

Comment #	Subject	Comment	Response to Comment
1:1	Introduction	<p>I would like to offer my comments below on the Department of Public Health's (Department's) proposed regulations pertaining to forensic alcohol testing laboratories (DPH-05-012). My comments include responses to the Initial Statement of Reasons (ISOR) included with the notice of the proposed action. The ISOR includes a preliminary section, which precedes the detailed discussion of the reasons for proposing the adoption, amendment, or repeal of each regulation. The bulk of my comments will address the detailed discussion of each regulation, however, the preliminary portion of the ISOR contains numerous factual errors which deserve at least a brief response.</p> <p>The preliminary section of the ISOR consists of four subsections: Summary of Proposal, Authority and Reference, Policy Statement Overview, and Consistency and Compatibility with Existing State Regulations.</p> <p>Summary of Proposal¹</p> <p>The Summary of Proposal begins by listing some examples of amendments to the regulations that "reflect changes in the applicable Health and Safety Code statutes." Included here was the requirement that "equipment used to determine breath alcohol concentrations must now be listed as conforming products in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation." In fact, the regulations were amended in 1985 to include this requirement.²</p>	
1:2	proficiency testing program	<p>The summary here also claims that "the proficiency testing of the laboratories must now conform to the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing." The current regulations require laboratories to participate in a proficiency testing program conducted by the Department. The comment in the ISOR appears to suggest that the statutory proficiency testing requirements (cf. Health and Safety Code §100701) somehow supersede or effectively repeal the current</p>	

		<p>regulatory proficiency testing requirements. In a 2011 opinion, the Attorney General’s office reviewed the Department’s authority to independently conduct a separate proficiency testing program that does not conform to the statutorily required proficiency testing program.³ The AG noted that the Department had found many shortcomings in the ASCLD/LAB proficiency test guidelines and has continued to operate a separate program. The AG concluded that the Department has the authority to impose its own, separate proficiency test requirements. This authority is not superseded by the 2004 change in the statutes.</p>	
1:3	<p>Authority and Reference</p>	<p>Authority and Reference</p> <p>The statutes define “authority” as “the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation” [cf. Government Code §11349 (b)]. The ISOR cites H&S Code §100725 as an authority. The statute here requires the Department to enforce the regulations, but does not appear to authorize the adoption of regulations. The authority citation for the proposed regulations should include H&S Code §131200, which establishes the Department of Public Health’s general authority to adopt regulations.</p>	
1:4	<p>Policy Statement Overview</p> <p>Instrument</p>	<p>Policy Statement Overview</p> <p>In the subsection “Problem Statement”, the ISOR summarizes several changes in the field of forensic alcohol analysis since the regulations were last revised in 1986. The ISOR suggests that these changes drive the revisions to the regulations proposed by the forensic alcohol review committee. The problem statement points out the changes in technology including “the advent of advanced data processing systems and mobile breath instruments has enabled alcohol testing to reach new levels of efficiency and accuracy. Instruments run diagnostics, run calibration checks, and prompt officers to follow the precautionary checklist, all automatically.”</p> <p>In fact, the improvements in breath instrument technology here have been mostly evolutionary and many of the instrument features described have been available for many years. But the main response here is to note that with one exception, the committee has not proposed any changes in the regulations to accommodate new technology. In</p>	

		<p>response to a recommendation made by Department staff,⁴ the committee has proposed to revise the references to an operator performing a periodic determination of accuracy [Sections 1221.4 (a)(2)(A)1 and 1221.4 (a)(6)] to accommodate instruments that perform determinations of accuracy automatically. Again, except for this change, which was proposed by the Department, the committee has not proposed any other changes in the regulations to accommodate new technology.</p> <p>The problem statement also notes the development of National Institute of Standards and Technology (NIST) traceable dry gas standards and points out this this makes it possible for “scientists to check the calibration of their instruments with every single subject breath test”. The policy statement contrasts this with, “the current Department regulations from the 1980’s, which require calibration every 10 days with a solution, an antiquated process.” The policy statement here is full of misinformation! First off, the description of a “calibration every 10 days” is incorrect. The regulations require that the accuracy of a breath test instrument is determined every 10 days or 150 subjects whichever comes sooner.⁵ Nothing in “the current Department regulations” requires a laboratory to conduct these determinations of accuracy using “solutions.”⁶ Dry gas calibrating units have been used by California laboratories for 20 years. Moreover, nothing in the current regulations precludes a laboratory from conducting periodic determinations of accuracy more often than once every 10 days. Two California laboratories currently train operators to conduct determinations of accuracy with each test subject. Maybe most significantly, there are no proposed changes in the revised regulations that would alter the current requirements. The proposed revisions do not require laboratories to use NIST traceable dry gas standards; in fact there’s no mention of these gases. There are no proposed changes in the required frequency of periodic determinations of accuracy. There are no changes in the types of calibrating units that may be used. In short, there are no changes in California’s “antiquated process.”</p>	
<p>1:5</p>	<p>NIST traceable alcohol standards</p>	<p>The problem statement next points out the availability of NIST traceable alcohol standards “with exceptional levels of accuracy and precision, standards that can replace the time consuming and less accurate titrated solution standards. These standards can be purchased with</p>	

	<p>many different concentrations, allowing for better instrument calibration and therefore more accurate tests.”⁷ The issues presented here are almost assuredly outside the ken of the author of the ISOR. As a consequence the problem statement comments are not fact based: Here are some facts:</p> <ol style="list-style-type: none"> 1) Nothing in the current regulations prevents a laboratory from purchasing and using NIST traceable alcohol reference materials as calibration standards. 2) The claim that the NIST traceable standards are available “with many different concentrations, allowing for better instrument calibration” doesn’t make any sense. The only US vendor of alcohol reference materials⁸ provides standards at eight different concentration levels (five of which are useful). This is certainly an adequate range, but laboratories that prepare their own standards, would have an unlimited number of concentrations available. <p>The claim that the NIST traceable standards provide “exceptional levels of accuracy and precision” is a bit misleading and deserves some clarification. First, the reference to the “precision” of the standard does not make any sense. The statistic “accuracy” might have some meaning with respect the ability of the vendor to match a target concentration, but the important parameter is the stated uncertainty of the concentration. The one available NIST traceable reference material does claim a low uncertainty, but it is important to note that the commercial reference materials are prepared gravimetrically, by weighing absolute ethanol. The standards are thus traceable to the kilogram. California regulations currently require that the concentrations of the secondary standards must be determined chemically by a direct oxidimetric analysis. In metrological terms, these standards are then traceable to the mole. An argument can be made for the metrological superiority of establishing chemical traceability. However, the regulations could be revised to permit California laboratories to prepare standards gravimetrically. Presuming the laboratories hire competent staff, there is no reason to believe that these staff would not be able to prepare standards with a stated concentration uncertainties equivalent to the commercial product. More importantly, the real impact of uncertainty of the calibration standard concentration on the total measurement uncertainty of the</p>	
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		method would need to be determined based on a determination of an uncertainty budget for the method. This would of course be individual to each laboratory, but published studies of the measurement uncertainty of gas chromatographic methods have not shown that the uncertainty of the calibrant is a major contributor to the overall uncertainty of the method. ⁹	
1:6	College coursework	The Policy Statement Overview claims that “college degrees, course work, class titles, and curriculum have advanced and changed to the point that it is difficult to correlate modern students’ coursework with the requirements of the 1986 regulations.” It’s difficult to determine what the author is talking about here. It’s not clear that there have been any changes in higher education that would affect laboratory staff performing forensic alcohol analysis. The current regulations require a fairly minimal amount of course work in college chemistry (11 semester hours) including quantitative analysis. The committee’s revisions eliminate the requirement for laboratory staff to have completed any chemistry at all!	
1:7	Legal Limit	The policy statement notes that the “legal limit” (i.e., per se and presumptive alcohol concentrations at which a person may be prosecuted) have changed from 0.10% to 0.08%. This is correct; however, the impact on the Title 17 regulations here is very indirect. The committee lowered the range of concentrations used for quality control samples and the range the reference samples to be used to determine the accuracy of instruments to include the 0.08% concentration. There is no requirement for the laboratories to actually employ these lower concentration values. The policy statement also notes that that there are new lower limits for commercial and juvenile drivers and claims that, “These changes in California law serve to further diminish the relevance of the current regulations.” The lower presumptive blood alcohol concentration limits for commercial drivers [CVC §23152 (d)] and drivers under the age of 21 [CVC §§ 23140 (a) and (b) and §13557] are not “new,” they date back more than 20 years. But more importantly, the review committee did not propose any revisions to the regulations to accommodate the lower alcohol values. Consequently the claim in the ISOR that these 20-year old changes in the law serve to diminish the relevance of the current regulations must be considered to be a complete non sequitur.	

<p>1:8</p>	<p>National standards</p>	<p>The Policy Statement Overview refers to the American Society of Crime Lab Directors/Laboratory Accreditation Board and notes that “95% of California’s crime laboratories are accredited by ASCLD/LAB” and that this “means they are held to national standards.” The Department has found shortcomings with these “national standards.” As the Director of the Department of Public Health noted in his December 2010 letter to the forensic alcohol review committee¹⁰, the Department found that “the ASCLD/LAB guidelines do not establish specific laboratory performance or procedure standards for blood alcohol analysis, nor mention breath alcohol analysis. The substitution of the ASCLD/LAB requirements for the current program would not achieve the statutory mandate of ensuring the competence of the laboratories and their employees performing chemical testing in support of California’s drinking-and-driving laws.” The voluntary ASCLD/LAB program, which is owned and operated by the crime laboratories, lacks regulatory authority. The Department’s regulatory program is a transparent, public process, while ASCLD/LAB’s entire program operates under rules of strict confidentiality.</p>	
<p>1:9</p>	<p>ISOR</p>	<p>The policy statement next very briefly outlines some of the proposed changes in the regulations. Again, the comments made in the ISOR are full of misinformation. For example, the ISOR notes that, “the Department will no longer require forensic alcohol laboratories to have on file with the Department written descriptions of the methods it uses for forensic alcohol analysis.” This statement is correct, but the policy statement then adds, “The laboratories will, however, still be required to maintain detailed, up-to-date written descriptions of each method and to make these available to the Department on request.” The statement is incorrect and very misleading. With the proposed regulations, the requirement for laboratories to make the written descriptions available for inspection by the Department on request [i.e., current Section 1220 (b)(1)] would be repealed! The committee also proposed to repeal the Department’s general authority to require laboratories to make records of their activities available for inspection by the Department on request (i.e., current Section 1222). The claim in the ISOR to the contrary here has to be viewed as a remarkable bit of misinformation or possibly disinformation. Either that or the author of the ISOR is remarkably unfamiliar with the regulations proposed by the committee.</p>	

<p>1:10</p>	<p>Changes to regulations</p>	<p>Finally, the policy statement section notes that, “Because 25 years have passed since the last revision of forensic alcohol testing regulations, the forensic community finds itself in a new era of technology, education, proficiency testing, and oversight.” This appears to be a repeat of an earlier theme. The appropriate response again is to point out that the committee has not proposed any significant changes to the regulations that address changes in technology. The changes in the education requirements for laboratory personnel appear to lower the current standards. The committee has proposed numerous changes in “oversight.” As frequently described in the ISOR discussion of each regulation, the committee’s proposed revisions were specifically intended to remove the Department’s current oversight authority to approve personnel qualifications,¹¹ approve sample collection procedures,¹² perform on-site inspections,¹³ evaluate proficiency tests,¹⁴ approve training programs,¹⁵ and even to request laboratory records.¹⁶ As stated many times by review committee members, the primary intent of these revisions was to replace current state-level oversight of forensic alcohol analysis with a regime of self-oversight by the laboratories. The problem here is that the elimination of state level oversight conflicts with the statutes, HSC 100725, which requires the Department to enforce the law and regulations in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)]. The legislature vested the California Department of Public Health with the specific authority to enforce the law and the regulations.</p>	
<p>1:11</p>	<p>ISOR</p>	<p>The ISOR includes a subsection “Objectives.” The first listed objective is to “Codify in the regulations the removal of the authority of the Department over the licensing of the state’s forensic alcohol laboratories.” This is quite reasonable. The 2004 legislation eliminated the Department’s authority to require the laboratories to be licensed [cf. H&S Code §100700 (b)]. However, the ISOR discussion of each regulation also describes the “codification” of the removal of the Department’s authority to approve training programs¹⁷ and proficiency testing.¹⁸ Similarly, the ISOR describes the removal of the Department’s authority to review and approve laboratory personnel¹⁹ and to conduct site inspections.²⁰ In each case, the ISOR claims that the losses in authority were directed by the enabling statute. In each case, the committee’s conclusion misrepresents the intent of the legislature. The 2004 change in the statutes repealed the Department’s authority to</p>	

		<p>require the laboratories to be licensed. The statutes do not prohibit the Department from any other activities associated with the regulation of the laboratories including approving training programs, conducting proficiency tests and examinations, approving personnel qualifications, conducting site inspections, etc. Again, the statutes specifically require the Department to enforce the law and the regulations (H&S Code §100725). The Attorney General’s office, in its 2011 opinion regarding the forensic alcohol program (Opinion 10-501)²¹ evaluated the legislative intent of the 2004 legislation and concluded, “Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure.”</p> <p>The ISOR claims that one of the benefits of the proposed regulations is that they “create a more- uniform and more-accurate testing environment...” As will be noted in the comments for each regulation, the proposed revisions create unrealistic method specificity standards, create confusing requirements for the calibration of method, eliminate meaningful personnel qualifications, eliminate any requirements for a laboratory to maintain instruments in good working order or to check instruments for accuracy and precision, etc. These changes will not create a more accurate testing environment. Regarding the benefit of more uniform testing, the ISOR frequently notes that the basic purpose of the committee’s proposed revisions was to replace the current State-level oversight with a self-oversight by the individual laboratories.</p> <p>Allowing the 40 individual laboratories to interpret the requirements of the regulations without any oversight or enforcement will not achieve the goal of more uniform testing. It will also not ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws as mandated by the statutes.</p>	
<p>1:12</p>	<p>Consistency and Compatibility with Existing State Regulations</p>	<p>Consistency and Compatibility with Existing State Regulations</p> <p>The ISOR states that, “No statute or regulation conflicts with this proposed regulatory update.” This statement is incorrect. Health and Safety Code §100725 requires the Department of Public Health to enforce the law and its regulations pertaining to forensic alcohol analysis</p>	

		<p>in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)]. A regulatory system clearly must be enforceable to be effective. Enforcement of regulations includes two elements: a system of oversight that allows the enforcement agency to discover and identify noncompliance; and a system for compelling observance of or compliance with the regulations.</p> <p>The current regulations provide the Department with a system of oversight, which includes authorities to review, test, and approve personnel qualifications, perform on-site inspections, evaluate laboratory proficiency tests, approve training, etc. These are all completely standard and necessary components of any laboratory regulatory program. They allow the Department to identify noncompliance. The revisions to the regulations proposed by the committee would eliminate all of the above oversight authorities.</p> <p>As noted above, enforcement must also include a system for compelling compliance with the regulations. In its 2011 opinion, the Attorney General's office considered the mechanisms by which the Department of Public Health would enforce the regulations in the absence of licensing. The AG concluded that under the current regulations, the Department would have proper legal standing to seek mandamus or injunctive relief to enforce compliance with the regulations.</p> <p>The rulemaking²² record shows that committee discussed the Department's enforcement of the regulations on numerous occasions. However, the committee never resolved the issue and certainly never proposed regulations that would enable the Department to achieve its statutory enforcement mandate. The committee's proposed revisions to the regulations by completely eliminating the current oversight role and by failing to incorporate any provisions in the regulations to enforce compliance are in conflict with H&S Code §100725. This conflict is not addressed in the ISOR, and in fact with the exception of an apparently incorrect reference to H&S Code §100725 as providing authority to promulgate regulations, the ISOR does not ever mention this statute. The ISOR never considers or discusses the issue of the enforcement of the regulations.</p>	
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<p>1:13</p>	<p>Section 1215</p>	<p>Article 1. General Section 1215</p> <p>Current Section 1215 cites the authority and reference for all of the regulations. As indirectly noted in the Initial Statement of Reasons (ISOR), the current statutes now require a citation of the authority and reference with each section of the regulations. Accordingly, Section 1215 serves no purpose and should be repealed. The Department’s Office of Regulations then renumbered the subsequent definitions section, 1215.1, as 1215. This does not conform to the format used by the regulations publisher, Westlaw.²³ Here a repealed regulation is represented by its number and title without any regulations text such that it remains cataloged within the California Code of Regulations. More importantly here, the Department’s renumbering format makes the revised regulations hard to follow. In order to clarify the situation, the comments presented below will identify the current section number as well as the proposed new number.</p>	
<p>1:14</p>	<p>Section 1215 (a) [Current Section 1215.1 (a)]</p>	<p>Section 1215 (a) [Current Section 1215.1 (a)]</p> <p>Clarity – The committee proposed no changes to the current definition of the word alcohol. The current definition provides two meanings of the word (i.e., “the unique chemical compound, ethyl alcohol” and “the generic class of organic compounds known as alcohols”) and thus the definition fails the clarity standard [cf. 1 CCR 16 (a)(1)]. The two definitions have not caused confusion in the past. The word “antiseptics” in the definition should be changed to “disinfectants.” There are no references to “antiseptics” in the regulations. The subsequent reference in the regulations describing the circumstances where it is necessary to avoid the use of the generic class of organic compounds known as alcohols, uses the term “disinfectants,” not “antiseptics” [see Section 1219.1 (b), current Section 1219.1 (c)].</p>	
<p>1:15</p>	<p>Section 1215 (b)24 [Current Section 1215.1 (b)]</p>	<p>Section 1215 (b)24 [Current Section 1215.1 (b)]</p> <p>Clarity/Necessity – The committee proposed several changes to the definition of forensic alcohol analysis. The deletion of the description of the persons performing the analyses (currently “trained laboratory</p>	

	<p>personnel”) appears to raise the question of who performs forensic alcohol analysis. The new term “specialized equipment” could have multiple meanings and thus is unclear.</p> <p>The committee has chosen to retain the word “breath” in the list of samples that can be analyzed and did so without comment and apparently without much analysis. While the inclusion of the analysis of breath samples under forensic alcohol analysis appears to be consistent with the 2004 revision to the Health and Safety Code,²⁵ which now includes the analysis of breath samples as a forensic alcohol analysis activity, the retention of the word breath here in the definition of forensic alcohol analysis actually represents a change in the regulations. To understand this apparent paradox, one needs to review a bit of the history of the statutes and regulations.</p> <p>The original statutes distinguished the analysis of biological samples in the laboratory by trained laboratory staff from the analysis of breath samples by law enforcement personnel. The two activities were defined under separate sections of the statutes (former H&S Code §§ 10071026 and 10071527). This distinction is reflected in the current regulations. Historically, there was one instance where the distinction was blurred. Prior to 1985, the Title 17 regulations described breath alcohol analysis procedures where a breath sample was captured for later analysis. Here the regular instrument operator (typically law enforcement personnel) would capture the sample, but the actual analysis of the captured breath sample was performed later in a licensed forensic alcohol laboratory by qualified laboratory personnel. The analysis of the captured breath sample was considered a forensic alcohol analysis subject to the same standards as the analysis of blood, urine, or tissue samples. The pre-85 regulations authorized this testing procedure [former Section 1221.1 (c)], and set standards of performance [former Section 1221.2 (b)] and standards of procedure [former Section 1221.4 (a)(2)(B)] for sample capture and later analysis. Based on these provisions, a breath sample could be analyzed in a forensic alcohol laboratory.</p> <p>The regulations were amended in 1985 [Amendment filed 12-20-85 as an emergency, effective upon filing (Register 85, No. 52)] to repeal the aforementioned sections and to eliminate the forensic alcohol analysis of</p>	
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	<p>captured breath samples as an authorized activity under the regulations. The references to “breath” samples under the definition of forensic alcohol analysis [current Section 1215.1 (b)] and also forensic alcohol laboratory [current Section 1215.1.(e)] should have been removed at that time, but were inadvertently retained. (Note: the references to “immediate analysis” of a breath sample under Sections 1221.1 (b)(1) and 1221.1 (b)(2) are also vestigial, serving to distinguish regular (immediate) breath alcohol analysis from a breath sample captured for later analysis.)</p> <p>As noted above, the 2004 revisions to the Health and Safety Code now describe the analysis of breath samples as a forensic alcohol analysis and consequently the references to breath samples under Section 1215 (b) and also under Section 1215 (e) may appear to agree with the new statutes. The review committee has proposed to retain the references to breath samples in the two sections. It is important to note here that the regulatory intent of the references to breath samples under Sections 1215 (b) and also 1215 (e), has changed from the original intent. As a consequence, the inclusion of breath sample analysis as a forensic alcohol analysis activity represents a new regulation and the reasons for the new regulation must be stated by the committee in order to demonstrate how the proposed change in the regulations is necessary to effectuate the purpose of the statutes.</p> <p>There are other clarity issues. The inclusion of samples of “breath” in the definition of forensic alcohol analysis under Section 1215 (b) in combination with the elimination of the description of the persons performing the analyses (currently trained laboratory personnel) could mean that all subsequent references to forensic alcohol analysis in the regulations (33 such references) could be interpreted as applying to the analysis of breath samples. This would mean that all of the standards of performance and procedure requirements set forth in current Article 6, Methods of Forensic Alcohol Analysis, would apply to breath alcohol analysis. This is not appropriate and presumably was not the intent of the review committee. The definition of forensic alcohol analysis must be revised to correctly describe and distinguish the separate analyses of blood, urine, or tissue samples by laboratory personnel from the analyses of breath samples by law enforcement. The committee has not</p>	
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		done this.	
1:16	Section 1215 (c) [Current Section 1215.1 (c)]	<p>Section 1215 (c) [Current Section 1215.1 (c)]</p> <p>Necessity/Clarity – The committee proposed here to change the term, “breath alcohol analysis” to “breath alcohol testing” and to change the words, “analysis of a sample of a person’s expired breath” to “sampling a person’s expired breath.” The committee also proposed to delete the specification of the purpose of the testing. The ISOR claims that the change from “analysis” to “testing” is more consistent with the verbiage used throughout the country, but did not provide any data to support this. In fact, a check of other states’ regulations revealed that the two terms are used interchangeably.²⁸ The terms are used interchangeably in the current regulations [See Sections 1215.1 (c), 1221.4 (a)(1), 1221.4 (a)(2)(B), 1221.4 (a)(5), 1222.1 (a) (6), etc.] and are also interchanged within the committee’s proposed revisions [See Sections 1215 (b), 1221.2 (a) (1), and 1221.2 (a)(3)(B)(i)]. The enabling statutes²⁹ refer to “forensic alcohol analysis tests.”</p> <p>The change from “breath alcohol analysis” to “breath alcohol testing” was originally proposed by a subcommittee of the forensic alcohol review committee that met in 2008.³⁰ The proposed change was discussed by the full committee at its April 10, 2009 meeting. Subcommittee Chair Patricia Lough explained that, “We distinguished between the 2 because breath alcohol testing is actually something that is performed, can be performed by non laboratory personnel. So that has been changed to the word “testing” throughout this.” Ms. Lough, added, “But we are trying to distinguish between the functions strictly performed by forensic alcohol laboratory personnel and those functions that may be performed by non-scientific personnel, which would be, for your purposes, a breath test taken out in the field by an officer.”³¹ While as discussed further below, it is very important to distinguish the analysis of blood samples in a laboratory setting from the analysis of breath samples by law enforcement, the committee has not demonstrated how the proposed change in terminology accomplishes the intended purpose. Accordingly, the ISOR and the committee have not demonstrated by substantial evidence how the proposed change</p>	

		<p>here is necessary to effectuate the purpose of the statutes.</p> <p>The other proposed revisions create significant clarity issues. The new term “sampling” would require a definition, but, more importantly, defining breath alcohol testing as the “sampling of a person's expired breath” and then deleting any specification of the purpose of the testing creates the question of how a breath alcohol “test,” which simply “samples” a person’s breath, produces a result. The regulations (Sections 1220.4 and 1221.3) subsequently refer to the “results” of a breath alcohol test and this creates the clarity issue. The issue could here possibly be resolved by providing a definition of the breath testing instrument, but this has not been done and in fact, the committee has proposed to delete the current general definition of an “instrument” [cf. repealed Section 1215.1 (j)].</p> <p>As discussed in the comments under Section 1215 (b), the distinction between the forensic alcohol analysis of blood, urine, and tissue samples from the analysis of breath samples is very important. Both are clearly analyses (or equivalently “tests”). They are distinguished by the personnel who perform the analyses (laboratory staff vs. law enforcement personnel) and by the typical location of the testing (a laboratory vs. police stations or even the road side). The definition of breath alcohol analysis proposed by the committee doesn’t address who performs the analysis (or even that an analysis was performed) or where the analysis takes place. As noted above, the proposed definition of forensic alcohol analysis includes the analysis of breath samples. The definition of breath alcohol analysis must properly distinguish this type of analysis from the analysis of other forensic alcohol sample types, but it fails to do so. This creates many clarity issues in the regulations.</p>	
1:17	Section 1215 (d) [Current Section 1215.1 (d)]	<p>Section 1215 (d) [Current Section 1215.1 (d)]</p> <p>Clarity - The reference in the definition of concentration to a “solid tissue specimen” creates a clarity issue, since the qualifier, “solid,” is not used anywhere else in the regulations to describe tissue samples.</p>	
1:18	Section 1215 (e) [Current Section 1215.1 (e)]	<p>Section 1215 (e) [Current Section 1215.1 (e)]</p> <p>Clarity/Consistency – The definition of a laboratory as a “place” here</p>	

		<p>creates many place-entity problems throughout the regulations. Other sections of the regulations impose requirements on the “laboratory.” Under the old statutes and regulations, the Department’s licensing process formally identified responsible persons at the laboratory and changed the “place” to a discrete and identifiable entity capable of assuming the responsibility of fulfilling the requirements of the regulations. Absent the license or some indicia of external approval and the identification of responsible persons, the laboratory remains just a physical place, incapable of accepting any of the responsibilities heaped upon it. The rulemaking record³² shows that the committee discussed the place-entity at a number of meetings, but never resolved the issue. The place-entity issue must be addressed in the regulations in order to establish regulatory accountability and to effectuate the purpose of the statutes.</p> <p>The committee’s definition also retains “breath” in the list of samples analyzed by the laboratory. As discussed in the comments under Section 1215 (b), prior to 1985, laboratories were authorized to perform analyses of captured breath samples. In 1985, this type of analysis was eliminated and the reference to breath samples here and under Section 1215 (b) should have been removed. Retaining the reference to breath samples creates clarity issues, since the laboratories do not analyze these samples. The new reference to “specialized” equipment is unclear since it could have multiple meanings.</p>	
<p>1:19</p>	<p>Section 1215 (f) [Current Section 1215.1 (f)]</p>	<p>Section 1215 (f) [Current Section 1215.1 (f)]</p> <p>Clarity/Necessity – This section currently defines the term, forensic alcohol supervisor. The ISOR states, “This definition eliminates the prior outdated and obsolete classification of forensic alcohol supervisor here and throughout this document.” The ISOR does not clearly describe the changes proposed here. The committee did not simply eliminate the supervisor classification, it proposed to change the name of the current forensic alcohol supervisor classification to “forensic alcohol analyst,” and to change the words, “who can be responsible” to “who is responsible.” The committee claimed that this latter change was intended to “provide clarity,” but in fact it appears to create new clarity issues. A laboratory may employ many staff (“analysts”). Clearly they will</p>	

		<p>not all be responsible for all aspects of the performance of forensic alcohol analysis.</p> <p>The ISOR claimed that the reason for the elimination of the supervisor classification was to remove ambiguity associated with, “the legal community/courts/juries who may incorrectly assume a “forensic alcohol supervisor” is an actual supervisor in the laboratory.” The committee did not provide any data to demonstrate the existence of this ambiguity and the current regulations clearly state that forensic alcohol supervisor “can be responsible” for the supervision of personnel. The current tripartite personnel structure consisting of forensic alcohol supervisor, forensic alcohol analyst, and forensic alcohol analyst trainee appears to be useful. It reflects the normal hierarchical structure of a laboratory and addresses the need for the laboratory to employ at least one experienced staff person. The entry-level analyst class represents a person qualified to perform the technical procedures of forensic alcohol analysis. The forensic alcohol supervisor is a person who can be responsible for all aspects of the performance of forensic alcohol analysis. Generally, the supervisor writes the methods, interprets the analytical results, directs corrective action for quality control failures, and may possibly supervise the personnel who perform the analyses. Consistent with these responsibilities, the supervisor is required to have a higher degree of knowledge and experience. The trainee level classification allows a person employed by a forensic alcohol laboratory to receive comprehensive practical experience and instruction in the technical procedures of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst. With the committee’s proposed flat structure, everyone would be responsible for forensic alcohol analyses and no one would be required to have any actual experience performing the tests. Again, the committee has not demonstrated by substantial evidence the need for the revisions to this regulation to effectuate the purpose of the statutes.</p> <p>There is another clarity issue. By changing the name of the current “forensic alcohol supervisor” definition to “forensic alcohol analyst,” the term, “forensic alcohol supervisor” is no longer defined. However, the term is used under proposed new Sections 1216.1 (b)(4), (B) and (C). The use of the undefined term in the regulations creates a clarity issue.</p>	
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		<p>Finally, the ISOR here describes the regulations as providing “guidelines” for the analysis of samples. This is incorrect. Regulations describe standards of performance and procedure that must be complied with under the force of law. By contrast, a guideline such as the ASCLD/LAB guidelines, is a statement of advice or an instruction describing best practices. The review committee members frequently seemed to be confused by the distinction between regulations and guidelines. This is evident here in the statement in the ISOR and with many of the revisions to the regulations proposed by the committee.</p>	
1:20	Current Section 1215.1 (g)33	<p>Current Section 1215.1 (g)33</p> <p>Clarity/Necessity – See comments under Section 1215 (f). The elimination of the current definition of the forensic alcohol analyst classification is consistent with the renaming of the former forensic alcohol supervisor class as forensic alcohol analyst. The ISOR does not describe this change. The ISOR states, “The requirements for analysts are defined in the enabling statute; thus their classification and definition (forensic alcohol analyst and forensic alcohol analyst trainee) are no longer required.” This awkwardly written and confusing claim is not correct. The “enabling” statutes do not define the “requirements for analysts.” The revised statutes do not define any personnel classifications. The review committee simply chose to rename the current forensic alcohol supervisor classification to “forensic alcohol analyst.” The committee made this choice without any direction from the statutes. The proposed revision to the regulations conflicts with the Department’s description of the effect of the regulation. This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)]. More importantly, the committee has not demonstrated by substantial evidence how the proposed repeal of this section is necessary to effectuate the purpose of the statutes.</p>	
1:21	Current Section 1215.1 (h)	<p>Current Section 1215.1 (h)</p> <p>Clarity/Necessity – See comments under Section 1215 (f).</p>	
1:22	Section 1215 (g) [Current Section 1215.1 (i)]34	<p>Section 1215 (g) [Current Section 1215.1 (i)]34</p> <p>Clarity/Necessity – The proposed change from “steps” to “procedures” in</p>	

		<p>the definition of the word “method” is unclear since the word being defined, “method” and its definition “procedure” are somewhat synonymous. Moreover, in the context of these regulations, “method” generally refers to the steps used in the laboratory to analyze a sample of blood, urine, or tissue (cf. current Title 17 Sections 1215.1 (b), 1215.1 (e), 1216.1 (e) (2) (D), 1217.3 (c), 1220, (a) & (b), 1220.1, 1220.2., etc.), while the term “procedures” is used for breath alcohol analysis [cf. current Sections 1216.1 (e)(2)(E), 1221.1., 1221.4 (a), 1221.4.(a)(3)(B), 1221.4.(a) (4)]. The separation is not perfect, but revised definition here further obscures the separation of the two types of analyses.</p> <p>The committee has not demonstrated by substantial evidence how the proposed amendments to this section are necessary to effectuate the purpose of the statutes.</p>	
23	Current Section 1215.1 (j)	<p>Current Section 1215.1 (j)</p> <p>Clarity – The committee has proposed to repeal the current definition of “instrument or device,” claiming that these words can be considered common language, and therefore do not require definition. The review committee’s claim is not completely correct. The word “instrument” as used in the regulations is a term of art that should be defined.³⁵ There are 15 current and 17 newly proposed instances of the word “instrument” in the regulations.</p> <p>The use of term “device” in the regulations and as referenced in the statutes is consistent with the general dictionary definition of the word, i.e. “a piece of equipment or a mechanism designed to serve a special purpose or perform a special function.”³⁶ Accordingly, it is appropriate to delete the definition of “device” in the regulations.</p>	
1:24	Section 1215 (h) [Current Section 1215.1 (l)]	<p>Section 1215 (h) [Current Section 1215.1 (l)]</p> <p>Clarity - The section was revised to incorporate the requirement that the breath sample shall be “essentially alveolar in composition” into one of the definitions of a sample or specimen. The requirement that the breath sample shall be essentially alveolar in composition is currently included under Section 1219.3. in Article 5, Collection and Handling of Samples. This is the appropriate place to impose requirements related to how the</p>	

		<p>breath sample is collected.</p> <p>Combining the requirements for the collection of the samples with the definition of the sample is confusing and obscures the critical importance of the collection of a proper sample. Moreover, in the regulations, definitions are intended to define terms, they should not impose requirements. There are other clarity issues. The terms “representative portion,” “essentially alveolar in composition,” and “artificially constituted material” are not clear and need definitions.</p>	
1:25	New Section 1215 (k)	<p>New Section 1215 (k)</p> <p>Clarity – The proposed definition of “competency test” is unclear in that it doesn’t specify how the “evaluation of a person’s ability” will be performed, or even who the person tested is. It also doesn’t define, “casework,” or specify what the time period prior to the performance of casework is.</p> <p>The ISOR states that the “definition of ‘Competency Test’ was added because it is used elsewhere in the proposed regulations and should be distinguished by [sic] the term “Proficiency Test.” Apparently, this means that the committee felt that it was important to differentiate a competency test from a proficiency test. However, it should be noted that no other state makes this differentiation or uses the term, “competency test” in its alcohol regulations.</p>	
1:26	New Section 1215 (l)	<p>New Section 1215 (l)</p> <p>Clarity/Consistency/Necessity – The proposed definition of a proficiency test is unclear in that the terms “continuing competence” and “technical support” are undefined. The Department uses proficiency tests to evaluate the ability of a laboratory’s method to meet the required standards of performance. This is operationally defined in the regulations [current Section 1220.1 (b)], but this definition is not captured here, thus creating consistency problems. There are also the continuing place-entity issues with the reference to the “performance of a laboratory.” The place/entity issue must be addressed in the regulations in order to demonstrate the necessity of the proposed regulation to effectuate the purpose of the statutes.</p>	

