

## Lough Revisions from the FARC Meeting 9-16-09

### NOTE TO SUBCOMMITTEE:

Please check grammar and tense as you review this document.  
References cited will need to be indexed and included in the packet.  
I have made subtle changes to the justification wording as needed. These have been noted if they were more significant.  
Need to review the comments in the margin.

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. FARC Vote on Article 1 through 1215.1(q): 6 yes; 1 no**

**FARC Vote on all sections in Article 1 needed - VOTE NEEDED**

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

This change will reflect current law. (California. Senate Bill 1623 - Johnson, August 27, 2004) [-----]

Comment [P1]: GOLDIE to check correct citation

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 for the purposes of these regulations.

1215.1 (b) **"Forensic Alcohol Analysis" means the ~~practical application use of specialized devices equipment,~~ instruments, and methods ~~by trained laboratory personnel~~ to measure the concentration of ethyl alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.**

This definition was changed to clarify the meaning of forensic alcohol analysis and to utilize more common language. To this end, "practical application" was replaced with "use", and "device" was replaced with "equipment." In Section 1215.1 (a), alcohol is defined as the unique chemical compound, ethyl alcohol. Therefore, the descriptor "ethyl" was removed from before the word alcohol in this definition to avoid redundancy. Finally, the reference to the operators of the equipment was removed from this definition, (trained laboratory personnel), as the

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definition should be restricted to the analysis itself. Appropriate personnel to perform these analyses are defined elsewhere.

- 1215.1 (c) **"Breath Alcohol Analysis Testing" means analysis the sampling of a sample of a person's expired breath, using a breath testing instrument. designed for this purpose, in order to determine the concentration of ethyl alcohol in the person's blood.**

The change from "analysis" to "testing" is more consistent with the verbiage used throughout the country. This definition was changed to more accurately reflect current law and more clearly state what breath alcohol testing means. The word "analysis" describes how the test results are achieved which is not suitable in this context, thus making this revised definition more appropriate. The word "sampling" reflects more accurately the limited function of the breath instrument operator in simply obtaining a breath alcohol test result. In 1991, in Assembly Bill 4318, 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. (California Assembly Bill 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 equipment, instruments, and methods are used by trained laboratory personnel forensic alcohol analysts to measure the concentration of alcohol in samples of blood, breath, urine, or tissues of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than in addition to forensic alcohol analysis.**

This definition was changed to increase its clarity and to provide consistency with other definitions. The "trained laboratory personnel" phrase was replaced with "forensic alcohol analysts" to be very specific. In addition, the word "apparatus" was changed to "equipment" and the word "forensic" was added to the phrase alcohol analysis, to provide

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consistency with other stated definitions. The phrase “other than” was changed to “in addition to” to provide more clarity.

1215.1 (f)

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

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

1215.1 (g)

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

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

1215.1 (h)

**~~"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.~~**

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

1215.1 (i)

**"Method" means the steps procedures used by a trained person forensic alcohol analyst to make a measurement of determine the alcohol concentration in a sample or specimen.**

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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~~ 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) **"Competency Test" means the evaluation of a person's ability to perform work in forensic alcohol analysis prior to the performance of independent casework.**

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This definition was added to define the term that is utilized in the text and distinguish it from a “proficiency” test. (ASCLD/LAB International, an ISO 17025 Program of Accreditation, Terms and Definitions, Page 1)

1215.1(p)

**“Proficiency Test” means a test to evaluate the continuing competence of analysts, technical support, and the performance of a laboratory.**

This definition was added to define the term that is utilized in the text and distinguish it from a “competency” test. (ASCLD/LAB International, an ISO 17025 Program of Accreditation, Terms and Definitions, Page 3)

1215.1(q)

**“Precautionary Checklist” means a guide to assist in the operation of a breath instrument.**

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

1215.1(r)

**“NIST” is an abbreviation for the National Institute of Science and Technology.**

This abbreviation has been added to define the term that is utilized in the text.

