

State of California—Health and Human Services Agency
Department of Health Services



California
Department of
Health Services

SANDRA SHEWRY
Director



ARNOLD SCHWARZENEGGER
Governor

January 31, 2005

TO: FORENSIC ALCOHOL ANALYSIS LABORATORIES

SUBJECT: STATUS OF THE FORENSIC ALCOHOL ANALYSIS REGULATORY PROGRAM
IN 2005

On January 1, 2005, new statutes, Health and Safety (H&S) Code Sections 100700 – 100703, went into effect, which eliminates the 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). A new H&S Code Section 100700(a) requires laboratories performing forensic alcohol analysis to comply with the current regulations until such time as these regulations are revised.

The new statutes also require the Department to convene a review committee to propose revisions to the regulations that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report test results and comply with applicable laws. The committee will then 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 will necessitate some changes in activities. The status of the current regulations and the Department activities that will be continued in 2005 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.

A handwritten signature in cursive script that reads 'Mary A. Soliman'.

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

Enclosure

Department of Health Services, Forensic Alcohol Regulatory Program Activities in 2005

Laboratory Proficiency Testing: The current regulations require the Department of Health Services (DHS) 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. Currently, DHS conducts proficiency testing of the 42 forensic alcohol laboratories in the state three times a year. DHS will continue this activity, but may reduce the frequency of testing to the extent that it is able to monitor compliance with the regulation using the results obtained by the laboratories in the annual external proficiency test required by the new statutes.

Qualification of Laboratory Personnel: The current regulations require that forensic alcohol analysis shall be performed only by persons qualified by DHS 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 DHS' review of a nominee's education and experience, and the nominee must successfully demonstrate accuracy in the analysis of proficiency test samples submitted by DHS, and must successfully pass an examination prescribed by DHS. The laboratories will be required to comply with the current regulations concerning the qualification of laboratory personnel. DHS 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 to qualify these personnel. In the past, DHS published lists of persons qualified to perform forensic alcohol analysis for each licensed laboratory. DHS will discontinue this practice. 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: DHS 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: 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.

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 DHS for review and approval. DHS will continue to impose this requirement.

Review Committee Establishment: New Health and Safety Code Section 100703 requires DHS to establish an eight-member review committee representing: prosecuting attorneys, law enforcement agencies, defense attorneys, coroners (or pathologists or medical examiners), criminalists, toxicologists, crime laboratory directors, and DHS itself. DHS has sent out letters to organizations representing each of the categories designated by the new statute. DHS will forward a list of nominated individuals to the Director, who will make the final appointments to the committee. DHS will inform the laboratories of these appointees. After the membership of the Committee is established, it is DHS' intention to have a Committee meeting in early 2005.