

California Code of Regulations  
Title 17. Public Health  
Division 1. Department of Health Care Services  
Chapter 2. Laboratories

Article 1. General

Repeal Section 1215:

~~§ 1215. Authority.~~

~~Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.~~

Note: Authority cited: Sections 102 and 208, Health and Safety Code.

Amend and renumber Section 1215.1 to read as follows:

§ ~~1215.1.~~1215. Definitions.

(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.

(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.

(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.~~

(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.

(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.

~~(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.~~

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

~~(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.

~~(i)~~ (g) "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.

~~(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.~~

~~(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.

~~(l)~~ (h) "Sample" or "Specimen" means a representative portion of ~~breath, blood, urine, or tissue,~~ or of an artificially constituted material, or a portion of expired breath which is essentially alveolar in composition ~~taken~~ obtained for the purpose of measuring its alcohol concentration.

~~(m)~~ (i) "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.

~~(n)~~ (j) "Department" means the California State Department of Public Health and its duly authorized representatives.

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

~~(l)~~ "Proficiency Test" means a test to evaluate the continuing competence of analysts, technical support, and the performance of a laboratory.

~~(m)~~ "Precautionary Checklist" means a guide to assist in the operation of a breath instrument.

~~(n)~~ "NIST" is an abbreviation for the National Institute of Science and Technology.

~~(o)~~ "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.

(p) "NIST Traceable" means that the properties of a reference material/standard are authenticated by a documented series of comparisons to a NIST standard reference material and the values are certified by the manufacturer.

(q) "Set" means a group of samples analyzed in a continuous time span.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

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

Amend Section 1216 to read as follows:

### **1216. Authorization Requirement.**

(a) Every laboratory performing forensic alcohol analysis shall have a valid license issued in accordance with the provisions of these regulations, provide the Department with the following:

(1) Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in these regulations for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees. A statement of intent to perform or stop performing alcohol analysis, to include fluid analysis, breath analysis, or both;

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

(2) The Department shall not be limited by these regulations in performing functions in administration of the alcohol analysis and licensing program. The laboratory's current address, as well as the name, address, and phone number of the laboratory's point of contact;

(3) A list of current laboratory personnel qualified to do forensic alcohol analysis; and

(4) A list of current instruments used by laboratory personnel for alcohol analysis.

(b) Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in Section 1216.1 for forensic alcohol analysts.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1216.1 to Read as Follows:

**1216.1. Qualifications for Licensing to Perform Forensic Alcohol Analysis.**

(a) A laboratory meets the qualifications ~~for licensing to perform forensic alcohol analysis~~ by:

~~(1) Employing at least one forensic alcohol supervisor. If forensic alcohol analysis is performed by persons other than forensic alcohol supervisors, such persons shall meet the qualifications set forth in these regulations for forensic alcohol analysts or forensic alcohol analyst trainees;~~

~~(2)(1) Maintaining a quality control program in forensic alcohol analysis procedures as specified in Section 1220.3;~~

~~(3)(2) Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department; Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702. Laboratories shall direct approved providers to submit all external proficiency test results as required by Health and Safety Code Section 100702 to the Department. The laboratories shall submit, at a minimum, one test per analyst per year. In addition, laboratory staff shall provide the Department any documentation pertaining to corrective actions with respect to proficiency tests.~~

~~(4) Passing such on-site inspections as the Department may require;~~

~~(5) Showing ability to meet the requirements set forth in these regulations.~~

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

(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.~~

(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.~~

~~(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.~~

(e)(b) A forensic alcohol ~~supervisor~~analyst is a person who meets the following qualifications:

(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.

(2) Has two years of analytical experience and experience in interpreting and correlating performing forensic alcohol analysis, such experienced to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol, or; or, in lieu of such two years of such experience, satisfactorily completes a training course approved by the Department, laboratory of employment. Such training course to include at minimum the following schedule of subjects:

- (A) Value and purpose of forensic alcohol analysis, including breath alcohol analysis;
- (B) Physiological action of alcohol;
- (C) Pharmacology and toxicology of alcohol;
- (D) Laboratory methods of forensic alcohol analysis;
- (E) Instruments and procedures for breath alcohol analysis testing;
- (F) Practical laboratory demonstration of the student's analyst's ability to perform forensic alcohol analysis;
- (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;
- (H) Court testimony;
- (I) Court decisions regarding chemical tests of alcohol to determine alcohol influence; and
- (J) Requirements of these Group 8 regulations.

(3) At a minimum, has Ssuccessfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department; completed 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; and

(D) Be analyzed utilizing the laboratory's forensic alcohol method.

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

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

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

(A) A person who, prior to January 1, 1971, qualified as a director of a clinical laboratory operating under the provision of the California Business and Professions Code.

(B) A person who was employed in the activities of a forensic alcohol supervisor for a period of one year prior to January 1, 1971.

(C) A person who was qualified by the Department as a forensic alcohol supervisor prior to January 1, 1971.

(D) A person who was qualified by the Department as a forensic alcohol analyst prior to January 1, 1971.

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

~~(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;~~

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

~~(3) Performs during the training period a minimum of 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol;~~

~~(4) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;~~

~~(5) Demonstrates ability to adhere to the provisions of these regulations; or (in lieu of (1), (2), and (3) above)~~

~~(6)(E) 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.

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

- ~~(1) Meets the educational qualification set forth as (1) for a forensic alcohol analyst;~~
- ~~(2) Is employed by a licensed forensic alcohol laboratory.~~

(c) Every laboratory performing forensic alcohol analysis shall provide to the Department the following:

- (1) A copy of the diploma(s) or transcripts of relevant education for each individual performing forensic alcohol analysis for the laboratory. The relevant education includes proof of a baccalaureate or higher degree in any applied physical or natural science;
- (2) A training summary of the topics outlined in 1216.1(b)(2) with a completion date for each individual performing forensic alcohol analysis for the laboratory;
- (3) Copies of qualifying tests to include written and/or practical examinations for each individual performing forensic alcohol analysis for the laboratory;
- (4) Proof of completion of a competency test which follows the requirements articulated in 1216.1(b)(3) for each individual performing forensic alcohol analysis for the laboratory;
- (5) Written notification to the Department alerting it that the individual has successfully completed his or her training prior to beginning casework; and
- (6) Proof of completion of a proficiency test as outlined in 1216.1(a)(2) for each analyst performing forensic alcohol analysis for the laboratory.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Sections 100700 and 100702, Health and Safety Code.

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

Repeal Article 3.

