

Group 8. Forensic Alcohol Analysis

Article 1. General

1215. Authority. These regulations are established pursuant to Sections 100700-100703 of the Health and Safety Code.
- 1215.1 Intent. These regulations are intended to set minimum standards for the practice of forensic alcohol analysis. Agencies¹ engaged in the practice of forensic alcohol analysis may exceed the requirements of these regulations.
- 1215.2 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 antiseptics² include the generic class of organic compounds known as alcohols.
 - (b) "Forensic Alcohol Analysis" means the practical application of specialized devices, instruments, and methods by trained personnel³ 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" means analysis of a sample of a person's expired breath, using a breath testing instrument designed for this purpose, in order to determine the concentration of ethyl alcohol in the person's breath.
 - (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 of weight of specimen.
 - (e) "Forensic Alcohol Laboratory" means a place at which specialized apparatus, instruments, and methods are used by trained laboratory personnel to measure the concentration of alcohol in samples of blood, breath⁴, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than Forensic Alcohol Analysis.
 - (f) "Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the technical procedures of forensic alcohol analysis, and meets the qualifications of 1216.2⁵.
 - (g) "Method" means the steps used by a trained person to make a measurement of alcohol concentration.
 - (h) "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.

- (i) “Sample” or “Specimen” means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material, taken for the purpose of measuring its alcohol concentration.
- (j) “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.
- (k) “Department” means the California State Department of Health and Human Services⁶ and its duly authorized representatives.

Article 2. Qualifications to Perform Forensic Alcohol Analysis

1216. Requirement for qualification to perform Forensic Alcohol Analysis.⁷

- (a) Forensic Alcohol Analysis shall be performed only in laboratories that meet the qualifications set forth in these regulations.⁸
- (b) Forensic Alcohol Analysis shall be performed only by persons who meet the qualifications set forth in these regulations.

1216.1 A laboratory meets the qualifications to perform Forensic Alcohol Analysis by:⁹

- (a) Maintaining a quality control program in forensic alcohol analysis procedures that meets or exceeds the requirements set forth in sections 1218.1 and 1218.2¹⁰; and,
- (b) Demonstrating satisfactory performance¹¹ in a proficiency testing program that follows the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB) proficiency test program guidelines¹² and uses an ASCLD-LAB approved proficiency test provider as specified in the Health and Safety Code Section 100701.^{13,14}
- (c) A laboratory must meet these qualifications at all times that it is engaged in the practice of Forensic Alcohol Analysis.

1216.2 A person meets the qualifications to perform Forensic Alcohol Analysis by:

- (a) Possessing a baccalaureate or higher degree in one of the physical or natural sciences¹⁵ which includes one year (2 semesters or 3 quarters)¹⁶ of general chemistry including lab work.
- (b) Having training and demonstrated competency¹⁷ in performing Forensic Alcohol Analysis. Such training¹⁸ shall include:

- (1) The methods of alcohol analysis employed in the laboratory;

- (2) Practical demonstration of the person's ability to perform alcohol analysis;
 - (3) The requirements of these regulations.
- (c) In lieu of (a) and (b) above, a person is qualified to perform Forensic Alcohol Analysis if that person was qualified by the Department of Health Services as a Forensic Alcohol Supervisor or Forensic Alcohol Analyst on or before December 31, 2004.¹⁹

Article 3. Collection and Handling of Blood, Urine and Tissue Samples

1217. General. Samples taken for forensic alcohol analysis shall be collected and handled in a manner as to ensure that the identity and integrity of the samples are maintained from collection to analysis and reporting.²⁰

1217.1 Blood Collection and Retention.²¹

- (a) Blood samples should be collected by venipuncture from living subjects²² as soon as feasible after an alleged offense and only by persons authorized by Section 23158 of the Vehicle Code.
- (b) Sufficient blood shall be collected to permit duplicate determinations.
- (c) Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. Aqueous benzalkonium chloride (Zephiran) or other suitable aqueous disinfectant shall be used.²³
- (d) Blood samples shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned or kept in alcohol or other volatile organic solvent.
- (e) 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) When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to insure an uncontaminated sample shall be employed, such as:
 - (1) Samples shall be obtained prior to the start of any embalming process.

