

|                    |                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>1:60</b></p> | <p>Section 1217 (a)</p> | <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&amp;S Code §100725). The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes (H&amp;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&amp;S Code §100703 (d)].</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |
| <p><b>1:61</b></p> |                         | <p>Section 1217.2</p> <p>Necessity – This section requires a laboratory to notify the Department of its intent to perform forensic alcohol analysis using application forms created by the Department. The repeal of this authority would prevent the Department from exercising its responsibility to enforce the regulations, since it wouldn’t even know who is performing the analyses. The legislature designated the Department of Public Health as the specific state agency with specific authority to enforce the law and its</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant</p>                                                                                                                                                                                                                                                                                                                                                                                        |

|             |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                     | <p>regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&amp;S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&amp;S Code §100703 (d)]. Amendments must be added to the section to clarify and make specific the required information to be included on the forms furnished by the Department.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” People v. Adams (1976) 59 Cal.App.3d 559, 567</p>                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>1:62</b> | <p>Sections 1217.3, (a) and (b)</p> | <p>Sections 1217.3, (a) and (b)</p> <p>Necessity/Consistency – These sections require a person responsible for forensic alcohol analysis at a laboratory to notify the Department of all changes or discontinuances of activities authorized under the regulations using forms created by the Department. A laboratory must report these changes within 30 days of their occurrence. The requirements described in these sections are consistent with and in harmony with H&amp;S Code §100725, which requires the Department enforce the law and regulations.</p> <p>The legislature designated the Department as the specific state agency with specific authority to enforce the law and its regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&amp;S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&amp;S Code §100703 (d)]. Amendments must be added to the section to clarify and make specific the required information to be</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” People v. Adams (1976) 59 Cal.App.3d 559, 567</p> |

|             |                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                | included on the forms furnished by the Department.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>1:63</b> | Section 1217.3 (c)             | <p>Section 1217.3 (c)</p> <p>Necessity/Consistency – The section describes the requirement that laboratory personnel must re-demonstrate their competence when transferring between different laboratories. In general, when someone transfers from one laboratory to another, there will be changes in methods and procedures and instruments and equipment. The authority provided here is consistent with mandate for the Department to enforce the law and regulations (cf. H&amp;S Code §100725) in order to ensure the competence of the laboratories and their employees. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&amp;S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&amp;S Code §100703 (d)].</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” People v. Adams (1976) 59 Cal.App.3d 559, 567</p> |
| <b>1:64</b> | Sections 1217.6 and 1217.6 (b) | <p>Sections 1217.6 and 1217.6 (b)</p> <p>Necessity – The committee proposes to repeal these sections, which describe the authority of the Department to enter a laboratory at all reasonable times to conduct an inspection in order to determine whether or not there is compliance with the provisions of the regulations. Such inspections are completely standard in all laboratory regulation programs. The Department needs regulatory authority to access the premises of the laboratory in order to conduct site inspections. The Department’s inspections are focused on blood and breath alcohol analysis. Reports of each inspection are prepared on standard forms</p>                                                                                                                                                                                                                                                                      | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts</p>                                                                                                                                                                                                                                                                                                    |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>filed with the Department. All of the requirements of the regulations are evaluated during an inspection.</p> <p>The rulemaking record<sup>57</sup> shows that the members of the review committee frequently noted that the majority of the laboratories are inspected by accreditation programs such as ASCLD/LAB. However, as noted in the comments under current Section 1216.1 (a)(4), the site inspections conducted at five-year intervals by these voluntary accreditation organizations are not specific to the requirements of forensic alcohol analysis and don't cover breath alcohol analysis at all. As specifically set forth in the ASCLD/LAB guidelines, records of its site inspections are strictly confidential. However, at a 2008 meeting of the State's Crime Lab Review Task Force (established by AB 1079, 2007), Task Force Vice Chair Barry Fisher (Director of the Los Angeles Sheriff's Dept. Laboratory), provided a copy of a report of a 2006 ASCLD/LAB inspection of his laboratory.<sup>58</sup> The Los Angeles Sheriff's Dept. performs tens of thousands of forensic alcohol analyses each year. However, alcohol analysis is not mentioned in the ASCLD/LAB inspection report. Alcohol analysis is a subdiscipline of toxicology. The toxicology evaluation during the site inspection consisted of four Yes/No questions: Does each analyst have a college degree?; Did each examiner complete an initial competency test?; Did each examiner complete an annual proficiency test?<sup>59</sup>; and the remarkably conclusionary question, "Does each examiner understand the instruments, and the methods and procedures used?" By contrast, the Department of Public Health's inspections are focused on blood and breath alcohol analysis. All of the requirements of the regulations are evaluated during an inspection. Reports of each inspection are prepared on standard forms.</p> <p>The current regulatory authority to conduct inspections is necessary to</p> | <p>have long recognized this self-enforcing aspect of Title 17 regulations, noting that the "regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence." <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|             |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                              | enable the Department to ensure the competence of the laboratories and employees and to enforce the law and regulations. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes, which requires the Department to enforce the law and the regulations (H&S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&S Code §100703 (d)].                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>1:65</b> | Sections 1217.7, (a) and (b) | <p>Sections 1217.7, (a) and (b)</p> <p>Necessity – These sections authorize the Department’s current site inspection and proficiency testing activities. The Department has stated that it needs to continue its current oversight of proficiency testing.<sup>60</sup> The Department’s laboratory proficiency testing program provides an objective, independent assessment of the competency of the laboratories. Section 1217.7 (b) describes the purpose of the proficiency tests which is to enable the Department to evaluate the accuracy of the forensic alcohol analyses performed by a laboratory. As discussed under Section 1216.1 (a) (4), site inspections for cause are needed to enable the Department to ensure the competence of the laboratories and employees. Again, site inspections and proficiency tests are completely standard procedures in any laboratory regulation program. The legislature designated the Department of Public Health as the specific state agency with specific authority to enforce the law and its regulations. There is no other agency or organization that provides oversight of the activities of the forensic alcohol laboratories. The committee has not demonstrated by substantial evidence how the repeal of these sections will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (H&amp;S Code §100725) in order to ensure the competence of the laboratories and personnel employed by the laboratories [cf. H&amp;S Code §100703 (d)].</p> | The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567 |