~~Article 3. Licensing Procedures.~~

~~§1217 Forensic Alcohol Laboratory License.~~

~~(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.~~

~~(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 Licenses.~~**

~~(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.~~

~~(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.~~

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

~~(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.~~**

~~(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.~~

~~(b) Such reports shall be made on forms furnished by the Department and shall set forth all pertinent information called for by the form.~~

~~(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.**~~

~~(a) Display of Licenses. Licenses issued under these regulations shall be displayed on request to representatives of the Department.~~

~~(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.**~~

~~(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.~~

~~(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.~~

Amend Article 4 to read as follows:

**Article 43. Training of Personnel**

Amend Section 1218 to read as follows:

**§1218. Training Program Approval**~~Review.~~

~~(a) Any organization, laboratory, institution, school, or college conducting a course of instruction for persons to qualify under these regulations section 1221.2(a)(3) shall submit provide a course summary and list of instructors and their qualifications the following to the Department for approval to demonstrate compliance with these regulations:~~

~~(1) A complete outline of the training which meets the requirements of Section 1221.2;~~

~~(2) A copy of the written examination together with the correct answers;~~

~~(3) A written description of the practical examination;~~

~~(4) A list of qualified instructors; and~~

~~(5) A description of the qualifications of instructors for the training, which at a minimum, shall mean persons that meet the requirements described under Section 1221.2(a)(4)(A).~~

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

~~(c) If the Department believes that the laboratory's training program does not comply with these regulations, the Department shall notify the laboratory in writing within 30 days with its specific concerns. The laboratory management shall respond to the Department in writing within 30 days.~~

~~Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.~~

Repeal Section 1218.1 to read as follows:

**§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.~~

Repeal Section 1218.2.

~~§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.~~

Amend Article 5 to read as follows:

**Article 54. Collection and Handling of Blood, Urine, and Tissue Samples**

Amend Section 1219 to read as follows:

**§1219 General.**

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.

Authority: Sections 100703 and 100725. Health and Safety Code. Reference: Sections 100700 and 100775. Health and Safety Code.

Amend Section 1219.1 to Read as Follows:

**§1219.1 Blood Collection and Retention.**

(a) Blood samples shall be collected by venipuncture from living individuals as soon as feasible after an alleged offense and processed in compliance with Vehicle Code Section 23158. ~~only by persons authorized by Section 13354 of the Vehicle Code.~~

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

~~(e)~~(b) 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).

~~(d)~~(c) Blood samples from living individuals shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned with or kept in alcohol or other volatile organic solvents.

(e)(d) The blood sample shall be deposited into a clean, dry container which is closed with an inert stopper.

(1) Alcohol or other volatile organic solvent shall not be used to clean the container.

(2) The blood shall be mixed with an anticoagulant and a preservative.

(f)(e) 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:

(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.~~

(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.

(g)(f) 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.

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

(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.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1219.2 to read as follows:

**§1219.2 Urine Collection and Retention.**

(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.

(b) The specimen shall be deposited in a clean, dry container which also contains a preservative.

(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.

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

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Sections 100700 and 100775, Health and Safety Code.

Repeal Section 1219.3.

**~~§1219.3 Breath Collection.~~**

~~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.~~

Amend Article 6 to read as follows:

**Article 6.5. Methods of Forensic Alcohol Analysis**

Amend Section 1220 to read as follows:

**§1220 General.**

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

(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.

(1) Such descriptions shall be immediately available to the person performing an analysis ~~and shall be available for inspection by the Department on request.~~

(2) Each such description shall include the calibration procedures and the quality control program for the method.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1220.1 to read as follows:

**§1220.1 Standards of Performance.**

(a) Methods for forensic alcohol analysis shall meet the following standards of performance:

(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;

(2) ~~The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement purposes.~~ The method shall be specific for the analysis of ethyl alcohol;

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

(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;

(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.

(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.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1220.2 to read as follows:

**§1220.2 Standards of Procedure.**

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

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

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

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

(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.

(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.

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

(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.

(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.

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

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

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1220.3 to Read as Follow:

**1220.3 Quality Control Program.**

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

- (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;
- (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;
- (3) Acceptable limits of variation for the method shall be set as follows:
  - (A) The lower limit shall be calculated by subtracting, from the mean value, 0.010 grams per 100 milliliters;
  - (B) The higher limit shall be calculated by adding, to the mean value, 0.010 grams per 100 milliliters;
- (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;
- (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;
- (6) Until such time as the error has been corrected, as shown by return of the analysis of the quality control reference material to values within the acceptable limits, no samples shall be analyzed for the purpose of forensic alcohol analysis.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1220.4 to read as follows:

**§1220.4 Expression of Analytical Results.**

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

(b) Analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present.

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

(d) ~~Blood~~ Alcohol concentrations less than 0.02% on post-mortem ~~blood~~ samples may be reported as negative.

(e) A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 1.3 milliliters of blood is equivalent to the amount of alcohol in 1 milliliter of urine.

~~(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.~~

~~(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.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Article 7 to read as follows:

**Article 76. Requirements for Breath Alcohol Analysis Testing**

Amend Section 1221 to read as follows:

**§1221. General.**

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

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1221.1 to read as follows:

**§1221.1. Authorized Procedures.**

(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.~~

(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.~~

(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.~~

(2) ~~Except for the requirements of Section 1220.4, such immediate analysis testing shall not be subject to the requirements of Article 65.~~

(3) ~~The breath sample shall be collected only after fifteen minutes during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.~~

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Sections 100700 and 100701, Health and Safety Code.

Repeal Section 1221.2.

~~§1221.2. Standard of Performance.~~

(a) ~~Instruments for breath alcohol analysis shall meet the following standard:~~

(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.~~

(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.~~

Repeal Section 1221.3.

~~§1221.3. Approved Instruments.~~

~~(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.~~

Amend Section 1221.4 to read as follows:

**§1221.42. Standards of Procedure.**

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

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

(2) ~~The accuracy of instruments shall be determined. The instruments shall be checked for accuracy with reference samples which are known water solutions or dry-gasses of alcohol.~~

(A) Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.010 grams % of the true value; these limits shall be applied to alcohol water concentrations and -/or dry-gas standards-reference samples of alcohol from 0.10 0.08 to 0.30 ~~0.25~~ grams %. The reference sample shall be provided by a forensic alcohol laboratory.

~~1-(i)~~ Such analysis shall be performed automatically on applicable instruments, or manually by an operator as defined in Section 1221.42(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 1221.42(a)(2)(A).

(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.

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

(A) Theory of operation;

(i) Value and purpose of forensic alcohol testing;

(ii) General processes of absorption, distribution, and elimination of alcohol;

(iii) Theory of breath alcohol analysis;

(iv) Discussion of the required 15 minute wait period; and

(v) Methods of breath alcohol testing.

(B) Detailed procedure of operation;  
(i) Procedures of analysis for the specific breath alcohol testing instrument used by the agency.

(C) ~~Practical experience; Precautionary checklist:~~  
(i) Description of, and adherence to, the Precautionary Checklist.

(D) ~~Precautionary checklist; Practical experience:~~  
(i) The Precautionary Checklist shall be incorporated into the testing sequence.  
(ii) Each instrument screen prompt shall be discussed and reviewed by the instructor.  
(iii) The operation of the breath instrument shall be demonstrated by the instructor.  
(iv) The instructor shall observe the trainee(s) perform a test on the instrument while he or she acknowledges each step of the Precautionary Checklist.

(E) ~~Written and/or practical examination.~~ At the completion of the training session, each breath instrument operator trainee will be required to successfully complete a written examination and to achieve a passing score of a minimum of 80%.

(F) Prior to the completion of the training session, each breath instrument operator trainee will be required to successfully complete a breath test, accurately following the Precautionary Checklist as outlined in 1221.2(a)(3)(C).

