INITIAL STATEMENT OF REASONS

FORENSIC ALCOHOL TESTING LABORATORIES

CALIFORNIA CODE OF REGULATIONS, TITLE 17

SUMMARY OF PROPOSAL

Senate Bill 1623, Chapter 337 (statutes of 2004), created section 100703 of the California Health and Safety Code, which took away the State Department of Public Health's (Department's) involvement in licensing forensic alcohol testing laboratories. The legislation created the requirement that the Department establish a review committee (Forensic Alcohol Review Committee; FARC) to evaluate Group 8 (commencing with section 1215) of subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

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

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

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

AUTHORITY AND REFERENCE

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

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

POLICY STATEMENT OVERVIEW

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

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

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

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

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

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[1] *Journal of Analytical Toxicology*. 1997;21(5):369-372. http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369.

[2] Soliman, Mary (2008).

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

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

For instance, proficiency testing. Proficiency testing is an integral part of an effective quality-assurance program. It is one of many measures used by a laboratory to monitor its own performance and to identify areas in which improvement may be needed. It verifies that technical procedures are valid and that the quality of the work product is maintained at a high level. Therefore, crime laboratories must take proficiency testing very seriously and must have stringent criteria for employing a proficiency-testing program. In these proposed regulations, laboratories must now meet the proficiency-testing criteria of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), which means they are held to national standards.[4] ASCLD/LAB is a national and international crime laboratory accreditation organization. Greater than 95% of California's crime laboratories are accredited by ASCLD/LAB.

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

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

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

- Codify in the regulations the removal of the authority of the Department over the licensing of the state's forensic alcohol laboratories.

- Adopt updated standards pertaining to forensic alcohol laboratory operations, including maintenance of records, testing protocols, proficiency testing, and training and supervision of laboratory staff, proposed by the review committee as necessary to effectuate the enabling legislation.

[3] Vehicle Code § 23152.
[4] Health and Safety Code §§ 100700 to 100775.

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

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

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

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

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

DETAILED DISCUSSION OF EACH REGULATION

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

Article 1. General

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

This section will now provide definitions of terms used in the regulations, which were previously in section 1215.1. The amendments to these definitions are reasonably necessary to provide for uniform interpretation of the text, consistency in the terminology used in the proposed regulations, and to effectuate the purposes of the enabling statute. New definitions are proposed for adoption, and outdated or unnecessary definitions are proposed for deletion. The reasons for each of the proposed changes are as follows.

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

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

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

Subsection 1215(d) This subsection remains unchanged.

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

Subsection 1215 (f) This definition eliminates the prior outdated and obsolete classification of forensic alcohol supervisor here and throughout this document. These regulations specify the qualifications required to be an analyst and the guidelines of those analyses. The revised language provides clarity, especially to the legal community, courts, and juries who may incorrectly assume a "forensic alcohol supervisor" is an actual supervisor in the laboratory. This is not in fact the case.

The words "can be" were changed to "is" to provide clarity.

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

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Subsection 1215.1 (h) The Department classification of forensic alcohol analyst trainee has been eliminated here and throughout this document. This classification had been used in administrative hearings by the Department of Motor Vehicles and is no longer appropriate.

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Subsection 1215.1 (i) This change specifies who uses the method, and gives a clearer definition as to what a method is. In addition, it provides for consistency of verbiage throughout the definitions.

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Subsection 1215.1 (j) This definition will be deleted in its entirety. The words "instrument" and "device" are considered common language, and therefore it is not deemed necessary to define them in this section.

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Subsection 1215.1(k) This definition of "license" was repealed because the enabling Legislation removed the Department's authority to issue such a license.

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

Subsection 1215(m~~i~~) This subsection remains unchanged.

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

Subsection 1215(n) This definition of "Department" was amended to reflect the change from the Department of Health Services to the Department of Public Health.

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

Subsection 1215(o) The definition of "Competency Test" was added because it is used elsewhere in the proposed regulations and should be distinguished by the term "Proficiency Test."[5]

Subsection 1215(p~~l~~) ~~The~~ The definition of "Proficiency Test" was added to define the term, which is used elsewhere in the proposed regulations and to help distinguish the term from a "competency test."[6]

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[5] 2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006.

[6] 2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006.