1:27	New Section 1215 (m)	New Section 1215 (m) Clarity – The words “guide to assist” are unclear.	
1:28	New Section 1215 (n)	New Section 1215 (n) Clarity – The definition of “NIST” is not correct. “NIST” is an abbreviation for the organization, “National Institute of Standards and Technology.”	
1:29	New Section 1215 (o)	New Section 1215 (o) Clarity – The definition of “NIST Standard Reference Material (SRM)” is not correct. The term, “NIST Standard Reference Material (SRM)” is trademarked by NIST and defined by NIST as “A CRM <certified reference material> issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material (NIST SP 260-136).” ³⁷	
1:30	New Section 1215 (p)	New Section 1215 (p) Clarity/Necessity – The term “NIST Traceable” is not clearly defined. While NIST establishes the traceability of materials that it issues, it does not evaluate or support claims of traceability made by other manufacturers. Rather, it asserts that “providing support for a claim of metrological traceability of the result of a measurement is the responsibility of the provider of that result, whether that provider is NIST or another organization; and that assessing the validity of such a claim is the responsibility of the user of that result.” ³⁸ As discussed in the comments to Section 1220.2 (a)(1)(B), the regulations proposed by the committee do not set forth any specific criteria or protocols to establish the traceability to a NIST standard. Thus, while vendors may sell NIST traceable materials, there are no procedures or standards in place to check or verify the manufacturer’s claim. Accordingly, the term “NIST Traceable” is unclear. The committee has not demonstrated by substantial evidence how the introduction of this term in the regulations is necessary to effectuate the purpose of the statutes.	
1:31	Article 2 Requirements for	Article 2 Requirements for Forensic Alcohol Laboratories	

	Forensic Alcohol Laboratories	<p>Consistency - Article 2 sets forth the required qualifications that must be maintained by each laboratory (inspections and examinations, personnel requirements). Article 3 describes the Department’s procedures for administering its regulatory program. Article 3 is the appropriate location for establishing laboratory notification requirements. While as noted below, the references to licensing under Article 3 must be removed, this article must continue to describe the requirement for a laboratory to notify the Department of its intent to perform forensic alcohol analysis and the authorities of the Department to perform such examinations as are required for a laboratory to complete its qualifications to perform forensic alcohol analysis. This is consistent with the Department’s mandated responsibility to enforce its regulations (cf. H&S Code §100725) and the requirement for laboratories to comply with those regulations [cf. H&S Code §100700(a)].</p>	
1:32	Section 1216	<p>Section 1216</p> <p>Clarity/Consistency – The term “authorization” in the section title implies the existence of an authority, an official body that makes a decision to permit or deny an activity. The Department currently fulfills that role with a regulatory program that includes site inspections of laboratories [cf. Section 1217.7 (a)], approval of the qualifications of laboratory personnel [cf. Sections 1216.1., (e)(4), (f)(5), and (g)(1)], evaluation of proficiency tests [cf. Section 1220.1 (b)], and approval of training programs (cf. Section 1218). The committee has proposed to repeal each of these authorities. Accordingly, the proposed regulation here (i.e., the section title, “Authorization”) is either unclear or inconsistent with the other revisions proposed by the committee.</p>	
1:33	Section 1216 (a)	<p>Section 1216 (a)</p> <p>Necessity - This section, which requires a laboratory to provide information to the Department creates place-entity issues, since a laboratory, defined as a “place” [cf. renumbered Section 1215 (e)], is not an identifiable entity and is unable to provide anything. Again, the place-entity problem was previously addressed with the Department’s licensing process which identified responsible persons at the laboratory and changed the “place” to an entity capable of assuming the</p>	

		<p>responsibility of fulfilling the requirements of the regulations. The place/entity issue must be addressed in the regulations in order to demonstrate the necessity of the proposed regulation to effectuate the purpose of the statutes.</p>	
<p>1:34</p>	<p>New or Revised Sections 1216 (a), (1) – (4)</p>	<p>New or Revised Sections 1216 (a), (1) – (4)</p> <p>Clarity/Necessity/Consistency – These sections as revised by the committee describe several items of information that each laboratory must provide the Department. As discussed above, Article 3 is the appropriate location for establishing laboratory notification requirements. The committee’s proposed revisions create clarity/necessity problems.</p> <p>The committee’s proposed language describes a very minimal amount of information that a laboratory must submit to the Department. The proposed regulations do not require the laboratories to submit a number of items of information that are currently used by the Department to evaluate the ability of a laboratory to perform forensic alcohol analysis. Included here are requirements for the laboratory to submit written descriptions of a method [cf. Section 1220 (b)] that demonstrate compliance with the standards of procedure requirements of the regulations as well as experimental data demonstrating that the methods meet the standard of performance requirements set forth under Section 1220.1. As discussed below, there is no requirement for laboratory personnel to be qualified by the Department. The committee’s revisions do not describe the initial proficiency test and on-site survey [cf. current Sections 1216.1 (a)(4) and 1217 (a)] currently required for any laboratory initiating forensic alcohol analysis.</p> <p>The reference to “fluid analyses” under subsection 1216 (a)(1) is unclear since this term is undefined. Subsection 1216 (a)(1) requires a laboratory to provide the Department “a statement of intent to perform or stop performing alcohol analysis...” These are apparently one-time events. There is no requirement to notify the Department of any changes of activities authorized under the regulations. This is required now under Article 3, Sections 1217.3, (a) and (b), which include a time limit for reporting changes in activities. The Department obviously cannot exercise its responsibility to enforce the regulations if it doesn’t have up-to-date information on the laboratory activities being performed.</p>	

		<p>The current regulations [Sections 1216.1 (a)(5) and 1217 (b)] require the Department to review and approve the qualifications of a laboratory. The revised regulations do not describe any role for the Department in evaluating the qualifications of a laboratory that “notifies” the Department of its intent to perform forensic alcohol analysis. Instead, each laboratory by submitting a “letter of intent” would apparently be authorized to determine for itself whether or not it meets the requirements of the regulations without any evaluation by the Department or any external agency. This self-certification process is not consistent with the statutes, which require the Department to enforce the law and the forensic alcohol analysis regulations (cf. Health and Safety Code §100725).</p> <p>The ISOR states the purpose of the “notification” requirement is “to notify the Department it will be performing alcohol or breath analyses, so there is a repository of information on who is performing breath (sic) analyses in the state in compliance with Title 17. These records will be kept for public access.” The statutes do not describe a role for the Department as a repository for public information and this role is not described in the regulations. The stated purpose in the ISOR clearly would not enable the Department to meet its mandated responsibility to enforce the law and its regulations. This creates a conflict with the statutes (H&S Code §100725).</p> <p>The committee has not demonstrated by substantial evidence that the proposed revisions to this section will effectuate the purpose of the statutes (H&S Code §100725) which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:35</p>	<p>Section 1216 (b)</p>	<p>Section 1216 (b)</p> <p>Clarity - The ISOR states, “This subsection remains unchanged.” However, the proposed amendments here create an entirely new subsection. The requirements are similar to those set forth under current Section 1216 (a)(1). Obviously, the proposed amendment to this section conflicts with the Department’s description of the effect of the regulation</p>	

		(i.e., “unchanged”) and this creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)]. Also, the word “section” should be shown in lower case, since this is consistent with the current format used in the California Code of Regulations.	
1:36	Section 1216.1 (a)	<p>Section 1216.1 (a)</p> <p>Necessity - This section, which requires a laboratory to meet certain qualifications, again creates place-entity issues, since a laboratory, defined as a “place” [cf. renumbered Section 1215 (e)], is not an identifiable entity and is unable to meet any “qualifications.” Again, the place-entity problem was previously addressed with the Department’s licensing process which identified responsible persons at the laboratory and changed the “place” to an entity capable of assuming the responsibility of fulfilling the requirements of the regulations. The committee’s proposed self-certification procedures do not accomplish this. The place/entity issue must be addressed in the regulations in order to demonstrate the necessity of the proposed regulation to effectuate the purpose of the statutes.</p>	
1:37	Current Section 1216.1 (a)(1)	<p>Current Section 1216.1 (a)(1)</p> <p>Clarity/Necessity - This section currently requires each laboratory to employ at least one forensic alcohol supervisor. In effect this requires the laboratory to have at least one person on staff who has experience in performing forensic alcohol analysis. With the revisions proposed by the committee a laboratory could operate without having any staff with actual experience performing the tests.</p> <p>The ISOR claims that, “This subsection is amended because the Department classification of forensic alcohol supervisor has been eliminated by the enabling statute.” This is completely incorrect. The changes in the statutes with the 2004 legislation did not eliminate the forensic alcohol supervisor classification. The revised statutes do not eliminate or change any personnel classifications. Accordingly, once again the proposed repeal of this section conflicts with the Department’s description of the effect of the regulation. This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p>	

		<p>The committee has not demonstrated by substantial evidence that the proposed repeal of this section will effectuate the purpose of the statutes which must ensure the competence of the laboratories and their employees to perform forensic alcohol analysis [cf. H&S Code §100703 (d)].</p>	
1:38	<p>Section 1216.1 (a)(1) [Current Section 1216.1 (a)(2)]39</p>	<p>Section 1216.1 (a)(1) [Current Section 1216.1 (a)(2)]39</p> <p>Consistency - This section as amended does not adequately describe all of the standard of procedure requirements set forth under Section 1220.2, which include the calibration of the method with secondary alcohol standards [Section 1220.2 (a)(1)], the analysis of a blank [Section 1220.2 (a)(2)], maintenance of equipment [Section 1220.2 (a)(4)], and routine checks of accuracy and precision [current Section 1220.2 (a)(5)], as well as maintaining a quality control program [Sections 1220.2 (a)(3) and 1220.3]. Accordingly, this section is not consistent with other provisions of law (i.e., the aforementioned Title 17 Sections).</p> <p>The ISOR for Section 1216.1 (a)(1) presents a confusing mix of comments apparently intended to explain the proposed repeal of current Section 1216.1 (a)(1) as well as the amendments to the subsequent section [Section 1216.1 (a)(2)], which would be renumbered as “1216.1 (a)(1).”</p>	
1:39	<p>Section 1216.1 (a)(2) [Current Section 1216.1 (a)(3)]</p>	<p>Section 1216.1 (a)(2) [Current Section 1216.1 (a)(3)]</p> <p>Clarity/Necessity/Consistency – This section is proposed to be amended to eliminate the requirement that the laboratories must demonstrate satisfactory performance in a proficiency testing program conducted by or approved by the Department. This requirement would be replaced with a reference to the requirements of H&S Code §100702, i.e., the requirement that laboratories meet the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) “guidelines” for proficiency testing.</p> <p>The committee’s reference to the statutory requirements creates many clarity issues. The requirements set forth in H&S Code §100702 are not clear and need further specification in regulation. For example, the</p>	

		<p>statutes employ many terms (“examiner,” “external proficiency testing,” “corrective actions,” and “inconsistent test results”) that are all unclear and need definition. The statutes do not even require that a laboratory’s performance on the external proficiency test be satisfactory.</p> <p>The committee has also proposed revisions that would require the laboratories to direct proficiency tests providers to submit external proficiency test results to the Department. The laboratories would also be required to submit “any documentation pertaining to corrective actions with respect to proficiency tests.”⁴⁰ The committee’s proposed language does not describe what the Department will do with the submitted data, which again creates clarity issues. However, as captured in the transcripts of the Committee’s meetings,⁴¹ several committee members repeatedly stated that they did not want the Department to evaluate the proficiency test data in any way.</p> <p>The reference in the proposed regulations to analyst proficiency test data is unclear since the section refers to external proficiency test results as required by H&S Code §100702, but the statutes here do not require the analyst (or “examiner”) proficiency tests to be obtained from an external provider. Moreover, the language, “The laboratories shall submit, at a minimum of one per analyst per year” is vague and would appear to only establish a rate or frequency. It doesn’t clearly require each analyst to submit a test result. The reference to analyst proficiency test data here is also inconsistent with various international standards for proficiency testing, which describe the use of inter-laboratory proficiency test data to evaluate the whole laboratory and its management system rather than the individual analysts.⁴²</p> <p>The Department has determined that the statutory proficiency test requirements are not an adequate substitute for current Departmental oversight of proficiency testing.⁴³ The Department’s proficiency test requirements are more stringent than ASCLD/LAB’s and include: more frequent testing; the requirement that laboratories with multiple methods complete separate tests for each method; and the evaluation of test results based on the accuracy and precision requirements set forth in California’s regulations. The acceptable ranges of results used by the Department are one and a half to two times narrower than those</p>	
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	<p>employed by ASCLD/LAB.⁴⁴ This assures that laboratory errors will not go undetected. A laboratory that has an unsatisfactory performance on a proficiency test is required to provide the Department with a written report of the corrective action taken and experimental data demonstrating that the method after the corrective action meets the required standard of performance. ASCLD/LAB is a voluntary accreditation program operated by the crime laboratories, which lacks regulatory authority. Finally, the Department’s regulatory program is a public process, while ASCLD/LAB’s entire program operates under rules of “strict confidentiality.”⁴⁵</p> <p>The Department has stated that it needs to continue its current oversight of proficiency testing.⁴⁶ The Department’s proficiency testing is a critical component in its regulatory program that is needed to ensure and document the competence of the laboratories and their employees performing chemical testing in support of California’s drunk driving laws. The Department’s laboratory proficiency testing program provides an objective, independent assessment of the competency of the laboratories. This establishes the scientific validity of the chemical testing in support of the State’s drunk driving laws.</p> <p>The ISOR for this section states the proficiency test information “will be kept for public access.” The ISOR here and also under Section 1216 (a) describes the role of the Department as merely a repository for public information. Again, the statutes do not describe this role for the Department and this role would not satisfy the Department’s mandated responsibility to enforce the law and its regulations. This creates a consistency issue since the proposed regulations conflict with the statutes (H&S Code §100725). Additionally, the committee has not demonstrated by substantial evidence how the elimination of the Department’s current proficiency tests in forensic alcohol analysis will effectuate the purpose of the statutes (H&S Code §100725) which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].</p> <p>Finally, the other ISOR comments for this section deserve a response.</p>	
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		<p>The meandering comments here, which reference the discontinuation of site inspections of California laboratories in 2005, are completely irrelevant to the amendments proposed for this section, which again pertain to the proficiency testing of laboratories. The ISOR presents some misinformation regarding the Department's site inspections, which should be addressed. In 2005, the Department discontinued routine site inspections not in response to the loss of licensing authority, but rather in response to the removal of specific statutory mandate (HSC §100735) to periodically inspect the labs. As noted in the 2005 advisory to the laboratories, the Department retained its regulatory authority to conduct inspections for cause.⁴⁷ The Department has continued to conduct these inspections. The ISOR then notes that "Health and Safety Code Section 100702 requires ASCLD/LAB, the accrediting body of crime laboratories in California, annual audits of all accredited areas, as well as reaccreditation inspections every 5 years." This grammatically challenged statement appears to suggest that Health and Safety Code §100702 requires laboratories to be accredited. In fact, HSC §100702 simply requires the laboratories to follow the voluntary ASCLD/LAB guidelines for proficiency testing. There is no requirement in statutes or regulation for a laboratory to be accredited by ASCLD/LAB or any other organization. The ISOR references the ASCLD/LAB "annual audits". Here it should be noted that these are self-assessments by management at the laboratory. Finally, the ISOR notes that "all laboratories' work product may be scrutinized in the court system." In its discussions, the committee members frequently claimed that the adversarial process in the courts provides de facto oversight of the crime labs. The appropriate response here is to note that the overwhelming majority, more than 90 percent, of the state's nearly 175,000 annual drunk-driving arrests, end in negotiated pleas. As a consequence, the evidence is never subjected to any judicial review. Moreover, the legislature was surely aware of the role of the judicial system in reviewing crime lab evidence, but chose to pass laws that specifically called for the regulation of the laboratories performing testing in drunk driving cases. The legislature vested the California Department of Public Health with the specific authority to enforce the law and the regulations. Again, the comments in the ISOR have nothing to do with the amendments proposed by the committee for this section. However, the ISOR comments do appear to reflect several general misapprehensions</p>	
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		<p>frequently expressed by members of the committee and thus deserved a brief response.</p>	
<p>1:40</p>	<p>Current Section 1216.1 (a)(4)</p>	<p>Current Section 1216.1 (a)(4)</p> <p>Necessity/Consistency – – The committee has proposed to repeal the requirement that a laboratory must pass the Department’s on-site inspections. The justification presented in the ISOR for this section [and also section 1216.1 (a)(5)] states only that, “These subsections were repealed because the Department no longer has the jurisdiction to license laboratories.” The ISOR analysis here again is incomplete and ill-informed. While the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed, the statutes do not prohibit the Department from conducting site inspections for cause. The Department has the general authority to “commence and maintain all proper and necessary actions and proceedings” to enforce its regulations” [H&S Code §100170(a)(1)] and the Department retained its mandated responsibility to enforce the law and its regulations (cf. H&S Code §100725).</p> <p>The current regulations (here and under Sections 1216.1 (d)(1) and 1217.7.) provide the Department with regulatory authority to conduct site inspections of California laboratories. Site inspections are a completely standard and necessary component of any laboratory regulatory program. The Department must have the ability to conduct onsite inspections for cause to enable it to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d) and to enforce the law and regulations as required by Health and Safety Code §100725.</p> <p>The misplaced comments in the ISOR under Section 1216.1 (a)(2) concerning the ASCLD/LAB site inspections were perhaps intended to apply here. The site inspections conducted by voluntary third party accreditation programs such as ASCLD/LAB are not sufficient to ensure the competence of the laboratories to perform forensic alcohol analysis. The ASCLD/LAB guidelines are very broadly conceived, covering ten separate forensic disciplines. The ASCLD/LAB guidelines do not establish any laboratory performance or procedure standards for blood</p>	

		<p>alcohol analysis and they don't even mention breath alcohol analysis. The Department's site inspections are focused on blood and breath alcohol analysis and cover all of the requirements of the regulations.</p> <p>The repeal of this section creates a consistency issue since the loss of authority to conduct site inspections conflicts with the statutory mandate to enforce the law and the regulations (cf. H&S Code §100725). Additionally, there is a necessity issue since the committee has not demonstrated by substantial evidence how the Department's general [H&S Code §100170 (a)(1)] and specific (H&S Code §100725) mandates to enforce the law and its regulations will be accomplished with the repeal of this section.</p>	
<p>1:41</p>	<p>Current Sections 1216.1 (a)(5) and 1216.1 (b)</p>	<p>Current Sections 1216.1 (a)(5) and 1216.1 (b)</p> <p>Consistency/Necessity – The committee has proposed to repeal the requirement for a laboratory to show the ability to meet the requirements of the regulations [cf. Section 1216.1</p> <p>(a)(5)] and to maintain its qualifications at all times [cf. Section 1216.1 (b)]. The ISOR here claims that the subsection was repealed “because the Department no longer has the authority to license laboratories.” The ISOR analysis again is incomplete and ill informed. The requirement for laboratories to meet the requirements of the regulations is not simply a licensing issue and is obviously fundamental to the purpose of the regulations. However, this does presuppose some external, state-level oversight of the laboratories. This oversight is in fact completely consistent with the statutory requirement for the Department to enforce the law and its regulations (cf. Health and Safety Code §100725) in order to ensure the competence of the laboratories as required by Health and Safety Code §100703 (d). Moreover, it appears that this oversight could serve as a basis for establishing the forensic alcohol laboratory as an entity thus solving the ever-present place/entity question.</p> <p>The review committee must demonstrate by substantial evidence how its proposed repeal of these sections allows the Department to meet its mandate to enforce the law and its regulations and establish the status</p>	

		of a forensic alcohol laboratory as an entity.	
1:42	Current Section 1216.1 (c)	<p>Current Section 1216.1 (c)</p> <p>Consistency/Necessity – Current Section 1216.1 (c) authorizes the Department to deny or take disciplinary action against a laboratory license when there is a failure by a laboratory to maintain qualifications in a manner which meets the Department’s standards for approval. The ISOR explains that this subsection was repealed because the Department no longer has the authority to license laboratories. This explanation is overly simplistic. The statutes require the Department to enforce the law and the regulations (H&S Code §100725). The 2011 Attorney General’s evaluation of the Department’s forensic alcohol program⁴⁸ reviewed the Department’s current regulatory authority to meet this mandate. The AG’s opinion specifically cited Section 1216.1 (c) as granting the Department authority to “take disciplinary action against laboratories for failure to meet FAP standards.” The AG applied this rule, even after the elimination of the licensing requirement. The AG noted that the regulatory authority here is consistent with the general statutory authority provided under H&S Code §100170 (a)(1), which allows the Department to “commence and maintain all proper and necessary actions and proceedings” to enforce its regulations” and the specific statutory authority provided under H&S Code §100725.</p> <p>The AG considered the mechanisms by which the Department of Public Health would enforce the regulations as required by H&S Code §100725. The AG, citing Section 1216.1 (c), concluded that the Department would have proper legal standing to seek mandamus or injunctive relief to enforce compliance with the regulations. The results of these analyses show that the Department must retain its authority to discipline a laboratory that fails to comply with the requirements of the regulations as provided for in this section. A discussion of the AG’s 2011 opinion was included on the agenda of the July 23, 2012 meeting of the forensic alcohol review committee, so presumably the committee members were familiar with the issues here.</p>	

		<p>This authority provided by Section 1216.1 (c) is needed to enable the Department to ensure the competence of the laboratories. This authority is consistent and in harmony with the Department’s mandated responsibility to enforce the law and its regulations pertaining to forensic alcohol analysis (cf. H&S Code §100725). The section of course must be revised to describe the mechanisms (mandamus or injunctive relief) by which the Department would take disciplinary action against a forensic alcohol laboratory in the absence of licensing authority. The requirements must be added here to enable the Department to exercise its mandated responsibility to enforce the law and the Department’s regulations.</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes (H&S Code §100725) which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:43</p>	<p>Section 1216.1 (b) [Current Section 1216.1 (e)]</p>	<p>Section 1216.1 (b) [Current Section 1216.1 (e)]</p> <p>Clarity - The ISOR states, this subsection remains unchanged. The subsection was in fact amended to change “forensic alcohol supervisor” to “forensic alcohol analyst.” As a result, again, the proposed revision to the regulations conflicts with the Department’s description of the effect of the regulation (i.e., “unchanged”). This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p>	
<p>1:44</p>	<p>Section 1216.1 (b)(1) [Current Section 1216.1 (e)(1)]</p>	<p>Section 1216.1 (b)(1) [Current Section 1216.1 (e)(1)]</p> <p>Clarity/Necessity – There are several clarity issues with the proposed revisions to this section. The reference to “physical or natural science” is redundant since natural science includes physical science.⁴⁹ The term “applied physical science” is unclear and probably unnecessary. It does not indicate “hands on versus theoretical experience” as stated in the ISOR.⁵⁰ It typically refers to engineering and technology degrees. If it is retained, it would certainly need definition. The proposed revisions, which remove the requirements for any chemistry course work, actually lower the current academic standards for the personnel who can ultimately be responsible for the operation of the laboratory.</p>	

		<p>The committee has not demonstrated by substantial evidence that the proposed amendments are necessary to effectuate the purpose of the statute.</p>	
<p>1:45</p>	<p>Section 1216.1 (b)(2) [Current Section 1216.1 (e)(2)]</p>	<p>Section 1216.1 (b)(2) [Current Section 1216.1 (e)(2)]</p> <p>Clarity/Necessity – As noted in the comments under Article 1 for Section 1215 (f) [Current Section 1215.1 (f)] the committee changed the requirements for the current entry level forensic alcohol analyst classification simply by changing the name of the more advanced forensic alcohol supervisor classification to “forensic alcohol analyst.” With the committee’s proposed revisions, all forensic alcohol laboratory staff will be lumped into one class. This is not realistic. The existence of two separate classification levels based on experience correctly reflects the structure of a typical laboratory. New hires will generally not have two years’ of experience performing forensic alcohol analysis. These staff will need training and practice in basic forensic alcohol analysis techniques. The requirements for this basic training are covered under current Sections 1216.1 (f), (2) and (3). As discussed below, the committee proposes to repeal these sections. The training described under current Section 1216.1 (e)(2) was intended for staff already qualified as forensic alcohol analysts but lacking two years’ experience. The training here would reasonably be described as higher level and intended to allow staff to interpret the results of chemical tests for alcohol. The description in the regulations of the training formerly intended to qualify staff as forensic alcohol supervisors is not appropriate for new staff that have no experience in forensic alcohol analysis.</p> <p>The language of the proposed amendments creates other clarity issues. The revised requirement that a person must have “two years of analytical experience” is unclear in that it doesn’t specify the analyte (alcohol) or the analytical procedure employed (forensic alcohol analysis). The requirement that a person shall have “experience in interpreting and correlating the demeanor and behavior of persons who have ingested known amounts of alcohol,” is vague and fails to show that the appropriate experience involves correlating the results obtained</p>	

	<p>for the analysis of a sample obtained from a person who has ingested known amounts of alcohol with the behavior and demeanor of that person.</p> <p>The committee’s proposed amendments would also eliminate the requirement for Departmental approval of the training provided to laboratory staff that do not have two years’ experience in forensic alcohol analysis. Authority to approve such training would be transferred to “the laboratory of employment.” Again, there are place-entity issues here, since this section requires the laboratory, a “place”, to both approve and then provide the training. A “place” cannot approve anything or provide any training. More generally, as noted below, the language of this section does not provide enough specificity to satisfy the Administrative Procedure Act (APA) clarity requirements. The regulations here should be revised to specify who provides the training, how it is provided, the specific content of the training, numbers of hours that are acceptable to cover the content, what a practical demonstration of analyst’s ability must include, what is needed to satisfactorily complete the training, etc. However, even with this added detail, absent any external approval of the training, there’s nothing to “ensure” that the laboratory- provided training will provide the trainee with the equivalent of two years’ experience performing forensic alcohol analysis.</p> <p>The ISOR states “This subsection was amended to replace the phrase “approved by the department” with “laboratory of employment.” This clarifies that an individual must be qualified by his or her specific Forensic Alcohol Laboratory.” As noted in the comments under Section 1216 (a) (1), the purpose of the forensic alcohol supervisor classification is to identify and document the qualifications of laboratory staff with considerable experience in performing forensic alcohol analyses. Under the current regulations, each laboratory is required to employ at least one such experienced person who can be take responsibility for the laboratory’s forensic alcohol analysis activities. The alternative training path “in lieu” of this experience was originally intended to ensure that there would be adequate staffing for the laboratories to initiate operations under the new regulations. Historically, only one agency, the California Department of Justice (DOJ), ever offered the supervisor training course. The curriculum of the DOJ’s 5-day course was carefully</p>	
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		<p>reviewed and approved by the Department to determine that it satisfied the specific requirements of the regulations and also provided the trainee with the knowledge and skills equivalent to those that would be obtained with two years of experience in forensic alcohol analysis. As noted above, the proposed regulations do not set any meaningful standards for the training and transfer the responsibility for designing and approving the training to each individual laboratory. A laboratory could conclude that the requirements were satisfied with a 10-minute training course. The proposed regulations, which require a laboratory to design, approve, and conduct the training of staff without any meaningful performance requirements or any external oversight in effect require a laboratory to do whatever it wants to do. Such regulations are clearly unnecessary.</p> <p>The Department has stated that it must retain its current authority to approve all training offered to qualify individuals under the regulations in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d) and to enforce the law and regulations as required by Health and Safety Code §100725.51 The committee has not demonstrated by substantial evidence how the transfer of authority to approve the training to each individual laboratory would effectuate the purpose of the statutes (H&S Code §100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:46</p>	<p>Section 1216.1 (b)(2)(A) [Current Section 1216.1 (e)(2)(A)]</p>	<p>Section 1216.1 (b)(2)(A) [Current Section 1216.1 (e)(2)(A)]</p> <p>Clarity – The committee proposed to remove the reference to breath alcohol analysis. The ISOR notes that as defined under Section 1215 (b), forensic alcohol analysis includes the analysis of breath samples. This is correct, but as noted in the comments under Section 1215 (b), there are continuing clarity issues surrounding the unqualified inclusion of the analysis of breath samples by law enforcement personnel as a forensic alcohol analysis activity.</p>	
<p>1:47</p>	<p>Section 1216.1 (b)(2)(E) [Current Section 1216.1 (e)(2)(E)]</p>	<p>Section 1216.1 (b)(2)(E) [Current Section 1216.1 (e)(2)(E)]</p> <p>Necessity – The proposed change here from “breath alcohol analysis” to</p>	

	(e)(2)(E)]	“breath alcohol testing” is unnecessary since the words analysis and testing are synonymous. The committee has not demonstrated by substantial evidence that the proposed change is necessary or how it accomplishes the purpose of distinguishing breath alcohol analysis from blood alcohol analysis.	
1:48	Section 1216.1 (b)(2)(F) [Current Section 1216.1 (e)(2)(F)]	Section 1216.1 (b)(2)(F) [Current Section 1216.1 (e)(2)(F)] Clarity – The committee’s proposed amendment creates a clarity issue. The ISOR notes that the word “student” was replaced with "analyst," because an analyst is not a student.” The substitution of “analyst’s” for “student’s” is not appropriate here because the laboratory personnel are not qualified as forensic alcohol analysts during their training. The appropriate term here would be “trainee’s.” The reference to a “practical demonstration of analyst’s ability” is unclear since there is no specification of the required standard of performance.	
1:49	Section 1216.1 (b)(2)(G) [Current Section 1216.1 (e)(2)(G)]	Section 1216.1 (b)(2)(G) [Current Section 1216.1 (e)(2)(G)] Clarity - The proposed amendment here would change one instance of “alcohol analysis” to “forensic alcohol analysis,” while leaving another instance unchanged. The change is internally inconsistent and therefore unclear. The reference to “subjective observations of the demeanor” is unclear since it lacks specificity and there are no required standards of performance.	
1:50	Sections 1216.1 (b)(2), (H) and (I) [Current Sections 1216.1 (e)(2), (H) and (I)]	Sections 1216.1 (b)(2), (H) and (I) [Current Sections 1216.1 (e)(2), (H) and (I)] Clarity - Subsections (H) and (I), which require the training course to include the subjects, “court testimony” and “court decisions regarding chemical tests of alcohol to determine alcohol influence,” again lack specificity as to what is required and therefore are unclear.	
1:51	Section 1216.1 (b)(2)(J) [Current Section 1216.1 (e)(2)(J)]	Section 1216.1 (b)(2)(J) [Current Section 1216.1 (e)(2)(J)] Clarity/Necessity – Subsection 1216.1 (b)(2)(J), which requires the training to include the subject, “requirements of these Group 8 regulations,” again lacks the specificity needed to set forth any	

		<p>meaningful requirements and thus does not satisfy the clarity requirements of the APA. This comment would apply to each of the subsections under Section 1216.1 (b)(2). From a practical standpoint, this was less of a problem when an objective scientific body like the Department of Public Health was authorized to review and approve proposed training procedures. None of the current voluntary laboratory accreditation organizations provides any oversight of training. As a consequence, with the proposed revisions to the regulations, there would be no external oversight of employee training and each laboratory would individually determine how to fulfill the loosely defined training requirements. Because of this, the proposed revisions to the regulations do not meet the statutory mandate of ensuring the competence of the forensic alcohol laboratory employees. [cf. H&S Code §100703 (d)].</p>	
<p>1:52</p>	<p>Section 1216.1 (b)(3), (A) – (E) [Current Section 1216.1 (e)(3)]</p>	<p>Section 1216.1 (b)(3), (A) – (E) [Current Section 1216.1 (e)(3)]</p> <p>Clarity/Necessity – The committee proposes here to replace the current requirement for the forensic alcohol analyst to successfully complete a proficiency test and a written examination conducted by the Department with a requirement that the analyst complete a “competency test.”</p> <p>The ISOR states here that the description of the competency test was based on recommendations made by ASCLD/LAB, but did not provide any reference supporting this statement. The requirements for the competency test were discussed by the committee at its July 2, 2009 meeting. During this discussion, none of the members described these requirements as originating from ASCLD/LAB. It does not appear that the committee based the requirements for a competency test on specific recommendations made by ASCLD/LAB or any other national body. The committee will have to separately justify the proposed revisions here. In fact, the committee’s proposed revisions create many clarity issues. The revised regulations do not specify the matrix of the competency test samples and the references to “predetermined values” under paragraph (A) and “known value” under paragraph (E) are not clear since the regulations do not specify how the values are “predetermined” and “known.” The proposed regulations do not describe whether the “competency test” must be obtained from a source external to the laboratory or prepared in-house. The phrase, “at a minimum” is unnecessary, since the regulations generally set minimum standards.</p>	

		<p>The committee's proposed revisions eliminate the requirement for any examination of the analyst candidate's knowledge of the laboratory's methods and the Title 17 regulations.</p> <p>The ISOR claims again here that "The references to the Department" were removed to reflect the change in the statute." This reflects a significant misunderstanding of the statutes. Again, while the 2004 change in the statutes repealed the Department's authority to require the laboratories to be licensed, it did not repeal Departmental jurisdiction over forensic alcohol analysis including conducting laboratory and staff proficiency tests and staff written examinations. The Attorney General's office, in its 2011 opinion regarding the forensic alcohol program (Opinion 10-501) evaluated the legislative intent of the 2004 legislation and concluded, "Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure." The AG referenced the Department's proficiency tests and written examinations as part of the oversight program.</p> <p>The Department has stated that it needs to retain its current authority to review, test, and approve the qualifications of laboratory personnel.⁵² Under the current regulations, the Department requires all staff employed in forensic alcohol analysis to successfully complete an external proficiency test and a written examination. The Department also reviews staff's training, experience, and educational qualifications in order to assure competency of the employees and to enable the Department to meet the mandate of H&S Code §100725. The voluntary ASCLD/LAB accreditation program operated by the laboratories does not provide any oversight of the qualification of laboratory personnel. It is critically 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.</p> <p>The committee has not demonstrated by substantial evidence how the elimination of the Department's current authority to review, test, and approve the qualifications of persons employed by a laboratory would effectuate the purpose of the statutes (H&S Code § 100725), which</p>	
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		<p>requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:53</p>	<p>Current Section 1216.1 (e)(4)</p>	<p>Current Section 1216.1 (e)(4)</p> <p>Necessity/Consistency – The language of current Section 1216.1 (e)(4) authorizes the Department to evaluate the qualifications of personnel performing forensic alcohol analysis. The committee has proposed to repeal this section. As noted under the comments for Section 1216.1 (b)(3), the Department has stated that it needs to retain its current authority to review, test, and approve the qualifications of laboratory personnel.⁵³ This authority is consistent with an ongoing state oversight role assumed by the Department as mandated by H&S Code §100725.</p> <p>The ISOR for this section states,⁵⁴ “The information presented here is no longer accurate. Instead, previous subsection (b)(5) is tabulated for easier reading as (b)(4).” It is difficult to decipher what the ISOR author meant here. Most probably, the reference to the “previous subsection (b)(5)” should read, the “subsequent subsection (b)(5).” The ISOR does not describe why the information “is no longer accurate.” The section requires that laboratory personnel must demonstrate the ability to adhere to the provisions of the regulations. This requirement does make sense only in terms of some ongoing external oversight of the laboratories and laboratory staff. Absent such oversight, there would be no entity for forensic alcohol staff to demonstrate ability to. However, the oversight described in the current regulations [Section 1216.1 (e)(4)] is completely consistent with the Department’s mandated responsibility to enforce the regulations which ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws. This oversight must be continued in order to ensure the competence of the testing,</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes (H&S Code §100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure</p>	

		the competence of the laboratories [cf. H&S Code §100703 (d)].	
1:54	Sections 1216.1 (b)(4), (A) and (B) [Current Section 1216.1 (e)(5)]	<p>Sections 1216.1 (b)(4), (A) and (B) [Current Section 1216.1 (e)(5)]</p> <p>Necessity – According to the Department, no one has sought qualification under the grandfather provisions described here for more than 30 years. Furthermore, it is unlikely that records prior to 1971 would be available to substantiate an application to qualify under this section. The committee has not demonstrated by substantial evidence the need for this regulation to effectuate the purpose of the statute.</p> <p>As noted in the comments under Section 1215 (f), the reference in subsection (B) [and also below under subsection (C)] to the term “forensic alcohol supervisor,” would appear to require the retention of a definition of this term under Article 1.</p>	
1:56	New Sections 1216.1 (b)(4), (C) and (D)	<p>New Sections 1216.1 (b)(4), (C) and (D)</p> <p>Clarity - The date (“January 1, 1971”) shown in the committee’s proposed regulations is obviously incorrect. Presumably, the committee intended that the date here would be replaced with the date the new regulations are adopted. In any event, the proposed regulations are unclear.</p>	
1:57	Current Sections 1216.1 (f), (1) – (5)	<p>Current Sections 1216.1 (f), (1) – (5)</p> <p>Necessity – Sections 1216.1 (f), (1) – (5), which specify the requirements of the forensic alcohol analyst classification, are proposed to be repealed because the former forensic alcohol supervisor classification is proposed to be renamed as the forensic alcohol analyst class.</p> <p>Sections 1216.1 (f), (2) and (3), currently describe the requirement that new analysts must complete a training period in alcohol analysis [current Section 1216.1 (f)(2)] including at least 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol [current Section 1216.1 (f)(3)]. As noted in the comments under Section 1216.1 (b)(2), the proposed analyst training requirements in that section</p>	