(G) Upon successful completion of the training session and successful completion of both the written and practical examinations, the trainee will be issued a certificate. The certificate will indicate the operator's name, ID/Badge #, agency, and include the instructor's name.

(4) Training curriculum in the procedures of breath alcohol analysis testing shall be developed by under the supervision of persons who qualify as forensic alcohol supervisors-a forensic alcohol analysts or forensic alcohol analyst trainees in a licensed forensic alcohol laboratory. Department notification of the proposed curriculum will follow Section 1218.

(A) After approval as set forth in Section 1218, the forensic alcohol laboratory is responsible for the training and qualifying of its instructors. The instructors will be, at minimum, certified breath instrument operators with 2 years of practical experience or a forensic alcohol analyst who has successfully completed the breath instrument training and has at least 6 months of practical experience with the instrument. Training in the Theory of Operation, pursuant to 1221.2(a)(3), shall be coordinated by a forensic alcohol analyst.

(B) The breath instrument operator trainees will receive, at a minimum, 4 hours of instructional training by a certified breath instrument operator.

(C) If a breath instrument operator trainee has already undergone training to operate an approved breath testing instrument, the trainee may receive instruction as above excluding the portion covering 1221.2(a)(3)(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 1221.42(a)(3) and 1221.2(a)(4) and who may be called upon to operate a breath testing instrument in the performance of his or her duties.

(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.

(A) Records shall be kept for each instrument at a ~~licensed~~ forensic alcohol laboratory showing compliance with this Section.

(b) A precautionary checklist shall be available at the location of each instrument.

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1221.5 to read as follows:

**§1221.53. Expression of ~~Analytical~~ Results.**

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

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Article 8 to read as follows:

**Article 87. Records**

Amend Section 1222 to read as follows:

**§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.~~

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Amend Section 1222.1 to read as follows:

**§1222.1. Forensic Alcohol Laboratory Records.**

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

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

(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;

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

(4)(3) Records of the quality control program;

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

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

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

Authority: Sections 100703 and 100725, Health and Safety Code. Reference: Section 100700, Health and Safety Code.

Repeal Section 1222.2.

**§1222.2. Breath Alcohol Analysis Records.**

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

(1) Records of instrument determinations of accuracy;

(2) Records of analyses performed, results and identities of the persons performing analyses;

(3) At the location of each instrument, the precautionary checklist to be used by operators of  
then instrument.

**INITIAL STATEMENT OF REASONS**

**FORENSIC ALCOHOL TESTING LABORATORIES**

**CALIFORNIA CODE OF REGULATIONS, TITLE 17**

**SUMMARY OF PROPOSAL**

Senate Bill 1623, Chapter 337 (statutes of 2004), created section 100703 of the California Health and Safety Code, which took away the State Department of Public Health's (Department's) involvement in licensing forensic alcohol testing laboratories.

The legislation created the requirement that the Department establish a review committee (Forensic Alcohol Review Committee; FARC) to evaluate Group 8 (commencing with section 1215) of subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

FARC has the mandate to revise those regulations to ensure the competence of laboratories that perform forensic alcohol testing. The revisions to the regulations must ensure the proper performance of the employees in testing, analyzing, and reporting the results of the tests and ensure those laboratories and employees comply with applicable laws. The California Health and Human Services Agency reviews the revisions to the regulations and has 90 days to disapprove of any of the revisions. When the revisions are finalized, the Department must adopt the revisions as regulations, all pursuant to section 100703.

The purpose of this proposal is to amend the regulations governing the requirements laboratories are held to when performing forensic alcohol testing. Those laboratories provide key information used in prosecutions for driving under the influence of alcohol, particularly when there have been traffic accidents.

The amendments update the regulations to reflect changes in the applicable Health and Safety Code statutes. For instance, the Department no longer licenses laboratories to conduct forensic alcohol testing. In addition, equipment used to determine breath alcohol concentrations must now be listed as conforming products in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation. Also, the proficiency testing of the laboratories must now conform to the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The revised regulations reflect these changes in the statutes.

**AUTHORITY AND REFERENCE**

This rulemaking action implements, interprets, and makes specific the California statutes governing the operation of forensic alcohol testing laboratories in California. The statutory authorities cited for this regulatory proposal are found in California Health

and Safety Code sections 100703 and 100725. The reference cited in this regulatory proposal is California Health and Safety Code section 100700.

## **POLICY STATEMENT OVERVIEW**

*Problem Statement:* The regulations that make specific, interpret, and implement the broad Health and Safety statutes located at section 100700, et seq., are in Title 17 of the California Code of Regulations. These regulations were last updated in 1986.

In the previous 25 years, technology, educational requirements for college degrees, and California law with regard to forensic alcohol testing have changed dramatically. For instance, the advent of advanced data processing systems and mobile breath instruments has enabled alcohol testing to reach new levels of efficiency and accuracy. Instruments run diagnostics, run calibration checks, and prompt officers to follow the precautionary checklist, all automatically.

The introduction of National Institute of Standards and Technology (NIST) traceable dry gas standards in late 1990's<sup>1</sup> has allowed breath testing to become significantly easier to perform and allows for scientists to check the calibration of their instruments with every single subject breath test. This is in contrast to the current Department regulations from the 1980's, which require calibration every 10 days with a solution, an antiquated process. NIST is a national standards-setting federal agency in the Department of Commerce. NIST traceable standards for blood alcohol testing can be purchased, standards with exceptional levels of accuracy and precision, standards that can replace the time consuming and less accurate titrated solution standards. These standards can be purchased with many different concentrations, allowing for better instrument calibration and therefore more accurate tests.<sup>2</sup>

Improvement in technology includes the capability for instruments to reject a test when a test parameter is not met. Instruments have become mobile, allowing for roadside breath testing. Data can be downloaded, transferred, collated, and compiled, allowing for better and more modern data management. This also facilitates the discovery process, much of which is becoming electronic.

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

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<sup>1</sup> *Journal of Analytical Toxicology*. 1997;21(5):369-372.

[http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21\(5\)%3A369](http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369).

<sup>2</sup> Soliman, Mary (2008).

California law addressing driving under the influence has changed, creating the need for altered criteria in alcohol testing. Whereas the current regulations center on a 0.1% level, the pertinent legal limit is actually at 0.08%.<sup>3</sup> Driving under the influence laws for juvenile and commercial drivers require alcohol programs that check the accuracy of their levels down to a 0.01%. These changes in California law serve to further diminish the relevance of the current regulations.

Laws regarding the Department's role in the regulation of forensic alcohol analysis laboratories have also changed. The changes and updates to these regulations reflect these changes.

For instance, proficiency testing. Proficiency testing is an integral part of an effective quality-assurance program. It is one of many measures used by a laboratory to monitor its own performance and to identify areas in which 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 must take proficiency testing very seriously and must have stringent criteria for employing a proficiency-testing program. In these proposed regulations, laboratories must now meet the proficiency-testing criteria of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), which means they are held to national standards.<sup>4</sup> ASCLD/LAB is a national and international crime laboratory accreditation organization. Greater than 95% of California's crime laboratories are accredited by ASCLD/LAB.