- (2) Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid.
 - (3) The sample should be taken from a major vein or heart. Care should be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom.
 - (4) Post-mortem samples shall contain a preservative.²⁴
- (g) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.
- (1) In post-mortem cases, blood samples shall be retained for at least 1 year 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 in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in accordance with the lab or agency policies and procedures. The samples shall be provided in a clean container together with the identifying information carried on the original sample container to include, at a minimum, the subject's name and a unique numerical identifier.²⁵

1217.2 Urine Collection²⁶ and Retention.

- (a) The only approved urine sample 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 in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in accordance with the lab or agency policies and procedures. The samples shall be provided in a clean container together with the identifying information carried on the original sample container to include, at a minimum, the subject's name and a unique numerical identifier.²⁷

1217.3 Tissue collection and Retention

(To be determined in committee)

Article 4. Methods of Alcohol Analysis of Blood, Urine, or Tissue

1218. General.

- (a) All laboratory methods used for forensic alcohol analysis of blood, urine, or tissue samples shall be subject to standards set forth in this article.
- (b) Each laboratory shall have²⁸ detailed, up-to-date, written descriptions of each method it uses for forensic alcohol analysis of blood, urine, or tissue samples.
 - (1) Such descriptions shall be immediately available to the person performing an analysis.
 - (2) Each such description shall include the calibration²⁹ procedures and the quality control program for the method.³⁰

1218.1. Standards of Performance.

- (a) Methods for forensic alcohol analysis of blood, urine, or tissue samples shall meet the following standards of performance:

³¹The method shall be capable of the analysis of a reference sample of known alcohol concentration³² within accuracy and precision limits of plus or minus 5 percent of the known value of the reference between 0.08% and 0.25% alcohol.³³

- (1) The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement.
 - (2) The method should³⁴ be free from interference from anticoagulants and preservatives added to the sample.³⁵
 - (3) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ethyl alcohol by qualitative test.
 - (4) The method shall give a test result which is always less than 0.010³⁶ grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.³⁷
- (b) The ability of methods to meet the standards of performance set forth in this article shall be demonstrated by the laboratory³⁸ quality control program and proficiency testing as required under section 1216.1(a) and 1216.1(b).

1218.2. Standards of Procedure.

- (a) Methods for forensic alcohol analysis³⁹ shall meet the following standards of procedure.⁴⁰
 - (1) The method shall be calibrated with standards, which are water solutions of alcohol.

- (A) Such alcohol solutions are secondary standards.⁴¹
 - (B) Each forensic alcohol laboratory shall establish the concentration of each lot of secondary alcohol standards it prepares by an oxidimetric method⁴² which employs a primary standard⁴³, such as United States National Institute of Standards and Technology (NIST) potassium dichromate; or purchase NIST traceable secondary alcohol standards.⁴⁴ Acceptable validation of NIST traceable secondary standards shall include receipt by the laboratory of a certificate of independent analysis verifying the value of the standard, or the laboratory may verify the value by analyzing the new standard concurrently with a previously analyzed standard. Each laboratory's written procedure must specify their quality control protocol for the use of such standards and lots of each standard.
- (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.
 - (3) The procedure shall also include analysis of quality control reference samples as described in Section 1218.3
 - (4) The procedure shall include at least duplicate analyses of samples for forensic alcohol analysis.
 - (5) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.
 - (6) Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis;
 - (7) All instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision.

1218.3. 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 laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which shall be analyzed along with each set of samples; the alcohol concentration in the reference material shall be between 0.080 and 0.200 grams per 100 milliliters of liquid.

- (2) For each lot of quality control reference material, the laboratory shall determine a mean value⁴⁵ of at least 20 replicate analyses, performed over a minimum of 5 separate days, with the method used for analysis of samples for forensic alcohol analysis.
- (3) Acceptable limits of variation for the method shall be plus or minus 5% of the determined mean.⁴⁶
- (4) At least one sample of the quality control reference material shall be analyzed with each set of samples analyzed for the purpose of forensic alcohol analysis;
- (5) Whenever analysis of the quality control reference material is outside the acceptable limits, the analysis shall be regarded to be in error⁴⁷, and the Laboratory will 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 of blood, urine, or tissue shall be analyzed for the purpose of forensic alcohol analysis.

1218.4. Expression of Analytical Results.

- (a) Analytical results of blood or urine samples shall be expressed as the number of grams of alcohol per 100 milliliters of blood.
 - (1) The symbols, gram(s) %⁴⁸, g%, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of blood.
- (b) The average of the analytical results shall be reported to the two decimal places, deleting the digit in the third decimal place.
- (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) Analytical results of tissue samples shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.