		<p>do not specify the analyte or the sample matrix, which together describe the measure and, blood alcohol. As a consequence, the regulations as proposed by the committee, do not include any specific requirement for training in forensic alcohol analysis and no requirements for any experience performing these analyses.</p> <p>Rather, as noted in the ISOR, each forensic alcohol laboratory will be independently responsible for ensuring that its analysts are competent to conduct alcohol analysis. This is another example of regulations that require a laboratory to do whatever it wants to do. Again, such regulations are clearly unnecessary.</p> <p>Again, the committee has not demonstrated by substantial evidence that the proposed repeal of the current analyst training and experience requirements here will ensure the competence of the laboratories as required by Health and Safety Code §100703(d).</p>	
<p>1:58</p>	<p>New Section 1216.1 (c)</p>	<p>New Section 1216.1 (c)</p> <p>Clarity/Necessity/Consistency - As described in the general comments under Article 2, the requirements for laboratories to notify the Department of any changes in activities authorized under the regulations, including the qualification of personnel are currently included under Article 3. This is the appropriate location for establishing these requirements.</p> <p>The committee proposed revisions that would require laboratories to “notify” the Department of the qualification of staff and to provide copies of the staff’s diploma or transcripts, a summary of the “topics” included in the training, a copy of the written and/or practical examinations completed by the individual, and “proof of completion” of a competency test and annual proficiency tests. The committee repealed existing regulations [Section 1216.1 (e)(4)] that describe the Department’s evaluations of personnel’s qualifications and the requirement that laboratory personnel must successfully complete a proficiency test and written examination prescribed by the Department. Despite this, the ISOR claims that the information submitted to the Department, “will allow oversight of the laboratories to ensure compliance with these regulations.” It is not clear how this “oversight” will be accomplished</p>	

	<p>given that the committee’s proposed regulations do not describe what the Department would do with the submitted information. This obviously creates clarity issues. Moreover, the committee members repeatedly stated that they did not want to provide any authority to the Department to review, approve or test the qualifications of laboratory staff. For example, at the March 6, 2013 meeting, committee member Dan Jeffries stated, “I think maybe even weakening the word ‘submit’ to ‘provide’ would sound better. So it would read, ‘Every laboratory performing forensic alcohol analysis shall provide to the Department the following.’ Then it makes it clear that there is no overview or oversight or approval, it’s just simply a matter of giving a copy.”⁵⁵ Accordingly, the committee’s intent in proposing the amendment to this section conflicts with the Department’s description of the effect of the regulation (i.e., “allow oversight of the laboratories”) and this creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p> <p>As noted in the comments to Section 1216.1 (b)(3), the Department has stated that it needs to retain its current authority to evaluate the qualifications of laboratory personnel. This authority is consistent and in harmony with the statutes (H&S Code §100725), which requires the Department to enforce the law and the regulations. The committee has not demonstrated by substantial evidence how transferring the authority to evaluate staff qualifications to each individual laboratory will effectuate the purpose of the statutes (H&S Code §100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the testing [H&S Code §100703(d)].</p> <p>The committee’s proposed revisions also create several other clarity issues. For example, in listing certain items of information to be submitted to the Department, it requires this submission “for each individual performing forensic alcohol analysis for the laboratory.” The language here might suggest that the entire set of information must be submitted even for those staff qualified under the current regulations [cf. Section 1216.1 (b)(4)]. Under paragraph (2), laboratories are required to submit summary of training topics “outlined in Section 1216.1 (b)(2)⁵⁶ for each individual performing forensic alcohol analysis for the</p>	
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		<p>laboratory.” However, as set forth under Section 1216.1 (b)(2), personnel with two years’ experience performing forensic alcohol are not required to complete any training. Paragraph (3) requires the laboratory to submit “qualifying tests including written and/or practical examinations,” but these qualifying tests/examinations and written and/or practical examinations are not otherwise described in the regulations. Requiring a laboratory to submit records of activities that are not defined or even mentioned in the regulations obviously creates both consistency and necessity issues.</p>	
<p>1:59</p>	<p>Article 3. Licensing Procedures</p>	<p>Article 3. Licensing Procedures</p> <p>Necessity/Consistency – All of Article 3 is proposed to be repealed. The initial statement of reasons here states that, “This article was repealed because it pertained only to matters previously under the jurisdiction of the Department but that are no longer (sic)”. It is apparent here that the committee proposed to repeal the entire article simply based on its title, “Licensing Procedures” and the 2004 legislation, which removed the Department’s authority to require the laboratories to be licensed. However, Article 3 establishes a number of requirements and authorities that are not specifically licensing activities. Included here is the requirement to file a notification with the Department of a laboratory’s intent to perform forensic alcohol analysis [Section 1217 (a)], the requirement to file reports of changes or discontinuances of activities [Section 1217.3], and the authority of the Department to perform site inspections and conduct proficiency tests [Section 1217.7]. While the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed, the statutes do not prohibit the Department from requiring the laboratories to file applications and reports. Similarly, the 2004 change in the statutes does not prohibit the Department from evaluating a laboratory’s proficiency test performances or conducting site inspections for cause. As noted in the comments under Article 2, Article 3 is the appropriate location for establishing the Department’s procedural requirements for administering its forensic alcohol analysis regulatory program.</p> <p>The regulatory authorities provided under Article 3 are consistent with and in harmony with the statutes (H&S Code §100725), which requires</p>	

		<p>the Department to enforce the law and the regulations. The committee must separately demonstrate by substantial evidence the need for the repeal of the each of the aforementioned sections and in each case to demonstrate how the Department's general [H&S Code §100170 (a) (1)] and specific (H&S Code §100725) mandates to enforce the law and its regulations will be accomplished with these repeals.</p>	
1:60	Section 1217 (a)	<p>Section 1217 (a)</p> <p>Necessity/Consistency – This section describes the requirement that a laboratory must notify the Department of its intent to perform forensic alcohol analysis and that the Department shall in turn submit the required proficiency test samples, qualify laboratory personnel, and perform such examinations as are necessary for that laboratory to meet the requirements of the regulations. These are completely standard procedures in any laboratory regulation program. The legislature designated the Department of Public Health as the specific state agency with specific authority to enforce the law and its regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The requirement for laboratories to notify the Department is consistent with and in harmony with the statutes (H&S Code §100725). The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes (H&S Code §100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)].</p>	
1:61		<p>Section 1217.2</p> <p>Necessity – This section requires a laboratory to notify the Department of its intent to perform forensic alcohol analysis using application forms created by the Department. The repeal of this authority would prevent the Department from exercising its responsibility to enforce the regulations, since it wouldn't even know who is performing the analyses. The legislature designated the Department of Public Health as the specific state agency with specific authority to enforce the law and its</p>	

		<p>regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)]. Amendments must be added to the section to clarify and make specific the required information to be included on the forms furnished by the Department.</p>	
1:62	Sections 1217.3, (a) and (b)	<p>Sections 1217.3, (a) and (b)</p> <p>Necessity/Consistency – These sections require a person responsible for forensic alcohol analysis at a laboratory to notify the Department of all changes or discontinuances of activities authorized under the regulations using forms created by the Department. A laboratory must report these changes within 30 days of their occurrence. The requirements described in these sections are consistent with and in harmony with H&S Code §100725, which requires the Department enforce the law and regulations.</p> <p>The legislature designated the Department as the specific state agency with specific authority to enforce the law and its regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)]. Amendments must be added to the section to clarify and make specific the required information to be included on the forms furnished by the Department.</p>	
1:63	Section 1217.3 (c)	<p>Section 1217.3 (c)</p> <p>Necessity/Consistency – The section describes the requirement that laboratory personnel must re-demonstrate their competence when transferring between different laboratories. In general, when someone</p>	

		<p>transfers from one laboratory to another, there will be changes in methods and procedures and instruments and equipment. The authority provided here is consistent with mandate for the Department to enforce the law and regulations (cf. H&S Code §100725) in order to ensure the competence of the laboratories and their employees. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:64</p>	<p>Sections 1217.6 and 1217.6 (b)</p>	<p>Sections 1217.6 and 1217.6 (b)</p> <p>Necessity – The committee proposes to repeal these sections, which describe the authority of the Department to enter a laboratory at all reasonable times to conduct an inspection in order to determine whether or not there is compliance with the provisions of the regulations. Such inspections are completely standard in all laboratory regulation programs. The Department needs regulatory authority to access the premises of the laboratory in order to conduct site inspections. The Department’s inspections are focused on blood and breath alcohol analysis. Reports of each inspection are prepared on standard forms filed with the Department. All of the requirements of the regulations are evaluated during an inspection.</p> <p>The rulemaking record⁵⁷ shows that the members of the review committee frequently noted that the majority of the laboratories are inspected by accreditation programs such as ASCLD/LAB. However, as noted in the comments under current Section 1216.1 (a)(4), the site inspections conducted at five-year intervals by these voluntary accreditation organizations are not specific to the requirements of forensic alcohol analysis and don’t cover breath alcohol analysis at all. As specifically set forth in the ASCLD/LAB guidelines, records of its site inspections are strictly confidential. However, at a 2008 meeting of the State’s Crime Lab Review Task Force (established by AB 1079, 2007), Task Force Vice Chair Barry Fisher (Director of the Los Angeles Sheriff’s Dept. Laboratory), provided a copy of a report of a 2006 ASCLD/LAB inspection of his laboratory.⁵⁸ The Los Angeles Sheriff’s Dept. performs tens of thousands of forensic alcohol analyses each</p>	

		<p>year. However, alcohol analysis is not mentioned in the ASCLD/LAB inspection report. Alcohol analysis is a subdiscipline of toxicology. The toxicology evaluation during the site inspection consisted of four Yes/No questions: Does each analyst have a college degree?; Did each examiner complete an initial competency test?; Did each examiner complete an annual proficiency test?"⁵⁹; and the remarkably conclusionary question, "Does each examiner understand the instruments, and the methods and procedures used?" By contrast, the Department of Public Health's inspections are focused on blood and breath alcohol analysis. All of the requirements of the regulations are evaluated during an inspection. Reports of each inspection are prepared on standard forms.</p> <p>The current regulatory authority to conduct inspections is necessary to enable the Department to ensure the competence of the laboratories and employees and to enforce the law and regulations. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes, which requires the Department to enforce the law and the regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)].</p>	
<p>1:65</p>	<p>Sections 1217.7, (a) and (b)</p>	<p>Sections 1217.7, (a) and (b)</p> <p>Necessity – These sections authorize the Department's current site inspection and proficiency testing activities. The Department has stated that it needs to continue its current oversight of proficiency testing.⁶⁰ The Department's laboratory proficiency testing program provides an objective, independent assessment of the competency of the laboratories. Section 1217.7 (b) describes the purpose of the proficiency tests which is to enable the Department to evaluate the accuracy of the forensic alcohol analyses performed by a laboratory. As discussed under Section 1216.1 (a) (4), site inspections for cause are needed to enable the Department to ensure the competence of the laboratories and employees. Again, site inspections and proficiency tests are completely standard procedures in any laboratory regulation program. The legislature designated the Department of Public Health as the specific state agency with specific authority to enforce the law and its regulations. There is no other agency or organization that provides</p>	

		oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)].	
1:67	Article 3. Training of Personnel (Current Article 4.)61 Section 1218	Article 3. Training of Personnel (Current Article 4.)61 Section 1218 Clarity – The review committee proposes here to change the section title from “Training Program Approval” to “Training Program Review.” As discussed below, the committee deleted all references to the Department’s “approval” of training in the section. However, the proposed revisions to the article do not describe any “review” of training programs submitted by a laboratory and consequently the change in the section title still creates clarity issues.	
1:68	Section 1218 (a)	Section 1218 (a) Clarity/Necessity/Consistency – This section currently describes the requirement that the Department must approve all training intended to qualify persons under the regulations. The review committee deleted all references to the Department’s “approval” of training and substituted language, which requires the training organization to submit descriptions of the training in order to, “demonstrate compliance with these regulations.” Subsequently, under Section 1218 (b), the committee’s proposed revision refers to the submission process in Section 1218 as a “notification” to the Department. The language here is not completely clear, but it suggests that the mere act of submitting something demonstrates compliance with the regulations. The ISOR comments for the entire article state that, “The proposed regulations further codify the removal of the Department’s jurisdiction over training.” The reference here to codification suggests that the proposed revisions, which remove Department’s authority to approve training, follow some statutory directive. The committee’s ISOR	

	<p>frequently attempts to justify the review committee’s proposed revisions with the claim that it was the intent of the legislature to eliminate oversight by the Department. (Note: the adverb “further” here in the ISOR comment suggests that this is a continuation of this theme). However as noted previously, nothing in the legislative record indicates that the legislature intended to eliminate state-level oversight. The legislature retained the mandate for the Department to enforce the law and the forensic alcohol analysis regulations (cf. Health and Safety Code §100725) and the statutes specifically require the laboratories to comply with the Department’s regulations [cf. Health and Safety Code §100700 (a)]. The only specific limitation placed on the Department by the legislature was the elimination of the authority to require that the laboratories be licensed. The Attorney General’s Office, in its 2011 opinion⁶² regarding the forensic alcohol program evaluated the legislative intent of the 2004 legislation and concluded, “Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure.”</p> <p>The committee cannot rely on the incorrect, one sentence claim implying that the revisions proposed under this article simply carry out some sort of legislative intent. The committee must demonstrate by substantial evidence that replacing the Department’s current regulatory authority to approve training with a process that permits the 40 individual laboratories to self-certify their trainings will ensure the competence of the laboratories as required by Health and Safety Code §100703 (d).</p> <p>The committee also revised the section to specifically refer to the training described under Section 1221.2 (a)(3). This would mean that descriptions of the training authorized under proposed Section 1216.1 (b)(2), i.e., training provided to laboratory staff in lieu of a requirement for two years of experience performing forensic alcohol analysis, would not ever be submitted to the Department or subjected to any kind of external evaluation or review.</p> <p>The committee’s proposed revisions create a new clarity/consistency issue. The scope of Section 1218 (a) is set by the language, “Any</p>	
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	<p>organization, laboratory, institution, school, or college conducting a course of instruction...” There are two types of training described in the regulations. Training for breath instrument operators [cf. Section 1221.2 (a)(3)] and the training provided to laboratory staff in lieu of a requirement for two years of experience performing forensic alcohol analysis [cf. current Section 1216.1 (b)(2)]. The committee has proposed to totally exempt the latter training from any of the requirements of Section 1218. This leaves only the breath instrument operator training. As described in the comments under Section 1221.2 (a)(4) (former Section 1221.4 (a)(4)), training of breath instrument operators appears to require the participation of a forensic alcohol laboratory at least in the initial “development” of the training “curriculum.” Accordingly, it is not clear how the non-laboratory entities described by the language, “Any organization,...., institution, school, or college conducting a course of instruction” would be permitted to provide training for breath instrument operators. The language proposed by the committee here and under Article 6 (current Article 7) is very vague, but it appears that there is at least a clarity and perhaps a consistency issue here.</p> <p>While the committee repealed the specific language, which required the Department’s review and approval of training, at its last two meetings it added a new Section 1218 (c), which authorizes the Department to notify a laboratory in writing if it “believes” that a laboratory’s training program does not comply with the regulations. The language here appears to contradict the provisions of subsection (a), which state that a laboratory demonstrates compliance with the regulations by simply submitting certain items of information. The ISOR for this section managed to capture the contradiction here by noting that revisions to the section clarify that the “discretion regarding the content of training programs lies with the laboratories, not the Department. However, it allows the Department to notify a laboratory if the Department believes the training program is out of compliance with these regulations.” The obvious clarity issues with the committee’s proposed revisions here are discussed further below under the comments for Section 1218 (c).</p> <p>Finally, there are the ongoing place-entity issues in this section since a laboratory (a place) can’t conduct a course of instruction. The place/entity issue must be addressed in the regulations in order to</p>	
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		<p>effectuate the purpose of the statutes.</p> <p>The Department has stated that it needs to continue its current approval authority of all training described under the forensic alcohol regulations [i.e., training described under Section 1216.1 (b)(2) and Section 1221.2 (a)(3)] in order to ensure the competence of the laboratories and employees and to enforce the law and the Department’s regulations.⁶³ The legislature vested the Department of Public Health as the specific state agency with specific authority to enforce the law and its regulations. No other agency or organization provides any oversight of the forensic alcohol laboratories’ training programs. The Department’s current review and approval of training is absolutely critical in maintaining standardized alcohol testing in California. Allowing each individual laboratory to separately determine what training is required without any oversight at all will not ensure the competency and consistency of the training.</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:69</p>	<p>Sections 1218 (a), (1) – (5)</p>	<p>Sections 1218 (a), (1) – (5)</p> <p>Clarity/Necessity - The list of required information that a training organization must submit is unclear and not complete. The requirement to submit a “complete outline” is vague. According to comments made by the representative of the Department at the September 26, 2012 meeting of the review committee,⁶⁴ the Department currently requires the training organization to submit copies of all training materials (training handouts, precautionary checklists, PowerPoint presentations, etc.). In response to the Department staff’s comments, Committee member Jennifer Shen responded that she was “not interested in providing this information.”⁶⁵ The committee must either demonstrate by substantial evidence that these additional items (i.e., training materials) are not necessary to effectuate the purpose of the statutes or these</p>	

		items must be added to the list of records to be submitted to the Department.	
1:70	Section 1218 (b)	<p>Section 1218 (b)</p> <p>Necessity/Clarity –The new language proposed by the review committee here is unnecessary. Nothing in the current regulations prohibits a training organization from updating its training programs. The proposed revisions to the regulations here and also the ISOR discussion of the proposed revisions describe training offered by a “laboratory.” As noted previously, the regulations [Section 1218 (a)] refer to training offered by “Any organization, laboratory, institution, school, or college conducting a course of instruction...” [See also comments under Section 1218 (a)]. The specific references to laboratory-provided training in this section create clarity and possibly consistency issues. Also, there are the ongoing place-entity issues in this section since a laboratory (a place) cannot conduct a course of instruction. The place/entity issue must be addressed in the regulations in order to effectuate the purpose of the statutes.</p> <p>The committee added language stating “The changes will be subject to Department notification as outlined in this Section.” Regulations do not “outline” requirements.⁶⁶ Regulations are rules or directives made and enforced by an authority. Regulations are distinct from voluntary guidelines such as the guidelines published by ASCLD/LAB, which may represent best practices, but do not have the force of law. Finally, the word “section” should be shown in lower case, since this is consistent with the current format used in the California Code of Regulations.</p> <p>The committee has not demonstrated by substantial evidence how the proposed addition of this section will effectuate the purpose of any statute.</p>	
1:71	Section 1218 (c)	<p>Section 1218 (c)</p> <p>Necessity/Clarity – This new section apparently permits a response from Department in those instances where the Department “believes that the laboratory’s training program does not comply with these regulations...”</p>	

	<p>The committee’s proposed revisions do not otherwise describe the Department’s “review” of a laboratory’s proposed training program or show how the Department would come to “believe” that a training program does not comply with the regulations, which obviously creates clarity issues. Again, the committee’s proposed revisions would repeal the current, specific requirements that the Department must “approve” all training. At the March 6, 2013 meeting, committee member Jennifer Harmon explained that, “the training program that has been approved by the laboratory is what is being submitted to the Department for them to have on record not for them to dictate to us how it should or shouldn’t read.”⁶⁷</p> <p>The proposed revisions set 30-day time limits for the Department to communicate its “beliefs” and for “laboratory management” (an undefined term) to respond. The 30-day limits are unclear since the regulations do not specify when the clock starts. Moreover, the regulations do not describe the consequences of a failure by either party to meet the 30-day deadline or of a failure by “laboratory management” to respond at all. It is not clear whether the notification/response process is a one-time event or it can continue indefinitely. These questions need to be clarified in the regulations. However, there is a more fundamental question of the necessity of this regulation. As noted previously, the Department has the general authority to “commence and maintain all proper and necessary actions and proceedings to enforce its regulations” [cf. H&S Code §100170(a)(1)]. Certainly, the authority here includes writing a letter to a laboratory that is not complying with the regulations. The Department not only has the authority to do this, but the statutes actually require the Department to take these actions in order to enforce the regulations (cf. H&S Code §100725). The statutes here do not impose any time limits on the Department in taking enforcement actions.</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes, which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
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<p>1:72</p>	<p>Section 1218.2</p>	<p>Section 1218.2</p> <p>Necessity - The committee proposes here to repeal the Department’s authority to contract out the administration of proficiency tests and written examinations to third parties. The regulations here do not permit the Department to delegate any discretionary functions including the evaluation of tests and examinations. This is appropriate and consistent with the Department’s exclusive responsibility for enforcing the law and the regulations that ensure the competence of forensic alcohol analysis in the State. No other entity fulfills this role.</p> <p>The ISOR claims that the section was “repealed because the Department no longer has this authority under the amended Health and Safety code statute.” Once again, the committee did not appear to have the benefit of informed legal counsel in forming this opinion. As noted previously, the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed. The statutes do not prohibit the Department from any other of the activities associated with the regulation of the laboratories including conducting proficiency tests and examinations. As a result, the provisions here enabling the Department to contract out some of these activities to a nongovernmental, third party vendor might in the future prove to be cost effective for the Department. For example, at the September 26, 2011 meeting of the review committee, Department staff presented a report, “Ideas for Forensic Alcohol Analysis Regulations,”⁶⁸ which described a program whereby some site inspections of laboratories would be conducted by ASCLD/LAB inspectors. In the Department’s proposal, the inspections would be based on the Title 17 requirements. The committee members did not accept the proposal, but it serves as an example of the type of contractual partnering that could be possible under current Section 1218.2.</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as</p>	

		<p>required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:73</p>	<p>Article 4. Collection and Handling of Blood, Urine, and Tissue Samples (Current Article 5.)⁶⁹</p> <p>Section 1219.</p>	<p>Article 4. Collection and Handling of Blood, Urine, and Tissue Samples (Current Article 5.)⁶⁹</p> <p>Section 1219.</p> <p>Necessity/ Consistency – The review committee here proposes to remove current state-level oversight of the requirements for the collection and handling of samples. The ISOR explanation for this removal was, “The Department no longer has the power to approve per enabling statute.” As noted previously (many times now), the conclusion here misrepresents the intent of the legislature. The review committee apparently reached its conclusion here without the benefit of competent legal counsel. Again, the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed; the statutes do not prohibit the Department from any other regulatory activity including setting standards for the collection of samples for forensic alcohol analysis.</p> <p>The ISOR quotes the committee in stating that the “court system provides the ultimate oversight of proper collection and handling because these issues are challenged in most driving under the influence cases.” The committee did not provide any evidence of the effectiveness of judicial oversight here.⁷⁰ As noted previously, the overwhelming proportion of the State’s annual 175,000 drunk driving arrests never go to trial and the evidence is not subjected to any judicial scrutiny. Moreover, as a general rule, the courts will not substitute their own scientific judgment in evaluating evidence. For regulated testing, this role should be assigned to the administrative agency that writes and enforces the regulations. As noted in the ISOR, the committee also found that with regard to the specific procedures employed for the collection of samples, it was their intent to, “address these particulars (chain of custody logs, labeling, security etc.) as each laboratory entity sees fit.” First off, the reference in the ISOR to the “laboratory entity” is inconsistent with the definition in the regulations of a laboratory as a place [cf. renumbered Section 1215 (e)]. But aside from the ongoing</p>	

		<p>place-entity issue, the committee’s proposed approach here does not achieve one of the benefits of regulation stated in the ISOR Policy Statement Overview, which is to ensure that the chemical testing in drunk driving cases is performed uniformly throughout the state. This will not be achieved if 40 different laboratories independently determine their sample collection procedures. It is completely appropriate to retain state-level oversight of the procedures for the collection of samples for forensic alcohol analysis. The California Department of Public Health 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.</p> <p>Regarding the stated goal in the section to maintain sample identity and integrity, the regulations should incorporate by reference the document, “Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis.” Section 23158 (j) of the Vehicle Code describes the adoption of these uniform standards by the Department of Health Services (now California Department of Public Health), the Department of Justice, and the California Highway Patrol, but does not specifically name the standards or require their use.</p> <p>These standards, which spell out the required collection procedures and the procedures for maintenance of sample identity and integrity and chain of custody in drunk driving cases, must be adopted by reference in order to give them the force of regulations. Laboratories would be required to describe procedures for the collection and handling of samples, which comply with the Uniform Standards.</p> <p>The Department’s current regulatory authority to approve procedures for the collection and handling of samples is consistent with the Department’s mandated responsibility to enforce its regulations (cf. H&S Code §100725). The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
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<p>1:74</p>	<p>Section 1219.1 (a)</p>	<p>Section 1219.1 (a)</p> <p>Clarity/Consistency –The ISOR states that the section was amended simply to reflect changes in the California Vehicle Code. This analysis is incomplete. The proposed correction in the Vehicle Code section reference is itself a non-substantive change. However, the committee’s proposed revisions here would also eliminate the description of the referenced Vehicle Code section as identifying the personnel authorized to collect samples for forensic alcohol analysis. The section as revised by the committee now indicates that the referenced Vehicle Code section describes sample collection and processing requirements. In fact, the Vehicle Code does not describe any collection or processing requirements and only specifies the categories of personnel authorized to collect samples. This is correctly described with the language of the current regulations. The proposed revisions to this section are not clear and not consistent with or in harmony with the provisions of the cited Vehicle Code Section. Also, the current requirement to collect a sample “as soon as feasible” is not clear.</p>	
<p>1:75</p>	<p>Current Section 1219.1 (b)</p>	<p>Current Section 1219.1 (b)</p> <p>Consistency/Necessity – The committee proposed to repeal this section, which requires the collection of a volume of sample which is sufficient to permit duplicate analyses. The ISOR commented that the “section is vague, and puts the onus on the technician drawing the blood to determine what amount is sufficient.” The ISOR adds, “It is proposed that the analyst will be required to determine whether the sample collected is sufficient to perform duplicate analyses.”</p> <p>There are several problems with the committee’s proposed revisions. The regulations require at least duplicate analyses of the samples [cf. Section 1220.2 (a)(3)]. Nothing new is proposed under Section 1220.2 (a)(3) that would now require the analyst to determine whether a sufficient volume of sample was collected. This has always been a practical requirement. The collection of a volume of sample which is not sufficient to permit duplicate analyses would mean that the analyses could not be completed in compliance with the regulations. The current</p>	

		<p>regulations seek to avoid this by requiring the initial collection of a sufficient sample volume.</p> <p>There is a second issue here. The collection of very small volumes of sample when mixed with anticoagulant and preservative (typically weighing 120 mg) would create analytical problems for the laboratory. It would be difficult to aliquot a sample from the resultant liquid-solid slurry and potentially at least, there could be a loss of alcohol from such a matrix. One published study⁷¹ found small losses (2 - 3%) in alcohol concentration when the volume of sample collected was deficient. The appropriate solution here would be to specify the minimum volume of sample to be collected. The laboratory would determine the required volume and transmit this information to the person collecting the sample.</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statute that requires regulations that ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
1:76	Section 1219.1 (b) [Current Section 1219.1 (c)]	<p>Section 1219.1 (b) [Current Section 1219.1 (c)]</p> <p>Clarity – As revised by the committee, the regulations do not define or even require the use of a “suitable aqueous disinfectant,” but the regulations then list examples of suitable aqueous disinfectants. This creates a clarity issue. The terms, “suitable aqueous disinfectant” and also “volatile organic disinfectant” need to be defined in the regulations.</p>	
1:77	Sections 1219.1, (d), (d)(1), and (d)(2) [Current Sections 1219.1, (e), (e)(1), and (e)(2)]	<p>Sections 1219.1, (d), (d)(1), and (d)(2) [Current Sections 1219.1, (e), (e)(1), and (e)(2)]</p> <p>Clarity – Section 1219.1 (d) and the subsequent subsections [1219.1 (d), (1) and (2)] should be revised to clarify whether the sample handling requirements here apply to post-mortem samples.⁷² Section 1219.1 (d)(2) should also be revised to clarify that the sample container contains the anticoagulant and preservative.</p>	
1:78	Section 1219.1 (e) [Current Section	Section 1219.1 (e) [Current Section 1219.1 (f)]	

	1219.1 (f)]	Clarity/Necessity – The language here “all practical precautions to ensure an uncontaminated sample shall be employed” must be revised for clarity. Also, for the reasons described in the comments to current Section 1219.1 (b), the regulations must specify a minimum volume of sample collected.	
1:79	Section 1219.1 (e)(1) [Current Section 1219.1 (f)(1)]	Section 1219.1 (e)(1) [Current Section 1219.1 (f)(1)] Clarity/Necessity – The committee proposes to repeal the provision that exempts samples collected by a coroner and stored under refrigeration from the requirement that the sample must contain a chemical preservative. The committee must cite the scientific study relied upon to justify this change. Moreover, as noted under Section 1219.1 (d) et. seq., the regulations do not clearly state that post-mortem samples must be treated with an anticoagulant and preservative, so there are remaining clarity issues here that must be resolved.	
1:80	Section 1219.1 (e)(2) [Current Section 1219.1 (f)(2)]	Section 1219.1 (e)(2) [Current Section 1219.1 (f)(2)] Clarity – The language here, “Care shall be taken to avoid contamination by alcohol...” and the reference to a “major vein” must be revised for clarity.	
1:81	Section 1219.1 (f) [Current Section 1219.1 (g)]	Section 1219.1 (f) [Current Section 1219.1 (g)] Clarity - The section should be revised to clarify who retains the samples and to specify the storage conditions.	
1:82	Section 1219.1 (f)(1) [Current Section 1219.1 (g)(1)]	Section 1219.1 (f)(1) [Current Section 1219.1 (g)(1)] Clarity – The ISOR states, “This subsection was amended to replace “coroner” with “medical examiner.” The ISOR adds that “the term “medical examiner” is more accurate and will apply to either system.” In fact, the revisions proposed by the committee do not replace the term “coroner” with “medical examiner,” but rather add a reference to medical examiner cases (i.e., “coroner’s/medical examiner cases”). As a consequence, the proposed revision to the regulations here conflicts	

		<p>with the Department’s description of the effect of the regulation. This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p> <p>The section should be revised to clarify the types of samples retained (blood, tissue) and to describe who retains the samples and the sample storage conditions.</p>	
1:83	Section 1219.1 (f)(2) [Current 1219.1 (g)(2)]	<p>Section 1219.1 (f)(2) [Current 1219.1 (g)(2)]</p> <p>Consistency/Authority/Reference/Clarity - the proposed revision of “forensic alcohol laboratory” to “forensic laboratory” creates clarity and authority/reference issues. The term “forensic laboratory” is undefined. The statutes (H&S Code §100700) specifically reference laboratories that conduct alcohol testing by and for law enforcement and new Section 1215 (e) defines such laboratories as “forensic alcohol laboratories.” The proposed change is also inconsistent with the terminology (i.e., “forensic alcohol laboratory”) used throughout the regulations. Regarding the listing of agencies other than forensic alcohol laboratories, i.e., “law enforcement agency, or coroner/medical examiner’s office,” these terms require definition and it is not clear that the statutes provide the Department with the authority to regulate these entities. The requirement to provide “identifying information” with the sample also creates clarity issues since the required identifying information is not specified anywhere in the regulations (See also comments under Section 1219). Finally, the reference to “sufficient sample” is not clear.</p>	
1:84	Section 1219.2	<p>Section 1219.2</p> <p>Clarity/Necessity - The section should be amended to add a minimum sample volume collection requirement. The requirement here would be analogous to the requirement under current Section 1219.1 (b) and the comments offered under that section apply here. The review committee must consider the need for this requirement in order to effectuate the purpose of the statutes.</p>	
1:85	Section 1219.2 (a)	Section 1219.2 (a)	

		<p>Necessity/Consistency – The ISOR notes, “This subsection was amended to delete “an approved” sample because the Department does not approve of certain practices.” The awkwardly worded statement here appears to be a reiteration of the claim made under Section 1219 that, “The Department no longer has the power to approve per enabling statute.” Again this conclusion misrepresents the intent of the legislature. The 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed; the statutes do not prohibit the Department from any other regulatory activity including setting standards for the collection of samples for forensic alcohol analysis. Again, the Department’s current regulatory authority to approve procedures for the collection and handling of samples is consistent with the Department’s mandated responsibility to enforce its regulations (cf. H&S Code §100725). The committee has not demonstrated by substantial evidence how its proposed revision to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> <p>The ISOR also claims that the purpose of the proposed addition of the modifier, “from a living individual” to the description of the urine sample was to point out that the “procedures are not utilized when dealing with urine collection from a deceased person.” In fact, there are no provisions in the regulations for the collection of post-mortem urine samples. As a consequence, the added clarification that the subject urine sample was obtained from a living person is not necessary to effectuate the purpose of any statute or regulation.</p>	
<p>1:86</p>	<p>Section 1219.2 (c)</p>	<p>Section 1219.2 (c)</p> <p>Clarity - The section should be revised to clarify who retains the samples and to specify the storage conditions.</p>	
<p>1:87</p>	<p>Section 1219.2 (c)(1)</p>	<p>Section 1219.2 (c)(1)</p> <p>Clarity/Necessity - The ISOR identifies this section incorrectly as</p>	