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

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

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

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

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

Article 2. Requirements for Forensic Alcohol Laboratories

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

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

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

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

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

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

Subsection 1216(b) This subsection remains unchanged.

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

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

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

Subsection 1216.1(a)(2)
This subsection has been amended to include the addition of a citation to clarify the location of the requirements, thereby avoiding redundancy in the proposed regulations.

Subsection 1216.1(a)(3) This section has been amended to include the addition of a cite to clarify the location of the requirements, thereby avoiding redundancy in this document. (Health and Safety Code Section 100702 (a)) The new regulations cited in Health and Safety Code Section 100702 (a) are quite different from the regulations currently laid out in Title 17.

It is important to note, therefore, that the Department's proficiency testing program is not currently sufficient to meet accreditation requirements mandatory for accredited crime laboratories. New regulations require an ASCLD/LAB approved proficiency test provider. An approved proficiency test provider is an individual, organization, or company which has applied for and obtained approval from ASCLD/LAB (or other accrediting body as approved by the legislature) to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines, for which the provider has been approved.[7] The Department is not recognized as an approved proficiency test provider. This puts accredited laboratories in a difficult position. Although the Department requires that approved forensic alcohol testing laboratories participate in a proficiency testing program, the Department will not allow that program to be comprised of only approved providers. The Department still mandates that laboratories participate in the Department provided proficiency testing at least once a

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[7] "Proficiency Review Program" American Society of Crime Laboratory Directors, Ver. 2.1, 2008, pages 9-11

year.[8] Since this participation does not fulfill accreditation requirements, laboratories are forced to participate in a substandard program along with the accredited program. This is not efficient, and adds nothing to the qualifications of a laboratory. It therefore seems redundant, and a waste of state resources, for the Department to supply an unnecessary program.

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Subsection 1216.1(a)(4~~2~~) In 2005 the Department discontinued onsite inspections following the change in the Health and Safety Code that took away the Department's licensing authority. This subsection was amended to reflect the change. Health and Safety Code section 100702 requires ASCLD/LAB, the accrediting body of crime laboratories in California, annual audits of all accredited areas, as well as reaccreditation inspections every 5 years. In addition, all laboratories' work product may be scrutinized in the court system.

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

Subsection 1216.1(a)(~~(3) (~~5) This section was removed as vague and redundant.

Subsection 1216.1(b-d) This section has been amended to remove provisions related to the Department's licensing of the laboratory; the enabling legislation removed that authority.
~~These subsections were repealed because the Department no longer has the jurisdiction to license laboratories.~~

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Subsection 1216.1(e~~b~~) This section was amended to remove the word supervisor as the supervisor classification has been eliminated.~~This subsection remains unchanged.~~

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

Subsection 1216.1(e~~b~~)(2) This subsection was amended to replace the phrase "approved by the department" with "laboratory of employment." This clarifies that an individual must be qualified by his or her specific Forensic Alcohol Laboratory. The expectations of the course training are outlined in the following sections. Giving the

[8] Reporting Results of Laboratories' Annual Participation in Proficiency Testing, California Department of Public Health, September 23, 2008

laboratories control of the approval of courses appropriate for training forensic alcohol analysts allows for local laboratory control of when, where, and by whom these courses will be offered.

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

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

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

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

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

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

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

Section 1216.1(e~~b~~)(2)(G) This subsection was amended to add the word "forensic" for clarity and consistency. In addition "student's was changed to "trainee's" for consistency.

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

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

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

Section 1216.1(e~~b~~)(3) This subsection was amended for clarity. Completion of "competency" tests rather than "proficiency" tests is more accurate in this context. The addition of the definition of competency tests under Section 1215.1 ~~(k)~~ will aid in the clarity of this section. The references to "the Department" were removed to reflect the change in the statute. It is proposed that ASCLD/LAB national guidelines be used.

The reference to passing examinations prescribed by the Department is deleted because the laboratory of employment has requirements that will be the determining factor in deciding whether a person is deemed competent in forensic alcohol analysis.

This is referred to in the Section 1216.1(c)(4). Testing by accredited laboratories, whether by written or practical examinations, is more current and relevant to today's technological advances. The following are the proposed changes:
~~are those recommended by ASCLD/LAB:~~

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

Section 1216.1(e~~b~~)(4) This section is redundant and is deleted in its entirety. The information is already required in a previous section.

