

Review of Forensic Alcohol Laboratory Regulations in Title 17, California Code of Regulations (CCR), Sections 1215 to 1222.2 for Compliance with the Standards of the California Administrative Procedures Act (APA) for the purpose of Revision of those regulations by the Forensic Alcohol Regulations Review Committee (FARC)

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(NOTE: This regulation review is based on the current text in Title 17 CCR. The redrafted language, when offered, includes language proposed by CACLD at the October 25, 2005 Meeting of the FARC and as proposed by the FARC subcommittee in its meeting on December 14, 2005. The following is “proposed” text as of January 5, 2006. Nothing that is present in the following text is absolutely required, though much is strongly recommended to meet the standards of the APA. There continue to be multiple questions and concerns that must be addressed for many of the regulations to be rewritten to the standards of the APA. Yellow highlights designate areas addressed but of continued concern after the subcommittee’s meeting. The gray highlights speak of all the changes to the current regulation text. The comments regarding the continuing concerns in the proposed text are specified in red in the gray highlighted areas.

Further, no proposed regulation may be included in the final proposal without the necessity of that regulation being demonstrated in the Statement of Reasons (ISOR) for this regulation package. The assumption at this time is that the enforcement of these regulations and the related statute will be concluded through the courts. The formatting of this document for the “Proposed Regulations” is not acceptable for filing with the Office of Administrative Law (OAL). The formatting will be addressed when the drafting of proposed regulations is complete.)

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R-05-012

5 January 2006

Proposed Regulations

Article 1. General

1215. Authority. ~~Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.~~

NOTE: Authority cited: Sections 102 and 208, Health and Safety Code. (Per OAL, it is not necessary to “update” the recodified sections of the H&S Code in the Authority and Reference notes in repealed regulations, as repealed regulations no longer have authority and no statute is being interpreted, implemented, or specified in the repealed regulation.)

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.** (This was technically two definitions of the same word and is therefore inherently unclear according to the APA as determined by OAL. The subcommittee determined the references in the proposed regulations to skin antiseptics or disinfectants did not need specification as “alcohols.” Therefore, this definition was amended to remove the double definition.)

(b) “Forensic Alcohol Analysis” means the ~~practical application~~use of specialized ~~devices, instruments, and methods by trained laboratory personnel~~forensic alcohol analysts to measure the concentration of ethyl alcohol in samples of blood, **breath**, urine, or tissue of persons involved in traffic accidents or traffic violations. (“Practical application” is not a clear term, recommend changing to simplify. How are the devices, instruments, and methods “specialized” beyond the definitions of these terms in regulation? Please delete “specialized” or define for the purposes of clarity. Further, “devices” and “instruments” means the same thing in regulation. Inclusion of both is redundant and not necessary. “Trained laboratory personnel” is not defined in regulation whereas “forensic alcohol analyst” is. If you must use “trained laboratory personnel,” the term will need to be defined and the qualifications specified. **The inclusion of breath analysis in this definition created clarity problems in some other sections. The subcommittee determined to remove breath alcohol analysis from the definition of this term and use it in addition to forensic alcohol analysis when needed. The only problem with this approach is the statute includes breath alcohol analysis in the term forensic alcohol analysis. Technically, forensic alcohol analysis should include all types of alcohol analysis and when the regulation needs to specify the type of alcohol analysis, the regulation should state the specific type.**)

(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

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5 January 2006

determine the concentration of ~~ethyl~~ alcohol in the person's ~~blood~~breath. (It is not recommended to use a term that is being defined in the language of a definition. Such use of the term is not clear because it needs to be defined. This is a requirement of the OAL's interpretation of the APA. Since "instrument" is defined in regulation as "any item or combination of items of equipment used to make a measurement of alcohol concentration," when is a breath testing instrument not "designed for this purpose" in the language of this text?)

(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, ~~or, in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit weight of specimen~~a tissue sample. ("Solid" is not used anywhere else to discuss tissue samples in regulation. For clarity, recommend its removal. Is the tissue sample under specific conditions? Wet? Dry? After or before processing? The subcommittee determined that the issues related to tissue sample processing were within the purview of the coroner's office and medical pathology and therefore, needed to be addressed, if necessary with consultation from the committee's medical examiner representative. Further, we have a problem in defining a term with two definitions. This is a clarity issue for the APA. Recommend the tissue analysis components be addressed using a different term to offer the definition. I do not have a recommended term and again the subcommittee determined to seek consultation from the medical examiner representative to the committee. There are questions in the Article 6 that may help with the determination of how best to address this.)

(e) "Forensic Alcohol Laboratory" means **a place** at which ~~specialized apparatus, instruments, and methods are used by trained laboratory personnel~~forensic alcohol analysts or instruments and procedures are used by breath alcohol operators 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 than forensic alcohol analysis and breath alcohol analysis. ("Specialized apparatus" either needs to be defined as to how it is different from "instruments," which is defined in regulation, or deleted from the text. "Trained laboratory personnel" is not a defined term and begs the question of trained by whom or with what qualifications, etc., all of which will need to be specified in regulation. Forensic alcohol analyst is defined and qualifications specified (somewhat) in proposed regulation.

Of continued concern is the problem of the concept of the forensic alcohol laboratory as "a place" rather than as an entity or a legally specified person. The current regulation language defines these laboratories as "a place" and has been able to do so because the laboratories have been licensed. This process of the department issuing a license created the entity of the "licensed laboratory" in regulation, because the licensed laboratory could be defined as a discrete and identifiable entity that had certain characteristics specified in regulation. Further, the current regulation specified various

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R-05-012

5 January 2006

personnel in the forensic alcohol laboratory that were accountable for various activities. Without the process of licensing and the creation of the licensed laboratory, and without the specification of accountable personnel, there is no identifiable entity or person that can be held responsible for anything. All that is left is the forensic alcohol laboratory as “a place” that can be anything or anywhere the “instruments and methods” of alcohol analyses “are used.” This does not allow the forensic alcohol laboratory to be an identifiable entity or person that can be held responsible for anything. The problem of this specification becomes notable in the regulations that the subcommittee desires that address training and supervision of forensic alcohol analysts and breath alcohol operators, but it is a problem in many other regulations as well. Further, it is the desire of the subcommittee to include under the purview of these regulations, police officers and the like in the field using breath-testing instruments. To do this, it is necessary to use language that allows the laboratory to be extended into the field. The need for this broad language is the basis for the use of “a place” in the definition. However, as the laboratory is a place and not an entity or person, it cannot take responsibility to train, supervise, or calibrate and repair instruments, etc. If we use language that makes the laboratory an entity or a person, then we may have a problem regarding police officers conducting breath alcohol analysis in the field, as they could be interpreted as not part of the forensic alcohol laboratory because the forensic alcohol laboratory does not technically employ them. It is possible to argue that entity that is the forensic alcohol laboratory is not a bricks and mortar structure but a defined business or person that conducts the forensic alcohol analysis and/or breath alcohol analysis regardless of where that activity occurs.

In addition, the problem of the entity that is a forensic alcohol laboratory having certain regulatory responsibility for law enforcement officers might be addressed through a definition of “employed” or “employee” that includes police officers and other field breath alcohol operators. Since the statute specifies that the committee’s authority to adopt regulations is to ensure the competency of the “laboratories” and “employees,” it is necessary to make breath alcohol operators “employees.” Our Statement of Reasons (ISOR) may be able to support the broad definition by arguing that the statute makes the labs responsible for ensuring the breath alcohol testing instruments and calibrating devices meet certain requirements (section 100701), and since the vast majority of these instruments are used by police officers in their management of drunk driving situations, it could be argued that forensic alcohol laboratories therefore need to ensure these instruments are used properly. That argument may or may not be acceptable to demonstrate authority, but we can try to use it and see. Further in this debate, there is the concern that arises because H&S Code section 100715, which provided specific authority to regulate law enforcement activity in breath alcohol analysis, was repealed in SB1623, and it could be argued that with that repeal, the legislature specifically repealed the authority of the department to regulate law enforcement in this area. Unfortunately, the language of the statute creates this difficulty and is not easily

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5 January 2006

managed. Program counsel is asked to assist with this discussion and help the committee determine its authority in this matter and the most reasonable means to achieve its goals of establishing standards that hold the forensic alcohol laboratories responsible for various activities and also include law enforcement activities in breath alcohol analysis within the purview of the proposed regulations. Of course, the solution must meet the standards of the APA.

