

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
 TITLE 17. PUBLIC HEALTH
 DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
 CHAPTER 2. LABORATORIES
 SUBCHAPTER 1. SERVICE LABORATORIES
 GROUP 8. FORENSIC ALCOHOL ANALYSIS AND BREATH ALCOHOL ANALYSIS¹
 ARTICLE 1. GENERAL

This database is current through 05/12/06, Register 2006, No. 19.

s 1215. Authority.

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

Comment [GH1]: Repealed as a Rule 100 change.

s 1215.1. Definitions.

(a) "Alcohol" means the unique chemical compound, ethyl alcohol, with the exception that reference in these regulations to compounds to be avoided as skin antiseptics includes the generic class of organic compounds known as alcohols.

(b) "Forensic Alcohol Analysis" means the ~~practical application use~~ of specialized devices, instruments, and methods by ~~trained laboratory forensic alcohol~~ personnel² to measure the concentration of ~~ethyl~~ alcohol in samples of blood, breath³, urine, or tissue of persons involved in traffic accidents or traffic violations.[1]

(c) "Breath Alcohol Analysis" means ~~analysis-an examination~~ of a sample of a person's expired breath, using a breath testing instrument designed for this purpose, in order to determine the concentration of ~~ethyl~~ alcohol in the person's ~~blood~~breath.¹

(d) "Concentration" means the weight amount of alcohol contained in a unit volume of liquid or a unit volume of gas under specified conditions of temperature and pressure; in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit weight of specimen.

(e) "Forensic Alcohol Laboratory" means a place at which specialized apparatus, instruments, and methods are used by ~~trained laboratory forensic alcohol~~ personnel⁴ to measure the concentration of alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other

Comment [DoHS2]: Page: 1
 OOR: Amendments to definitions were proposed in the regulations redraft dated 1/26/06. Some of those still would be advisable. All the amendments suggested in the proposed regulation text are for the purposes of clarity of the current language so that the use of the term is understandable in the operating standards and does not suggest multiple meanings.

¹ The reference here to breath alcohol analysis is not necessary and should be deleted. H&S Code section 100700(a) refers to "forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath...". This indicates that "forensic alcohol analysis" includes the analysis of breath samples.

² The new term, "forensic alcohol personnel" is not defined in regulation. It will now need to be defined with the qualifications specified.

³ Inclusion of "breath" in the list of samples covered by forensic alcohol analysis, while consistent with the statutes [H&S Code Section 100700(a)], means that all subsequent references to forensic alcohol analysis in the regulations (total of 28 such references) could be interpreted as applying to the analysis of breath samples.

⁴ Replacing the term "trained laboratory personnel" with "forensic alcohol personnel," does not sufficiently distinguish the laboratory analysts from the trained breath instrument operators (typically law enforcement personnel). Also, as noted above, the new term, "forensic alcohol personnel" is not defined in regulation.

than forensic alcohol analysis.⁵

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

(g) "Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the ~~technical procedures methods~~ 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 methods~~ⁱⁱ of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.

(i) "Method" means the steps used by a trained person to make a measurement of alcohol concentration in a sample or specimen.^{iii, 6, iv, 7, 8}

(j) "Instrument" or "Device"⁹ 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.~~

Comment [GH3]: Repealed as a Rule 100 change.

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

Comment [DoHS4]: Page: 2
OOR: "taken" is a term that does not readily apply to "artificially constituted material." Could the term "obtained" be used instead?

(m) "Alveolar" refers to the smallest air sacs in the lungs and to that portion of the expired breath which is in equilibrium with respect to alcohol with the immediately adjacent pulmonary blood.

⁵ The definition of a forensic alcohol laboratory should be revised to be consistent with the recent changes to the forensic alcohol analysis laboratory statutes. Additional definitions for the general term "laboratory" and for entities engaged only in breath alcohol analysis should be considered.

⁶ The committee considered eliminating the added language, "in a sample or specimen", but ultimately decided to retain it.

⁷ The committee considered the need to differentiate methods used by laboratory staff from procedures used by law enforcement, but did not reach a decision on this.

⁸ The definition of method here is broad enough to include the steps used by law enforcement to analyze a breath sample. Accordingly, every reference to "method" in the regulations (total of 24 such references) could be interpreted as applying to breath alcohol analysis.

⁹ The definition of the word "device" here as an item of equipment used to measure alcohol concentration is not consistent with its use in the statutes. H&S Code 100701 uses the term "calibrating devices." Calibrating devices (or calibrating units) are used to provide a sample of known alcohol concentration to check the accuracy of the breath instrument. They do not have any capability of measuring alcohol concentration. The term "device" is used in DOT publications to refer both to items of equipment that measure alcohol concentration (e.g., "Model Specifications for Devices to Measure Breath Alcohol") and that are used to deliver samples of known alcohol concentration. The use of the term device in the statutes and in DOT publications is consistent with the general dictionary definition of the word, i.e. "a piece of equipment or a mechanism designed to serve a special purpose or perform a special function." Accordingly, it would be appropriate to delete inclusion of the word device here thus eliminating the restriction of the use of the term to mean only equipment used to measure alcohol concentration and instead rely on the common dictionary definition of the word, "device".

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

ARTICLE 2. REQUIREMENTS FOR FORENSIC ALCOHOL LABORATORIES

s 1216. Authorization Requirement.

~~(a) Every laboratory performing forensic alcohol analysis shall have a valid license issued in accordance with the provisions of these regulations.~~

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

(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.~~

s 1216.1. Qualifications ~~for Licensing to perform forensic alcohol analysis.~~

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

(1) Employing at least one forensic alcohol supervisor or analyst.^{10,vi} If forensic alcohol analysis is performed by persons other than forensic alcohol supervisors, such persons shall meet the qualifications set forth in ~~these regulations this section~~ for forensic alcohol analysts or forensic alcohol analyst trainees; [2]¹¹

(2) Maintaining a quality control program in forensic alcohol analysis procedures as specified in section 1220.3; [2a]

~~(3) Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department; Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702.~~ [3]

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

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

¹⁰ The added term "analyst" here should be corrected to "forensic alcohol analyst" [cf. Section 1215.1.(g)].

¹¹ With the proposed revision to eliminate the requirement that a laboratory must employ a forensic alcohol supervisor, the remainder of this section, which describes the requirements for forensic alcohol analysis by persons other than forensic alcohol supervisors, should now be revised or eliminated since it simply repeats the requirements of current Section 1216.(a)(1).

Comment [GH5]: Repealed as a Rule 100 change.

Comment [DoHS6]: Page: 3
OOR: Possible reasoning to include in the ISOR to support this "rule 100" change might involve a statement that the term "Department" is repealed because the committee did not determine that the direct involvement of the CDHS in a regulatory program was necessary to ensure the competence of the labs or employees and as a result, the committee chose to remove all reference to the "Department" from the current regulation text. Although Health and Safety Code section 100725 states that CDHS shall enforce the statutes and regulations, the law does r... [1]

Comment [GH7]: The subcommittee intention is to repeal the entire Section 1216. This d... [2]

Comment [GH8]: Repealed as a Rule 100 change.

Comment [DoHS9]: Page: 3
OOR: the term "these regulations" is vague and can be construed to... [3]

Comment [DoHS10]: Page: 3
OOR: The question arises as to whether the requirements in (a)... [4]

Comment [DoHS11]: Page: 3
OOR: Possible reasoning to include in the ISOR to support the... [5]

Comment [GH12]: Repealed as a Rule 100 change.

Comment [GH13]: Repealed as a Rule 100 change.

Comment [GH14]: JUSTIFICATIO
N: The deletions are required by changes in the law. However, t... [6]

Comment [GH15]: Repealed as a Rule 100 change.

Comment [DoHS16]: Page: 3
OOR: This language is not truly "regulatory," but can be used if... [7]

Comment [DoHS17]: Page: 3
OOR: Do national standards make the requirement that a person v... [8]

Comment [DoHS18]: Page: 3
OOR: Is the QA program specified in section 1220.3 based on comp... [9]

Comment [let19]: Current section repealed as a Rule 100 change. Alternative language inserted... [10]

Comment [GH20]: Stipulation of the location of the proficiency testing requirements is necessary to... [11]

Comment [GH21]: Repealed as a Rule 100 change.

Comment [DoHS22]: Page: 3
OOR- This language is very vague. It offers no understanding of v... [12]

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

Comment [Jet23]: Rule 100 change

~~(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.~~

Comment [DoHS24]: Page: 4
OOR: This again is a subsection that does not make much sense in light of the repeal of licensing requirements. This requirement is something that is standard in regulation text that has an enforcement component that involves CDHS action. It flows in licensing regulations from the criteria to be licensed needing to be maintained because the licensing is an action that happens at a distinct point in time, and then in theory, the licensee could decide after that point not to continue to meet the criteria set as necessary to be licensed. In this case, there is no distinct point in time when a lab becomes a forensic alcohol lab. The lab makes this determination for itself, and it is something that is a continuous process of decision that happens every time the lab accepts a specimen for analysis. That is, if the lab calls itself a forensic alcohol lab, then it legally is if it meets the requirements of this section. Requiring that the lab has to continue to meet the qualifications does not really logically flow in this spe... [13]

~~(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) A forensic alcohol supervisor is a person who meets the following qualifications:¹²

(1) Possesses a baccalaureate or higher degree, ~~or an equivalent¹³~~, in any physical or natural science in chemistry, biochemistry, or other appropriate discipline as determined by the Department;

Comment [GH25]: Repealed as a Rule 100 change.