		<p>“Subsection 1219(c)(1).” The regulation itself is identical to Section 1219.1 (f)(2) and thus the comments for that section apply here. There is an additional necessity issue here. The review committee added “coroner/medical examiner’s office” to the list of agencies that could be in possession of a sample. However, Section 1219.2 (c)(1) pertains to the retention of urine samples. The samples retained by a coroner or medical examiner’s office, which is not also a forensic alcohol laboratory, would be post mortem samples. As noted in the comments under Section 1219.2 (a), there are no provisions in the regulations for the collection of post-mortem urine samples for forensic alcohol analysis and consequently there would be no reason for a coroner or medical examiner’s office to be in possession of forensic alcohol urine samples. Accordingly, the proposed revision to add “coroner or medical examiner’s office” is unnecessary.</p>	
1:88	Section 1219.3	<p>Section 1219.3</p> <p>Clarity/Consistency – The committee proposed transferring the requirements of this section to Article 6 (current Article 7), while also amending the requirements. It would appear to be more appropriate to retain this section, which describes the requirements for the collection of a breath sample, here under Article 4 (current Article 5), which is currently titled, “Collection of Samples.”</p>	
1:89	Article 5. Methods of Forensic Alcohol Analysis (Current Article 6.)73 Section 1220	<p>Article 5. Methods of Forensic Alcohol Analysis (Current Article 6.)73 Section 1220</p> <p>Section 1220 simply contains the title, “General.” and this was left unchanged. The Initial Statement of Reasons (ISOR) for this section commented on the entire article, noting, “This article outlines the requirements for conducting the analysis of the samples. It includes discussions on sample handling, testing procedures, standards, controls, and quality assurance.” The comments in the ISOR here reflect the committee’s lack of understanding of the role of regulations. Regulations do not “outline” or “discuss” requirements; they are rules or directives made and enforced by an authority. Regulations are distinguished from voluntary guidelines such as the guidelines published</p>	

		by ASCLD/LAB, which may represent best practices, but do not have the force of law.	
1:90	Section 1220 (b)	<p>Section 1220 (b)</p> <p>Necessity/Consistency – The proposed amendment to this section would eliminate the requirement that the laboratories must file their written method descriptions with the Department. The ISOR states that the “subsection was amended to remove reference to the authority of the Department, jurisdiction that was removed by enabling statute.” The ISOR analysis once again is superficial and inaccurate. As noted previously, the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed, but it did not repeal Departmental jurisdiction over forensic alcohol analysis. The statutes specifically require the Department to enforce the forensic alcohol regulations (Health and Safety Code §100725). The statutes also provide the Department with general authority to “commence and maintain all proper and necessary actions and proceedings” to enforce its regulations” [H&S Code §100170(a)(1)]. The 2011 Attorney General’s review of the Department’s forensic alcohol program after the 2004 legislation⁷⁴ noted, “Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure.”</p> <p>In the ISOR included with the committee’s submission of the proposed regulations to the California Health and Human Services Agency,⁷⁵ the committee justified the repeal of the requirement to file method descriptions with the Department on the presumption that the California Public Records Act provides the Department with access to these records. The committee was incorrect. The provisions of the public records act apply primarily to governmental agencies and government records and accordingly may not apply to private laboratories performing forensic alcohol analysis,⁷⁶ even when these laboratories enter into contractual agreements with cities and counties to perform testing. Moreover, the California Public Records Act is subject to exceptions to disclosure and the procedures for obtaining copies of records are cumbersome. It is important to continue the requirement for laboratories</p>	

		<p>to file written method descriptions and other records with the Department. This provides the Department with ready access to the records it needs to enforce the law and the regulations pertaining to forensic alcohol analysis and to protect public safety. The filing of the written method descriptions with the Department serves to document the procedures used to generate analytical results that are admitted in legal proceedings. These become official procedures and they are available to all parties in any criminal or civil legal procedure. The Department's current regulatory authority to require laboratories to file written method descriptions and other records is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&S Code §100725). The committee has not demonstrated by substantial evidence how its proposed amendment to this section will effectuate the purpose of the statutes (Health and Safety Code §100725), which requires the Department to enforce the law and its regulations. These regulations are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:91</p>	<p>Section 1220 (b)(1)</p>	<p>Section 1220 (b)(1)</p> <p>Clarity/Necessity/Consistency – The proposed amendment to this section would eliminate the requirement that laboratories must make their written method descriptions available to the Department on request. This was the only amendment to the section. The ISOR states that the “section was amended to address an important factor that the analyst has immediate access to methods used.” The ISOR then notes that access to the written method is required by Section 5.4 of the ISO 17025 guidelines. The statements in the ISOR have nothing to do with the proposed amendment to the section. First, there was no change proposed here with respect to the requirement that the written method description shall be immediately available to the analysts. This has been a requirement in the California regulations for more than 40 years. Secondly, this important laboratory requirement is actually articulated less forcefully in the ISO 17025 standards, which require that, “All instructions, standards, manuals and reference data...shall be made readily available to personnel” (ISO 17025 Clause 5.4.1). Finally, it must be noted that not all California laboratories are accredited to the ISO 17025 standards and there is no requirement in the regulations for such</p>	

		<p>accreditation. The committee’s proposed revision in this section conflicts with the description in the ISOR of the effect of the regulation. This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p> <p>In proposing to repeal the requirement to make method descriptions available to the Department on request, the committee again noted the provisions of the California Public Records Act.⁷⁷ As described in the comments under Section 1220 (b), the committee’s reasoning here was faulty. Accordingly, the committee has not demonstrated by substantial evidence how its proposed revision to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (Health and Safety Code §100725) in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d). The Department’s current regulatory authority to require laboratories to provide records on request is consistent with the Department’s mandated responsibility to enforce its regulations (cf. H&S Code §100725).</p>	
<p>1:92</p>	<p>Section 1220 (b)(2)</p>	<p>Section 1220 (b)(2)</p> <p>Clarity/Consistency – The committee proposed no changes to this section. The regulations here should be revised to completely describe the minimum required elements of a complete written description of a forensic alcohol method. This would include: the procedures for collection and handling of samples, lists of reagents and equipment used, the procedures for determining the concentrations of the secondary standards, the procedures for calibrating the method, a definition of a sample set, the quality control program for the method, the procedures for calculating and reporting analytical results, routine checks of accuracy and precision, and the maintenance of the required records. In each case, these requirements can be referenced to other requirements under the regulations.</p> <p>The ISOR in explaining the review committee’s failure to revise this section to completely describe the required elements of a method claimed that, the “ASCLD/LAB accrediting guidelines far exceed the requirements set forth in this document.” However, the ASCLAD/LAB voluntary guidelines, which cover 10 different crime lab disciplines, are</p>	

		<p>very general and do not adequately address the specific requirements for a forensic alcohol method. Moreover, it must be noted again that there is no requirement in the law or regulations that a laboratory be accredited by ASCLD/LAB or any other organization.</p> <p>Finally, the ISOR notes that, “For those laboratories that are not accredited, this guideline is appropriate.” Obviously, the very incomplete description of the elements of a written method description is not appropriate for any laboratory. Also, the description of the regulations as a “guideline” again reveals the committee’s lack of understanding of the role of regulations.</p> <p>Regulations describe standards of performance and procedure that must be complied with under the force of law. By contrast, a guideline such as the voluntary ASCLD/LAB guidelines is a statement of advice or an instruction describing best practices, which doesn’t have the force of law.</p> <p>The regulations here must be revised to clearly and completely describe the minimum required elements of a complete written description of a forensic alcohol method.</p>	
<p>1:93</p>	<p>Section 1220.1 (a)</p>	<p>Section 1220.1 (a)</p> <p>Clarity – The committee proposed no changes to this section. The current regulations set standards of performance metrics for accuracy and precision [cf. Section 1220.1 (a)(1)], specificity (cf. Section 1220.1 (a)(2)), non-interference of anticoagulants and preservatives [cf. Section 1220.1 (a)(3)], and results less than 0.01% for alcohol free subjects [cf. Section 1220.1 (a)(5)]. The regulations do not define these metrics or describe how a laboratory’s staff demonstrate that a method is capable of meeting the required standards. Simply listing the performance standards without describing how these standards are met creates clarity issues. The Department’s forensic alcohol program has published guidelines describing the experimental data that enable a laboratory’s staff to demonstrate a method’s capabilities.</p> <p>California laboratories have employed these experimental demonstrations for more than 30 years. The experimental data are submitted along with the written descriptions of the method filed with the</p>	

		<p>Department. The Department's guidelines should be incorporated into the regulations. The details are presented below under each subsection. In each case, the review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p>	
<p>1:94</p>	<p>Section 1220.1 (a)(1)</p>	<p>Section 1220.1 (a)(1)</p> <p>Clarity/Necessity – The committee's proposed revision here to change the lower limit for which the accuracy standard of performance applies from 0.10 grams % to 0.08 grams % is consistent with the changes made to the Vehicle Code Sections 23152 (b), 23153 (b), etc., which lowered the per se and presumptive blood alcohol concentrations at which an individual can be prosecuted from 0.10 grams % to 0.08 grams %.⁷⁸ The committee chose to retain the current 5% accuracy and precision limits. The committee must provide a reference to the studies relied upon to set this standard. This would likely involve an evaluation of the expected measurement uncertainties of California forensic alcohol analysis methods.⁷⁹</p> <p>As discussed under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standards for accuracy and precision. Simply listing a standard without describing how the standard is met creates a clarity issue. The regulations would need to set forth the minimum requirements for these experimental demonstrations. The Department's current forensic alcohol program defines these requirements and describes procedures for experimentally demonstrating that the method meets the required standard of performance. For example, the Department requires laboratories to demonstrate that their methods meet the specified accuracy and precision standards using samples prepared in biological matrices (blood and urine), and requires 21 replicate analyses at each of three alcohol concentrations. The Department has also established procedures for determining the known alcohol concentrations of these reference samples. These requirements would need to be spelled out in the regulations. The regulations should also specify what circumstances require new experimental demonstrations. For example, currently, anytime a laboratory relocates or changes a method, the Department</p>	

		requests a re-demonstration of the method’s ability to meet the required standards of performance. The Department’s evaluations of these data provide appropriate state-level oversight and assure proper accountability. No other entity currently performs these evaluations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.	
1:95	Section 1220.1 (a)(2)	<p>Section 1220.1 (a)(2)</p> <p>Clarity/Necessity – The committee has proposed changes in the description of the standard of performance requirements for method specificity. While the current language is not clear, the committee’s proposed revisions are also vague, and create new clarity issues. The revised regulation, which reads, “For traffic law enforcement purposes the method shall be specific for the analysis of ethyl alcohol,”⁸⁰ would reasonably be interpreted as requiring a method for forensic alcohol analysis to be absolutely specific for alcohol. Diffusion-oxidation methods, which are used by some California laboratories, are not absolutely specific for alcohol and thus would not meet this new and more restrictive standard of performance requirement. It does not appear that this was the committee’s intent, and accordingly, the amendments create clarity issues. The committee has not demonstrated by substantial evidence how the imposition of this new standard of performance requirement is necessary and will effectuate the purpose of the statutes. The committee must reevaluate the requirements for method specificity and set requirements that are in fact “adequate and appropriate for traffic law enforcement.” The committee must also consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the specificity standards. Simply listing a standard without describing how the standard is met creates a clarity issue. The regulations would need to set forth the minimum requirements for this experimental demonstration. Again, the review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p>	
1:96	Section 1220.1 (a)(3)	Section 1220.1 (a)(3)	

		<p>Clarity/Necessity – The committee’s proposed revision to this section, which describes the standard of performance requirements with respect to a potential interference from anticoagulant and preservative added to the sample, substitutes the language, “The method should” with “The method shall” in order for the section to read as a regulation. As noted in the comments under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standard regarding the freedom from interference from anticoagulants and preservatives added to the sample and to set forth the minimum requirements for this experimental demonstration in the regulations. This demonstration is needed to effectuate the purpose of the statutes. Again, the Department has published guidelines describing this demonstration. These guidelines should be incorporated into the regulations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p>	
1:97	Section 1220.1 (a)(4)	<p>Section 1220.1 (a)(4)</p> <p>Clarity – The committee’s proposed revisions are not substantive and do not address several clarity issues in this section. The term, “oxidizable substance” needs to be defined, and the requirements of the qualitative test must be specified. The appropriate way to address the requirements here would be to list the desired characteristics of the “qualitative test” and/or to specify the appropriate method(s) of analyses that must be used to qualitatively identify ethyl alcohol.</p>	
1:98	Section 1220.1 (a)(5)	<p>Section 1220.1 (a)(5)</p> <p>Clarity/Necessity – The committee proposed no changes to this subsection. As noted in the comments under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standards when analyzing an alcohol-free sample and to set forth the minimum requirements for this experimental demonstration in the regulations. Simply listing a standard without</p>	

		<p>describing how the standard is met creates a clarity issue. An experimental demonstration is needed to effectuate the purpose of the statutes. Again, the Department has published guidelines describing this demonstration. These guidelines should be incorporated into the regulations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p>	
<p>1:99</p>	<p>Section 1220.1 (b)</p>	<p>Section 1220.1 (b)</p> <p>Clarity/Necessity/Consistency – The review committee’s proposed amendment here would eliminate the requirement for the Department to evaluate the ability of each laboratory’s method(s) to meet the required standard of performance using the laboratory’s proficiency test results.⁸¹ The authority to perform these evaluations would be transferred to a forensic alcohol analyst (presumably but apparently not necessarily an employee of the laboratory). The ISOR claimed that the elimination of the Department’s evaluations “brings this subsection in line with the intent of the legislature to remove the Department’s jurisdiction.” The ISOR also notes that Department oversight was removed in order to “codify (sic) the oversight of the proficiency program to the individual laboratories.” As discussed in the comments under Section 1220 (b), the committee’s determination of legislative intent, is not supported by the legislative record.</p> <p>Again, while the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed, it did not repeal Departmental jurisdiction over forensic alcohol analysis including evaluating laboratory proficiency tests. The statutes (Health and Safety Code §100725) require the Department to enforce the regulations.</p> <p>The ISOR also claims that the review of proficiency test data by the voluntary laboratory accreditation program, ASCLD/LAB, “provides the oversight needed to ensure methods are functioning according to required specifications.” However, the proficiency-testing requirements included in the voluntary ASCLD/LAB accreditation program are not an adequate substitute for the Department of Public Health’s current regulatory program. The Department’s proficiency</p>	

	<p>test requirements are more stringent than ASCLD/LAB's and include more frequent testing,⁸² a requirement that laboratories with multiple methods complete separate tests for each method, and the evaluation of test results based on the accuracy and precision requirements set forth in California's regulations. The acceptable ranges of results used by the Department are narrower than those employed by ASCLD/LAB.⁸³ This assures that laboratory errors will not go undetected. A laboratory that fails a proficiency test is required to provide the Department with a written report of the corrective action taken and experimental data demonstrating that the method after the corrective action is capable of meeting the required standard of performance.</p> <p>Finally, the Department's regulatory program is a public process, while ASCLD/LAB's entire program operates under rules of "strict confidentiality."⁸⁴</p> <p>In its 2011 opinion, the Attorney General's office reviewed the Department's authority to independently conduct a separate proficiency testing program that does not conform to the statutorily required proficiency testing program.⁸⁵ The AG noted that the Department had found many shortcomings in the ASCLD/LAB proficiency test guidelines and has continued to operate a separate program. The AG concluded that the Department has the authority to impose its own, separate proficiency test requirements.</p> <p>The ISOR concludes with the claim, "The requirements are set forth in these regulations in a manner sufficient to accommodate those laboratories that are not currently accredited." This claim immediately followed the discussion in the ISOR of the appropriateness of substituting the voluntary ASCLD/LAB proficiency testing requirements for current state-level oversight. Ignoring the many shortfalls of the ASCLD/LAB program, it is indisputable that the program does not apply to laboratories that are not accredited. Accordingly, the claim in the ISOR that the regulations are "sufficient to accommodate those laboratories that are not accredited" is puzzling. The puzzle is solved by referring to the version of the ISOR that was included with the committee's submission of the proposed regulations to the California Health and Human Services Agency.⁸⁶ The ISOR here explains the sufficiency of the requirements of the proposed regulations by</p>	
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	<p>referencing the “justification section 1216.1 (a)(3)” for additional comments. This section cites Health and Safety Code Section 100702, which describes certain statutory proficiency test requirements. As noted in the comments under former Section 1216.1 (a)(3), now renumbered as “1216.1 (a)(2),” the statutes here are not clear and will require clarification and specification in regulation. Accordingly, the regulations pertaining to proficiency testing as proposed by the committee do not accommodate laboratories that are not currently accredited any more than they accommodate the accredited labs.</p> <p>The ISOR here does not discuss or even mention the review committee’s recent revision to Section 1216.1 (a)(2), which would require laboratories to direct proficiency test providers to submit external proficiency test results to the Department. As noted in the comments under Section 1216.1 (a)(2), the committee’s proposed language does not describe what the Department will do with the submitted data, which creates clarity issues. Accordingly, even with this change, the regulations do not clearly require any state-level, external oversight of a laboratory’s performances on external proficiency tests. This oversight is a completely standard component of any competent laboratory regulation program. The self-regulation scheme proposed by the committee wherein each laboratory evaluates its own performance is completely inadequate.</p> <p>The rulemaking record⁸⁷ shows that the Department has stated that it must retain its current authority to evaluate laboratory proficiency test results in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d) and to enforce the law and regulations as required by Health and Safety Code §100725. The Department’s current oversight here provides an objective, external, independent assessment of the competency of the laboratories. This establishes the scientific validity of the chemical testing in support of the State’s drunk driving laws. The Department’s current regulatory authority to evaluate the competence of a laboratory’s methods using proficiency test results is consistent with the Department’s mandated responsibility to enforce its regulations (cf. H&S Code §100725).</p>	
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		<p>The committee has not demonstrated by substantial evidence how the revisions proposed for this section, which remove any state level or external oversight of laboratory proficiency tests, will effectuate the purpose of the statutes (H&S Code § 100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
1:100	Section 1220.2 (a)(1)	<p>Section 1220.2 (a)(1)</p> <p>Clarity/Consistency – The committee has proposed a revision here to state that the calibration requirements in the regulations apply to an “instrument” and not to the “method.” The proposed revision is not consistent with other requirements of the regulations. As described under Section (a), each of the listed standards of procedure applies to the “method.” Calibration is a process that utilizes all of the procedural steps of a method. Accordingly, it is the “method” that is calibrated. As described under Section 1220.3 (a)(5), when the analysis of the quality control reference material, which is also processed using all of procedural steps of a method [cf. Section (a)(2)], yields out-of-control results, the “method” is considered to be in error. Also, for wet chemistry methods (e.g., Smith-Widmark diffusion oxidation method), there is no “instrument”.</p> <p>There are also several other clarity issues. The term “calibrate” should be defined. Also, the current definition of the term “instrument” [current Section 1215.1 (j)] would be repealed with the committee’s proposed revisions. The use of the plural form of the word “standards” is potentially confusing. It implies multi-level calibration. Some laboratories analyze a single standard concentration. The committee must correct these clarity and consistency issues.</p>	
1:101	Section 1220.2 (a)(1)(A)	<p>Section 1220.2 (a)(1)(A)</p> <p>Clarity/Necessity – The committee proposes here to add the statement that the definition of the secondary alcohol standard, “applies to</p>	

		<p>prepared or purchased solutions.” This amendment is unnecessary since the current regulations do not preclude the use of a “purchased” material. In fact, the subsequent section, current Section 1220.2 (a)(1)(B) refers to “secondary alcohol standards...whether prepared or acquired...” The added phrase, “which, for the purposes of these regulations...” is awkward and adds nothing to the requirements of the regulations. Also, the terminology “secondary standard” here implies the existence of a “primary standard,” but as discussed below under the comments to Section 1220.2 (a)(1)(B), the revisions proposed by the committee would apparently provide the laboratory with an option that eliminates the primary standard. As a consequence, the reference to a “secondary” standard here creates clarity issues. Finally, there is a punctuation problem in that the coma should precede the word “which.”</p> <p>The committee has not demonstrated by substantial evidence the need for the proposed revision to effectuate the purpose of the statutes.</p>	
<p>1:102</p>	<p>Section 1220.2 (a)(1)(B)</p>	<p>Section 1220.2 (a)(1)(B)</p> <p>Clarity – The committee proposes here to add language allowing a laboratory to “purchase (NIST)88 traceable secondary alcohol standards.” This creates clarity issues. The term “NIST traceable secondary alcohol standard” is inherently unclear. First, the terminology here combines a term, “secondary alcohol standard” that is probably used only in California regulations, with the term “NIST traceable.” No vendor produces “NIST traceable secondary alcohol standards.” Commercial NIST traceable alcohol reference materials are available.⁸⁹ However, NIST (National Institute of Standards and Technology) currently does not have any specific criteria or protocol to define, “NIST traceability” for aqueous alcohol materials. Vendors may sell “NIST traceable” products, but there are no procedures or standards in place to check or verify the vendors’ claims of traceability. In order to include provisions in the regulations that permit the use of “NIST traceable” reference materials without independently determining the concentrations of these materials, the regulations would have to set forth procedures and standards to authenticate the claim of NIST traceability. [See also comments under Section 1215 (p)].</p>	

		<p>There is another significant clarity issue with the committee’s amendments. The proposed language that describes the option to “prepare a secondary alcohol standard using a direct oxidimetric method, which employs a primary standard, such as the NIST potassium dichromate” is incorrect. The secondary alcohol standard solutions are not “prepared” by an oxidimetric method. They are prepared by dilution of pure alcohol standards. When a regulation uses language incorrectly it does not comply with the clarity standard under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(4)].</p> <p>Presumably, the committee intended here to retain the current requirement for the laboratory to determine the concentrations of standards prepared in-house using a direct oxidimetric method which employs a primary standard, such as United States National Bureau of Standards potassium dichromate. However, the language of the section is now so mangled, that this important requirement has been eliminated. The committee obviously must correct these clarity issues.</p> <p>There are also several errors in the committee’s ISOR. As noted above, the statement, “For the past 30 years, CA laboratories have been required by regulation to prepare their own secondary alcohol standards using a direct oxidimetric method.” is incorrect. Again, the secondary standards are not “prepared” by an oxidimetric method. They are prepared by dilution of pure alcohol standards. The statement, “These secondary standards were then utilized to check the calibration of the instruments.” suggests that there is some prior, independent calibration procedure. This is not correct. As required by regulations [Section 1220.2 (a)(1)], the secondary alcohol standards are used to calibrate the method.</p>	
<p>1:103</p>	<p>Section 1220.2 (a)(1)(C)</p>	<p>Section 1220.2 (a)(1)(C)</p> <p>Clarity/Consistency – The committee proposes here to add language requiring the laboratory staff to “verify the concentration of any new secondary standard used in the method by analyzing the new secondary standard concurrently with a NIST standard reference material.” The proposed language here is vague in that it doesn’t specify the particular NIST standard used, the method used to “verify” the concentration of the</p>	

		<p>secondary standard, the qualifications of the “forensic alcohol laboratory personnel” (an undefined term) verifying the secondary standard, the criteria for verification, or even what “verify” means.</p> <p>Based on the committee’s discussions, it seems likely that the committee was referring to NIST aqueous alcohol standard reference materials analyzed using the laboratory’s forensic alcohol method. All forensic alcohol methods are relative methods. They require calibration based on a comparison of method responses for an unknown sample and a known standard. Accordingly, the proposal here to verify the concentration of a new secondary standard, using the forensic alcohol method would necessarily involve a comparison of two aqueous alcohol samples.</p> <p>However, aqueous alcohol solutions, whether prepared or purchased are labile, subject to evaporative losses. As a result, using one aqueous standard to verify another can introduce errors. The current regulations address this issue by requiring that each new lot of secondary standard must be referenced back to a true primary standard using the direct oxidimetric method (hence the name “secondary” alcohol standard). In terms of the analytical chemistry involved here, the direct oxidimetric method is an absolute method. The concentration of the secondary standard is determined directly based on the mass of the primary standard used and known reaction stoichiometry. The primary standard must have several critical characteristics. It must be very pure, very stable, have a relatively high molecular weight, and can be easily weighed.</p> <p>The primary standard NIST potassium dichromate possesses all four characteristics. Alcohol is not a suitable primary standard. Primary standards are commonly employed in analytical chemistry to ensure the highest levels of accuracy. While there could be value in requiring the analysis of a NIST SRM ethanol standard or a commercial certified reference material to evaluate method bias, analyzing each lot of secondary standard against a primary standard using the direct oxidimetric method ensures greater accuracy than any forensic alcohol method.</p> <p>There are several errors in the committee’s ISOR, which individually</p>	
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	<p>may be minor, but taken together suggest a fundamental lack of understating of the regulations and science behind the calibration of a forensic alcohol method. As noted in the comments under Section 1220.2 (a)(1)(B), the statement in the ISOR that “secondary standards are then utilized to check the calibration of the instruments used for forensic alcohol analysis” suggests that there is some prior, independent calibration procedure. This is not correct. As required by regulations [Section 1220.2 (a)(1)], the secondary alcohol standards are used to calibrate the method. As discussed above in the comments under Section 1220.2 (a)(1)(B), the statement, “Currently, laboratories make their own secondary standards using a direct oxidimetric method.” is incorrect. The standards are not “made” by an oxidimetric method. They are prepared by dilution of pure alcohol. The statement, “the regulations currently allow for a 5% error rate in the preparation of these solutions” is completely incorrect. The regulations do not set forth any “error rate” requirements for the preparation of the standards used to calibrate the method. The regulations [Section 1220.1 (a)(1)] do require the forensic alcohol method to be accurate and precise within plus or minus 5%. This standard of performance requirement applies to the entire method including aliquoting the biological sample, sample dilution, sample transfer, instrumental analysis, calculating, and reporting. The uncertainty in the concentration of the secondary standards contributes to the total error, but certainly much less than 5%. The ISOR then contrasts the fictitious “5% error rate” with “established error rate of less than 1.2% for all concentration levels” for the NIST ethanol-water SRMs. Here it can be noted that listed NIST uncertainties are based on gravimetric preparation. More importantly, the critical issue is not the uncertainty of the NIST SRM, but rather the uncertainty of the forensic alcohol method used to “verify” the secondary alcohol standards. Here, the ISOR claims that the analysis of the secondary standard by the forensic alcohol method represents “a final verification and most accurate test of the secondary standards”. The accuracy of the forensic alcohol method depends on the accuracy of the standards, but then introduces many additional sources of uncertainty. Again, Section 1220.1 (a)(1) sets the accuracy requirements for the entire method at plus or minus 5%. Laboratory staff should establish uncertainty budgets for each laboratory method, but the 5% figure can be used as an estimate and this would indicate that the relative uncertainty in the</p>	
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		<p>verification of the secondary standard using the method for forensic alcohol analysis would be no better than 5%. The Department's uncertainty budget for the direct oxidimetric method of analysis indicates an expanded uncertainty of 2%. This clearly shows that the direct oxidimetric method is the more accurate test of the secondary standards.</p> <p>Finally, the ISOR notes that the SRM "produced by NIST is clearly of a higher quality, and is much more accurate than any of the secondary standards the state, city, or private laboratories currently produce." This may or may not be true,⁹⁰ but it's not a meaningful comparison. Secondary alcohol standards are used to calibrate the method. The regulations as revised by the committee do not require or even permit⁹¹ a laboratory to use the NIST SRM as the secondary alcohol standard used to calibrate the method. The role of the NIST SRM is limited to "verifying" the laboratory's secondary standards, whatever that means.</p> <p>The committee has not demonstrated by substantial evidence how the amendment adding the requirement to "verify" the concentration of the secondary standards eliminates the need to establish the concentration based on a primary standard using the direct oxidimetric method [cf. current Section 1220.2 (a)(1)(B)] or how the proposed revision will effectuate the purpose of the statutes which are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:104</p>	<p>Section 1220.2 (a)(2)</p>	<p>Section 1220.2 (a)(2)</p> <p>Clarity/Necessity – The committee apparently intended here to "clarify" the requirements for the analysis of a blank and secondary standard. The ISOR states that the subsection was amended because "the original language is vague as to when the blank and secondary standard can be analyzed in a given day, and does not address situations where multiple instruments are in use." The review committee did not discuss any situations where the current language caused any actual confusion here and in any case, the committee's proposed amendments introduce new clarity problems. The reference to the analysis of standards "concurrently or prior to analysis of subject samples" is vague. In all methods, individual samples are analyzed one at a time in serial fashion.</p>	

		<p>It is impossible to analyze samples “concurrently.” In practice, most laboratories’ methods include the analysis of standards at the beginning of the run, but some laboratories’ methods describe the analysis of additional standards at the conclusion of the run. The later practice would apparently be prohibited with the committee’s proposed revisions. The reference to the analysis of standards on “any instrument used” is vague especially in view of the fact that the regulations no longer define the word, “instrument.” (Note: with the Department’s current regulatory program, each instrument is treated as a separate method, i.e., the use of two instruments would mean the laboratory had two methods.)</p> <p>The ISOR also states, that “requiring blank and secondary sample analysis (sic) be performed on each instrument used for analysis...provides the most accurate approach to determining an instrument’s accuracy.” The references here to “secondary sample analysis” and “determining an instrument’s accuracy” again suggest a lack of understanding of the science behind the calibration of a forensic alcohol method. As required by Section 1220.2 (a)(1), the analysis of the secondary alcohol standard is used to calibrate the method, not to determine an instrument’s accuracy.</p> <p>The committee has not demonstrated by substantial evidence how the revisions proposed for this section will effectuate the purpose of the statutes which are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:105</p>	<p>Section 1220.2 (a)(2)(A)</p>	<p>Section 1220.2 (a)(2)(A)</p> <p>Necessity – The committee proposes to repeal this section, which requires that the blank and secondary alcohol standard samples shall be taken through all steps of the method used for the forensic alcohol analysis of samples. The ISOR claimed that the same requirements are provided under Section 1220.2 (a)(2). However, the cited section requires only that a “blank and secondary standard shall be analyzed...”; it doesn’t specifically require that that a “blank and secondary alcohol standard samples shall be taken through all steps of the method. Accordingly, it is appropriate to retain requirements of Section 1220.2</p>	

		<p>(a)(2)(A).</p> <p>The committee has not demonstrated by substantial evidence how the repeal of his section will effectuate the purpose of the statutes, which is to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
1:106	Section 1220.2 (a)(3)	<p>Section 1220.2 (a)(3)</p> <p>Clarity – The committee proposed no changes to this section. There is a clarity issue with the current language. This section imposes two completely separate requirements (i.e., the analysis of a quality control reference material and the duplicate analyses of unknown case samples).</p> <p>These two requirements are not related and for clarity, the two different requirements should be stated under separate sections. Also, the word “section” should be shown in lower case, since this is consistent with the current format used in the California Code of Regulations.</p>	
1:107	Section 1220.2 (a)(4)	<p>Section 1220.2 (a)(4)</p> <p>Clarity - The committee proposed no changes to this section. This section should probably be revised to substitute “forensic alcohol analysis” for “alcohol analysis” for clarity and to be consistent with the terminology employed throughout these regulations.</p>	
1:108	Section 1220.2 (a)(5)	<p>Section 1220.2 (a)(5)</p> <p>Necessity – The committee has proposed to repeal the requirement that all instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision. The ISOR claims that the requirements here are “redundant and unnecessary given the provisions above. These provisions will ensure instruments are in good working order and checked for precision.” The committee’s earlier comments⁹² clarified that the “provisions above” are the other</p>	

		<p>procedural standards under Section 1220.2. The committee’s conclusion that the referenced procedural standards will ensure that instruments are in good working order and routinely checked is unwarranted. Even when a laboratory follows the proper procedural steps (i.e., analysis of blanks and standards, analysis of quality control samples, duplicate analyses of samples, etc.), the instruments and equipment still obviously need to be in good working order. This status should be routinely checked. Requirements for instrument maintenance and periodic checks are commonly included in lab regulations and in the ISO-IEC 17025 standards.⁹³ They are included in the CLIA⁹⁴ regulations. The Department currently requires laboratories to include descriptions of maintenance and accuracy check procedures in their written method descriptions. These requirements should be spelled out in the regulations. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes [H&S Code § 100703 (d)], which requires the regulations to ensure the competence of the laboratories to perform forensic alcohol analysis.</p>	
1:109	Section 1220.3 (a)(1)	<p>Section 1220.3 (a)(1)</p> <p>Clarity/Necessity - The committee’s proposed revision to change the lower limit of the concentrations allowed for the quality control material is consistent with the changes in the per se and presumptive blood alcohol concentrations in the Vehicle Code. There are still clarity issues in the section. The reference to a “suitable” quality control material is inherently vague in that the regulations do not specify what is suitable and what is not. There are also the continuing place entity issues here with the requirement that a laboratory (a place) “shall make or acquire” and then “analyze” a quality control reference material.⁹⁵ The place/entity issue must be addressed in the regulations in order to effectuate the purpose of the statutes.</p>	
1:110	Section 1220.3 (a)(2)	<p>Section 1220.3 (a)(2)</p> <p>Clarity/Necessity – The intent of the committee’s proposed revision, which is to clarify that the concentration of the quality control sample should be determined to three decimal places, is appropriate, however,</p>	

		the proposed language is awkward and again, there are place entity issues associated with the requirement that a laboratory (a place) “shall determine a mean value...”.	
1:111	Section 1220.3 (a)(4)	<p>Section 1220.3 (a)(4)</p> <p>Clarity/Necessity – The committee here proposes to revise the requirement for the analysis of a quality control material to include analyses of the material at the beginning and the end of the run. There are clarity and necessity issues with the committee’s proposed revisions. Since under Section 1215.1 (h), a sample is defined as a representative portion (singular) of the material being analyzed, the reference here to a sample (singular) being analyzed twice is awkward and probably not clear. Also, while the forensic alcohol methods employed by California laboratories often include the analyses of at least two replicates of a quality control reference material, this is not always the case. Increasing the required frequency of the analyses of a quality control reference material will need justification, since there were no reported problems with the current regulations, which require only a single analysis of the quality control reference material. The committee has not demonstrated by substantial evidence the need for the proposed revision to effectuate the purpose of the statutes.</p>	
1:112	Section 1220.4 (a)	<p>Section 1220.4 (a)</p> <p>Consistency – The committee proposed no changes to this section. This creates a significant consistency issue. Section 1220.4 (a) requires that “all analytical results shall be expressed in terms of the alcohol concentration in blood”. This requirement is not consistent with the proposed new provisions under Sections 1220.4 (a)(1) and 1220.4 (f), which will permit the expression of breath test results as breath alcohol concentrations. The committee must resolve this inconsistency.</p>	

<p>1:113</p>	<p>Section 1220.4 (a)(1)</p>	<p>Section 1220.4 (a)(1)</p> <p>Clarity/Consistency – The committee proposes here to define the symbols grams %, %, and % (W/V) as abbreviations of “grams per 100 milliliters of blood” instead of the current “grams per 100 milliliters of liquid.” The ISOR states that, “The word “liquid” was changed to “blood” to be consistent with the Vehicle Code.” In fact, the Vehicle Code does not employ a symbol to represent grams of alcohol per 100 mL of blood. Instead, it describes blood alcohol concentrations using the words percent by weight of alcohol in his or her blood.</p> <p>The change in the definition of the symbols creates a consistency issue. The symbol “grams %” is used in Section 1221.2 (a)(2)(A) to set concentration limits for “alcohol water concentrations and/or dry-gas reference samples of alcohol.” While as discussed below in the comments for Article 6 (current Article 7), the committee’s proposed revisions to Section 1221.2 (a)(2)(A) create clarity issues, it is still clear that the “water concentrations” or “dry-gas reference samples of alcohol” are not concentrations of alcohol in blood. Redefining the symbol “grams %,” as a blood concentration unit creates a consistency issue.</p> <p>The committee also proposes to allow the use of the symbols grams %, %, and % (W/V) to represent units of grams per 210 liters of breath. The use of the percent symbol (“%”) to represent units of grams per 210 liters appears to be dimensionally incorrect since percent literally means parts per hundred. It would appear to be preferable to provide distinct units for abbreviating the distinct quantity, grams per 210 liters of alveolar breath.</p>	
<p>1:114</p>	<p>Section 1220.4 (c)</p>	<p>Section 1220.4 (c)</p> <p>Clarity/Necessity – Section 1220.4 (c), provides that blood alcohol results less than 0.01% for samples from living subjects may be reported as “negative.” The committee proposes to eliminate the qualifier “blood”, thus permitting any alcohol concentration in living subjects less than 0.01% to be reported as negative. It is not clear that this revision is necessary. The regulations describe four types of samples: blood, breath, urine, and tissue. The provision of Section 1220.4 (c) would not apply to tissue samples, which are reported in units of weight amount of</p>	