The idea of using language that states the forensic alcohol laboratory is “a place and/or an entity” was proposed to deal with this dilemma, as it is the definition used in federal and state regulation for medical/diagnostic laboratories. This language is not applicable here because is not acceptable to meet the clarity standard of the APA. The test for this standard in relation to definitions is to substitute the language of the definition in every location where the term is used in regulation. If the language of the definition makes sense and is clear, then the definition is clear. If the language of the definition does not make sense and is unclear, then the definition is unclear. The language of “a place and/or an entity” is unclear in the case of forensic alcohol laboratories, as the question arises when is the laboratory a place, when is it an entity, when is it both. To make such language work in these regulations, the regulations would need to stipulate all the circumstances when a laboratory is a place and when it is an entity and how and who is responsible in each circumstance for the purpose of determining the regulating focus of the proposed regulation. This kind of language works in the medical/diagnostic laboratory regulations because those laboratories are licensed and certain personnel are stipulated for various requirements to have a means of determining regulatory accountability.

The concept of making the forensic alcohol laboratory director or some other “person” the responsible party was discussed by the subcommittee to assist with this dilemma, but if a specific position or person is stipulated, then the regulations will need to address who and what this person is, his or her qualifications, his or her responsibilities, and anything else necessary to allow that person to be responsible for whatever is required in regulation. The subcommittee did not wish to specify such requirements in regulation. The use of language that specifies a legal person and defines that “person” as a person or business, etc. may be a means to allow the broadest determination of the forensic alcohol laboratory that can be held accountable for various actions and activities; however, in making this specification we will be allowing the forensic alcohol laboratory to take on many forms as long as it can meet the minimal requirements specified in section 1216.1. This opens the door, so to speak, for nontraditional laboratory operations conducting this analysis, and the committee truly needs to consider its goals in this area in determining the best means to address this difficult problem.

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The subcommittee did not resolve this dilemma and the question is put to the committee to assist. Please review the comments made in almost all the other proposed regulation sections for the specifics of how the concept of a laboratory as a place is problematic.)

~~(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.~~

~~(gf) "Forensic Alcohol Analyst" means a person employed by who is an employee of a forensic alcohol laboratory who performs the technical procedures methods of forensic alcohol analysis and meets the qualifications specified in section 1216.2. (This means that if a forensic alcohol laboratory does not employ this person, then he or she is not a forensic alcohol analyst. Because the statute says you can only determine the qualifications for competency for "employees," it is necessary to make this designation one of the qualifications of forensic alcohol analysts. However, the subcommittee determined that forensic alcohol laboratories frequently utilized the services of graduate students who were imminently qualified to be forensic alcohol analysts but were barred from that designation due to their failure to be an "employee" of the forensic alcohol laboratory. The subcommittee wishes for such persons to be able to be included in this designation. Therefore, a definition for "employee" is required to include such persons and the stipulation of employment will need to be included in the qualifications section in section 1216.2 and the necessity for that status be explained in the ISOR. Further, it will be necessary to define "employee" so that it encompasses more than the traditional definition, especially as the proposed regulations are specifying competency qualifications for "breath alcohol operators" of breath alcohol analysis equipment, and statutory authority to do so is in question at this point. Of course, then the problem of necessity will arise regarding the reasons the committee extended this definition to include others who are not immediately defined as employees as employees of a laboratory. Again, statutory authority to define "employee" more broadly than the usual dictionary definition is in question because it is not defined in statute and that authority will need to be determined. The subcommittee requests that Program counsel address this authority issue and offer guidance.)~~

~~(h) "Forensic Alcohol Analyst Trainee" means a person employed by a forensic alcohol laboratory for the purpose of receiving comprehensive practical experience and instruction in the technical procedures of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.~~

~~(ig) "Method" means the steps used by a trained person forensic alcohol analyst to make a measurement of alcohol concentration in a sample. ("Trained person" is not defined in regulation and therefore is not clear, while "forensic alcohol analyst" is defined and the qualifications specified. If you are going to use this term, it must be defined and the qualifications specified. Further, it is not clear if the "procedure" specified in the Breath Alcohol Analysis Article is a "method." The subcommittee determined that forensic alcohol analysts performs "methods" and breath alcohol operators performed~~

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5 January 2006

“procedures.” The regulation text was amended to use these terms in this manner for the purposes of clarity.)

(j) “Instrument” or “Device” means any item or combination of items of equipment used to make a measurement of alcohol concentration; ~~simple and complex devices are included in this meaning.~~ (Usually recommend the use of one term to mean what is being defined for clarity in the regulation text. “Instrument” was determined to be the term most used in the current regulation text and the subcommittee chose to accept that term exclusively for the proposed regulations. “Device” was included in a title that is incorporated by reference in the previous proposed regulations. As the document cited is specified in the H&S Code as the required reference, the subcommittee determined the statute was clear and there was no need to interpret, implement, or further specify it in regulation. The proposed incorporation by reference was removed and so the use of the term “device” was no longer necessary in this definition. The subcommittee determined to not define “simple and complex devices” and the stipulation was removed from the text.)

(k) “License” means a document issued by the State Department of Health to a laboratory to perform the tests referred to in the Health and Safety Code, Sections 436.51 and 436.52.

(l) “Sample” or “Specimen” means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material such as a reference or a standard, ~~taken for the purpose of measuring its~~ from which an alcohol concentration is measured by forensic alcohol analysis or breath alcohol analysis. (Will need to define “reference” and “standard,” regardless of the use of these terms here. “Artificially constituted material” is not “taken for the purpose of measuring. (emphasis added)” If it is, please specify from where it is “taken” for the purposes of the ISOR, since this is not immediately or logically apparent when read.)

(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.~~ (The subcommittee chose to amend the language in the regulation text that used this term, therefore, the term does no longer need to be defined in regulation and is repealed.)

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

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

Other definitions proposed:

“Breath alcohol operator” means a forensic alcohol analyst or other person who has completed the training specified in section 1221.4(a)(3).

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“Organic volatile” means a carbon-based chemical compound that may evaporate.

“Agency” means an entity that employs breath alcohol operators and/or maintains samples from persons involved in traffic accidents or in traffic violations???. (This is problematic as it is very vague. Technically, a forensic alcohol laboratory could be an agency by this definition. Is an agency always law enforcement? Is it ever any other kind of entity?)

“Internal standard” means a chemical compound introduced into the sample to ensure that the instrument is working during the forensic alcohol analysis.

“Employee” means a forensic alcohol analyst or breath alcohol operator. (This is a convoluted definition because the term forensic alcohol analyst means “a person who is an employee of the forensic alcohol laboratory...” Other possible language is “Employee means a person who conducts forensic alcohol analysis or breath alcohol analysis as part of a forensic alcohol laboratory.” This is problematic because the implication is the forensic alcohol laboratory is not responsible for the employee. Other possible language is “Employee means a person who conducts forensic alcohol analysis or breath alcohol analysis under the direction of a forensic alcohol laboratory.” This will only work if the forensic alcohol laboratory is an entity, as “a place” cannot direct. But as stated before in the discussion in the definition of the term “forensic alcohol laboratory,” offering a broad definition of employee to encompass too much will trigger the question of the committee having the statutory authority to make that definition.)

“Reference sample” means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material containing a pre-determined alcohol concentration.

“Standard” means a water solution with a pre-determined concentration of alcohol.

“Blank standard” means a sample that does not contain alcohol. (Is a blank standard always a water solution? If it can be a different material, we will need to use a different term instead of “standard.”)

“Primary standard” means a water solution with a pre-determined concentration of alcohol, the concentration of which is certified by an organization that is recognized by ??? and is used by the forensic alcohol laboratory to create a secondary standard. (Who is the recognizing body?)