1215.1(s)

**“NIST Traceable” means that the properties of a reference are authenticated by a documented series of comparisons to a NIST reference and the values are certified by the manufacturer.**

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

Comment [P2]: FARC to review at Oct 09 meeting

1215.1(t)

**“NIST Standard Reference Material (SRM)” is a controlled reference material that meets NIST specific certification criteria, and is issued with a certificate of analysis that details its characteristics and provides information on its appropriate uses.**

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

Comment [P3]: FARC to review at Oct 09 meeting; Janet to provide reference for statement at next meeting for packet

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

**FARC Vote on Article 2: 7 yes; 1 no - COMPLETED**

1216. Authorization Requirement.

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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.

1216 (a) (1) **Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in these regulations Section 1216.1 for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.**

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

Comment [P4]: I added the last sentence.

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

The Department classification of trainee has been eliminated. This document states how alcohol analysis will be performed and who will perform the analysis. Only a qualified analyst, as defined in this document, can perform this function. ~~This subsection will remain as is currently worded, as it accurately reflects current practice in forensic laboratories and is good policy.~~

Comment [P5]: I added additional justification here.

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 and the elimination of licensing.

1216.1 **Qualifications for Licensing to perform forensic alcohol analysis.**

The reference to “licensing” per a Rule 100 change has been eliminated.

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

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~~alcohol supervisors, such persons shall meet the qualifications set forth in these regulations for forensic alcohol analysts or forensic alcohol analyst trainees;~~

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

1216.1 (a) (2)

**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 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;~~  
**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

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program. In order to provide proficiency tests, a company must comply with regulations mandated by the accrediting body. An approved proficiency test provider is an individual, organization, or company which has applied for and obtained approval from ASCLD/LAB (or other accrediting body as approved by the FARC) 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:

**Comment [P6]:** NOTE: FARC has the ability to approve other accrediting bodies; these regulations are not meant to imply that ASCLD/LAB is the only accrediting body recognized.

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:

**Comment [P7]:** QUESTION to FARC: do you want to include this criteria in a section within the regulations to insure this is done?

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

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laboratory. It therefore seems redundant, and a waste of state resources, for the Department to supply an unnecessary program.

1216.1 (a) (4)

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

Since 2005 the Department has discontinued on-site inspections following the change in the Health and Safety code.

This section was removed as it was the intent of the legislature to diminish the oversight of the Department. It should be noted that the inspections conducted by the Department are not done on a regular or frequent basis. Laboratories can, and do, go many years without an inspection conducted by the Department. As 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.~~**

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Removed due to change in statute regarding licensing, and the general statement is unnecessary because there is no language that allows a lab to deviate from the qualifications at any time.

- 1216.1 (c) ~~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 elimination of licensing and forensic alcohol supervisor classification.

- 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.

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

The supervisor classification has been eliminated.

- 1216.1 (e) (1) **Possesses a baccalaureate or higher degree, or an equivalent, in chemistry, biochemistry, or other appropriate discipline as determined by the Department; in any applied physical or natural science.**

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.

**Comment [P8]: FARC:** Goldie says to avoid the term "appropriate." Need to revisit this wording and check the wording in the licensed clinical field; double check that this is the wording we want

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1216.1 (e) (2)

**Has two years of ~~experience~~ analysis experience, and ~~experience in interpretation and correlation performing forensic alcohol analysis, such experience to include 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 at the laboratory of employment ~~or approved by [appropriate] laboratory personnel,~~ sSuch training course to include at minimum the following schedule of subjects:**

Comment [P9]: FARC: review the wording in this paragraph from July meeting

The phrase “approved by the department” was replaced with “at 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. The word “ethyl” was eliminated to be consistent with rest of document and type of alcohol has already been defined.

