

Ideas for Forensic Alcohol Analysis Regulations

Program has prepared proposals that would enable CDPH to reduce its direct involvement in the forensic alcohol analysis program while still maintaining appropriate state-level oversight of forensic alcohol analysis. This would be accomplished by partnering with existing commercial proficiency test providers and voluntary laboratory accreditation programs. The discussion below covers five areas of CDPH's current oversight program (Proficiency Testing, Qualification of Laboratory Personnel, Site Inspections, Approval of Training, and Access to Records). In addition, Program is proposing that laboratory registration procedures be described in the revised regulations and that several key procedure and performance requirements of the current regulations be retained.

Proficiency Testing

Proficiency testing is an important component of any laboratory regulation and oversight program. However, since open proficiency tests measure the best performance that a laboratory is capable of producing, proficiency testing must be viewed as only part of a regulatory program. CDPH certainly must continue to evaluate California laboratories' performances on proficiency tests, but it may be possible to reduce the Department's level of involvement. Below is a summary of the key elements of a program that would enable the Department to utilize commercial proficiency test providers to prepare and distribute samples used in the required proficiency testing of California forensic alcohol analysis laboratories:

- Laboratories would be required to subscribe to the full suite of test samples offered each year by the available providers¹;
- Laboratories with multiple methods would be required to obtain separate sets of test samples for each method;
- Laboratories would direct providers to report test results to CDPH;
- CDPH would continue to independently evaluate the test results using currently established criteria and would report the results of these evaluations;
- CDPH would continue to require a laboratory with an unsatisfactory performance on a proficiency test to submit a written description of the corrective actions taken together with experimental data to demonstrate that the method is capable of meeting the standard of performance requirements of the regulations.

Qualification of Laboratory Personnel

The stated goal of CDPH's regulations is to "ensure the competence of the laboratories and employees..." The Department is specifically required to enforce the regulations. Qualification of laboratory personnel is clearly a key component of CDPH's current regulation and oversight program. The Department qualifies personnel based on a review of the applicant's education and experience, and each applicant must successfully complete a proficiency test and written examination. It is important to retain state-level oversight of the qualification of laboratory personnel in order to ensure and document the competency of staff performing forensic alcohol analyses. The current voluntary laboratory accreditation programs do not certify individual staff. CDPH oversight provides the only external review of the qualifications of laboratory personnel performing forensic alcohol analysis. Below, is a summary of the key elements of a program that

¹ Collaborative Testing Services provides two proficiency tests per year. College of American Pathologists provides three sets of samples each year. CDPH currently conducts proficiency tests three times each year.

would permit the Department to continue its laboratory personnel qualification program utilizing proficiency tests obtained from approved providers:

- Laboratories would submit summaries of the qualifications of laboratory staff who will be performing forensic alcohol analysis. The Department would review and approve the applicants' qualifications;
- Laboratory staff lacking the requisite two years' experience performing forensic alcohol analysis would be required to complete a training course approved by CDPH (See Training Program Approval);
- Laboratory staff applying for qualification would be required to participate in an external proficiency test from an approved provider;
- CDPH would submit a written examination to each applicant;
- CDPH would evaluate the applicant's proficiency test and written examination using currently established criteria;
- CDPH and the Review Committee should consider a requirement for annual external proficiency testing of all personnel. (In effect, the committee here would be concluding that the statutes [H&S Code § 100702, (a) and (c)] require that each examiner must complete an annual external proficiency test.)

Site Inspections

Laboratory site inspections are a standard component of a laboratory regulation and oversight program. As noted above, proficiency testing measures the best performance level that a laboratory is capable of. Test samples alone are not enough to ensure that a laboratory is competent. Site inspections ensure that all regulatory requirements are being met and that the laboratory is properly documenting its procedures and is using properly trained staff. Many laboratories are currently being periodically inspected by third party laboratory accreditation organizations such as ASCLD/LAB². Unfortunately, these inspections do not adequately cover forensic alcohol analysis activities, including breath alcohol analysis. The Department would need to augment the requirements of the voluntary accreditation groups. Below is a summary of the elements of a program that could enhance CDPH's mandated oversight of forensic alcohol analysis laboratories by partnering with existing third party laboratory accreditation programs for laboratory inspections. The summary uses ASCLD/LAB as an example:

- CDPH would enter into a contract with ASCLD/LAB, which would provide laboratory inspection services that evaluate California's accredited forensic alcohol laboratories for compliance with the higher standards contained in California regulations;
- CDPH would provide training to the ASCLD/LAB inspectors and would need to evaluate some of the initial inspections;
- ASCLD/LAB would provide the results of the inspections to CDPH using standard forms prepared by the department. CDPH would evaluate these reports in order to determine compliance with California regulations;
- CDPH would retain its regulatory authority to conduct additional inspections for cause.

² In California, 26 laboratories are accredited by ASCLD/LAB; one laboratory is accredited by Forensic Quality Services; one laboratory is accredited by the National Association of Medical Examiners, and one laboratory is accredited by the American Board of Forensic Toxicology.

Approval of Training

Approval of training is a standard component of any laboratory regulation and oversight program. No other entity currently provides this oversight. Accordingly, CDPH's current role here must be continued. In California, training program approval also provides important state-level oversight of breath alcohol analysis. Every state regulates breath testing to ensure that breath alcohol tests are performed consistently and competently by law enforcement personnel throughout the state. The Department must retain its regulatory authority (CCR, Title 17 §1218) to approve breath test instrument operator training as well as any other training intended for persons to satisfy the requirements of the regulations. Since the current voluntary laboratory accreditation organizations such as ASCLD/LAB do not provide any certification of the qualifications of individual staff, there are no opportunities for partnerships here, and the Department's current program must be retained in its present form.

