidimetric method which employs a primary standard, such as United States National Bureau of Standards potassium dichromate;**

This section will be changed to read: *Each forensic alcohol laboratory shall purchase National Institute of Standards and Technology (NIST) traceable secondary alcohol standards, or establish the concentration of each lot of secondary standards it prepares using a direct oxidimetric method which employs a primary standard, such as NIST potassium dichromate.*

- Accurate calibration of instruments used in forensic alcohol testing is critical, as the results directly affect criminal prosecutions. For the past 30 years, laboratories have largely relied on preparing their own secondary alcohol standards using a direct oxidimetric method employing potassium dichromate as a primary standard. These secondary standards were then utilized to calibrate the instruments. Although this is a procedure that many laboratories may want to continue to utilize, with the advent of ethanol-water standard reference materials (SRMs), produced by the National Institute of Standards (NIST), an alternate methodology has presented itself. 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.

1220.2 (a) (1) (C)

This subsection will be added to read: *The forensic alcohol laboratory personnel shall verify the concentration of any new secondary (traceable) standards used in the method by analyzing the new secondary standard concurrently with a NIST standard reference material.*

This was added to ensure that the new standards are as advertised, and will perform appropriately using a specific method, prior to relying on the standard for casework.

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.**

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.**

The following sections will have the phrase “secondary alcohol standard samples” replaced with “secondary alcohol standard samples, or tertiary alcohol standard samples having a concentration established by a purchased secondary standard.”

- This change reflects the changes made in the preceding subsection 1220.2 (a) (1) (A).

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;**

These subsections will be left as written, as they reflect current and accepted practice.

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

This subsection will be deleted in its entirety as redundant.

1220.3 **Quality Control Program.**

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

This subsection will remain as written as it serves to introduce the following requirements.

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 and 0.20 grams per 100 milliliters of liquid;**

The range will be changed to “*between 0.08 and 0.20 grams per 100 milliliters of liquid*”, to reflect current law. (Vehicle Code Section 23152 (b))

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, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis;**

This section will be changed to read, in part: *For each lot of quality control reference material, the laboratory shall determine a mean value of alcohol concentration of at least 20 replicate analyses, to three decimal places, at a rate of...*”

- 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)

**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, 0.01 grams per 100 milliliters;**

1220.3 (a) (3) (B)

**The higher limit shall be calculated by adding, to the mean value, 0.01 grams per 100milliliters;**

The 0.01 in the preceding subsections will be changed to read 0.010 to reflect the change already noted in 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)

**At least one sample of the quality control reference material shall be analyzed with each set of samples analyzed for the purpose of forensic alcohol analysis;**

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

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 shall take remedial action to investigate and correct the source of error;**

The phrase “*or forensic alcohol analyst*” will be added after “and a forensic alcohol supervisor”.

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

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.**

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

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 liquid.**
- 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.**
- 1220.4 (g) **Tissue analysis results shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.**

This section will be re-ordered in the following manner to improve clarity and flow of the section.

1220.4 (a) *The symbols, grams %, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of liquid, or grams per 210 liters of breath.*

- 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. (Assembly Bill No. 4318. 1989-1990 regular session)

- 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) *Alcohol concentrations less than 0.01% in living subjects may be reported as negative.*
- The word “Blood” was removed from the phrase “Blood alcohol” to make this section inclusive of all sample types as is appropriate.
- 1220.4 (d) *Alcohol concentrations less than 0.02% on post-mortem samples may be reported as negative.*
- The word “Blood” was removed from the phrase “Blood alcohol” to make this section inclusive of all sample types as is appropriate.
- 1220.4 (e) *Analytical results for blood shall be based on the number of grams of alcohol per 100 milliliters of blood.*
- 1220.4 (f) *Analytical results for breath shall be based on the number of grams of alcohol per 210 liters of breath.*
- 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. (Assembly Bill No. 4318. 1989-1990 regular session)
- 1220.4 (g) *Analytical results for tissue analysis shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.*
- 1220.4 (h) *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.*

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

1221.

### **General.**

**Breath alcohol analysis shall be performed in accordance with standards set forth in this Article.**

This section will remain as written.