|                    |                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>1:67</b></p> | <p>Article 3. Training of Personnel (Current Article 4.)61 Section 1218</p> | <p>Article 3. Training of Personnel (Current Article 4.)61 Section 1218</p> <p>Clarity – The review committee proposes here to change the section title from “Training Program Approval” to “Training Program Review.” As discussed below, the committee deleted all references to the Department’s “approval” of training in the section. However, the proposed revisions to the article do not describe any “review” of training programs submitted by a laboratory and consequently the change in the section title still creates clarity issues.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>The change in title clarifies the role of the Department from a role of “Approval” to a role of “Review” consistent with the proposed changes.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p><b>1:68</b></p> | <p>Section 1218 (a)</p>                                                     | <p>Section 1218 (a)</p> <p>Clarity/Necessity/Consistency – This section currently describes the requirement that the Department must approve all training intended to qualify persons under the regulations. The review committee deleted all references to the Department’s “approval” of training and substituted language, which requires the training organization to submit descriptions of the training in order to, “demonstrate compliance with these regulations.” Subsequently, under Section 1218 (b), the committee’s proposed revision refers to the submission process in Section 1218 as a “notification” to the Department. The language here is not completely clear, but it suggests that the mere act of submitting something demonstrates compliance with the regulations.</p> <p>The ISOR comments for the entire article state that, “The proposed regulations further codify the removal of the Department’s jurisdiction over training.” The reference here to codification suggests that the proposed revisions, which remove Department’s authority to approve training, follow some statutory directive. The committee’s ISOR frequently attempts to justify the review committee’s proposed revisions</p> | <p>The deletion of “approval” and reference to “notification” are consistent with the proposed changes. Provisions for notification by the Department will allow the Department to notify a laboratory if the Department believes the training program is out of compliance with these regulations. Any non-compliance with the regulations impacts the weight given by the court to the evidence. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed</p> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                    |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>with the claim that it was the intent of the legislature to eliminate oversight by the Department. (Note: the adverb “further” here in the ISOR comment suggests that this is a continuation of this theme). However as noted previously, nothing in the legislative record indicates that the legislature intended to eliminate state-level oversight. The legislature retained the mandate for the Department to enforce the law and the forensic alcohol analysis regulations (cf. Health and Safety Code §100725) and the statutes specifically require the laboratories to comply with the Department’s regulations [cf. Health and Safety Code §100700 (a)]. The only specific limitation placed on the Department by the legislature was the elimination of the authority to require that the laboratories be licensed. The Attorney General’s Office, in its 2011 opinion<sup>62</sup> regarding the forensic alcohol program evaluated the legislative intent of the 2004 legislation and concluded, “Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure.”</p> <p>The committee cannot rely on the incorrect, one sentence claim implying that the revisions proposed under this article simply carry out some sort of legislative intent. The committee must demonstrate by substantial evidence that replacing the Department’s current regulatory authority to approve training with a process that permits the 40 individual laboratories to self-certify their trainings will ensure the competence of the laboratories as required by Health and Safety Code §100703 (d).</p> <p>The committee also revised the section to specifically refer to the training described under Section 1221.2 (a)(3). This would mean that descriptions of the training authorized under proposed Section 1216.1 (b)(2), i.e., training provided to laboratory staff in lieu of a requirement</p> | <p>standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” People v. Adams (1976) 59 Cal.App.3d 559, 567</p> |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>for two years of experience performing forensic alcohol analysis, would not ever be submitted to the Department or subjected to any kind of external evaluation or review.</p> <p>The committee's proposed revisions create a new clarity/consistency issue. The scope of Section 1218 (a) is set by the language, "Any organization, laboratory, institution, school, or college conducting a course of instruction..." There are two types of training described in the regulations. Training for breath instrument operators [cf. Section 1221.2 (a)(3)] and the training provided to laboratory staff in lieu of a requirement for two years of experience performing forensic alcohol analysis [cf. current Section 1216.1 (b)(2)]. The committee has proposed to totally exempt the latter training from any of the requirements of Section 1218. This leaves only the breath instrument operator training. As described in the comments under Section 1221.2 (a)(4) (former Section 1221.4 (a)(4)), training of breath instrument operators appears to require the participation of a forensic alcohol laboratory at least in the initial "development" of the training "curriculum." Accordingly, it is not clear how the non-laboratory entities described by the language, "Any organization,...., institution, school, or college conducting a course of instruction" would be permitted to provide training for breath instrument operators. The language proposed by the committee here and under Article 6 (current Article 7) is very vague, but it appears that there is at least a clarity and perhaps a consistency issue here.</p> <p>While the committee repealed the specific language, which required the Department's review and approval of training, at its last two meetings it added a new Section 1218 (c), which authorizes the Department to notify a laboratory in writing if it "believes" that a laboratory's training program does not comply with the regulations. The language here appears to contradict the provisions of subsection (a), which state that a</p> |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>laboratory demonstrates compliance with the regulations by simply submitting certain items of information. The ISOR for this section managed to capture the contradiction here by noting that revisions to the section clarify that the “discretion regarding the content of training programs lies with the laboratories, not the Department. However, it allows the Department to notify a laboratory if the Department believes the training program is out of compliance with these regulations.” The obvious clarity issues with the committee’s proposed revisions here are discussed further below under the comments for Section 1218 (c).</p> <p>Finally, there are the ongoing place-entity issues in this section since a laboratory (a place) can’t conduct a course of instruction. The place/entity issue must be addressed in the regulations in order to effectuate the purpose of the statutes.</p> <p>The Department has stated that it needs to continue its current approval authority of all training described under the forensic alcohol regulations [i.e., training described under Section 1216.1 (b)(2) and Section 1221.2 (a)(3)] in order to ensure the competence of the laboratories and employees and to enforce the law and the Department’s regulations.<sup>63</sup> The legislature vested the Department of Public Health as the specific state agency with specific authority to enforce the law and its regulations. No other agency or organization provides any oversight of the forensic alcohol laboratories’ training programs. The Department’s current review and approval of training is absolutely critical in maintaining standardized alcohol testing in California. Allowing each individual laboratory to separately determine what training is required without any oversight at all will not ensure the competency and consistency of the training.</p> <p>The committee has not demonstrated by substantial evidence how its</p> |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|             |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                   |
|-------------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                              | proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>1:69</b> | Sections 1218 (a), (1) – (5) | <p>Sections 1218 (a), (1) – (5)</p> <p>Clarity/Necessity - The list of required information that a training organization must submit is unclear and not complete. The requirement to submit a “complete outline” is vague. According to comments made by the representative of the Department at the September 26, 2012 meeting of the review committee,<sup>64</sup> the Department currently requires the training organization to submit copies of all training materials (training handouts, precautionary checklists, PowerPoint presentations, etc.). In response to the Department staff’s comments, Committee member Jennifer Shen responded that she was “not interested in providing this information.”<sup>65</sup> The committee must either demonstrate by substantial evidence that these additional items (i.e., training materials) are not necessary to effectuate the purpose of the statutes or these items must be added to the list of records to be submitted to the Department.</p> | The committee considered the issue and concluded that a detailed and rigid list of training materials should not be addressed by statute or regulation, as these materials and items are likely to change with changes in procedures and technology, and concluded that a reasonable practitioner in the field would understand the meaning of “complete outline” |
| <b>1:70</b> | Section 1218 (b)             | <p>Section 1218 (b)</p> <p>Necessity/Clarity –The new language proposed by the review committee here is unnecessary. Nothing in the current regulations prohibits a training organization from updating its training programs. The proposed revisions to the regulations here and also the ISOR discussion of the proposed revisions describe training offered by a “laboratory.” As noted previously, the regulations [Section 1218 (a)] refer to training offered by “Any organization, laboratory, institution, school, or college conducting a</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | The committee concluded that the addition of this language clarified the intent to allow for changes in training as necessitated by advances in technology as appropriate without the requirement of additional legislative changes.                                                                                                                              |