1216.1 (e) (2) (A)

**Value and purpose of forensic alcohol analysis, ~~including breath alcohol analysis;~~**

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

1216.1 (e) (2) (B)

**Physiological action of alcohol;**

This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

1216.1 (e) (2) (C)

**Pharmacology and toxicology of alcohol;**

This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

1216.1 (e) (2) (D)

**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 testing;**

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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 Section 1215.1 (c).

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

The word “forensic” was added for clarity and consistency. Analyst replaces student for clarity.

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

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

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

This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

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

This section will be retained in its current form as it accurately depicts an appropriate topic for instruction of a forensic alcohol analyst.

- 1216.1 (e) (2) (J) **Requirements of ~~these regulations~~ Title 17 of the California Code of Regulations, Sections 1215 to 1222.1 inclusive;**

The words “these” were removed and the title and phrase “Sections 1215 to 1222.1 inclusive” were added to clarify the section.

- 1216.1(e)(3) **At a minimum, ~~S~~successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department; complete a competency test comprised of at least 4 samples that must:**

**(A) Have differing, predetermined values;**

**(B) Range from 0 to 0.25 percent alcohol concentration;**

**(C) Have values unknown to the test taker;**

**(D) And be analyzed utilizing the laboratory's forensic alcohol method.**

**(E) Results must fall within plus or minus 5% of the known value.**

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

It is of note that in the 1999 audit 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 is redundant and is deleted. The information is already required in a previous section.

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- 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. 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 and Analyst on or before (date to be inserted for the expected filing of the public notice with OAL.)~~

Comment [P10]: GOLDIE to provide grandfather clause wording

This will serve to clarify this section.

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

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

- 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;**~~

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

- 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;**~~

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

- 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 in Section 1216.1(e)(2). The forensic alcohol laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. This is also covered in Section 1216.1(e)(4). Running 25 samples with

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known results serves only as practice for an analyst, and does not show competence. In most instances, the laboratory program will have much more stringent training requirements than the Department. The competency test requirement outlined in Section 1216.1 (e)(3) is a true test of an analyst's competency, as the answers to the test are unknown to the analyst.

**Comment [P11]: FARC:** I removed the statement that results are unknown to the laboratory – I believe this was decided in committee at a previous meeting.

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;**~~

This section is deleted as the analyst proficiency testing is now in Section 1216.1(e)(3).

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 is deleted as the analyst employment requirements are now located under Section 1216.1(e)(4).

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.)*

**Comment [P12]: GOLDIE** to work on grandfather clause.

This will serve to clarify this section.

1216.1 (g)

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

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The trainee classification has been eliminated thus this section is no longer applicable.

1216.1 (g) (1) ~~Meets the educational qualification set forth as (1) for a forensic alcohol analyst;~~

The trainee classification has been eliminated thus this section is no longer applicable.

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

The trainee classification has been eliminated thus this section is no longer applicable.

### Article 3. Licensing Procedures.

**FARC Vote on Article 3: 7 yes, 1 no - COMPLETED**

~~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~~

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~~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.~~

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~~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 and the elimination of licensing. References to the maintenance of proficiency test records and analyst training records are redundant as they are included in Article 8.

Comment [P13]: FARC: I have rewritten this justification based on committee comments..

### Article 4. Training of Personnel.

**FARC Vote on Article 4: 7 yes; 1 no - COMPLETED**

~~1218 — Training Program Approval.~~

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~~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, enhanced the requirements of the analyst, and have given such oversight to the employing laboratory entities, as noted in Sections 1216.1 (e) (4) and 1216.1 (f) (4), this section becomes irrelevant. In addition, the training curriculum required is spelled out in Section 1216.1 (e) (2) A-I. This would appear to make this section redundant as well.

Comment [P14]: FARC: I added this comment

### Article 5. Collection and Handling of blood, urine, and tissue samples.

**FARC Vote on Article 5: 7 yes; 1 no - COMPLETED**

1219

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

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 Section 1219.1, the laboratory’s protocols will address these particulars (chain of custody

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logs, labeling, security etc.) as each laboratory entity sees fit, while fulfilling the requirements outlined in Section 1219. The court system provides for the ultimate oversight of proper collection and handling, as these issues are challenged in most driving under the influence cases.

