

**INITIAL STATEMENT OF REASONS**  
**Revisions to the Regulations Pertaining to Forensic Alcohol Analysis**  
**Title 17, California Code of Regulations**

Under existing law, the State Department of Public Health regulates laboratories engaged in the performance of forensic alcohol analysis by or for law enforcement agencies on blood, urine, tissue, or breath for the purpose of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations. These regulations are detailed in Title 17, Subchapter 1 of Chapter 2 of Division 1.

**History**

Prior to 1969, laboratories performing forensic alcohol analysis were largely unregulated. The forensic community recognized a need for consistency and guidelines to provide the most accurate forensic alcohol testing. In 1969, legislation was passed authorizing the Department of Health Services (DHS) to adopt regulations for the testing of biological samples for alcohol content from persons subject to the implied consent provisions of the Vehicle Code. The new law required DHS to form an Advisory Committee on Alcohol Determination comprised of district attorneys, public defenders, coroners, criminalists, pathologists, and analytical chemists. The committee met in 1970, and the Department's regulations, commonly referred to as Title 17, were in place in 1971. All laboratories engaged in the performance of forensic alcohol analysis by or for a law enforcement agency were now licensed and subject to these regulations. The regulations were last revised in 1986. Only laboratories performing alcohol analysis for law enforcement were required to be licensed. All other laboratories and all other forensic disciplines were, and remain, exempt from state regulation.

The original role of DHS with respect to the regulation of alcohol analysis was to do the following:

- ▶ provide timely reviews of methods submitted by laboratories,
- ▶ to approve new employees to conduct analyses,
- ▶ to conduct regular on-site laboratory inspections,
- ▶ to provide and oversee a proficiency testing program,
- ▶ to conduct regular meetings of the advisory committee,
- ▶ and to license laboratories to perform alcohol analysis.

After 1986, the relationship between DHS and the forensic alcohol laboratories began to deteriorate. In 1991, the Advisory Committee was disbanded by the legislature, effectively shutting off communication between the department and the laboratories. DHS personnel began to stray from the original intent of the regulations, and began mandating numerous additional regulations. Laboratories were forced to comply with these guidelines, or face extreme delays in method review and analyst classification and approval. On-site inspections dwindled, and became almost non-existent. In 1999, the Bureau of State Audits conducted an audit of the DHS' Forensic Alcohol Program (FAP), and released a report titled *Department of Health Services: The Forensic Alcohol Program Needs to Reevaluate its Regulatory Efforts*. This audit was a conducted to follow up on issues identified during a 1998 audit of 19 local forensic laboratories.

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The auditors from the Bureau of State Audits summarized the following:

*This report concludes that the Department of Health Services regulatory efforts primarily emphasize reviewing written methods. Although necessary and important, the reviews are not completed promptly and focus on issues that do not improve the lab's analyses. Further, although the Department also conducts periodic site visits and proficiency tests, a greater emphasis on these activities may be more beneficial to labs than method reviews. Finally, the department's requirements for training operators of breath alcohol equipment are unnecessarily restrictive.*

The auditors also noted:

*Furthermore, a professional society within the forensic community accredits laboratory activities; nonetheless, the FAP does not consider the accreditation requirements as meeting the regulations. By relying on the accreditation when appropriate, the FAP may be able to redirect its regulatory efforts to areas that provide more value...the FAP does not consider accreditation when regulating labs under Title 17 and, in effect, may be duplicating requirements to demonstrate compliance with regulations.*

As a result of this audit, as well as the increased reliance of laboratories on the superior standards of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), Senate Bill 1849 was authored to curtail DHS's regulatory role with respect to forensic alcohol programs. That bill was unanimously approved by both the Senate and Assembly. In 2000, Governor Gray Davis vetoed SB 1849 stating that, in spite of the concerns raised by the Bureau of State Audits, he was "confident that the DHS (currently called DPH) can address the issues that have been raised and am directing DHS to make these concerns a high priority." The Governor said he would consider signing a modified version of the bill if DHS did not make significant progress within the next year towards solving the noted problems. Significant progress was not made.

Senate Bill 1623 was chaptered in 2004, an act to amend Section 100425 of, to add Sections 100701, 100702, and 100703 to, to repeal Sections 100710, 100715, 100720, 100730, 100735, 100740, 100745, 100750, 100755, 100760, 100765, and 100770 of, and to repeal and add Section 100700 of, the Health and Safety Code, relating to laboratories. Please see Appendices 1 and 2 for the specific language of what was added and repealed. Senate Bill 1623 was approved and signed into law in August, 2004, with the intent to greatly reduce state oversight of forensic alcohol analysis and to eliminate DHS licensing of laboratories performing such analysis. A newly appointed Forensic Alcohol Review Committee (FARC) comprised of scientific, law enforcement, and legal representatives, was given the authority to evaluate regulations and "determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws."