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

Comment [GH26]: Repealed as a Rule 100 change.

(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 alcohol analysis;

(E) Instruments and procedures for breath alcohol analysis;

(F) Practical laboratory demonstration of the student's ability to perform 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;

Comment [GH27]: Repealed as a Rule 100 change.

Comment [DoHS28]: Page: 4
OOR: Again, this is not regulating language. OOR recommends the language used in the redraft of 1/26/06, but if the committee wishes to retain this language, it may, as there is no qualifying process... [14]

Comment [GH29]: Justification: All scientific disciplines that are relevant to the practice of forensic alcohol analysis and insures the competence of those performing forensic alcohol analysis are included. This additionally provides uniformit... [15]

Comment [GH30]: Repealed as a Rule 100 change. (OOR: to support the "rule 100" change, the committee will need to determine that it does not see a role for CDHS in course approval as necessary to ensure the competence of labs or employees.)

¹² The committee should clarify whether individuals are qualified as forensic alcohol supervisors at a specific forensic alcohol laboratory. (Note: this would also apply to the forensic alcohol analyst and forensic alcohol analyst trainee classifications.)

¹³ The committee discussed the need to retain "or equivalent," but there was no final decision on this.

Comment [DoHS31]: Page: 4
OOR: Have the listed subjects been determined necessary to ensure competence by an accrediting body or some other expert source? It might be possible to simply cite the experience of CDHS in enforc... [16]

(H) Court testimony;

(I) Court decisions regarding chemical tests of alcohol to determine alcohol influence; and

(J) Requirements of ~~these regulations~~ Title 17 of the California Code of Regulations, sections 1215 to 1222.2¹⁴ inclusive;

~~(3) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department. At a minimum successfully replicate the known results of a variety of four competency test samples ranging from zero to 0.25 percent alcohol using the methods of Article 6.^{15, ix}~~

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

(5) Or in lieu of (1) and (2) above, e^{xi} 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,^{16, xii} or be qualified by the Department of Health Services [4] as a Forensic Alcohol Supervisor on or before (we will insert date for the expected filing the public notice with OAL).

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

(1) Possess a baccalaureate or higher degree in one of the physical or natural sciences that includes one year (2 semesters or 3 quarters) of general chemistry including lab work^{17, xiii} 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; [5]

(2) Successfully completes a training period in forensic 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;^{xiv} [6]~~

~~(4) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department. At a minimum successfully replicate the known results of a variety of four competency test samples~~

¹⁴ Since the committee proposed deleting Section 1222.2, this should be changed to "1222.1."

¹⁵ The term "competency test samples" should be defined and distinguished from proficiency testing which is referenced in the statutes and used elsewhere in the regulations. The requirement to "successfully replicate the known results" should be clarified by defining what constitutes a successful replication and who determines this. The regulations should also clarify whether the competency test is external or internal.

¹⁶ The committee considered eliminating the grandfathering provisions here and under Section 1216.1.(f)(6), but did not make a decision.

¹⁷ The committee briefly discussed eliminating the specific chemistry coursework requirements here, but did not reach a decision.

Comment [GH32]: Repealed as a Rule 100 change.

Comment [DoHS33]: Page: 5
 OOR- It is appreciated that this is the current language, but it is vague. This language was supported by the forensic alcohol program's guidance documents that described how one was to demonstrate this ability. Since there will no longer be a department determining this ability, this is a questionable provision to maintain. Unless the regulation describes something that assists the forensic alcohol supervisor in knowing how he is to "demonstrate" his ability and provide guidance for the courts so this can be measured, OOR recommends this provision be repealed and organize the grandparenting subsection differently to assist with logical flow. If the committee elects to keep this provision, then the ISOR will need to offer some statement that labs will determine this for themselves so that courts will not be put in the position of making decisions regarding this demonstration each time a supervisor is there. Of course, if the labs ... [17]

Comment [DoHS34]: Page: 5
 OOR: This grandparenting language was from the initial promulgation of the FAL regulations and is 36 years old. Are there any persons in practice now who are qualified as FA ... [18]

Comment [GH35]: Justification: Addition of this statement allows for all applicable grandparenting under this provision. (OOR- There is a mechanism for making these kinds of stipulations in regulation. We ... [19]

Comment [DoHS36]: Page: 5
 OOR: Please refer to the note in DoHS 28.

Comment [GH37]: Justification: Proposed regulations require analysts have a science degree as a minimal qualification, consistent with forensic science community requirements for analytical work. The original ... [20]

Comment [GH38]: Justification: The term "period" is vague and has been deleted for clarity.

Comment [GH39]: References to "clinical" have been deleted as the regulations pertain to the defined forensic lab only and the training should be specific to forensic alcohol testing. (OOR- While it is per ... [21]

Comment [GH40]: Justification: The term "period" is vague and has been deleted for clarity.

Comment [GH41]: Repealed as a Rule 100 change.

ranging from zero to 0.25 percent alcohol using the methods of Article 6.^{xv}

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

Comment [DoHS42]: Page: 6
OOR- Please see comments in DoHS 33 comment. Issues are the same here.

(6) Or in lieu of (1) and (2) above, eE^{xvii}; either is a person who, prior to January 1, 1971, was a clinical laboratory technologist licensed under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol analyst or be qualified by the Department of Health Services as a Forensic Alcohol Analyst on or before (we will insert date for the expected filing the public notice with OAL) the effective date these regulations are promulgated.

Comment [GH43]: Justification:
Addition of this statement allows for all applicable grandparenting under this provision. (OOR- Please see OOR comments in DoHS 34 and 35.)

(g) A forensic alcohol analyst trainee is a person who meets the following qualifications:¹⁸

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

Comment [DoHS44]: Page: 6
OOR- The ISOR will need to discuss briefly or at least cross reference to the reasoning for the requirement of a greater amount of education in amended regulations of qualifications for the trainee. A note that offers that trainees become analysts on completion of the training would suffice to support the change.

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

Comment [GH45]: Repealed as a Rule 100 change.

ARTICLE 3. LICENSING PROCEDURES

~~s 1217. Forensic Alcohol Laboratory License.~~

Comment [GH46]: The entire contents of Article 3 have been repealed as a Rule 100 change.

~~(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.~~

~~s 1217.1. Renewal of 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.~~

¹⁸ The committee should consider placing a time limit on the trainee class qualification (one-year under the current regulations).

~~(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.~~

~~s 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.~~

~~s 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.~~

~~s 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.~~

~~s 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.~~

~~s 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.~~

~~s 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.~~

~~s 1217.8. Fees and Other Procedures.~~

~~The annual application fee for a Forensic Alcohol Laboratory License or its renewal shall be one hundred dollars (\$100). A laboratory operated by the state, city or county or other public organization shall be exempt from the annual application fee requirement. Other procedures in the administration of these regulations shall be carried out as set forth in Chapter 5 (commencing with section 436.50) of Part 1 of Division 1 of the Health and Safety Code. Such other procedures include suspension or revocation of license, denial of license, and disciplinary action.~~

~~ARTICLE 4. TRAINING OF PERSONNEL~~ ¹⁹

~~s 1218. Training Program Approval.~~

~~Any organization, laboratory, institution, school, or college conducting a course of instruction for persons to qualify under these regulations shall submit a course summary and list of instructors and their qualifications to the Department for approval.~~

~~s 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.~~

~~s 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.~~

ARTICLE 5. COLLECTION AND HANDLING OF SAMPLES

s 1219. General.

~~Samples taken for forensic alcohol analysis and breath alcohol analysis shall be collected and handled in a manner approved by the Department. The identity and integrity of the samples shall be maintained through collection to analysis and reporting.~~ [7]

Comment [GH47]: The entire contents of Article 4 have been repealed as a Rule 100 change. (OOR- This is arguably not a Rule 100 change. The statute repeals the licensing of the laboratories; however, it does not say that the CDHS shall not approve training of personnel. OOR recommends that the ISOR reasoning offer that the committee determined that CDHS was not the appropriate body to determine the suitability of training for personnel nor was CDHS the appropriate body to require and monitor examinations or other such tests nor is CDHS oversight necessary in these areas to ensure the competence of employees of the lab, and the reasons for that determination. This extra reasoning will help support the repeal as part of non-emergency rulemaking in the APA.)

Comment [GH48]: Repealed as a Rule 100 change. (OOR: reasoning is recommended to address that the committee determined that CDHS approval of collection and handling procedures is not necessary to ensure competence of labs and employees.)

¹⁹ The committee did not discuss the reasons for deleting Article 4.

s 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 only by persons authorized by Section ~~13354~~23158(a) of the Vehicle Code.

Comment [DoHS49]: Page: 9
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

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

Comment [GH50]: Vehicle Code section 13354 was renumbered in Stats 1985, c.735,S4 to Vehicle Code section 23158(a).

(c) Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. Aqueous benzalkonium chloride (zephiran), ~~aqueous merthiolate~~^{xviii} or other suitable aqueous disinfectant²⁰ shall be used.

Comment [GH51]: NOTE FOR COMMITTEE: Use of merthiolate was not deleted to avoid making a change to this section. (OOR: In light of the OAL determination, it is reasonable to make the amendment if the committee so desires.)

(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:[8]

(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.~~^{xix}

Comment [GH52]: NOTE TO COMMITTEE: Use of preservatives was not revised to avoid making a change to this section. (OOR: In light of the OAL determination, it is reasonable to make the amendment if the committee so desires.)

(2) Care shall be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom. The sample shall be taken from a major vein or the heart.