### 1219.1 **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 processed in compliance with CVC Section 23158. ~~only by persons authorized by Section 13354 of the Vehicle Code.~~**

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.

#### 1219.1 (c) **Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. ~~Aqueous benzalkonium chloride (zephiran), aqueous merthiolate or other suitable aqueous disinfectant shall be used. Examples of suitable aqueous disinfectants include: aqueous povidine-iodine (Betadine) or aqueous benzalkonium chloride (zephiran chloride.)~~**

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 with or kept in alcohol or other volatile organic solvents.**

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### Blood samples should be collected according to the standards accepted in the applicable B&P Codes .....

Comment [P15]: LAURA to revisit 1219.1(d) through 1219.1(e)(1) and to check it with the CVC and provide language

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.**
- Sections 1219.1(e), (e)(1), and (e)(2) will remain as written as they reflect current accepted practice.
- 1219.1 (f) **When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to ~~insure~~ ensure an uncontaminated sample shall be employed, such as:**
- 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.~~**
- 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 section 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 section will remain as written as it reflects current accepted practice.

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

Different jurisdictions may use a coroner system while others use a medical examiner system. The term "coroner" in this sense may be incorrect. The term "medical examiner" is more accurate and will apply to either system. Also the treatment of medical examiner cases is sufficiently different and has been renumbered to reflect this.

- 1219.1 (g) (2) **Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic ~~alcohol~~ laboratory, ~~or~~ law enforcement agency, or coroner/medical examiner's office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried on the original sample container.**

This inclusion created a more accurate representation of current practices.

### 1219.2 **Urine Collection and Retention**

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

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 section 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 section 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~~**

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**laboratory, or law enforcement agency, or coroner/medical examiner's office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried by on the original sample container.**

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 Section 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.**~~

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

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

**FARC –reviewed at the 9-16-09 meeting; VOTE NEEDED**

1220 (a)

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

This section 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.**

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.~~**

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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 section will remain as written. This section is fairly general in its requirement for available methods to include calibration and quality control procedures. This section can stand on its own as currently written, because it provides general guidelines that are fleshed out in great detail in the requirements of the accrediting bodies utilized by most crime laboratories. The ASCLD/LAB accrediting guidelines far exceed the requirements set forth in this document. (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**

No change is required.

1220.1 (a)

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

This section 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~~ 0.08 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 specific for the analysis of ethyl alcohol ~~capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement purposes.~~**

Comment [P16]: FARC revised wording for review from 9-09 meeting

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This section has been revised to provide clarity.

- 1220.1 (a) (3) **The method ~~should~~ shall be free from interference from anticoagulants and preservatives added to the sample;**

This section will remain as written with the more correct replacement of “shall” 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 a qualitative test;**

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

- 1220.1 (a) (5) **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 section 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~~ 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 a forensic alcohol analyst to give oversight of the proficiency program to the individual laboratories. This serves to clarify who must make the determination that a method is meeting requirements, and brings this section in line with the intent of the legislature. All of the California 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

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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.**

No change is required.

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~~ instrument(s) shall be calibrated with standards which are water solutions of alcohol.**

The word "method" will be changed to "instrument" to clarify this section, and to describe actual practice.

1220.2 (a) (1) (A)

### **Such alcohol solutions are secondary standards which, for the purposes of these regulations, applies to prepared or purchased solutions.**

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

1220.2 (a) (1) (B)

### **Each forensic alcohol laboratory shall purchase (NIST) traceable secondary alcohol standards, or prepare a secondary alcohol standard establish the concentration of each lot of secondary alcohol standards it uses, whether prepared or acquired, by an using a direct oxidimetric method which employs a primary standard, such as United**

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### ~~States National Bureau of Standards~~ the 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, CA laboratories have been required by regulation to prepare their own secondary alcohol standards using a direct oxidimetric method. These secondary standards were then utilized to check the calibration of the instruments. Commercially prepared secondary standards and NIST SRMs are now widely available at critical concentration levels. In this revision laboratories are given the opportunity to continue to prepare secondary standards themselves or take advantage of the availability of commercially prepared NIST traceable secondary standards. See the justification outlined for section 1220.2 (a) (1) (A).