Article 5. Requirements for Breath Alcohol Analysis

1219. General. Evidential breath alcohol analysis⁴⁹ shall be performed in accordance with standards set forth in this Article.⁵⁰ The Provisions of Articles 3 and 4 do not apply to breath testing.⁵¹
- 1219.1. ⁵²Only such types and models of instruments and related accessories that are approved by U.S. Department of Transportation or are named in the “Conforming Products List”⁵³ 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.
- 1219.2. 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.
- 1219.3. Results of breath alcohol analysis shall be expressed as grams of alcohol per 210 liters of breath.⁵⁴
- 1219.4. 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 substances⁵⁵, regurgitated, vomited, or smoked.⁵⁶
- 1219.5. For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples which result in determinations of breath alcohol concentrations which do not differ from each other by more than 0.02 grams per 210 liters.
- 1219.6. The accuracy of instruments shall be determined, at a minimum, by periodic analysis of a reference solution or gas sample of known alcohol concentration 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.⁵⁷
- 1219.7. Standards of Performance⁵⁸
- (a) Instruments shall be tested for accuracy by analysis of a reference alcohol/water standard or a dry gas alcohol standard of known concentrations between 0.080 and 0.250 grams/210 liters. The results of such determinations of accuracy shall be within limits of plus or minus 0.010 grams/210 liters of the known value.⁵⁹
 - (b) Each forensic alcohol laboratory shall establish the concentration of each lot of reference standards it prepares by an oxidimetric method which employs a primary standard, such as United States National Institute of Standards and Technology (NIST) potassium dichromate; or purchase NIST traceable reference standards.⁶⁰ Acceptable validation of NIST traceable reference standards shall include receipt by the laboratory of a certificate of independent analysis verifying the value of the standard, or the laboratory may verify the value by analyzing the new solution concurrently with a previously analyzed standard. Each laboratory's written procedure must specify their quality control protocol for the use of such standards and lots of each standard.

- 1219.8. Breath results of less than 0.010 grams per 210 liters shall be reported as negative.
- 1219.9. Breath results shall be reported to two decimal places.
- 1219.10. Breath alcohol analysis shall be performed only with instruments for which the operators have received training and demonstrated competency through written and/or practical examination.⁶¹ Breath alcohol analysis may be performed by operators who do not meet the requirements of a forensic alcohol analyst if they have received training⁶² for a specific instrument under a training program supervised by laboratories engaged in the practice of forensic alcohol analysis that is responsible for the maintenance of those instruments. Training may include the use of multimedia presentations, secondary trainers, and/or other methods, as approved by the laboratory. The training of operators shall include at minimum the following subjects:⁶³
- (A) Basic theory of operation;
 - (B) Detailed procedure of operation;
 - (C) Practical experience;
 - (D) Written and/or practical examination.

Article 6. Records

1220. General. Forensic alcohol laboratories and law enforcement agencies shall maintain records which clearly represent their activities which are covered by these regulations.
- 1220.1. Forensic Alcohol Laboratory Records.
- (a) Each laboratory that performs forensic alcohol analysis shall keep the following records for a period of at least five years:
 - (1) An up-to-date record of persons in its employ who are qualified to perform forensic alcohol analysis; the record shall include the qualifications of each such person, including education, experience, training and performance in proficiency and competency tests⁶⁴ and examinations;
 - (2) Records of samples analyzed by that laboratory under these regulations, their results and the identity of persons performing the analyses;
 - (3) Records of the quality control program;
 - (4) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;
 - (5) Records of such determinations of accuracy of breath testing instruments as a laboratory may perform for law enforcement agencies;
 - (6) Records of such training as a laboratory may provide to persons who operate breath testing instruments for law enforcement agencies.

1220.2. Evidential Breath Alcohol Analysis Records.

- (a) Each agency shall keep for a period of at least five years the following records for breath testing instruments which are under its jurisdiction:
 - (1) Records of instrument determinations of accuracy;
 - (2) Records of subject tests performed, results and identities of the persons performing analyses;
 - (3) Records of all maintenance and accuracy tests performed on each instrument;⁶⁵
 - (4) Records of all operators trained by the agency, including the names of instructors and the date of the training.⁶⁶

¹ Under 1215.1. on line 2, the term “agencies” is undefined. With the current regulations, “agency” was used in the context of law enforcement agencies. Applying that definition here would appear to require forensic alcohol laboratories to be operated by law enforcement. On lines 2 – 4, the statement, “Agencies....may exceed the requirements of these regulations” does not appear to be a regulation.

² Under 1215.2.(a), on line 3, correct “antiseptics” to “disinfectants” to agree with language used under proposed Section 1217.1.(c).

³ Under 1215.2.(b), on line 2, and the definition of forensic alcohol analysis, the change from “trained laboratory personnel” to “trained personnel” appears to be intended to broaden the scope of this regulation to include the analysis of breath samples by trained, non-laboratory personnel, i.e., law enforcement. This appears to create problems with the subsequent use of the term forensic alcohol analysis to mean the laboratory analysis of blood, urine, and tissue samples (see Sections 1216, 1217, 1218).

⁴ Under 1215.2.(e), on lines 2 –4, it should be noted that “trained laboratory personnel” do not normally “measure the concentration of alcohol in samples of...breath”.

⁵ Under 1215.2.(f), on line 3, and the requirement that a forensic alcohol analyst “meets the qualifications of 1216.2.,” note that the definitions section is normally used to define terms, but is not used to impose requirements.

⁶ Under 1215.2.(k), on lines 1 and 2, correct “Department of Health and Human Services” to “Department of Health Services”.

