

Comment #	Subject	Comment	Response to Comment
1:1	ISOR	<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>	<p>This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
1:2	ISOR	<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</p>	<p>This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.</p>

		<p>§100701) somehow supersede or effectively repeal the current 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	Authority and Reference	<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>	Instructed not to answer.
1:4	ISOR	<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</p>	This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.

		<p>note that with one exception, the committee has not proposed any changes in the regulations to accommodate new technology. In 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>	
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<p>1:5</p>	<p>NIST traceable alcohol standards (ISOR- Problem Statement)</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 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</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
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1:6	College coursework ISOR –Policy Statement Overview	<p>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!</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
1:7	Legal Limit ISOR – Policy Statement	<p>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</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>

		<p>“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	National standards ISOR – Policy Statement	<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>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
1:9	ISOR – Policy Statement	<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</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>

		<p>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>	
1:10	Changes to regulations ISOR – Policy Statement	<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 statues, 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>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
1:11	ISOR - Objectives	<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</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures</p>

		<p>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 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>followed by the agency in proposing or adopting the action.</p>
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1:12	<p>Consistency and Compatibility with Existing State Regulations ISOR</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 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>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</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>	
1:13	Section 1215 Technical numbering issue	<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>	Technical numbering issue for OR
1:14	Section 1215 (a) [Current Section 1215.1 (a)] Definition of	<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</p>	<p>Sentence restructured slightly to add clarity.</p> <p>Antiseptic was changed to disinfectant to provide consistency with</p>

	"alcohol"	<p>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>the regulations. The definition now reads "Alcohol" means the unique chemical compound, ethyl alcohol. When referencing compounds to be avoided, such as skin antiseptics, alcohol means any organic compound in which the hydroxyl functional group is bound to a saturated carbon atom.</p>
1:15	<p>Section 1215 (b)24 [Current Section 1215.1 (b)] Definition of "Forensic Alcohol Analysis"</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 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.</p>	<p>The definition of forensic alcohol analysis was meant to describe the testing, not the personnel conducting the testing.</p> <p>Equipment is common vernacular within the forensic environment. The committee felt this was a more appropriate term than "device."</p> <p>The regulations have included breath sample analysis under the definition of Forensic Alcohol Analysis for the past 30 years. There have been no clarity issues the committee is aware of. In addition, the regulations clearly articulate what requirements are specifically for breath or fluid analyses, so the committee felt this definition is not unclear and change was unnecessary.</p>

		<p>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 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</p>	
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		<p>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 done this.</p>	
<p>1:16</p>	<p>Section 1215 (c) [Current Section 1215.1 (c)]</p> <p>Breath analysis to breath testing</p> <p>Analysis to sampling</p>	<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 committee wished to clarify the distinction between breath and fluid alcohol analysis. The change from “analysis” to “testing” is more consistent with the verbiage used throughout the country. This definition was changed to more accurately reflect current law and more clearly state what breath alcohol testing means. The word “analysis” describes how the test results are achieved which is not suitable in this context, thus making this revised definition more appropriate.</p> <p>The committee agrees that sampling is</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 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</p>	<p>not an appropriate word choice. Sampling will be changed to analysis. The definition will now read: “Breath Alcohol Testing” means the analysis of a person’s expired breath, using a breath testing instrument to obtain a breath alcohol result.</p> <p>The definition of breath alcohol testing was meant to describe the testing, not the personnel conducting the testing., or the location of that testing.</p>
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1:17	<p>Section 1215 (d) [Current Section 1215.1 (d)] Solid?</p>	<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>	<p>The committee agrees with the comment, and the work “solid” has been removed.</p>
1:18	<p>Section 1215 (e) [Current Section 1215.1 (e)] Place-entity issue Breath inclusion in definition.</p>	<p>Section 1215 (e) [Current Section 1215.1 (e)]</p> <p>Clarity/Consistency – The definition of a laboratory as a “place” here creates many place-entity problems throughout the regulations. Other sections of the regulations impose requirements on the “laboratory.”</p> <p>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</p>	<p>The committee agrees there is a place/entity issue. The definition “Laboratory” was added to mean: an entity capable of assuming the responsibility of fulfilling the requirements of the regulations.</p> <p>The regulations have included breath sample analysis under the definition of Forensic Alcohol Analysis for the past 30 years. There have been no clarity issues the committee is aware of. In addition, the regulations clearly articulate what requirements are specifically for breath or fluid analyses, so the committee felt this definition is not unclear and change was unnecessary.</p>

