

Regulatory Component	Program's Ideas for FAA Regulations	Subcommittee's Discussions (from Jennifer Shen's 9/20/11 Memo, Sub Committee Ideas)
Proficiency Testing	<p>Laboratories required to subscribe to the full suite of test samples offered each year by an available provider;</p> <p>Laboratories required to obtain separate sets of test samples for each method used for forensic alcohol analysis;</p> <p>Laboratories would direct providers to report test results to CDPH;</p> <p>CDPH would independently evaluate test results using currently established criteria and report the results of these evaluations;</p> <p>CDPH would 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.</p>	<p>"laboratory staff would perform the proficiency tests, and the results would be forwarded to the Dept. for monitoring"</p> <p>Website exemplar lists, "<b>Current in Prof Tests: YES</b>"</p>
Qualification of Laboratory Personnel	<p>Laboratories would submit summaries of the qualifications of laboratory staff to CDPH and the department would review and approve the applicants' qualifications;</p> <p>Applicants lacking the requisite two year's experience performing forensic alcohol analysis would be required to complete a training course approved by CDPH;</p> <p>Applicants would be required to participate in an external proficiency test from an approved provider;</p> <p>CDPH would submit a written examination to each applicant;</p> <p>CDPH would evaluate the applicant's proficiency test and written examination using currently established criteria;</p> <p>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&amp;S Code § 100702, (a) and (c)] require that each examiner must complete an annual <u>external</u> proficiency test.)</p>	<p>"We discussed a drop down menu that could contain the names of certified analysts employed in that laboratory. This was something that caused a little consternation among my staff however."</p>

<p>Site Inspections</p>	<p>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;</p> <p>CDPH would provide training to the ASCLD/LAB inspectors and would need to evaluate some of the initial inspections;</p> <p>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;</p> <p>CDPH would retain its regulatory authority to conduct additional inspections for cause.</p>	<p>“We discussed the possibility of ASCLD/LAB handling the ‘work’ while the Dept. monitored the results.”</p> <p>“The accrediting body would handle the inspections etc., and proof of accreditation would be forwarded to the Dept. “</p> <p>“We discussed a “checklist” of required items that could be added into the ASCLD/LAB inspections. This list would include things the Department deemed necessary to ensure accurate testing results.”</p>
<p>Training</p>	<p>The Department would 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.</p> <p>Oversight of instrument training provides critical state-level oversight of breath alcohol analysis.</p> <p>Voluntary laboratory accreditation organizations such as ASCLD/LAB do not provide any oversight of breath instrument operator training and do not certify the qualifications of individual staff.</p> <p>CDPH could make its program more attractive to the laboratories by publishing exemplar breath instrument operator training manuals, precautionary checklists, and report forms.</p>	<p>“We discussed that the breath program is the one area where we really need some oversight. The fluid analysis is covered by ASCLD/LAB already, and all government labs in CA are in fact accredited. Those laboratories that have the breath calibration oversight by ISO, probably are OK, all others may need some Departmental oversight. Perhaps instead of focusing on providing proficiency tests that are deemed insufficient, the Dept. could focus on providing breath oversight?”</p> <p>“We discussed leaving the training up to the individual laboratories. A compromise with the Department could be the following: The Department will assist in forming the outline of what needs to be covered. (This can be taken largely from Title 17 as stands) and the individual laboratory management would ensure that the topics are covered. The training records must be available for review. This is already the case for our accreditation; there is no reason that the Dept. could not have access to the records as well. If the outline is in laboratory manuals, then it will have to be covered by trainers in order to pass muster for ASCLD/LAB.”</p>

<p>Access to Records</p>	<p>All forensic alcohol records would remain available to CDPH (cf. CCR, Title, §§ 1220.(b)(1) and 1222.)</p> <p>Laboratories would be required to inform CDPH of the initiation of forensic alcohol analysis activities [cf. §1217 (a)] and must report any change or discontinuance of an activity [cf. Section 1217.3]. Amendments to the regulations are needed to clarify and make specific the required information to be provided to CDPH.</p>	<p>Under Training, the subcommittee noted, “The training records must be available for review. This is already the case for our accreditation; there is no reason that the Dept. could not have access to the records as well.”</p>
<p>Laboratory Registration</p>	<p>To ensure compliance with CDPH regulations, all laboratories intending to perform forensic alcohol analysis would need to be registered with the department;</p> <p>Registration would be completed using a web-based portal;</p> <p>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;</p> <p>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.</p>	<p>“We discussed the possibility of a website that was run by the Dept., and was accessible to the public at large. This website would contain the information that shows a particular lab and its analysts have followed the State’s criteria for alcohol testing, and that the laboratory is (or is not) in good standing. Example: You could pull up a particular laboratory on the site. .</p> <p><b>San Diego Police Department Crime Laboratory Accredited: Yes</b>  <b>Accrediting Body: ASCLD/LAB</b>  <b>Current in Prof Tests: YES</b>  <b>Lab in Good Standing: YES”</b></p>
<p>Other Revisions to the Regulations</p>	<p><u>Collection and Handling of Samples</u> - Retain state-level oversight of the procedures for the collection and handling of samples for forensic alcohol analysis (cf. current Section 1219).</p> <p><u>Collection of Sufficient Sample Volumes</u> - Retain requirement of Section 1219.1 (b) to collect a sufficient volume of sample to permit duplicate analyses.</p> <p><u>Maintenance of Equipment</u> - Retain requirement of Section 1220.2(a)(5) to maintain equipment in good working order and routinely checked for accuracy and precision.</p> <p><u>Reviews of Written Method Descriptions</u> - Retain requirement of Section 1220(b) that laboratories must file written method descriptions with CDPH. 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.</p>	<p>“We discussed that, at a minimum, Title 17 must be very clear, so that it is not up for interpretation. Many of our issues stem from contrasting views of what is or is not mandated under those regs.”</p>

Other Revisions to  
the Regulations  
(Cont.)

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.

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.

Preliminary Alcohol Screening Tests - Revise the regulations (Section 1221) to 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.