⁷ Under 1216.(a), the current regulatory format requires that sections of the regulations with multiple subsections begin with the letter designator, “(a)”.

⁸ Under 1216.(a), the requirement that, “Forensic Alcohol Analysis shall be performed only in laboratories...” does not appear to be consistent with new definition of forensic alcohol analysis [1215.2.(b)], which apparently includes the analysis of breath samples by non-laboratory personnel.

⁹ Under 1216.1., it would appear that there should be a requirement here that a laboratory employ persons qualified to perform forensic alcohol analysis. Also, the committee may wish to consider the need to qualify supervisory staff who can be responsible for all aspects of the performance of forensic alcohol analysis. The current regulations set forth specific experience requirements for supervisors (i.e., “two years of experience in performing forensic alcohol analysis, such experience to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol; or, in lieu of such two years of experience, satisfactorily completes a training course approved by the Department...”).

¹⁰ Under 1216.1.(a), on line 3, the reference to requirements for a quality control program “set forth in sections 1218.1 and 1218.2” is incorrect. Section 1218.3, describes the proposed requirements for the quality control program.

¹¹ Under 1216.1.(b), on line 1, “satisfactory performance” on a proficiency test needs to be defined. (Note: according to ASCLD/LAB guidelines, successful completion of a proficiency test shall mean either obtaining the correct response on the proficiency test or taking corrective actions in accordance with laboratory policy.) The committee should also note that a requirement here for “satisfactory performance,” may exceed the requirements of the law, since H&S Code §100702(b) only requires the laboratories to “participate” in an external proficiency test from an ASDCLD/LAB approved provider.

¹² Under 1216.1.(b), on line 3, the proposed language here is difficult to understand. The reference to a “proficiency testing program that follows the...(ASCLD-LAB) proficiency test program guidelines” appears to suggest ASCLD/LAB has published guidelines for proficiency testing programs. In fact, the guidelines are intended to apply to the laboratories. The language contained in the law [H&S Code § 100702(a)], i.e., “laboratories...shall follow...(ASCLD/LAB) guidelines for proficiency testing.” is clearer, but introduces the question as to whether each laboratory will be required to purchase an ASCLD/LAB technical manual in order to “follow” the current ASCLD/LAB guidelines. Moreover, the ASCLD guidelines for proficiency testing require the accredited labs to meet the requirements of a Proficiency Review Program. This program would not be available to non-accredited laboratories.

More generally, the Committee should consider the need to clarify and make specific the actual proficiency test requirements in regulation. The committee should consider frequency of proficiency testing and whether a laboratory should be required to participate in a proficiency test for each method it uses. The basic ASCLD/LAB requirement of only one proficiency test per year does not appear to be sufficient to adequately monitor the competence of the laboratories. Chemical standards and reagents degrade, instruments fail over time, etc. For this reason, laws and regulations covering clinical and workplace drug testing require three proficiency tests per year. The Department currently conducts three tests per year. Another reason for more frequent proficiency tests is that it gives a laboratory that fails a test, a chance, after correcting the analytical problem, to quickly demonstrate with a subsequent successful proficiency test that it’s back on track. Testing once a year would mean that it would take a year for a laboratory to re-demonstrate its proficiency.

¹³ Under 1216.1.(b), on line 5, correct the cited Health and Safety Code Section, i.e., correct “100701” to “100702”.

¹⁴ Under 1216.1.(b), on line 5, the regulations should clarify and make specific the requirements of H&S Code §107002(d) by clarifying what constitutes, “test results <that> are inconsistent with expected test results.” The committee should consider the need to describe the required corrective action taken in the regulations. Under the Department’s current program, a California laboratory that fails a proficiency test is required to provide DHS with a written report of the corrective action taken and

experimental data demonstrating that the method following this corrective action again meets the required standard of performance.

¹⁵ Under 1216.2.(a), on line 2, the reference to “natural sciences” (i.e., biology, chemistry, geology, physics, etc.) would appear to include the “physical sciences” referenced on line 1.

¹⁶ Under 1216.2.(a), on line 2, the requirements for coursework in chemistry are reduced here. The current requirements for the forensic alcohol analyst classification are 2 semesters of general chemistry plus a course in quantitative analysis, so there is a reduction in the required chemistry coursework here. To qualify for the current forensic alcohol supervisor class, a person must possess a baccalaureate or higher degree, or an equivalent, in chemistry, biochemistry, or other appropriate discipline as determined by the Department. In evaluating appropriateness of other disciplines the Department requires completion of upper division coursework in chemistry.