(g) 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 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 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. [9]

²⁰ The regulations should define the term, "suitable aqueous disinfectants."

s 1219.2. Urine Collection and Retention. ²¹

(a) The ~~only approved~~ urine sample shall be ~~a sample~~^{xx} collected no sooner than twenty minutes after first voiding the bladder.

Comment [DoHS53]: Page: 10
OOR: The regulation does not say who approves the urine sample? This could be rewritten like the rest of the section: "A urine sample shall be collected"

(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 a clean container together with a copy or transcript of the identifying information carried by²² the original sample ~~container~~.^{23, xxi}

Comment [DoHS54]: Page: 10
OOR: The language in subsections (c) and (c)(1) are inconsistent. Subsection (c) refers to labs because that is what you propose to be regulating and (c)(1) refers to labs and law enforcement agencies retaining the specimen. If law enforcement has the specimen, how is the lab to "retain for one year after the date of collection" as specified in (c)? This language needs to be redrafted if you wish to retain these provisions.

s 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.~~^{xxii} The breath sample shall be collected only after the subject has been under continuous [10] 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. [11]

Comment [GH55]: Repealed as a Rule 100 change. New H&S code dictates instruments on the DOT list that can be used. Laboratories no longer need to perform this testing. (OOR- Recommend providing further explanation, because it is not clear how the instruments specified make it unnecessary to specify this quantity of sample. OAL will probably not understand this either, so please explain so it is clear how this is a Rule 100 change.)

ARTICLE 6. METHODS OF FORENSIC ALCOHOL ANALYSIS

s 1220. ~~General~~.

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

Comment [DoHS56]: Page: 10
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

(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.

Comment [GH57]: Repealed as a Rule 100 change.

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

Comment [GH58]: Repealed as a Rule 100 change. (OOR- Recommend that the "on file" part be repealed as well because the question arises "on file" with whom from the phrasing that remains. It may be reasonable to require that the lab will have these descriptions "on site.")

(2) Each such description shall include the calibration procedures and the quality control

Comment [GH59]: Repealed as a Rule 100 change. (OOR- Recommend that you remove the "and shall be available for inspection on request" part because the question arises as to inspection by whom and why.)

²¹ The regulations should include a requirement to collect a sufficient volume of urine sample to permit duplicate determinations analogous to the requirement for blood samples under Section 1219.1.(b).

²² The phrase, "by the original sample container," is shown here, but under Section 1219.1.(g)(2), the equivalent requirement uses the phrase, "on the original sample container."

²³ The committee discussed OOR's concerns regarding the application of this section to the laboratory and to law enforcement, but decided not to make any changes.

program for the method. [12]

s 1220.1. Standards of Performance.

(a) Methods for forensic alcohol analysis shall meet the following standards of performance: [13]

(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 ~~0.100,08~~ grams per 100 milliliters or higher;

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

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

(4) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ethyl alcohol by qualitative test;

(5) The method shall give a test result which is always less than 0.01 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.

(b) The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by the laboratory's designated²⁴ forensic alcohol supervisor or forensic alcohol analyst^{xxiii} Department using a laboratory's proficiency test results and such ability must meet the requirements of these regulations. [14]

s 1220.2. Standards of Procedure.

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

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

(A) Such alcohol solutions are secondary standards.

(B) Each forensic alcohol laboratory shall purchase National Institute of Standards and Technology (NIST) traceable secondary alcohol standards, [15] or establish the concentration of each lot of secondary alcohol standards it prepares using uses, whether prepared or acquired, by an oxidimetric method [16] which employs a primary standard, such as United States National Bureau of Standards-NIST potassium dichromate.

(C) The forensic alcohol laboratory shall verify the concentration of any new secondary standards used in the method by analyzing the new secondary standard concurrently with a previously analyzed secondary standard. [17]

Comment [DoHS60]: Page: 11
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

Comment [GH61]: Repealed as a Rule 100 change. (OOR- This is not really a rule 100 change. The change is for the same reason as offered in GH62, GH71, and GH82. It is best to explain this in the ISOR as a change in the CA Vehicle Code standard of legal intoxication and the need of the labs to be able to accurately test at this level.)

Comment [GH62]: Justification: Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

Comment [GH63]: Repealed as a Rule 100 change. (OOR- So who is it evaluated by? Anybody who chooses to? Defense attorneys, maybe? Courts? And what if they choose to evaluate it by some other means or measures? What is anyone going to do about it? This is a remnant of the repealed CDHS licensing provisions. OOR recommends that all of subsection (b) be repealed because it is meaningless without the "by the Department" statement in it.)

Comment [DoHS64]: Page: 11
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

Comment [GH65]: NOTE to FARC: Use of dry gas units has not been introduced here.

Comment [GH66]: Justification: Use and acceptance of NIST traceable standards in the scientific community (such as CA licensed clinical) has long been in existence due to their enhanced international reliability. This change includes the alternative use of NIST traceable standards within the laboratory setting. (OOR- This sounds like it is some sort of standard established in the laboratory community. If so, is it written anywhere? If so, the ISOR needs to cite and provide that document to support the inclu[... [22]

Comment [GH67]: Justification: The National Bureau of Standards is now known as NIST.

Comment [GH68]: Justification: This is a general scientific practice utilized in scientific laboratories. The purpose of including it here is to mandate this practice by the laboratories. (OOR- Please provide some written source or other [... [23]

²⁴ The new reference here to a "designated" staff person is not clear.

(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 1220.3 and shall include at least duplicate analyses of samples for forensic alcohol analysis.

(A) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.

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

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

s 1220.3. Quality Control Program.

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

(1) For each method of forensic alcohol analysis it performs, each forensic alcohol laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which it shall analyze along with each set of samples; the alcohol concentration in the reference material shall be between ~~0.10~~0.08 and 0.20 grams per 100 milliliters of liquid;

(2) For each lot of quality control reference material, the laboratory shall determine a mean value of at least 20 replicate analyses, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis; [18]

(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, 0.01 grams per 100 milliliters; [19]

(B) The higher limit shall be calculated by adding, to the mean value, 0.01 grams per 100 milliliters; [19]

(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 method shall be regarded to be in error, and a forensic alcohol supervisor or forensic alcohol analyst^{25,xxv} shall take remedial action to investigate and correct the source of error;

Comment [DoHS69]: Page: 12
OOR-There is vague language here, and it may allow for any definition of "good working order" and "routinely checked" to apply. More specifics are needed. Further, it seems the labs could not meet the other procedure standards unless their machines worked and were checked. Why is this requirement necessary to ensure competence? Could it be repealed and the same outcome achieved?

Comment [DoHS70]: Page: 12
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

Comment [GH71]: Justification:
Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

²⁵ This amendment was proposed by the committee, but was not fully discussed. The revision is included here,

(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.

s 1220.4. Expression of Analytical Results.

(a) With the exception of tissue analysis, ~~all~~^{xxvi} 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, or in breath, based on the number of grams of alcohol per 210 liters of breath.²⁶

(1) The symbols, grams %, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of liquid or grams of alcohol per 210 liters of breath. [20]

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

(c) ~~Blood a~~lcohol^{xxvii} concentrations less than 0.01% in living subjects may be reported as negative.

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

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

~~(f) A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood.~~

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

Comment [GH72]: This is a Rule 100 change. Justification: Vehicle Code Section 23152(a) was amended to read "For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath." (OOR- When was this amendment? Please cite the chaptered bill and date.) Statutes 1990, ch. 708, § 1.

Comment [GH73]: This is a Rule 100 change. Justification: Vehicle Code Section 23152(a) was amended to read "For purposes of this article and Section 34501.16, percent, by weight, of alcohol in a person's blood is based upon grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath." (OOR- When was this amendment? Please cite the chaptered bill and date.) Statutes 1990, ch. 708, § 1.

Comment [GH74]: Justification is the updated CVC, 2100:1 ratio no longer used. (OOR- When was this amended? As above? Please cite the chaptered bill and date.) Statutes 1990, ch. 708, § 1.

ARTICLE 7. REQUIREMENTS FOR BREATH ALCOHOL ANALYSIS

s 1221. General.

~~Breath alcohol analysis shall be performed in accordance with standards set forth in this Article.~~ [21]

s 1221.1. Authorized Procedures. [22]

since permitting a forensic alcohol analyst to take corrective action is consistent with the proposed revision to Section 1216.1.(a)(1) to eliminate the specific requirement for a laboratory to employ a forensic alcohol supervisor.

²⁶ The added language, "or in breath, based on the number of grams of alcohol per 210 liters of breath," could conceivably be interpreted as providing an alternative way of expressing any result thus permitting the expression of blood alcohol results as breath values.

(a) Breath alcohol analysis shall be performed only with instruments and ~~related accessories/calibrating units~~ which meet ~~the standards of performance set forth in these regulations the requirements specified in Health and Safety Code section 100701.~~^{xxviii} [24]

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

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

(2) Except for the requirements of Section 1220.4, such immediate analysis shall not be subject to the requirements of Article 6.

~~s 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.~~

~~-standard of performance set forth in this section shall be tested by the U.S. Department of Transportation.~~

~~s 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.~~

~~Breath alcohol instruments and calibrating units used in breath alcohol analysis shall meet the requirements specified in Health and Safety code Section 100701.~~²⁷

s 1221.4. Standards of Procedure.