Section 1216.1(e)(5) This section was deleted in its entirety, as it is no longer applicable to any practicing forensic alcohol analysts as far as the Department is aware.

Section 1216.1(f) This section has been deleted in its entirety as the analyst qualifications are now located in Section 1216.1(e).

~~Previous~~ S~~section~~ 1216.1(f)(1)–(6) This subsection was repealed in its entirety. This element is covered in general in Section 1216.1(b)(2). The forensic alcohol laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. This is also covered in Section 1216.1(b)(4). Running 25 samples with known results serves only as practice for an analyst and does not show competence. The competency test requirement outlined in Section 1216.1(b)(3) is a true test of an analyst's competency because the answers to the test are unknown to the analyst.

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

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

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

~~**Previous section 1216.1(f)(1)–(6)** This subsection was repealed in its entirety. This element is covered in general in Section 1216.1(b)(2). The forensic alcohol laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. This is also covered in Section 1216.1(b)(4). Running 25 samples with known results serves only as practice for an analyst and does not show competence. The competency test requirement outlined in Section 1216.1(b)(3) is a true test of an analyst's competency because the answers to the test are unknown to the analyst.~~

Comment [WU3]: How should we interpret the use of eliminated v deleted? Inconsistent usage throughout document. Suggest using repeal when applicable for consistency.

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

Article 3. Licensing Procedures

This article was repealed because it pertained only to matters previously under the jurisdiction of the Department but that are no longer. References to the maintenance of proficiency test records and analyst training records are redundant as they are included in Article 2.

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New Article 3. Training of Personnel

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

Section 1218 (a-c) This section is amended to enumerate what must be submitted to the Department regarding training programs to ensure compliance with these regulations.

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

Section 1218.1 This section is ~~combined into Section 1218.~~removed.

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

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

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

Subsection 1219.1 This section will remain as written.

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

S~~Previous s~~ubsection 1219.1(b) This subsection was repealed in its entirety. This section is vague and puts the onus on the technician drawing the blood to determine what amount is sufficient versus on the analyst with the knowledge to support that decision-making process. It is proposed that the analyst will be required to determine whether the sample collected is sufficient to perform duplicate analyses.

S~~New s~~ubsection 1219.1(c~~b~~) ~~These subsections were re-designated.~~

Some amendments to the language were made to update the section as to suitable disinfectants. In 2002, the Department determined that the aqueous merthiolate or other mercury containing compounds should not be used to clean the skin as these compounds are now known to cause cancer or reproductive toxicity. Therefore, it is proposed that less dangerous substances be used.

S~~New s~~ubsection 1219.1(d~~c~~) This subsection was amended to increase clarity and to make it grammatically correct.

New subsection 1219.1(e~~d~~) This subsection remains unchanged.

S~~New s~~ubsection 1219.1(f~~e~~) The subsection was amended to change the word "insure" to "ensure" for grammatical correctness.

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

S~~New s~~ubsection 1219.1(f~~e~~)(2) This subsection remained nearly as written because it reflects current best practices.

S~~New s~~ubsection 1219.1(g~~f~~)(1) This subsection was amended to replace "coroner" with "medical examiner." Different jurisdictions may use a coroner system, whereas others use a medical examiner system. The term "coroner" in this sense may be incorrect. The term "medical examiner" is more accurate and will apply to either system.

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

Subsection 1219.2(a) This section has been amended to clarify what an appropriate sample collection is, removing the ambiguity of "an approved" sample. It also clarifies

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

Subsection 1219.2(b) This subsection remains unchanged.

Subsection 1219.2(c) This subsection remains unchanged.

Subsection 1219.2(c)(1) This subsection was amended to include "or coroner/medical examiner's office" to create a more accurate representation of current practices. The change of "by" to "on" provides consistency with prior language contained in Section 1219.1(g)(2).

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

New Article 5. Methods of Forensic Alcohol Analysis

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

Subsection 1220(a) This subsection remains unchanged.

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

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

Subsection 1220(b)(2) This section remained as written. This section is fairly general in its requirement for available methods to include calibration and quality-control procedures. This section can stand on its own as currently written because it provides general guidelines that are ~~fleshed out~~presented in great detail in the requirements of the accrediting bodies used by most crime laboratories. The ASCLD/LAB accrediting

guidelines far exceed the requirements set forth in these regulations.[9] For those laboratories that are not accredited, this guideline is appropriate.