CDPH could make this program more attractive to the laboratories by publishing exemplar breath instrument operator training manuals, precautionary checklists, and report forms. Perhaps the State could partner with instrument manufacturers to develop these and other training materials. The laboratories would be free to use these documents in order to expedite the review and approval of their instrument operator training procedures. Another area where the Department could become involved in breath alcohol analysis would be the testing and certification of dry-gas calibrating units used to periodically determine the accuracy of instruments. Other states do this. Alaska actually manufactures the dry-gas units.

Access to Records

Ready access to laboratory records is a standard component of any laboratory regulation and oversight program. The regulations (CCR, Title 17, §§ 1220(b)(1) and 1222.) require laboratories to maintain specified records and to make these records available for inspection by the Department on request. These requirements must be retained. In order to meet the statutory mandate of enforcing the forensic alcohol analysis regulations, CDPH clearly must know who is performing the analyses and what analyses are being performed. The current regulations include requirements that a laboratory intending to perform forensic alcohol analysis must submit an application to the Department [Section 1217 (a)] and a laboratory must report any change or discontinuance of an activity [Section 1217.3]. These notification requirements must be retained in order for CDPH to meet its mandated responsibility to enforce the regulations pertaining to forensic alcohol analysis (cf. H&S Code Section 100725). Amendments to the regulations are needed to clarify and make specific the required information to be provided to CDPH.

Additional Proposed Revisions to the Regulations

Laboratory Registration - To ensure compliance with CDPH regulations, all laboratories intending to perform forensic alcohol analysis would need to be registered with the department. Registration would be completed using a web-based portal. This registration will identify laboratory locations, the person responsible for the activities of the laboratory, and a summary of the laboratory's activities as authorized by the regulations. The information will be used by CDPH to ensure regulatory compliance and to allow CDPH to enforce the law and regulations as mandated by Health and Safety Code Section 100725. The registration process, which will identify responsible persons at each laboratory, will also address the place-entity issues associated with the current definition of a laboratory simply as a place where certain activities occur.

Collection and Handling of Samples - Retain state-level oversight of the procedures for the collection and handling of samples for forensic alcohol analysis as provided for under current

Section 1219. CDPH is the appropriate body to set standards for the scientific validity as well as the health and safety of the procedures for collecting bodily fluids.

Collection of Sufficient Sample Volumes - Retain requirement of Section 1219.1 (b) to collect a sufficient volume of sample to permit duplicate analyses. The regulations require duplicate analyses of a sample [cf. Section 1220.2 (a) (3)]. The collection of a volume of sample that is not sufficient to permit duplicate analyses would mean that the analyses could not be completed in compliance with the regulations.

Maintenance of Equipment in Good Working Order - Retain requirement of Section 1220.2 (a) (5) to maintain equipment in good working order and routinely checked for accuracy and precision. Requirements for instrument maintenance and periodic checks are commonly included in lab regulations.

Reviews of Written Method Descriptions - Retain requirement of Section 1220 (b) that laboratories must file written method descriptions with CDPH. Clearly authorize in regulation the requirement that the Department must review the written descriptions submitted by the laboratories to ensure that they demonstrate full and explicit compliance with the requirements of the regulations. These reviews are needed in order for the Department to ensure that the analyses are performed in accordance with regulations adopted by the Department as mandated by Health and Safety Code Section 100725, and to ensure that forensic alcohol analysis is performed competently and consistently throughout the state.

Experimental Demonstrations of Method Performance - Amend Section 1220.1 to require laboratories to experimentally demonstrate that their methods are capable of meeting the required standards of performance, i.e., accuracy and precision, non-interference from anticoagulants and preservatives added to the sample, and results less than 0.01% when testing samples from living subjects free of alcohol. The regulations would set forth the minimum requirements for these experimental demonstrations and the Department would review the data to determine whether the method meets the requirements. The Department's evaluations of these data provide appropriate state-level oversight of forensic alcohol analysis and assure proper accountability.

Written Descriptions of Procedures for the Periodic Determinations of Accuracy of Breath Instruments - Revise the regulations (Section 1221) to include a requirement that laboratories prepare detailed, up-to-date written descriptions of the procedures employed in support of breath alcohol analysis performed by law enforcement agencies. These descriptions would include procedures for periodically determining the accuracy of the instruments. The regulations should set forth requirements for the contents and the availability of the written descriptions. The written descriptions would be subject to review and approval by CDPH. The requirements here would be analogous to the requirements under Article 6, Section 1220 that a laboratory prepare written descriptions of its forensic alcohol method(s).

Preliminary Alcohol Screening Tests - Revise the regulations (Section 1221) to clarify and make specific the requirement that when preliminary alcohol screening devices are used to measure alcohol concentration in breath, then this testing is subject to Department regulations.

Continuous Observation of Subject Prior to Breath Test - Retain requirement of Section 1221.1(b)(3) [formerly Section 1219.3] to continuously observe the subject prior to a breath test. The prohibited activities during the 15-minute period (ingestion of alcoholic beverages or other fluids, regurgitation, vomiting, eating, or smoking) can introduce alcohol into the oral cavity. It is imperative that the oral cavity be free of alcohol in order obtain a meaningful test result. A discontinuous observation period (e.g., three 5-minute observations interspersed during a total 20-minute period) could result in the operator failing to observe one of the prohibited activities.