“Secondary standard” means a water solution with a pre-determined concentration of alcohol that is either obtained by the forensic alcohol laboratory from an organization

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that certifies the concentration or is created by the forensic alcohol laboratory from a primary standard as specified in section 1220.2.

“Reference alcohol/water or a dry gas alcohol sample” means ??? (A definition needs to be specified.)

“Procedure” means the steps used by a breath alcohol operator to conduct a breath alcohol analysis.

(General note: Defined terms are used for all references to a particular definition. The complete term must appear in the regulation text and if it does not, then it is a new term that may or may not need to be defined. But for clarity purposes, always use the complete defined term to refer to the issue being regulated. Example: when speaking of “alcohol analysis,” you must use the term “forensic alcohol analysis” or “breath alcohol analysis,” but not simply alcohol analysis. Another example is reference to “laboratory,” must always say “forensic alcohol laboratory,” as that is the defined term.)

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Proposed Regulations

Article 2. Requirements for Forensic Alcohol Laboratories

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 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.~~

1216.1. Qualifications for Licensing to Perform Forensic Alcohol Analysis and Breath Alcohol Analysis.

~~(a) A laboratory meets the qualifications for licensing by: To perform forensic alcohol analysis or breath alcohol analysis a forensic alcohol laboratory shall: (This is problematic, as the forensic alcohol laboratory is "a place" and each place where breath alcohol analysis is conducted cannot meet all these requirements, yet by this language, is required to meet these requirements (i.e. the highway where a DUI arrest is conducted). It may be necessary to create a separate section that speaks to the qualifications to perform breath alcohol analysis, but then all the stipulations related to breath alcohol analysis may need to be separated from the forensic alcohol analysis and we will have some significant duplication of requirements. This still needs to be considered very carefully at this point and the committee is asked to assist with this determination.)~~

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

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

~~(3) Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department; Meet the proficiency testing requirements specified in Health and Safety Code Section 100702. (This stipulation is technically not necessary if we are not going to further interpret the statute or make it more specific, as the statute specifies the proficiency testing requirement and it may not need to be further stipulated in regulation as its requirements are somewhat clear. The subcommittee determined that the stipulations of the statute were acceptable and did not need to be duplicated in regulation, but stipulation of the location of the proficiency testing requirements was~~

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5 January 2006

considered necessary to inform forensic alcohol laboratories of the statutory requirements and provide guidance to the location of the mandates.

The reasons the subcommittee preferred to not specify the proficiency testing further in regulation was the determination that the ASCLD/LAB program was clear and did not need further specifying and that the further stipulations in the statute were the minimums and did not require further specification. The statute can stand as the only specification of the proficiency testing requirements, and if the committee determines that it does not need to further stipulate the requirements of the statute to make the revisions “reasonably necessary to ensure the competency of the laboratories and employees,” then the laboratories will be expected to follow it as specified in statute and the courts will determine if there is further interpretation that is needed. Since the courts are going to be enforcing the statute and regulations anyway, it may be reasonable to allow them to make any further determinations. However, if the committee determines it wishes a role in this interpretation, then regulations will need to be drafted.

Does the committee agree that the statute does not need to be further specified? If the committee does not, then agreement needs to be reached as to what components of proficiency testing need to be specified and why.

The argument can be made that the statute is unclear because the term “external proficiency testing” is unclear in subsection 100702(b). What is “external”? Who in the laboratory must conduct this external proficiency testing? Do the “examiners” in subsection 100702(c) need to complete this external test? That subsection does not specify that. Further, the question arises as to what constitutes participation in the proficiency testing for the forensic alcohol laboratory. Also, if the forensic alcohol laboratory is defined as “a place” in our definition, then how does a place conduct proficiency testing? Of course, if our definition of forensic alcohol laboratory extends to the breath alcohol analysis conducted by police officers in the field, then where they do the analysis is a laboratory and therefore would appear to be accountable to conduct this proficiency testing. Is this the case? Do the officers in the field conduct proficiency testing? Are they considered “examiners” as specified in subsection 100702(c)? It would seem that they are; however, in current practice, are they? If yes, then they may need to be included in a definition of “examiner” that specifies that. If no, then that also needs to be specified, as it can be argued that since the statute does not define the term “examiner,” then it is unclear and regulation needs to be adopted to interpret the statute and make it more specific. Also, what are the components or the “procedure” specified in subsection 100702(d) and what is “corrective action” to address “inconsistent” test results? These questions can be left to the courts to determine on a case-by-case basis as to whether the forensic alcohol laboratory meets the statutory requirements and allows the laboratories the greatest degree of latitude in this matter. However, if the committee believes the laboratories need greater regulation in this and

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5 January 2006

the courts need more specifics to ensure the laboratories and their employees are competent, then it is likely necessary to adopt regulations regarding the proficiency testing requirements in the statute and then point to those regulations here as a requirement of the forensic alcohol laboratory rather than pointing to the requirements of the statute.)

(3) Collect and handle samples as specified in Article 5.

~~(4) Passing such on-site inspections as the Department may require; Perform forensic alcohol analysis as specified in Article 6.~~

~~(5) Showing ability to meet the requirements set forth in these regulations. Perform breath alcohol analysis as specified in Article 7.~~

(6) Maintain records as specified in Article 8.

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

~~(c) The Department may deny a license or renewal thereof, or take disciplinary action against a licensee, for failure to maintain these qualifications in a manner which meets the Department's standards for approval.~~

~~(d) Whenever a licensed laboratory employing only one forensic alcohol supervisor loses that person, the Department may upon petition of the laboratory extend the license for a period not exceeding 90 days during which time the laboratory shall hire another forensic alcohol supervisor.~~

~~(1) Such an extension shall be contingent on the laboratory's having in its employ at least one forensic alcohol analyst and upon the laboratory's successfully demonstrating to the Department continued competence in forensic alcohol analysis through such proficiency tests, examinations, and on-site inspections as the Department may require.~~

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

~~(1) Possesses a baccalaureate or higher degree, or an equivalent in chemistry, biochemistry, or other appropriate discipline as determined by the Department.~~

~~(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 such experience, satisfactorily completes a training course approved by the Department, such training course to include at minimum the following schedule of subjects:~~

~~(A) Value and purpose of forensic alcohol analysis, including breath alcohol analysis;~~

~~(B) Physiological action of alcohol;~~

~~(C) Pharmacology and toxicology of alcohol;~~

~~(D) Laboratory methods of 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;~~

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(H) Court testimony;

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

~~(J) Requirements of these regulations;~~

~~(3) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;~~

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

~~(5) Either is a person who, prior to January 1, 1971, qualified as director of a clinical laboratory operating under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol supervisor.~~

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

~~(1) Successfully completes at least 60 semester hours, or their equivalent in quarter hours, of college level courses, including 8 hours of general chemistry and 3 hours of quantitative analysis;~~

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

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

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

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

~~(6) Either is a person who, prior to January 1, 1971, was a clinical laboratory technologist licensed under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol analyst.~~

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

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

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

NOTE: Authority cited: Sections 100275 and 100703 Health and Safety Code.

Reference: Sections 100702 and 100703, Health and Safety Code.

(Proposed section 1216.1 is based on the CACLD proposed regulations. The repealed provisions include qualifying other laboratory personnel categories and if determined to still be necessary to ensure the competency of laboratory personnel, will need to be rewritten to meet the clarity standard of the APA. The subcommittee did not chose to include the qualifying provisions proposed for repeal.)

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R-05-012

5 January 2006

1216.2. Qualifications of Forensic Alcohol Analysts.

(a) To perform forensic alcohol analysis or breath alcohol analysis, a forensic alcohol analyst shall:

(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.

(2) Have training and demonstrated competency in performing Forensic Alcohol Analysis. Training shall include:

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

(B) Practical demonstration of the person's ability to perform alcohol analysis;

(C) The requirements of Title 17, Division 1, Chapter 2, Subchapter 1, Group 8 of the California Code of Regulations.

(3) In lieu of the qualifications specified in (a)(1) and (a)(2), be qualified by the Department of Health Services as a Forensic Alcohol Supervisor or Forensic Alcohol Analyst on or before (date to be determined). (The date is the date that the regulations are promulgated to allow for all applicable grandparenting under this provision.)

