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**Department of Health Services**



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TO: FORENSIC ALCOHOL ANALYSIS LABORATORIES

SUBJECT: STATUS OF THE FORENSIC ALCOHOL ANALYSIS REGULATORY PROGRAM  
IN 2006

In 2005, new statutes, Health and Safety (H&S) Code Sections 100700 – 100703, went into effect, which eliminated the California Department of Health Services' authority to license laboratories engaging in the performance of tests by or for law enforcement agencies for the purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or traffic violations. The Department retains its general authority to enforce the laws and regulations pertaining to forensic and breath alcohol analysis (H&S Code Section 100725) and H&S Code Section 100700(a) requires laboratories performing forensic alcohol analysis to comply with all of the current regulations until such time as these regulations are revised.

The Department convened an eight-member review committee to evaluate the Department's current regulations pertaining to Forensic Alcohol Analysis. The committee will propose revisions to the regulations necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report test results and comply with applicable laws. To date, the review committee has conducted four meetings to propose such revisions. The meetings are still ongoing, and when the process has been completed, the committee will submit a summary of the proposed revisions to the California Health and Human Services Agency for approval.

The statutes clearly require the Department to continue a regulatory program. However, the loss of authority to license the laboratories has necessitated some changes in activities. The status of the current regulations and the Department activities that will be continued while the committee is reviewing the regulations are summarized in an enclosure.

Thank you for your ongoing support of the Forensic Alcohol Regulatory Program. If you should require any further information or clarification, please contact me at (510) 412-6220.

Mary Soliman, Ph.D., Chief  
Food and Drug Laboratory Branch

Enclosure

## **Department of Health Services, Forensic Alcohol Regulatory Program Activities in 2006**

**Laboratory Proficiency Testing:** The current regulations require the California Department of Health Services (CDHS) to evaluate the ability of forensic alcohol methods to meet the standards of performance requirements using a laboratory's proficiency test results. Such ability must meet the requirements of the regulations. CDHS will continue this activity, but will reduce the number of required testing events from three per year to two per year, and will substitute the forensic alcohol laboratories' required participation in an ASCLD/LAB approved proficiency-testing program for one of these two tests. However, the laboratories will be required to provide their analytical results in the ASCLD/LAB approved proficiency-testing program to the Department. The Department is imposing the two-test requirement during this interim period while the committee continues to review the regulations.

**Qualification of Laboratory Personnel:** The current regulations require that forensic alcohol analysis shall be performed only by persons qualified by CDHS as forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees. Individuals are nominated by the laboratories for qualification. This qualification is based on CDHS' review of a nominee's education and experience, and the nominee must successfully demonstrate accuracy in the analysis of proficiency test samples submitted by CDHS, and must successfully pass an examination prescribed by CDHS.

The laboratories will be required to comply with the current regulations concerning the qualification of laboratory personnel. CDHS will continue to qualify laboratory personnel based on a review of applications submitted by the laboratories and will continue to conduct proficiency tests and written examinations two times a year (in addition to the Laboratory Proficiency Test detailed above) to enable the laboratories to qualify personnel in a timely fashion. Each laboratory will continue to be required to keep up-to-date records of persons in its employ who have been qualified as forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.

**Site Inspections of Laboratories:** CDHS will continue to have the regulatory authority to conduct laboratory inspections for cause in order to inspect records and to ensure compliance with the regulations when necessary.

**Filing of Written Descriptions of Forensic Alcohol Methods:** CDHS will no longer require forensic alcohol laboratories to have on file with CDHS 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 CDHS on request.

**Approval of Training Programs:** The current regulations require that laboratories providing any training intended for persons to satisfy the requirements of the regulations (e.g., breath alcohol instrument operator training) must submit descriptions of this training to CDHS for review and approval. CDHS will continue this practice.