|      |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                  | <p>course of instruction...” [See also comments under Section 1218 (a)]. The specific references to laboratory-provided training in this section create clarity and possibly consistency issues. Also, there are the ongoing place-entity issues in this section since a laboratory (a place) cannot conduct a course of instruction. The place/entity issue must be addressed in the regulations in order to effectuate the purpose of the statutes.</p> <p>The committee added language stating “The changes will be subject to Department notification as outlined in this Section.” Regulations do not “outline” requirements.<sup>66</sup> Regulations are rules or directives made and enforced by an authority. Regulations are distinct from voluntary guidelines such as the guidelines published by ASCLD/LAB, which may represent best practices, but do not have the force of law. Finally, the word “section” should be shown in lowercase, since this is consistent with the current format used in the California Code of Regulations.</p> <p>The committee has not demonstrated by substantial evidence how the proposed addition of this section will effectuate the purpose of any statute.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 1:71 | Section 1218 (c) | <p>Section 1218 (c)</p> <p>Necessity/Clarity – This new section apparently permits a response from Department in those instances where the Department “believes that the laboratory’s training program does not comply with these regulations...” The committee’s proposed revisions do not otherwise describe the Department’s “review” of a laboratory’s proposed training program or show how the Department would come to “believe” that a training program does not comply with the regulations, which obviously creates clarity issues. Again, the committee’s proposed revisions would repeal</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>Non-compliance with 30-day limits would potentially impact the weight given by the court to the evidence. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to</p> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                      |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>the current, specific requirements that the Department must “approve” all training. At the March 6, 2013 meeting, committee member Jennifer Harmon explained that, “the training program that has been approved by the laboratory is what is being submitted to the Department for them to have on record not for them to dictate to us how it should or shouldn't read.”<sup>67</sup></p> <p>The proposed revisions set 30-day time limits for the Department to communicate its “beliefs” and for “laboratory management” (an undefined term) to respond. The 30-day limits are unclear since the regulations do not specify when the clock starts. Moreover, the regulations do not describe the consequences of a failure by either party to meet the 30-day deadline or of a failure by “laboratory management” to respond at all. It is not clear whether the notification/response process is a one-time event or it can continue indefinitely. These questions need to be clarified in the regulations. However, there is a more fundamental question of the necessity of this regulation. As noted previously, the Department has the general authority to “commence and maintain all proper and necessary actions and proceedings to enforce its regulations” [cf. H&amp;S Code §100170(a)(1)]. Certainly, the authority here includes writing a letter to a laboratory that is not complying with the regulations. The Department not only has the authority to do this, but the statutes actually require the Department to take these actions in order to enforce the regulations (cf. H&amp;S Code §100725). The statutes here do not impose any time limits on the Department in taking enforcement actions.</p> <p>The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes, which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to</p> | <p>ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|             |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                | ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>1:72</b> | Section 1218.2 | <p>Section 1218.2</p> <p>Necessity - The committee proposes here to repeal the Department's authority to contract out the administration of proficiency tests and written examinations to third parties. The regulations here do not permit the Department to delegate any discretionary functions including the evaluation of tests and examinations. This is appropriate and consistent with the Department's exclusive responsibility for enforcing the law and the regulations that ensure the competence of forensic alcohol analysis in the State. No other entity fulfills this role.</p> <p>The ISOR claims that the section was "repealed because the Department no longer has this authority under the amended Health and Safety code statute." Once again, the committee did not appear to have the benefit of informed legal counsel in forming this opinion. As noted previously, the 2004 change in the statutes repealed the Department's authority to require the laboratories to be licensed. The statutes do not prohibit the Department from any other of the activities associated with the regulation of the laboratories including conducting proficiency tests and examinations. As a result, the provisions here enabling the Department to contract out some of these activities to a nongovernmental, third party vendor might in the future prove to be cost effective for the Department. For example, at the September 26, 2011 meeting of the review committee, Department staff presented a report, "Ideas for Forensic Alcohol Analysis Regulations,"<sup>68</sup> which described a program whereby some site inspections of laboratories would be conducted by ASCLD/LAB inspectors. In the Department's proposal, the</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the "regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence." <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |

|             |                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                                                                                                                      | <p>inspections would be based on the Title 17 requirements. The committee members did not accept the proposal, but it serves as an example of the type of contractual partnering that could be possible under current Section 1218.2.</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>1:73</b> | <p>Article 4. Collection and Handling of Blood, Urine, and Tissue Samples (Current Article 5.)<sup>69</sup></p> <p>Section 1219.</p> | <p>Article 4. Collection and Handling of Blood, Urine, and Tissue Samples (Current Article 5.)<sup>69</sup></p> <p>Section 1219.</p> <p>Necessity/ Consistency – The review committee here proposes to remove current state-level oversight of the requirements for the collection and handling of samples. The ISOR explanation for this removal was, “The Department no longer has the power to approve per enabling statute.” As noted previously (many times now), the conclusion here misrepresents the intent of the legislature. The review committee apparently reached its conclusion here without the benefit of competent legal counsel. Again, the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed; the statutes do not prohibit the Department from any other regulatory activity including setting standards for the collection of samples for forensic alcohol analysis.</p> <p>The ISOR quotes the committee in stating that the “court system provides the ultimate oversight of proper collection and handling</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>because these issues are challenged in most driving under the influence cases.” The committee did not provide any evidence of the effectiveness of judicial oversight here.<sup>70</sup> As noted previously, the overwhelming proportion of the State’s annual 175,000 drunk driving arrests never go to trial and the evidence is not subjected to any judicial scrutiny. Moreover, as a general rule, the courts will not substitute their own scientific judgment in evaluating evidence. For regulated testing, this role should be assigned to the administrative agency that writes and enforces the regulations. As noted in the ISOR, the committee also found that with regard to the specific procedures employed for the collection of samples, it was their intent to, “address these particulars (chain of custody logs, labeling, security etc.) as each laboratory entity sees fit.” First off, the reference in the ISOR to the “laboratory entity” is inconsistent with the definition in the regulations of a laboratory as a place [cf. renumbered Section 1215 (e)]. But aside from the ongoing place-entity issue, the committee’s proposed approach here does not achieve one of the benefits of regulation stated in the ISOR Policy Statement Overview, which is to ensure that the chemical testing in drunk driving cases is performed uniformly throughout the state. This will not be achieved if 40 different laboratories independently determine their sample collection procedures. It is completely appropriate to retain state-level oversight of the procedures for the collection of samples for forensic alcohol analysis. The California Department of Public Health is the appropriate body to set standards for the scientific validity as well as the health and safety of the procedures for collecting bodily fluids.</p> <p>Regarding the stated goal in the section to maintain sample identity and integrity, the regulations should incorporate by reference the document, “Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis.” Section 23158 (j) of the Vehicle Code describes the adoption of these uniform standards by the</p> |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|                    |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    |                           | <p>Department of Health Services (now California Department of Public Health), the Department of Justice, and the California Highway Patrol, but does not specifically name the standards or require their use.</p> <p>These standards, which spell out the required collection procedures and the procedures for maintenance of sample identity and integrity and chain of custody in drunk driving cases, must be adopted by reference in order to give them the force of regulations. Laboratories would be required to describe procedures for the collection and handling of samples, which comply with the Uniform Standards.</p> <p>The Department's current regulatory authority to approve procedures for the collection and handling of samples is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&amp;S Code §100725). The committee has not demonstrated by substantial evidence how its proposed revisions to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>1:74</b></p> | <p>Section 1219.1 (a)</p> | <p>Section 1219.1 (a)</p> <p>Clarity/Consistency –The ISOR states that the section was amended simply to reflect changes in the California Vehicle Code. This analysis is incomplete. The proposed correction in the Vehicle Code section reference is itself a non-substantive change. However, the committee's proposed revisions here would also eliminate the description of the referenced Vehicle Code section as identifying the personnel authorized to collect samples for forensic alcohol analysis. The section as revised by the committee now indicates that the referenced Vehicle Code</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>In addition to provisions relating to categories of personnel authorized to collect samples, Vehicle Code section 23158 provides for privacy in collection methods to maintain accuracy of the specimen, and provides for the department to adopt uniform standards for the withdrawal, handling, and preservation of samples. The committee addressed those procedures in the proposed revisions to Section 1219.1.</p> |