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

(1) For each person tested, breath alcohol analysis shall include analysis of 2 separate breath

Comment [GH75]: Repealed as a Rule 100 change. (OLS - The term "places other than forensic alcohol laboratories" should be made more specific by replacing it with a term such as "breath alcohol laboratories" or "law enforcement laboratories" and defining that term in section 1215.1 to clarify that it includes use of breath alcohol analysis by law enforcement agencies. Under the new law governing forensic alcohol laboratories, places authorized to perform breath alcohol analysis would fall within the general category of "laboratories." (See Health and Safety Code sections 100700, 100701) See also comment in DoHS54.)

Comment [GH76]: Repealed as a Rule 100 change.

Comment [GH77]: Repealed as a Rule 100 change. H&S 100701

Comment [GH78]: Repealed as a Rule 100 change.

Comment [GH79]: Rule 100 change. It is not necessary to duplicate the statute in regulation. The subcommittee determined that the specification was necessary for the purposes of informing the forensic alcohol laboratories of the existence and location of the statutory requirements for the instruments used to calibrate and conduct breath alcohol analysis. This should be an acceptable reason to duplicate statute in regulations according to the APA.

Comment [DoHS80]: Page: 14 OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

²⁷ The text here was transferred to Section 1221.1.(a).

samples which result in determinations of blood alcohol concentrations²⁸ which do not differ from each other by more than 0.02 grams per 100 milliliters.

~~(2) The instrument shall be calibrated with standards, which are water solutions and or dry-gas of alcohol.~~^{xxix, 29}

(23) The accuracy of instruments shall be determined.

(A) Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration [25] within accuracy and precision limits of plus or minus 0.01 grams % of the true value; [26] these limits shall be applied to alcohol ~~water~~ concentrations ~~and or dry-gas standards~~ from ~~0.10-0.08~~ to ~~0.30-0.25~~ grams %. The reference sample shall be provided by a forensic alcohol laboratory.^{xxx}

1. Such analysis shall be performed by an operator as defined in Section 1221.4 (a)(5), [27] and the results shall be used by a forensic alcohol laboratory to determine if the instrument continues to meet the accuracy set forth in Section 1221.4 (a)(2)(A). [28]

(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 shall be performed only with instruments for which the operators have received training, such training to include at minimum the following schedule of subjects:

(A) Theory of operation;

(B) Detailed procedure of operation;

(C) Practical experience;

(D) Precautionary checklist;

(E) Written and/or practical examination.

(4) Training in the procedures of breath alcohol analysis shall be under the supervision of ~~persons who qualify as~~ forensic alcohol supervisors, forensic alcohol analysts or forensic alcohol analyst trainees ~~inat^{xxxi}~~ a ~~licensed~~ forensic alcohol laboratory. [29]

~~(A) After approval as set forth in Section 1218, the forensic alcohol laboratory is responsible for the training and qualifying of its instructors.~~

²⁸ In specifying the required agreement between the duplicate breath results, the reference to "determinations of blood alcohol concentrations" is now inconsistent with the proposed amendments to Section 1220.4, which are intended to permit the direct reporting of breath alcohol concentrations. The subsequent reference to "0.02 grams per 100 milliliters" is also inconsistent with the direct expression of breath results.

²⁹ The added reference here to calibration of breath test instruments is very vague and does not specify the requirements for such calibrations including: How often are instruments calibrated? Who does this? How are the concentrations of the reference sample determined?

Comment [GH81]: FARC: note this does not specify using dry gas or wet bath calibrating units. Do we want to differentiate the standard accuracy tests with dry gas/wet bath units vs the lab staff checking the calibration of an instrument using secondary standard solutions only???? Advise.

Comment [GH82]: Justification: Reflects change in CA Vehicle Code from 0.10 to 0.08 by Stats. 1989, ch.479.

Comment [GH83]: Justification: Not all instruments that measure alcohol concentration are linear (accurate) above the 0.25 grams % levels. For this reason, the upper limit of accuracy and precision was reduced to 0.25 grams, which is well above the 0.08 grams % legal limit for driving under the influence laws.

Comment [GH84]: Rule 100 change; DoHS no longer qualifies individuals as FAS, FAA, or FATs. (OOR- The reasoning for the repeal is not understandable. What does CDHS not approving or qualifying these classifications have to do with repealing the language "persons who qualify as"? The regulation specifies qualifications that persons must meet for labs to call these persons by a particular classification. The labs have to determine if these persons qualify for a particular classification, so the phrase "persons who qualify as" still appears to be relevant.)

Comment [DoHS85]: Page: 15
OOR: What is the process of approval for law enforcement officers by FA supervisors or analysts? What are the required qualifications of the officers? Can the FA supervisors and analysts decide this for themselves? Is the lab to decide this? How many supervisors or analysts must approve since the plural is used, two? more? Do you really mean one? This process and criteria for qualification will either need to be described in regulation or the ISOR will need to specify that the lab may conduct this approval in any manner it desires. Of course, then you cannot say that the labs must only "approve" experienced operators and the point then becomes why do they have to approve at all. Why cannot the law enforcement ... [24]

Comment [GH86]: Rule 100 change.

Comment [DoHS87]: Page: 16
OOR- Section 1218 is repealed, so this subsection is repealed unless you want to simply repeal the "After approval as set forth in Section 1218," part and maintain the rest. The repeal of the rest of this subdivision appears to be related to the repeal of "persons who qualify as" in ... [25]

(5) An operator shall be a forensic alcohol supervisor, forensic alcohol analyst, forensic alcohol analyst trainee or a person who has completed successfully the training described under Section 1221.4 (a) (3) and who may be called upon to operate a breath testing instrument in the performance of his duties.

(6) Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of the person performing the determination of accuracy. [30]

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

Comment [GH88]: Rule 100 change.

(b) The precautionary checklist³⁰ to be used by operators of the instrument shall be available at the location of each instrument.^{xxxii}

s 1221.5. Expression of Analytical Results.

Results of breath alcohol analysis shall be expressed as set forth in Section 1220.4.³¹

ARTICLE 8. RECORDS

s 1222. General.

~~Forensic alcohol laboratories and law enforcement agencies shall maintain records which clearly represent their activities which are covered by these regulations. Such records shall be available for inspection by the Department on request.~~

Comment [DoHS89]: Page: 16
OOR: The current regulation has no meaning without the concept of inspection from an outside entity. This made sense when CDHS licensed the labs, but does not now.

Comment [GH90]: Repealed as a Rule 100 change.

Comment [GH91]: Repealed as a Rule 100 change.

s 1222.1. Forensic Alcohol Laboratory Records.

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

Comment [DoHS92]: Page: 16
OOR- Since these record keeping requirements were part of the needs of CDHS to conduct its inspections for licensing, what is the point of them now? You can say this is a Rule 100 change from the perspective of eliminating the phrase, but then the point of the regulation comes into question. Do labs need to maintain these records for three years for some other reason? Is it for the courts? Is three years adequate for that purpose? Is a regulation requiring this record keeping necessary? Is this needed for the purpose of ensuring the competence of the lab or its employees? The ISOR should explain the purpose of this section beyond the Rule 100 change in order to demonstrate why it is not being repealed, and if this is not in the ISOR, it is likely that this will need to be explained in response to public comments on this point. It is a good practice to head off public comments by having a strong and comprehensive ISOR to support your actions in a regulation package. It will save much grief in the public process part of regulation promulgation.

(1) An up-to-date record of persons in its employ who are qualified as forensic alcohol supervisors and forensic alcohol analysts; the record shall include the qualifications of each such person, including education, experience, training and performance in proficiency tests and examinations;³²

(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;

³⁰ The committee should consider the need to define "precautionary checklist."

³¹ Committee member Tanney suggested repealing this section since Section 1221.1.(b)(2) implies that the requirements of Section 1220.4. will be applied to breath test results. The committee discussed, but did not agree to this change.

³² Since the review committee has proposed to eliminate the requirement that laboratory personnel complete a written examination [cf. Sections 1216.1.(e)(3) and 1216.1.(f)(4)], the reference here to records of such examinations should be removed.

- (3) Records of samples analyzed by that laboratory under these regulations, their results and the identity of persons performing the analyses;
- (4) Records of the quality control program;
- (5) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;
- (6) Records of such determinations of accuracy, maintenance, and or calibration^{xxxiii}, ³³ of ~~breath~~^{xxxiv} testing instruments as a laboratory may perform for law enforcement agencies;³⁴
- (7) Records of such training as a laboratory may provide to persons who operate breath testing instruments for law enforcement agencies.

~~s 1222.2. Breath Alcohol Analysis Records.~~

~~(a) Each agency shall keep the following records for breath testing instruments which are under its jurisdiction:~~

~~(1) Records of instrument determinations of accuracy;~~

~~(2) Records of analyses performed, results and identities of the persons performing analyses;~~^{xxxv}

~~(3) At the location of each instrument, the precautionary checklist to be used by operators of the instrument.~~^{xxxvi}

³³ Since there are no specifications in the regulations describing what is required with regard to "maintenance, and or calibration" of breath instruments, the regulated public would not know what records needed to be kept. [Note: For blood alcohol analysis, the committee has proposed repealing the requirement to maintain instruments in good working order with routine checks of accuracy and precision, i.e., deleted Section 1220.2.(a)(5)].

³⁴ This recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed *by* or *for* law enforcement agencies. The phrase "as a laboratory may perform for law enforcement agencies," is not needed and should be deleted.

