

SUPPLEMENTAL STATEMENT OF REASONS
FORENSIC ALCOHOL TESTING LABORATORIES
CALIFORNIA CODE OF REGULATIONS, TITLE 17

SUMMARY OF PROPOSAL

Senate Bill 1623, Chapter 337 (statutes of 2004), created section 100703 of the California Health and Safety Code, which removed the State Department of Public Health's (Department's) authority to license forensic alcohol testing laboratories. The legislation required the Department establish a review committee (the 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 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 Health and Safety Code. The 1986 regulations are outdated and inconsistent with California law, current health advisories, and modern instrumentation and technology. Therefore, the regulations needed to be reviewed in their entirety, and re-written where applicable. This second round of proposed changes provides further clean up in response to public comment and committee discussion.

AUTHORITY

The authority for this rulemaking action is Health and Safety Code section 100703. The regulations implement and make specific the Health and Safety Code section governing the operation of forensic alcohol testing laboratories in California at Health and Safety Code section 100700 *et seq.*

Please note that the authority for each section has been changed in the regulations.

DETAILED DISCUSSION OF EACH REGULATION

California Code of Regulations, Title 17, Sections 1215 to 1222.2

Article 1. General

Section 1215

The definitions in this section have been alphabetized and therefore redesignated ((a), (b), etc.).

Redesignated subsection (a) “Alcohol”: Sentence restructured slightly to add clarity. “Antiseptic” was changed to “disinfectant” to provide consistency with the regulations.

Redesignated subsection (c) “Breath Alcohol Testing”: In response to public comments, the committee reassessed the word choice of “sampling” and agrees with the public commenter that it is not an appropriate word choice. Therefore, the Committee changed “sampling” to “analysis.” See Comment 1:16.

Redesignated subsection (d) “Competency Test”: In response to public comment, the committee proposes to change the word “casework” to “testing” to add clarity. With this change, the committee feels the definition of “competency test” is clear. The committee felt that it was appropriate and necessary to differentiate between the terms “proficiency test” and “competency test.”

Redesignated subsection (e) “Concentration”: The committee proposed to remove the word “solid” from the definition because it is redundant. Punctuation changes were also made for clarity.

New subsection (j) “Laboratory”: This definition was added to clarify the difference between a laboratory as a place (see “forensic alcohol laboratory” definition) and a laboratory as the responsible entity for ensuring these statutes and regulations are complied with.

Redesignated subsection (l) “NIST”: This definition was corrected to accurately spell out the abbreviation.

New subsection (m) “NIST Certified Reference Material (CRM)”: The committee proposes to add this definition because CRM is referenced in the “NIST Standard Reference Material (SRM)” definition in redesignated subsection (n). Defining CRM is required for defining SRM.

Redesignated subsection (n) “NIST Standard Reference Material (SRM)”: The committee amended this proposed definition to match the definition provided by NIST.

Redesignated subsection (o) “NIST Traceable”: The committee amended this proposed definition so that it more closely matches the definition provided by NIST.

Redesignated subsection (q) “Proficiency Test”: The committee removed the words “technical support” to clarify the definition. The committee felt the inclusion of this definition is important to differentiate it from “competency test.”

Section 1216

Subsection (a): A time limit was added for when laboratories must submit the documents required under this section. This is necessary to ensure compliance.

Section 1216.1

Subsection (b): The word “trained” was added to clarify that the criteria that follow are what qualifies an analyst as fully trained.

Subsection (b)(1): In response to public comment, the committee proposes to change the subject matter of the educational degree to “life sciences or physical science.” The committee agreed with the commenter that natural science includes physical science.

Subsection (b)(2): The committee added “performing alcohol analysis” to clarify what “analytical experience” means. “Such” was added for clarity and ease of reading.

Subsection (b)(2)(F): The committee proposes to replace “analyst’s” with “trainee’s” to clarify that a trainee is not an analyst. “Successfully” was added to clarify that the trainee must not just perform forensic alcohol analysis, but must do so successfully.

Subsection (b)(2)(G): The committee deleted the word “forensic” because it does not apply here.

Subsection (b)(3)(E): In reassessing the proposed regulations, the committee recognized that this subsection as written was not reasonable because 5% of a small number (0.02 for instance) is too small for laboratories to adhere to. Therefore, the committee has created a standard for larger results and for lesser results.

Subsection (b)(4): The committee removed the language regarding those personnel who were operating under the law prior to 1971 because according to department personnel, there are no such persons left performing alcohol analyses in the state. A

new sentence was added to clarify that if persons meet the personnel standards in these new regulations, they may perform analyses.

Subsection (c)(1): In response to public comment, the committee proposes to change the subject matter of the educational degree to “life sciences or physical science.” The committee agreed with the commenter that natural science includes physical science. The committee also agreed to separate out the document submission requirements for a new analyst versus a practicing one.

Subsection (c)(3): The committee proposes to remove “written” and/or “practical” tests, and replace that verbiage with “any qualifying” to be more encompassing.

Subsection (c)(5): The committee, in response to public comment, seeks to replace “casework,” a nebulous term, to “testing,” a term that is better understood and defined.

Subsection (d): This subsection was rewritten for clarity. These are nonsubstantial changes.