		<p>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>ISOR Forensic Alcohol Supervisor</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 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</p>	<p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p> <p>It was the intent of the committee to remove all references to Forensic Alcohol Supervisor. Therefore a definition is not necessary.</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>

		<p>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> <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	Current Section 1215.1 (g)33	This comment is "irrelevant" as it is not specifically directed at the agency's

		<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>	<p>proposed action or the procedures followed by the agency in proposing or adopting the action.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</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>	<p>The committee felt that the removal of the three personnel titles (supervisor, analyst, and trainee) added clarity and conciseness to the regulations. As the old titles are not used in current laboratories, and the title “supervisor” in particular causes some confusion, the committee felt it best to have one title, and to articulate through the regulations what an analyst must do to be considered proficient.</p>
1:22	Section 1215 (g) [Current Section 1215.1 (i)]34 Steps to Procedures	<p>Section 1215 (g) [Current Section 1215.1 (i)]34</p> <p>Clarity/Necessity – The proposed change from “steps” to “procedures” in 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”</p>	<p>The committee felt that “procedure” was more applicable in this definition than “steps.”</p> <p>The committee does not need direction from the statute. The statute clearly</p>

		<p>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>	empowers the committee to review and rewrite these regulations as it deems necessary.
1:23	<p>Current Section 1215.1 (j)</p> <p>Define instrument</p>	<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>	The committee feels that instrument is a common term, and does not require a separate definition.
1:24	<p>Section 1215 (h) [Current Section 1215.1 (l)]</p> <p>Combining definitions and requirements for breath sample</p>	<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 breath sample is collected.</p> <p>Combining the requirements for the collection of the samples with the</p>	<p>The committee felt that the phrase “essentially alveolar in composition” is descriptive, and lends itself to providing clarity of the definition “sample.” It does not constitute an imposition of a collection requirement.</p> <p>The committee feels these phrases are common terms, and do not require definitions.</p>

		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.	
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 ; 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>	<p>The committee agreed to change the word casework to testing to add clarity. With this change, the committee feels the definition of competency test is clear.</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
1:26	New Section 1215 (l) Proficiency test definition Place entity issues	<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>	<p>The committee removed the words “technical support” from the definition. The committee feels the term “continuing competence” is common vernacular, and does not need a definition, nor does it lend itself to clarity issues.</p> <p>The committee agrees there is a place/entity issue. The definition “Laboratory” was added to mean: an entity capable of assuming the responsibility of fulfilling the requirements of the regulations.</p>

1:27	New Section 1215 (m) Precautionary Checklist definition	New Section 1215 (m) Clarity – The words “guide to assist” are unclear.	The committee added the word “written” to the definition for additional clarity. The definition will now read: “Precautionary Checklist” means a written guide to assist in the operation of a breath instrument.
1:28	New Section 1215 (n) NIST	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.”	The committee corrected the definition to read: “NIST” is an abbreviation for the National Institute of Standards and Technology.
1:29	New Section 1215 (o) NIST	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	The committee corrected the definition to read: “NIST Standard Reference Material (SRM)” means 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.
1:30	New Section 1215 (p) NIST Traceable	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	The committee feels this is an accurate and appropriate definition. This is also a necessary definition, as NIST Traceable is referred to in the regulations. The discussions had by the committee and the decisions made, provide substantial evidence that its actions are necessary to effectuate the purposes of the statute.