[1] Under Section 1215.1.(b)., the review committee needs to consider changes in the definition of forensic alcohol analysis in response to the changes in the statutes. Prior to the passage of SB1623, the statutes contained separate descriptions of the analysis of blood, urine, or tissue samples by or for law enforcement agencies (i.e., former H&S Code Section 100710), and the testing of breath samples by or for law enforcement agencies (i.e., former H&S Code Section 100715). The old statutes did not define or even use the term, "forensic alcohol analysis." This term is defined in the regulations and the regulations generally distinguish forensic alcohol analysis and breath alcohol analysis.

SB 1623 repealed the aforementioned sections and the new law [H&S Code Section 100700(a)] now refers generally to "Laboratories engaged in the performance of forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath..." The new law in effect now defines forensic alcohol analysis in statutes and combines the tests of blood, urine, and tissue samples performed in a forensic alcohol laboratory by trained laboratory personnel and the testing of breath samples, which is normally conducted outside the laboratory by trained law enforcement personnel.

Section 1215.1.(b) defines forensic alcohol analysis, and includes the analysis of breath samples. Similarly, Section 1215.1.(e), which defines the term, "forensic alcohol laboratory," includes breath samples in the list of samples analyzed. In both cases the analyses are performed by "trained laboratory personnel." The review committee may wonder why breath samples are included in these definitions, since the regulations generally distinguish breath alcohol analysis from forensic alcohol analysis. Historically, there was one instance where breath alcohol analysis was considered a forensic alcohol analysis activity. Prior to 1985, the Title 17 regulations described breath alcohol procedures where the breath sample was captured for later analysis. Here the regular instrument operator (typically law enforcement personnel) would capture the sample, but the actual analysis was performed later in a licensed forensic alcohol laboratory by qualified laboratory staff. The analysis of the captured breath sample was considered a forensic alcohol analysis subject to the same requirements as the analysis of blood, urine, or tissue samples. The pre-85 regulations described authorized procedures for sample capture and later analysis [former Section 1221.1.(c)], as well as standards of performance [former Section 1221.2.(b)], and procedures for determining the accuracy of the sample capture equipment [former Section 1221.4.(a)(2)(B)]. These sections were included under Article 6, Methods of Forensic Alcohol Analysis.

The regulations were amended in 1985 [Amendment filed 12-20-85 as an emergency; effective upon filing (Register 85, No. 52)] to repeal the aforementioned sections and to eliminate the forensic alcohol analysis of captured breath samples as an authorized activity under the regulations. The references to "breath" samples under the definitions of forensic alcohol analysis [1215.1.(b)] and also forensic alcohol laboratory [1215.1.(e)] should have been removed at that time, but were inadvertently retained. (Note: the references to "immediate analysis" of a breath sample under Sections 1221.1.(b)(1) and 1221.1.(b)(2) are also vestigial, serving to distinguish regular (immediate) breath alcohol analysis from breath sample capture for later analysis.)

Since the revisions to the Health and Safety Code now describe the analysis of breath samples as a forensic alcohol analysis activity, the references to breath samples under 1215.1.(b) and

1215.1.(e) appear to agree with the new statutes. The subcommittee had proposed to retain these two sections without any changes.

[2] Under Section 1216.1.(a)(1), and the requirement that a laboratory employ at least one forensic alcohol supervisor, the review committee should consider addressing the issue of what happens if laboratory loses its only forensic alcohol supervisor. The Department's response under this circumstance is described under Section 1216.1.(d) of the current regulations.

OOR in its comments asked whether the requirement for a laboratory to hire a person with the qualifications of a forensic alcohol supervisor is necessary to ensure the competence of the labs or employees. It might be helpful to consider the role of the supervisor classification under the current regulations. As defined under Section 1215.1.(f), the supervisor is a person who can be responsible for all aspects of the performance of forensic alcohol analysis. Generally, the supervisor writes the methods, interprets the analytical results, directs corrective action for quality control failures, and supervises the personnel who perform the analyses. By contrast, the entry-level analyst class represents a person qualified to perform the technical procedures of forensic alcohol analysis. Consistent with the higher level of responsibilities, the supervisor is required to have a higher degree of knowledge and experience.

[2a] Under Section 1216.1.(a)(2), and the requirement that laboratories maintain a quality control program that complies with Section 1220.3., OOR commented that "CLIA uses proficiency testing as a QA mechanism." [DoHS18]. It's important to note here that the CLIA requirements also include standard control procedures to monitor the accuracy and precision of the complete analytical process. Under CLIA, quantitative procedures must include two control materials at different concentrations. (cf. CFR Title 42, Chapter 4, §493.1256). It's also important to keep in mind that the CLIA regulations are directly enforced by oversight programs.

[3] Under Section 1216.1.(a)(3), the review committee may wish to consider the need to clarify and make specific the actual proficiency test requirements in regulation.

[4] Under Section 1216.1.(e)(5), the review committee should note that as a result of the California Public Health Act of 2006, effective July 1, 2007, the responsibilities of the current Department of Health Services' forensic alcohol analysis regulatory program will be transferred to a new department, the California Department of Public Health (CDPH). CDPH will still be within the existing Health and Human Services Agency. As a result of this change, references in the regulations to the "California Department of Health Services" should be corrected to the "California Department of Public Health," here and where applicable throughout the regulations.

[5] Under Section 1216.1.(f)(1), the review committee should note that the requirement here that the forensic alcohol analyst must possess a baccalaureate or higher degree in a physical or natural science would appear to completely disqualify persons with degrees in the social or behavioral sciences (e.g., psychology, criminology) and several technical disciplines (i.e., math, statistics, computer science). Under the current regulations, these individuals can qualify as forensic alcohol analysts provided that they have completed the specified core chemistry curriculum.

The review committee should also consider retaining the current quantitative chemistry course requirement for the technical, analyst class. The Department imposes similar requirements for its various clinical scientist classifications. Quantitative analysis coursework provides instruction in a number of areas of importance to forensic alcohol analysis including: chemical equilibrium, standard states, redox chemistry, gravimetric, volumetric, and titrametric procedures and the 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

[6] Under Section 1216.1.(f)(3), the review committee should consider the training requirements necessary to qualify employees of a forensic alcohol laboratory, which does not conduct analyses of blood, urine, or tissue samples, and instead performs only the activities that support breath alcohol analysis. These laboratories are not able to easily satisfy the requirement for staff to complete a minimum of 25 analyses of alcohol concentration in blood samples.

[7] The subcommittee has proposed deleting Section 1219. This section requires: 1) that all samples taken for forensic alcohol analysis shall be collected and handled in a manner approved by the Department and 2) the identity and integrity of the samples shall be maintained through collection to analysis and reporting. The committee should note that Section 1219 is specifically referenced in a statutorily mandated document the, "Uniform Standards for the Collection of Blood Samples for Forensic Alcohol Analysis" (Uniform Standards). The Uniform Standards were adopted by the Department of Health Services, the Department of Justice, and the California Highway Patrol as required by Section 23158(f) of the Vehicle Code. The standards set forth the required procedures for maintenance of sample identity and integrity as required by current Section 1219. The first section of the Uniform Standards reads:

"Blood samples collected from persons involved in traffic accidents or traffic violations shall be collected, handled, and preserved as required by Sections 1219 and 1219.1 of Title 17..."

At its last meeting, the review committee discussed Section 1219 from the standpoint of the general need to include requirements for the maintenance of sample identity and integrity, but concluded that these requirements were probably adequately covered under Section 1219.1. (See transcript p. 79, lines 18 – 23). The review committee should take note here that there are actually no requirements under Section 1219.1., or anywhere in the regulations regarding the labeling of samples (i.e., subject name, date/time sample drawn, name of person withdrawing samples, etc.). There are also no requirements in the regulations for securing the samples, maintaining chain of custody, logging in the samples at the laboratory, etc. All these requirements are certainly necessary to ensure the maintenance of the identity and integrity of the samples and they are contained in the Uniform Standards. The Department currently requires laboratories to incorporate the Uniform Standards as part of their written method descriptions.

As noted above, the Uniform Standards are required by Section 23158(f) of the Vehicle Code. However, the Vehicle Code does not specifically name these standards. Accordingly, in order to keep the regulated public informed of the requirements of the Uniform Standards here, it is appropriate to incorporate the specific document in the regulations by reference.

[8] Under current Section 1219.1.(f), subject matter experts on the review committee should evaluate the requirements for collecting and handling post mortem blood samples including: the addition of preservatives with and without refrigeration [cf. Section 1219.1.(f)(1)]; the need for cautionary instructions regarding the potential for contamination of the sample [cf. Section 1219.1.(f)(2)]; and the apparent requirement to collect only venous blood [cf. Section 1219.1.(f)(2)].

[9] Under Section 1219.1.(g)(2), and the requirement to provide the defendant with a “copy or transcript of the identifying information carried on the original sample container,” the committee should consider the comments offered above. The Office of Regulations previously noted that there are clarity issues involved here since, “nothing in these regulations specifies labeling of samples.” In fact, as discussed above, the labeling requirements are set forth in the Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis. Section 1219.1.(g)(2), extends the labeling requirements to the sample provided to a defendant. The requirements here are also consistent with Vehicle Code Section 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.”

[10] Under Section 1219.3., the review committee should consider the need to clarify the requirements for the “continuous” observation period. In preparation for the October 25, 2005 meeting, the representative from the California Association of Criminalists submitted draft regulatory language to more clearly define the “continuous” observation requirement. A subcommittee met on December 14, 2005, and proposed deleting requirement for continuous observation altogether, in order to “allow the courts to decide the adequacy of the observation.” The subcommittee stated, “that it is unreasonable to require the forensic alcohol laboratories to have to deal with this as a requirement.” The full committee discussed this issue at its March 27, 2006 meeting without reaching any agreement.