## 1221.1

### Authorized Procedures

1221.1 (a)

**Breath alcohol analysis shall be performed only with instruments and related accessories which meet the standards of performance set forth in these regulations.**

This section will be changed to read: *Breath alcohol analysis shall be performed only with instruments and calibrating units/devices which meet the requirements specified in Health and Safety Code Section 100701.*

- This section was changed to clarify what must meet requirements. The Department 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)

**Such instruments may be used for the analysis 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 by persons other than forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees shall be restricted to the immediate analysis 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 shall not be subject to the requirements of Article 6.**

This section will have the word “licensed” removed from it to address the Rule 100 change. The remainder of the subsection will remain as written as it reflects current and acceptable practice.

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.**

These sections were removed in their entirety as redundant.

- The specifications set out here are outlined in Health and Safety Code Section 100701, referenced in 1221.1 (a).

1221.4 **Standards of Procedure**

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

The word "analysis" will be replaced with "testing" to provide conformity with the rest of this document and the definitions in section 1215.1.

1221.4 (a) (1) **For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples which result in determinations of blood alcohol concentrations which do not differ from each other by more than 0.02 grams per 100 milliliters.**

The phrase "grams per 100 milliliters" will be replaced with 210 liters of breath. This will be consistent with Assembly Bill 4318.

1221.4 (a) (2)

The following subsection will be added to read: *The instrument shall be checked for accuracy with standards which are water solutions or dry-gasses of alcohol.*

- This subsection was added to specify what types of standards are appropriate for checking the accuracy of the instrument. The dry-gas standard has become common place over the past decade, and this addition now reflects common and accepted practice.

Note: Subsequent sections will need to be renumbered/lettered to reflect addition of (2).

1221.4 (a) (2)

**The accuracy of instruments shall be determined.**

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 0.01 grams % of the true value; these limits shall be applied to alcohol concentrations from 0.10 to 0.30 grams %. The reference sample shall be provided by a forensic alcohol laboratory.**

This section will be changed to read: *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 of alcohol from 0.08 to 0.25 grams %. The reference sample shall be provided by a forensic alcohol laboratory.*

- 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, than 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. (Vehicle Code Section 23152 (b))

1221.4 (a) (2) (A) 1. **Such analysis shall be performed by an operator as defined in Section 1221.4 (a)(5), and the results shall be used by a forensic alcohol laboratory 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 shall be performed only with instruments for which the operators have received training, such training to include at minimum the following schedule of subjects:**

1221.4 (a) (3) (A) **Theory of operation;**

1221.4 (a) (3) (B) **Detailed procedure of operation;**

1221.4 (a) (3) (C) **Practical experience;**

1221.4 (a) (3) (D) **Precautionary checklist;**

1221.4 (a) (3) (E) **Written and/or practical examination.**

These subsections will remain as written as they accurately reflect current and accepted practice.

1221.4 (a) (4) **Training in the procedures of breath alcohol analysis shall be under the supervision of persons who qualify as forensic alcohol supervisors, forensic alcohol analysts or forensic alcohol analyst trainees in a licensed forensic alcohol laboratory.**

This section will be changed to read: *Training in the procedures of breath alcohol testing shall be under the supervision of forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.*

- The word “analysis” was changed to “testing” to conform to the rest of this document, and to the definitions listed in 1215. The phrase “of persons who qualify as” was removed as redundant, and to increase the clarity of the subsection. The phrase “in a licensed forensic alcohol laboratory” was removed as a result of the Rule 100 change. In addition, the removal of this phrase allows for off-site training, which is very relevant in today’s environment.

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.**

This section will be deleted in its entirety.

- 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 laboratory, so this section (1221.4 (a) (4) (A)) becomes redundant as well.

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 who may be called upon to operate a breath testing instrument in the performance of his duties.**

The word “his” will be replaced with “his or her.”

1221.4 (a) (6)

**Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of the person performing the determination of accuracy.**

The words “a manual” will be added into the subsection just prior to “determination of accuracy” so that the section will now read:  
*Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of the person performing a manual 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)

**Records shall be kept for each instrument at a licensed forensic alcohol laboratory showing compliance with this Section.**

The word “licensed” was removed because of the Rule 100 change.

1221.4 (b)

*A precautionary checklist shall be available at the location of each instrument.*

This subsection 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.

**Expression of Analytical Results.**

**Results of breath alcohol analysis shall be expressed as set forth in Section 1220.4.**

This section will remain as written as it accurately reflects current practice.

## 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.**

The phrase “Such records shall be available for inspection by the Department on request” will be removed.