Another change is that the Department will no longer require forensic alcohol laboratories to have on file with the Department written descriptions of the methods it uses for forensic alcohol analysis. The laboratories will, however, still be required to maintain detailed, up-to-date written descriptions of each method and to make these available to the Department on request.

Because 25 years have passed since the last revision of forensic alcohol testing regulations, the forensic community finds itself in a new era of technology, education, proficiency testing, and oversight.

*Objectives:* The broad objectives of this proposed regulatory action are to accomplish the following:

- Codify in the regulations the removal of the authority of the Department over the licensing of the state's forensic alcohol laboratories.
- Adopt updated standards pertaining to forensic alcohol laboratory operations, including maintenance of records, testing protocols, proficiency testing, and

<sup>3</sup> Vehicle Code § 23152.

<sup>4</sup> Health and Safety Code §§ 100700 to 100775.

training and supervision of laboratory staff, proposed by the review committee as necessary to effectuate the enabling legislation.

*Benefits:* The anticipated benefits from this proposed regulatory action are the following:

- Clarification of the Department's role in the oversight of forensic alcohol testing laboratories.
- Clarification of the educational and experience requirements for forensic alcohol analysts.
- Clarification of the testing procedure.
- Create a more-uniform and more-accurate testing environment, which will lead to better results in the prosecution and defense of alcohol-related offenses.
- Allow the state to better control drunk driving.

### **CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS**

The Department and FARC evaluated whether the proposed regulations are inconsistent or incompatible with existing State regulations. This evaluation included a review of the Department's laws and specifically those statutes and regulations related to forensic alcohol testing. The Department and FARC also conducted a review of California Vehicle Code statutes related to prosecutions for driving under the influence of alcohol and considered several research publications and reports.

No statute or regulation conflicts with this proposed regulatory update. No other State regulation addresses the same subject matter, and this proposal is not inconsistent or incompatible with other State regulations.

#### **Business Reporting Requirement:**

None

### **DETAILED DISCUSSION OF EACH REGULATION**

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

#### **Article 1. General**

**Section 1215:** It is proposed this section be amended to remove the prior authority. The section had been adopted prior to the creation of the Office of Administrative Law in 1980. Regulations adopted or modified after 1980 include statements of authority as part of each regulation.

This section will now provide definitions of terms used in the regulations, which were previously in section 1215.1. The amendments to these definitions are reasonably necessary to provide for uniform interpretation of the text, consistency in the

terminology used in the proposed regulations, and to effectuate the purposes of the enabling statute. New definitions are proposed for adoption, and outdated or unnecessary definitions are proposed for deletion. The reasons for each of the proposed changes are as follows.

**Subsection 1215(a)** This definition was maintained in its current form because it accurately reflects the definition of "alcohol" for the purposes of these regulations.

**Subsection 1215(b)** This definition was changed to clarify meaning and to use more-common language. To this end, "practical application" was replaced with "use," and "device" was replaced with "equipment." In section 1215(a), "alcohol" is defined as the unique chemical compound ethyl alcohol. Therefore, the descriptor "ethyl" is proposed to be struck in this definition to avoid redundancy. Finally, the reference to the operators of the equipment was struck from this definition ("trained laboratory personnel") because the definition should be restricted to the analysis itself. Appropriate personnel to perform these analyses are defined elsewhere.

**Subsection 1215(c)** The change from "analysis" to "testing" is proposed because it is more consistent with the accepted verbiage used throughout the country. The word "analysis" describes how the test results are achieved, which is not suitable in this context. Thus, its removal makes this revised definition more clear and appropriate. The word "sampling" reflects more accurately the limited function of the breath instrument operator in simply obtaining a breath alcohol test result.

**Subsection 1215(d)** This subsection remains unchanged.

**Subsection 1215(e)** This definition was changed to increase its clarity and to provide consistency with other definitions. The "trained laboratory personnel" phrase was replaced with "forensic alcohol analysts" to be very specific. In addition, the word "apparatus" was changed to "equipment," and the word "forensic" was added to the phrase "alcohol analysis," to provide consistency with other stated definitions. The phrase "other than" was changed to "in addition to" to provide more clarity.

**Subsection 1215 (f)** This definition eliminates the prior outdated and obsolete classification 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 revised language provides clarity, especially to the legal community, courts, and juries who may incorrectly assume a "forensic alcohol supervisor" is an actual supervisor in the laboratory. This is not in fact the case. The words "can be" were changed to "is" to provide clarity.

**Subsection 1215(g)** The definition for "forensic alcohol analyst" is now located in Section 1215.1(f). The requirements for analysts are defined in the enabling statute; thus their classification and definition (forensic alcohol analyst and forensic alcohol analyst trainee) are no longer required. Therefore those definitions have been repealed. The subsections were then re-designated. This subsection now defines "method." The changes to the definition specify who uses the method and gives a more clear definition as to what a method is. In addition, it provides for consistency of verbiage throughout the definitions and their use elsewhere in the proposed regulations.

**Subsection 1215(h)** This definition has been amended to more accurately define a breath sample or specimen. A breath sample should be alveolar in composition. The scientific nature of breath alcohol analysis requires deep lung air (i.e., alveolar air) because it best represents the alcohol concentration in an individual. This is also consistent with Title 17 as currently written.

**Subsection 1215(i)** This subsection remains unchanged.

**Subsection 1215(j)** The definitions of "instrument" and "device" were repealed. The words "instrument" and "device" are common terms, and therefore it is not necessary to define them.

This definition of "Department" was amended to reflect the change from the Department of Health Services to the Department of Public Health.

**Subsection 1215(k)** This definition of "license" was repealed because the enabling legislation removed the Department's authority to issue such a license.

The definition of "Competency Test" was added because it is used elsewhere in the proposed regulations and should be distinguished by the term "Proficiency Test."<sup>5</sup>

**Subsection 1215(l)** The definition of "Proficiency Test" was added to define the term, which is used elsewhere in the proposed regulations and to help distinguish the term from a "competency test."<sup>6</sup>

**Subsection 1215(m)** This definition of "Precautionary Checklist" was added to define the term, which is used elsewhere in the proposed regulations.

**Subsection 1215(n)** This abbreviation of "NIST" (National Institute of Standards and Technology) was added to define the term, which is used elsewhere in the proposed regulations. NIST is a national standards-setting federal agency in the Department of Commerce, widely viewed by expert as setting the best standards in the country.

<sup>5</sup> 2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006.

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

**Subsection 1215(o)** This definition of "NIST Standard Reference Material (SRM)" was added to define a term used elsewhere in the proposed regulations and to distinguish the term from a NIST traceable material.

**Subsection 1215(p)** This definition of "NIST Traceable," which indicates manufacturer certification of the values, was added to define a term used elsewhere in the proposed regulations and to distinguish the term from a NIST Standard Reference Material.

**Subsection 1215(q)** This definition of "set" was added to define a term that is used elsewhere in the proposed regulations and to provide clarity.

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

**Subsection 1216(a)** This subsection was amended to remove the language regarding the Department's jurisdiction over issuing licenses. The Department no longer has that authority. Instead, each laboratory will have to provide the Department with certain information to ensure there is a repository of information for the public.