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

1220.2 (a) (1) (C)

### **The forensic alcohol laboratory personnel shall verify the concentration of any new secondary standard used in the method by analyzing the new secondary standard concurrently with a NIST standard reference material.**

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

Currently, laboratories make their own secondary standards using a direct oxidimetric method. These secondary standards are then utilized to check the calibration of the instruments used for forensic alcohol analysis. This process has inherent difficulties, as the process is fraught with the possibility for human error. This error rate is exacerbated by the fact that laboratories do not have to perform this method on a regular basis, and often a different analyst does the work each time. The regulations currently allow for a 5% error rate in the preparation of these solutions. In contrast, the NIST ethanol-water 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 (GC-FID)

Comment [P17]: SHEN to review reference information

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detection. The National Metrology Laboratory (CSIR-NML) in Pretoria, South Africa, provides measurements for each of the concentrations of ethanol in water using a titrimetric method. The National Analytical Reference Laboratory (NARL) in Sydney, Australia, provides measurements using an exact isotope dilution-gas chromatography. The certified concentrations of ethanol in water of the SRMs are based upon a combination of the gravimetry (NIST), GC-FID (NML), and the NARL measurements. The product produced by NIST is clearly of a higher quality, and is much more accurate than any of the secondary standards the state, city, or private laboratories currently produce.

A review of accredited laboratories in all 50 states indicates that the restriction of using titrated secondary standards for calibration purposes is mandated only in California. Although other states have laboratories that use the direct oxidation procedure to titrate secondary standards, this is a matter of choice, not state mandate. It would appear that California's requirement is overly restrictive, and does not necessarily produce the best product. (List of United States Accredited Laboratories, contacted by San Diego Police Department Personnel)

1220.2 (a) (2)

**~~The procedure shall include blank and secondary alcohol standard samples at least once each day that samples are subjected to forensic alcohol analysis. A blank and secondary standard shall be analyzed concurrently or prior to analysis of subject samples on each day of analysis and on any instrument used.~~**

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

1220.2 (a) (2) (A)

**~~The blank and secondary alcohol standard samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.~~**

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

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.**

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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;**

Sections 1220.2 (a)(3), (a)(3)(A), and (a)(4) 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 section will be deleted in its entirety as redundant and unnecessary.

1220.3 **Quality Control Program.**

No change is required.

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

This section 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~~ 0.08 and 0.20 grams per 100 milliliters of liquid;**

The alcohol concentration range will be changed 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 to three decimal places, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis;**

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.

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

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

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

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

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

1220.3 (a) (4) **At least one sample of the quality control reference material shall be analyzed at the beginning and end of ~~with~~ each set of samples analyzed for the purpose of forensic alcohol analysis;**

This section revision is more specific and provides clarity, and a greater frequency, as to when a quality control reference material is to be analyzed. This additional mandate will demonstrate a higher degree of confidence that the instrument remained in calibration throughout the entire analysis of all samples.

**Comment [P18]:** FARC reps check with your representative groups on this language; GOLDIE – check on use of wording “set”

1220.3 (a) (5) **Whenever analysis of the quality control reference material is outside the acceptable limits, the method shall be regarded to be in error, and a forensic alcohol ~~supervisor~~ analyst shall take remedial action to investigate and correct the source of error;**

This change reflects the deletion of the forensic alcohol supervisor classification.

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

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**

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**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.**

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

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, or grams per 210 liters of breath.**

Comment [P19]: LAURA: to work with Pattie on recent case law regarding partition ratios.