		<p>alcohol per unit weight of the specimen [cf. Section 1220.4 (g) and urine alcohol results must be converted to blood alcohol concentrations before reporting [cf. Section 1220.4 (e)]. Accordingly, the provisions of this section would apply to only blood or breath samples. As was discussed in the comments under Section 1220.4 (a)(1), there are clarity issues associated with using the % abbreviation (i.e., parts per 100) to report breath alcohol concentration units, which are in units of in parts per 210,000. The same concerns would apply here. Based on this, the special provisions for reporting results less than 0.01% level would apply only to blood alcohol results and consequently the proposed revision is unnecessary.</p> <p>The ISOR claimed that the word “may” was retained because, “Different laboratories may be able to satisfy greater reliability of analysis at lower levels. Also as technical advances occur, more laboratories may have a greater capacity to test for smaller levels, and this language would apply.” The comments here again evidence a misunderstanding of the science and the regulations. Section 1220.4 (b) requires that analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present. Based on this provision of the regulations, a result less than 0.01 grams%, would be reported as 0.00 grams%. Section 1220.4 (c) provides the option (i.e., “may be reported”) of reporting such a result as “negative.” These are the only two choices. A laboratory’s ability “to test for smaller levels” is not an issue here. The committee may at some point wish to address measurement issues such as limits of detection and limits of quantification, but to date it has not done so and this should not be part of the discussion of the revisions proposed for this section.</p>	
<p>1:115</p>	<p>Section 1220.4 (d)</p>	<p>Section 1220.4 (d)</p> <p>Clarity/Necessity – This section provides that blood alcohol results less than 0.02% for samples from post-mortem subjects may be reported as “negative.” The committee proposes to remove the qualifier “blood.” The ISOR explains that the intent here was “to make this section inclusive of all sample types as is appropriate.” The proposed change is unnecessary. As discussed in the comments to Section 1219.2 (a),</p>	

		<p>which describes the collection of urine samples from living subjects, there are no provisions in the regulations for the collection of post mortem urine samples. Obviously, there are no provisions for the collection of breath samples post-mortem. The provisions of Section 1220.4 (d) would not apply to post-mortem tissue samples, since again the results here are reported in units of the weight amount of alcohol per unit weight of the specimen [cf. Section 1220.4 (g)]. Accordingly, Section 1220.4 (d) can only refer post-mortem blood samples and consequently the committee’s proposed revision is unnecessary.</p>	
1:116	Section 1220.4 (e)	<p>Section 1220.4 (e)</p> <p>Clarity – The committee proposed no changes to this section. There is a minor clarity issue with the current language. The two separate (although related) requirements to: 1) convert a urine alcohol result to a blood concentration; and 2) employ a specific calculation to accomplish this conversion should be presented as two separate sentences.</p>	
1:117	Section 1220.4 (f)	<p>Section 1220.4 (f)</p> <p>Clarity – The committee’s proposed revision is intended to eliminate the requirement to convert a breath alcohol concentration to an equivalent blood alcohol concentration. This is consistent with the changes to Vehicle Code Section 23152 (b). The committee’s proposed language here, “Analytical results for breath shall be based...” is not clear. Since Section 1220.4 is titled Expression of Results,” it would appear to be preferable to replace “based” with “expressed” or perhaps “reported.”</p>	
1:118	Article 6. Requirements for Breath Alcohol Testing (Current Article 7)96	<p>Article 6. Requirements for Breath Alcohol Testing (Current Article 7)96</p> <p>Necessity - The proposed change in the article title from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since as noted in the comments under Section 1215 (c), the words “analysis” and “testing” are synonymous. The review committee claimed that the proposed change here was intended to distinguish the analysis of blood samples in a laboratory setting from the testing of breath samples by law</p>	

		<p>enforcement, but the committee has not demonstrated by substantial evidence how the proposed change accomplishes this purpose. As a consequence the committee has not shown that the proposed change is necessary to effectuate the purpose of any statute.</p>	
1:120	Section 1221.	<p>Section 1221.</p> <p>Necessity/Consistency - The proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since as noted previously, the words analysis and testing are synonymous and do not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples.</p> <p>Section 1221 should be revised 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 and procedures for training instrument operators. The requirement here would be consistent with the requirement under Section 1220 (b) for a laboratory to prepare written descriptions of its methods for forensic alcohol analysis.⁹⁷</p> <p>These written descriptions should be filed with the Department to ensure proper accountability. The regulations under Article 6 (current Article 7) would need to clarify the specific requirements for the contents of these written descriptions. The review committee must consider the need for these requirements in order to effectuate the purpose of the statutes.</p>	
1:121	Section 1221.1 (a)	<p>Section 1221.1 (a)</p> <p>Necessity/Clarity/Consistency/Authority/Reference – As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary. The committee also proposed a revision here that would require breath alcohol testing to be performed only with instruments which “meet the requirements specified in Health and Safety Code §100701.” The problem here is that the cited Health</p>	

	<p>and Safety Code Section does not directly establish any performance requirements for instruments. The referenced statute requires laboratories to ensure that breath alcohol instruments and calibrating devices used in testing are listed in the Conforming Products Lists published by the US Department of Transportation (DOT). As such the cited statute imposes a requirement on laboratories not on the instruments used. This creates a consistency issue.</p> <p>There are also significant scope and authority problems with the proposed amendment. Breath alcohol analysis is typically performed by law enforcement personnel away from the laboratory. The proposed revisions here would impose requirements on law enforcement by specifying the equipment that must be used when performing breath alcohol analysis. It does not appear that the Department of Public Health has the statutory authority and reference to impose regulatory requirements on law enforcement when performing breath alcohol analysis either directly or indirectly by authorizing a laboratory to impose these requirements. This authority was formerly provided by H&S Code §100715,98 which authorized the Department to adopt regulations describing the procedures used by law enforcement agencies when analyzing breath samples and required law enforcement to follow these procedures. This statute was repealed with the 2004 legislation (SB 1623, Johnson, Chapter 337). The aforementioned H&S Code §10070199 appears to give the Department the authority to regulate laboratories, but not law enforcement agencies or personnel.</p> <p>The Department's Office of Legal Services (OLS) reviewed the Department's authority to regulate law enforcement personnel performing breath alcohol analysis and concluded that as a result of the 2004 revisions to the statutes, the Department's authority is strictly limited to the regulation of laboratories. OLS presented its findings to the review committee at its January 28, 2008 meeting.¹⁰⁰</p> <p>There are also practical issues here. As provided by the options included under Section 1221.1 (b), the analyses conducted by law enforcement personnel may not even be under the jurisdiction of a forensic alcohol laboratory. Accordingly, it is not clear that the laboratory will have any direct control over breath alcohol analysis. Absent some</p>	
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		<p>jurisdictional control of breath testing, there is no way for the laboratory to “ensure” that the breath testing equipment used meets the DOT standards.</p> <p>There is another clarity issue. The text of the committee’s proposed revisions reads, “Breath alcohol analysis testing shall be performed only with instruments and related accessories calibrating units/devices which meet the standards of performance set forth in these regulations requirements specified in Health and Safety Code Section 100701.” The word “accessories” is included in the current regulations and should not be underlined here. More importantly, the regulations would now refer to “instruments and accessories calibrating units/devices.” The noun “accessories” here is apparently used incorrectly as an adjective. When a regulation uses language incorrectly it does not comply with the clarity requirements under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(4)].</p>	
<p>1:122</p>	<p>Section 1221.1 (b)</p>	<p>Section 1221.1 (b)</p> <p>Clarity/Necessity/Authority/Reference – As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since the words analysis and testing are synonymous and do not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples. The provisions of this section that permit a forensic alcohol laboratory to have jurisdiction over breath alcohol analysis when performed by law enforcement personnel create place/entity issues, since a laboratory (a place) can’t have jurisdiction over anything. There would also appear to be additional problems when the laboratory is operated as a non-governmental, private business. The former licensing procedures solved both problems. It transformed a laboratory location into an entity. It also gave the non-governmental laboratory entity an official duty making it comparable to a governmental agency capable of applying the law and assuming jurisdiction over the breath alcohol analysis activities.</p> <p>Besides the place/entity issue, there is also an authority/reference issue. Since breath alcohol analysis is invariably performed by law enforcement personnel, the language here that requires that breath alcohol analysis must be under the jurisdiction of a governmental</p>	

		agency or a forensic alcohol laboratory again appears to impose a requirement on law enforcement. As noted in the comments under Section 1221.1 (a), with the changes in the statutes, it is not clear that the Department has the authority to impose such requirements with its regulations either directly or indirectly as proposed here by authorizing a laboratory to impose the requirements. There is also a clarity issue with the phrase “may be used” and the reference to “places other than forensic alcohol laboratories” is not clear especially since virtually all breath alcohol analysis is conducted away from the laboratory.	
1:123	Section 1221.1 (b)(1)101	<p>Section 1221.1 (b)(1)101</p> <p>Clarity/Necessity - As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary. Moreover, the entire section is unnecessary and it should be repealed. The undefined reference to “immediate analysis” (now “immediate testing”) is unclear since there are no references in the regulations to non-immediate analyses or tests. Similarly, the language here limiting the analysis to “samples collected by direct expiration of the subject into the instrument” is also unclear since there are no provisions in the regulations for alternative modes of sample collection for analysis. The language here had meaning at one time when the analysis of a captured breath sample for latter analysis was authorized under the regulations.¹⁰² This authorization was removed in 1985 and the references to “immediate analysis” of a breath sample here and also under Section 1221.1 (b)(2) are now vestigial and should be repealed.</p>	
1:124	Section 1221.1 (b)(2)	<p>Section 1221.1 (b)(2)</p> <p>Clarity/Necessity - As discussed previously, the proposed change from “analysis” to “testing” is unnecessary. Also, as discussed in the comments under Section 1221.1 (b)(1), the word “immediate” must be stricken since it is undefined and has currently no meaning.</p> <p>Section 1221.1 (b) (2) is intended to exempt breath alcohol analysis from the requirements of Article 5. As noted in the comments under Article 1, the inclusion of samples of “breath” in the definition of forensic</p>	

		<p>alcohol analysis could be interpreted to mean that all subsequent references to forensic alcohol analysis in the regulations apply to the analysis of breath samples. This would include the requirements under Article 5, Methods of Forensic Alcohol Analysis. The exemption provided here may partially address this issue. More likely, the contradictory language in the regulations creates clarity issues. Also, the exemption here could be interpreted as not applying to a breath test performed by laboratory staff. Should this unlikely event occur, the test would apparently need to comply with all the requirements of Article 5. This would be impossible from a practical standpoint and certainly not the intent of the regulations.</p>	
<p>1:125</p>	<p>Section 1221.1 (b)(3)</p>	<p>Section 1221.1 (b)(3)</p> <p>Clarity/Necessity - The requirements for collecting a breath sample are currently included in Section 1219.3, under Article 5, "Collection of Samples". The committee has proposed to relocate the requirements here. Current Article 5, which describes the collection of samples, is a more appropriate location for these requirements. Besides relocating the section, the committee proposes to delete the specific language requiring that the collected breath sample shall be "expired breath which is essentially alveolar in composition" and also the specific requirement that the subject must be continuously observed for 15 minutes prior to collecting a sample.</p> <p>The analysis of an alveolar breath sample is critical for accurate testing. The committee has proposed to describe this requirement in three sections under Article 1, Definitions. As a general rule, definitions in regulations should not be relied upon to establish requirements.</p> <p>Moreover, the very important requirement of collecting an alveolar sample would now be stated in a tortuous thread that requires the reader to extend the requirements of the definition of a breath test to the definition of a "sample," and the definition of "alveolar" to the process of "sampling" as part of a breath test.¹⁰³ As a consequence, the critically important requirement to collect an alveolar sample is not clearly stated. The language requiring the collection and analysis of an alveolar breath sample must be retained here under Article 6 (current Article 7).</p>	

		<p>The elimination of the requirement for the continuous observation of the subject for 15 minutes prior to the test is very problematic. The ISOR states, “The continuous observation” is vague and lacks specificity as to how that will be accomplished. The new wording clearly requires that no test will be performed in (sic) less than 15 minutes after a subject eats, smokes, etc., in order to ensure a more accurate test.” In fact, there are significant clarity issues with the proposed new language which would read: “The breath sample shall be collected only after fifteen minutes during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.” There are many questions here. When does the 15 minutes start? Does the specific reference to 15 minutes, mean that a pretest period of 16 minutes would not be acceptable? How would the breath instrument operator assure that none of the prohibited activities has occurred without continuously observing the subject? How would the breath instrument operator document this?</p> <p>The prohibited activities during the 15-minute period (i.e., “the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.”) can introduce alcohol or interfering substances into the oral cavity. It is imperative that the oral cavity be free of alcohol in order to obtain an accurate test result. A discontinuous observation period (e.g., three 5-minute observations interspersed during a 20-minute period) could result in the operator failing to observe one of the prohibited activities. Eliminating the requirement for continuous observation of the subject could result in analytical errors and will likely lead to legal challenges to the accuracy of breath testing results. The committee has not demonstrated by substantial evidence how the proposed revisions to this section are necessary to effectuate the purpose of the statutes.</p> <p>Finally, the requirements here should be amended to add the use of mouth spray, gum, or mints to the list of prohibited activities during the 15-minute observation period prior to the collection of a breath sample. Each of these activities could potentially interfere with breath alcohol analysis and the activities can easily be monitored. Prohibition of these activities could be accomplished by adding an expanded definition of the</p>	
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		<p>term, “ingest” or by simply prohibiting the subject from putting anything in his/her mouth.</p>	
<p>1:126</p>	<p>Sections 1221.2 and 1221.3</p>	<p>Sections 1221.2 and 1221.3</p> <p>Clarity/Necessity – The committee proposes to repeal Section 1221.2, “Standard of Performance” and Section 1221.3, “Approved Instruments.” The ISOR notes that the two sections “were repealed because they are redundant. The specifications set out here are outlined¹⁰⁴ in California Health and Safety Code Section 100701 and referenced in Section (a) of these regulations.” As noted in the comments for Section 1221.1 (a), there are authority and scope issues with the proposed changes to this section. Assuming, the authority and reference issues could be resolved, there is still a clarity issue created by the committee’s proposal to repeal Sections 1221.2 and 1221.3. Current Section 1221.2 (a) sets requirements for the standard of performance for instruments used for breath alcohol analysis by requiring that instruments and accessories shall be capable of conforming to the “Model Specifications for Evidential Breath Testing Devices” published by the National Highway Traffic Safety Administration of the U.S. Department of Transportation (DOT). Section 1221.2 (b) clarifies that the ability of instruments to conform to the standard of performance set forth in this section shall be tested by the DOT. Current, Section 1221.3 describes the requirement that the instruments must be named on Conforming Products List published by the DOT.</p> <p>Sections 1221.2 and 1221.3 together clearly describe the standards of performance requirements of breath testing instruments to be used in California. Health and Safety Code Section 100701 simply refers to instruments that are “listed in the conforming products list,” but again in the context of a requirement imposed on the laboratories. The cited Health and Safety Code section does not clearly describe the standards of performance requirements for breath testing instruments or how the requirements are satisfied. These requirements would need to be clarified and made specific with regulations equivalent to current Sections 1221.2 and 1221.3.</p> <p>The committee has not demonstrated by substantial evidence how the</p>	

		proposed repeals of these sections are necessary to effectuate the purpose of the statutes.	
1:127	Section 1221.2 (a) [Current Section 1221.4 (a)]105	Section 1221.2 (a) [Current Section 1221.4 (a)]105 Necessity - As discussed previously, the proposed change here from “breath alcohol analysis” to “breath alcohol testing” is unnecessary and does not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples. As a consequence, the proposed change is not necessary to effectuate the purpose of any statute.	
1:128	1221.2 (a)(1) [Current Section 1221.4 (a)(1)]	1221.2 (a)(1) [Current Section 1221.4 (a)(1)] Necessity - As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary since the two terms are synonymous. This is particularly evident in the proposed wording of this section, which would read, “breath alcohol testing shall include analysis of 2 separate breath samples...” The mixing of the two terms as proposed by the review committee here again reflects the fact that they are completely interchangeable. The ISOR here states that the other change in the section to reference breath alcohol concentrations instead of blood alcohol concentrations was intended to make the “regulation consistent with the enabling legislation.” This is not correct. The changes here were necessitated by changes in the Vehicle Code and subsequent court decisions.	
1:129	Section 1221.2 (a)(2) [Current Section 1221.4 (a)(2)]	Section 1221.2 (a)(2) [Current Section 1221.4 (a)(2)] Clarity/Consistency – The committee’s proposed language here, which refers to “known water solutions or dry-gasses of alcohol,” is so awkward as to be unclear. The committee’s proposed revisions are apparently intended to describe the two types of calibrating units used to determine the accuracy of instruments. The regulations must clearly define the new terms, “water solutions or dry-gasses of alcohol” and	

		<p>must show that in both cases, a gaseous vapor sample is analyzed. There are other clarity issues. The regulations must specify how the concentration of the reference sample is determined and therefore “known.” The regulations must also specify how the reference samples are prepared or obtained and describe the required procedures employed with their use. For example, for a vapor sample from a water-alcohol solution delivered using a wet-bath calibrating unit, the required procedures must include the use of an approved calibrating unit, stepwise procedures for the preparation and determination of the concentration of the aqueous-alcohol reference sample, conversion of the alcoholic concentration of the liquid sample to a breath alcohol equivalent vapor sample concentration, procedures for the delivery of the reference solution to the instrument site, a limitation on the number of uses of a given reference solution, and the need to record the reference solution temperature with each use.</p> <p>The proposed change in wording from determination of accuracy to a “check” of accuracy is inconsistent with the subsequent references under Sections 1221.2 (a)(2)(A), 1221.2 (a)(2)(A)(i),(a)(2)(B), 1221.2 (a)(6), and 1222.1 (a)(5), which retain the language, “determination of accuracy.” Moreover, the proposed change here from “determination” to “check” appears to diminish the significance of the determination of accuracy procedures, which are fundamental to ensuring the competence of breath alcohol analysis.</p> <p>The ISOR states that, “This subsection was amended to specify what types of reference samples are best for checking the accuracy of the instrument...” The description here of the regulations as describing best practices again betrays the committee’s lack of understanding of the role of regulations. Regulations describe standards of performance and procedure that must be complied with under the force of law. The role of regulations here is different than that of voluntary guidelines such as those published by ASCLD/LAB, which may describe best practices, but do not have the force of law.</p> <p>The clarity and consistency issues in this section must be resolved by the committee.</p>	
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<p>1:130</p>	<p>Section 1221.2 (a)(2)(A) [Current Section 1221.4 (a)(2)(A)]</p>	<p>Section 1221.2 (a)(2)(A) [Current Section 1221.4 (a)(2)(A)]</p> <p>Clarity/Necessity - As noted in the comments for Section 1221.2 (a)(2), the two types of reference samples, which are awkwardly referred to here as “water concentrations and/or 106 dry- gas reference samples of alcohol,” need specific definitions. In both cases, the definitions should show that an alcohol vapor sample is analyzed. Also, the regulations must specify how the “known concentration” and “true value” are determined.</p> <p>The change in the lower limit of the reference sample concentration range to 0.08% is consistent with the changes made to the Vehicle Code, which lowered the per se and presumptive blood alcohol concentrations at which an individual can be prosecuted from 0.10 grams % to 0.08 grams %. The committee also proposed to reduce the upper limit of the concentration range from 0.30% to 0.25%. The ISOR did not discuss this change. However, in the earlier ISOR, included with the committee’s submission of the proposed regulations to the California Health and Human Services Agency,¹⁰⁷ the committee claimed that upper limit of the allowed concentration range was lowered because some instruments are incapable of demonstrating the required accuracy for samples above 0.25 grams%. No scientific evidence was provided to support this claim and it is difficult to understand what information the committee may have relied upon here. The DOT Model Specifications,¹⁰⁸ which describe the procedures used to evaluate all breath instruments used in California, employ aqueous-alcohol reference test samples with a maximum concentration of 0.160 grams %. The committee did not cite any evidence that laboratories in California are preparing and using high concentration aqueous- alcohol reference samples in wet bath calibrating units and the highest concentration for a dry- gas reference sample listed on the DOT Conforming Products List¹⁰⁹ is 0.105 grams% (273.5 ppm).¹¹⁰ Consequently, it is not clear what experimental studies the committee members may have relied upon to reach the conclusion that some instruments are incapable of demonstrating the required accuracy for samples above 0.25 grams%. The committee has not demonstrated by substantial evidence how the proposed revision here is necessary to effectuate the purpose of the statutes.</p>	
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		<p>The ISOR also noted that, “Many laboratories are using NIST traceable dry-gas standards to perform accuracy checks on a regular basis.” The committee, however, did not include any requirement that the reference sample delivered by a dry-gas calibrating unit must be “NIST traceable.” Accordingly, the relevance of this comment in the ISOR is not apparent.</p>	
1:131	<p>Section 1221.2 (a)(2)(A)(i)111 [Current Section 1221.4 (a)(2)(A)(1)]</p>	<p>Section 1221.2 (a)(2)(A)(i)111 [Current Section 1221.4 (a)(2)(A)(1)]</p> <p>Clarity - The committee has proposed revisions here to accommodate instruments that can perform periodic determinations of accuracy automatically without any operator involvement. The reference in the committee’s revised regulations to two categories of breath testing instruments (automatic, manual) will require greater specificity and definition. The committee also proposed to change the assignment of the responsibility for using the results of a periodic determination of accuracy to determine whether an instrument is accurate from the laboratory to a forensic alcohol analyst. While this may appear to solve a laboratory place-entity issue, it raises a new question, namely is there any connection between a law enforcement agency and the laboratory or may an individual forensic alcohol analyst employed by any laboratory independently evaluate the periodic determination of accuracy results for any law enforcement agency in the state. The regulations here must be revised to clarify the specific procedures employed for a periodic determination of accuracy of an instrument.</p> <p>The ISOR states here that, “The change from the entity of a laboratory to an analyst is more specific as to who will make the determination of accuracy.” The reference here to a “laboratory entity” is inconsistent with the definition in the regulations of a laboratory as a place [cf. renumbered Section 1215 (e)].</p>	
1:132	<p>Section 1221.2 (a)(3) [Current Section 1221.4 (a)(3)]</p>	<p>Section 1221.2 (a)(3) [Current Section 1221.4 (a)(3)]</p> <p>Clarity/Reference/Necessity – Again, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary. The committee also revised the wording from, “Breath alcohol analysis shall</p>	

		<p>be performed only with instruments for which the operators have received training..." to "Breath alcohol testing shall be performed only with procedures for which the operators have received training..." 112 The revised language is awkward. The requirement here would perhaps be better stated "Breath alcohol testing shall be performed using procedures..." The language of this section is still not clear, since it appears to describe a limitation on the procedures used, when in fact the limitation is placed on the qualifications of the operator. The word "procedures" or better, "breath alcohol analysis procedures," would need to be defined.</p> <p>The procedures would be specific to an instrument, but would also include agency specific details such as the entry of operator and subject information, instructions given to the subject, the operator's monitoring of the subject before and during the analysis, completion of paperwork, etc.</p> <p>The requirement that "Breath alcohol testing shall be performed only with procedures for which the operators have received training..." again imposes a requirement on law enforcement. As noted in the comments to Section 1221.1 (a), there are authority and reference issues here associated with the regulation of law enforcement personnel performing breath alcohol analysis. The statutes (H&S Code §§ 100700 and 100701) appear to give the Department the authority to regulate laboratories, but not law enforcement agencies or personnel. Moreover, the authority provided under H&S Code §100701 only limits the choice of instruments used, but does not address the "procedures" employed or the training of operators in these procedures.</p>	
<p>1:133</p>	<p>Sections 1221.2 (a)(3), (A) through (D) [Current Sections 1221.4 (a)(3), (A) through (D)]</p>	<p>Sections 1221.2 (a)(3), (A) through (D) [Current Sections 1221.4 (a)(3), (A) through (D)]</p> <p>Necessity – The committee's ISOR comments for this group of subsections, state that, "These subsections were enhanced to more closely resemble the training section for blood alcohol in Title 17." and "The training for breath analysis and for blood analysis are (sic) not identical, of course, but they would now closely resemble each other." It is difficult to understand what the author of the ISOR meant by these comments. Even the reference here to "breath analysis" is inconsistent</p>	

		<p>with the committee’s preference to change all instances of “breath alcohol analysis” to “breath alcohol testing.” More significantly, with the committee’s proposed regulations there is actually no general description of training requirements for laboratory staff in blood alcohol analysis that would serve as a model for the committee’s description of training in breath alcohol analysis. The committee proposed to repeal the current requirement for the analyst to complete a training period in alcohol analysis [repealed Section 1216.1 (f)(2)] and to perform during that training period a minimum of 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol [repealed Section 1216.1 (f)(3)]. The committee retained the description of the specialized training which would allow a person who does not have two years of experience performing forensic alcohol analysis [Section 1216.1 (b)(2)] to qualify as a forensic alcohol analyst. The training described under Section 1216.1 (b)(2) would reasonably be described as high level and intended to allow staff to interpret the results of chemical tests for alcohol. This higher level training can be quite involved. The training offered by the Department of Justice and approved by the Department of Public Health as satisfying the requirements of this section was 40 hours in duration. The instrument operator training described in the proposed regulations is 4 hours in duration [cf. proposed Section 1221.2 (a)(4)(B)]. It does not appear that the requirements under Section 1216.1 (b)(2) informed the committee’s determinations of the training requirements for breath instrument operators in any way. As a consequence, the ISOR does not describe the specific purpose of the proposed revisions to this section and therefore, the committee has not demonstrated by substantial evidence how the proposed revisions to this section are necessary to effectuate the purpose of the statutes.</p>	
<p>1:134</p>	<p>Section 1221.2 (a)(3)(C) [Current Section 1221.4 (a)(3)(C)]</p>	<p>Section 1221.2 (a)(3)(C) [Current Section 1221.4 (a)(3)(C)]</p> <p>Clarity – The committee has proposed to add additional detail describing the requirements for training using the precautionary checklist. The language, “Description of, and adherence to, the Precautionary Checklist.” is not punctuated correctly and is awkward. It would be appropriate to specify the required period of instruction on this subject.</p>	

<p>1:135</p>	<p>Section 1221.2 (a)(3)(D), (i) – (iv) [Current Section 1221.4 (a)(3)(D)]</p>	<p>Section 1221.2 (a)(3)(D), (i) – (iv) [Current Section 1221.4 (a)(3)(D)]</p> <p>Clarity/Necessity – The committee has proposed to add additional detail describing the requirements for the practical experience subject of the breath instrument operator training. This is appropriate, but the proposed language here creates clarity issues. The reference to “screen prompts” is unclear and would need to be defined. The requirement that, “The Precautionary Checklist shall be incorporated into the testing sequence.” is confusing. As defined under Section 1215 (m), the precautionary checklist is “a guide to assist in the operation of a breath instrument.” The checklist, a printed document, summarizes the testing sequence. It is not properly described as “being incorporated into the testing sequence.” Some instruments do try to incorporate the text of the precautionary checklist into the instrument prompts. This is the reverse of the requirement proposed here. There has been some expectation that these instrument prompts may satisfy the requirement of current Section 1222.2 (a)(3)113, i.e., “A precautionary checklist shall be available at the location of each instrument.” However, the regulations appear to describe the precautionary checklist as a record, not a series of screen prompts. This ambiguity of the current regulations is not addressed with the new requirements here. It would also be appropriate to specify the required period of instruction on this subject.</p> <p>The committee has not demonstrated by substantial evidence how the proposed revisions to this section are necessary to effectuate the purpose of the statutes.</p>	
<p>1:136</p>	<p>Section 1221.2 (a)(3)(E) [Current Section 1221.4 (a)(3)(E)]</p>	<p>Section 1221.2 (a)(3)(E) [Current Section 1221.4 (a)(3)(E)]</p> <p>Clarity/Consistency – This section should be titled “Written Examination” to be consistent with the other sections and to explain subsequent references in the regulations.</p>	
<p>1:137</p>	<p>Section 1221.2 (a)(3)(F)</p>	<p>Section 1221.2 (a)(3)(F)</p> <p>Clarity/Consistency/Necessity – The committee has proposed here to add the requirement that the breath instrument operator trainee shall “successfully complete a breath test accurately...” The requirement to “complete a breath test accurately” is not clear since the regulations do</p>	

		<p>not describe how the “accuracy” of the test will be determined. It would appear to be important to include the analysis of simulated or actual breath samples in the training in order to effectuate the purpose of the statutes.</p> <p>The ISOR did not provide a statement of the specific purpose for the adoption of Section 1221.2 (a)(3)(F). The ISOR included a comment for Sections 1221.2 (a)(3), (F) and (G) describing the purpose of the requirement to issue a training certificate. This has nothing to do with proposed adoption of Section 1221.2 (a)(3)(F). As a consequence, the committee’s proposed revision conflicts with the description in the ISOR of the effect of the regulation, which creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p> <p>The proposed revisions to Section 1221.2 (a)(3)(F) include a reference to Section 1221.2 (a)(3)(C). This reference should be preceded by the word “section.” Also, the section should be titled, “Practical Examination” to be consistent with the other sections and to explain subsequent references in the regulations.</p>	
<p>1:138</p>	<p>New Section 1221.2 (a)(3)(G)114</p>	<p>New Section 1221.2 (a)(3)(G)114</p> <p>Clarity/Reference/Necessity – The committee here has proposed to add the requirement that the breath instrument operator shall be issued a certificate upon successful completion of training. There are obviously again place/entity issues here, since apparently the laboratory (“a place”) would be issuing the certificate. It would also appear that there would need to be specific statutory authority to enable any entity to issue a legal “certificate.” Before the 2004 legislation, the Department had specific statutory authority to issue licenses to laboratories. The Department never had statutory authority to issue personal licenses or certificates. The revised statutes do not describe the issuance of any certificates and thus it does not appear that the Department would have the ability to adopt regulations that would authorize and require a laboratory to issue a “certificate” to breath instrument operators. There may be additional problems when non-governmental laboratories are required to issue the certificates.</p>	

<p>1:139</p>	<p>Section 1221.2 (a)(3), after (G)</p>	<p>Section 1221.2 (a)(3), after (G)</p> <p>Necessity - The Department has commented that it would be appropriate to include two more training subjects: 1) legal aspects of breath tests; and 2) any periodic determination of accuracy activities performed by regular instrument operators.¹¹⁵ The review committee should consider the need to include these topics in order to effectuate the purpose of the statutes.</p>	
<p>1:140</p>	<p>Section 1221.2 (a)(4) [Current Section 1221.4 (a)(4)]</p>	<p>Section 1221.2 (a)(4) [Current Section 1221.4 (a)(4)]</p> <p>Clarity/Necessity/Reference – Again, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary and does not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples. This section of the regulations currently requires qualified laboratory staff to supervise the training of breath instrument operators. The word “supervise” as used throughout the regulations implies direct, active, on- site supervision. The committee proposed here to replace the current requirement for laboratory staff to directly supervise the training with a requirement that laboratory staff “develop” the training curriculum. The revised requirement here is so vague that it certainly raises clarity issues. But the language does seem to eliminate the current requirement that laboratory staff shall supervise the training. The regulations as revised by the committee do not describe any role of the laboratory or laboratory staff in conducting the training once the curriculum is “developed.” Removal of the requirement for any supervision of the training, or any laboratory involvement after the initial “development” of the training curriculum, taken together with the removal of State-level (or any external approval) of the training, would eliminate the current scientific oversight of breath instrument operator training.¹¹⁶ Breath alcohol analysis procedures involve scientific measurements performed by generally technically unsophisticated law enforcement personnel. It is essential to maintain direct scientific oversight of breath instrument operator training. The Department has stated that it is critically important to retain the requirement that training in the procedures of breath alcohol analysis must be under the supervision of qualified laboratory staff in order to assure proper scientific oversight of the operator training. This is necessary to ensure that breath alcohol analysis is performed correctly,</p>	

	<p>competently, and consistently in California. Every state directly or indirectly oversees breath instrument operator training. The changes proposed by the committee here and under Article 4 would put California at odds with the rest of the country. The committee has not demonstrated by substantial evidence how the elimination of the requirement for the direct supervision of breath instrument operator training by qualified laboratory staff will ensure the competence of the testing.</p> <p>The committee also proposed eliminating the descriptor, “persons who qualify as” before “forensic alcohol analysts.” The ISOR states, “The phrase ‘of persons who qualify as’ was removed as redundant, thus increasing the clarity of the section.” In fact, it appears that the language “persons who qualify” should be retained. Absent any state-level or any external approval of personnel, the category, “forensic alcohol analyst,” is not a stand-alone entity. A person is “qualified” by an individual laboratory, so the phrase “persons who qualify as” appears to be relevant.</p> <p>The committee also proposed eliminating the requirement that the forensic alcohol analyst must be qualified “in a forensic alcohol laboratory.” For the reasons noted immediately above, this requirement should be retained. In the ISOR, the committee indicated that it was concerned that retaining this language would prevent off-site training. This has never been the case. More importantly, removal of the reference to laboratory appears to now eliminate any requirement for the laboratory to be involved in the training at all. Individual forensic alcohol analysts could apparently provide operator training for any law enforcement agency independent of any particular laboratory.</p> <p>Finally, as discussed in the comments under Article 3 (current Article 4), the committee has not demonstrated by substantial evidence how the proposed added language here, which authorizes the laboratory to “notify” the Department of its training, will ensure the competence of breath alcohol analysis in the absence of the independent authority of a state agency to approve the training.</p>	
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<p>1:141</p>	<p>Section 1221.2 (a)(4)(A) [Current Section 1221.4 (a)(4)(A)]</p>	<p>Section 1221.2 (a)(4)(A) [Current Section 1221.4 (a)(4)(A)]</p> <p>Clarity/Necessity/Reference – The review committee proposed here to eliminate the current authority of the Department to approve a laboratory’s procedures for training and qualifying instructors for breath instrument operator training. To explain the removal of the Department’s current approval authority, the committee’s ISOR, states that, “This subsection as previously written is now obsolete because Section 1218 was repealed.” The author of the ISOR is obviously confused here. Section 1218 was not repealed; it was amended. The ISOR then continues, “In addition, the training curriculum required is spelled out in Section 1216.1 (b). This would appear to make this section redundant as well.” Again, the ISOR author is confused here, seemingly to the point of bewilderment. The training curriculum described under Section 1216.1 (b), covers the specialized training for laboratory staff who do not have two years of experience performing forensic alcohol analysis [cf. Section 1216.1 (b)(2)]. This is completely different from the training provided to breath instrument operators and thus has no relevance here.</p> <p>The ISOR also notes that, “the oversight of training programs has been removed from the Department and given to the employing laboratory entities...” The reference here to “employing laboratory entities” is noteworthy in that it reveals the committee’s misunderstanding of the laboratory place-entity issues. As noted previously, a laboratory as defined under Section 1215(e) is a place. It is not an entity capable of assuming any responsibilities. Moreover, the proposed regulations do not appear to give oversight of training to the laboratory, but rather to individual analysts. Section 1221.2 (a) (4) requires that the training curriculum shall be “developed by a forensic alcohol analyst.” There is no mention in that section of a “laboratory.” More importantly, in the context of statewide laboratory regulations the idea of giving oversight of training to the laboratories can be viewed as an oxymoron. Regulatory oversight implies oversight by an external agency, not 40 individual laboratories. State level oversight of breath alcohol analysis is imperative to ensure the competency and consistency of this testing in California. Assuring that the instructors and supervisors of that training are qualified is an important component of that oversight.</p>	
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		<p>With the confusing discussion in the ISOR, the committee clearly has not demonstrated by substantial evidence how removal of the current requirement that the Department must approve the laboratory’s qualifications of instructors will effectuate the purpose of the statutes. These statutes require the Department to enforce the law and its regulations pertaining to forensic alcohol analysis (H&S Code § 100725) and which must ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> <p>There are other proposed changes to the section that are not mentioned in the ISOR. The proposed revisions would permit a certified breath instrument operator with two years’ experience to be an instructor. Regarding the description here of a “certified” operator, the authority/reference issues associated with issuing the operator trainee a certificate were discussed in the comments under Section 1221.2 (a)(3)(G). More generally, the use of experienced operators (i.e., law enforcement personnel) as training instructors works so long as the training is supervised by qualified laboratory staff [cf. current Section 1221.4 (a)(4)].</p> <p>However, as discussed above, the committee has proposed to eliminate any requirement for supervision of the training.</p> <p>At its last meeting on May 20, 2013, the committee added the new requirement that, “Training in the Theory of Operation, pursuant to 1221.2 (a)(3)117 shall be coordinated by a Forensic Alcohol Analyst.” This is a separate requirement and should be presented as a separate subsection. More importantly, the word “coordinated” is hopelessly vague and the reference to Section 1221.2 (a)(3) is incomplete. Consequently the added language creates additional clarity issues.</p> <p>The committee has not demonstrated by substantial evidence how any of the proposed revisions to this section are necessary to effectuate the purpose of the statutes.</p>	
<p>1:142</p>	<p>New Section 1221.2 (a)(4)(B)</p>	<p>New Section 1221.2 (a)(4)(B)</p> <p>Clarity/Necessity/Consistency/Reference – The committee proposes here to require a minimum of four hours of instruction for the breath instrument operator training. The very brief ISOR states that “4 hours</p>	