(4) Is an employee of a forensic alcohol laboratory. (Again, this is problematic, as "a place" cannot employ persons.)

NOTE: Authority cited: Sections 100275 and 100703 Health and Safety Code.

Reference: Sections 100702 and 100703, Health and Safety Code.

(Proposed section 1216.2 is based on the CACLD proposed regulations.

Subsection (a)(2) continues to be problematic. For clarity it must be much more specific. It needs to specify who provides the training, how it is provided, numbers of hours that are acceptable for covering the content, specifically what the content must include, what a practical demonstration must include, what is needed to demonstrate competency, etc. This sounds like orientation to the FAL's policies and procedures with return demonstration so that the lab knows the analyst can perform its methods on its instruments. Is it really necessary to specify in regulation as a qualification? Is it necessary for the courts? Do you have to prove this anyway each time you are in court? By meeting the APA requirement of clarity, you will be requiring each lab to meet your vision of this training. The subcommittee did not want to do that, as it was not the intent of the statute to restrict the laboratories. Is it necessary for the specification in regulation of the qualifications for the forensic alcohol analyst? The subcommittee thought that it was necessary because each lab does its testing using specific instruments and methodologies related to those instruments. The justification that will be offered in the ISOR will include a discussion of the desire of the committee to not be

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R-05-012

5 January 2006

overly burdensome on labs and that the means of the training is not the standard of general application needing specification in regulation and only the basic content and the provision that competency be determined by the means specified is necessary to ensure the competency of the forensic alcohol analyst as required by H&S Code 100703. The determination of the adequacy to the training is based on the outcome specified as the competency of the forensic alcohol analyst in the suggested regulation text below. Since the courts will be “enforcing” these requirements anyway, this will be argued to be adequate to their needs for determining competency of the forensic alcohol analyst, as the requirements are outcome oriented rather than process oriented in regulation.

For the purposes of discussion the following text is offered for subsection (a)(2):

(2) Have training and demonstrate competency in performing Forensic Alcohol Analysis.

(A) Training shall be provided by the forensic alcohol laboratory (a place??) and shall include:

1. The methods of alcohol analysis employed in the forensic alcohol laboratory;
2. The instruments used by the forensic alcohol laboratory in its methods; and
3. The requirements of Title 17, Division 1, Chapter 2, Subchapter 1, Group 8 of the California Code of Regulations.

(B) Competency shall be demonstrated to the forensic alcohol laboratory and shall consist of the forensic alcohol analyst conducting FA analysis &/or BA analysis using the FAL’s methods and obtaining the pre-determined measurements of the alcohol concentration in a sample specific to the method for ??? number of samples.

For subsection (a)(3), the term forensic alcohol supervisor is no longer defined and specified. We will need to speak to this in the ISOR, so that the background is understood.

For subsection (a)(4), to be consistent with the definition of forensic alcohol analyst, the analyst must be an “employee” of a forensic alcohol laboratory. It is necessary to define “employee” for the purposes of these regulations in order to broaden the scope of that concept as the common definition will not work well for us in these regulations.)

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R-05-012

5 January 2006

Proposed Regulations

Article 3. Licensing Procedures

(NOTE: The regulation provisions in this article are proposed for repeal based on the elimination of the department's authority to license laboratories. If any of the provisions present in this article are desired, then the language will need to be amended to remove the connection to licensing and the necessity for the provision will need to include some discussion of the purpose outside of licensing and the means for monitoring if necessary to support the provision. The subcommittee determined that none of the provisions of this Article were necessary to include in the proposed regulations. However, if the components of proficiency testing are determined to be necessary for stipulation in regulation, a current section number in this article could be used and the article renamed to reflect that use.)

1217. Forensic Alcohol Laboratory License.

~~(a) Upon receipt of a completed application which shows ability to meet the requirements set forth in these regulations, and upon payment of any required fee, the Department shall submit such proficiency test samples and perform such examinations as are required for that laboratory to complete the qualifications.~~

~~(b) Upon the laboratory's successfully completing all the qualifications, the Department shall issue to the applicant laboratory a forensic alcohol laboratory license.~~

1217.1. Renewal 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.~~

~~(3) An application for renewal shall not list as a forensic alcohol analyst trainee any person who fails to comply with the requirements of Section 1216.1(f)(4) within a period of one year after he was first listed with the Department as a trainee. The Department may extend this period for a justifiable reason such as illness.~~

1217.2. Application Forms. ~~Application for license and renewal thereof, shall be made on forms furnished by the Department. The applicant shall set forth all pertinent~~

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R-05-012

5 January 2006

~~information called for by the forms. The applicant shall set forth all pertinent information called for by the form.~~

1217.3. Report of Change or Discontinuance.

~~(a) A person responsible for the operation of a forensic alcohol laboratory shall report to the Department in writing within 30 days any change in qualified personnel who may be performing forensic alcohol analysis, change of ownership, change of address or change or discontinuance of an activity authorized under these regulations.~~

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

1217.4. License Implications. ~~Licenses issued under these regulations shall not imply approval of anything carried out by a laboratory other than what is specified on the document.~~

1217.5. Licensing Records. ~~Forensic Alcohol Laboratory Licenses shall become part of permanent records available to the courts for legal proceedings or to the Department.~~

1217.6. Inspection and Additional Requirements.

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

~~(b) Access to Premises. The Department may enter at all reasonable times upon any laboratory for the purpose of determining whether or not there is compliance with the provisions of these regulations.~~

1217.7. Surveys, and Proficiency Tests

~~(a) Laboratories having been licensed or applying for licensing As forensic alcohol laboratories shall be subject to on-site surveys by representatives of the Department, the results of which must meet the requirements of these regulations, and shall accept periodic evaluation samples, perform analyses and report the results of such analyses to the Department.~~

~~(b) These analytical results shall be used by the Department to evaluate the accuracy of the forensic alcohol analyses performed by the laboratory, and the results must meet the requirements of these regulations.~~

1217.8 Fees and Other Procedures. ~~The annual application fee for a Forensic Alcohol Laboratory License or its renewal shall be one hundred dollars (\$100). A laboratory operated by the state, city or county or other public organization shall be exempt from the annual application fee requirement. Other procedures in the administration of these regulations shall be carried out as set forth in Chapter 5 (commencing with section~~

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R-05-012

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5 January 2006

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~~436.50) of Part 1 of Division 101 of the Health and Safety Code. Such other procedures include suspension or revocation of license, denial of license, and disciplinary action.~~

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R-05-012

5 January 2006

Proposed Regulations

Article 4. Training of Personnel

(NOTE: The regulation provisions in this article are proposed for repeal as written as they open to great interpretation. Further, unless the proposed regulations provide a basis for the need for the approval of a training program, there will not be necessity to support regulations addressing this issue. If any of the provisions present in this article are desired, then the language will need to be amended to address the clarity problem and the necessity for the provision will need to include some discussion of the purpose and the means for conducting the approval processes. The subcommittee determined that none of the provisions of this Article were necessary to include in the proposed regulations.)

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.~~

1218.1. Additional Requirements. ~~At the discretion of the Department, any phase or portion of a training program shall be subject to alteration in an effort to update the program as technological advances are made or if a portion has been judged inappropriate.~~

1218.2. Contracts. ~~The Department may contract with persons it deems qualified to administer such practical tests and written or oral examinations as may be required under these regulations. This section shall not be construed to authorize the delegation of any discretionary functions conferred on the Department by law, including, but not limited to, the evaluation of tests and examinations.~~

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R-05-012

5 January 2006

Proposed Regulations

Article 5. Collection and Handling of Samples

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.~~

Note: Authority cited: Sections 102 and 208, Health and Safety Code. Reference: Section 436.50, Health and Safety Code.