In general, the requirement for the “continuous” observation period assures the scientific validity of the breath sample by allowing the detection of certain activities that could yield inaccurate (elevated) results. The scientific requirements for the collection of the breath samples are set by the Department's regulations.

[11] The review committee should consider amending Section 1219.3. to add the use of mouth spray, gum, or mints to the list of prohibited activities during the 15-minute observation period prior to the collection of a breath sample. Each of these activities could potentially interfere with breath alcohol analysis and the activities can easily be monitored.

[12] Under Section 1220.(b)(2), the review committee should note that a complete written description of a forensic alcohol method would include: the procedures for collection and handling samples, lists of reagents and equipment used, the procedures for determining the concentrations of the secondary standards, the calibration procedures, a definition of a sample set, the quality control program for the method, the procedures for calculating and reporting analytical results, and the maintenance of the required records. These elements are all standard components of a laboratory's written method description, and in each case can be referenced to other requirements under the regulations. Section 1219.1 sets forth the requirements for the

collection and handling of samples. Section 1220.2.(a)(1)(B) describes the requirements for determining the concentrations of the secondary standards. Section 1220.4. describes the requirements for reporting results, and Section 1222.1. describes the requirements for the maintenance of records of forensic alcohol analysis. The number of samples included in a “set” is an important characteristic of the method with respect to the application of the requirements of the Section 1220.3.(a)(4), i.e., “At least one sample of the quality control reference material shall be analyzed with each set of samples...”

Section 1220.(b)(2) should be amended to revise the specification of the minimum required elements of the written description of a method for forensic alcohol analysis of blood, urine, and tissue samples as shown below:

1220.(b)(2) Each such description shall ~~include~~ specify lists of reagents and equipment used, the procedures for collection and handling of samples, the procedures for determining the concentrations of the secondary standards, the steps used in the method, definition of a sample set, the calibration procedures, the procedures for calculating and reporting analytical results, and the quality control program for the method, and the maintenance of required records.

[13] Regarding the various standard of performance requirements listed under Section 1220.1.(a), given the amendments now proposed by the subcommittee, the regulations would apparently allow a laboratory to independently evaluate the ability of its method(s) to meet the required standards of performance.

[14] Under Section 1220.1.(b), and the requirement to complete an evaluation of the ability of forensic alcohol methods to meet the standard of performance requirements based on proficiency test results, the review committee should consider who makes this evaluation and what criteria are used.

[15] Under Section 1220.2.(a)(1)(B), on lines 1 - 2, the requirement that each laboratory “purchase...NIST traceable secondary alcohol standards” should be clarified. First, the review committee should note that according to NIST (National Institute of Standards and Technology), this organization currently does not have any specific criteria or protocols to define, “NIST trace ability” for aqueous alcohol standards. NIST itself does manufacture a suite of aqueous alcohol standard reference materials or SRM’s (SRM’s 1828B, 1847, and 2891 – 2899).

The regulations should also clarify how any standards “purchased” from a vendor such as NIST are actually used. For example, the regulations could be revised to qualify the NIST SRM’s as the actual secondary standard. However, this product is fairly expensive (~\$50 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 the laboratory’s forensic alcohol method. There are two problems with this approach: 1) it would conflict with the requirements of the proposed regulations [i.e., proposed Section 1220.2.(a)(1)(B)], which state in principal part, “Each forensic alcohol laboratory shall... establish the concentration of each lot of secondary alcohol standards it prepares using an oxidimetric method...”; and 2) the new standard qualified against the NIST SRM by the forensic alcohol method, would be properly characterized as a tertiary standard, not a secondary standard.

The NIST SRMs appear to be too expensive for routine use, but even if a less expensive alternative were available, the review committee should carefully consider 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 used 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 method (e.g., gas chromatography) could introduce errors. Introducing multiple levels of indirect analysis would increase the likelihood of error.

[16] Under Section 1220.2.(a)(1)(B), on line 4, the review committee should consider adding a definition of the term “oxidimetric method” or perhaps “direct oxidimetric method” to emphasize the fact that alcohol is added directly to the oxidizing media in the method for the quantitative determination of the alcohol present in the aqueous alcohol solutions.

“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.”

[17] The review committee should carefully evaluate the value of the requirements contained in the newly added Section 1220.2.(a)(1)(C), i.e., “The forensic alcohol laboratory shall verify the concentration of any new secondary standards used in the method by analyzing the new secondary standard concurrently with a previously analyzed secondary standard.” The new language fails to specify how the analysis would be conducted, but for the sake of discussion, it can be assumed that the laboratory’s forensic alcohol method would be used here. The current regulations [Section 1220.2.(a)(1)(B)] require the laboratory to establish the concentration of the secondary alcohol standard by an oxidimetric method, which employs a primary standard. The current regulations address this issue by requiring that each new lot of secondary standard must be referenced back to the primary standard.

[18] Under Section 1220.3.(a)(2), the review committee should consider the need to specify the number of significant figures used to represent the mean alcohol concentration value of the quality control material. Based on the precision provided with current forensic alcohol methods, and the importance of the quantitative forensic alcohol results, it would appear that the laboratories should employ three significant figures (i.e., three decimal places) here. The regulations should require laboratories to determine the mean alcohol concentrations of the quality control reference material to three decimal places.

[19] Under Section 1220.3.(a)(3), (A) and (B), the review committee should consider the need to specify how many significant figures must be used in setting the acceptable limits of variation in the quality control results. If three decimal places are used, the total acceptable range will be 0.020 grams %, but, by using a truncated 2 decimal place result, the total range of acceptable three decimal place results will be increased to 0.029 grams %. This is nearly 50% greater than the 0.02 grams % range implied by the +/- 0.01 grams % limits. This analysis shows that the

range of acceptable results required by the regulations, +/- 0.01 grams %, can only be accurately applied by using all three significant figures. The regulations should require laboratories to set the range of acceptable results for the analysis of the quality control reference material to three decimal places.

[20] Under Section 1220.4.(a)(1), the proposal to use of symbols, “grams %”, “%”, or “% (W/V)” to represent the units, grams per 210 liters would appear to be dimensionally confusing and may not meet the required clarity standards of California’s rule making procedures. More importantly, the use of symbols that dimensionally represent grams per 100 milliliters of liquid to represent grams per 210 liters of breath would in effect administratively impose the 2100:1 conversion ratio and suggest that the breath results have been converted to blood alcohol concentrations. .

[21] Under Section 1221., the review committee should consider including a 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. These descriptions would include procedures for periodically determining the accuracy of the instruments and procedures for training instrument operators. The regulations should set forth requirements for contents and the availability of the written descriptions. The requirements here would be analogous to the requirements under Article 6, Section 1220 that a laboratory prepare written descriptions of its forensic alcohol method(s).

[22] The review committee may wish to consider the need to clarify and make specific the requirements of the Health and Safety Code with respect to the use of preliminary alcohol screening (PAS) devices to measure alcohol concentration.

The review committee may wish to add language that would clarify and make specific the requirements of the law here by declaring that PAS testing when used to determine the concentration of alcohol (as opposed to merely the presence or absence of alcohol) is subject to all of the requirements of the regulations pertaining to breath alcohol analysis. Alternatively the review committee may wish to specifically exclude PAS testing

[23] Under 1221.1.(a), which the subcommittee decided to retain, the requirement here that instruments and related accessories shall meet the “standards of performance set forth in these regulations” appears to refer to Section 1221.2., Standards of Performance, which was repealed by the subcommittee.

[24] Under Section 1221.3., on line 1, the review committee should note that the proposed language here referring to, “calibrating units”, is not consistent with the terminology used in H&S Code Section 100701, which refers to “calibrating devices.” The term “calibrating units” is used in the DOT model specifications and conforming products lists. More generally, the review committee should note that reference to calibrating equipment here is included under the section, “Approved Instruments.” However, as defined under Section 1215.1.(j), an “‘instrument’ refers to equipment used to make a measurement of alcohol concentration.” The calibrating units are used to provide a sample of known alcohol concentration to check the accuracy of the breath instrument. The calibrating units lack any capability of measuring alcohol concentration.

[25] Under Section 1221.4.(a)(2)(A), the review committee should consider revisions to the regulations to clarify and make specific the requirements for periodically determining the accuracy of breath testing instruments.

[26] Under Section 1221.4.(a)(2)(A), the review committee should consider the need to specify how many significant figures must be used in setting the acceptable limits for the results of a periodic determination of accuracy analysis. The regulations set acceptable limits of variation for the analysis of the reference sample at plus or minus 0.01 grams % around the known alcohol concentration, but do not specify how many significant figures must be used in evaluating the results of the periodic analysis of the reference sample. The instruments are capable of displaying three decimal place results. If all three decimal places are used, the total acceptable range will be 0.020 grams %, but, by using a truncated 2 decimal place result, the total range of acceptable three decimal place results would be increased to 0.029 grams %. This is nearly 50% greater than the 0.02 grams % range implied by the +/- 0.01 grams % limits. This analysis shows that the range of acceptable results required by the regulations, +/- 0.01 grams %, can only be accurately applied by using all three significant figures. The regulations should require laboratories to employ three significant figures when evaluating the accuracy of the instruments.

[27] Section 1221.4.(a)(2)(A)1., requires that the periodic determination of accuracy analyses must be performed by an operator (i.e., a person) as defined under Section 1221.4 (a)(5). Some modern instruments have the capability of automatically performing determinations of accuracy without any operator involvement. The regulations should require that an operator must perform the determinations of accuracy for automated breath testing instruments.