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.**

No change was made to this section. It remains current.

1220.4 (c) **~~Blood~~ Alcohol concentrations less than 0.01% in living subjects may be reported as negative.**

The word "Blood" was removed to make this section inclusive of all sample types as is appropriate.

1220.4 (d) **~~Blood~~ Alcohol concentrations less than 0.02% on post-mortem ~~blood~~ 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) **A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based**

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**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.**

No change was made to this section. It remains current.

- 1220.4 (f) **~~A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood.~~ Analytical results for breath shall be based on the number of grams of alcohol per 210 liters of breath.**

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) **Tissue analysis Analytical results for tissue analysis shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.**

This sentence was restructured to be more grammatically correct.

### Article 7. Requirements for Breath Alcohol ~~Analysis~~ Testing.

**FARC – reviewed at 9-16-09 meeting; VOTE NEEDED**

Analysis has been replaced with “testing” here and in the following sections to be consistent with the definition section and throughout this document.

1221. **General.**  
**Breath alcohol analysis testing shall be performed in accordance with standards set forth in this Article.**

#### 1221.1 **Authorized Procedures**

No change is required.

- 1221.1 (a) **Breath alcohol analysis testing shall be performed only with instruments and related accessories calibrating units/devices which meet the ~~standards of performance set forth in these regulations~~ requirements specified in Health and Safety Code Section 100701.**

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

1221.1 (b)

**Such instruments may be used for the analysis testing of breath samples in places other than ~~licensed~~ forensic alcohol laboratories and by persons other than ~~forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees~~ only if such places and persons are under the direct jurisdiction of a governmental agency or ~~licensed~~ forensic alcohol laboratory.**

Analysis changed to testing for consistency; reference to licensing deleted as a Rule 100 change; and references to forensic alcohol supervisors and analyst trainees were deleted for consistency.

1221.1 (b) (1)

**Breath alcohol analysis testing by persons other than ~~forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees~~ shall be restricted to the immediate analysis testing of breath samples collected by direct expiration by the subject into the instrument in which the measurement of alcohol concentration is performed.**

The word “analysis” was changed to “testing,” and references to forensic alcohol supervisors and analyst trainees were deleted for consistency throughout this document.

1221.1 (b) (2)

**Except for the requirements of Section 1220.4, such immediate analysis testing shall not be subject to the requirements of Article 6.**

The word “analysis” was replaced with “testing” for consistency throughout the document.

~~1219.3~~ 1221.1(b)(3)

**~~A breath sample shall be expired breath which is essentially alveolar in composition. The quantity of the breath sample shall be established by direct volumetric measurement. The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.~~**

Comment [P20]: FARC: Revisit use of word continuous with full committee. This is an old discussion but some feel it should be revisited.

The original section 1219.3 has been relocated to this section where it is more relevant. The first sentence has been deleted as redundant because the information is already listed in the definitions section. The second

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sentence was deleted as it does not accurately reflect modern technology. Currently, most instrumentation will not necessarily measure and report a quantity of breath sample; rather, the instruments are set to require a minimum volume of breath in the chamber prior to proceeding with testing.

~~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.**~~

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

1221.4 **Standards of Procedure**

No change is required.

1221.4 (a) **Procedures for breath alcohol analysis testing 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.

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- 1221.4 (a) (1) **For each person tested, breath alcohol analysis testing shall include analysis of 2 separate breath samples which result in determinations of breath alcohol concentrations which do not differ from each other by more than 0.02 grams-per-100 milliliters 210 liters of breath.**

The word blood will be changed to breath, and 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 instrument shall be checked for accuracy with standards which are water solutions or dry-gasses of alcohol.**~~

Comment [P21]: I removed this added section and used it below.

~~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.~~

- 1221.4 (a) (2) **The accuracy of instruments shall be determined. The instruments shall be checked for accuracy with standards which are water solutions or dry-gasses of alcohol.**

Comment [P22]: FARC needs to be more specific on how these solutions or gasses are prepared/obtained to insure they are accurate or reference another location in the document that covers that.