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

Subsection 1220.1(a)(1) This subsection was amended to replace "0.10 grams per 100 milliliters" with "0.08 grams per 100 milliliters" to reflect the change in the state legal limit.[10]

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

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

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

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

Subsection 1220.1(b) This subsection was amended to remove the reference to the Department and replace it with "a forensic alcohol analyst" to codify the oversight of the proficiency program to the individual laboratories. This serves to clarify who must make the determination that a method is meeting requirements and brings this subsection in line with the intent of the legislature to remove the Department's jurisdiction. Accredited laboratories have mandated quality-assurance programs, with quality-assurance managers that are tasked with implementing, running, and overseeing a proficiency test program.

The laboratory must follow accreditation proficiency testing requirements and is held accountable through the Proficiency Review Program (PRP), applicable to both the ASCLD/LAB Legacy accreditation program as well as the ASCLD/LAB-International accreditation program. To retain accredited status for a full 5-year term, a laboratory must continue to meet the standards under which it was accredited. One of the means by which ASCLD/LAB monitors compliance is by reviewing proficiency-testing reports submitted by approved test providers. The PRP outlines the roles and responsibilities of the Proficiency Review Committees (PRCs), approved test providers, the ASCLD/LAB Proficiency Test Program Manager, and others in carrying out the elements of the proficiency review process. This program provides the oversight

[9] General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories.
[10] California Vehicle Code § 23152(b).

needed to ensure methods are functioning according to required specifications.[11] The requirements are set forth in these regulations in a manner sufficient to accommodate those laboratories that are not currently accredited.

Subsection 1220.2(a) This section will remain as written as it is merely an introduction to the following requirements.

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

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

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

Accurate calibration of instruments used in forensic alcohol testing is critical because the results directly affect criminal prosecutions. For the past 30 years, California laboratories have been required by regulation to prepare their own secondary alcohol standards using a direct oxidimetric method. These secondary standards were then used to check the calibration of the instruments. Commercially prepared secondary standards and NIST Standard Reference Materials (SRMs) are now widely available at critical concentration levels. Under the amendments here, laboratories are given the opportunity to continue to prepare secondary standards themselves or take advantage of the availability of commercially prepared NIST traceable secondary standards. See the justification outlined for section 1220.2(a)(1)(A).

The word "direct" was added to emphasize the fact that alcohol is added directly to the oxidizing media in the method for the quantitative determination of the alcohol present in the aqueous alcohol solutions. Also, the United States National Bureau of Standards no longer exists and has been replaced by the National Institute of Standards and Technology.

Subsection 1220.2(a)(1)(C) An additional requirement was added as a final verification and most accurate test of the secondary standards that will be used to check the calibration of the instrument for testing. NIST SRM solutions are designed to provide consistency and reliability for use in all countries and for all methods.

Currently, laboratories make their own secondary standards using a direct oxidimetric method. These secondary standards are then used to ~~check the~~ calibrate~~ion of~~ the instruments used for forensic alcohol analysis. This process has inherent difficulties

[11] "Proficiency Review Program." American Society of Crime Laboratory Directors, Version 2.1; 2008.

because the process is fraught with the possibility of human error. This error rate is exacerbated by the fact that laboratories do not have to perform this method on a regular basis, and often a different analyst does the work each time. The regulations currently allow for a 5% error rate in the preparation of these solutions. By contrast, the NIST ethanol-water SRMs have an established error rate of less than 1.2% for all concentration levels.[12]

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

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

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

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

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

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

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

[12] National Institute of Standards and Technology, Certificate of Analysis, Standard Ref. Material 1828b.

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

Subsection 1220.3(a) This section will remain as written.

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

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

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

Subsection 1220.3(a)(3)(B) The 0.01 was changed to read 0.010 to reflect the change proposed in Section 1220.3(a)(2).

It should be noted that if three decimal places are used, the +/- range for a sample would be 0.020%. If, however, the truncated two-decimal-place range is used, then the total range of acceptable three-decimal-place results are effectively increased to 0.029%. This is nearly 50% greater than the 0.02% range implied by the +/- 0.01 grams % limits. This analysis shows that the acceptable results required by current regulations can only be accurately applied by using all three significant figures.