The FARC was legislatively mandated in August of 2004 with SB 1623, which acted, in part, to add Section 100703 to the Health and Safety Code relating to laboratories. This addition mandates the following:

- (a) *On or before July 1, 2005, the department shall establish a review committee.*
- (b) *The review committee shall have eight members, including one person representing each of the following: (1) Prosecuting Attorneys, (2) Law Enforcement Agencies, (3) Defense Attorneys, (4) Coroners, Pathologists, or Medical Examiners, (5) Criminalists, (6) Toxicologists, (7) Crime Laboratory Directors, and (8) The Department of Health Services.*
- (d) *The review committee shall evaluate Group 8 (commencing with Section 1215) of Subchapter 1 of the Chapter 2 of Division 1 of Title 17 of the California Code of Regulations and determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws.*

A committee was established, and it is of note that its members represent hundreds of employees across the spectrum of law enforcement and the forensic science community. The members brought many unique and divergent opinions to the process, and, in the end, put together a work product that was overwhelmingly approved.

The review committee met fifteen times over the past five years to revise Title 17. As the regulations that were being reviewed were last updated in 1986, the committee had several goals when considering revisions. These goals included updating the verbiage within the regulations to meet current APA guidelines, to modernize the scientific techniques and educational requirements, to divest laboratories of redundant oversight and inadequate proficiency testing programs, and to accommodate for a new era of accreditation with the advent of accrediting bodies that are utilized by a vast majority of the alcohol laboratories in California. Each and every change in these regulations have been dissected, discussed, contemplated, and reviewed. As a result, this committee feels that the revisions meet and exceed the goals of both the committee and the legislators.

### **Reasons to Update Regulations**

#### **Regulations are out of Compliance**

Existing 1986 regulations are not in compliance with the Administrative Procedures Act, and are outdated and inconsistent with California law, current health advisories, and modern instrumentation and technology. Therefore, the regulations needed to be re-written entirely.

#### **Technology has Advanced**

In the past 25 years, technology, educational requirements for college degrees, and California law, have all changed and modernized.

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 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, versus every 10 days with a solution. Data is 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. 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. 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 standards. These standards can be purchased with many different values, allowing for better instrument calibration.

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.

California laws regarding driving under the influence have also changed, creating the need for altered criteria in alcohol testing. While the current regulations center requirements on a 0.10% level, the pertinent legal limit is actually a 0.08%. DUI 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 current regulations.

### **The Department of Health Services Has Become Obsolete**

With the advances in technology and the advent of accreditation for crime laboratories, the Department's role in regulating the forensic alcohol program has become largely obsolete, and is generally an exercise in redundancy. Therefore, although the point of some contention with DHS representatives, the changes and updates to these regulations, put forth by the FARC, attempt to remove DHS (currently referred to as the Department of Public Health, and referenced as DPH throughout the rest of this document) oversight where unnecessary, and place that oversight back onto the laboratories that have to answer to their accrediting bodies. As of 2010, every government forensic alcohol laboratory in California is accredited, and must adhere to those very stringent accrediting guidelines. Currently, according to their website, DPH is tasked with four primary activities. These include:

- ▶ proficiency testing,
- ▶ on-site inspections,
- ▶ review and approval of methods and procedures,
- ▶ and coordinating the meetings of the current advisory committee on alcohol determination.

When each is examined, it is very clear that DPH oversight is not necessary to ensure the competency of forensic alcohol laboratories.

Proficiency testing: Along with the removal of licensing authority and the establishment of a review committee, SB 1623 mandated one more important change with respect to proficiency testing. This legislation inserted language that was very specific as to how the proficiency tests should be administered.

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SB 1623 states, in part, the following:

- 100702. (a) All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The required proficiency test must be obtained from any ASCLD/LAB approved test provider.*
- (b) Each laboratory shall participate annually in an external proficiency test for alcohol analysis.*
- (c) Each examiner shall successfully complete at least one proficiency test annually.*
- (d) Each laboratory shall have a procedure in writing that describes a review of proficiency test results, and, if applicable, the corrective action taken when proficiency test results are inconsistent with expected test results.*

The pertinent language in this addition is, of course, that “All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing.” This new regulation vastly changes the way proficiency testing programs in forensic alcohol laboratories are to be handled. The language states very clearly that “the required proficiency testing must be obtained from any ASCLD/LAB approved test provider.” As DHS is not an approved provider, this certainly makes the activity of providing proficiency tests unnecessary, or at best redundant.

On-Site Inspections: Senate Bill 1623 specifically repealed Section 100735 of the Health and Safety Code. This section stated the following:

*100735. Every approved and licensed laboratory shall be periodically inspected by the department. Reports of each inspection shall be prepared on forms furnished by the department and shall be filed with the department.*

With this section no longer existing under current law, DPH is no longer is tasked with inspecting laboratories. This was due in large part to the lack of any consistency in the inspections, which were sporadic at best. DPH was averaging approximately one inspection per laboratory every 10 years.