[28] Under Section 1221.4.(a)(2)(A)1., the regulations specifically require the laboratory to evaluate the results of the periodic determinations of accuracy in order to make the scientific determination as to whether the instrument continues to meet the required standards. The regulations should require the laboratories to employ specific procedures here. For example, for wet-bath calibrating units this involves recording the reference solution temperature, calculating the acceptable range of results, and the maintenance of records showing the laboratory's review of results.

[29] Under Section 1221.4.(a)(4), the review committee should consider carefully the subcommittee's proposal to allow law enforcement officers to supervise the training of breath instrument operators. The regulations currently require that the training of breath instrument operators must be conducted by a forensic alcohol laboratory under the supervision of qualified laboratory staff.

The proposed amendment to Section 1221.4.(a)(4) doesn't set forth any specific qualifications for law enforcement officer supervisor, or any ongoing role for the laboratory in conducting the training. This suggests that the law enforcement agencies could be more or less independently training the operators. It should be noted that the former *ad hoc* Advisory Committee on Alcohol Determination, a group which included representatives from the crime laboratories, recommended that specially qualified law enforcement personnel (breath test operator supervisors) could be permitted to train other officers, but only after the operator supervisor had received special advanced training from the forensic alcohol laboratory. The advisory committee agreed that the requirements for the advanced training should be described in regulations.

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 subcommittee commented that, "Due to the simplicity of use of breath alcohol Instruments currently approved by the USDOT, crime laboratory staff should have the authority to delegate some of the breath instrument training functions to experienced law enforcement instrument operators." [GH58]. The program would offer a couple of responses here. First, in terms of ease of operation, the current generation of breath testing instruments are arguably more difficult to operate than previous generations. The Intoxilyzer 5000 from the 80's was literally a one-button instrument. The current generation of instruments are considerably more difficult to use. Secondly, data entry prior to the test is much more involved, as are the steps associated with uploading data to the host computer. There are also more procedural steps involved in operating the instrument. Additionally, the current hand-held fuel cell instruments have less capability to automatically detect mouth alcohol. More generally, even though an instrument may be simple to use in its normal operation, training/oversight becomes critical when the tests don't work. The operator needs to be able to recognize a malfunction. This is why training is so important.

Based on the above discussion, the review committee should evaluate carefully the proposal to transfer the responsibility for supervision of operator training to law enforcement personnel. Minimally, the committee should consider more detailed requirements here. The committee may also decide to continue the current requirements whereby the training in the scientific procedures of breath alcohol analysis would be reserved for laboratory. While the laboratory can certainly call upon an experienced operator to assist in the practical instruction of the trainees [cf. Section 1221.4.(a)(4)(A)], the responsibility for the supervision of the training would still rest with the laboratory.

[30] Under Section 1221.4.(a)(6), the review committee should consider the need to modify the requirement to maintain records of the "identity of the person performing the determination of accuracy" for instruments capable of automatically performing such determinations.

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- i Transcript (5/21/07) p. 67
 - ii Transcript (5/21/07) p. 63
 - iii Transcript (5/21/07) p. 63
 - iv Transcript (5/21/07) pp. 54, 55, 58
 - v Transcript (5/21/07) p. 66
 - vi Transcript (5/21/07) p.142
 - vii Transcript (5/21/07) p. 82
 - viii Transcript (5/21/07) p. 84
 - ix Transcript (5/21/07) p. 132
 - x Transcript (5/21/07) p. 138, 141
 - xi Transcript (5/21/07) p. 140
 - xii Transcript (5/21/07) p.138
 - xiii Transcript (5/21/07) p. 144)
 - xiv Transcript (5/21/07) p. 146
 - xv Transcript (5/21/07) p. 146
 - xvi Transcript (5/21/07) p. 146
 - xvii Transcript (5/21/07) p. 146
 - xviii Transcript (5/21/07) p. 147
 - xix Transcript (5/21/07) p. 147
 - xx Transcript (5/21/07) p. 148
 - xxi Transcript (5/21/07) p. 151
 - xxii Transcript (5/21/07) p. 148
 - xxiii Transcript (7/03/07) p. 24
 - xxiv Transcript (7/03/07) p. 31
 - xxv Transcript (7/03/07) p.____
 - xxvi Transcript (7/03/07) p. 32
 - xxvii Transcript (7/03/07) p. 32
 - xxviii Transcript (7/03/07) p. 59
 - xxix Transcript (7/03/07) p. 69
 - xxx Transcript (7/03/07) p. 67
 - xxxix Revision made at 01/28/08 meeting
 - xxxii Transcript (7/03/07) p.107
 - xxxiii Transcript (7/03/07) p. 95
 - xxxiv Transcript (7/03/07) p. 95
 - xxxv Transcript (7/03/07) p. 104
 - xxxvi Transcript (7/03/07) p. 107

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OOR: Possible reasoning to include in the ISOR to support this “rule 100” change might involve a statement that the term “Department” is repealed because the committee did not determine that the direct involvement of the CDHS in a regulatory program was necessary to ensure the competence of the labs or employees and as a result, the committee chose to remove all reference to the “Department” from the current regulation text. Although Health and Safety Code section 100725 states that CDHS shall enforce the statutes and regulations, the law does not require CDHS's direct involvement in a regulatory program.

The subcommittee intention is to repeal the entire Section 1216. This draft only repeals paragraph (a) and (2) as Rule 100 changes.

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OOR: the term “these regulations” is vague and can be construed to mean all the regulations in the CCR. While this is likely not to be the meaning the public will ascribe to the term, It has been OOR's experience to have OAL find the use of the term “these regulations” to be vague and unclear due to this possible broad interpretation of the term. It is suggested that the committee remove the term and use a specific cross reference to replace it in current text.

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OOR: The question arises as to whether the requirements in (a)(1) and (a)(1)(A) are standards that are used by accrediting bodies or some other national or local group to ensure competence of labs or employees. There will need to be some such justification to support the retention of these requirements in regulation.

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OOR: Possible reasoning to include in the ISOR to support the determination that this repeal is a “rule 100” change is that the 2004 statute repealed the licensing requirement for FALs and since the committee views licensing as CDHS's only role in the current regulation text, the committee determined the statute operationally repealed all requirements in current regulation related to licensing and CDHS's role in that process. In addition, the reasoning needs to offer that the committee has also determined that no other role for CDHS is necessary to ensure the competence of labs and employees. However, the committee could determine that CDHS has some role that is necessary to ensure the competence of laboratories and employees, and could specify that role in the proposed regulations. Since the regulation text draft of the subcommittee did not contain any reference to any such role for CDHS, it is assumed that at least the subcommittee does not see CDHS as having any other role. If the committee concurs, the repeal of all references to licensing or CDHS having an action or requirement will be presented as a rule 100 change because all current text containing a CDHS role exists to support the licensing program that was repealed by operation of law.

JUSTIFICATION: The deletions are required by changes in the law. However, to insure competent forensic alcohol analysis, the regulations must articulate minimal quality control requirements including such proficiency testing as required by H&S 100702. (OOR: Further reasoning for the ISOR might include that the text is amended to reference the statute to inform the regulated public of the location of the requirements for proficiency testing in the Health and Safety Code.)

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OOR: This language is not truly “regulatory,” but can be used if it is the committee's desire. OOR would recommend that the language format offered in the 1/26/06 redraft be used instead, as it is regulatory rather than suggestive of the requirements. However, as offered above, if the

proposed regulations are intended to be standards that are self-enforced by the labs and may be used by the courts, the nuances of legal language are not truly critical to the purpose and likely will not be an issue with OAL.

Page 3: [8] Comment [DoHS17] Dept. of Health Services

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OOR: Do national standards make the requirement that a person with the qualifications of the FA supervisor is necessary to ensure the competence of the labs or employees? This job classification was not included in the draft of January 2006 and OOR does not recall anyone offering that this supervisor was a necessary component of the lab to ensure competence or to be accredited or anything else. This is especially important because the qualifications for the education of the supervisor and analyst are slightly different and it will be necessary to offer the reasons for why this is the case. It does not logically flow from the reading of the text and, since it is necessary to propose the need for all retained provisions, the need for the supervisor might need specific justification versus the global offering that the retained provisions meet a national standard or something to the end.

Page 3: [9] Comment [DoHS18] Dept. of Health Services

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OOR: Is the QA program specified in section 1220.3 based on components in the standards of the accrediting organizations? Is there some other body that proposes these components as necessary to ensure competence? Or perhaps the committee can cite the FAL program's experience with its requirement of these components as ensuring competence. CLIA uses proficiency testing as a QA mechanism. Does it require other specific mechanisms that could be cited as applied in the requirements of the QA program in these regulations?

Page 3: [10] Comment [let19] Itanne

Current section repealed as a Rule 100 change. Alternative language inserted, see comment below.