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

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

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

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

Subsection 1220.4 This section will remain as written, as it reflects current and accepted practice.

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Subsection 1220.4 (a) This section will remain as written, as it reflects current and accepted practice.

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

Subsection 1220.4(b) This subsection remains unchanged.

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

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

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

New Article 6. Requirements for Breath Alcohol Testing

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

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

Subsection 1221.1(a) The US Department of Transportation uses the word "units," whereas the California Health and Safety Code uses the word "devices." The change

will serve to clarify this difference. In addition, the Health and Safety Code section reference was added to identify the specific applicable requirements.

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

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

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

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

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

~~New~~ S~~s~~ubsection 1221.4~~2~~(a) This subsection was amended to change "analysis" to "testing" for consistency throughout the regulations.

Subsection 1221.4~~2~~(a)(1) This subsection was amended to change the word "blood" to "breath," and the phrase "grams per 100 milliliters" to "210 liters of breath." This makes the regulation consistent with the enabling legislation.

Subsection 1221.4~~2~~(a)(2) This subsection was amended to specify what types of reference samples are best for checking the accuracy of the instrument consistent with nationally recognized best practices.

Subsection 1221.4~~2~~(a)(2)(A) This subsection was amended in the following ways for the following reasons:

If three decimal places are used, the +/- range for a sample would be 0.020%. If, however, the truncated two decimal place range is used, then the total range of acceptable three decimal place results are effectively increased to 0.029%. This is nearly 50% greater than the 0.02% range implied by the +/- 0.01 grams percentage limits. The acceptable results required by current regulations can only be accurately applied by using all three significant figures. Therefore, the 0.01 grams percentage precision limit was changed to 0.010 grams percentage.

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

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

Subsection 1221.4~~2~~(a)(2)(A)(1) This subsection was amended because instruments are now available that automatically perform accuracy checks. The change from the entity of a laboratory to an analyst is more specific as to who will make the determination of accuracy.

Subsection 1221.4~~2~~(a)(2)(B) This subsection remains unchanged.

Subsection 1221.4~~2~~(a)(3) This subsection was amended to change “analysis” to “testing” for consistency throughout the regulations ~~. “Procedures” replaces “instruments” because the procedure encompasses all aspects of the testing process, including the instrumental portion.~~

Subsection 1221.4~~2~~(a)(3)(A) through (D) These subsections were enhanced to more closely resemble the training section for blood alcohol in Title 17. The breath alcohol section did not have the specific detail for breath alcohol instrument operator training, so it was added. The training for breath analysis and for blood analysis ~~are~~is not identical, of course, but they would now closely resemble each other.

Subsection 1221.4~~2~~(a)(3)(E) This subsection was amended because both a written and practical examination should be required to ensure the operator has sufficient information and experience to perform a test.

Subsection 1221.4~~2~~(a)(3)(F) and (G) Because breath alcohol analysts are required to take specific training, a certificate provides proof that they have done so. An officer will need to be able to prove in a court of law that he or she has in fact completed the training. A certificate is a typical way to provide that verification.

Subsection 1221.4~~2~~(a)(4) This subsection was amended because the phrase “under the supervision of” is vague. The development of the training curriculum has been clearly defined as a responsibility of the forensic alcohol analyst.

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

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

The term “licensed” was removed to reflect the removal of the Department’s jurisdiction.

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

Subsection 1221.4~~2~~(a)(4)(A) This subsection as previously written is now obsolete because Section 1218 was repealed. Section 1218 discussed appropriate training programs, programs that were deemed suitable by the Department. Because the oversight of training programs has been removed from the Department and given to the employing laboratory entities, this subsection became irrelevant. In addition, the training curriculum required is spelled out in subsection 1216.1(b). This would appear to make this section redundant as well. The changes made here have given oversight to the forensic alcohol analyst.

Subsection 1221.4~~2~~(a)(4)(B) ~~Here, 4 hours was chosen to resemble blood training. Both breath and blood analysis training require a comparable amount of time~~This was added to ensure that the breath instrument operators get at least 4 hours of training, a time frame the committee felt was reasonable to cover listed topics..

Subsection 1221.4~~2~~(a)(4)(C) This proposed regulation was included so that peace officers and others moving between different jurisdictions, where there may be different instruments used, are not required to repeat trainings that would be redundant and unnecessary for them to repeat.