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 ~~1335423158(a)~~ of the Vehicle Code. (Recodification makes this a Section 100 change. If we change nothing else in this section, then we do not need to rewrite the section or explain necessity. If we make other changes, then we must change the highlighted language to meet the standard of clarity and must explain necessity in the ISOR. **The subcommittee determined that the recodification was not the only amendments to this section. The timeframe for blood collection was proposed for repeal as the subcommittee maintained that if the regulation text was made less vague it would be too restrictive and the timeframe is stipulated in the Vehicle Code or Evidence Code. The section(s) of the Vehicle Code or Evidence Code will need to be determined and provided for the ISOR.**)

~~(b) Sufficient blood shall be collected to permit duplicate determinations.~~ (How much? By what methods of completing the determinations? Does all equipment require the same amount of blood? Does everyone who might collect the blood know how much blood is "sufficient"? The defense labs representative at the public meetings addressed the need for two tubes to be drawn to meet the duplicate determinations need. Should two tubes be stipulated? Is one actually sufficient and two just something that would be nice? What about the issue of air exposure as brought up by the defense labs representative? This is very vague as currently written and allows for multiple questions that need to be considered to determine the clearest language for the regulation. **The subcommittee determined that the amount of blood could not be specified as it depended on the method and instruments used by the forensic alcohol laboratory. Further, the subcommittee determined that forensic alcohol laboratories would accept any amount of blood as a sample, regardless of their ability to perform duplicate determinations, and would do what they could with the sample to determine a blood alcohol concentration. With that being the case, the subcommittee had no reason to stipulate this requirement in regulation, so it is proposed for repeal.**)

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R-05-012

5 January 2006

(~~eb~~) Alcohol **or other volatile organic disinfectant** shall not be used to clean the skin where a specimensample is to be collected. ~~Aqueous benzalkonium chloride (zephiran), aqueous merthiolate or other suitable aqueous disinfectant shall be used. (The subcommittee determined that all the instruments used currently in forensic alcohol laboratories were able to make the determination of the presence and amount of concentration of other volatile organic solvents and disinfectants. As a result, the subcommittee could not determine a reason to maintain this restriction in regulation. Further, the subcommittee determined that it did not see a need to stipulate the skin disinfectants that could be used to draw blood samples, as the sample and the forensic alcohol analysis was not affected by whether such disinfectants were used or not as the preservative in the collection tube prevented alcohol degradation in the sample by introduced bacteria. The subcommittee determined the forensic alcohol laboratories could make the determination or the use of disinfectants, and even if no disinfectant was used, the subcommittee did not determine it impacted on competence of the laboratory or its employees to prepare, analyze, and report results of the blood alcohol tests.)~~

(~~ec~~) 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**. **(See discussion above.)**

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

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

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

(~~fe~~) ~~When b~~ **Blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to insure an uncontaminated sample shall be employed, such as:**

(1) ~~Samples shall be obtained prior to the start of any embalming procedure on the body. Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid. Coroner's samples do not need a preservative added if stored under refrigeration.~~

(2) ~~Care shall be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom. The sample shall be and taken from a major vein blood vessel or the heart. (The subcommittee determined the only requirements needing stipulating in regulation for post-mortem blood collection were those included above. The point of the two stipulations was to prevent contamination of the sample with embalming fluid and GI tract fluid. The technique by which the blood is collected post-mortem was determined by the subcommittee to be unnecessary to stipulate in regulation as it did not impact on the blood alcohol analysis.)~~

(~~gf~~) In order to allow for analysis by the defendant, the remaining portion of the sample shall be **retained for one year** **(by whom?)** after the date of collection. **(Can anyone else use this sample? This regulation says "no.")**

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R-05-012

5 January 2006

(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** (**These regulations do not regulate law enforcement agencies as written. Question of authority to regulate based on new statute.**) in possession of the original sample **shall continue such possession** (**For how long? As it reads, if the sample is insufficient, then possession is not maintained? Or is the point, the lab does not give it to the defendant if there is not a "sufficient sample"? The language is not clear.**), but shall provide the defendant with **a portion** (**How much?**) of the remaining sample in a clean container together with a copy or transcript of the **identifying information carried on the original sample container**. (**Nothing in these regulations specifies labeling of samples. Do you want to make this specification? Why necessary in regulation? If not specified, this requirement cannot be included in rewritten regulations. Is the labeling required specified in some other statute or regulation?**)

(The subcommittee did not have any recommendations for the text in subsection (f) and asks the committee, and most specifically the representatives for the public defenders, the prosecutors, and the CHP to assist with the problems in subsection (f).)

NOTE: Authority cited: Sections 100275 and 100700, Health and Safety Code.

Reference: Section 100703(f), Health and Safety Code.

1219.2. Urine Collection and Retention.

(a) ~~The only approved~~ A urine sample shall be a sample collected no sooner than twenty minutes after first voiding the bladder of the person involved in a traffic accident or traffic violation. (**The subcommittee determined that further stipulation of the procedure was not necessary as it is specific to the forensic alcohol laboratory and the courts will determine its adequacy on a case-by-case basis, as is currently the situation.**)

(b) The ~~specimens~~sample 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** (**By whom? Under what conditions? Does it matter?**) 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 on the original sample container**.

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R-05-012
5 January 2006

(The subcommittee did not have any recommendations for the text in subsection (c) and asks the committee, and most specifically the representatives for the public defenders, the prosecutors, and the CHP to assist with the problems in subsection (c).)

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.
Reference: Section 100703, Health and Safety Code.

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.~~ (a) The breath sample shall be collected only after the subject has been under **continuous observation** for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, burped, belched, or smoked. (The subcommittee determined that rather than stipulate “continuous” in the observation requirement, it was reasonable to delete the language and allow the courts to decide the adequacy of the observation that the police officer conducted, rather than require the forensic alcohol laboratory to have to make this determination. The subcommittee maintains that the courts make this determination now on a case-by-case basis and it is unreasonable to require the forensic alcohol laboratories to have to deal with this as a requirement. Of course, the question then arises as to the reason to specify any of the components in the proposed regulation, as it can be argued the courts will decide the adequacy of the sample collection on a case-by-case basis regardless of the regulatory “requirements.” But assuming we need to make this specification, are there any other caveats on what they can’t do?)

Further, this section’s content was moved in the CACLD proposed regulations to the article addressing breath analysis. The presence of a section with the “Breath Collection” label here makes it more reasonable to continue to specify these requirements here, as the section number and label will remain and persons seeking the information will likely look here first. The subcommittee determined that keeping the collection content in this section added to clarity in the regulations.)

(b) For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples that result in determinations of breath alcohol concentrations which do not differ from each other by more than 0.02 grams per 210 liters. (Moved from section 1221.4 and amended for clarity. Necessity for the changes of “blood” to “breath” and the volumes will need to be provided for the ISOR.)

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.
Reference: Section 100703, Health and Safety Code.

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R-05-012

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5 January 2006

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(Tissue collection and analysis? Is it needed, since it is not currently in regulation?
Why? The subcommittee determined the regulation of tissue collection was
unnecessary.)

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R-05-012

5 January 2006

Proposed Regulations

Article 6. Methods of Forensic Alcohol Analysis for Blood, Urine, and Tissue

1220. General. (Is this still needed? Statute only requires a procedure that describes a review of proficiency test results and corrective action if needed. Are other procedures needing to be required in regulation? Why? The answers to these questions are needed for the ISOR.)

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

~~(ba) 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. (Must specify what constitutes “detailed” and how up-to-date is “up-to-date”? These are vague terms that have multiple meanings and must be specified to meet the clarity standard. Is it necessary to make the specification of “detailed, up-to-date”? The subcommittee determined that it did not need to further specify what was considered “detailed” or “up-to-date” and all that was necessary was that the methods be written and be the methods the forensic alcohol laboratory “uses.”)~~

~~(1) Such descriptions shall be immediately available to the person forensic alcohol analyst performing an forensic alcohol analysis and shall be available for inspection by the Department on request. (Do you mean at the bench? Or somewhere in the lab? Or can they be on-line? Or can they be in another room behind a locked door? “Immediately available” is too vague. Need to specify. The subcommittee decided to delete the vague term “immediately” and allow the dictionary definition of “available” to stand as the meaning of the concept. The Oxford American Dictionary of Current English, 1999, defines “available” as “1. Capable of being used; at one’s disposal. 2. Within reach.”)~~

~~(2) Each such description shall include specify the steps to the method, the instruments used in the method, the persons qualified to conduct the method, the calibration procedures for the method as specified in section 1220.2, and the quality control program as specified in section 1220.3 for the method. (Is anything else needing to be included in the method description? A statement of inclusion implies other requirements that need to be specified for clarity. All components that are required to be present must be specified.)~~

~~(b) Each forensic alcohol laboratory shall follow the written descriptions specified in subsection (a) when conducting forensic alcohol analysis. (The subcommittee felt this was necessary to ensure the forensic alcohol laboratories used the written descriptions and did not just write them, as was currently the requirement in regulation. This may seem a simple point, but without this stipulation, the forensic alcohol laboratories truly do not need to use the written descriptions, they only have to write them. It can be argued that the specification of the descriptions be of “each method it uses” (see subsection (a)) requires the written descriptions to be used, but technically, it does not,~~

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R-05-012

5 January 2006

as the written description does not have to match the method and it is still the method that is practiced.)

