

PROPOSED REGULATION TEXT

**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 Section 1215.1 to read as follows:

§ ~~1215.1.~~1215. Definitions.

(a) "Alcohol" means the unique chemical compound, ethyl alcohol. When referencing compounds to be avoided, such as skin disinfectants, alcohol means any organic compound in which an hydroxyl functional group is bound to a saturated carbon atom., 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.

~~(m)~~(b) "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.

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

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

~~(d)~~(e) "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.

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

~~(b)~~(g) "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.

~~(f)~~(h) "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~~.

~~(e)~~(i) "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.

(j) "Laboratory" means an entity capable of assuming the responsibility of fulfilling the requirements of the regulations.

~~(i)~~(k) "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.

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

(m) "NIST Certified Reference Material (CRM)" means a reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

~~(e)~~(n) "NIST Standard Reference Material (SRM)" means a CRM issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material. ~~is a controlled reference material that also meets additional NIST specific certification criteria, and is issued with a certificate or a certificate of analysis that reports the results of details its characteristics characterizations and provides information regarding the on its appropriate use(s) of the material.~~

~~(p)(o) "NIST Traceable" means a commercially produced reference material with a well-defined traceability linkage to existing NIST standards for chemical measurements, 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.~~

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

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

~~(l)(r) "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.~~

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

~~(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.~~

~~(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.~~

Authority: Section 100703, 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~~Notification 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 within 90 days of any change to the information listed in 1-4 below:

(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: Section 100703, 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 trained 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 a life science or physical science.

(2) Has two years of analytical experience performing alcohol analysis, 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 successfully perform forensic alcohol analysis;

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

(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 S~~successfully 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 if the value is at a 0.100% or higher. If the value is lower than a 0.100%, the result must be within plus or minus 0.005.

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

~~(5)(4) Persons who have completed 1216.1(b)(2)(A), (D), (F), and 1216.1(b)(3) may conduct analysis of samples for the purpose of determining alcohol concentration. 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.~~

(5) The qualification requirements set forth in subdivisions (b)(1), (b)(2), and (b)(3) shall not apply to persons who were qualified by the Department as a forensic alcohol analyst prior to January 1, 2016.

~~(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) 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 for each newly trained forensic analyst:

(1) A copy of the diploma(s) or transcripts of relevant education. The relevant education includes proof of a baccalaureate or higher degree in any life science or physical 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 any qualifying tests 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 the training outlined in 1216.1(b)(4), prior to beginning testing.

(d) Every laboratory performing forensic alcohol analysis shall provide to the Department 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: Section 100703, 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:

~~§1217.8. 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 Title 17, Division 1, Chapter 2, subchapter 1, Group 8, sections 1215 through 1222.1:

(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 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 of the receipt of the materials with its specific concerns. The laboratory

management shall respond to the Department in writing within 30 days of receipt of the Department's concerns.

Authority: Section 100703, 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 and Urine 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: Section 100703, 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.~~

~~(c)~~(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.

(3) Postmortem blood samples shall be mixed with an anticoagulant and preservative.

~~(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: Section 100703, 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 on the original sample container.

Authority: Section 100703, Health and Safety Code. Reference: Section 100700, 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 65. 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 instrument calibration procedures and the quality control program for the method.

Authority: Section 100703, 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 0.100% or higher. If the value is lower than 0.100%, the result must be within plus or minus 0.005; 0.10 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.~~ The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate. ~~For~~ traffic law enforcement.

(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 specifically identified as the oxidizable substance is identified as ethyl alcohol by qualitative test; and

(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: Section 100703, 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 shall ~~employ~~be calibrated ~~with standard(s)~~ with standard(s) which ~~is/are~~ is/are water solution(s) of ethyl 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 CRMs, or prepare a secondary alcohol standard, establishing the concentration of the prepared standard by ~~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 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 SRM.

(D) If a purchased secondary standard (CRM) has been certified as analytically verified against a NIST SRM, the verification pursuant to 1220.2 (a)(1)(C) is not required.

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

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

(B) All blank(s), secondary standard(s), and samples shall be taken through all steps of the method.

~~(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) All samples shall minimally be analyzed in duplicate. Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis; Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware used for alcohol analysis. If volatile organic solvents are employed in the maintenance of equipment, the solvents must be thoroughly removed.~~

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

Authority: Section 100703, 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;

(A) If the quality control reference material is NIST traceable, and has been verified against a NIST SRM, and the quality control reference material is from a different lot than the secondary standards, then 1220.3(a)(2) is not required.

(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; and

(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: Section 100703, 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, a~~ 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 with the exception of tissue analysis and breath test results.

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

(b) Analytical results shall be reported to the second or third decimal place. When reporting to the second decimal place, the digit in the third decimal place shall be deleted.~~deleteing the digit in the third decimal place when it is present.~~

(c) ~~Blood~~-Alcohol concentrations less than 0.010% in living subjects may be reported as negative.

(d) ~~Blood~~-Alcohol concentrations less than 0.020% on post-mortem ~~blood~~-samples may be reported as negative.

(e) A urine alcohol concentration shall be converted and expressed as a to an ~~equivalent~~ blood alcohol concentration. The converted blood alcohol concentration shall be determined by dividing the urine alcohol concentration by 1.3. ~~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.~~ A breath alcohol concentration shall be expressed as 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: Section 100703, 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: Section 100703, 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, and calibrating units and 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, or affiliated with, 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 6.~~

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

Authority: Section 100703, 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:

§1221.4~~2~~. 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 ~~400 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 reference samples of alcohol from ~~0.10-0.08~~ to 0.30 grams %. The reference sample shall be provided by a forensic alcohol laboratory.

~~4-(i)~~ Such analysis shall be performed automatically on applicable instruments, or manually by an operator as defined in Section 1221.4~~2~~2(a)(5), and the results shall be used by a forensic alcohol laboratory analyst to determine if the instrument continues to meet the accuracy set forth in Section 1221.4~~2~~2(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 using~~ 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) The Precautionary Checklist shall be incorporated into the testing process.
- (D) ~~Precautionary checklist;~~ Practical experience:
(i) Each instrument screen prompt shall be discussed and reviewed by the instructor.
(ii) The operation of the breath instrument shall be demonstrated by the instructor.
(iii) The instructor shall observe the trainee(s) perform a successful test on the instrument.
- (E) ~~Written and/or practical examination.~~ Written Examination;

(i) 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) Upon successful completion of the training session and successful completion of both the written and practical examinations, the trainee will be issued a certificate by the laboratory. 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 conducted 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 for consultation at each instrument location.

Authority: Section 100703, 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: Section 100703, 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 describe and document their activities which are covered by these regulations. ~~Such records shall be available for inspection by the Department on request.~~

Authority: Section 100703, 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~~ performs 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) Breath test results under these regulations, and ~~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: Section 100703, 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.~~