|             |                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                 |
|-------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                   | <p>section describes sample collection and processing requirements. In fact, the Vehicle Code does not describe any collection or processing requirements and only specifies the categories of personnel authorized to collect samples. This is correctly described with the language of the current regulations. The proposed revisions to this section are not clear and not consistent with or in harmony with the provisions of the cited Vehicle Code Section. Also, the current requirement to collect a sample “as soon as feasible” is not clear.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                 |
| <b>1:75</b> | <p>Current Section 1219.1 (b)</p> | <p>Current Section 1219.1 (b)</p> <p>Consistency/Necessity – The committee proposed to repeal this section, which requires the collection of a volume of sample which is sufficient to permit duplicate analyses. The ISOR commented that the “section is vague, and puts the onus on the technician drawing the blood to determine what amount is sufficient.” The ISOR adds, “It is proposed that the analyst will be required to determine whether the sample collected is sufficient to perform duplicate analyses.”</p> <p>There are several problems with the committee’s proposed revisions. The regulations require at least duplicate analyses of the samples [cf. Section 1220.2 (a)(3)]. Nothing new is proposed under Section 1220.2 (a)(3) that would now require the analyst to determine whether a sufficient volume of sample was collected. This has always been a practical requirement. The collection of a volume of sample which is not sufficient to permit duplicate analyses would mean that the analyses could not be completed in compliance with the regulations. The current regulations seek to avoid this by requiring the initial collection of a sufficient sample volume.</p> | <p>The existing language is vague as to the meaning of “sufficient” and is unnecessary. If a sample collected is insufficient for duplicate analysis, the reasons for the insufficient sample would go to the weight given to the results by the trier of fact, and not to the admissibility of the sample.</p> |

|             |                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                |
|-------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                                                                             | <p>There is a second issue here. The collection of very small volumes of sample when mixed with anticoagulant and preservative (typically weighing 120 mg) would create analytical problems for the laboratory. It would be difficult to aliquot a sample from the resultant liquid-solid slurry and potentially at least, there could be a loss of alcohol from such a matrix. One published study<sup>71</sup> found small losses (2 - 3%) in alcohol concentration when the volume of sample collected was deficient. The appropriate solution here would be to specify the minimum volume of sample to be collected. The laboratory would determine the required volume and transmit this information to the person collecting the sample.</p> <p>The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statute that requires regulations that ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> |                                                                                                                                                                                                                                                                                                                                |
| <b>1:76</b> | Section 1219.1 (b) [Current Section 1219.1 (c)]                                             | <p>Section 1219.1 (b) [Current Section 1219.1 (c)]</p> <p>Clarity – As revised by the committee, the regulations do not define or even require the use of a “suitable aqueous disinfectant,” but the regulations then list examples of suitable aqueous disinfectants. This creates a clarity issue. The terms, “suitable aqueous disinfectant” and also “volatile organic disinfectant” need to be defined in the regulations.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | The term “suitable aqueous disinfectant” coupled with examples of currently existing suitable aqueous disinfectants, provide sufficient guidance and clarity to a person reasonably skilled in the art of forensic analysis, while providing flexibility for advances in the science and without requiring further definition. |
| <b>1:77</b> | Sections 1219.1, (d), (d)(1), and (d)(2) [Current Sections 1219.1, (e), (e)(1), and (e)(2)] | <p>Sections 1219.1, (d), (d)(1), and (d)(2) [Current Sections 1219.1, (e), (e)(1), and (e)(2)]</p> <p>Clarity – Section 1219.1 (d) and the subsequent subsections [1219.1 (d), (1) and (2)] should be revised to clarify whether the sample handling requirements here apply to post-mortem samples.<sup>72</sup> Section 1219.1 (d)(2) should also be revised to clarify that the sample container contains the anticoagulant and preservative.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>As postmortem sample collection is well detailed in 1219.1 (e), further clarification in 1219.1 (d) would be redundant.</p> <p>1219.1 (e) should include an additional subsection, (3), that states that postmortem blood samples shall be mixed with anticoagulant and preservative.</p>                                   |

|             |                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                     |
|-------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | (e)(2)]                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                     |
| <b>1:78</b> | Section 1219.1 (e) [Current Section 1219.1 (f)]       | Section 1219.1 (e) [Current Section 1219.1 (f)]<br><br>Clarity/Necessity – The language here “all practical precautions to ensure an uncontaminated sample shall be employed” must be revised for clarity. Also, for the reasons described in the comments to current Section 1219.1 (b), the regulations must specify a minimum volume of sample collected.                                                                                                                                                                                                                                                         | The existing language is clear and unambiguous. If a sample collected is insufficient for duplicate analysis, the reasons for the insufficient sample would go to the weight given to the results by the trier of fact, and not to the admissibility of the sample. |
| <b>1:79</b> | Section 1219.1 (e)(1) [Current Section 1219.1 (f)(1)] | Section 1219.1 (e)(1) [Current Section 1219.1 (f)(1)]<br><br>Clarity/Necessity – The committee proposes to repeal the provision that exempts samples collected by a coroner and stored under refrigeration from the requirement that the sample must contain a chemical preservative. The committee must cite the scientific study relied upon to justify this change. Moreover, as noted under Section 1219.1 (d) et. seq., the regulations do not clearly state that post-mortem samples must be treated with an anticoagulant and preservative, so there are remaining clarity issues here that must be resolved. | 1219.1 (e) should include an additional subsection, (3), that states that postmortem blood samples shall be mixed with anticoagulant and preservative.                                                                                                              |
| <b>1:80</b> | Section 1219.1 (e)(2) [Current Section 1219.1 (f)(2)] | Section 1219.1 (e)(2) [Current Section 1219.1 (f)(2)]<br><br>Clarity – The language here, “Care shall be taken to avoid contamination by alcohol...” and the reference to a “major vein” must be revised for clarity.                                                                                                                                                                                                                                                                                                                                                                                                | The language is sufficiently clear and the committee did not feel a revision is necessary.                                                                                                                                                                          |
| <b>1:81</b> | Section 1219.1 (f)                                    | Section 1219.1 (f) [Current Section 1219.1 (g)]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | The language is sufficiently clear and the committee did not feel that further regulation                                                                                                                                                                           |