Note: Authority cited: Sections ~~102100110, and 208100275,~~ and 100703, Health and Safety Code. Reference: Section ~~436.50100703,~~ Health and Safety Code.

1220.1. Standards of Performance.

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

(1) The method shall be capable of the analysis of a reference sample of ~~known alcohol concentration~~ within accuracy and precision limits of plus or minus 5 percent of the value pre-determined alcohol concentration; these limits shall be applied to alcohol concentrations which are ~~0.10 grams per 100 milliliters or higher~~ between 0.08% and 0.25% alcohol; (The reason for the changes in the concentrations in regulations is to allow for multiple determinations of the capabilities of the method and to allow a range of concentrations that represent the majority of DUI samples received by forensic alcohol laboratories from the legal limit of intoxication to a level well above the legal limit. The subcommittee asserted that most forensic alcohol laboratories test their methods with several samples within this range and this is a reasonable range to expect a method to be accurate.)

(2) The method shall be capable of ~~the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement~~ identifying alcohol from other organic volatiles that would be in blood, urine, or tissue of the human body, or from an internal standard used in the method, or from a substance used to clean the skin for sample collection; ~~(The current text is too vague and required clarification to specify the exact "specificity." The subcommittee determined that the forensic alcohol laboratory's method must be able to do those things specified above.)~~

(3) The method ~~should~~ shall be demonstrated to be free from interference from anticoagulants and preservatives added to the sample; ~~(The subcommittee determined that the means the forensic alcohol laboratory used to demonstrate that its method is free from interference was not necessary to specify as long as they could do it. This is an outcome standard and the ISOR will speak to this.)~~

(4) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance (define) is identified as ~~ethyl~~ alcohol by qualitative test (specify what this is); ~~(The subcommittee did not feel comfortable determining appropriate language for this subsection, as it is within the purview of the medical examiner's work. The subcommittee requests the assistance of the representative from the medical examiner's on the committee to assist with appropriate language to address the amendment of this subsection. Of course, the question of necessity to retain the subsection in regulation is also open to debate.)~~

(5) The method shall be demonstrated to give a test result which is always less than 0.010 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol

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R-05-012

5 January 2006

are tested. ~~(The subcommittee determined that the means the forensic alcohol laboratory used to demonstrate that its method gave the required test result was not necessary to specify as long as they could do it. This is an outcome standard and the ISOR will speak to this. The subcommittee added the third decimal place in the result to "allow for analytical variation.")~~

~~(b) The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by the Department using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.~~

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

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 secondary standards ~~which are water solutions of alcohol.~~

~~(A) Such alcohol solutions are secondary standards.~~

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

(B) The forensic alcohol laboratory shall verify the concentration of all secondary standards used in the method by analyzing the new secondary standard concurrently with a previously analyzed secondary standard. ~~(The subcommittee determined that since forensic alcohol laboratories already verify their secondary standards regardless of whether they are purchased and certified or are created by the forensic alcohol laboratory it was simpler to just require that they make this verification rather than specify in regulation all the needed information regarding independent analysis and certification of secondary standards. However, an outstanding issue remains regarding tissue standards. Does the forensic alcohol laboratory create secondary standards for tissue analysis? Is it the same as for blood and urine? Or does this above process only apply to blood and urine secondary standards? This needs clarifying for the ISOR.)~~

(2) The ~~procedure~~method shall include blank and secondary alcohol standards ~~samples~~ at least once each day that blood, urine, or tissue samples, are ~~subjected to~~ tested by forensic alcohol analysis. ~~(A) The blank and secondary alcohol standards samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.~~

(3) The ~~procedure~~method shall also include analysis of quality control reference samples as ~~described~~ specified in Section 1220.3. ~~(A) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.~~

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R-05-012
5 January 2006

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

~~(5) All instruments used for forensic alcohol analysis shall be in good working order and routinely checked for accuracy and precision. (The subcommittee determined that since a method could not be run and meet the requirements of section 1220.2 if the instruments for the method were not working and checked for precision and accuracy, the vagueness of this subsection made it unnecessary. Therefore, the subsection was proposed for repeal.)~~

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.
Reference: Section 100703, Health and Safety Code.

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** (This implies a specific method, must specify unless can be done by many accepted methods and no one cares. **The subcommittee determined the forensic alcohol laboratory could determine its own means of making or acquiring a quality control reference sample and therefore, deleted the word "suitable" to allow for this allowance. Again, this will be presented as an outcome standard in the ISOR.**) a **suitable** quality control reference ~~material~~sample containing alcohol, a sample of which it shall analyze along with each set of blood, urine, or tissue samples; the alcohol concentration in the reference material shall be between 0.40080 and 0.20**50** grams per 100 milliliters of liquid; **(The concentrations were changed by the subcommittee for consistency in requirements in regulation, since the upper level of 0.250 grams was the upper level in section 1220.1(a)(1).)**

(2) For each lot of quality control reference ~~material~~sample, the laboratory shall determine a mean value of at least 20 replicate analyses, ~~at a rate of no more than 2 analyses per day performed over a minimum of 5 separate days,~~ with the method ~~used for analysis of samples for forensic alcohol analysis;~~ **(Can these days be months apart? Based on this language, they can. Is your intent that the lab can determine when these 5 days take place? The subcommittee determined that indeed the forensic alcohol laboratory may determine the separation of the 5 days. The intent of requiring 5 days is for the purpose of detecting instrument variation and it does not matter if the 5 days are consecutive days or 5 months apart from each other.)**

(3) Acceptable limits of variation for the method shall be plus or minus 5% of the mean of the quality control reference sample determined in (a)(2). ~~set as follows:~~

(A) ~~The lower limit shall be calculated by subtracting, from the mean value, 0.01 grams per 100 milliliters;~~

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

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R-05-012

5 January 2006

(4) At least one sample of the quality control reference ~~material~~sample shall be analyzed with each **set** of blood, urine, or tissue samples analyzed for the purpose of forensic alcohol analysis; **(Forensic alcohol laboratories run their analyses of blood, urine, or tissue samples in volume "sets," that is batches of 10 to 100 or possibly more, in order to make this analysis process cost effective for the lab. The forensic alcohol laboratory is allowed to determine the number of samples in these sets and no regulation of that amount is needed to ensure competent analysis. All that is needed is to require the forensic alcohol laboratory to run at least one quality control reference sample with the set, regardless of size, to ensure that the samples run in the set are analyzed accurately by the method used.)**

(5) Whenever analysis of the quality control reference ~~material~~sample is outside the acceptable limits specified in (a)(3), the ~~method~~forensic alcohol analysis shall be regarded to be in error, and a forensic alcohol ~~supervisor~~analyst shall take remedial action to investigate and correct of the source of the error, as shown by return of the analysis of the quality control reference sample to values within the limits specified in (a)(3);

(6) Until such time as the error has been corrected, as shown by return of the forensic alcohol analysis of the quality control reference material~~sample~~ to a values within the acceptable limits specified in (a)(3), no blood, urine, or tissue samples shall be analyzed for the purpose of forensic alcohol analysis.