		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 Forensic Alcohol Laboratories Article 2 v 3	<p>Article 2 Requirements for Forensic Alcohol Laboratories</p> <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>	The committee removed Article 3 in its entirety, so the notification requirements were placed in Article 2.
1:32	Section 1216 Authorization vs. Notification	<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>	The committee changed “Authorization Requirement” to “Notification Requirement” to add to the clarity of the regulations, and to increase consistency with the other revisions proposed by the committee.
1:33	Section 1216 (a) Place- Entity	<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</p>	The committee agrees there is a place/entity issue. The definition “Laboratory” was added to mean: an entity capable of assuming the

		<p>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 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>responsibility of fulfilling the requirements of the regulations.</p>
<p>1:34</p>	<p>New or Revised Sections 1216 (a), (1) – (4) Department Oversight Definition of Fluid analysis</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</p>	<p>The committee removed Article 3 in its entirety, so the notification requirements were placed in Article 2.</p> <p>Laboratories have not been required for several years to submit their written methods to the Department for various reasons. The update to the regulations merely codifies this practice.</p> <p>Personnel are required to follow regulations to achieve proficiency in the area of Forensic Alcohol Analysis. Information showing this process will be forwarded to the Department to show compliance with the regulations. Please refer to Article 2, 1216.1 (c) 1-6</p> <p>The committee feels “fluid analysis” is a common term and does not require a definition.</p> <p>The committee added time frames for providing the listed information. 1216 (a) now reads: Every laboratory performing forensic alcohol analysis shall provide the</p>

		<p>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</p>	<p>Department the following within 90 days of a change of any information listed in 1-4 below.</p> <p>The committee intends that forensic alcohol laboratories will follow the regulations, and provide documentation of their compliance to the Department. Submission of these documents to the Department with this information meets the requirements for the Department to enforce regulations.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p>
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		to ensure the competence of the laboratories [cf. H&S Code §100703 (d)].	
1:35	Section 1216 (b) ISOR	Section 1216 (b) 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 (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.	This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.
1:36	Section 1216.1 (a) Place-Entity Issue	Section 1216.1 (a) 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.	The committee agrees there is a place/entity issue. The definition “Laboratory” was added to mean: an entity capable of assuming the responsibility of fulfilling the requirements of the regulations.
1:37	Current Section 1216.1 (a)(1) Forensic Supervisor Issue	Current Section 1216.1 (a)(1) 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.	The committee felt that the removal of the three personnel titles (supervisor, analyst, and trainee) added clarity and conciseness to the regulations. As the old titles are not used in current laboratories, and the title “supervisor” in particular causes some confusion, the committee felt it best to have one title, and to articulate through the

		<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>	<p>regulations what an analyst must do to be considered proficient. This change also reflects a laboratory’s ability to operate without a forensic alcohol supervisor. Current practice has many laboratories utilizing forensic alcohol analysts (FAAs) to do all of the alcohol analysis and interpretation, while using supervisors that are not necessarily FASs to supervise the personnel within the unit.</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p>
1:38	<p>Section 1216.1 (a)(1) [Current Section 1216.1 (a)(2)]39</p> <p>Standard of procedure requirements</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</p>	<p>The committee feels that the description is adequate, as the specificity of Standards of Procedures is outlined elsewhere in the regulations. (1221.2)</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>

		<p>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>	
<p>1:39</p>	<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 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</p>	<p>The committee disagrees, and finds the requirements in H&S 100702 to be very clear.</p> <p>“The laboratories shall submit, at a minimum of one per analyst per year” is clear, and reflects best practices in the forensic community.</p> <p>The committee disagrees. The Department’s proficiency tests have been inadequate for decades. Using ASCLD/LAB approved test providers is common practice and accepted throughout the forensic community.</p> <p>It is important to note that the Department’s proficiency testing program is not currently sufficient to meet accreditation requirements mandatory for accredited crime laboratories. In order to provide proficiency tests, a company must comply with regulations mandated by the accrediting body. An approved proficiency test provider is an individual, organization, or company which has applied for and obtained approval from ASCLD/LAB (or other accrediting body as approved by the legislature) to prepare and provide proficiency tests to participating</p>

