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California Department of Public Health



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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

DPH-05-012 Forensic Alcohol Testing Laboratories
Notice Published: June 5, 2015

PUBLIC PROCEEDINGS

The California Department of Public Health (Department) is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement overview section of this notice.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on July 20, 2015, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-05-012" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 440-5747;
3. By Postal Service to: California Department of Public Health, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377;

4. Hand-delivered to Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, DPH-05-012, author's name and mailing address.

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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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.

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's¹ 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.

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.

¹ *Journal of Analytical Toxicology*. 1997;21(5):369-372.

[http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21\(5\)%3A369](http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369).

² Soliman, Mary (2008).

³ Vehicle Code § 23152.

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.

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.

⁴ Health and Safety Code §§ 100700 to 100775.

- 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.

EVIDENCE SUPPORTING THAT THE PROPOSED REGULATORY ACTION IS COMPATIBLE WITH EXISTING STATE REGULATIONS:

FARC and the Department have 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.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

FORMS INCORPORATED BY REFERENCE: None.

OTHER STATUTORY REQUIREMENTS: None.

BUSINESS REPORTING REQUIREMENT: None.

LOCAL MANDATE

FARC and the Department have 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.

FISCAL IMPACT ASSESSMENT

- A. Cost to any Local Agency or School District: None. The Department is not aware of any cost impacts that a local government agency or school district that would necessarily incur in complying with the proposed action.
- B. Cost or Savings to any State Agency: Yes. See 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.

C. Cost or Savings in Federal Funding to State: None.

D. 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.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS:

FARC and the Department are not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT OF HOUSING

FARC and the Department have determined that the proposed regulations will not have a financial impact on housing.

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.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

FARC and the Department have made an initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Based on the economic impact analysis, FARC and the Department have determined that the regulation would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.

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.

ALTERNATIVES INFORMATION

FARC and the Department 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.

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

- American Society of Crime Laboratory Directors (2008). *Proficiency Review Program*. Version 2.1.
<http://www.ascl-d-lab.org/overview-proficiency-review-program/>
- American Society of Crime Laboratory Directors (2008). *Proficiency Test Provider Program*. Ver 2.0.
<http://www.ascl-d-lab.org/approved-proficiency-test-provider-program/>
- American Society of Crime Laboratory Directors, International (2006). *General Requirements for the Competence of Testing and Calibration Laboratories and Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories*. 2nd ed.
<http://www.ascl-d-lab.org/international-testing-program/>
- American Society of Crime Laboratory Directors/Laboratory Accreditation Board (2006). *2006 Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories*. Section 3, p. 5.
<http://www.ascl-d-lab.org/international-testing-program/>
- American Society of Crime Laboratory Directors/Laboratory Accreditation Board (2008). *Approved Proficiency Test Providers*. Retrieved from:

<http://www.ascl-d-lab.org/approved-proficiency-test-provider-program/>

- California Association of Criminalists. (2008). California Association of Criminalist Lab Directory. Retrieved from:
http://www.cacnews.org/membership/lab_directory.shtml
- California Food and Drug Laboratory Branch. (2004). *List of Licensed Forensic Alcohol Analysis Laboratories*.
- California State Auditor (1999). *Department of Health Services: The Forensic Alcohol Program Needs to Reevaluate Its Regulatory Efforts – Report 97025.1*. Sacramento: Bureau of State Audits.
<http://www.bsa.ca.gov/pdfs/reports/97025.1.pdf>
- Larson, Clay (2002). Collection of Blood Samples for Forensic Alcohol Analysis, Suitable Aqueous Disinfectants. *Department of Health Services, Food and Drug Laboratory Branch*. Revised: May 24, 2002.
http://remotehealthatlas.nt.gov.au/collection_of_blood_for_alcohol_or_drug_forensic_analysis.pdf
- National Institute of Standards and Technology. *Certificate of Analysis, Standard Ref. Material 1828b*. March 26, 2004.
<https://www-s.nist.gov/m-srmors/certificates/1828b.pdf>
- *People v. Bransford*, 884 P. 2d 70 (Cal. Supr. Ct. 1994)
http://scholar.google.com/scholar_case?case=1732976132662815944&q=%EF%83%98%09People+v.+Bransford,+884+P.+2d+70&hl=en&as_sdt=2006&as_vis=1
- Soliman, Mary (2008). Reporting Results of Laboratories' Annual Participation in Proficiency Testing Conducted by an ASCLD/LAB Approved Proficiency Test Provider. *California Department of Public Health*. Revised: September 23, 2008.
- 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](http://www.ncbi.nlm.nih.gov/pubmed/?term=Journal+Analytical+Toxicology+21(5)%3A369).

CONTACT PERSON: Steve Woods, Center for Environmental Health, (916) 440-7883. All other inquiries concerning the action described in this notice may be directed to Dawn Basciano, Office of Regulations, at (916) 440-7367, or to the designated backup contact person, Linda Cortez (916) 440-7683.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS:

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7367 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

FINAL STATEMENT OF REASONS: A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS: Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

Date:

Karen L. Smith, MD, MPH
Director and State Health Officer