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

1220.4. Expression of Analytical Blood, Urine, and Tissue Alcohol Analysis Results.

(a) ~~With the exception of tissue analysis, all analytical Blood and urine alcohol analysis results shall be expressed in terms of the alcohol concentration in blood, based on the number of grams of alcohol per 100 milliliters of blood. (1) The symbols: grams %, g%, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of liquid. (Why are abbreviations necessary to specify in regulation? Cannot labs determine any abbreviation, if they can communicate what it is they mean? The subcommittee offered that these abbreviations are specified in the Vehicle Code. The section number of the Vehicle Code will need to be determined for discussion in the ISOR.)~~

(b) ~~Analytical Blood, urine, and tissue alcohol analysis~~ results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present.

(c) Blood alcohol concentrations less than 0.01% in living subjects **may** be reported as negative. **(But they do not have to be? Why specify in regulation? Does it matter? Will need to address in the ISOR, as the allowance for discretion must be made clear for the purposes of providing a reason for such discretion in regulation. Technically, when**

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R-05-012

5 January 2006

there is discretion for the regulated public, no regulation is required. The subcommittee related that this discretion is needed because of other forensic alcohol work, not related to traffic accidents or violations, that requires more specificity and labs sometimes just report numbers at all times and those numbers are just as valid as the statement of the sample being "negative.")

(d) Blood alcohol concentrations less than 0.02% on post-mortem blood samples **may** be reported as negative. **(But they do not have to be? Please see the comments in previous subsection.)**

(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.~~
(Is moved to the specifications in section 1221.5 if you want to rewrite the few parts of this section that need it. Section 1221.5 should also contain some of the requirements specified in the breath analysis article.)

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

NOTE: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

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R-05-012

5 January 2006

Proposed Regulations

Article 7. Requirements for Breath Alcohol Analysis

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

Note: Authority cited: Sections 102 and 208, Health and Safety Code. Reference: Section 436.50, Health and Safety Code.

1221.1. Authorized Procedures.

~~(a) Breath alcohol analysis shall be performed only with instruments and related accessories which meet the standards of performance set forth in these regulations.~~

~~(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.~~

Note: Authority cited: Sections 208 and 436.50, Health and Safety Code. Reference: Section 436.52, Health and Safety Code.

1221.2. Standard of Performance.

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

~~(1) The instrument and any related accessories shall be capable of conforming to the "Model Specifications for Evidential Breath Testing Devices" of the National Highway Traffic Safety Administration of the U.S. Department of Transportation, which were published in the Federal Register, Vol. 49, No. 242 Pages 48854—48872 December 14, 1984 and are hereby adopted and incorporated.~~

~~(b) The ability of instruments and any related accessories to conform to the standard of performance set forth in this Section shall be tested by the U.S. Department of Transportation.~~

Note: Authority cited: Sections 208 and 436.50, Health and Safety Code. Reference: Section 436.52, Health and Safety Code.

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R-05-012

5 January 2006

1221.3. Approved Instruments.

(a) ~~Only such types and models of instruments and related accessories as are named in the "Conforming Products List of published 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 instruments used in breath alcohol analysis shall meet the requirements specified in Health and safety Code Section 100701.** (It is not necessary to duplicate the statute in regulation. However, 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 for and conduct breath alcohol analysis. This is an acceptable reason to duplicate statute in regulation according to the APA.)

Note: Authority cited: Sections ~~208~~100275 and ~~436.50~~100703, Health and Safety Code.
Reference: Section ~~436.52~~100701 Health and Safety Code.

1221.4. Standards of Procedure for Breath Alcohol Analysis.

(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 samples which result in determinations of blood alcohol concentrations which do not differ from each other by more than 0.02 grams per 100 milliliters. (Moved to section 1219.3 for clarity.)~~

~~(2) The accuracy of instruments shall be determined. The forensic alcohol laboratory shall be responsible for determining the accuracy of breath alcohol instruments.~~ (The subcommittee determined that it is the intent of this requirement to place the responsibility for the calibration and precision and accuracy determinations of these instruments on the forensic alcohol laboratory. However, since a forensic alcohol laboratory is "a place" this is problematic. A place cannot take responsibility for anything. Again, this needs to be resolved to make this requirement possible. To add to this, the subcommittee reported that these accuracy determinations are sometimes delegated to the law enforcement agencies after the forensic alcohol laboratory trains someone in the agency to do this. The subcommittee did not want to restrict this practice by regulation, but still wanted the forensic alcohol laboratory to have the final responsibility in the effort. The regulations as written for subsection (a)(1)(A) through (a)(1)(E) allow for this practice, as they do not specify that the laboratory do the determination of accuracy, they simply specify the laboratory is "responsible" for determining and the means of that determination is left open to interpretation. This will need to be discussed in the ISOR so that it is understood that the purpose of this regulation is to allow this flexibility in the process of determining accuracy. The following is an attempt to provide the regulation for specifying the requirement of accuracy

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R-05-012

5 January 2006

determination and they assume the forensic alcohol laboratory is an entity that can take responsibility for this practice.)

~~(A) Such Determination of accuracy of instruments shall consist, at a minimum, of periodic breath alcohol analysis of a reference alcohol/water or a dry gas alcohol sample of known alcohol concentration between 0.080 and 0.250 grams/210 liters. The results of determinations of accuracy shall be within limits of plus or minus 0.010 grams/210 liters of the known concentration of the sample. within accuracy and precision limits of plus or minus 0.010 grams % of the true value; these limits shall be applied to alcohol concentrations from 0.10 to 0.30 grams %. The reference sample shall be provided by a forensic alcohol laboratory.~~

~~1. Such analysis shall be performed by an operator as defined in Section 1221.4 (a)(5), 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).~~

~~(B) For the purposes of such determinations of accuracy, "periodic" means The accuracy determination specified in subsection (a) shall occur once in either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner.~~

~~(C) Whenever analysis of the reference alcohol/water or a dry gas alcohol sample is outside the limits specified in (a)(1)(A), the breath alcohol analysis shall be regarded to be in error, and a forensic alcohol analyst shall take remedial action to investigate and correct of the source of the error, as shown by return of the breath alcohol analysis of the reference alcohol/water or a dry gas alcohol sample to concentration within the limits specified in (a)(1)(A);~~

~~(D) Until such time as the error has been corrected, as shown by return of the breath alcohol analysis of the reference alcohol/water or a dry gas alcohol sample to a concentration within the limits specified in (a)(1)(A), no breath samples shall be analyzed for the purpose of breath alcohol analysis.~~

~~(E) A forensic alcohol laboratory shall establish the concentration of each lot of reference alcohol/water or a dry gas alcohol sample it prepares by an oxidimetric method, which employs a primary standard, such as United States National Institute of Standards and Technology (NIST) potassium dichromate; or purchase NIST traceable reference standards. The laboratory shall verify the value by analyzing the new reference alcohol/water or a dry gas alcohol sample concurrently with a previously analyzed reference alcohol/water or a dry gas alcohol sample.~~

(32) 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;

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R-05-012

5 January 2006

(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 in a licensed forensic alcohol laboratory.

(CACLD Proposed) Breath alcohol analysis shall be performed only with instruments for which the operators have received training and demonstrated competency through written and/or practical examination. Breath alcohol analysis may be performed by operators who do not meet the requirements of a forensic alcohol analyst if they have received training for a specific instrument under a training program supervised by laboratories engaged in the practice of forensic alcohol analysis that is responsible for the maintenance of those instruments. Training may include the use of multimedia presentations, secondary trainers, and/or other methods, as approved by the laboratory. The training of operators shall include at minimum the following subjects:

(A) Basic theory of operation;

(B) Detailed procedure of operation;

(C) Practical experience;

(D) ~~Precautionary Checklist~~

(D) Written and/or practical examination.