**Subsection 1216(a)(1)** The proposed amendment clarifies that the Department no longer determines who performs alcohol analyses, and the references to the supervisor and trainee classifications have been removed to be consistent with the changes in these regulations. It is proposed that each laboratory provide the Department with a statement of intent, to notify the Department it will be performing alcohol or breath analyses, so there is a repository of information on who is performing breath analyses in the state in compliance with Title 17. These records will be kept for public access.

**Subsection 1216(a)(1)(A)** This subsection is repealed in its entirety because the Department classification of trainee and supervisor has been eliminated. They were eliminated because the distinction is irrelevant because under these proposed regulations, anyone meeting the performance standards may perform analyses.

**Subsection 1216(a)(2)** This subsection is amended because the enabling legislation removed the Department's jurisdiction to provide licenses. Instead, laboratories must submit certain information, including their addresses.

**Subsection 1216(a)(3)** A list of current laboratory personnel qualified under these regulations to perform forensic alcohol analysis must be provided to the Department.

**Subsection 1216(a)(4)** A list of current instruments used to perform alcohol analysis must be provided to the Department.

**Subsection 1216(b)** This subsection remains unchanged.

**Section 1216.1** This section has been amended to remove provisions related to the Department's licensing of the laboratory; the enabling legislation removed that authority.

**Subsection 1216.1(a)** This subsection has been amended to remove provisions related to the Department's licensing of the laboratory; the enabling legislation removed that authority. The addition of "forensic alcohol" to the laboratory description provides improved clarity.

**Subsection 1216.1(a)(1)** This subsection is amended because the Department classification of forensic alcohol supervisor has been eliminated by the enabling statute. This change reflects a laboratory's ability to operate without a forensic alcohol supervisor classification. The educational requirements for a forensic alcohol analyst have increased (see section 1216.1(f)(1)) such that having an additional classification of a forensic alcohol supervisor is not necessary for the performance of all of the functions of forensic alcohol analysis.

This subsection has been amended to include the addition of a citation to clarify the location of the requirements, thereby avoiding redundancy in the proposed regulations.

**Subsection 1216.1(a)(2)** In 2005 the Department discontinued onsite inspections following the change in the Health and Safety Code that took away the Department's licensing authority. This subsection was amended to reflect the change. Health and Safety Code section 100702 requires ASCLD/LAB, the accrediting body of crime laboratories in California, annual audits of all accredited areas, as well as reaccreditation inspections every 5 years. In addition, all laboratories' work product may be scrutinized in the court system.

It is proposed that laboratories must now report the results of all external proficiency test results to the Department, with a minimum being one test per analyst per year. Laboratories must also provide all documentation of corrective action with respect to any poor proficiency test results. This information will be kept for public access.

**Subsection 1216.1(a)(3)–(5)** These subsections were repealed because the Department no longer has the jurisdiction to license laboratories.

**Subsection 1216.1(b)** This subsection remains unchanged.

**Subsection 1216.1(b)(1)** This subsection was amended to remove "or an equivalent" to further clarify the section. The phrase "in any applied physical or natural science" was added to allow employers more-specific instruction over educational requirements because "appropriate discipline" was too vague. In addition, "applied" indicates hands-on experience versus theoretical experience. Hands on is preferred because it shows experience and application of theoretical experience. Finally, the reference to the Department was repealed because it no longer has oversight in this area.

**Subsection 1216.1(b)(2)** This subsection was amended to replace the phrase "approved by the department" with "laboratory of employment." This clarifies that an individual must be qualified by his or her specific Forensic Alcohol Laboratory. The

expectations of the course training are outlined in the following sections. Giving the laboratories control of the approval of courses appropriate for training forensic alcohol analysts allows for local laboratory control of when, where, and by whom these courses will be offered.

The word "ethyl" was eliminated to be consistent with the rest of the document and because the type of alcohol has already been defined.

**Section 1216.1(b)(2)(A)** This subsection was amended to remove the phrase "including breath alcohol analysis" because it is redundant. The term "Forensic Alcohol Analysis" is defined in Section 1215(b) and includes a reference to breath alcohol analysis.

**Section 1216.1(b)(2)(B)** This subsection remains unchanged.

**Section 1216.1(b)(2)(C)** This subsection remains unchanged.

**Section 1216.1(b)(2)(D)** This subsection was amended to include the word "forensic" for clarity and consistency.

**Section 1216.1(b)(2)(E)** This subsection was amended to replace the word "analysis" with "testing" to more accurately reflect the training topic. This also reflects the change in the definition of "Breath Alcohol Testing" noted in Section 1215(c).

**Section 1216.1(b)(2)(F)** This subsection was amended to add the word "forensic" for clarity and consistency. "Analyst" replaces "student" because an analyst is not a student.

**Section 1216.1(b)(2)(G)** This subsection was amended to add the word "forensic" for clarity and consistency.

**Section 1216.1(b)(2)(H)** This subsection remains unchanged.

**Section 1216.1(b)(2)(I)** This subsection remains unchanged.

**Section 1216.1(b)(2)(J)** This subsection was amended to remove the words "these regulations," and the location of the specific regulations were added for clarity.

**Section 1216.1(b)(3)** This subsection was amended for clarity. Completion of "competency" tests rather than "proficiency" tests is more accurate in this context. The addition of the definition of competency tests under Section 1215(k) will aid in the clarity of this section. The references to "the Department" were removed to reflect the change in the statute. It is proposed that ASCLD/LAB national guidelines be used.

The reference to passing examinations prescribed by the Department is deleted because 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 Section 1216.1(c)(4). Testing by accredited laboratories,

whether by written or practical examinations, is more current and relevant to today's technological advances. The following proposed changes are those recommended by ASCLD/LAB:

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

**Section 1216.1(b)(4)** The information presented here is no longer accurate. Instead, previous subsection (b)(5) is tabulated for easier reading as (b)(4).

**Section 1216.1(c)** This section lists the information a laboratory must submit to the Department regarding their forensic alcohol analysts. This requirement will allow oversight of the laboratories to ensure compliance with these regulations.

**Previous subsections (b) through (e)** These subsections were repealed because the Department no longer has the authority to license laboratories.

**Previous section 1216.1(f)(1)–(6)** This subsection was repealed in its entirety. This element is covered in general in Section 1216.1(b)(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(b)(4). Running 25 samples with known results serves only as practice for an analyst and does not show competence. The competency test requirement outlined in Section 1216.1(b)(3) is a true test of an analyst's competency because the answers to the test are unknown to the analyst.

**Previous section 1216.1(g)** This subsection was repealed because the trainee classification has been eliminated; thus this subsection is no longer applicable.

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

This article was repealed because it pertained only to matters previously under the jurisdiction of the Department but that are no longer.

### **New Article 3. Training of Personnel**

This article discussed appropriate training programs, programs that are deemed suitable by the Department. The proposed regulations further codify the removal of the Department's jurisdiction over training.

**Section 1218** This section is amended to enumerate what must be submitted to the Department regarding training programs to ensure compliance with these regulations.

This section clarifies that the discretion regarding the content of training programs lies with the laboratories, not the Department. However, it allows the Department to notify a laboratory if the Department believes the training program is out of compliance with these regulations.