|             |                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                   |
|-------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | [Current Section 1219.1 (g)]                          | Clarity - The section should be revised to clarify who retains the samples and to specify the storage conditions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | of who retains the samples and how they are stored is necessary.                                                                                                                                                                                                                                                                                                  |
| <b>1:82</b> | Section 1219.1 (f)(1) [Current Section 1219.1 (g)(1)] | <p>Section 1219.1 (f)(1) [Current Section 1219.1 (g)(1)]</p> <p>Clarity – The ISOR states, “This subsection was amended to replace “coroner” with “medical examiner.” The ISOR adds that “the term “medical examiner” is more accurate and will apply to either system.” In fact, the revisions proposed by the committee do not replace the term “coroner” with “medical examiner,” but rather add a reference to medical examiner cases (i.e., “coroner’s/medical examiner’s cases”). As a consequence, the proposed revision to the regulations here 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 section should be revised to clarify the types of samples retained (blood, tissue) and to describe who retains the samples and the sample storage conditions.</p> | The addition of the term “coroner/medical examiner’s office” allows for greater clarity in the regulation as it applies to either system.                                                                                                                                                                                                                         |
| <b>1:83</b> | Section 1219.1 (f)(2) [Current 1219.1 (g)(2)]         | <p>Section 1219.1 (f)(2) [Current 1219.1 (g)(2)]</p> <p>Consistency/Authority/Reference/Clarity - the proposed revision of “forensic alcohol laboratory” to “forensic laboratory” creates clarity and authority/reference issues. The term “forensic laboratory” is undefined. The statutes (H&amp;S Code §100700) specifically reference laboratories that conduct alcohol testing by and for law enforcement and new Section 1215 (e) defines such laboratories as “forensic alcohol laboratories.” The proposed change is also inconsistent with the terminology (i.e., “forensic alcohol laboratory”) used throughout the regulations. Regarding the listing of agencies other than forensic alcohol</p>                                                                                                                                                                                                               | A cardinal rule of statutory construction is that a statute should be read as a harmonious whole, with its various parts being interpreted within their broader statutory context in a manner that furthers statutory purposes. Accordingly, not all words and terms need to be defined when the ordinary meaning of the word or phrase is clear and unambiguous. |

|             |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                    | laboratories, i.e., “law enforcement agency, or coroner/medical examiner’s office,” these terms require definition and it is not clear that the statutes provide the Department with the authority to regulate these entities. The requirement to provide “identifying information” with the sample also creates clarity issues since the required identifying information is not specified anywhere in the regulations (See also comments under Section 1219). Finally, the reference to “sufficient sample” is not clear.                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>1:84</b> | Section 1219.2     | Section 1219.2<br><br>Clarity/Necessity - The section should be amended to add a minimum sample volume collection requirement. The requirement here would be analogous to the requirement under current Section 1219.1 (b) and the comments offered under that section apply here. The review committee must consider the need for this requirement in order to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                              | The existing language is clear and unambiguous. If a sample collected is insufficient for duplicate analysis, the reasons for the insufficient sample would go to the weight given to the results by the trier of fact, and not to the admissibility of the sample.                                                                                                                                                                                                                                                                                              |
| <b>1:85</b> | Section 1219.2 (a) | Section 1219.2 (a)<br><br>Necessity/Consistency – The ISOR notes, “This subsection was amended to delete “an approved” sample because the Department does not approve of certain practices.” The awkwardly worded statement here appears to be a reiteration of the claim made under Section 1219 that, “The Department no longer has the power to approve per enabling statute.” Again this conclusion misrepresents the intent of the legislature. The 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed; the statutes do not prohibit the Department from any other regulatory activity including setting standards for the collection of samples for forensic alcohol analysis. Again, the Department’s current regulatory authority to | The proposed language is clear and unambiguous. The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this |

|             |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                          |
|-------------|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                       | <p>approve procedures for the collection and handling of samples is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&amp;S Code §100725). The committee has not demonstrated by substantial evidence how its proposed revision to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations as required by Health and Safety Code §100725 in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> <p>The ISOR also claims that the purpose of the proposed addition of the modifier, "from a living individual" to the description of the urine sample was to point out that the "procedures are not utilized when dealing with urine collection from a deceased person." In fact, there are no provisions in the regulations for the collection of post-mortem urine samples. As a consequence, the added clarification that the subject urine sample was obtained from a living person is not necessary to effectuate the purpose of any statute or regulation.</p> | <p>self-enforcing aspect of Title 17 regulations, noting that the "regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence." <i>People v. Adams</i> (1976) 59 Cal. App. 3d 559, 567</p> |
| <b>1:86</b> | Section 1219.2 (c)    | <p>Section 1219.2 (c)</p> <p>Clarity - The section should be revised to clarify who retains the samples and to specify the storage conditions.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>The language is sufficiently clear and the committee did not feel that further regulation was necessary</p>                                                                                                                                                                           |
| <b>1:87</b> | Section 1219.2 (c)(1) | <p>Section 1219.2 (c)(1)</p> <p>Clarity/Necessity - The ISOR identifies this section incorrectly as "Subsection 1219(c)(1)." The regulation itself is identical to Section 1219.1 (f)(2) and thus the comments for that section apply here. There is an additional necessity issue here. The review committee added "coroner/medical examiner's office" to the list of agencies that could be</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>The addition of the term "coroner/medical examiner's office" allows for greater clarity in the regulation as it applies to either system.</p>                                                                                                                                         |

|             |                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                             |
|-------------|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
|             |                                                                                                    | <p>in possession of a sample. However, Section 1219.2 (c)(1) pertains to the retention of urine samples. The samples retained by a coroner or medical examiner's office, which is not also a forensic alcohol laboratory, would be post mortem samples. As noted in the comments under Section 1219.2 (a), there are no provisions in the regulations for the collection of post-mortem urine samples for forensic alcohol analysis and consequently there would be no reason for a coroner or medical examiner's office to be in possession of forensic alcohol urine samples. Accordingly, the proposed revision to add "coroner or medical examiner's office" is unnecessary.</p> |                                                             |
| <b>1:88</b> | Section 1219.3                                                                                     | <p>Section 1219.3</p> <p>Clarity/Consistency – The committee proposed transferring the requirements of this section to Article 6 (current Article 7), while also amending the requirements. It would appear to be more appropriate to retain this section, which describes the requirements for the collection of a breath sample, here under Article 4 (current Article 5), which is currently titled, "Collection of Samples."</p>                                                                                                                                                                                                                                                 | Appropriate amendments are contained in proposed Article 6. |
| <b>1:89</b> | Article 5. Methods of Forensic Alcohol Analysis (Current Article 6.) <sup>73</sup><br>Section 1220 | <p>Article 5. Methods of Forensic Alcohol Analysis (Current Article 6.)<sup>73</sup><br/>Section 1220</p> <p>Section 1220 simply contains the title, "General." and this was left unchanged. The Initial Statement of Reasons (ISOR) for this section commented on the entire article, noting, "This article outlines the requirements for conducting the analysis of the samples. It includes discussions on sample handling, testing procedures, standards, controls, and quality assurance." The comments in the ISOR here reflect the committee's lack of understanding of the role of regulations.</p>                                                                          | The committee understands the role of regulators.           |