		<p>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 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.</p>	<p>forensic laboratories, in the forensic disciplines, for which the provider has been approved. The Department is not recognized as an approved proficiency test provider. Proficiency tests themselves must adhere to strict guidelines. The Department proficiency tests do not adhere to these guidelines. This puts accredited laboratories in a difficult position. Although the Department requires that approved forensic alcohol testing laboratories participate in a proficiency testing program, the Department will not allow that program to be comprised of only approved providers. The Department still mandates that laboratories participate in the Department provided proficiency testing at least once a year. Since this participation does not fulfill accreditation requirements, laboratories are forced to participate in a substandard program along with the accredited program. This is not efficient, and adds nothing to the qualifications of a laboratory. It therefore seems redundant, and a waste of state resources, for the Department to supply an unnecessary program.</p> <p>The committee disagrees. Proficiency tests by approved providers with results forwarded to the Department is the best and most effective practice.</p>
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	<p>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. 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</p>	<p>Hence the new requirements set forth in H&S Code §100702.</p> <p>This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
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		<p>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 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</p>	<p>The Department has not conducted on-site inspections routinely for decades. The regulations were modified to reflect actual practice.</p> <p>Inspections conducted by the Department are not done on a regular or frequent basis. Laboratories can, and do, go many years without an inspection conducted by the</p>

		<p>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 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</p>	<p>Department. As all government forensic laboratories in California are accredited, this function would appear to be redundant, as ASCLD/LAB, the accrediting body used by the majority of crime laboratories in California, requires <u>annual</u> audits of all accredited areas, <u>annual</u> on-site inspections, as well as reaccreditation inspections every 5 years. In addition, for those laboratories that are not accredited, their work product must pass scrutiny on all adjudicated cases through the court system.</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or adopting the action.</p>
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		with the repeal of this section.	
1:41	Current Sections 1216.1 (a)(5) and 1216.1 (b)	<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 (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 of a forensic alcohol laboratory as an entity.</p>	<p>The committee feels that laboratories will provide required information to ensure sufficient regulatory oversight.</p> <p>As the requirements are laid out in the regulations, the committee felt this sentence was irrelevant.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p>
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</p>	<p>AG held up authority of the Department while waiting for the committee to complete its work. Department should respond to this?</p> <p>The Department is receiving information from laboratories to show that they are, in fact, following the</p>

	<p>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</p>	<p>regulations. This allows the Department to comment when it feels the laboratories are not following regulations. This is the disciplinary action the committee discussed and agreed to, with Department representation.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p>
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		<p>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>	
1:43	Section 1216.1 (b) [Current Section 1216.1 (e)]	<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>	This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.
1:44	Section 1216.1 (b)(1) [Current Section 1216.1 (e)(1)]	<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>	The committee agrees and the regulations have been changed to state: Possesses a baccalaureate or higher degree, in life science or physical science.
1:45	Section 1216.1 (b)(2) [Current Section 1216.1 (e)(2)]	<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</p>	The committee feels that one classification was most appropriate for purposes of this legislation. In

(e)(2)]	<p>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.”</p> <p>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 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</p>	<p>addition, it reflects current laboratory practice. It also removes the confusing title of “supervisor.”</p> <p>The committee agrees, and will add in “performing alcohol analysis” to read:</p> <p>Has two years of analytical experience performing alcohol analysis, and experience in interpreting and correlating...</p> <p>The committee disagrees that this is vague.</p> <p>The committee agrees there is a place/entity issue. The definition “Laboratory” was added to mean: an entity capable of assuming the responsibility of fulfilling the requirements of the regulations.</p> <p>The committee feels that with the submission of the training outline and additional listed documents, the Department has sufficient materials to ensure adequate oversight. The committee also felt that laboratories are best suited to train their own employees, as is done in every other forensic discipline.</p> <p>This comment is “irrelevant” as it is not specifically directed at the agency’s proposed action or the procedures followed by the agency in proposing or</p>
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		<p>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 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</p>	<p>adopting the action.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p>
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		<p>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>	
1:46	Section 1216.1 (b)(2)(A) [Current Section 1216.1 (e)(2)(A)]	<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>The committee feels that the removal of breath alcohol analysis from (A) and inclusion of breath alcohol testing in (E) serves to clarify the regulations.</p> <p>This section was amended to remove the phrase “including breath alcohol analysis” as it is redundant. The term Forensic Alcohol Analysis is defined in Section 1215.1 (g), and includes a reference to breath alcohol analysis.</p>
1:47	Section 1216.1 (b)(2)(E) [Current	<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>	<p>The committee wished to clarify the distinction between breath and fluid alcohol analysis. We felt that “testing”</p>