The committee should consider retaining the quantitative chemistry course requirement for the technical, analyst class. The Department imposes similar requirements for its various clinical scientist classifications. Quantitative analysis provides instruction in a number of areas of importance to forensic alcohol analysis including: chemical equilibrium, standard states, redox chemistry, gravimetric, volumetric and titrimetric procedures and use of indicators, method calibration, preparation of standards and reference materials, sampling procedures, and the statistical evaluation of data (precision, accuracy, reliability). Modern quantitative analysis courses typically also provide introductions to instrumental analysis covering spectrophotometry and chromatography.

¹⁷ Under 1216.2.(b), on line 1, the personnel qualification requirements appear to be significantly reduced here. The current regulations require the Department to evaluate personnel qualifications and set forth specific training and experience requirements and then require a demonstration of competency based on the completion of an external proficiency test and written examination provided by DHS. The committee may wish to clarify and make specific the requirements of new H&S Code Section 100702(c), which states, “Each examiner shall successfully complete at least one proficiency test annually.” However, according to the ASCLD/LAB guidelines, this annual proficiency test requirement can be satisfied by an “internal” proficiency test, i.e., samples prepared by the laboratory itself or even simply retests of case samples passed around among the analysts. Since the requirement here is entirely internal to the laboratory, the language of proposed Section 1216.1.(b) may be sufficient. The regulations should, however, at least define “examiner,” which is not otherwise defined in California law or regulations.

¹⁸ Under 1216.2.(b), on line 2, the committee should consider the need to provide a more detailed description of the training required to qualify a person to perform forensic alcohol analysis. This could include, a required period of training, the minimum number of samples analyzed, completion of an external proficiency test and written examination,

etc.. The regulations should recognize the different training requirements for staff of a laboratory that only supports breath alcohol analysis.

¹⁹ Under 1216.2.(c), the Department has qualified personnel employed by forensic alcohol laboratories in 2005 and will continue to do so. These individuals would apparently be excluded under the proposed new regulatory language.

²⁰ Under 1217, the general requirement here that samples be collected and handled in a manner that ensures that sample identity and integrity are maintained seems vague. Under the current regulations [Section 1219], Department approval is required and the Department reviews and approves the sample handling procedures described in the written methods submitted to the Department or available to the Department for inspection.

²¹ Under 1217.1., the Committee should consider the need to incorporate the Uniform Standards for the Collection of Blood Samples for Forensic Alcohol Analysis by reference. These standards, which are authorized by Vehicle Code Section 23158.(j), set forth requirements for the maintenance of the identity and integrity of the collected samples.

²² Under 1217.1.(a), on line 1, what is the significance of the proposed change here, "living individuals" to "living subjects"?

²³ Under 1217.1.(c), on line 3, the list of skin disinfectants should be revised to include povidone-iodine. In addition, the qualities of a suitable aqueous disinfectant should be defined, e.g., "A suitable aqueous disinfectant means a chemical agent dissolved in water, which is capable of destroying microbial flora on the skin surface."

²⁴ Under 1217.1.(f)(4), the regulations should be revised to state whether post-mortem samples should be treated with an anticoagulant.

²⁵ Under 1217.1.(g)(2), the minimum sample identifying information listed here should be evaluated with respect to the requirements of VC § 23158(c), which states, "Upon the request of the person tested, full information concerning the test taken at the direction of the peace officer shall be made available to the person or the person's attorney." The committee should also consider the sample identification requirements contained in the Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis [authorized by VC § 23158(j)]. The required information here includes: full name of subject, date and time blood drawn, initials/name of person drawing blood, initials/signature of witnessing officer, submitting agency, and geographical location where blood sample was drawn.

²⁶ Under 1217.2., the committee should consider a requirement here for the collection of sufficient sample to permit duplicate determinations analogous to the requirement included under proposed Section 1217.1.(b).

²⁷ See recommendation for 25, above.

²⁸ Under 1218.(b), on line 1, consider replacing “have” to “prepare.” The more active verb, prepare, more clearly connotes the need to maintain, detailed and up-to-date written method descriptions.

²⁹ Under 1218.(b)(2), on line 1, clarify the reference to “calibration” [also “calibrated” under 1218.2.(a)(1)] by adding a definition under Section 1215.2., e.g., “Calibration’ means the process of determining the relationship of the method response in the analysis of a secondary alcohol standard to the concentration of the standard.”

³⁰ Under 1218.(b)(2), on line 2, note that a complete written description of a forensic alcohol method would include: the procedures for collection and handling of samples, lists of reagents and equipment used, the procedures for standardization of secondary alcohol standards, the calibration procedures, the quality control program for the method, the procedures for calculating and reporting of results, and the maintenance of required records. The Department currently administratively requires laboratories to include these elements in their written method descriptions.

³¹ After 1218.1.(a), the text that begins, “The method shall be capable of the analysis of a reference sample...”, needs a section number.