|             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                  | Regulations do not “outline” or “discuss” requirements; they are rules or directives made and enforced by an authority. Regulations are distinguished from voluntary guidelines such as the guidelines published by ASCLD/LAB, which may represent best practices, but do not have the force of law.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>1:90</b> | Section 1220 (b) | <p>Section 1220 (b)</p> <p>Necessity/Consistency – The proposed amendment to this section would eliminate the requirement that the laboratories must file their written method descriptions with the Department. The ISOR states that the “subsection was amended to remove reference to the authority of the Department, jurisdiction that was removed by enabling statute.” The ISOR analysis once again is superficial and inaccurate. As noted previously, the 2004 change in the statutes repealed the Department’s authority to require the laboratories to be licensed, but it did not repeal Departmental jurisdiction over forensic alcohol analysis. The statutes specifically require the Department to enforce the forensic alcohol regulations (Health and Safety Code §100725). The statutes also provide the Department with general authority to “commence and maintain all proper and necessary actions and proceedings” to enforce its regulations” [H&amp;S Code §100170(a)(1)]. The 2011 Attorney General’s review of the Department’s forensic alcohol program after the 2004 legislation<sup>74</sup> noted, “Considering the alternatives, we are confident that the Legislature intended for FAP laboratories to continue to comply with, and for the Department to continue to enforce, all regulations other than those requiring licensure.”</p> <p>In the ISOR included with the committee’s submission of the proposed regulations to the California Health and Human Services Agency,<sup>75</sup> the committee justified the repeal of the requirement to file method</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal.App.3d 559, 567</p> |

|             |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                     |
|-------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
|             |                     | <p>descriptions with the Department on the presumption that the California Public Records Act provides the Department with access to these records. The committee was incorrect. The provisions of the public records act apply primarily to governmental agencies and government records and accordingly may not apply to private laboratories performing forensic alcohol analysis,<sup>76</sup> even when these laboratories enter into contractual agreements with cities and counties to perform testing. Moreover, the California Public Records Act is subject to exceptions to disclosure and the procedures for obtaining copies of records are cumbersome. It is important to continue the requirement for laboratories to file written method descriptions and other records with the Department. This provides the Department with ready access to the records it needs to enforce the law and the regulations pertaining to forensic alcohol analysis and to protect public safety. The filing of the written method descriptions with the Department serves to document the procedures used to generate analytical results that are admitted in legal proceedings. These become official procedures and they are available to all parties in any criminal or civil legal procedure. The Department's current regulatory authority to require laboratories to file written method descriptions and other records is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&amp;S Code §100725). The committee has not demonstrated by substantial evidence how its proposed amendment to this section will effectuate the purpose of the statutes (Health and Safety Code §100725), which requires the Department to enforce the law and its regulations. These regulations are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> |                                                                                                                                     |
| <b>1:91</b> | Section 1220 (b)(1) | Section 1220 (b)(1)<br><br>Clarity/Necessity/Consistency – The proposed amendment to this                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>section would eliminate the requirement that laboratories must make their written method descriptions available to the Department on request. This was the only amendment to the section. The ISOR states that the “section was amended to address an important factor that the analyst has immediate access to methods used.” The ISOR then notes that access to the written method is required by Section 5.4 of the ISO 17025 guidelines. The statements in the ISOR have nothing to do with the proposed amendment to the section. First, there was no change proposed here with respect to the requirement that the written method description shall be immediately available to the analysts. This has been a requirement in the California regulations for more than 40 years. Secondly, this important laboratory requirement is actually articulated less forcefully in the ISO 17025 standards, which require that, “All instructions, standards, manuals and reference data...shall be made readily available to personnel” (ISO 17025 Clause 5.4.1). Finally, it must be noted that not all California laboratories are accredited to the ISO 17025 standards and there is no requirement in the regulations for such accreditation. The committee’s proposed revision in this section conflicts with the description in the ISOR of the effect of the regulation. This creates a clarity issue under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(2)].</p> <p>In proposing to repeal the requirement to make method descriptions available to the Department on request, the committee again noted the provisions of the California Public Records Act.<sup>77</sup> As described in the comments under Section 1220 (b), the committee’s reasoning here was faulty. Accordingly, the committee has not demonstrated by substantial evidence how its proposed revision to this section will effectuate the purpose of the statutes which requires the Department to enforce the law and its regulations (Health and Safety Code §100725) in order to ensure the competence of the laboratories and employees as required</p> | <p>Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the “regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence.” <i>People v. Adams</i> (1976) 59 Cal. App. 3d 559, 567</p> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|             |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                     | by Health and Safety Code §100703 (d). The Department's current regulatory authority to require laboratories to provide records on request is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&S Code §100725).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>1:92</b> | Section 1220 (b)(2) | <p>Section 1220 (b)(2)</p> <p>Clarity/Consistency – The committee proposed no changes to this section. The regulations here should be revised to completely describe the minimum required elements of a complete written description of a forensic alcohol method. This would include: the procedures for collection and handling of samples, lists of reagents and equipment used, the procedures for determining the concentrations of the secondary standards, the procedures for calibrating the method, a definition of a sample set, the quality control program for the method, the procedures for calculating and reporting analytical results, routine checks of accuracy and precision, and the maintenance of the required records. In each case, these requirements can be referenced to other requirements under the regulations.</p> <p>The ISOR in explaining the review committee's failure to revise this section to completely describe the required elements of a method claimed that, the "ASCLD/LAB accreditation guidelines far exceed the requirements set forth in this document." However, the ASCLD/LAB voluntary guidelines, which cover 10 different crime lab disciplines, are very general and do not adequately address the specific requirements for a forensic alcohol method. Moreover, it must be noted again that there is no requirement in the law or regulations that a laboratory be accredited by ASCLD/LAB or any other organization.</p> <p>Finally, the ISOR notes that, "For those laboratories that are not accredited, this guideline is appropriate." Obviously, the very incomplete</p> | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the "regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence." <i>People v. Adams</i> (1976) 59 Cal. App. 3d 559, 567</p> |

|             |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                    | <p>description of the elements of a written method description is not appropriate for any laboratory. Also, the description of the regulations as a “guideline” again reveals the committee’s lack of understanding of the role of regulations.</p> <p>Regulations describe standards of performance and procedure that must be complied with under the force of law. By contrast, a guideline such as the voluntary ASCLD/LAB guidelines is a statement of advice or an instruction describing best practices, which doesn’t have the force of law.</p> <p>The regulations here must be revised to clearly and completely describe the minimum required elements of a complete written description of a forensic alcohol method.</p>                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>1:93</b> | Section 1220.1 (a) | <p>Section 1220.1 (a)</p> <p>Clarity – The committee proposed no changes to this section. The current regulations set standards of performance metrics for accuracy and precision [cf. Section 1220.1 (a)(1)], specificity (cf. Section 1220.1 (a)(2)), non-interference of anticoagulants and preservatives [cf. Section 1220.1 (a)(3)], and results less than 0.01% for alcohol free subjects [cf. Section 1220.1 (a)(5)]. The regulations do not define these metrics or describe how a laboratory’s staff demonstrate that a method is capable of meeting the required standards. Simply listing the performance standards without describing how these standards are met creates clarity issues. The Department’s forensic alcohol program has published guidelines describing the experimental data that enable a laboratory’s staff to demonstrate a method’s capabilities.</p> <p>California laboratories have employed these experimental demonstrations for more than 30 years. The experimental data are submitted along with the written descriptions of the method filed with the</p> | <p>The experimental data that supports the methodology employed by California labs is guided by the minimum expectations of standards of performance as outlined in the regulation. The methods employed in the labs are also reviewed by ASCLD/LAB and other accrediting bodies as appropriate.</p> <p>The regulation provides the metrics and it is up to the laboratories to demonstrate their compliance which is vetted through the courts and accreditation achievements.</p> |