**Section 1218.1** This section is combined into Section 1218.

**Section 1218.2** This section is repealed because the Department no longer has this authority under the amended Health and Safety code statute.

#### **New Article 4. Collection and Handling of Blood, Urine, and Tissue Samples**

This article is amended to update the requirements for collecting the samples used in forensic alcohol testing. The title of this article was amended to more accurately reflect the kinds of samples being collected under these regulations.

**Section 1219.** This section was amended to remove the phrase "approved by the Department." The Department no longer has the power to approve per the enabling statute. Appropriate handling is outlined in the regulations. For those issues not specifically outlined in Section 1219.1, it is proposed that the laboratory's protocols address these particulars (chain of custody logs, labeling, security, etc.) as each laboratory entity sees fit, while fulfilling the requirements outlined in Section 1219. FARC believes this is the best option because the adversarial justice system provides for the ultimate oversight of proper collection and handling, because these issues are challenged in most driving-under-the-influence cases.

**Subsection 1219.1(a)** This subsection was amended to reflect a change in the California Vehicle Code.

**Previous subsection 1219.1(b)** This subsection was repealed 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. It is proposed that the analyst will be required to determine whether the sample collected is sufficient to perform duplicate analyses.

**New subsection 1219.1(b)** These subsections were re-designated.

Some amendments to the language were made to update the section as to suitable disinfectants. In 2002, the Department determined that 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. Therefore, it is proposed that less dangerous substances be used.

**New subsection 1219.1(c)** This subsection was amended to increase clarity and to make it grammatically correct.

**New subsection 1219.1(d)** This subsection remains unchanged.

**New subsection 1219.1(e)** The subsection was amended to change the word "insure" to "ensure" for grammatical correctness.

**New subsection 1219.1(e)(1)** This subsection was amended to reflect current crime laboratory best practices. Current best practices recommend the addition of a preservative irrespective of refrigeration. Current best practice also is to store blood specimens in a refrigerated environment.

**New subsection 1219.1(e)(2)** This subsection remained nearly as written because it reflects current best practices.

**New subsection 1219.1(f)(1)** This subsection was amended to replace "coroner" with "medical examiner." Different jurisdictions may use a coroner system, whereas 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.

**Subsection 1219.1(f)(2)** This subsection was amended to create a more accurate representation of current practices.

**Subsection 1219.2(a)** This subsection was amended to delete "an approved" sample because the Department does not "approve" of certain practices. It also clarifies that the protocol in this section refers to a living individual, because these procedures are not used when dealing with urine collection from a deceased person.

**Subsection 1219.2(b)** This subsection remains unchanged.

**Subsection 1219.2(c)** This subsection remains unchanged.

**Subsection 1219(c)(1)** This subsection was amended to include "or coroner/medical examiner's office" to create a more accurate representation of current practices. The change of "by" to "on" provides consistency with prior language contained in Section 1219.1(g)(2).

**Section 1219.3** This subsection was relocated to Article 6 (Requirements for Breath Alcohol Testing) as Section 1221.1(b)(3).

### **New Article 5. Methods of Forensic Alcohol Analysis**

This article outlines the requirements for conducting the analysis of a sample. It includes discussions on sample handling, testing procedures, standards, controls, and quality assurance.

**Subsection 1220(a)** This subsection remains unchanged.

**Subsection 1220(b)** This subsection was amended to remove reference to the authority of the Department, jurisdiction that was removed by the enabling statute.

**Subsection 1220(b)(1)** This subsection was amended to address an important factor, that the analyst has immediate access to methods used. This is a criterion addressed in Section 5.4 (Test and Calibration Methods and Method Validation) of ISO 17025 Program of Accreditation, currently used by ASCLD/LAB-International. All accredited crime laboratories will be following the ISO guidelines within the next five years.

**Subsection 1220(b)(2)** This section remained 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 used by most crime laboratories. The ASCLD/LAB accrediting guidelines far exceed the requirements set forth in these regulations.<sup>7</sup> For those laboratories that are not accredited, this guideline is appropriate.

**Subsection 1220.1(a)** This subsection remained as written because it is merely an introduction to the following requirements.

**Subsection 1220.1(a)(1)** This subsection was amended to replace "0.10 grams per 100 milliliters" with "0.08 grams per 100 milliliters" to reflect the change in the state legal limit.<sup>8</sup>

**Subsection 1220.1(a)(2)** This subsection was amended to provide clarity because the phrase "adequate and appropriate" is vague.

**Subsection 1220.1(a)(3)** This subsection remained as written with the more correct replacement of "shall" because interference from the anticoagulants and preservatives that could alter the testing results is not a viable option. Interference is not acceptable when quantifying results.

**Subsection 1220.1(a)(4)** The word "a" was added to be grammatically correct. The rest of the subsection remained as written because it reflects current accepted practice.

**Subsection 1220.1(a)(5)** This subsection remained as written because it reflects current accepted practice.

**Subsection 1220.1(b)** This subsection was amended to remove the reference to the Department and replace it with "a forensic alcohol analyst" to codify the 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 subsection in line with the intent of the legislature to remove the Department's jurisdiction. Accredited laboratories have mandated quality-assurance programs, with quality-assurance

<sup>7</sup> General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories.

<sup>8</sup> California Vehicle Code § 23152(b).

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 5-year term, a laboratory must continue to meet the standards under which it was accredited. One of the means by which ASCLD/LAB monitors compliance is by reviewing proficiency-testing reports submitted by approved test providers. The PRP outlines the roles and responsibilities of the Proficiency Review Committees (PRCs), 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 needed to ensure methods are functioning according to required specifications.<sup>9</sup> The requirements are set forth in these regulations in a manner sufficient to accommodate those laboratories that are not currently accredited.

**Subsection 1220.2(a)(1)** This subsection was amended. The word "method" was changed to "instrument(s)" for clarification and to describe actual practice.

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

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

Accurate calibration of instruments used in forensic alcohol testing is critical because the results directly affect criminal prosecutions. For the past 30 years, California laboratories have been required by regulation to prepare their own secondary alcohol standards using a direct oxidimetric method. These secondary standards were then used to check the calibration of the instruments. Commercially prepared secondary standards and NIST Standard Reference Materials (SRMs) are now widely available at critical concentration levels. Under the amendments here, 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. Also, the United States National Bureau of Standards no

<sup>9</sup> "Proficiency Review Program." American Society of Crime Laboratory Directors, Version 2.1; 2008.

longer exists and has been replaced by the National Institute of Standards and Technology.

**Subsection 1220.2(a)(1)(C)** An 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 used to check the calibration of the instruments used for forensic alcohol analysis. This process has inherent difficulties because the process is fraught with the possibility of 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. By contrast, the NIST ethanol-water SRMs have an established error rate of less than 1.2% for all concentration levels.<sup>10</sup>

The concentration of the SRMs have been tailored to legally relevant percentages (0.02%, 0.04%, 0.08%, 0.10%, 0.2%, and 0.3%). The ethanol-water SRMs are prepared gravimetrically, and the concentrations of ethanol in water are confirmed at NIST by using gas chromatography with flame ionization (GC-FID) detection. The National Metrology Laboratory (CSIR-NML) in Pretoria, South Africa, provides measurements for each of the concentrations of ethanol in water using a titrimetric method. The National Analytical Reference Laboratory (NARL) in Sydney, Australia, provides measurements using an exact isotope dilution-gas chromatography. The certified concentrations of ethanol in water of the SRMs are based upon a combination of the gravimetry (NIST), GC-FID (NML), and the NARL measurements. The product produced by NIST is clearly of a higher quality and is much more accurate than any of the secondary standards the state, city, or private laboratories currently produce.