~~(The specification of the breath alcohol analysis training needs work in the proposed regulations. The CACLD proposed regulations do not meet the APA standards either. The subcommittee did not determine the needed specificity for this, as the problem continues to exist of who or what is responsible for this training. Further, the subcommittee determined the methodologies used by labs and agencies are varied and the subcommittee did not wish to make specific requirements that curtailed the independence of the labs and agencies in determining the means that best met their training needs for breath alcohol operators. As a result, if these requirements are to be specified in regulation, some research with labs and agencies will need to be conducted to determine what needs to be required in regulation and justification for the broadness of those likely requirements provided for the ISOR. Further, as with the training for forensic alcohol analysts, the ISOR will need to address the outcome versus the process specification of the competency determination specified in regulation to support the necessity for the training while the specifics of the training are allowed to be so open for the laboratory to determine for itself how best to meet the requirement. Some suggested language that mirrors the training language for forensic alcohol analysts in proposed section 1216.2 follows and it again assumes the forensic alcohol laboratory to be "an entity":~~

~~(2) To perform breath alcohol analysis, a breath alcohol operator shall have training and demonstrate competency in performing breath alcohol analysis.~~

~~(A) Training shall be provided by the forensic alcohol laboratory (a place??) and shall include:~~

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R-05-012

5 January 2006

1. The procedure(s) of breath alcohol analysis used by the forensic alcohol laboratory (agency?):

2. The use of breath alcohol instruments used by the forensic alcohol laboratory (agency?); and

3. The requirements of Title 17, Division 1, Chapter 2, Subchapter 1, Group 8, Article 7 of the California Code of Regulations.

(B) Competency shall be demonstrated to the forensic alcohol laboratory (a place?) and shall consist of the breath alcohol operator conducting breath alcohol analysis using the forensic alcohol laboratory's (agency's?) procedure(s) and obtaining the pre-determined measurements of the alcohol concentration in a reference alcohol/water or a dry gas alcohol sample specific to the procedure(s) for ??? number of reference alcohol/water or dry gas alcohol samples for each procedure tested.

The problem of the forensic alcohol laboratory being "a place" continues for this subsection. Forensic alcohol laboratories are responsible for the training of breath alcohol operators in current regulation. If it is an entity, it can take responsibility. If it is a place, it cannot. But if it is an entity, then how are law enforcement officers employees of this entity? If we say they are under the direction of the entity, how is an entity at the side of a highway providing direction? Possibly it can be argued that the entity is not a bricks and mortar structure, but a defined business or person that conducts the forensic alcohol analysis and/or breath alcohol analysis regardless of where that activity occurs. If it is a place, the work of law enforcement officers at the side of a highway may possibly make them employees. If we define the employee as simply the person conducting the analysis, then anyone conducting such analysis anywhere at anytime is an employee. The question arises of overextension of statutory authority with such a broad definition, but since medical/diagnostic laboratories use this means to allow for regulation outside a specific location, we can try to argue the same point. This is a very convoluted problem and it unfortunately stems from the language in the statute. Since we must live with that language, we will do our best to resolve this to meet the goals desired.

Of note, the repealed H&S Code section 100715, that used to provide the authority for the regulation of police officers in breath alcohol analysis did not specify training and in the "Notes of Decisions" for that section there was a case cited (People v. Rawlings (App. 2 Dist 1974) 117 Cal.Rptr. 651, 42 Cal.App.3d 952) that determined that since the statute and regulation did not specify that "operators" had to be trained for their analyses to be admissible in court, a breath analysis conducted by an officer who was not trained was admissible as evidence. Although there may be other rulings that offer something else, it is reasonable to ask that since H&S Code section 100715 was repealed, and there is no specific mandate in the new statute to regulate law enforcement, and even when there was a mandate in statute to regulate law enforcement, the lack of training did not render the analysis inadmissible into court, do

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R-05-012

5 January 2006

we still need to specify this training in regulation? It can be argued that this is a smart move for law enforcement to be certain they can demonstrate their officers know how to properly use the breath alcohol instruments and therefore they should be trained, but does that mean these regulations need to specify that training? Or could law enforcement decide how best to ensure they have the qualifications to complete breath alcohol analysis and contract with forensic alcohol laboratories if they think that will meet the requirement. They are the ones who appear poorly in court if their evidence is found lacking. The current statute only requires that labs “ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal register by the National Highway Traffic Safety Administration of the United States Department of Transportation.” (H&S Code section 100701.) This does not require the laboratory to make sure the instruments are used and calibrated properly. And if the committee determined that it did not want to regulate law enforcement in the proposed regulations, it definitely could be argued that law enforcement is not part of a forensic alcohol laboratory nor is a police officer an employee of a forensic alcohol laboratory.

As always, if the committee determines it wishes to continue to regulate law enforcement in breath alcohol analysis, the necessity for the inclusion of the training requirements in regulation will need to be addressed for the ISOR, and it is very likely that OAL will ask about the authority of the committee to extend the regulations to address law enforcement and its use of breath alcohol instruments. Program counsel is asked to help with the legal discussion in this area, as it will need specification.)

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

~~(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.~~

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

Note: Authority cited: Section ~~436.50~~100703, Health and Safety Code. Reference: Section ~~436.50~~100703, Health and Safety Code.

1221.4. Expression of Analytical Breath Alcohol Analysis Results.

(a) Results of breath alcohol analysis shall be expressed as set forth in Section 1220.4 as grams of alcohol per 210 liters of breath. (No abbreviations?)

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(b) Breath alcohol analysis results of less than 0.010 grams per 210 liters shall be reported as negative.

(c) Breath alcohol analysis results shall be reported to two decimal places.

Note: Authority cited: Sections 100275 and 100703 Health and Safety Code. Reference: Section 100703, Health and Safety Code.

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R-05-012

5 January 2006

Proposed Regulations

Article 8. Records

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.~~

Note: Authority cited: Sections 102 and 208, Health and Safety Code. Reference: Section 436.50, Health and Safety Code.

1222.1. Forensic Alcohol Laboratory Records.

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

(1) ~~An up-to-date record of persons in its employ who are qualified as forensic alcohol supervisors and forensic alcohol analysts; the record shall include the qualifications of each such person, including education, experience, and training, and performance in proficiency tests and examinations;~~ (You can only require the lab to keep records that are needed to determine qualifications of personnel as in specified regulation in proposed section 1216.2.)

(2) ~~A list of persons in its employ who are forensic alcohol analyst trainees, the date on which each such person began his training period and the number and results of analyses performed during the training period;~~

(3) ~~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 of breath testing instruments as a laboratory may perform for law enforcement agencies;~~

(7) ~~Records of such training as a laboratory may provide to persons who operate breath testing instruments for law enforcement agencies of breath alcohol operators, including names of instructors and dates of training.~~

(8) ~~Records of all maintenance performed on each instrument that the forensic alcohol laboratory uses to conduct forensic alcohol analysis or breath alcohol analysis.~~

~~(None of these records are specified anywhere. How does a lab know what to keep? These will have to be specified to include content required or the ISOR will have to state that the lab can keep anything and call it the record specified. Of course, one of the issues in this regard becomes the necessity for the requirement of maintenance of a record that is not specified as to content and questionable as to purpose. If anything~~

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R-05-012

5 January 2006

will qualify as this record, then why bother to require it in regulation? The offering of the desire to not restrict the labs, argues for not making the requirement in regulation at all.)

Note: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

1222.2. Breath Alcohol Analysis Records Maintained by Agencies.

(a) Each **agency** (**define**) shall keep the following records for breath testing instruments which are under its jurisdiction for a period of 3 years: (for consistency with 1222.1)

(1) Records of instrument determinations of accuracy;

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

(3) ~~At the location of each instrument, the precautionary checklist to be used by operators of the instrument.~~ **Records of all maintenance and accuracy tests performed on each instrument;**

(Same issue of lack of clarity in the requirements as discussed in section 1222.1 above. The content of the records will need to be specified.)

(4) Records of all operators trained by the agency, including the names of instructors and the date of the training.

(There is a question of regulatory authority here. What is the agency and do we have anything to say about their training? It is assumed this is a law enforcement entity such as a police department. Program counsel is asked to offer guidance regarding the statutory authority of the committee to require the maintenance of the above records by an agency, as they are not a forensic alcohol laboratory or an employee of one. If the committee has the authority, then the regulations will need to specify the training and who may provide, etc.)

Note: Authority cited: Sections 100275 and 100703, Health and Safety Code.

Reference: Section 100703, Health and Safety Code.

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5 January 2006