|             |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                       | Department. The Department's guidelines should be incorporated into the regulations. The details are presented below under each subsection. In each case, the review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>1:94</b> | Section 1220.1 (a)(1) | <p>Section 1220.1 (a)(1)</p> <p>Clarity/Necessity – The committee's proposed revision here to change the lower limit for which the accuracy standard of performance applies from 0.10 grams % to 0.08 grams % is consistent with the changes made to the Vehicle Code Sections 23152 (b), 23153 (b), etc., which lowered the per se and presumptive blood alcohol concentrations at which an individual can be prosecuted from 0.10 grams % to 0.08 grams %.<sup>78</sup> The committee chose to retain the current 5% accuracy and precision limits. The committee must provide a reference to the studies relied upon to set this standard. This would likely involve an evaluation of the expected measurement uncertainties of California forensic alcohol analysis methods.<sup>79</sup></p> <p>As discussed under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standards for accuracy and precision. Simply listing a standard without describing how the standard is met creates a clarity issue. The regulations would need to set forth the minimum requirements for these experimental demonstrations. The Department's current forensic alcohol program defines these requirements and describes procedures for experimentally demonstrating that the method meets the required standard of performance. For example, the Department requires laboratories to demonstrate that their methods meet the specified accuracy and precision standards using samples prepared in biological matrices</p> | The section should be revised to state, "The method shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 5 percent of the value; these limits shall be applied to alcohol concentrations which are 0.100 grams per 100 milliliters or higher. For samples below 0.100 grams per 100 milliliters, the method shall be capable of the analysis of a reference sample of known concentration within the accuracy and precision limits of plus or minus 0.005 grams per 100 milliliters. |

|             |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                       | (blood and urine), and requires 21 replicate analyses at each of three alcohol concentrations. The Department has also established procedures for determining the known alcohol concentrations of these reference samples. These requirements would need to be spelled out in the regulations. The regulations should also specify what circumstances require new experimental demonstrations. For example, currently, anytime a laboratory relocates or changes a method, the Department requests a re-demonstration of the method's ability to meet the required standards of performance. The Department's evaluations of these data provide appropriate state-level oversight and assure proper accountability. No other entity currently performs these evaluations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>1:95</b> | Section 1220.1 (a)(2) | Section 1220.1 (a)(2)<br><br>Clarity/Necessity – The committee has proposed changes in the description of the standard of performance requirements for method specificity. While the current language is not clear, the committee's proposed revisions are also vague, and create new clarity issues. The revised regulation, which reads, "For traffic law enforcement purposes the method shall be specific for the analysis of ethyl alcohol," <sup>80</sup> would reasonably be interpreted as requiring a method for forensic alcohol analysis to be absolutely specific for alcohol. Diffusion-oxidation methods, which are used by some California laboratories, are not absolutely specific for alcohol and thus would not meet this new and more restrictive standard of performance requirement. It does not appear that this was the committee's intent, and accordingly, the amendments create clarity issues. The committee has not demonstrated by substantial evidence how the imposition of this new standard of performance requirement is necessary and will effectuate the purpose of | The comment is correct in its assertion that the new language implies that the method must be specific for ethyl alcohol and many current techniques being employed in California laboratories would not meet this standard. This includes diffusion-oxidation methodology and gas chromatography with flame ionization detector technology.<br><br>The regulation modifications should be removed and the original wording should remain. |

|             |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                       | <p>the statutes. The committee must reevaluate the requirements for method specificity and set requirements that are in fact “adequate and appropriate for traffic law enforcement.” The committee must also consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the specificity standards. Simply listing a standard without describing how the standard is met creates a clarity issue. The regulations would need to set forth the minimum requirements for this experimental demonstration. Again, the review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>1:96</b> | Section 1220.1 (a)(3) | <p>Section 1220.1 (a)(3)</p> <p>Clarity/Necessity – The committee’s proposed revision to this section, which describes the standard of performance requirements with respect to a potential interference from anticoagulant and preservative added to the sample, substitutes the language, “The method should” with “The method shall” in order for the section to read as a regulation. As noted in the comments under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standard regarding the freedom from interference from anticoagulants and preservatives added to the sample and to set forth the minimum requirements for this experimental demonstration in the regulations. This demonstration is needed to effectuate the purpose of the statutes. Again, the Department has published guidelines describing this demonstration. These guidelines should be incorporated into the regulations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p> | <p>The experimental data that supports the methodology employed by California labs is guided by the minimum expectations of standards of performance as outlined in the regulation. The methods employed in the labs are also reviewed by ASCLD/LAB and other accrediting bodies as appropriate.</p> <p>The regulation provides the metrics and it is up to the laboratories to demonstrate their compliance which is vetted through the courts and accreditation achievements.</p> |