A review of accredited laboratories in all 50 states indicates that the restriction of using titrated secondary standards for calibration purposes is mandated only in California. Although other states have laboratories that use the direct oxidation procedure to titrate secondary standards, this is a matter of choice, not state mandate. California's requirement is overly restrictive, outdated, and not necessary.

**Subsection 1220.2(a)(2)** This subsection was amended because the original language was vague as to when the blank and secondary standard can be analyzed in a given day and did not address situations in which multiple instruments are in use. This amendment is clarifying the time frame of when the blank and standard samples must be run during the day. Further, the revisions clarify the issue by requiring blank and secondary sample analysis be performed on each instrument used for analysis, which provides the most accurate approach to determining an instrument's accuracy.

<sup>10</sup> National Institute of Standards and Technology, Certificate of Analysis, Standard Ref. Material 1828b.

**Subsection 1220.2(a)(2)(A)** This subsection was repealed in its entirety. Applicable information has been incorporated more clearly into Section 1220.2(a)(2).

**Subsection 1220.2(a)(3)** This subsection remains unchanged.

**Subsection 1220.2(a)(3)(A)** This subsection remains unchanged.

**Subsection 1220.2(a)(4)** This subsection remains unchanged.

**Subsection 1220.2(a)(5)** This subsection was repealed because it is redundant and unnecessary given the provisions above. Those provisions will ensure instruments are in good working order and are checked for precision.

**Subsection 1220.3(a)(1)** This subsection was amended. The alcohol concentration range was changed to reflect current law in the California Vehicle Code section 23152(b).

**Subsection 1220.3(a)(2)** This subsection was amended to add that the analyses must be determined to the third decimal place, in order to accurately apply uncertainty measurements and ensure a higher level of confidence in the test.

**Subsection 1220.3(a)(3)(A)** This subsection was amended. The 0.01 was changed to read 0.010 to reflect the change proposed in section 1220.3(a)(2).

**Subsection 1220.3(a)(3)(B)** The 0.01 was changed to read 0.010 to reflect the change proposed 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.

**Subsection 1220.3(a)(4)** This subsection was amended to be more specific and provides clarity and a greater frequency as to when a quality-control reference material is to be analyzed. This additional mandate demonstrates a higher degree of confidence that the instrument remained in calibration throughout the entire analysis of all samples. The term "set" has been included in Section 1215 for clarity.

**Subsection 1220.3(a)(5)** This subsection was amended to reflect the deletion of the forensic alcohol supervisor classification.

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

**Subsection 1220.3(a)(6)** This subsection remains unchanged.

**Subsection 1220.4(a)(1)** The phrase "or grams per 210 liters of breath" was added to the subsection to address the change in law regarding the partition ratio. In 1991, A.B. 4318 changed the law so that the breath test was a reflection of the alcohol concentration in the deep lung air and was not necessarily linked to the blood concentration. In other words, the breath test result is a measure of the breath and not the blood. The word "liquid" was changed to "blood" to be consistent with the Vehicle Code.

**Subsection 1220.4(b)** This subsection remains unchanged.

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

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

**Subsection 1220.4(f)** In 1991, A.B. 4318 changed the law so that the breath test was a reflection of the alcohol concentration in the deep lung air and was not necessarily linked to the blood level. In other words, the breath test result is a measure of the breath and not the blood. This subsection was amended to reflect the change in the law.

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

### **New Article 6. Requirements for Breath Alcohol Testing**

This article outlines the regulations for breath alcohol testing. The word analysis has been replaced with "testing" in the article title and in the following sections to be consistent with the definition section (Section 1215) and the remainder of this document.

**Subsection 1221** This subsection was amended to replace "analysis" with "testing," to provide consistency with the definition section.

**Subsection 1221.1(a)** The US Department of Transportation uses the word "units," whereas the California Health and Safety Code uses the word "devices." The change will serve to clarify this difference. In addition, the Health and Safety Code section reference was added to identify the specific applicable requirements.

**Subsection 1221.1(b)** This subsection was amended to change "analysis" to "testing" for consistency. References to licensing were deleted because the Department's licensing authority was removed by the enabling statute. References to forensic alcohol supervisors and analyst trainees were deleted because these designations no longer apply.

**Subsection 1221.1(b)(1)** This subsection was amended to change "analysis" to "testing" for consistency. References to licensing were deleted because the Department's licensing authority was removed by the enabling legislation. References to forensic alcohol supervisors and analyst trainees were deleted because these designations no longer apply.

**Subsection 1221.1(b)(2)** This subsection was amended to change "analysis" to "testing" for consistency throughout the regulations.

**Subsection 1221.1(b)(3)** The original Section 1219.3 was relocated to this section, where it is more relevant. The first sentence was deleted as redundant because the information is already listed in the definitions section (§ 1215). The second sentence was deleted because it does not accurately reflect modern technology. Currently, most instrumentation will not necessarily measure and report a quantity of breath sample; rather, the instruments are set to require a minimum volume of breath in the chamber prior to proceeding with testing. The "continuous observation" is vague and lacks specificity as to how that will be accomplished. The new wording clearly requires that no test will be performed in less than 15 minutes after a subject eats, smokes, etc., in order to ensure a more accurate test.

**Subsections 1221.2 and 1221.3** These were repealed because they are redundant. The specifications set out here are outlined in California Health and Safety Code section 100701 and referenced in Section 1221.1(a) of these regulations.

**New subsection 1221.2(a)** This subsection was amended to change "analysis" to "testing" for consistency throughout the regulations.

**Subsection 1221.2(a)(1)** This subsection was amended to change the word "blood" to "breath," and the phrase "grams per 100 milliliters" to "210 liters of breath." This makes the regulation consistent with the enabling legislation.

**Subsection 1221.2(a)(2)** This subsection was amended to specify what types of reference samples are best for checking the accuracy of the instrument consistent with nationally recognized best practices.

**Subsection 1221.2(a)(2)(A)** This subsection was amended in the following ways for the following reasons:

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 percentage limits. The acceptable results required by current regulations can only be accurately applied by using all three significant figures. Therefore, the 0.01 grams percentage precision limit was changed to 0.010 grams percentage.

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

The range of 0.08 to 0.25 grams percent was inserted to more accurately reflect meaningful alcohol levels. In particular, the 0.08% reflects current state law in the California Vehicle Code Section 23152(b).

**Subsection 1221.2(a)(2)(A)(1)** This subsection was amended because instruments are now available that 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.

**Subsection 1221.2(a)(2)(B)** This subsection remains unchanged.

**Subsection 1221.2(a)(3)** This subsection was amended to change "analysis" to "testing" for consistency throughout the regulations. "Procedures" replaces "instruments" because the procedure encompasses all aspects of the testing process, including the instrumental portion.