This change specifies what types of standards are appropriate for checking the accuracy of the instrument.

- 1221.4 (a) (2) (A) **Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.010 grams % of the true value; these limits shall be applied to alcohol water concentrations and/or dry-gas standards of alcohol from ~~0.10~~ 0.08 to 0.30 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, then the total range of acceptable three decimal place results are effectively increased to 0.029%. This is nearly 50% greater than the 0.02 % range implied by the +/- 0.01 grams % limits. The acceptable results required by current regulations can only be accurately applied by using all three significant figures. Therefore, the 0.01 grams % precision limit was changed to 0.010 grams %.

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

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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 automatically on applicable instruments, or manually by an operator as defined in Section 1221.4 (a)(5), and the results shall be used by a forensic alcohol laboratory analyst to determine if the instrument continues to meet the accuracy set forth in Section 1221.4 (a)(2)(A).**

Instruments are now available with the ability to automatically perform accuracy checks. The change from the entity of a laboratory to an analyst is more specific as to who will make the determination of accuracy. .

- 1221.4 (a) (2) (B) **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;**

sections 1221.4(a)(2)(B) through 1221.4(a)(3)(D) will remain as written as they accurately reflect current and accepted practice.

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

Both a written and practical examination are now required to insure the operator has sufficient information and experience to perform a test.

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

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The word “analysis” was changed to “testing” to conform to the rest of this document, and to the definitions listed in Section 1215. The phrase “of persons who qualify as” was removed as redundant, and 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 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 analyst~~, so section 1221.4 (a)(4)(A) becomes redundant as well.

Comment [P23]: I changed language to be consistent with prior change

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/her duties.~~**

The word “his” will be replaced with “his or her.” Deleted supervisor and trainee classification have been removed to be consistent throughout the document.

1221.4 (a) (6)

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

The words “a manual” will be added into the subsection just prior to “determination of accuracy.” This insertion is to address the current technology offered by many breath programs that includes automatic calibration checks. Many instruments are set up to perform calibration checks as needed, prompted by the software program using guidelines determined by laboratory personnel. Therefore, it is feasible that in many programs, the operator will be the person administering the breath test. In one breath program, a calibration check is performed automatically

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

- 1221.5. **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

**FARC Vote on Article 8: 7 yes; 1 no - COMPLETED**

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 reference to “law enforcement agencies” has been deleted. These regulations are not intended to regulate the law enforcement community. The phrase “Such records shall be available for inspection by the Department on request” will be removed as a Rule 100 change. In addition, as discussed previously, any and all such records would be available to the Department through the California Public Records Act upon request. (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

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manuals, records, logs, etc. Department oversight here would be redundant.

### 1222.1 **Forensic Alcohol Laboratory Records.**

No change is required.

#### 1222.1 (a) **Each laboratory which ~~is licensed to~~ performs 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 qualifications of each such person, including but not limited to the records of education, experience, training.**

This change was made to be more grammatically correct and 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 section will be removed because the trainee classification has been deleted.

#### 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;**

Sections 1221.1(a)(3), (4), and (5) will remain the same as they are still accurate.

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

The phrase “maintenance and/or calibration” was added to further clarify what records need to be maintained for three years. In addition, this

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recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed *by or for* law enforcement agencies. Therefore, the phrase “as a laboratory may perform for law enforcement agencies,” is not needed and should be deleted. The term “breath” was removed to clarify that records should be maintained for all types of tests.

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

This section 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**~~

~~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.**~~

Section 1222.2 will be deleted in its entirety as redundant, ~~as each subsection in section 1222.2 is covered previously.~~ Title 17 (is concerned with) the regulation of laboratories and not law enforcement agencies. As with reference to laboratories, each subsection is covered.

Comment [P24]: LAURA had a term used here that I can't read from my notes. Laura to check.

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