³² After 1218.1.(a), on line 2, the regulations should define the term, “reference sample of known alcohol concentration.” In this instance, the reference samples should be prepared in a biological matrix. The requirements for the preparation and use of these samples to demonstrate that a method meets the required standard of performance were previously contained in guidelines published by the Department, but now should be spelled out in the regulations.

³³ After 1218.1.(a), on line 3, the regulations should define the accuracy and precision standard of performance requirements. Currently, DHS defines these requirements and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance. Also, anytime a laboratory relocates or changes a method, DHS requires a redemonstration of the methods ability to meet the required standards of performance.

³⁴ Under 1218.1.(a)(2), on line 1, correct, “The method should” to “The method shall” in order for the section to read as a regulation.

³⁵ Under 1218.1.(a)(2), on line 2, the regulations should define the freedom from interference from anticoagulants and preservative requirement. Currently, DHS defines this requirement and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance.

³⁶ Also, under 1218.1.(a)(4), on line 1, the proposed revision changing the criterion for reporting a negative result from “0.01%” to “0.010%” does not appear to actually change the requirements here.

³⁷ Under 1218.1.(a)(4), the regulations should more specifically define the requirement for results less than 0.01% requirement for the testing of subjects free of alcohol. Currently, DHS defines this requirement and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance.

³⁸ Under 1218.1.(b), on line 2, the regulations apparently would allow a laboratory to independently evaluate the ability of its methods to meet the required standards of performance. The committee should consider the need for state-level oversight in order to assure proper accountability.

³⁹ Under 1218.2.(a), see comment for 1215.2.(b). On line 1, the term “forensic alcohol analysis” here appears to refer exclusively to the analysis of blood, urine, and possibly tissue samples. However, the definition of “forensic alcohol analysis” provided under Section Under 1215.2.(b) includes the analysis of breath samples (Note: same comment applies to §§ 1218.2.(a)(2), 1218.2.(a)(2)(A), 1218.2.(a)(2)(A)(4), 1218.3.(a), etc.).

⁴⁰ Under 1218.2.(a), on line 2, the appropriate punctuation here would be a colon “:”.

⁴¹ Under 1218.2.(a)(1)(A), the definition of the term, “secondary alcohol standard” should be moved to Section 1215.2.

⁴² Under 1218.2.(b)(1)(B), on lines 2 – 3, clarify the reference to “oxidimetric method” (or more specifically “direct oxidimetric method”) by adding a definition under Section 1215.2., e.g. “Direct oxidimetric method’ means a method used for the quantitative determination of the alcohol present in an aqueous alcohol sample where the sample is directly mixed with and completely oxidized by a primary standard.” In addition, the regulations should set forth the requirements for employing the direct oxidimetric method, i.e., required number of replicate analyses, required precision, number of significant figures used to record results, etc. These requirements were previously contained in guidelines published by the Department, but now should be spelled out in the regulations.

⁴³ Under 1218.2.(a)(1)(B), on line 3, clarify the reference to “primary standard” by adding a definition under Section 1215.2., e.g., “Primary Standard’ means a material which is chemically pure, of known chemical equivalence and stoichiometry, stable, and can be dried and weighed out for the preparations of solutions of accurately known concentrations for use in the analysis of alcohol using a direct oxidimetric method.”

⁴⁴ Under 1218.2.(a)(1)(B), on lines 5 – 6, the terms, “NIST traceable secondary standards” and “certificate of independent analysis verifying the value of the standard” should be clarified. According to NIST (National Institute of Standards and Technology), this organization currently does not have any criteria or protocols to define “NIST traceability” for aqueous alcohol standards. NIST does manufacture a suite of aqueous alcohol standard reference materials or SRM’s (SRM’s 1828B, 1847, and 2891 – 2899)). The regulations could be revised to qualify this material as the secondary standard. However, the NIST alcohol SRM’s are fairly expensive (~\$60 per 1.2 mL

ampoule) and there would be an obvious incentive for a laboratory to prepare its own standard and then qualify it by analyzing the new standard concurrently with the NIST SRM by a gas chromatographic (GC) method. There are two problems with this approach: 1) it would conflict with the requirements of the proposed regulations (proposed section 1218.2.(a)(1)(B) states, "Each forensic alcohol laboratory shall establish the concentration of each lot of secondary alcohol standards it prepares by an oxidimetric method..."); and 2) the new standard qualified against the NIST SRM by the indirect GC method, would be properly characterized as a tertiary standard, not a secondary standard.

The committee should carefully consider the option of retaining the requirement that each laboratory establish the concentration of each lot of secondary alcohol standards it uses, whether prepared or acquired, by an oxidimetric method which employs a primary standard. Primary standards are commonly employed in analytical chemistry. They establish a reference point that helps ensure that the analyses are accurate and reliable. Primary standards are chosen based on very specific characteristics. They must be extremely pure, very stable, and have a high molecular weight. Based on these criteria, alcohol would not qualify as a primary standard. The primary standard and secondary standard should be linked by an absolute chemical method. Qualifying a standard based on an indirect chromatographic method could introduce errors. Introducing multiple levels of indirect analysis could increase the likelihood of error. The approach required by the current regulations, which involves the direct analysis of the secondary standard appears to be superior. Introducing any potential errors in an analytical system, which is designed to yield results that become evidence in legal proceedings, does not seem warranted.