Page 3: [11] Comment [GH20] Gary Harris

[Stipulation of the location of the proficiency testing requirements is necessary to inform the forensic alcohol laboratories of the statutory requirements and provide guidance to the location of the mandates.](#)

Page 3: [12] Comment [DoHS22] Dept. of Health Services

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OOR- This language is very vague. It offers no understanding of what is necessary to "show ability...". If the committee wants to require something along this track, it is preferred that the language be reworked as in the redraft of 1/26/06. However, as all the other sections maintain a requirement that the lab shall meet some mandate or standard, it is not really clear why it is necessary for this to be stated in this section. This was a qualification for licensing and made sense as such even though it was still vague and the forensic alcohol program had needed to offer clarity through its application processes. It truly is a different situation now that licensing is no longer at issue. Showing ability to collect samples, run analysis methods, keep records, etc. is a question of "showing" to whom? The laboratories are going to be self-regulating, and if they have a quality control program and pass the statutory proficiency testing, should they not also have the capability to meet these other standards, which are specified that they have to meet in other sections anyway? An alternative to offering the greater specificity is to simply repeal this language. It truly is unenforceable as written now and could prove difficult if the courts start interpreting what the labs have to do to "show ability." If it is kept as written, then the ISOR should offer that this is something that the labs must determine for themselves. But of course if this is the case, then why state it in law if the lab can truly do anything it wants and that this "shows ability"? OOR recommends this subsection be repealed.

Page 4: [13] Comment [DoHS24] Dept. of Health Services

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OOR: This again is a subsection that does not make much sense in light of the repeal of licensing requirements. This requirement is something that is standard in regulation text that has

an enforcement component that involves CDHS action. It flows in licensing regulations from the criteria to be licensed needing to be maintained because the licensing is an action that happens at a distinct point in time, and then in theory, the licensee could decide after that point not to continue to meet the criteria set as necessary to be licensed. In this case, there is no distinct point in time when a lab becomes a forensic alcohol lab. The lab makes this determination for itself, and it is something that is a continuous process of decision that happens every time the lab accepts a specimen for analysis. That is, if the lab calls itself a forensic alcohol lab, then it legally is if it meets the requirements of this section. Requiring that the lab has to continue to meet the qualifications does not really logically flow in this specific situation. It is difficult for OOR to discern the need for this regulation, but if the committee decides it still wishes to make this statement, then something explaining the idea that labs might call themselves a forensic alcohol lab one day and not the next might need to be offered.

Page 4: [14] Comment [DoHS28] Dept. of Health Services

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OOR: Again, this is not regulating language. OOR recommends the language used in the redraft of 1/26/06, but if the committee wishes to retain this language, it may, as there is no qualifying process by CDHS or any other governmental agency and so anyone who has the qualifications listed can call themselves a forensic alcohol supervisor, analyst, or trainee. This is something the labs will have to determine for themselves as to how they will assess these qualifications and assign their personnel to the work regardless of the person's possession of the listed qualifications. OOR also recommends that the formatting be altered if the current qualifications are to be used, as they currently flow in a confusing manner and can be easily adapted to offer greater clarity with the grandparenting component that is included.

Page 4: [15] Comment [GH29] Gary Harris

Justification: All scientific disciplines that are relevant to the practice of forensic alcohol analysis and insures the competence of those performing forensic alcohol analysis are included. This additionally provides uniformity in the field of practice. The original vague language previously used, such as "appropriate" has been deleted. The enhanced educational requirement for analysts to possess a degree is consistent and in compliance with the majority of the forensic science community and accrediting body requirements. (OOR requests that copies of the accrediting body standards to support this assertion be provided to the committee. They will be needed for the rulemaking file in duplicate. A question arises regarding the need for supervisors to have a degree if the standards cited to support the reasoning is only for analysts. While supervisors usually would have been analysts at some point and should be at least as qualified as the folks they supervise, the need for justification here is for the classification of supervisor. The reasoning needs to support that and providing accrediting standards that require supervisors to have specific degrees would be very helpful to support the reasoning for this requirement.)

Page 4: [16] Comment [DoHS31] Dept. of Health Services

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OOR: Have the listed subjects been determined necessary to ensure competence by an accrediting body or some other expert source? It might be possible to simply cite the experience of CDHS in enforcing this requirement over the years as the basis for the assertion that these subjects are the necessary subjects to ensure competence. If the committee believes that is the case, are these the subjects, or are there other subjects more likely to ensure competence?

Page 5: [17] Comment [DoHS33] Dept. of Health Services

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OOR- It is appreciated that this is the current language, but it is vague. This language was supported by the forensic alcohol program's guidance documents that described how one was to demonstrate this ability. Since there will no longer be a department determining this ability, this is a questionable provision to maintain. Unless the regulation describes something that assists the forensic alcohol supervisor in knowing how he is to "demonstrate" his ability and provide guidance for the courts so this can be measured, OOR recommends this provision be repealed and organize the grandparenting subsection differently to assist with logical flow. If the committee elects to keep this provision, then the ISOR will need to offer some statement that labs will

determine this for themselves so that courts will not be put in the position of making decisions regarding this demonstration each time a supervisor is there. Of course, if the labs are doing this themselves, then what is the point of making the provision law, as the lab can do whatever it wants and state it meets the requirements?

Page 5: [18] Comment [DoHS34] Dept. of Health Services

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OOR: This grandparenting language was from the initial promulgation of the FAL regulations and is 36 years old. Are there any persons in practice now who are qualified as FA supervisors based on this language? If not, it would be reasonable to repeal the language and only include the language that speaks to the CDHS qualified supervisors as of the specified date. If there is someone in practice who is qualified based on the pre-1971 language, then the question arises if that person would still be qualified because he is currently qualified by CDHS or because of this grandparenting language in current regulation. This is a question that program will have to help answer.

Page 5: [19] Comment [GH35] Gary Harris

[Justification: Addition of this statement allows for all applicable grandparenting under this provision.](#) (OOR- There is a mechanism for making these kinds of stipulations in regulation. We will set the date when we get closer to the date for public noticing. Is CDHS still qualifying persons for these various positions or have they already stopped doing this? The answer impacts on the date we can set.)

Page 5: [20] Comment [GH37] Gary Harris

[Justification: Proposed regulations require analysts have a science degree as a minimal qualification, consistent with forensic science community requirements for analytical work. The original language should be deleted.](#) (OOR- You will need reasoning that demonstrates that this increased level of qualification is necessary. You offered above in the supervisor section that there are accrediting body standards that support this. Citing such standards will be necessary to support this increased requirement. Of course, since it has not been necessary before, who will be impacted by this even though there is grandparenting in this package? It is possible there are people who are in this process of not yet being approved and who do not have degrees. If there are, you need to address this. If not, and I suggest that you conduct some research to be reasonably certain this is the case, then you need to state this. You might want to do a poll of your labs and find out if this is an issue. Also, why are chemistry with lab educational requirements in this amendment and not in the supervisor's requirements. The supervisor's requirements seem to be less than those for the analyst. While you may do this, you will need to provide a reason for the difference in the ISOR.)

Page 5: [21] Comment [GH39] Gary Harris

References to "clinical" have been deleted as the regulations pertain to the defined forensic lab only and the training should be specific to forensic alcohol testing. (OOR- While it is perfectly acceptable for you to make the requirements more stringent, you will need to explain why are you doing this with the intent of looking to demonstrate that this is what is necessary to ensure competence in light of the fact that it was not required before to ensure competence. Simply stating that only forensic training is best is not enough. You must provide something that supports that clinical laboratory training does not provide the training needed for conducting forensic work. Is there evidence from accrediting bodies that those without only forensic training are less competent or make more errors? Perhaps you could offer some discussion of forensic laboratory standards being different from clinical laboratory standards, assuming this is the case. Certainly, forensic handling procedures are different and that could be cited as part of the reasoning. If you know that no forensic lab will hire an analyst that does not have training in a forensic lab, then you could cite that as supporting your reasoning, but essentially, you will need evidence based reasoning to support this more stringent requirement.)

Page 11: [22] Comment [GH66] Gary Harris

[Justification: Use and acceptance of NIST traceable standards in the scientific community \(such as CA licensed clinical\) has long been in existence due to their enhanced international reliability.](#)

This change includes the alternative use of NIST traceable standards within the laboratory setting. (OOR- This sounds like it is some sort of standard established in the laboratory community. If so, is it written anywhere? If so, the ISOR needs to cite and provide that document to support the inclusion of this in regulation. Is it in the CLIA requirements?)

Page 11: [23] Comment [GH68]

Gary Harris

Justification: This is a general scientific practice utilized in scientific laboratories. The purpose of including it here is to mandate this practice by the laboratories. (OOR- Please provide some written source or other evidence of this practice as a standard in scientific laboratories. Also, please provide some statement that explains what can happen if labs do not conduct this verification. This is the dotting "i's" and crossing "t's" of writing a statement of reasons for proposed regulation text and can greatly save time in responding to public comment in the public process of regulation promulgation.)

Page 15: [24] Comment [DoHS85]

Dept. of Health Services

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OOR: What is the process of approval for law enforcement officers by FA supervisors or analysts? What are the required qualifications of the officers? Can the FA supervisors and analysts decide this for themselves? Is the lab to decide this? How many supervisors or analysts must approve since the plural is used, two? more? Do you really mean one? This process and criteria for qualification will either need to be described in regulation or the ISOR will need to specify that the lab may conduct this approval in any manner it desires. Of course, then you cannot say that the labs must only "approve" experienced operators and the point then becomes why do they have to approve at all. Why cannot the law enforcement agencies decide? All this will need to be explained in the ISOR.

Page 15: [25] Comment [DoHS87]

Dept. of Health Services

Page: 16

OOR- Section 1218 is repealed, so this subsection is repealed unless you want to simply repeal the "After approval as set forth in Section 1218," part and maintain the rest. The repeal of the rest of this subdivision appears to be related to the repeal of "persons who qualify as" in subdivision (a)(4). What is the rationale for this repeal? See OOR comment GH84.