Subsection 1221.4~~2~~(a)(5) This subsection was amended to replace the word “his” with “his or her.” Supervisor and trainee classifications have been removed to be consistent throughout the regulations. The reference to (a)(4) was added because it also applies.

Subsection 1221.4~~2~~(a)(6) This subsection was amended to add the words “a manual” into the section just prior to “determination of accuracy.” This insertion is to address the current technology offered by many breath programs that includes automatic calibration checks. Many instruments are set up to perform calibration checks as needed, prompted by the software program, using guidelines determined by laboratory personnel. Therefore, it is feasible that in many programs, the operator will be the person administering the breath test. In one breath program, a calibration check is performed automatically before and after every subject test. In actuality then, the “calibration check” is being done by the instrument at the prompting of the officer. If the

instrument is receiving additional service, and a calibration check is part of that service, and is essentially a "manual calibration check," then that operator will be recorded as having performed that check.

Subsection 1221.4~~2~~(a)(6)(A) The word "licensed" was removed to reflect the removal of the Department jurisdiction contained in the enabling legislation.

Subsection 1221.4~~2~~(b) This subsection was added here to finish the discussion of required records. It was removed from Section 1222.2 and put here as a more appropriate location.

New subsection 1221.5~~3~~ This subsection was amended. The word "analytical" was removed as unnecessary. The word "analysis" was changed to "testing" for consistency throughout the regulations.

New Article 7. Records

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

Section 1222 The reference to "law enforcement agencies" has been deleted. These regulations are not intended to regulate the law-enforcement community. The phrase "Such records shall be available for inspection by the Department on request" was deleted to reflect the removal of the Department's jurisdiction. In addition, as discussed previously, any and all such records would be available to the Department through the California Public Records Act upon request. It is therefore not necessary to include that here. Also, as previously noted, most laboratories in California are accredited, and as such, have stringent requirements placed upon their manuals, records, logs, etc. Department oversight here would be redundant.

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

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

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

~~New~~ **Subsection 1222.1(a)(3~~2~~)** This subsection remains unchanged.

~~New~~ **Subsection 1222.1(a)(4~~3~~)** This subsection remains unchanged.

~~New~~ **Subsection 1222.1(a)(5~~4~~)** This subsection remains unchanged.

~~New~~ S~~s~~ubsection 1222.1(a)(6~~5~~) The phrase "maintenance and/or calibration" was added to further clarify what records need to be maintained for 3 years. In addition, this recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed by or for law enforcement agencies. Therefore, the phrase "as a laboratory may perform for law enforcement agencies" is not needed and was deleted. The term "breath" was removed to clarify that records should be maintained for all types of tests.

~~New~~ Subsection 1222.1(a)(7~~6~~) This subsection was amended to provide clarity to the requirements. This recordkeeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed by or for law enforcement agencies. Therefore the phrase "for law enforcement agencies" is not needed and was deleted.

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

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

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- State of California Department of Health Services: Food and Drug Laboratory. *Proficiency Test and Written Examination (Forensic Alcohol Analyst).* Revised September 1987.

- Silverman LJ, Confirmation of ethanol compressed gas standard concentrations by an NIST-traceable, absolute chemical method and comparison with wet breath alcohol simulators. *Journal of Analytical Toxicology*. 1997;21(5):369-372. http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369.

REASONABLE ALTERNATIVES CONSIDERED

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

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

LOCAL MANDATE

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

EFFECT ON SMALL BUSINESS

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

EFFECT OF HOUSING

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

ECONOMIC IMPACT ASSESSMENT

1. Fiscal impact on local government: None. The Department is not aware of any cost impacts that a local government agency would necessarily incur in complying with the proposed action.

2. Fiscal impact on state government: Yes. See Form 399. The Department anticipated a reduction in costs as a result of the Department staff that will no longer be needed to perform the licensing and oversight duties that were previously performed, before SB 1623. The Department is not aware of any other cost impacts that state government would necessarily incur in complying with the proposed action.

3. Fiscal impact on federal funding or state programs: None.

4. Fiscal impact on private persons or businesses directly affected: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in complying with the proposed action. See Form 399.

5. Other nondiscretionary cost or savings imposed on local agencies: There are no known costs or savings imposed on local agencies in connection to this proposed action.

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

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