	<p>was chosen to resemble blood training. Both breath and blood analysis training require a comparable amount of time.” In fact, the regulations do not set any time requirements for the training of a forensic alcohol analyst (i.e., “blood analysis training”). Moreover, the training in the procedures for blood alcohol analysis here would be expected to be much more extensive than the training for breath instrument operators. As noted in the comments for Section 1221.2 (a)(3), (A) through (D), the training in forensic alcohol analysis offered by the Department of Justice in lieu of two years’ experience [cf. current Section 1216.1 (e)(2)] was 40 hours in duration. The proposed four hour training period for operator training is quite de minimis. Some state’s regulations require 30 - 40 hours of training.¹¹⁸ With the confusing discussion in the ISOR, the committee has not demonstrated by substantial evidence why the four hour time period for the training is appropriate.</p> <p>There are other proposed changes to the section that are not mentioned in the ISOR. The proposed restriction here to “training by a certified breath instrument operator” is inconsistent with the provisions under Section 1221.2 (a)(4)(A), which permit a forensic alcohol analyst to be an instructor. The analyst typically will not be a “certified breath instrument operator.” This creates a consistency issue. Again, the authority/reference issues associated with issuing the trainee a certificate were discussed in the comments under Section 1221.2 (a)(3)(G). Also, as discussed in the comments under Section 1221.2 (a)(4), the reference to training being conducted by an instrument operator again suggests that the laboratory will have no involvement with the training. As noted previously, breath alcohol analysis procedures involve scientific measurements performed by generally technically unsophisticated law enforcement personnel. It is critically important to maintain direct scientific oversight breath instrument operator training. Every state regulates breath alcohol analysis. In many states, a state level agency is directly involved in the training of the instrument operators or in some cases the training instructors. These states issue permits or certificates to document the satisfactory completion of the operator training. State agencies are also often responsible for maintaining and periodically determining the accuracy of the breath testing instruments. California is unique in that it delegates all these responsibilities to the individual forensic alcohol laboratories. In</p>	
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		<p>California, the Department of Public Health provides oversight of breath testing by approving the laboratory’s training procedures, determining the qualifications of the training instructors, and the qualifications of laboratory staff that are required to directly supervise the training. Through these mechanisms, California provides state-level oversight of breath alcohol analysis. This oversight ensures that breath alcohol tests are performed consistently and competently by law enforcement personnel throughout the state. Breaking any one of these links would prevent the Department from providing critical state-level oversight of breath alcohol analysis. The revisions to the regulations proposed by the review committee would break all of the aforementioned links.</p> <p>The committee has not demonstrated by substantial evidence how the proposed elimination of scientific oversight of instrument operator training effectuates the purpose of the statutes.</p>	
1:143	New Section 1221.2 (a)(4)(C)	<p>New Section 1221.2 (a)(4)(C)</p> <p>Necessity –The committee’s stated purpose in proposing adoption of this section was to try and eliminate replicative training for operators who have been trained on another approved instrument. Such officers would be exempted from any further training on the Theory of Operation of the instrument [cf. Section 1221.2 (a)(3)(A)].¹¹⁹ Current test instruments employ either infrared spectrophotometry or fuel cell electrochemistry to measure alcohol. The theory of operation is different in each case. The exemption proposed by the committee here would not be appropriate if the theory of operation of the new instrument is different from the theory of operation of the instrument for which the operator previously received training. Moreover, with the revisions proposed by the committee for Section 1221.2 (a)(4)(B), the total training time for the course is only four hours. As a consequence, the actual reduction in training time afforded by the proposed exemption here would appear to be quite de minimis. The committee has not demonstrated by substantial evidence how the proposed exemption effectuates the purpose of the statutes in such cases.</p>	
1:144	Section 1221.2 (a)(5) [Current	Section 1221.2 (a)(5) [Current Section 1221.4 (a)(5)]	

	<p>Section 1221.4 (a)(5)]</p>	<p>Authority/Reference – This section sets forth the qualifications of the operator of a breath testing instrument. It requires that breath instrument operators, who are not qualified laboratory staff, must have successfully completed the described instrument operator training. There are again scope and authority issues here. As previously noted, breath instrument operators are typically law enforcement personnel. Accordingly, this section imposes requirements on law enforcement. As discussed in the comments under Section 1221.1 (a), former H&S Code §100715 specifically authorized the Department to impose these requirements. This authority was repealed with the 2004 legislation. The revised statutes, in particular H&S Code §§ 100700 and 100701, give the Department authority to regulate laboratories, but not law enforcement agencies or personnel. It is not clear that new section, H&S Code §100701 imposes any requirements on law enforcement personnel, but if it does, these requirements would appear to be limited to the instruments and accessories used. The statutes don't impose any requirements on the training the operator must complete or on the testing procedures that the operator must follow. The statutes don't appear to authorize the Department to impose such requirements on law enforcement personnel through regulation.</p>	
<p>1:145</p>	<p>Section 1221.2 (a)(6) [Current Section 1221.4 (a)(6)]120</p>	<p>Section 1221.2 (a)(6) [Current Section 1221.4 (a)(6)]120</p> <p>Clarity – The proposed change from “the person performing...” to “any person performing...” is at least awkward and possibly unclear since it suggests a level of indiscriminate randomness in the identification of the person performing the analysis. It would also suggest the possibility that a periodic determination of accuracy on a non-automated instrument might somehow be completed without any operator involvement. Also, as noted in the comments under Section 1221.2 (a)(2)(A)(i), the apparent reference to two types of breath testing instruments (manual and automatic) will require greater specificity and definition.</p>	
<p>1:146</p>	<p>Section 1221.2 (b) [Current Section 1221.4 (b)]</p>	<p>Section 1221.2 (b) [Current Section 1221.4 (b)]</p> <p>Authority/Reference – The requirement to make the precautionary checklist available at the instrument site was previously contained under current Article 8, Section 1222.2 (a)(3), as one of the records that law</p>	

		<p>enforcement agencies must maintain. The committee deleted Section 1222.2 in its entirety, based in part on the conclusion that the regulations were not intended to regulate law enforcement.¹²¹ The committee then apparently concluded that placing the requirement to make the precautionary checklist available at each instrument site here under Article 6 (current Article 7) imposes a requirement on the laboratory. However, as a practical matter, most breath testing sites are physically located in areas which are under law enforcement’s jurisdiction. Accordingly, this section still imposes a requirement on law enforcement. As discussed in the comments under Section 1221.1 (a), the laboratory may not even have any jurisdictional authority over breath testing in which case it would not be able to comply with the requirements imposed here. The statutes do not appear to give the Department authority to impose requirements on law enforcement either directly or indirectly by authorizing a laboratory to impose these requirements.</p>	
<p>1:147</p>	<p>Section 1221.3 [Current Section 1221.5]</p>	<p>Section 1221.3 [Current Section 1221.5]</p> <p>Necessity – The committee again proposes to change “breath alcohol analysis” to “breath alcohol testing.” As discussed previously, the change is unnecessary, since the words “analysis” and “testing” are synonymous and do not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples. The committee also proposes to delete the adjective “analytical” in the section title. The section, which would now be titled, “Expression of Results,” sets forth the requirements by referring to Section 1220.4, which is titled, “Expression of Analytical Results.” It should also be noted that the review committee was somewhat inconsistent in proposing to transfer the requirements for the collection of breath samples from Article 4 (current Article 5) to Article 6 (current Article 7), while leaving the requirements for the expression of breath analytical results under Article 5 (current Article 6).</p> <p>The committee has not demonstrated by substantial evidence how the proposed revision effectuates the purpose of the statutes.</p>	
<p>1:148</p>	<p>Article 7. Records (Current Article 8.</p>	<p>Article 7. Records (Current Article 8. Records)¹²² Section 1222. Consistency/Necessity - The committee has proposed to repeal the</p>	

	<p>Records)122 Section 1222.</p>	<p>description of the requirement for law enforcement agencies to maintain certain specified records. In its Initial Statement of Reasons (ISOR), the review committee noted that the reference to law enforcement agencies was deleted, because the “regulations are not intended to regulate the law-enforcement community.” This conclusion may be correct since as discussed previously in the comments for Section 1221.1 (a), the Department lost its specific authority and reference to regulate law enforcement agencies performing breath alcohol analysis as a consequence of the repeal with the 2004 legislation of former H&S Code §100715.123 However, as noted in the comments under Article 6 (current Article 7), the committee has chosen to retain a number of other requirements that clearly regulate law enforcement personnel when performing breath alcohol analysis. Included here are the requirements that the instrument operators must have completed specified training, the use of specified instruments, the required periodic determinations of accuracy of those instruments, and the requirements imposed when conducting a breath test (i.e., 15-minute observation period, duplicate analyses, required precision, reporting requirements). The general question of the authority of the Department to impose requirements on law enforcement agencies and law enforcement personnel must be resolved in order that the law here can be consistently applied in the regulations.</p> <p>The committee has also proposed to repeal the requirement that laboratories shall make records of their activities under the regulations available to the Department on request. The ISOR states that this requirement was deleted “to reflect the removal of the Department's jurisdiction.” As noted many times in these comments, the claim that the Department’s jurisdiction over forensic alcohol analysis has been removed is not supported by the legislative record. The 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed; it did not prohibit the Department from any other regulatory activity. The Department is still charged with the authority and responsibility to enforce the laws and regulations pertaining to forensic alcohol analysis (cf. H&S Code §100725). It is obviously important for the Department to have access to critical laboratory records to carry out its mandate. In its original comments on this proposed change,124 the review committee claimed that, “any and</p>	
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		<p>all such records would be available to the Department through the California Public Records Act upon request.” As noted in the comments under Section 1220 (b), the Public Records Act (PRA) does not apply to private laboratories performing forensic alcohol analysis.¹²⁵ Moreover, the PRA is subject to exceptions to disclosure and the procedures for obtaining copies of records are cumbersome. The Department needs immediate access to the laboratories’ records in order to meet its legal mandate and to enforce the laws and regulations pertaining to forensic alcohol analysis and to protect public safety.</p> <p>The ISOR comments for entire article stated, “This article outlines the type of documentation necessary for forensic alcohol testing laboratories to generate and maintain. The statements here again reflect the committee’s lack of understanding of the role of regulations. Regulations do not “outline” requirements, they are rules or directives made and enforced by an authority. Regulations are distinct from voluntary guidelines such as the guidelines published by ASCLD/LAB, which may represent recommendations for best practices, but do not have the force of law.</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
<p>1:149</p>	<p>Section 1222.1 (a)</p>	<p>Section 1222.1 (a)</p> <p>Necessity – Requiring a laboratory (a place) to keep records again creates place-entity issues. The place/entity issue must be addressed here and throughout the regulations in order to effectuate the purpose of the statutes.</p> <p>The ISOR states, “The phrase ‘is licensed to perform’ was repealed and replaced with ‘performs.’ This amendment implements the removal of the Department’s jurisdiction.” Again, the ISOR misinterprets the statutes here. The amendment here simply implements the removal of the Department’s specific authority to require laboratories to be licensed.</p>	

<p>1:150</p>	<p>Section 1222.1 (a)(1)</p>	<p>Section 1222.1 (a)(1)</p> <p>Clarity/Consistency – The proposed revisions to this section would remove the requirement that the laboratory keep records of staff’s performance on proficiency tests and examinations. The elimination of the requirement to retain records of staff’s examinations is consistent with the committee’s proposal under Section 1216.1 (b)(3) [current Section 1216.1 (e)(3)] to eliminate the requirement that staff must successfully complete a written examination prescribed by the Department. With this revision, there would be no specific regulatory requirement to test the knowledge of staff. The review committee’s reasoning in eliminating the requirement to maintain employee “proficiency test” records is more difficult to understand. H&S Code §100702 (c) requires that “Each examiner shall successfully complete at least one proficiency test annually.” As discussed in the comments under Section 1216.1 (a)(2), the term “examiner” is not defined or even used in the regulations. Also, there is apparently no requirement that the examiner proficiency test be obtained from an external source and the statutes do not even specifically state that the required proficiency test involves alcohol analysis. As a consequence, with the revisions proposed by the committee, there would be no specific requirement that the competence of staff performing forensic alcohol analyses is ever evaluated by an external entity. Despite these limitations, presumably the committee would see some value in maintaining records of staff’s performance on proficiency tests. Accordingly, it would appear that the current requirement for a laboratory to keep these records should be retained.</p> <p>In its comments, the committee noted that the section was amended to be “more grammatically correct,” however, it does not appear that any of the proposed revisions actually address grammar issues. The committee’s added language, “including but not limited to the records...,” is vague and could create clarity issues. It would be better to list all of the records that must be retained. Finally, the language here should be revised to require laboratories to retain records of staffs’ former</p>	

		<p>qualifications as forensic alcohol supervisors since this can be the basis for the qualification as a forensic alcohol analyst under Section 1216.1 (b)(4)(C).</p>	
<p>1:151</p>	<p>Current Section 1222.1 (a)(2)</p>	<p>Current Section 1222.1 (a)(2)</p> <p>Consistency – The elimination of the requirement to keep records of staff qualified as forensic alcohol analyst trainees is consistent with the committee’s proposed elimination of this classification. However, laboratories will need to retain these records for a period of time (probably at least three years) to cover any current or recent forensic alcohol analysis activities performed by these staff. This would be consistent with the general requirements of Section 1222, i.e., “forensic alcohol laboratories shall maintain records which clearly represent their activities which are covered by these regulations.”</p>	
<p>1:152</p>	<p>Section 1222.1 (a)(5) [Current Section 1222.1 (a)(6)]</p>	<p>Section 1222.1 (a)(5) [Current Section 1222.1 (a)(6)]</p> <p>Clarity/Reference/Consistency/Necessity – The committee’s proposed revisions to this section create numerous clarity issues. The ISOR notes that the “phrase ‘maintenance and/or calibration’ was added to further clarify what records need to be maintained...” However, the new terms “maintenance” and “calibration” are not defined in the regulations. The ISOR also claims that the term "breath" was removed to clarify that the records (i.e., “Records of determinations of accuracy, maintenance and/or calibration...”) should be maintained not just for breath tests, but “for all types of tests.” However, there are no requirements in the regulations for a laboratory to “calibrate” or “maintain” breath testing instruments and with the committee’s proposed revisions, there are no requirements to determine the accuracy of any “testing instrument” other than breath testing instruments (i.e., the instruments used to analyze alcohol in blood, urine, or tissue samples). Moreover, the committee has proposed to repeal the current requirement under Section 1220.2 (a)(5) for laboratories to “maintain” laboratory equipment used to analyze blood, urine, or tissue samples. Requiring a laboratory to keep records of activities that are not defined or even mentioned in the regulations obviously creates both consistency and necessity issues.</p>	

		<p>The ISOR notes that the committee found that the limitation on the scope of the record keeping to testing performed for law enforcement agencies was not appropriate and claimed that “the record keeping requirement should apply to all forensic alcohol laboratories regardless of whether the analyses are performed by or for law enforcement agencies.” Based on this conclusion, the committee deleted the phrase “as a laboratory may perform for law enforcement agencies” from the description of the record keeping requirements. The committee’s proposal to remove this limitation on the scope of the record keeping is not appropriate. The statutes [HSC§100700(a)] specifically limit the scope of the regulations to, “Laboratories engaged in the performance of forensic alcohol analysis tests by or for law enforcement agencies” (emphasis added). Moreover, the term forensic alcohol analysis is defined in the regulations as the analysis of samples from, “persons involved in traffic accidents or traffic violations...” A laboratory likely conducts many activities other than forensic alcohol analysis. There should be no requirements under the Department’s forensic alcohol regulations for a laboratory to maintain records of these other activities.</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statute which requires that the regulations shall ensure the competence of forensic alcohol analysis [cf. §100703 (d)]. Current Section 1222.1 (a)(6) should remain unchanged in order to clearly state the specific requirement for the laboratory to maintain records of the periodic determination of accuracy of breath testing instruments used by law enforcement agencies.</p>	
<p>1:153</p>	<p>Section 1222.1 (a)(6) [Current Section 1222.1 (a)(7)]</p>	<p>Section 1222.1 (a)(6) [Current Section 1222.1 (a)(7)]</p> <p>Clarity/Consistency/Reference – The removal of the reference to a forensic alcohol laboratory providing the training here may appear to solve one of the persistent place-entity issues, but it also creates new issues and raises the question of whether the forensic alcohol laboratory will be involved at all in the training of instrument operators. As noted previously, the review committee has also removed references to the supervision of training by laboratory staff [cf. revised Section 1221.2 (a)(4)], and subsequently described the training as being provided by a “certified breath instrument operator” [cf. revised Section 1221.2</p>	

		<p>(a)(4)(B)]. The committee’s revisions here create clarity issues, but could be interpreted as permitting the training to be conducted without any laboratory or scientific oversight. The committee has not demonstrated by substantial evidence how these changes are reasonably necessary to effectuate the purpose of the statutes, which require that the regulations shall ensure the competence of forensic alcohol analysis [cf. §100703 (d)].</p> <p>The committee again proposed here to remove the current limitation on the scope of the record keeping to records of the testing performed for law enforcement agencies. The comments in the ISOR again noted that the record keeping requirements for training should apply to all forensic alcohol laboratories regardless of whether the analyses are performed by or for law enforcement agencies.” As noted in the comments under Section 1222.1 (a)(5), the scope of the regulations is limited by the statutes to the activities of laboratories “engaged in the performance of forensic alcohol analysis tests by or for law enforcement agencies...” [cf. HSC §100700(a)]. Evidential breath tests are performed after the arrest of an individual by law enforcement personnel. Accordingly, the limitation of the scope of the record keeping to training provided for law enforcement agencies must be retained.</p>	
<p>1:154</p>	<p>Section 1222.2</p>	<p>Section 1222.2</p> <p>Clarity/Consistency – Section 1222.2, which sets forth requirements for law enforcement agencies to maintain specified records, is proposed to be repealed in its entirety. In the ISOR, the committee claimed that the record keeping requirements were “redundant.” This is incorrect and reflects a significant misunderstanding on the part of the committee. The requirements imposed on law enforcement here (i.e., maintenance of records of determinations of accuracy and records of breath alcohol analyses by law enforcement agencies) are not spelled out anywhere else in the regulations.</p> <p>As discussed under Section 1222., the elimination of the record keeping requirements here may be consistent with the committee’s presumption that the regulations should not apply to law enforcement, but as noted previously, the regulations, even as revised, continue to impose many requirements on law enforcement agencies. The question of the</p>	

		authority of the Department to impose regulatory requirements on law enforcement agencies must be resolved in order that the law can be correctly and consistently applied in the regulations.	
1:155	Technical, Theoretical, and/or Empirical Studies, Reports, or Documents Relied Upon	<p>Technical, Theoretical, and/or Empirical Studies, Reports, or Documents Relied Upon</p> <p>The statutes require that the initial statement of reasons must identify “each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies in proposing the adoption, amendment, or repeal of a regulation” [Government Code §11346.2. (b)(2)]. The review committee’s ISOR here attempts to satisfy this requirement by presenting a very general list of resources. Except for the several outdated references to various ASCLD/LAB guidelines and the 2002 Department of Public Health advisory regarding suitable aqueous disinfectants, it is not clear that any of other listed documents were actually relied upon by the committee in proposing its regulations. The transcripts show that with the exceptions noted above, the other documents were never discussed by the committee.</p> <p>It does not appear that the list of documents included in the ISOR represents a real effort to identify the documents relied upon by the review committee or alternatively, the committee’s proposed revisions were not based on any actual technical, theoretical, or empirical reports or studies.</p>	
2:1	Part (A) Top Level Comments and Concerns:	<p>Part (A) Top Level Comments and Concerns:</p> <p>Read the proposed regulations and prepare to be dumbfounded, stunned and shocked at the level of incompetency identified in both the proposed regulations and supporting documents applicable to forensic alcohol testing laboratories. The Forensic Alcohol Review Committee and CDPH should be embarrassed to have their names on these documents. The framework for understanding how there came to be such a poor product can be captured in the following two statements:</p> <p>1) The Authority and Reference codes are incomplete. Authority codes listed are Health and Safety Codes 100703 and 100705. Reference Codes listed are Health and Safety Codes 100700, 100701, 100702,</p>	

		<p>100775. The Forensic Alcohol Review Committee (FARC) and California Dept. of Public Health (CDPH) do not appear to understand and have not applied the results of the legislative activities affecting the department in 2007.</p> <p>The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties; powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050, 131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>These proposed regulations are posted on the CDPH website; the chair of FARC is a CDPH employee; and an attorney from CDPH-Office of Legal Services is the contact person. CDPH cannot distance itself from this regulatory package. This lack of knowledge, lack of attention to detail, and refusal to accept responsibility for actions applicable to this package demonstrates the level of incompetency apparent in these proposed regulations.</p>	
2:2		<p>2) The poor quality of these proposed regulations is the result of a statutory quagmire from which extrication will be very difficult. Neither FARC nor CDPH, whether jointly or separately, has been able to detach itself and disconnect from this mess. These proposed regulations only serve to demonstrate the extent of the difficulty.</p> <p>a) In 2004, due to CDPH incompetency and unwillingness to update the forensic alcohol regulations, the legislature took action in the form of Senate Bill 1623 which removed CDPH authority to license forensic alcohol testing laboratories. The legislation required creation of the FARC, a volunteer group tasked with determining revisions necessary to</p>	

		<p>ensure the competence of laboratories and employees to prepare, analyze, and report test results applicable to forensic alcohol and comply with applicable law. FARC was specifically charged with considering the development and advancement of scientific processes.</p> <p>The minutes of the 24 FARC meetings held over the years between 2004 and 2015 document the adversarial positions of each party. FARC members (all volunteers), by sheer numbers, consistently demonstrated their animosity toward CDPH by voting down almost every position CDPH placed on the table. It became clear that, with the exception of the chair (a CDPH designee), the intent of FARC members was to remove CDPH oversight of any kind. See FARC Meeting Minutes accessed at www.cdph.ca.gov > services> Boards and Advisory Committees > Forensic Alcohol Review Committee > March 5, 2015 Meeting and Previous Meetings.</p> <p>This 'advisory committee' then removed many of the existing regulations (note the number of sections struck through in the proposed regulations); watered down the remaining regulations; and placed the rest of its duties under the oversight of the American Society of Crime Laboratory Directors/Laboratory Accreditation Board. Thus a government function was delegated to a national trade group. Membership in this national trade group is voluntary; accreditation is based on guidelines; it is not a regulatory body; result reporting is confidential, and the accreditation body has a poor track record with respect to its ethical and Professional practices. The intent of the 2004 statute was to ensure the competence of the laboratories and its employees to prepare and report the results of certain tests applicable to forensic alcohol testing. The ISOR explanation of Subsection 1216.1(a)(2) indicates that FARC also expects the court system in California to perform some oversight duties currently assigned to FARC.</p> <p>b) FARC neglected to incorporate standards of modern laboratory practices to reflect an understanding and application of quality management systems (QMS). Quality management systems seek to standardize a lab's policies, processes, and procedures and thus, its test results, by applying universal quality elements across all aspects of the</p>	
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		<p>lab's operations. Six of twelve of those quality elements are absent from these proposed regulations. The six which are present are incomplete, often unclear and inconsistent.</p> <p>In summary, this is hardly a modern system of robust checks and balances with respect to forensic alcohol testing. Actions taken by FARC indicate it to be a committee which does not want to be responsible for quality in the forensic alcohol laboratory. CDPH cannot pretend it is not responsible for FARC activities.</p>	
<p>2:3</p>	<p>General Comments</p>	<p>Part (B): General Comments</p> <p>The stated purpose of the enabling statute for forensic alcohol testing laboratories was (a) to remove the authority of CA Dept. of Public Health (CDPH) to license laboratories which perform forensic alcohol testing and (b) to assign the Forensic Alcohol Review Committee (FARC) with the task of determining necessary revisions to the existing regulations. The goal was to ensure the competence of the laboratories and its employees to prepare and report the results of certain tests applicable to forensic alcohol testing. The statute did not remove the authority of CDPH to regulate and oversee forensic alcohol labs; it removed CDPH's authority to license these labs.</p> <p>After 10 years, 24 full committee meetings, and a number of sub-committee meetings, the best that the FARC could come up with is a set of regulations which are nearly unreadable and do not meet the six APA standards, especially the clarity and consistency standards. The regulations as a whole are missing not only a consistent structure but also descriptive content applicable to modern forensic laboratories. These proposed regulations do a serious disservice to the affected public because the content of many sections is not standardized; the overall structure of the proposed regulations is not easy to navigate and the sentence structure is convoluted, unclear, and not easily understandable. Many of the sub-sections within the sections are "orphans" meaning they appear to have little or no relation to the others in that same section or article.</p> <p>Note the following examples:</p>	

		<ul style="list-style-type: none"> • These regulations are incomplete because they do not contain regulations on six critical elements of a modern laboratory. The missing elements are (1) managing computerized and non-computerized information; (2) managing nonconforming events; (3) developing and managing process improvement activities; (4) facility and safety activities; (5) customer service activities; and (6) purchasing and inventory requirements. • The definitions are not in alphabetical order. • The definition of "Alcohol" contains three different issues each of which should be broken out. • Sections such as 1216.1 contain mixtures of issues; the 'mixing' is not always consistent. Sec 1216.1 contains a mix of Personnel, Assessment, and Process Management issues. These should each be broken out and placed in their respective unit/component. • Article 4 is Collection and Handling of Blood, Urine, and Tissue Samples; Article 5 is Methods of Forensic Alcohol Analysis; and Article 6 is Requirements for Breath Alcohol Testing. "Methods" is stuck in the middle of two sections on collection. This sequence is not logical, nor is it easy for the affected public to navigate. Not even the language is standardized. • Article 4 is Collection and Handling of Blood, Urine, and Tissue Samples but there is no section specific to collection and handling of tissue. <p>Most importantly these proposed regulations do not modernize the existing regulations. With the exception of four nominal areas (removal of CDPH's authority to license FA labs; updating the existing legal limit for driving under the influence; inserting language which requires FA labs to meet proficiency testing guidelines of ASCLD-LAB; and identifying NIST-traceable dry gas standards for breath testing), the proposed regulations are stuck in 1984, a time period in which labs focused only on quality control of the product, the technical area of testing. Modern labs of all kinds have implemented or are in the process of implementing continuous quality improvement practices which stress quality management, quality assurance, and the use of risk management tools <u>in addition to quality control</u>. These elements are</p>	
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		<p>laboratory practices which embed quality into the culture of the organization. In modern labs, these intentions and practices are codified into a structured, comprehensive, coordinated approach called a Quality Management System (QMS). These proposed regulations do not even mention a QMS or its applicability to forensic alcohol testing. No reasons are given for this major omission.</p>	
<p>2:4</p>		<p>The content of these proposed regulations does not meet the modern standard of incorporating laboratory practices into a quality management system. There is not a structured, comprehensive, coordinated approach evident in these proposed regulations. A QMS should reflect the forensic alcohol lab's commitment to quality by applying universal quality elements across all lab operations. A QMS goes far beyond quality control and quality assurance. A QMS links the two "arms" of lab work, the technical work and the management structure which supports it by applying a set of 12 interlocking essential elements, known as Quality System Essentials (QSE), which are organized as structure, process, and outcome. Each QSE is a collection of essential information that describes a critical managerial activity. For the lab's technical work to be performed successfully, each QSE must be managed properly. When implemented, this system standardizes practices, is comprehensive and coordinated, reduces or eliminates errors, meets customer requirements and meets governmental and accreditation requirements. It heightens quality management to the level of organizational culture to attain and sustain quality objectives. Inexplicably, the committee removed some of the structure and much of the content in the existing regulations which could have been used to build a QMS. The ISOR does not explain why this approach was taken although reasons for it can be surmised from the recorded FARC meeting minutes during the development period for these proposed regulations.</p> <p>FARC, and CDPH in collusion, have chosen to tweak language to capture only the low-hanging fruit in only four areas: removal of CDPH's authority to license these labs; updating the existing legal limit for driving under the influence; inserting language which requires forensic alcohol labs to meet proficiency testing guidelines of ASCLD-LAB; and identifying NIST-traceable dry gas standards for breath testing. What</p>	

		<p>has been updated is incomplete.</p> <p>To substantiate its claims of modernizing FA testing in these regulations, ASCLD-LAB is cited five times in the Studies, Reports and Documents Relied Upon section in the ISOR. ASCLD-LAB accreditation is based on a voluntary commitment to a broad set of suggested guidelines. ASCLD-LAB is a trade organization which has questionable credibility and a spotty track record with respect to assuring quality in forensic labs. The public is not well-served when there is only voluntary oversight by such an organization of such a critical area of public health.</p> <p>Incredibly, what should have been the cornerstone but is completely missing from the FARC documents is the development of proposed regulations based on that QMS or any other QMS. ASCLD-LAB's accreditation is based on a QMS, however inadequate, poorly defined and executed it may be. If California's forensic alcohol testing labs are relying on ASCLD-LAB's accreditation standards to support their claims of assuring quality, then why have those same standards not been used as the basis for regulations at the state level? ASCLD-LAB accreditation is based on international standards for calibration labs called ISO 17025. FARC cannot proclaim its support for ASCLD-LAB standards but provide no explanation of why it did not, at minimum, incorporate at least the spirit of those standards into these proposed regulations. CDPH cannot distance itself from and disavow its responsibility for activities of FARC and the resulting poor product promulgated by this committee. Again, no explanation is provided for the approach taken.</p> <p>FARC, under the insistence, guidance, direction, and oversight of CDPH, needs to step up its game, withdraw this package and re-write these regulations. FA regulations should be based on the 12 quality system essentials of a QMS. A QMS is a good starting point from which to explore and implement ISO 17025 calibration standards into the regulations for forensic alcohol testing labs. A QMS will provide a standardized, consistent, and complete framework from which to bring FA regulations into modern laboratory practice. Doing so will make these regulations consistent with:</p> <ul style="list-style-type: none"> a) Current good laboratory practices; b) ASCLD-LAB voluntary accreditation guidelines which FARC says 	
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		<p>are already implemented in their labs; and The means necessary to effectuate the purpose of the statute which requires the Department to enforce the law and its regulations in order to ensure the competence of the laboratories and employees as required by Health and Safety Codes.</p>	
2:5	ISOR Claims	<p>The ISOR makes a number of claims regarding how and why these proposed regulations will ensure the competence of the laboratories and its employees to prepare and report the results of certain tests applicable to forensic alcohol testing. For example, the ISOR claims these regulations:</p> <ul style="list-style-type: none"> • Clarify the Department's role in the oversight of FA testing labs but they do not. While the statute removes the Department's authority to license FA labs, it does not remove the Department's statutory obligation for oversight and enforcement with respect to forensic alcohol labs, contrary to the committee's interpretation of the statute. It does not clarify the Department's role in regulating these laboratories • Clarify educational and experience requirements of FA analysts but they contain only partial information relevant to the QSE "Personnel." • Clarify the testing procedure but they do not. See the QSE "Process Management" for a more complete description of what should be included in these regulations but is not in these proposed regulations. • Create a more uniform and accurate testing environment but they do not fully accomplish their stated goal. Other than the 4 areas, the 1984 language is still unclear, incomplete, inconsistent, and at least once, incorrect. These proposed regulations do not modernize forensic alcohol testing by using a standardized structured approach to quality management. Instead, they focus on the quality control of a few technical areas. • In a number of sections, the ISOR specifically states that some activities will be left to the individual labs to manage as they see fit. This is hardly a method to standardize policies, processes and procedures in the forensic alcohol test environment. The discussion on components of a Quality Management System 	

		<p>identifies what should be included in these proposed regulations but are not.</p> <ul style="list-style-type: none"> • Will allow the state to better control drunk driving but they do not demonstrate that they will accomplish their stated goal. The discussion on components of a Quality Management System identifies what should be included in these proposed regulations but are missing from the proposed regulations. <p>In short, these regulations do not meet the 6 APA standards and, with a few, specific limited ways, do not modernize forensic alcohol testing for the state of California. They are incomplete, inconsistent and contain incorrect information. Therefore the regulations proposed should be denied by OAL and withdrawn by FARC.</p> <p>c)</p>	
<p>2:6</p>	<p>PART II: A NEW WAY FORWARD</p>	<p>The legislatively enacted FARC resulted in capitulation of the regulator to stakeholder demands. The watered-down process is wholly inadequate and reflects an old 1980s ways of thinking with respect to regulation of forensic alcohol labs. Forensic alcohol testing today demands a new modern approach. In today's labs, the two 'arms' of management and technical work must be linked. The result is a mindset of continuous quality improvement which embeds a culture of quality into the organization across all of its activities. To develop this culture of quality, national and internationally, laboratories of all kinds are moving into a quality management systems approach.</p> <p>Regulatory language should be written with the goal of assuring the safety of the people of California with respect to forensic alcohol testing. Decisions with respect to that language should not be based on a popular vote nor should they be characterized as a "we-win-you-lose-we-override-you" situation. The minutes of the FARC over the years reflect the tension between the roles of the FARC and the role of the Department. That tension and lack of understanding and agreement is reflected in the poor quality of these regulations. The tension will be minimized when the following takes place:</p> <ul style="list-style-type: none"> • FARC members understand and accept that technical testing alone cannot be relied upon to ensure quality and that quality 	