	Section 1216.1 (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.	was a more accurate representation of the process used to obtain a breath result. This also reflects the change in the definition of "Breath Alcohol Testing" noted in Section 1215.1 (c).
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.	The committee agrees. The wording will be changed to read: Practical laboratory demonstration of the analyst's trainee's ability to perform forensic alcohol analysis... The committee agrees. For clarification, the word "successfully" will be added. The regulations will now read: Practical laboratory demonstration of the analyst's trainee's ability to successfully perform forensic alcohol analysis;
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.	The committee agrees, and will remove the word "forensic" to now read: Interpretation of results of alcohol analysis, including correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of alcohol; This is established historical language, and the committee feels it is clear and requires no modification.
1:50	Sections 1216.1 (b)(2), (H) and (I)	Sections 1216.1 (b)(2), (H) and (I) [Current Sections 1216.1 (e)(2), (H) and (I)]	The terms "court testimony" and "court decisions regarding chemical tests of

	(I) [Current Sections 1216.1 (e)(2), (H) and (I)]	Clarity - Subsections (H) and (I), which require the training course to include the subject , “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.	alcohol to determine alcohol influence,” will be included in the training outline submitted to the Department.
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 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)].	Training summary in “requirements of these Group 8 regulations,” will be included in submitted training documentation.
1:52	Section 1216.1 (b)(3), (A) – (E) [Current Section 1216.1 (e)(3)]	Section 1216.1 (b)(3), (A) – (E) [Current Section 1216.1 (e)(3)] 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.” The ISOR states here that the description of the competency tests 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	The committee feels that “competency test” is a common term used in forensic laboratories to describe a practical examination that shows “competency” prior to a trainee being allowed to do independent casework. The inclusion of “competency test” here versus “proficiency test” more closely resembles common practice. The committee feels that the level of detail suggested here is not necessary.

		<p>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. 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</p>	<p>Proof of completion of the competency test, and its adherence to the regulations will be forwarded to the Department for review.</p> <p>This comment is "irrelevant" as it is not specifically directed at the agency's proposed action or the procedures followed by the agency in proposing or adopting the action.</p> <p>The elements of the competency test are laid out in the regulations. The competency test is a practical examination which will be outlined in the training documentation submitted to the Department. It is in addition to a written test and an annual proficiency test. The proficiency test will be from an approved external provider, as specified in H&S 100702. It reads:</p> <p>(a) <i>All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The required proficiency test must be obtained from any ASCLD/LAB approved test provider.</i></p> <p>(b) <i>Each laboratory shall participate annually in an external proficiency test for alcohol analysis.</i></p>
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		<p>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 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>(c) <i>Each examiner shall successfully complete at least one proficiency test annually.</i></p> <p>(d) <i>Each laboratory shall have a procedure in writing that describes a review of proficiency test results, and, if applicable, the corrective action taken when proficiency test results are inconsistent with expected test results.</i></p> <p>The new regulations require all staff employed in forensic alcohol analysis to complete an external proficiency test and a written test, along with a competency test, all of which will be submitted to the Department. The committee, along with Department representatives agreed that submission of the documents outlined in the regulations accomplished Department oversight to an appropriate degree.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</p> <p><u>**The committee recognizes that 1216.1 (b) (3) (E) is not reasonable, as 5% of a small number (0.02 for instance) is too small for laboratories to</u></p>
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			<p><u>adhere to. Therefore, the language will be changed to read:</u> <u>Results must fall within plus or minus 5% of the known value if the value is above a 0.08%. If the value is lower than a 0.08%, the result must be within plus or minus 0.005.</u></p>
1:53	Current Section 1216.1 (e)(4)	<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</p>	<p>This section is redundant and is deleted in its entirety. The information is already required in a previous section.</p> <p>The new regulations require all staff employed in forensic alcohol analysis to complete an external proficiency test and a written test, along with a competency test, all of which will be submitted to the Department. The committee, along with Department representatives agreed that submission of the documents outlined in the regulations accomplished Department oversight to an appropriate degree.</p>