**Subsection 1221.2(a)(3)(A) through (D)** These subsections were enhanced to more closely resemble the training section for blood alcohol in Title 17. The breath alcohol section did not have the specific detail for breath alcohol instrument operator training, so it was added. The training for breath analysis and for blood analysis are not identical, of course, but they would now closely resemble each other.

**Subsection 1221.2(a)(3)(E)** This subsection was amended because both a written and practical examination should be required to ensure the operator has sufficient information and experience to perform a test.

**Subsection 1221.2(a)(3)(F) and (G)** Because breath alcohol analysts are required to take specific training, a certificate provides proof that they have done so. An officer will need to be able to prove in a court of law that he or she has in fact completed the training. A certificate is a typical way to provide that verification.

**Subsection 1221.2(a)(4)** This subsection was amended because the phrase "under the supervision of" is vague. The development of the training curriculum has been clearly defined as a responsibility of the forensic alcohol analyst.

The word "analysis" was changed to "testing" to conform to the rest of the regulations and to the definitions listed in Section 1215.

The phrase "of persons who qualify as" was removed as redundant, thus increasing the clarity of the section. The supervisor and trainee classification were eliminated to be consistent with the other sections of the regulations.

The term "licensed" was removed to reflect the removal of the Department's jurisdiction.

The word "laboratory" was removed to allow for off-site training in facilities other than laboratories, which is very relevant in today's environment. Analysts will go to various agencies to deliver the training onsite. Because the testing machines are portable this makes it possible to take the training to the many, rather than have the many come to a specific laboratory.

**Subsection 1221.2(a)(4)(A)** This subsection as previously written is now obsolete because Section 1218 was repealed. Section 1218 discussed appropriate training programs; programs that were deemed suitable by the Department. Because the oversight of training programs has been removed from the Department and given to the employing laboratory entities, this subsection became irrelevant. In addition, the training curriculum required is spelled out in subsection 1216.1(b). This would appear to make this section redundant as well. The changes made here have given oversight to the forensic alcohol analyst.

**Subsection 1221.2(a)(4)(B)** Here, 4 hours was chosen to resemble blood training. Both breath and blood analysis training require a comparable amount of time.

**Subsection 1221.2(a)(4)(C)** This proposed regulation was included so that peace officers and others moving between different jurisdictions, where there may be different instruments used, are not required to repeat trainings that would be redundant and unnecessary for them to repeat.

**Subsection 1221.2(a)(5)** This subsection was amended to replace the word "his" with "his or her." Supervisor and trainee classifications have been removed to be consistent throughout the regulations. The reference to (a)(4) was added because it also applies.

**Subsection 1221.2(a)(6)** This subsection was amended to add the words "a manual" into the section just prior to "determination of accuracy." This insertion is to address the current technology offered by many breath programs that includes automatic calibration checks. Many instruments are set up to perform calibration checks as needed, prompted by the software program, using guidelines determined by laboratory personnel. Therefore, it is feasible that in many programs, the operator will be the person administering the breath test. In one breath program, a calibration check is performed automatically before and after every subject test. In actuality then, the "calibration check" is being done by the instrument at the prompting of the officer. If the instrument is receiving additional service, and a calibration check is part of that service, and is essentially a "manual calibration check," then that operator will be recorded as having performed that check.

**Subsection 1221.2(a)(6)(A)** The word "licensed" was removed to reflect the removal of the Department jurisdiction contained in the enabling legislation.

**Subsection 1221.2(b)** This subsection was added here to finish the discussion of required records. It was removed from Section 1222.2 and put here as a more appropriate location.

**New subsection 1221.3** This subsection was amended. The word "analytical" was removed as unnecessary. The word "analysis" was changed to "testing" for consistency throughout the regulations.

### **New Article 7. Records**

This article outlines the type of documentation necessary for forensic alcohol testing laboratories to generate and maintain:

**Section 1222** 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" was deleted to reflect the removal of the Department's jurisdiction.

**Subsection 1222.1(a)** The phrase "is licensed to perform" was repealed and replaced with "performs." This amendment implements the removal of the Department's jurisdiction.

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

**Subsection 1222.1(a)(2)** This subsection was repealed because the trainee classification has been deleted. The rest of the subsections are renumbered.

**New Subsection 1222.1(a)(2)** This subsection remains unchanged.

**New Subsection 1222.1(a)(3)** This subsection remains unchanged.

**New Subsection 1222.1(a)(4)** This subsection remains unchanged.

**New subsection 1222.1(a)(5)** The phrase "maintenance and/or calibration" was added to further clarify what records need to be maintained for 3 years. In addition, this recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed by or for law enforcement agencies. Therefore, the phrase "as a laboratory may perform for law enforcement agencies" is not needed and was deleted. The term "breath" was removed to clarify that records should be maintained for all types of tests.

**New Subsection 1222.1(a)(6)** This subsection was amended to provide clarity to the requirements. 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 was deleted.

**Section 1222.2** This section was repealed because it is redundant with the proposed amended regulations.

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON**

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[369](http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369).

### **REASONABLE ALTERNATIVES CONSIDERED**

FARC determined that no reasonable alternative considered or otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons and equally effective in implementing the intent of the enabling legislation, Senate Bill 1623, Chapter 337, statutes of 2004.

SB 1623 created an independent review committee that was charged with considering a narrow range of alternatives when crafting these proposed regulations to carry out the purposes of the statute. As intended by the enabling legislation, the review committee did consider, as explained in detail elsewhere in this document, matters involving laboratory procedures, proficiency testing, training and oversight of laboratory staff, and maintenance of records.

### **LOCAL MANDATE**

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

### **EFFECT ON SMALL BUSINESS**

FARC and the Department have determined that there will be a small financial impact on small businesses who must comply with the regulations.

### **EFFECT OF HOUSING**

The Department has determined that the proposed regulations will not have a financial impact on housing.

### **FISCAL IMPACT ASSESSMENT**

1. Fiscal impact on local government: None. The Department is not aware of any cost impacts that a local government agency would necessarily incur in complying with the proposed action.
2. Fiscal impact on state government: Yes. See 399. The Department anticipated a reduction in costs as a result of the Department staff that will no longer be needed to perform the licensing and oversight duties that were previously performed, before SB 1623. The Department is not aware of any other cost impacts that state government would necessarily incur in complying with the proposed action.

3. Fiscal impact on federal funding or state programs: None.
4. Fiscal impact on private persons or businesses directly affected: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in complying with the proposed action. See 399.
5. Other nondiscretionary cost or savings imposed on local agencies: There are no known costs or savings imposed on local agencies in connection to this proposed action.

### **Economic Impact Analysis**

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

Based on the economic impact analysis, the Department has determined that the regulation would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

### ***Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment***

The proposed regulations are necessary to protect the health and welfare of California residents. This modernization of the laws applicable to forensic alcohol testing will work to ensure that the evidence presented against those charged with driving under the influence is accurate and that justice is served. The ability to present accurate evidence will further serve to protect Californians from the harms of drunk driving, by enabling more prosecutions to go forward when, previous to these updated regulations, some prosecutions failed because of poor forensic alcohol analysis.