Section 1217

Subsection (a): The committee feels that “Title 17” is more clear than “these regulations.”

Subsection (b): The committee removed “forensic alcohol” in front of “laboratory” to ensure that it was understood that it was the laboratory a responsible entity that was meant, not simply as a place where analyses occur.

Section 1218

Subsection (c): The committee added times frame references for review and submission of concerns, both for the Department and the laboratory.

Article 4 title: “Tissue” was removed because this article does not address tissue sampling.

Section 1219.1

Subsection (e) (3): In response to public comment, the committee believes that (e) should include an additional subsection that states that postmortem blood samples shall be mixed with anticoagulant and preservative.

Section 1220

Subsection (b)(2): The committee added the word “instrument” to clarify what is to be calibrated.

Section 1220.1

Subsection (a)(2): This is a nonsubstantial change. This sentence was reworked for ease of reading.

Subsection (a)(4): The committee added “specifically identified” to clarify that only ethyl alcohol results that are specifically identified as such shall be reported. The change is meant to remove previously added terms that were not defined in the regulations.

Section 1220.2

Subsection (a)(1): The verbiage here was changed slightly to remove “instrument.” This is now inclusive of wet chemistry techniques.

Subsection (a)(1)(B) and (C): “CRMs” replaces “secondary alcohol standards” to ensure clarity, and the definitions now define “CRM.” Likewise, “SRM” replaces “standard reference material” for the same reason in (C). In addition, language was clarified to more correctly portray the direct oxidation process.

Subsection (a)(1)(D): This subsection was added to reflect best practices in the forensic analysis field.

Subsection (a)(2): The subsection was amended to simplify the procedure requirement regarding blank and secondary alcohol standards.

Subsection (a)(2)(B): The committee make a change to reflect that the subsection is addressing the analysis of blank and secondary standards, not forensic alcohol analysis.

Subsection (a)(3): The requirement that the procedure include at least duplicate analyses of samples was removed because the analysis of reference samples and the analysis of forensic alcohol samples are separate issues and should not be combined here.

Subsection (a)(4): This is to clarify that analysis of each sample shall be done at least twice.

Subsection (a)(5): This sentence was kept, requiring all instruments are maintained in good working order, as is necessary for the gathering of accurate results. The revised

regulations under 1220.1 (a)(1), 1220.1 (b), 1220.2 (a)(1), 1220.2 (a)(1)(C) and 1220.3 sufficiently demonstrate routine checks of accuracy and precision, and this component of the removed text is redundant and unnecessary.

Section 1220.3

Subsection (a)(1)(A): The committee changed this in response to public. The committee believes that less stringent requirements than those in subsection (a)(2) are sufficient if the reference material meets the high standards in new subsection (a)(1)(A).

Section 1220.4

Subsection (a): The beginning of the sentence was removed because this proposed regulation does not apply to tissue or breath-test analyses, only blood.

Subsection (a)(1): See rationale for subsection (a).

Subsection (b): This amendment to the proposed regulation clarifies that results may be reported to the third decimal place and that, if reporting to the second decimal place, the third digit is to be removed (rather than rounding up).

Subsection (a)(c) and (d): A zero was added for clarity.

Subsection (e) and (f): These subsections were rewritten for clarity and grammatical correctness.

Section 1221.1

Subsection (a): This subsection was rewritten for clarity, nonsubstantive changes.

Subsection (b): “Or affiliated with” was added because “jurisdiction” has a legal meaning that may not fit all relationships between laboratories and operators.

Old subsection (b)(1) and (2): These requirements were deleted because the department does not have the ability to regulate law enforcement.

New subsection (b)(1): “Continuous” was inserted to clarify that the observation of the subject must be for an uninterrupted 15 minutes, not 15 minutes total.

Section 1221.2

Subsection (a)(2)(A): The committee thought it best to revert to 0.30 grams %. The upper limit change is less crucial and therefore it is suggested to remain at 0.30%. Further committee discussion occurred, and the committee feels there is no scientific or compelling reason to change the limit from 0.30 to 0.25. This limit has been in place for 30 plus years. Therefore, the regulations will be changed back to 0.30%.
Subsection (a)(3): Nonsubstantive change for ease of reading.

Subsection (a)(3)(C)(i) and (D): This change was made to clarify that the precautionary checklist must be part of what operators are training in and that the operators must use the checklist during the testing process. The sections regarding the practical experience and the precautionary checklist were switched.

Subsection (a)(3)(E): Because this subsection deals with only written exams, this was reflected in the title.

Old subsection (a)(3)(F): The committee believed that this subsection was redundant in light of the other changes made to this subsection.

New subsection (a)(3)(F): "By the laboratory" was added to clarify who issues the certificate.

Subsection (a)(4): This change was made because the committee believes a forensic alcohol analyst is the best person to conduct the training in Theory of Operation.

Subsection (b): Nonsubstantive change to reflect that the precautionary checklist must be available for an operator to consult at the location of the instrument. This is important because the precautionary checklist must be followed.

Section 1222

Subsection (a)(2)(F): The committee thought that "describe and document" was more specific and therefore clear than "represent."

Section 1222.1

Subsection (a)(2): The beginning of the sentence as now written was added to clarify that there will be records of breath test results and other test results.