The auditors from the Bureau of State Audits noted the following:

*Because the FAP invests so much time in reviews, during the past three years, it has visited an average of 4 labs each year. At this rate, it will take the FAP ten years to visit all 42 labs.*

In the past decade, laboratories in California have been relying upon their accrediting bodies for on-site inspections. ASCLD/LAB regulations require an on-site, in-depth inspection of forensic laboratories every five years. In addition, each section within the laboratory is inspected internally on an annual basis. These audits are conducted by scientists that specialize in the area of expertise they are auditing.

The auditors from the Bureau of State Audits recognized this fact and stated the following:

*To be accredited, a lab receives an inspection by a team of analysts from other accredited labs. The inspection team is knowledgeable in the types of work the lab performs. To maintain accreditation, a lab is inspected every five years. Thus, the ASCLD/LAB inspects accredited labs twice as often as the FAP does; as mentioned above, the FAP inspects labs only once every ten years. In addition, practicing forensic analysts conduct the ASCLD/LAB's inspection, while staff chemists-who are not well versed in the daily demands of a forensic lab-make the FAP's site visits.*

It is reasonable to conclude then, that site visits are not under the purview of DPH, and should not be considered a primary activity maintained by DPH personnel.

Review and Approval of Methods and Procedures: Prior to the passage of Senate Bill 1623, DPH spent a considerable amount of time and resources on forensic alcohol method approval. In fact, the detailed approval process of the methods was a very large problem for forensic laboratories, one which was noted in the audit conducted by the State Bureau of Audits in 1999.

The auditors noted the following in the final report:

*Of the three areas, reviewing labs' written procedures is the FAP's primary emphasis; however, the FAP does not complete its reviews in a timely fashion. At the same time, the labs complain that the reviews' modifications often address editorial aspects of the written procedures and do not improve the labs' overall methods.*

*In addition to creating obstacles through its lengthy approval process, the FAP can present further difficulties for the labs because its modifications to their methods may have little bearing on the quality of their analyses. During a method review, the assigned chemist lists changes in one of two categories: those necessary for compliance with Title 17, and those that are optional, but which the FAP still considers improvements. The following are examples of changes the FAP has required:*

- Modifying titles and word choice.*
- Specifying the source of a chemical.*
- Including an introduction.*
- Paginating a method.*

*Although these items may enhance written clarity, not one is a specific requirement under Title 17. Neither is it clear how these largely editorial changes affect the quality of analysis a lab performs, nor how they differ significantly from what the FAP considers optional modifications, such as altering word choice and correcting spelling and grammar.*

DPH concentrated its efforts on method review, but not on method development, or upon the work product produced by following the methods. Individual analysts were not interviewed, work product was not reviewed, and a concerted effort to stifle change was pervasive. As a result of the audit, and the passage of Senate Bill 1623, DPH altered its regulatory efforts to address these concerns.

In an excerpt from a letter dated January 2005, Status of the Forensic Alcohol Analysis Regulatory Program in 2005, this new oversight policy is laid out.

*Filing of Written Descriptions of Forensic Alcohol Methods: DHS will no longer require forensic alcohol laboratories to have on file with DHS written descriptions of the methods it uses for forensic alcohol analysis. The laboratories, however, will still be required to maintain detailed, up-to-date written descriptions of each method and to make these available to DHS on request.*

Currently, the forensic alcohol methods being utilized by forensic laboratories are not being approved of, or reviewed by, DPH.

In the last decade, as laboratories have become accredited, this is another area that has been addressed by the accrediting bodies, and again, the criteria by the accrediting bodies is more pertinent, relevant, and stringent than the oversight provided by DPH. Methods are reviewed every five years to ensure that they are scientifically sound, reflect what is actually being done by the analysts, are generally accepted within the scientific community, properly reflect adequate quality assurance and instrument maintenance, are easily available to analysts, are controlled, and are updated when necessary. Analysts are interviewed, and every chemist's work product is reviewed to ensure it meets laboratory, method, and scientific standards. A conduit to new method development and technological advances is readily available, and the process lends itself to ensuring accuracy and allowing modernization at the same time.

Therefore, this is another primary responsibility of DPH that is not relevant, and if enforced, is redundant.

Coordinating Meetings of the Current Advisory Committee on Alcohol Determination: DPH is currently coordinating the FARC meetings, attending them, and advising its members. This is, in fact, a responsibility that is being provided.

With the previous information firmly in mind, the Forensic Alcohol Review Committee members attempted to diminish the redundant oversight of DPH in the regulations, as the goal of the committee, as legislated in SB 1623, is to "evaluate Group 8 (commencing with Section 1215) of Subchapter 1 of the Chapter 2 of Division 1 of Title 17 of the California Code of Regulations and determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws."

As 25 years have passed since the last revision of Title 17, the forensic community finds itself in a new era of technology, education, accreditation, and oversight. We have found that the regulation provided by the Department of Public Health has become obsolete, and that Title 17 is outdated, causing inefficiency in our analytical procedures and keeps laboratories from modernizing to meet the times. Therefore, the Forensic Alcohol Review Committee proposes the following amendments to Title 17, Subchapter 1 of Chapter 2 of Division 1. The following section includes the current verbiage, the proposed changes, and the justification for each of those changes.