- This phrase was 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. (California First Amendment Coalition – Government Code Section 6250-6270) It is therefore not necessary to include that here. Also, as previously noted, most laboratories in California are accredited, and as such, have stringent requirements placed upon their manuals, records, logs, etc. Department oversight here would be redundant.

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:**

The phrase “is licensed to perform” will be removed and replaced with “performs”. This is a Rule 100 change.

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 the qualifications of each such person, including education, experience, training and performance in proficiency tests and examinations;**

The phrase “forensic alcohol analyst trainees” will be added, and the word “such” will be removed so that the subsection will read: *An up-to-date record of persons in its employ who are qualified as forensic alcohol supervisors, forensic alcohol analysts, and forensic alcohol analyst trainees; the record shall include the qualifications of each person, to including education, experience, training, and performance in proficiency tests and examinations;*

- This change was made to more accurately reflect whose records are required in the laboratory.

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;**

This subsection will be removed as it is redundant with the addition of the phrase “forensic alcohol analyst trainees” to the preceding subsection.

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;**

These subsections will remain as written as they reflect current practice.

1222.1 (a) (6) **Records of such determinations of accuracy of breath testing instruments as a laboratory may perform for law enforcement agencies;**

This section will be changed to read: *Records of determinations of accuracy, maintenance, and/or calibration of testing instruments;*

- 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.

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

This section will be changed to read: Records of the training provided to persons who operate breath testing instruments.

- This subsection was altered 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

**Breath Alcohol Analysis Records.**

1222.2 (a)

**Each agency shall keep the following records for breath testing instruments which are under its jurisdiction:**

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.**

This section will be deleted in its entirety as redundant, as each subsection in 1222.2 is covered previously.

## Works Cited

“Approved Proficiency Test Providers.” June 25, 2008. American Society of Crime Laboratory Directors. September 18, 2008. <http://www.ascl-d-lab.org/legacy/aslablegacyapprovedproviders.html>

“California Association of Criminalists Lab Directory”. September 19, 2008. California Association of Criminalists. September 22, 2008. [http://www.cacnews.org/membership/lab\\_directory.shtml](http://www.cacnews.org/membership/lab_directory.shtml)

California Codes. California First Amendment Coalition – Government Code Section 6250-6270. September 22, 2008. [http://www.cfac.org/Law/CPRA/Text/cpra\\_text.html](http://www.cfac.org/Law/CPRA/Text/cpra_text.html)

California Codes. Health and Safety Code, Section 100700-100775. September 26, 2008. <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=100001-101000&file=100700-100775>

California Law. “Vehicle Code Section 23152-23229.” September 17, 2008. <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=46907829597+1+0+0&WAIAction=retrieve>

California State Auditor. “Department of Health Services: The Forensic Alcohol Program Needs to Reevaluate Its Regulatory Efforts – Report 97025.1”. Sacramento: Bureau of State Audits, August 1999.

“General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories.” American Society of Crime Laboratory Directors, International. 2<sup>nd</sup> ed. 2006.

Larson, Clay. “Collection of Blood Samples for Forensic Alcohol Analysis, Suitable Aqueous Disinfectants”. Department of Health Services, Food and Drug Laboratory Branch. May 24, 2002.

“List of Licensed Forensic Alcohol Analysis Laboratories”. Richmond, CA: California Food and Drug Laboratory Branch, 2004.

“Proficiency Review Program.” American Society of Crime Laboratory Directors. Ver 2.1. 2008.

“Proficiency Test Provider Program.” American Society of Crime Laboratory Directors. Ver 2.0. 2008.

Soliman, Mary. "Reporting Results of Laboratories' Annual Participation in Proficiency Testing Conducted by an ASCLD/LAB Approved Proficiency Test Provider". California Department of Public Health. September 23, 2008.

State of California. Department of Health Services: Food and Drug Laboratory. "Proficiency Test and Written Examination (Forensic Alcohol Analyst)." Revised September 1987.

United States, ASCLD State Laboratories. Personal Interviews. September 30, 2008

United States. Assembly Bill No. 4318. 1989-1990 regular session. Washington, DC: U.S. Government Printing Office, March 2, 1990.

United States. National Institute of Standards and Technology. Certificate of Analysis, Standard Ref. Material 1828b. March 26, 2004.

United States. Senate Bill No. 1623 Chapter 337. Washington, DC: U.S. Government Printing Office, August 27, 2004.