⁴⁵ Under 1218.3.(a)(2), on line 2, the regulations should specify the number of significant figures used to represent the mean value. Based on the proposed revisions to the specification of the range of alcohol concentrations for the reference material, it would appear that the laboratories should employ three significant figures here.

⁴⁶ Under 1218.3.(a)(3), on line 2, the regulations should specify the number of significant figures employed in evaluating the acceptable limits. Based again on the proposed revisions to the specification of the range of alcohol concentrations for the reference material, it would appear that the laboratories should employ three significant figures here.

⁴⁷ Under 1218.3.(a)(5), on line 2, the amendment changing the words "the method shall be regarded to be in error " to "the analysis shall be regarded to be in error" would appear to now require a definition of the term, "analysis."

⁴⁸ Under 1218.4.(a)(1), on line 1, the revised symbol, "gram(s) %" (i.e., w/ the parentheses) is very awkward.

⁴⁹ Under 1219, on line 1, and the reference to "evidential breath alcohol analysis," the term "evidential" should be defined. (Note: If the intent here is to distinguish the post arrest breath tests from preliminary alcohol screening (PAS) tests, the addition of the

qualifier “evidential” may not be helpful. PAS results are frequently introduced as evidence. More generally, the committee may wish to consider the need to include PAS devices in the regulations since the Vehicle Code includes specific references to the use of these devices to measure alcohol concentration [e.g., Vehicle Code Section 23612(h)] and even the requirement for their use under certain circumstances [i.e., Vehicle Code Section 13388(a)].

⁵⁰ Under 1219, the regulations should include the requirement that laboratories prepare detailed, up-to-date written descriptions of the procedures employed in support of breath alcohol analysis performed by law enforcement agencies. The Department currently administratively imposes this requirement, which is analogous to the requirement under Section 1218.(b) that a laboratory prepare written descriptions of its forensic alcohol method(s). The procedures for breath alcohol analysis should include procedures for periodically determining the accuracy of the instruments and procedures for training instrument operators.

⁵¹ Section 1221.1.(b)(1) of the current regulations requires breath alcohol analysis to be under the direct jurisdiction of a governmental agency or licensed forensic alcohol laboratory. It would appear that some jurisdictional requirement should be retained.

⁵² Under 1219.1., this section actually describes the standard of performance of the breath testing instruments.

⁵³ Under 1219.1., on lines 1 – 3, incorporation of the NHTSA document by reference will require a full document citation to conform to the clarity requirements of the Administrative Procedures Act, which states that all published material cited in the regulations must be specifically identified.

⁵⁴ Under 1219.3, this section should be amended to specify the symbols used to express the units, grams per 210 liters.

⁵⁵ Under 1219.4. on lines 3 – 4, the proposed change in the list of prohibited activities, i.e. , “the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked” to “the subject must not have ingested alcoholic beverages or other substances, regurgitated, vomited, or smoked” does not appear to improve clarity.

⁵⁶ Under 1219.4, the committee should consider adding the use of mouth spray, gum, or mints to the list of prohibited activities.

⁵⁷ Section 1219.6., should be revised as follows:

- a) The clause defining “periodic” should be moved to a separate subsection (Otherwise, the two sentences should be separated by a period).
- b) On line 2, the reference to alternative analyses of a “reference solution or gas sample” is incorrect, since in both cases, the breath instrument is only capable of analyzing a gas-phase alcohol sample. Moreover, the regulations should

clarify the choices of equipment used to periodically determine the accuracy of the breath instruments. This would require definitions of the wet bath and dry gas calibrating units and a specification of any procedural requirements. For wet-bath units, this could include the allowed reference solution temperature range, need to record the solution temperature, limits on the number of uses of a given solution, etc. These requirements were previously contained in guidelines published by the Department, but now should be spelled out in the regulations.

- c) The regulations should clarify who supplies the reference samples used to periodically determine the accuracy of the instrument. (Note: Section 1221.4.(a)(2)(A) of the current regulations requires that the sample shall be provided by a forensic alcohol laboratory).
- d) The regulations should clarify who evaluates the results of the periodic analyses of the reference sample to determine whether the instruments continue to meet the accuracy requirements (Note: Section 1221.4.(a)(2)(A)1. of the current regulations requires that the results shall be used by a forensic alcohol laboratory to determine if the instrument continues to meet the required accuracy.)
- e) The regulations should set forth requirements for the maintenance of records of the laboratories' periodic determinations of accuracy including the frequency of such analyses and who performs the periodic analyses of the reference sample determine the accuracy of the instruments as required under Section 1221.4.(a)(6) of the current regulations.