		<p>must be built into the product. Demonstrating that understanding through regulatory promulgation within a structured framework provides the public with information on how and why. FA testing is performed. That demonstration gives the public confidence in the results of the testing.</p> <ul style="list-style-type: none"> • FARC's scope of involvement in regulatory promulgation is clearly defined and agreed to by all parties. • CDPH's scope of authority with respect to regulation and oversight of FA labs is clearly defined and agreed to by all parties. <p>CDPH has ceded its authority to oversee FA labs by turning over its statutory oversight responsibilities to a committee composed of volunteers from the public sector who have a vested interest in a certain outcome. That outcome is only partially based on better control of drunk driving. More often it is based on assuring that FA labs operate in a kind of 'wild west' atmosphere with only minimal regulations. CDPH needs to more forcefully exert its authority and develop and better articulate its responsibilities to the public health of the state of California with respect to drunk driving. To do that, it must develop its own criteria for regulation of FA labs and codify it in regulation. Whatever that plan is, it should be structured and embedded in a modern QMS. Use of a QMS makes it easy to move from one topic to the next; to understand the relationships among the individual topics, with no confusing mixing of topics or repetition of information.</p>	
	<p>Requirements of a Quality Management System</p>	<p>Requirements of a Quality Management System The requirements of a Quality Management System can be broken down in multiple parts in any number of ways. Most labs of all kinds (ie pharmaceutical, clinical, calibration, and device labs of all kinds including business and industries such as the automotive industry) narrow their systems to ten or twelve quality system essentials (QSE). Note that at minimum, each QSE should have a statement of policies, processes, and procedures. Policies are statements of intention; they describe "what to do." Processes describe how policies are carried out; they describe "how it happens." Procedures provide instructions; they describe "how to do it." The twelve QSEs, each with its own particular critical information, are:</p>	

		<ol style="list-style-type: none"> 1. Organization: identifies policies, processes and procedures which include the mission and vision of the organization, iteration of a Quality Plan, identification of resources to fulfill the Quality Plan; and identification of the legal implications of testing and reporting test results. The Quality Plan defines the purpose and scope of the laboratory's operation, the goals of the quality system, the organizational structure to support quality goals, and a description of the elements of a QMS including policies, critical processes, and documents, forms and records, necessary to carry out those quality objectives. This QSE should identify and distinguish the responsibilities of the FARC and the responsibilities of CDPH. Regulations organized around the QSE would codify those responsibilities. 2. Personnel: identifies policies, processes and procedures including basic concepts of communication, interpersonal relations, stress management, professional behavior, ethics, job specifications, job .qualifications, orientation, training and competence assessment. I-low are-drunk driving and other criminal convictions and/or activities managed? Regulations organized around the QSE would codify those policies, processes, and procedures. 3. Equipment: identifies policies, processes, and procedures including equipment selection, qualification, validation, calibration, maintenance, equipment decommissioning, and practical training on the use of laboratory equipment and information technology systems including laboratory information systems. Regulations organized around the QSE would codify those policies, processes, and procedures. 4. Purchasing and Inventory: identifies policies, processes and procedures including how to distinguish between supplier and customer, supplier selection, essential requirements of a contract and evaluation of the supplier. Regulations organized around the QSE would codify those policies, processes, and procedures. 	
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		<p>5. Process Management: identifies policies, processes and procedures including path of workflow, process validation, change management, quality control and quality assurance, calibrator material stability, specimen handling and storage, factors that influence test results and the ability to verify the validity of test results, practical training on how to assess instrument and test parameters to determine accuracy, precision and correlation with test results.</p> <p>In 2014, AB2425 directed the committee to consider measurement uncertainty with respect to forensic alcohol testing. This QSE is where that issue should be defined. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>6. Information Management: identifies policies, processes and procedures including managing computerized and non-computerized information, privacy and confidentiality, information security, data storage and retrieval, and • requirements for charging and billing for laboratory testing. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>7. Deviations, Nonconformances, and Complications: identifies policies, processes, and procedures including the implications of accuracy, remedial and corrective action, no-fault non-conformance reporting, recognition of test results and activities which require corrective and preventive actions, and troubleshooting testing and equipment. What is the Department's role when an erroneous PT report is submitted? Written? To contain what? To be submitted by when? To include what information on corrective and preventive action? Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>8. Assessments (Internal and External): identifies policies, processes and procedures including internal and external assessments, and developing a laboratory quality report. What is</p>	
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		<p>the Department's role in oversight? Should the Department require an annual report quality report from each lab on its activities of the previous year? To include such items as name, address, contact person, summary of the year's activities for example, number of FA tests performed on breath, on body fluids, on tissue, any PT failures, corrective and preventive activities, new QA activities (example: reporting Confidence Intervals, etc.), number of analysts, number of PT results reported, number of complaints and categorization of the complaints, complaint follow-up activities. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>The Department should compile and publish its own performance report to include the average performance of all FA labs (comparing one to the others) as well as assessing the individual performance of each individual in a specific lab, compared to other individuals in that lab and in the state. The information can be de-identified to maintain privacy and confidentiality.</p> <p>9. Process Improvement through Corrective and Preventive Action: identifies policies, processes, and procedures including identification of opportunities for improvement, prioritizing problems, and developing and implementing a plan for problem resolution. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>10. Customer Service: identifies policies, processes, and procedures including identification of customers, determining customer satisfaction, and development of a complaint response program. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>11. Facilities and Safety: identifies policies, processes, and procedures which include infection control, standard precautions, appropriate disposal of sharps, needles, and medical waste, space allocation, and laboratory design. How do labs meet OSHA requirements? What about ergonomic requirements?</p>	
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		<p>Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>12. Documents and Records: identifies policies, processes and procedures including development of a record management system and record retention schedule for paper and electronic records; policies, processes, and procedures to create, control, change and retire such documents. Regulations organized around the QSE would codify those policies, processes, and procedures.</p> <p>ISO Standards such as ISO 17025 provide broad guidelines and principles under which labs should operate; ISO does not prescribe specific ways to establish and maintain these activities. In contrast, regulations do prescribe the specific ways FA labs must establish and manage those activities. ISO guidelines are voluntary; regulations have the force of law; regulations must meet the six APA standards. Applying ISO concepts to forensic alcohol testing allows FARC and CDPH, in collaboration, to specify FA testing requirements in greater or lesser detail and document those details in regulation. Doing so demonstrates how it intends to assure FA labs consistently operate in a standardized manner across the state of California.</p> <p>A quality system is more than a checklist; it is also not a once-every-five-years rush to gather resources to pass an accreditation assessment. A quality system develops and embeds into the organization the habits and practices of a high-performance organization using modern tools of management and process improvement to achieve the goal of quality FA lab testing. These proposed regulations do not reflect that level of understanding of what it means to operate within an environment based on a quality management system. When only a few of the technical essential elements are regulated, forensic alcohol results cannot be considered 'controlled' and thus cannot be considered valid. Therefore the proposed regulations do not meet the legislative intent of the statute.</p>	
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<p>2:8</p>	<p>PART III- SECTION- SPECIFIC COMMENTS Article 1. General Part A</p>	<p>(A) Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050, 131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p>	
<p>2:9</p>	<p>Part B The Purpose of the Statute</p>	<p>(B) The committee has not demonstrated by substantial evidence how its proposed revisions to will effectuate the purpose of the statute which requires the Department to enforce the law and its regulations in order to ensure the competence of the laboratories and employees as required by Health and Safety Codes listed in (A) above. The ISOR should contain statements to support, by a preponderance of evidence, reasons why the regulatory changes are necessary. Many statements in the ISOR are vague and do not provide that supportive evidence. Moreover the committee assigns duties and responsibilities to CDPH which are not theirs to assign. Examples include:</p> <ol style="list-style-type: none"> 1. Sec 1216 (a) makes CDPH a record repository for forensic alcohol labs. That is not the statutorily mandated role of CDPH. FARC's overreach is not justified by its explanation in the ISOR. Furthermore, there is no explanation or supportive documentation demonstrating how this would be accomplished or what the Department would do with such records. Making the records available to the public has no meaning without further explanation. 2. The ISOR for Sec 1219 states that the "adversarial justice system provides for the ultimate oversight of proper collection 	

		<p>and handling because these issues are challenged in most driving-under-the-influence cases." This is incorrect. Most driving- under-the-influence cases are settled without going to trial and no judicial scrutiny of any parameters of forensic alcohol testing is ever applied to those cases. The ISOR provides no validation to the committee's claim that there is a quality system essential in the courts. Furthermore, the FARC claim of a system of quality control in the courts seeks to externalize regulatory functions assigned to it. FARC does not provide evidence to support its jurisdiction for so doing.</p> <ol style="list-style-type: none"> 3. One of the goals of regulation is to ensure that the chemical testing in drunk driving cases is performed consistently throughout the state. This will not be achieved if 40 different laboratories independently determine their sample collection procedures as stated in Sec 1219.l(b). Nor will there be standardized lab practices throughout the state if each lab is allowed to determine its own calibration and QC procedures as stated in 1220(b)(2). 4. RE Sec 1221.2(a)(6): FARC's attempt to define and identify the functions of a 'forensic alcohol analyst' versus those of a 'breath alcohol operator,' does not meet the clarity and consistency standards. For example, the proposed regulations acknowledge a "breath instrument operator trainee" who is trained to use equipment for breath alcohol testing. The "breath instrument operator trainee" is given a certificate at the end of training at which point it is presumed that he then becomes a "certified breath instrument operator." The officer performing the 'calibration check' on equipment used in forensic alcohol testing and collecting alveolar breath for testing is a kind of "forensic alcohol analyst" who is performing forensic alcohol testing! In fact, these operators meet some of the criteria of forensic alcohol analysts. <p>ISOR does not adequately explain these two career ladders, does not adequately define "breath instrument operator trainee" or breath instrument operator, nor does the ISOR adequately differentiate between the requirements for one versus the other. The ISOR does not provide adequate support for separating the requirements of a peace</p>	
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		<p>officer doing breath testing from that of a forensic alcohol analyst. The ISOR does not even acknowledge how they are alike and how they are different, a very confusing situation for the affected public!</p>	
<p>2:10</p>	<p>Part C Definitions</p>	<p>(C) Arrange all definitions in alphabetical order. The current order does not meet the clarity and consistency standards.</p> <p>Subsec 1215 (a): This sentence is unclear. The terms ethyl alcohol, generic class of organic compounds, and antiseptics" are three separate issues and must be broken out, each developed into its own regulatory statement and relocated to its respective Quality System Essential.</p> <p>Subsec 1215 (b): "person involved" is vague and does not meet the clarity standard. Are we to assume these persons include cops? Drivers? Passengers? Bystanders?</p> <p>Subsec 1215 (c): Define "sampling" to meet the clarity standard.</p> <p>Subsec 1215 (d): This sentence is convoluted and unclear. Break up the convoluted, run-on mish-mash structure into its component parts.</p> <p>Subsec 1215 (e): does not meet the clarity and consistency standards. Break out the component parts and relocate each to its own Quality System Essential. Are you actually calling cop cars or roadside stops in open air "laboratories?" Is this like food trucks are now called restaurants? There should be a distinct and clear differentiation between the personnel and activities of "forensic alcohol analysts" vs breath alcohol device operators. "Involved" is unclear.</p> <p>Subsec 1215 (f): Although "supervisor" was removed, it should have been kept and defined in the definitions. In the laboratory setting, FA analysts do not operate without supervision. Contains Personnel issues which should have been placed in the Personnel Quality System Essential.</p> <p>Subsec 1215 (g): Method is unclear and outdated; it is not widely used in the world of laboratories. The word "procedure" is standard laboratory language as in process and procedure. This standardized terminology is</p>	

		<p>used in almost any other kind of lab including clinical, calibration, device, pharmaceutical, etc. In fact, the three words have been standardized to such an extent that they are shortened to the term "3P.11</p> <p>The removed section (j) should have been incorporated into the Quality System Essential of Equipment.</p> <p>Subsec 1215 (h): Unclear and inconsistent. What is meant by an "artificially constituted ' material?" Do you mean "artificially reconstituted?" RE "essentially alveolar" and in (i) "alveolar": These are not the same; these definitions do not meet the clarity and consistency standards.</p> <p>Subsec 1215 (i): does not meet clarity and consistency standards. - "Refers to" vs "means" is inconsistent with wording in other definitions. See (h) for clarity issues with "alveolar" vs "essentially alveolar."</p> <p>Subsec 1215 (k)-Needs expansion. Does not meet clarity standards. Are they checked once and then never checked again? Standard laboratory practice with respect to competency assessment includes 6 components: (1) direct observation of routine test performance, specimen identification and collection, handling, processing and testing;(2) monitoring the recording and reporting of test results including reporting critical results; (3) review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records; (4) direct observation of performance of instrument maintenance and function checks; (5) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples.</p> <p>Subsec 1215 (l)-Unclear and incomplete. A better definition is this: "Proficiency testing is a form of external quality control used to ensure standardized testing across labs. It provides the lab an opportunity to evaluate its performance compared to peer groups. It uses commercially available materials and evaluations."</p> <p>Subsec 1215 (m)-Unclear and incomplete. Is the guide written? Spoken? Developed, controlled, updated and maintained by whom?</p>	
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<p>2:11</p>	<p>Article 2</p>	<p>Article 2 contains a mixture of the Quality System Essentials "Organization" and "Personnel." They should be split out and relocated into their respective QSE.</p> <p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050, 131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p>	

		<p>Subsec 1216 (a): The committee overreaches the scope of its authority. The statute removed the Department's authority to license FA labs. It did not remove the Department's authority to enforce the laws and regulations applicable to those labs. The committee makes the Department a record repository but does not adequately explain why nor does it explain what the Department should do with those records.</p> <p>Subsec 1216.l(a): Forensic alcohol analysts do not work in a vacuum; they work within organizations which normally have a 'job ladder.' The hierarchy of FA supervisor, FA analyst, and FA analyst trainee is wholly appropriate. But neither the proposed regulations nor the ISOR adequately define and explain why this career ladder is not in place. FA analysts do not become FA analysts without going through training. The trainee classification is appropriate for that level. Likewise FA analysts do not operate independently and without some sort of oversight.</p> <p>The FA supervisor classification is appropriate for that level of expertise. The committee does not seem to understand the need for these classifications. The proposed regulations are vague, unclear and incomplete and thus do not meet the APA standards of clarity, consistency, and necessity.</p> <p>Subsec 1216.1 (a)(4): The Department still has the authority to perform inspections for cause. The committee's statement in the ISOR and thus in the proposed regulations is incorrect. This subsection does not meet the authority and reference, clarity and consistency APA standards.</p> <p>Subsec 1216.l(b)(l): This subsection does not allow for a career ladder with respect to other scientific and technical professions who by means of their education, training and experience would surely qualify to either be or become a "forensic alcohol analyst." One of these professions is the "clinical laboratory scientist." Licensed and regulated by the state of California and operating under provisions of the Business and Professions Code, these professionals and the laboratories in which they work, are required to meet much more stringent requirements than forensic alcohol analysts. For example, competency assessments and continuing education requirements prior to re-licensure makes this</p>	
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		<p>category an obvious option for moving into the area of forensic science and particularly forensic alcohol testing. Yet the committee does not even recognize the validity of such professions much less develop a career ladder for professional employment opportunities.</p> <p>In yet another example of the outdated perspective of these proposed regulations, Subsec.1216 (b)(4)(A) proposes qualification requirements applicable to clinical laboratory directors qualified prior to 1971. This subsection is applicable to few if any such personnel. A discussion with CDPH-Laboratory Field Services would have verified the need for this subsection one way or the other.</p>	
<p>2:12</p>	<p>New Article 3. Training of Personnel</p>	<p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050,131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>Sec 1218 (a) and (b) are unclear, convoluted statements and do not meet clarity and consistency standards. "At the discretion of the forensic alcohol laboratory..." Explain how the laboratory has discretion to alter a training program.</p> <p>This article contains a mixture of the Organization and Personnel Quality System Essentials; they should be split out and described in their respective QSE.</p> <p>"Qualified instructors" is vague and unclear. What is a qualified</p>	

		instructor? What are the qualifications needed to become a 'qualified instructor?' Education, training and experience should be specified.	
2:13	New Article 4. Collection and Handling of Blood, Urine, and Tissue Samples	<p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1,2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 1310501, 131051, and 131050 lists divisions now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>This section contains many parts of the Quality System Essential "Process Control." It contains many clarity and consistency issues such as "disinfectants," vs "disinfectant"; "solvent" vs "solvents;" "sample" vs "samples."</p> <p>This section mixes elements of the Quality System Essentials "Process Control" and "Equipment." Each item in each of these QSE should be separated and placed in its respective QSE.</p> <p>While there is regulatory information re blood, urine and breath, there is no information on tissue even though tissue is listed in the header.</p>	
2:14	New Article 5. Methods of Forensic Alcohol Analysis	<p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and</p>	

		<p>HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050,131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>Article 5 contains information on the QSE "Process Control." There is little coordination of information between Article 4 and Article 5. They should both be placed under one QSE, that of "Process Control."</p> <p>This article also contains information on proficiency testing, an external type of assessment. This information should be placed in its own Quality System Essential "Assessments-Internal and External."</p> <p>Subsec 1220(b)(2): Calibration of what? Subsection contains clarity and consistency issues.</p> <p>Subsec 1220.3(a)(1): contains information on acquiring, analyzing, and defining acceptable values. Each of those items should be broken out and expressed separately.</p> <p>Sec 1220.3(a)(5): When the results are outside the acceptable limits, the method is out of control not "in error." Clarity issues.</p> <p>Sec 1220.4: "Expressing" and "reporting" are two different things; they are not interchangeable. Clarity and consistency issues. The title does not specify how to report results.</p>	
2:15	New Article 6. Requirements for Breath Alcohol Testing	<p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and</p>	

		<p>HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050, 131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 131052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>Title of this Article is not consistent with the title of Article 4. This article contains information on the QSE "Process Control, ""Personnel" including information on training, "Documents and Records," and "Equipment." Information pertinent to each QSE should be broken out and placed in its respective QSE.</p> <p>Sec 1221.1: The wording of this title is not consistent with the title for blood, urine and breath. The sentence structure in both (a) and (b) is unclear and inconsistent.</p> <p>Sec 1221.42 is incorrectly numbered.</p> <p>Re the Precautionary Checklist: is it standardized and consistent throughout the state? Who develops, approves, maintains and updates it? How and who controls it? Is it supplied with each device? Clarity and consistency issues.</p> <p>RE breath instrument operators: Despite descriptions to the contrary, the breath instrument operators are a type of forensic alcohol analysts. They perform forensic alcohol testing with specialized breath alcohol testing equipment. The distinction between these two classifications is not clearly identified and specified leading to clarity and consistency issues. These are closely related classifications of two different types. The distinction is not specifically articulated in the proposed regulations and the ISOR offers little explanation of how and why they should or should not be connected in some sort of over-arching umbrella of "Personnel Who Perform Forensic Alcohol Testing."</p>	
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2:16	New Article 7. Records	<p>Authority and References for the entire regulations package are incomplete and should be updated. The CA Dept. of Health Services was legislatively reorganized as of July 1, 2007 (S.B 162, ch.241, Stats 2006) into two separate departments, the new Dept. of Health Care Services and the new Dept. of Public Health. Health and Safety Code (HSC) section 131051 transferred the duties, powers, and responsibilities of the Retail Food Safety Program to the Dept. of Public Health, and HSC section 131200 vests the Dept. of Public Health with rulemaking authority for the execution of its duties.</p> <p>The correct Authority code is Health and Safety Code 131200. The correct Reference codes are Health and Safety Codes 131050,131051, and 131052. HSC section 131050 lists divisions that are now administered by CDPH. HSC section 131051 lists programs that are now administered by CDPH. HSC section 31052 lists statutes that cover some of CDPH programs including forensic alcohol testing.</p> <p>This Article contains information on the three Quality System Essentials of Documents and Records, Personnel, and Process Control. The information should be broken out and placed in its respective QSE.</p> <p>Sec 1222: The sentence is unclear. "Represent" should be "described and documented."</p>	
2:17	DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for DPH-05-012	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012</p> <p>FORENSIC ALCOHOL TESTING LABORATORIES</p> <p>Submitted 7-29-2015</p>	

	<p>FORENSIC ALCOHOL TESTING LABORATORIES</p> <p>(see PDFs A1, A2, A3, A4, and A5)</p>	<p>(A) Documents Applicable to ASCLD-LAB</p> <ol style="list-style-type: none"> 1. Document documenting that ASCLD-LAB's accreditation program for breath alcohol calibration is based on ISO/IEC 17025 and its Supplemental Requirements. 2. ASCLD-LAB Program Applications, Guidance and Interpretations for Breath Alcohol Calibration Laboratories. 3. Memorandum from Marvin Schechter, Esq.; "ASCLD-LAB and Forensic Laboratory Accreditation: An Analysis;" 3-25-2011. 4. Article "Crime labs under the microscope after a string of shoddy, suspect and fraudulent results;" American Bar Assn.; 10-1-2013. 5. Article "Is ASCLD-LAB crime-lab accreditation inadequate?" Blogspot by "Grits for Breakfast;" 3-15-2012. 	
<p>2:18</p>	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL TESTING LABORATORIES Submitted 7-29-2015</p> <p>(see PDFs B1, B2, B3, B4, and B5)</p>	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL TESTING LABORATORIES Submitted 7-29-2015</p> <p>(B) Documents Applicable to ISO 1 7025</p> <ol style="list-style-type: none"> 1. ISO/IEC 17025:2005: General requirements for the competence of testing and calibration laboratories; Published by International Organization for Standardization (ISO); 5-15-2005. 2. ISO/IEC 17025:2005: General requirements for the competence of testing and calibration laboratories; Published by American Society for Quality; Published 2005. 3. "What is ISO 17025 All About The Basics of Quality and Repeatability;" Published by The Modal Shop; accessed 7-28-2015. 	

		<p>4. "What is ISO/IEC 17025? Why is it important?" Published by Calibrate Inc.; 2015.</p> <p>5. Part 2: "The Lab Accreditation Process"; 1-10-2013; Part 3: ISO and the NC Forensic Sciences Act of 2011;" 1-22-2013; Both articles published by Forensics Wordpress.</p>	
2:19	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL TESTING LABORATORIES Submitted 7-29-2015 (see PDF)</p>	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL TESTING LABORATORIES Submitted 7-29-2015</p> <p>(C) Documents Applicable to Uncertainty</p> <p>"A Beginner's Guide to Uncertainty of Measurement;" Measurement and Good Practice Guide; No. 11-Issue 2; Stephanie Bell; published by the National Physical Laboratory; accessed 7-28- 2015.</p>	
2:20	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL</p>	<p>DOCUMENTS AND RECORDS SUPPORTING COMMENTS SUBMITTED BY ROSALIE DVORAK-REMIS for</p> <p>DPH-05-012 FORENSIC ALCOHOL TESTING LABORATORIES Submitted 7-29-2015</p> <p>(D) Documents Applicable to Quality Management Systems</p> <p>1. Definitions for quality system-related activities; American Society</p>	

	<p>TESTING LABORATORIES Submitted 7-29-2015 (see PDFs D1, D2, D3, D4, D5, D6, D7, D8, and D9)</p>	<p>for Quality (ASQ); accessed 7-28-2015.</p> <ol style="list-style-type: none"> 2. "New Quality Guidelines for Laboratories;" Lucia M. Berte; Medical Laboratory Observer; March 2000. 3. "The Quest for Quality Blood Banking Program in the New Millennium;" Kim Du; International Journal of Hematology; Aug 2002. 4. "Laboratory Quality Management: A Roadmap;" Lucia M. Berte; Clinics in Laboratory Medicine; published by Elsevier Saunders, 2007; pp771-790. 5. "Expert Says Time is Now for Labs to Adopt QMS;" Published in The Dark Report; 10-12-2009. 6. Description of AABB Standards and Accreditation for Cellular Therapies and a flowchart describing AABB's accreditation process; AABB (formerly American Assn. of Blood Banks); accessed 7-28-2015. 7. Description of the Quality Management System for AABB Committees entitled "AABB Committee Quality System Essentials (QSEs); published formerly American Assn. of Blood Banks); May 2014. 8. "UCLA Pathology & Laboratory Medicine Quality Management Plan;" Description of the application of AABB's Quality Management System to the AAS-accredited entities of pathology and the clinical laboratory at the University of California-LA Pathology and Laboratory Medicine Departments; Effective 9-1-2010. 9. "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices;" U.S. Food and Drug Administration; accessed 7-27-2015. The article identifies the expectations of FDA with respect to implementation of a quality system applicable to the manufacture of medical devices. 	
<p>3:1</p>	<p>Quality Control Program</p>	<p>We would like to see the option of purchasing a NIST traceable reference material that meets the requirements for a quality control reference material in Section 1220.3(a)(1). The way the regulations</p>	

		are currently written, the mean value of the reference material must be determined from "...at least 20 replicate analyses...at a rate of no more than 2 analyses per day..." This has always presented a problem for our busy laboratory in that it takes at least 10 days to determine the value of a new lot of prepared quality control reference material. If the new lot is replacing a faulty lot, our laboratory is in a state of suspended casework until the new lot number has been analyzed at least 20 times. This can create a significant backlog for our analysts and for the courts, who are relying on timely reports to be issued by our laboratory. Having the option to purchase a NIST traceable reference material would alleviate the 10 days of down time that could arise from having a lot of quality control reference material that needs to be replaced. The current revision seems to support the use of NIST traceable reference materials, as they're an option for calibration of instruments (Section 1220.2 of the proposed revision) and for periodic determinations of accuracy (Section 1221.4 of the proposed revision).	
3:2	Quality Control Program	We would like to see a revision to Section 1220.4(b) to incorporate Assembly Bill 2425, allowing laboratories who are accredited to ISO/IEC 17025 to express all analytical results to 3 digits.	
4.1		The recommendations include clarification on standards for analysis, training requirements, and document retention.	
5.1		While it is appreciated that the Forensic Alcohol Review Committee (FARC) has made some progress updating Title 17, the language and requirements do not mirror the verbiage and practices in the VIM (International Vocabulary of Metrology) and ISO 17025.	
5.2		Language on page 15 requiring verification of a purchased CRM (certified reference material) is redundant and unnecessary. Reference materials traceable to a NMI (National Metrology Institute) from vendors accredited to ISO 17025 and Guide 34 should be sufficient. Checking against a NIST primary standard is costly and excessive.	

5.3		Language on page 17 requiring labs to truncate to 2-digits is in conflict with AB 2425 for. ASCLD/LAB accredited labs. Results should be required.to be reported with uncertainty to the appropriate and significant number of digits per accreditation requirements. On-going conflict between Title 17 and AB 2425 is confusing and harmful to labs.	
5.4		Language on page 5 requiring forensic alcohol analysts to have two years of analytical experience OR complete a comprehensive training program including mastery of pharmacology and physiology concepts is detrimental to small labs that rely on having trained analysts perform analysis while training for impairment testimony. This single tier approach is limiting and impractical.	
5.5		Overall, Title 17 should reflect the language and requirements of the current scientific community.	
6.1		<p>I write to request a public hearing on the proposed action. The purpose of the requested public hearing is to provide comment on the record regarding the language that was used in the Notice published on June 5, 2015 stating that "crime laboratories must take proficiency testing very seriously ... and must meet the proficiency testing criteria of ASCLD/LAB."</p> <p>In at least two major metropolitan areas in the State of California (i.e., San Diego and San Francisco), laboratories that perform forensic alcohol analyses in dead and/or living subjects (including drivers) are NOT crime laboratories; they are forensic laboratories or toxicology laboratories. Both of these laboratories are accredited by the American Board of Forensic Toxicologists (ABFT) to perform forensic toxicology analyses in postmortem forensic toxicology cases AND human performance forensic toxicology cases (which include DUID analyses).</p> <p>Consequently, I propose that the language in your Notice be re-written to be inclusive of all government laboratories engaged in the area of forensic alcohol analysis: "Crime OR FORENSIC TOXICOLOGY laboratories must take</p>	

		proficiency testing very seriously and must meet the proficiency-testing criteria of ASCLD/LAB OR ABFT."	
7.1	Breath Test Operators	<p>I would like to publically applaud the work of the Forensic Alcohol Review Committee (PARC) and the Department of Public Health in attempting to update the current dated regulations relating to alcohol analysis. Many of these changes are long overdue.</p> <p>I do take strong exception to the proposed changes in Section 1221.4 relating to the training of Breath Test Operators. These changes are clearly unnecessary and would impose significant increased labor costs to some law enforcement agencies. It almost seems as if someone on the committee may have been attempting to codify what their own agency does rather than implement what is truly needed to ensure accurate breath alcohol test results.</p>	
7.2	Background	<p>When the regulations for operator training were originally created, the most commonly utilized breath alcohol testing instruments (Breathalyzer 900 series /Gas Chromatograph Intoximeter Mk II/Omicron Intoxilyzer) required significant operator involvement to produce an accurate result. Instruments had to be zeroed, waste bags emptied, switches or buttons had to be activated at various times during the test sequence. Despite the training challenges posed by these devices; the regulations required only that :</p> <p>(3) Breath alcohol analysis shall be performed only with instruments for which the operators have received training, such training to include at minimum the following schedule of subjects:</p> <p>(A) Theory of operation; (B) Detailed procedure of operation; (C) Practical experience; (D) Precautionary checklist; (E) Written and/or practical examination.</p> <p>There was no requirement relating to the length of the training and no requirement for issuing certificates to trained operators. This was left to</p>	

		<p>the local laboratory and agency to decide. Some conducted day long training sessions, others were a couple of hours. Some administered written tests, some practical tests, some both. Some issued certificates of training, others compiled lists of trained operators that were provided to prosecutors' offices.</p> <p>And these regulations worked.... Agencies throughout California routinely utilize breath testing with some agencies reporting over 90% of alcohol tests being successfully administered on breath test instruments.</p>	
<p>7.3</p>	<p>Proposed Changes</p>	<p>My question to the FARC and Department is simply "if it isn't broken, why fix it?"</p> <p>The current generation of fixed location breath alcohol testing instruments (Intoximeter EC/IR series / CMI Intoxilyzer 8000 & 9000 / Drager Alcotest 9510) are microprocessor controlled devices that oversee the entire analytical process from ensuring sampling of deep lung air to analysis to ensuring compliance with the 0.02% agreement requirement. Basically these instruments have a start button and the major involvement of the operator is to actively monitor the 15 minute observation period, make keyboard entries in response to prompts from the instrument and install mouthpieces. Additionally, some instruments now have optional Driver's License scanners that reduce operator involvement even more.</p> <p>Even the current portable instruments (Lifeloc FC10 series / Intoximeter Alco-Sensor series / Drager Alcotest 8610) are similarly microprocessor controlled and prompt the operator through the test sequence.</p> <p><i>So why are we upping the training requirements for instruments that are far easier to use?</i></p> <p>The proposed changes require a minimum of 4 hours of instructional training to include a variety of variety of newly required topics. Although I personally enjoy discussing various testing instruments and the sensing technologies they employ, I'm fairly certain that the average law enforcement officer is not terribly interested in this information. They</p>	

	<p>simply want to know how to administer a test.</p> <p>Having first become a Forensic Alcohol Analyst in 1978 and having trained thousands of breath test operators, I believe I have the requisite experience to state that the most important thing operators need to recall from their training is to faithfully follow the steps on the precautionary checklist. These checklists ensure that the 15 minute observation period has occurred, the instrument is being operated correctly and that the two breath sample readings do not differ from each other by more than 0.02%.</p> <p>I doubt that an extensive discussion of infrared theory, fuel cell technology or alcohol distribution and elimination in a training session is going to provide a police officer or deputy sheriff with the knowledge to testify about them in court. This is clearly the purview of the forensic laboratory staff.</p> <p>Imposing a 4 hour requirement also increases the labor costs associated with this training. The salary, including benefits, of a Deputy Sheriff with the San Bernardino County Sheriff's Department is roughly \$60 per hour. Increasing training from two to four hours results in an increased cost of \$120 per deputy. Increasing training from two to four hours results in an increased cost of \$120 per deputy. With over 2,300 deputies, the labor costs for the initial training on a new breath test instrument would increase by more than \$276,000. Additionally, this increased training cost would continue as deputies retire and new staff is hired. It should be noted that most agencies in the state have higher salary levels and will be even more impacted by the proposed changes.</p> <p>This proposal would also change the requirement from written and/or practical exam to written test and practical exam. I will admit I am not a fan of written exams in this situation. I suspect if one carefully examines the training materials (handouts and powerpoints) used by laboratories currently employing written tests, you would find that trainees are heavily encouraged to remember certain things that "they might see again." I doubt that if the same examination was given even a day later that the trainees would be able to successfully repeat their passing grades.</p>	
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		<p>The practical test, on the other hand, is essential. This tests the ability of the operator to follow the steps on the checklist so they can competently conduct a breath alcohol test. Isn't that the reason we are conducting the training in the first place?</p> <p>Conclusion</p> <p>I would like to reiterate my support for most of the proposed changes as they are long overdue. I would suggest to the FARC and Department that leaving the current regulations for the training of breath alcohol test operators in place would be far better than the proposed changes.</p>	
<p>8.1</p>	<p>Initial Statement of Reason</p>	<p>The Initial Statement of Reasons (ISOR) prepared by CDPH definitely deserves a special consideration: there are way too many errors, misstatements, pieces of misleading information, inconsistencies and at some point pure political spin in the ISOR. In a sense, I would consider it smoke and mirrors masterpiece! It appears that the author of the ISOR does not have a high level of expertise in the area discussed in the rulemaking process.</p> <p>Examples:</p> <p>1. There are multiple references in ISOR to "removal of the Department jurisdiction" to approve personnel qualifications approve sample collection procedures, perform on-site inspections, conduct and evaluate proficiency tests, evaluate and approve training procedures, authority to request laboratory records. Although H&S code §100700 (b) introduced by SB1623 (2004) removed the requirement for a forensic alcohol laboratory to be licensed by the Department, nothing in legislative record suggests the removal of CDPH's jurisdiction over the CA crime laboratories performing forensic alcohol analysis. On the contrary: when FARC submitted its first draft of its proposed regulations, CDPH rendered a rather unfavorable response, noting that FARC revision seemed to "substitute a state regulation program with self-regulations by the forensic laboratories themselves through voluntary accreditation programs administered by private entity like ASCLD/LAB." The CDPH option cited the following authorities.</p> <p>"Health and Safety (H&S) Code section 100703(d) states that the</p>	