		<p>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 the competence of the laboratories [cf. H&S Code §100703 (d)].</p>	
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>	The committee agrees. This section has been removed in its entirety.
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>	The committee agrees. This section has been removed in its entirety.
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</p>	The committee felt that the removal of the three personnel titles (supervisor, analyst, and trainee) added clarity and conciseness to the regulations. As the old titles are not used in current

		<p>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 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>laboratories, and the title “supervisor” in particular causes some confusion, the committee felt it best to have one title, and to articulate through the regulations what an analyst must do to be considered proficient. Therefore this section was removed in its entirety.</p> <p>The forensic alcohol laboratory will be required to ensure its analysts are competent to conduct alcohol analysis. Running 25 samples with known results serves only as practice for an analyst, and does not show competence. The competency test requirement outlined in Section 1216.1 (b) (3) is a true test of an analyst’s competency, as the answers to the test are unknown to the analyst.</p>
1:58	New Section 1216.1 (c)	<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</p>	<p>The committee removed Article 3 in its entirety, so the notification requirements were placed in Article 2.</p> <p>The committee feels that with the submission of the training outline and additional listed documents, the Department has sufficient materials to ensure adequate oversight. The committee also felt that laboratories are best suited to train their own employees, as is done in every other</p>

		<p>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 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</p>	<p>forensic discipline.</p> <p>The committee agrees, and the following clarifications were made to separate out documents submitted for newly trained analysts versus all analysts.</p> <p>(c) Every laboratory performing forensic alcohol analysis shall provide to the Department the following for each newly trained forensic alcohol analyst:</p> <p>(1) A copy of the diploma(s) or transcripts of relevant education for each individual performing forensic alcohol analysis for the laboratory. The relevant education includes proof of a baccalaureate or higher degree in any life science or physical science;</p> <p>(2) A training summary of the topics outlined in 1216.1 (b) (2) with a completion date for each individual performing forensic alcohol analysis for the laboratory;</p> <p>(3) Copies of qualifying tests to include written examinations for each individual performing forensic alcohol analysis for the laboratory;</p> <p>(4) Proof of completion of a competency test which follows the</p>
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		<p>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 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>requirements articulated in 1216.1 (b) (3) for each individual performing forensic alcohol analysis for the laboratory.</p> <p>(5) Written notification to the Department alerting it that the individual has successfully completed his or her training prior to beginning casework; and</p> <p>(d) Proof of completion of a proficiency test as outlined in 1216.1 (a) (2) for each analyst performing forensic alcohol analysis for the laboratory.</p> <p>The committee feels that "qualifying tests" is common language, and does not need defining.</p>
1:59	Article 3. Licensing Procedures	<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</p>	<p>The committee removed Article 3 in its entirety, so the notification requirements were placed in Article 2.</p> <p>The Department has not conducted on-site inspections for decades. The regulations were modified to reflect actual practice.</p> <p>The committee disagrees. The Department's proficiency tests have been inadequate for decades. Using ASCLD/LAB approved test providers is common practice and accepted</p>

		<p>[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 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>	<p>throughout the forensic community. Proficiency tests by approved providers with results forwarded to the Department is the best and most effective practice.</p> <p>The committee does not need direction from the statute. The statute clearly empowers the committee to review and rewrite these regulations as it deems necessary.</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</p>	<p>Article 3 has been removed in its entirety. Notifications have been moved to Article 2. Qualifications of a forensic alcohol analyst are laid out in Article 2.</p>

		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)].	
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