⁵⁸ Under 1219.7., the Section title here should be changed to "Standards of Procedure." The subsequent regulations under this section clearly set forth procedure requirements and are generally similar to those found under Section 1221.4., Standards of Procedure, of the current regulations.

⁵⁹ Under 1219.7.(a), see recommendation b) for 1219.6. The description of the analysis of a "reference alcohol/water standard or a dry gas alcohol standard..." is incorrect, since in both cases, the breath instrument is only capable of analyzing a gas-phase sample. (Note: the units, "grams/210 liters" shown on lines 3 and 5 would not make sense for an aqueous alcohol sample.)

⁶⁰ Under 1219.7.(b), on line 4, the procedures for purchasing and using dry-gas calibrating units must be clarified. The term "NIST traceable reference standards" needs to be defined. (Note: NIST does not currently certify "traceable reference standards." NIST does certify "NIST Traceable Reference Gas mixtures" (NTRM), including ethanol-nitrogen mixtures. Two manufacturers, Airgas and Scott Specialty Gases have NTRM agreements with NIST, but neither vendor makes the NTRM's available for sale. Both offer what can be described as NHTSA qualified calibrating units and conduct quality control programs, which include a comparison of each unit with their own NTRM's.

⁶¹ Under 1219.10., on lines 2 –3, the requirement that breath instrument operator trainees complete a “written and/or practical examination” is duplicated immediately below under Section 1218.10.D.

⁶² Under 1219.10., on line 5, the language, “Breath alcohol analysis may be performed by operators who do not meet the requirements of a forensic alcohol analyst if they have received training...” is not clear. If the intent here is to permit a forensic alcohol analyst (i.e., person qualified under 1216.2.) to perform a breath test, then language similar current regulations should be adopted (i.e., current Section 1221.4.(a)(5), which states, “An operator shall be a forensic alcohol supervisor, forensic alcohol analyst, forensic alcohol analyst trainee or a person who has completed successfully the training described under Section 1221.4 (a) (3) and who may be called upon to operate a breath testing instrument in the performance of his duties.”).

⁶³ Under 1219.10., the committee should strongly consider retaining the requirement that the training (and therefore the procedure for performing breath testing) include the precautionary checklist as required under current Section 1221.4.(a)(3)(D). The checklist serves to help document that a given test was properly administered. In many jurisdictions, the precautionary checklist plays a key role in assuring the identity and integrity of the results. These checklists are signed by the officer-operator and are used to record the officer’s observations.

⁶⁴ Under 1220.1.(a)(1), on lines 4 and 5, the references to “competency tests” and “examinations” must be clarified and defined since there are no requirements for either tests or examinations described under Section 1216.2. (The current regulations, Sections 1216.1.(e)(3) and 1216.1.(f)(4), require laboratory staff to successfully complete an external proficiency test and written examination conducted by the Department.)

⁶⁵ Under 1220.2.(a)(3), clarify the amendment to the regulations to require law enforcement agencies to keep records of “maintenance and accuracy checks” performed on the instruments. While instrument maintenance is not otherwise described in the regulations, in California, the standard of practice has been for the forensic alcohol laboratory, not law enforcement, to perform maintenance as part of its procedures for determining the accuracy of the instruments. Law enforcement personnel (qualified operators) may conduct the tests employed for the periodic determinations of accuracy, but this is already described under proposed Section 1220.2.(a)(1).

⁶⁶ Under 1220.2.(a)(4), clarify the amendment to the regulations to require law enforcement agencies to keep records of “all operators trained by the agency (emphasis added).” The current regulations [Section 1221.4.(a)(4)] require that such training be conducted by the laboratories under supervision of laboratory staff. All operator training programs must be approved by DHS (Section 1218). The proposed amendments to the regulations (new Section 1219.10) would apparently reduce the level of oversight to training “supervised by laboratories engaged in the practice of forensic alcohol analysis”. The new regulations would also add the vague language, “Training may

include the use of multimedia presentations, secondary trainers, and/or other methods, as approved by the laboratory.” The proposed revisions here to the record keeping requirements now suggest that the law enforcement agencies would be independently training the operators.

It should be noted that the former *ad hoc* Advisory Committee on Alcohol Determination, a group which included a representative from CACLD, recommended that specially qualified law enforcement personnel (breath test operator supervisors) be permitted to train other officers, but only after the operator supervisor had received special advanced training from the forensic alcohol laboratory. Representatives on the advisory committee from the laboratories agreed to develop a standardized operator supervisor training course covering the core competencies required for supervising breath instrument operators. The laboratories never completed this project.