		<p>purpose of the forensic alcohol analysis regulations is the "ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws." H&S Code Section 100725 requires CDPH to enforce the laws and regulations pertaining to forensic alcohol analysis, and H&S Code section 100700(a) requires laboratories performing forensic alcohol analysis to comply with CDPH regulations".</p> <p>2. The ISOR statement that, "The laboratories will, however, still be required to maintain detailed, up-to-date written descriptions of each method and to make these available to the Department on request" is NOT correct because this particular Section 1220 (b)(1) would be repealed as proposed by FARC.</p> <p>Section 1120 General.</p> <ul style="list-style-type: none"> a) All laboratory methods used for forensic alcohol analysis shall be subject to standards set forth in this Article. b) Each licensed forensic alcohol laboratory shall have on file with the Department detailed up-to-date written descriptions of each method it user for forensic alcohol analysis. <ul style="list-style-type: none"> 1. Such description shall be immediately available to the person performing an analysis and shall be available for the Department on request. 2. Each such description shall include the calibration procedures and the quality control program for the method. 3. The ISOR mentions "ASCLD/LAB" more than 10 times. Examples include: <ul style="list-style-type: none"> a. "95% of California's crime laboratories are accredited by ASCLD/LAB" and that this "means they are held to national standards." No specifics mentioned regarding the meaning of "national standards". I am aware of the shortcomings of the ASCLD/LAB standards. b. It is suggested that ASCLD/LAB directed proficiency testing somehow repeals the existing Department's forensic alcohol proficiency testing program. c. It is also misinforms the reader in the comments to Section 1216.1(a)(2) stating that "Health and Safety Code section 	
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		<p>100702 requires ASCLD/LAB, the accrediting body of crime laboratories in California, annual audits of all accredited areas, as well as reaccreditation inspections every 5 years." None of this is mentioned in H&S Code 100702.</p> <p>d. In the comment to Section 1216.1(b)(3), which as revised would replace the current requirement for laboratory staff to successfully complete a proficiency test conducted by CDPH with a "competency test," the ISOR portrays the competency test standards proposed by ASCLD/LAB as somehow highly superior to the PT program administered by the Department:</p> <p>The following proposed changes are those recommended by FARC:</p> <ul style="list-style-type: none"> (A) Have differing, predetermined values; (B) Range from 0 to 0.25 percent alcohol concentration; (C) Have values unknown to the test taker; and (D) Be analyzed utilizing the laboratory's forensic alcohol method. (E) Results must fall within plus or minus 5% of the known value. <p>The "superiority" of ASCLD/LAB "recommended" requirements doesn't seem to be that obvious when taking into consideration the fact that except (B) the CDPH proficiency "test program has all the above elements: FAP proficiency test range is from 0.100 to 0.300 % alcohol concentration. In its comments to Section 1220(b)(2) – calibration and quality control program for the method, the ISOR states that "The ASCLD/LAB accrediting guidelines far exceed the requirements set forth in these regulations". No evidence provided. Apart from being a complete spin, this statement delivered by CDPH representative conflicts with Department's 2010 opinion on the issue: "The ASCLD/LAB guidelines do not establish any laboratory performance or procedure standards for blood alcohol analysis and they don't even mention breath alcohol analysis."</p> <p>e. In comments to Section 1220.1 (b), the ISOR states the role of evaluation of the ability of the method to meet the standards of performance is shifted from Department to... forensic analyst to "codify the oversight of the proficiency program to the individual laboratories"! Apparently the ISOR is suggesting here that the best way to evaluate the competence of the laboratories is to outsource the judgment on lab's PT performance to ASCLD/LAB</p>	
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		<p>Proficiency Review Program (PRP). However, ISOR doesn't mention the fact that the results of PT result review by ASCLD/LAB unlike Department's PT result are never made public. In fact ALL ASCLD/LAB records are confidential, to the extreme: one official <u>ASCLD/LAB document</u> in its part "Record retention and disposal" reads as follows: "As part of the process Team Captains and Inspectors are asked to dispose of any notes and records maintained or created as part of an inspection following the final vote on accreditation".</p> <p>What is not mentioned about ASCOL/LAB is that:</p> <ul style="list-style-type: none"> - It is a trade organization that certifies labs for a fee of minimum \$5000/apiece up to \$35,000 and that provides a "seal of approval covering diverse laboratory systems which laboratories can utilize to bolster their credibility through in-court testimony by technicians plus ancillary services such as protection from outside inquiry, shielding of internal activities and where necessary, especially in the event of public condemnation, a spokesperson to buffer the laboratory from media inquiry"² - It has rather questionable reputation: an Internet search will reveal its close association with the topic of "crime lab scandals" - There is no evidence that ASCLD/LAB accreditation is equals to better lab performance, quite opposite, I am afraid: according to at least one source³ " between 2005 to 2011, there had been 50 significant failures at American crime labs; 28 of these occurred at ASCLD/LAB-certified laboratories" - All ASCLD/LAB or any other accreditation organization cares about is "specify what you do, do what you specified and prove that you follow your own procedures". So what if lab's QC program has multiple shortcomings in the way it is set up – it is OK, just make sure you have this QC policy written down and prove to the inspector that you follow the instructions as though they are gift from GOD! <p>4. SOR "Problem statement" suggests that advances in science as the driving force for _amending the Title 17. NIST c;1vailable alcohol standards with superior accuracy, dry gas</p>	
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		<p>standards to calibrate breath alcohol instruments, mobile breath instruments that "run diagnostics, run calibration checks ... all automatically", "college degrees, course work, class titles, and Curriculum" that "advanced and changed to the point that it is difficult to correlate modern students' coursework with the requirements of the 1986 regulations.", new lower limits for commercial and juvenile drivers that "require alcohol programs that check the accuracy of their levels down to a 0.01%". Nevertheless, guess how many changes were proposed by FARC to accommodate new technology into regulations? It is just ONE—actually recommended by the Department- revisions of the requirements of Sections 1221.4 (a)(2)(A)1 and 1221.4 (a)(6) -operator performing a periodic determination of accuracy for instruments capable of performing a determination of accuracy automatically. The rest appears to be smoke and mirrors statements bearing no relevance to the current rulemaking proposal.</p> <p>As for education requirements for laboratory personnel proposed by FARC, they appear to be lower than those in a current regulation: paradoxically, NO chemistry classes required for forensic alcohol analyst engaged in daily activity of performing chemical analysis of samples containing alcohol for law enforcement purposes. I found this really odd.</p>	
<p>8.2</p>	<p>Section-by-Section comments: Article 1 General Section 1215 (F)</p>	<p>Before approaching the proposed regulation review, I have familiarized myself with the Rulemaking procedures spelled out in Administrative Procedure Act (<u>Government Code</u> §11340 <i>et seq.</i> and regulations adopted by the Office of Administrative Law (OAL), <u>California Code of Regulations, Title 1, §§ 1-120</u>. I do NOT think the proposed by FARC regulations meet the APA standards for Authority, Reference, Clarity, Non-duplication, and Necessity.</p> <p>Article 1. General</p> <p>Section1215 (f)</p> <p>The proposed change to replace the current classification system consisting of forensic alcohol analyst, forensic alcohol supervisor, and</p>	

		<p>forensic alcohol analyst trainee with just a flat definition of "Forensic Alcohol Analyst" makes no sense here. The spectacular rate of personnel rotation, that usually takes place in a busy crime lab, might be the reason for current personnel hierarchical structure. People hired by any organization usually do not come in standardized form, possessing equal level of expertise, but rather they go through stages of the professional growth while within the same company or organization. It is virtually impossible that one person can be responsible for all aspects of forensic alcohol analysis the day after he or she gets hired, but this is exactly what the revisions to this section would allow.</p> <p>The reason stated by FARG for the elimination of, for example, supervisor classification was to remove ambiguity associated with, "the legal community/courts/juries who may incorrectly assume a "forensic alcohol supervisor" is an actual supervisor in the laboratory."⁴</p> <p>No facts or evidence of the existence of this kind of confusion was ever presented. Thus, the committee failed to demonstrate the very necessity of such change. The ISOR statement, "The requirements for analysts are defined in the enabling statute; thus their classification and definition (forensic alcohol analyst and forensic alcohol analyst trainee) are no longer required." is a remarkable blunder, since the "enabling" statutes do not define any personnel classifications!</p>	
<p>8.3</p>	<p>Section by Section comments – Article 1 General Section 1215 (G)</p>	<p>The change from "steps" to "procedures" in the method definition is unclear and unnecessary; "method" and "procedure" are somewhat synonymous. A close look at the regulations would reveal that "method" usually refers to the steps to perform an analysis of blood, urine, or tissue sample (§§1216.1 (e) (2) (D), 1217.3 (c), 1220, (a) & (b), 1220.1, 1220.2...). The term "procedures" is used for breath alcohol analysis (§§1216.1.(e) (2) (E), 1221.1., 1221.4.(a), 1221.4.(a) (4)). I think it makes sense to keep these terms separate. I do not see how FARC the proposed amendments are necessary to effectuate the purpose of the statutes.</p>	
<p>8.4</p>	<p>Section by Section comments – Article 1 General</p>	<p>The proposed definition of "competency test" creates clarity issues; it is not clear who is the "person" being evaluated by that test, how the "evaluation of a person's ability" will be done. Moreover, the</p>	

	Section 1215 (K)	definition of "casework" is never introduced.	
8.5	Section by Section comments – Article 1 General Section 1215 (L)	Definition of the "proficiency test" is not clear and is not complete. Proficiency testing comprises an inter-laboratory system for the regular testing of the accuracy that the participant laboratories can achieve. It is by definition an external quality control. In most cases it is used to evaluate the laboratory performance in standardized testing across a number of labs. How is proficiency test used to evaluate "technical support"? As currently used by the Department, proficiency testing serves the purpose of evaluation of the ability of a laboratory's method to meet the required standards of performance, which is defined in Section 1220.1 (b). The definition proposed by FARC is riot consistent with the existing one.	
8.6	Section by Section comments – Article 1 General Section 1215 (N)	The definition of "NIST" is not correct. "NIST" stands for "National Institute of Standards and Technology;" NOT "National Institute Of Science and Technology"!	
8.7	Section by Section comments – Article 1 General Section 1215 (O)	The definition of "NIST Standard Reference Material (SRM)" is incorrect. The term, "NIST" Standard Reference Material (SRM)" is defined by NIST as "A CRM issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material (NIST SP 260-136)." (Note: a CRM is separately defined as a "certified reference material")	
8.8	Section by Section comments – Article 2 - Requirements for Forensic Alcohol Laboratories 1216 (A), 1-4	I think this section is misplaced. It looks like the better place is under Article 3 of the current regulations. This amended section has necessity/consistency problems. It is my understanding that this section is supposed to convey the idea of the authority the Department has over the laboratories (hence the section title, "Authorization Requirement.") There is even specific mentioning under the Authority and Reference of H&S Code §100725, which is the Department's responsibility to enforce the law and its regulations. It is difficult to understand why the mere submission of a "statement of intent to perform or stop performing alcohol analysis ...", providing some	

		<p>information about "laboratory current address and phone number...", and "a list of current laboratory personnel qualified to do forensic alcohol analysis" can be the basis for authorizing a laboratory to conduct forensic alcohol analysis. Does this mean that the requirements are automatically satisfied by simply providing the Department with some information? Nothing here states what the Department is going to do with this information.</p> <p>The ISOR states that the purpose of the requirement for laboratories to provide those items of information was "to ensure there is a repository of information for the public." How does creating a "repository" satisfy the statutory requirement that "the Department shall enforce this chapter and regulations adopted by the Department"? Is there anything in the enabling statute that assigns the "public repository" role to the Department?</p>	
<p>8.9</p>	<p>Section by Section comments – Article 2 - Requirements for Forensic Alcohol Laboratories 1216.1 (a) 2 (Current section 1216.1 (a) (3)</p>	<p>The committee has proposed to eliminate CDPH's proficiency testing program and rely on the requirements of the voluntary ASCLD/LAB accreditation program. The laboratories would rely on ASCLD/LAB approved provider and perform proficiency tests once per year (100702(a), H&S Code). Committee members referred to the "superior standards of ASCLD/LAB" and have stated that Committee's goal is "to divest laboratories from redundant oversight and inadequate proficiency testing programs"⁶. I think public should scrutinize this particular amendment to the existing regulation. And here are my reasons why:</p> <p><u>First</u>, one PT testing event per year does not constitute adequate proficiency testing. International standards recommend conducting proficiency testing at least twice per year. Accreditation organizations such as A2LA require two PT events per year as well. There must be a reason for that. CDPH currently administers 3 PT rounds per year.</p> <p><u>Second</u>, the statute refers to American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) "guidelines" for proficiency testing. This word "guideline" really reflects the essence of this program: participation is voluntary and no specific performance criteria are set for forensic blood alcohol analysis.</p>	

	<p><u>Third</u>, I found no evidence that a proficiency test conducted by the ASCLD/LAB approved proficiency test providers is somehow superior to one administered by the Department. It is likely <i>vice versa</i>: blood spiked with alcohol used by one ASCLD/LAB approved provider is described as "human or animal whole blood" (the effect of replacing human blood with animal blood on the forensic alcohol analysis result is unknown); the glassware for pool preparation by one provider is not sterilized while preparing the blood pool, which means PT samples could be contaminated with bacteria and may cause the alcohol concentration in PT samples to change with time, especially when the PT provider allows for as much as 3 months for the sample to be analyzed; the test results are compared to participants nationwide, so as a consequence, the calculated statistical acceptance limits are wider, for example, for one of the PT provider (CTS) the limits are on average 1.5-2.2 times wider than those typical for more uniform CA only labs PT testing administered by the Department. Another PT provider (<u>CAP</u>) allows $\pm 25\%$ variation for forensic alcohol analysis, which doesn't reflect scientific reality or the metrological characteristics for this analysis. The current regulation in California requires the accuracy of forensic alcohol analysis of $\pm 5\%$. The statistical treatment of the results by the approved providers is very simple and does not take into consideration the type of distribution or possibility that it can be multimodal and thus require different approach when evaluating the PT results. Meanwhile, more sophisticated statistical analysis requirements have been adopted by the international community; see <u>International Harmonized Protocol for the Proficiency Testing of analytical chemistry laboratories</u> (IUPAC Technical Report). The Department's statistical evaluation of PT data is consistent with the information.</p> <p style="text-align: right;">The Department's statistical evaluation of PT Data is consistent with the international standards.</p> <p>The Department's statistical evaluation of PT Data is consistent with the international standards.</p> <p><u>Fourth</u>, unlike the Department's proficiency test program, the results of PT testing produced by "approved by ASCLD/LAB provider" are never made public since those providers operate under the rules of strict confidentiality.</p>	
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		<p><u>Fifth</u>, the statutes (H&S Code 100703) don't even require the satisfactory laboratory's performance in the external proficiency test!</p> <p><u>Finally</u>, for many good reasons the Attorney General, (<u>AG opinion No 10-501</u>), concluded that7: "Although laboratories engaged in performing forensic alcohol tests must follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing ... the Department of Public Health may nevertheless (a) require a laboratory to also perform separate proficiency tests under Department of Public Health regulations using samples not obtained from an ASCLD/LAB-approved provider, and (b) discipline a laboratory for failing to perform these additional tests. "</p> <p>Conclusion:</p> <p>External proficiency testing is the most important tool for verifying the lab's performance available to any regulatory program. The replacement of highly functional; tailored to the specifics of forensic alcohol analysis proficiency test program administered by the Department by the commercial ASCLD/LAB approved provider testing would NOT better serve the purpose of verifying the laboratory's performances. It will serve a very different purpose and for different people. I could see from the standpoint of the regulated community how this kind of setup is a completely win-win situation for them, including: wider acceptable limits allow missing the target concentration big time. ... and still pass the PT test. Under current regulations, the participant with results beyond $\pm 10\%$ of the consensus value concentration would get an official CDPH letter asking the laboratory to investigate the source of the discrepancy and to take corrective action. With the proposed new regulation, though, the very same participant would pass the CAP PT with flying colors and do not need to invest time and money into corrective and preventive actions. Moreover, the confidentiality of the ASCLD/LAB PT procedures, allows a laboratory to comfortably avoid any public scrutiny in case the participant managed to grossly miss the target concentration even with the generous wide-range limits of the PT provider.</p>	
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		<p>The committee's proposal to submit PT results to the Department as well as "any documentation pertaining to corrective actions with respect to proficiency tests." Does solve the problem since it is not clear with the Department is going to do with the results. Beside many committee members, for the reasons specified above , expressed contempt towards the idea of the Department doing any PT result evaluation.</p> <p>The committee has not demonstrated by substantial evidence that the proposed revisions to this section will effectuate the purpose of the statute (H&S Code §100725) which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories [cf. H&S Code §100703 (d)] concentration even with the generous wide-range limits of the PT provider</p>	
<p>8.10</p>	<p>Section by Section comments – Article 2 - Requirements for Forensic Alcohol Laboratories 1216.1 (b) 1 (Current section 1216.1 (a) (1)</p>	<p>The appearance of term "physical or natural science" mentioned in proposed regulations reveals pretty low erudition level of the Committee's members. Physical science is part of natural science. The term "applied physical science" is not clear at all. The ISOR author apparently relied on the FARC representation that for the term "Applied science", "applied indicates hands-on experience versus theoretical experience". This is incorrect. "Applied science" is a discipline of science that applies existing scientific knowledge to develop more practical applications, like technology or inventions. This includes a broad range of science fields from Engineering to Child Care. Pure science is the counterpart of applied science. Applied science is also often referred to as technology. Following this logic, a degree in engineering is covered by the term "applied physical science." So, someone with diploma in robotic engineering would be totally qualified to perform forensic alcohol analysis. If retained, it would certainly need definition. The most disturbing part of the committee's proposed revisions is that the requirement of any chemistry work is removed from regulation; no lab work experience is any longer required for someone to be responsible for the operation of the crime laboratory. The proposed amendments do nothing to effectuate the purpose of the statute, which isto ensure the competency of the lab in forensic alcohol analysis, those changes are not necessary.</p>	

<p>8.11</p>	<p>Section by Section comments – Article 2 - Requirements for Forensic Alcohol Laboratories 1216.1 (b) 2 (Current section 1216.1 (e) (2)</p>	<p>The proposed amendments would remove the Department's authority to review and approve training protocols. So, here is the new hire: no requirement for this person who will work in a crime lab to have any chemistry classes, let alone quantitative analysis as part of their education. As though this were not enough, this person will receive a training "approved by the laboratory of employment" meaning at least potentially by another staff member with no chemistry knowledge whatsoever. There is no accountability here! At this point the crime lab would effectively turns into the institutional black hole with "no light coming out" where, with the absence of any external authority to approve or verify the training program, nobody can ever find out if the training is adequate, efficient, comprehensive and, in fact, is equivalent of two years' experience performing forensic alcohol analysis. The accountability problem here is compounded by the proposed repeal by the FARC of Section 1216.1 (a) (4), which requires onsite inspections by the Department.</p> <p>Last but not the least: qualification of a future employee is an important factor for ensuring the competency of the laboratory personnel in performing any analysis. Here, the elimination of the requirement for the analyst to complete any chemistry course work is particularly troublesome. Let's see what the requirements are for the Chemist qualification posted on the CDPH website (open examination bulletin):</p> <p>MINIMUM QUALIFICATIONS: Qualifying experience may be combined on a proportionate basis if the following requirements include more than one pattern and are distinguished as either I, or II, or III, etc.</p> <p style="text-align: center;">Either I</p> <p>Education: Possession of a Bachelor's or advanced degree with a major in chemistry, biochemistry, toxicology, or a closely related chemistry discipline from a recognized institution. (Admission to a master's or a doctoral degree program in chemistry, biochemistry, toxicology, or a closely related scientific discipline shall be considered to meet these education qualifications.)</p> <p style="text-align: center;">Or II</p> <p>Education: Possession of a Bachelor's or advanced degree with a major in a scientific discipline from a recognized institution with a total of 18 semester units in general chemistry, quantitative analysis, and organic chemistry with related laboratories. (Two years professional experience performing duties as</p>	
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		<p>a chemist, as defined in the scope of this specification, may be substituted for the required coursework.)</p> <p>Education as indicated above. (Registration as a senior in a recognized institution will admit applicants to the examination, but they must produce evidence of a degree before they can be considered eligible for appointment.)</p> <p>GENERAL QUALIFICATIONS: In addition to the scope defined on this announcement, candidates must possess essential personal qualifications including integrity, initiative, dependability, good judgment, ability to work cooperatively with others, and a state of health consistent with the ability to perform the assigned duties of the class. A medical examination may be required.</p> <p><u>"Bachelor degree and "total of 18 semester units in general chemistry, quantitative analysis and organic chemistry with related laboratories."</u></p> <p>Apparently, the Department does care about the qualification of the future staff working in the laboratory. However, the FARC seem to be pretty smug about the possibility of someone with entomology or robotic engineer major ("applied science", right?) working in a crime lab, being trained by other potentially under qualified lab personnel, without any external oversight or review of the training protocol, performing a chemical testing with the results of an analysis having a potential to affect someone's life and freedom. This should be of great concern to the public because this is what exactly is going to happen if the proposed changes take place.</p>	
<p>8.12</p>	<p>Section by Section comments – Article 2 - Requirements for Forensic Alcohol Laboratories 1216.1 (b) (3), (A) - (E), (Current section 1216.1 (e) (3)</p>	<p>This section has significant clarity/necessity issues that need to be resolved. As proposed by the FARC members, the revision would replace the current requirement for the analyst to successfully complete written examination and proficiency test conducted by CDPH with a laboratory "competency test." Unfortunately, this term is very vaguely defined. For example, the reference to "Predetermined value" mentioned in 1216.1 (b)(3), (A) is not defined in regulation. Is it concentration value? How does this value is predetermined and by whom? Is the "predetermined value" equivalent of "true value" mentioned in 1216.1 (3) (E)? Are they are related to each other? How are they related? Is the "competency test" is prepared in the lab or</p>	

		<p>obtained from external provider? There are too many questions to make the regulations clear or even meaningful. Moreover, replacing the current external examinations and approval of staff qualifications by CDPH with the proposed self-regulatory scheme will not ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws.</p>	
8.13	<p>Section .1216.1 (c) [Replaces Current Section 1216.1 (c)]</p>	<p>Currently the Department evaluates laboratory staff's qualifications and requires staff to successfully complete a proficiency test administered by the Department and pass a written examination. The FARC managed to invent a new role for the Department: collection of the "notifications" from the crime labs regarding the candidates' qualifications, training, practical examinations, and "proof of completion" of proficiency test (not necessarily even external PT). Nothing is stated regarding what the Department is going to do with this information. Since there is no way for the Department to verify most of the information provided by the crime lab through "notifications", that section is yet another "black hole lab phenomenon" created by FARC. Nevertheless, the ISOR optimistically concludes that "this requirement" (i.e., information submission), "will allow oversight of the laboratories to ensure compliance with these regulations."! How does the submission of information alone ever ensure compliance? These proposed amendments will not "allow" any oversight and it creates multiple clarity issues.</p>	
8.14	<p>Article 3 Training of Personnel</p>	<p>Section 1218 (b)</p> <p>Proposed changes here are irrelevant and unnecessary. The Department doesn't prohibit the laboratory from updating its training program to include whatever science advances it consider necessary to incorporate into its training.</p> <p>Section 1218 (c)</p> <p>This section contains clarity/necessity issues. The Department has 30 days to render its "belief" regarding the "notification" of the training submitted by the lab. Does that 30-day period start from the time the lab "provides" the Department with an "outline of training" and other documents? And what is the meaning of "outline of training"? "The</p>	

		<p>laboratory management shall respond to the Department in writing within 30 days". How long many this notification/response process can continue?</p> <p>FARC proposed to remove the requirements that the Department must approve the training. Instead the authority of approval of any training is transferred to the individual laboratory. One particular comment from the committee member Jennifer Harmon was, "the training program that has been approved by the laboratory is what is being submitted to the Department for them to have on record not for them to dictate to us how it should or shouldn't read."8 With the FARC proposed amendments, the laboratory notifies the Department and by the mere action of notification, it somehow demonstrates compliance with the regulations.</p> <p>If the Department has the general authority to "commence and maintain all proper and necessary actions and proceedings" to enforce its regulations" (H&S Code §100170(a) (1)) and specific authority to enforce the regulations pertain to forensic alcohol analysis (H&S Code §100725), how does the transferring training approval to each individual lab satisfy the necessity requirement under the Government Code Section 11340 (a)?</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>	
8.15	Article 4. Collection and Handling of Blood, Urine, and Tissue Samples	<p>Section 1219.</p> <p>The review committee here proposes to remove state-level oversight of the collection and handling of samples. The ISOR here states, "The Department no longer has the power to approve per enabling statute." With all due respect, I disagree: SB1623 (statutes 2004) repealed the Department's authority to require the laboratories to be licensed; the statutes do not prohibit the Department from any other regulatory activity; setting uniform standards for sample collection for forensic alcohol analysis is not an exception.</p>	

		<p>ISOR's author's belief that "adversarial justice system provides for the ultimate oversight of proper collection and handling, because these issues are challenged in most driving-under- influence cases" is not correct when it comes to DUI cases because vast majority of them never end up in court.</p> <p>The proposed changes do nothing to ensure uniform forensic alcohol analysis in CA. I do not see this happening if each individual lab in CA sets its own sample collection and sample handling procedures.</p>	
8.16	Article 4. Collection and Handling of Blood, Urine, and Tissue Samples	<p>Current Section 1219.1 (b)</p> <p>This section requires the collection of a volume of sample to be sufficient for duplicate analysis. FARC proposed to repeal this section. The ISOR explained that the "section is vague, and puts the onus on the technician drawing the blood to determine what amount is sufficient."</p> <p>First of all, the repeal of this section creates a consistency problem (Government Code, Section 11249 (d)). Duplicate analysis of sample is required under Section 1220.2 (a) (3), no verbiage was added to this section to require that an analyst determine if the sample volume collected is sufficient for duplicate analysis. Second, repealing 1219.1 (b) is not only unnecessary but might be not scientifically justified. The amount of blood collected using standard vacutainer tubes could affect the analysis result. The sample collection container contains a given amount of anticoagulants/preservative (e.g. NaF and potassium oxalate). The blood sample volume to anticoagulants/preservative ratio has an effect on analysis result. In a study, "Blood Analysis by headspace Gas Chromatography: does a deficient sample volume distort alcohol concentration?" 9, it was concluded that the deficient volume of blood and excess of NaF actually lowers the concentration of ethanol by 2-3% or more depending on what internal standard is used. I am not sure the majority of crime lab personnel are actually aware of this fact. It makes sense to determine the minimum sample amount through inter-laboratory study and include it into the regulations.</p>	
8.17	Article 5 . Methods of Forensic	Section 1220 (b)(1)	

	<p>Alcohol Analysis</p>	<p>Contrary to ISOR statement that the "section was amended to address an important factor that the analyst has immediate access to methods used", the FARC actually proposed here to repeal in this section the requirement that the laboratories must make their written method descriptions available to the Department on request. The ISOR also mentioned that ISO 17025 guidelines (5.4) - access of the analysis to the written method. This is irrelevant because this requirement of "written description shall be immediately available for the person performing analysis" has been on books for quite a while (Section 1220.(b) (1)). The ISOR comments are further irrelevant because the regulations don't mandate any ISO 17025 accreditation.</p> <p>Section 1220.1 (b)</p> <p>FARC proposed to transfer the authority to decide if the method meets the required standards of performance to a forensic alcohol analyst! Not even the lab director or QA/QC manager.</p> <p>"The ability of methods to meet standards of performance set forth in this Section shall be evaluated by the Department a forensic alcohol analyst using a laboratory's proficiency test results and such ability must meet the requirement of these regulations."</p> <p>Combined with the ISOR claim that Department oversight was removed in order to "codify the oversight of the proficiency program to the individual laboratories." proposed by FARC idea of the method performance evaluation would boil down to the following statement by FARC:</p> <p>"We require the individual laboratory to do whatever it wants to do with the evaluation of their analytical method-and we wish to codify this in this regulation".</p> <p>It is absolutely not necessary to codify into the regulations the "requirement" for the labs to self-regulate themselves! Moreover, the proposed self-regulation will not ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws.</p>	
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<p>8.18</p>	<p>Article 5 . Methods of Forensic Alcohol Analysis</p>	<p>Section 1220.2 (a)(1)</p> <p>The proposed change from "the method shall be calibrated" to "instrument shall be calibrated" is not necessary. It is inconsistent with other sections where "method" not the instrument is mentioned". It is confusing and reflects poorly on the scientific judgment of the FARC committee members. First, wet chemistry forensic alcohol methods may not utilize any "instrument" for the analysis. Calibration cannot be separated from all other steps of chemical analysis. Every blank, sample, standard, quality control sample are taken through the same uniform steps of analytical method, therefore it is "method" not instrument that is calibrated. For this reason, the Department's current regulatory program treats each instrument as a separate method. If a laboratory has two instruments (even the same model/make), separate PT samples provided by the Department. PT samples are analyzed by those instruments, and the results are evaluated separately. The proposed repeal of Section 1215.1 (j) where instrument is defined creates clarity issue: if the definition of the "instrument" is absent from regulation, then what really is being calibrated?</p> <p>Section 1220.2 (a)(1)(C)</p> <p>The requirement for the "verification" (whatever it means) of the concentration of a "new secondary standard used in the method by analyzing the new secondary standard concurrently with a NIST standard reference material" is of rather questionable venue.</p> <p>There is a reason why the current regulations require determining the concentration of new lot of secondary by the direct oxidimetric method using the PRIMARY standard potassium dichromate. In analytical chemistry, primary standards must meet pretty steep requirements of high purity, stability in presence of air, absence of any waters of hydration which might vary with changing humidity and temperature. They must be easily weighed, easily dissolved to produce stable solutions in solvent of choice; they should possess a larger rather than smaller molar mass. A list of the most used primary standards is published by NIST. Primary standards when used provide the best accuracy and traceability of the analysis</p>	
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<p>8.19</p>	<p>Article 6. Requirements for Breath Alcohol Testing</p>	<p>Subsection 1221.1 (b)(3)</p> <p>Breath sample collection requirements are currently listed under Article 5, Section 1219.3 The FARC has proposed to repeal current Section 1219.3 and relocate the requirements into new Article 6 1221.1 (b) (3), which reads as follows:</p> <p>"The breath sample shall be collected only after fifteen minutes during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked."</p> <p>First, the relocation of the section is unnecessary and inconsistent with other proposed changes in these regulations. A sample of "breath" as proposed by FARC is included in the definition of "Forensic Alcohol</p>	

	<p>Analysis" together with "samples of blood, urine or tissue of persons involved in traffic accidents or traffic violations" under Section 1215.1 (b). For that reason it seems logical to me that Article 5 "Collection and Handling of Samples" is quite proper location for breath sample collection requirements.</p> <p>Second, FARC seemed to "throw the baby with the bath water" by deleting the reference to two. very important elements of the breath sample collection requirements listed under 1219.3, which reads as follows:</p> <p>"A breath sample shall be <u>expired breath which is essentially alveolar in composition</u>. The quantity of the breath sample shall be established by direct volumetric measurement. The breath sample shall be collected only after the subject has been under <u>continuous observation</u> for at <u>least fifteen minutes</u> prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked."</p> <p>It is absolutely imperative for accurate breath alcohol testing that an alveolar in composition sample be collected and subsequently analyzed because only alveolar breath concentration is truly representative of the blood alcohol concentration of the subject at the time the breath sample is collected. Article 1 (Definitions) proposed Section 1215 (i) contain definition "alveolar" portion of expired breath and Section proposed Section 1215 (h) defines "Sample" as "portion of expired breath which is essentially alveolar in composition". Specific technique exists to collect alveolar in composition samples. Therefore, those important elements of sample collection are not simply definitions but rather requirements; they belong with sample collection/handling section.</p> <p>"Continuous" 15-minute observation period is another important requirement of the breath sample collection. Suppose breath alcohol instrument operator is observing a subject for 7 minutes and then leaves a room and returns in 2 minutes to finish the observation period after 8 minutes. If during that 2 minutes of operator's absence, a subject "ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked" than mouth alcohol or other interfering substances</p>	
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		<p>may produce inaccurate results. At some point it may even prevent the sample from being collected, if difference between duplicates exceeds the maximum allowable range.</p> <p>FARC has not demonstrated by substantial evidence how the proposed revisions to this section are necessary to effectuate the purpose of the statutes.</p>	
8.20	<p>Subsection 1221.2 (a) (2) (A) [former Section 1221.4 (a)(2) (A)]</p>	<p>The section introduces the term "True value" of a reference sample, but this term is not defined anywhere in the regulation. That creates clarity issue.</p> <p>FARC proposed to lower the upper concentration limit from 0.30 to 0.25 grams %. ISOR states that the reason for the change is that some instruments are incapable of demonstrating the required accuracy for samples above 0.25 grams% 10. No scientific (bibliographic or experimental) evidence was provided to support this claim.</p>	
8.21	<p>Part III. Conclusion</p>	<ol style="list-style-type: none"> 1. Contrary to exaggerated ISOR statements the FARC proposed regulations do nothing to modernize forensic alcohol testing for the state of California. 2. I consider the case of FARC proposed regulation as a power grab by special interest groups that hijacked the CA legislature in their brazen attempt to in effect de-regulate forensic alcohol analysis. Here is why I think so: <ul style="list-style-type: none"> • The number five cause of death in USA (2010) is accidents <u>CDC</u>, roughly 27% of all accidents are motor vehicle related traffic crashes and out of that 27% approximately 31% is alcohol related fatalities 11. It is obvious that drunk-driving is a very important public health issue. EVERY state in US has some forensic alcohol lab regulations: in 16 states, breath alcohol analysis is regulated by a Department of Health. The Chief Medical Examiner is responsible for breath alcohol analysis in Maryland. In Indiana, it's the State Dept. Toxicology. In four other states (Maine, New Hampshire, North Dakota, and Pennsylvania), health departments regulate blood alcohol testing, but breath testing is regulated by public safety agencies. 	

		<p>For the other 28 states, breath testing is regulated by public safety agencies.</p> <ul style="list-style-type: none"> • And yet, in California the legislature assigns the task of revision of Forensic Alcohol Regulation to a Committee (FARC) that is 75% composed of members of regulated community and' has an intrinsic interest to push their own agenda of de-regulating themselves rather than to be an independent guardian of public health and safety! • There was a significant risk of abuse of discretion by the review committee; and that is exactly what happened. One check and balance available to the public is the requirement that Health and Human Services Agency can reject the proposed changes in regulation. And even that check, which was added by the legislature in 2004, was almost eliminated last year by legislation (AB 2425) sponsored by Santa Clara County DA's office. The bill as introduced in 02/21/2014 proposed that H&S cope §100703 (e,f) in its first and second versions would REMOVE the Health and Human 1 Services Agency check, so that the Agency has no choice but APPROVE FARC revisions, see below: <p>(e) Within 90 days of receiving the review committee's revisions, the California Health and Human Services Agency may disapprove of one or more of the revision shall approve those revisions.</p> <p>(f) (1) Except as provided in paragraph (2), the The department shall adopt regulations pursuant to this section that shall Incorporate the review committee's revisions. Nothing In this section shall be construed as exempting the regulations from the requirements of chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.</p> <p>(2)The department shall not adopt regulations to incorporate any review committee revisions that were disapproved under subdivision (e)</p> • The bill's author claimed, that "DPH's unwillingness to approve the regulations impedes FARC from completing the work they 	
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		<p>have been tasked to do. Additionally, antiquated regulations compromise our public safety and prosecution" -comment in.AB2425 by 08- 06-201 Senate Floor Analysis</p> <p>Sadly enough, that is beginning to look more like "government of the FARC, by the FARC, for the FARC'</p> <p>Why don't we delegate the regulation of pharmaceutical industry to the biggest pharmaceutical companies in US? They are definitely experts in that area and ISO 17025 self-regulation regime is definitely going to be the best approach to all the Problems. Right?</p> <p>Why don't we let the oil companies, logging companies, fishing companies, chemical producing companies ... etc. set the rules for environment protection in this country? We have reached "a new era of technology, education, proficiency testing, and oversight when everyone is following the ISO 17025 Program of Accreditation, armed with ISO guidelines, and that, by itself will ensure the public environmental safety! Right?</p> <p>Why do we need a set of national and state regulations for clinical chemistry and require each clinical laboratory technologist to possess an active license? ASCOL/LAB can take care of it as good as it takes care of forensic alcohol self-regulation!!! Right?</p> <p>The courts have ruled that "Where the Legislature attempts to delegate its powers to an administrative board made up of interested members of the industry, the majority of which can initiate regulatory action by the board in that industry, that delegation may well be brought into question ..." 12</p> <p>I think that it is time to bring the delegation of authority to FARC into question.</p> <p>Fortunately, the legislature added one last check and balance on the FARC. Regulations in California must be promulgated in accordance with Administrative Procedure Act (APA) as set forth in the Government Code, Sections</p>	
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		<p>11340 et seq. The requirements of the APA are designed to provide the public with a meaningful opportunity to participate in the adoption of state regulations and to ensure that regulations are clear, necessary and legally valid. The enabling statute specifically requires that the regulations proposed by FARC must adopted in compliance with the APA (H&S Code §100703 (f)(1)). This includes a review of the regulations by the Office of Administrative Law (OAL), which must consider public comment and the response to these comments by the Department.</p> <p>The proposed regulations should be denied by OAL, withdrawn by the Department, and returned to FARC for further consideration.</p>	