|             |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1:97</b> | Section 1220.1 (a)(4) | <p>Section 1220.1 (a)(4)</p> <p>Clarity – The committee’s proposed revisions are not substantive and do not address several clarity issues in this section. The term, “oxidizable substance” needs to be defined, and the requirements of the qualitative test must be specified. The appropriate way to address the requirements here would be to list the desired characteristics of the “qualitative test” and/or to specify the appropriate method(s) of analyses that must be used to qualitatively identify ethyl alcohol.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>The committee’s revision is non-specific and requires clarification. The language should either remain as the original text or modified to say, “Blood alcohol results on postmortem samples shall not be reported unless specifically identified as ethyl alcohol.”</p>                                                                                                                                                                                                         |
| <b>1:98</b> | Section 1220.1 (a)(5) | <p>Section 1220.1 (a)(5)</p> <p>Clarity/Necessity – The committee proposed no changes to this subsection. As noted in the comments under Section 1220.1 (a), the committee must consider the need to require the laboratories to experimentally demonstrate the capability of a method to meet the required performance standards when analyzing an alcohol-free sample and to set forth the minimum requirements for this experimental demonstration in the regulations. Simply listing a standard without describing how the standard is met creates a clarity issue. An experimental demonstration is needed to effectuate the purpose of the statutes. Again, the Department has published guidelines describing this demonstration. These guidelines should be incorporated into the regulations. The review committee must consider the need for continued state-level oversight here in order to assure proper accountability and to effectuate the purpose of the statutes.</p> | <p>The experimental data that supports the methodology employed by California labs is guided by the minimum expectations of standards of performance as outlined in the regulation. The methods employed in the labs are also reviewed by ASCLD/LAB and other accrediting bodies as appropriate.</p> <p>The regulation provides the metrics and it is up to the laboratories to demonstrate their compliance which is vetted through the courts and accreditation achievements.</p> |
| <b>1:99</b> | Section 1220.1 (b)    | <p>Section 1220.1 (b)</p> <p>Clarity/Necessity/Consistency – The review committee’s proposed amendment here would eliminate the requirement for the Department to</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>The committee considered the role of the Department as it pertains to the enforcement of regulations. Issues of non-compliance with Title 17 regulations are given weight in the</p>                                                                                                                                                                                                                                                                                             |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>evaluate the ability of each laboratory's method(s) to meet the required standard of performance using the laboratory's proficiency test results.<sup>81</sup> The authority to perform these evaluations would be transferred to a forensic alcohol analyst (presumably but apparently not necessarily an employee of the laboratory). The ISOR claimed that the elimination of the Department's evaluations "brings this subsection in line with the intent of the legislature to remove the Department's jurisdiction." The ISOR also notes that Department oversight was removed in order to "codify (sic) the oversight of the proficiency program to the individual laboratories." As discussed in the comments under Section 1220 (b), the committee's determination of legislative intent, is not supported by the legislative record.</p> <p>Again, while the 2004 change in the statutes repealed the Department's authority to require the laboratories to be licensed, it did not repeal Departmental jurisdiction over forensic alcohol analysis including evaluating laboratory proficiency tests. The statutes (Health and Safety Code §100725) require the Department to enforce the regulations.</p> <p>The ISOR also claims that the review of proficiency test data by the voluntary laboratory accreditation program, ASCLD/LAB, "provides the oversight needed to ensure methods are functioning according to required specifications." However, the proficiency-testing requirements included in the voluntary ASCLD/LAB accreditation program are not an adequate substitute for the Department of Public Health's current regulatory program. The Department's proficiency test requirements are more stringent than ASCLD/LAB's and include more frequent testing,<sup>82</sup> a requirement that laboratories with multiple methods complete separate tests for each method, and the evaluation of test results based on the accuracy and precision requirements set forth in California's regulations. The acceptable ranges of results used by the</p> | <p>credibility of evidence governed by these provisions, but do not affect the admissibility of the evidence. As such, laboratories are aware of this compliance requirement, which serves as a substantial and significant enforcement mechanism to ensure compliance and competence. California courts have long recognized this self-enforcing aspect of Title 17 regulations, noting that the "regulations are an expressed standard for competency of the test results; in effect, they are a simplified method of admitting the results into evidence." <i>People v. Adams</i> (1976) 59 Cal. App. 3d 559, 567</p> |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>Department are narrower than those employed by ASCLD/LAB.<sup>83</sup> This assures that laboratory errors will not go undetected. A laboratory that fails a proficiency test is required to provide the Department with a written report of the corrective action taken and experimental data demonstrating that the method after the corrective action is capable of meeting the required standard of performance.</p> <p>Finally, the Department's regulatory program is a public process, while ASCLD/LAB's entire program operates under rules of "strict confidentiality."<sup>84</sup></p> <p>In its 2011 opinion, the Attorney General's office reviewed the Department's authority to independently conduct a separate proficiency testing program that does not conform to the statutorily required proficiency testing program.<sup>85</sup> The AG noted that the Department had found many shortcomings in the ASCLD/LAB proficiency test guidelines and has continued to operate a separate program. The AG concluded that the Department has the authority to impose its own, separate proficiency test requirements.</p> <p>The ISOR concludes with the claim, "The requirements are set forth in these regulations in a manner sufficient to accommodate those laboratories that are not currently accredited." This claim immediately followed the discussion in the ISOR of the appropriateness of substituting the voluntary ASCLD/LAB proficiency testing requirements for current state-level oversight. Ignoring the many shortfalls of the ASCLD/LAB program, it is indisputable that the program does not apply to laboratories that are not accredited. Accordingly, the claim in the ISOR that the regulations are "sufficient to accommodate those laboratories that are not accredited" is puzzling. The puzzle is solved by referring to the version of the ISOR that was included with the committee's submission of the proposed regulations to the California</p> |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>Health and Human Services Agency.<sup>86</sup> The ISOR here explains the sufficiency of the requirements of the proposed regulations by referencing the “justification section 1216.1 (a)(3)” for additional comments. This section cites Health and Safety Code Section 100702, which describes certain statutory proficiency test requirements. As noted in the comments under former Section 1216.1 (a)(3), now renumbered as “1216.1 (a)(2),” the statutes here are not clear and will require clarification and specification in regulation. Accordingly, the regulations pertaining to proficiency testing as proposed by the committee do not accommodate laboratories that are not currently accredited any more than they accommodate the accredited labs.</p> <p>The ISOR here does not discuss or even mention the review committee’s recent revision to Section 1216.1 (a)(2), which would require laboratories to direct proficiency test providers to submit external proficiency test results to the Department. As noted in the comments under Section 1216.1 (a)(2), the committee’s proposed language does not describe what the Department will do with the submitted data, which creates clarity issues. Accordingly, even with this change, the regulations do not clearly require any state-level, external oversight of a laboratory’s performances on external proficiency tests. This oversight is a completely standard component of any competent laboratory regulation program. The self-regulation scheme proposed by the committee wherein each laboratory evaluates its own performance is completely inadequate.</p> <p>The rulemaking record<sup>87</sup> shows that the Department has stated that it must retain its current authority to evaluate laboratory proficiency test results in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d) and to enforce the law and regulations as required by Health and Safety Code</p> |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|                     |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                |
|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                              | <p>§100725. The Department's current oversight here provides an objective, external, independent assessment of the competency of the laboratories. This establishes the scientific validity of the chemical testing in support of the State's drunk driving laws. The Department's current regulatory authority to evaluate the competence of a laboratory's methods using proficiency test results is consistent with the Department's mandated responsibility to enforce its regulations (cf. H&amp;S Code §100725).</p> <p>The committee has not demonstrated by substantial evidence how the revisions proposed for this section, which remove any state level or external oversight of laboratory proficiency tests, will effectuate the purpose of the statutes (H&amp;S Code § 100725), which requires the Department to enforce the law and its regulations pertaining to forensic alcohol analysis in order to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> |                                                                                                                                                                                                                |
| <p><b>1:100</b></p> | <p>Section 1220.2 (a)(1)</p> | <p>Section 1220.2 (a)(1)</p> <p>Clarity/Consistency – The committee has proposed a revision here to state that the calibration requirements in the regulations apply to an “instrument” and not to the “method.” The proposed revision is not consistent with other requirements of the regulations. As described under Section (a), each of the listed standards of procedure applies to the “method.” Calibration is a process that utilizes all of the procedural steps of a method. Accordingly, it is the “method” that is calibrated. As described under Section 1220.3 (a)(5), when the analysis of the quality control reference material, which is also processed using all of procedural steps of a method [cf. Section (a)(2)], yields out-of-control</p>                                                                                                                                                                                                                                                                   | <p>The language should be modified to to incorporate wet chemistry techniques. The language should be, “ The method shall employ calibration standard(s) which is/are water solution(s) of ethyl alcohol.”</p> |

|              |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                           |
|--------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                          | <p>results, the “method” is considered to be in error. Also, for wet chemistry methods (e.g., Smith-Widmark diffusion oxidation method), there is no “instrument”.</p> <p>There are also several other clarity issues. The term “calibrate” should be defined. Also, the current definition of the term “instrument” [current Section 1215.1 (j)] would be repealed with the committee’s proposed revisions. The use of the plural form of the word “standards” is potentially confusing. It implies multi-level calibration. Some laboratories analyze a single standard concentration. The committee must correct these clarity and consistency issues.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                           |
| <b>1:101</b> | Section 1220.2 (a)(1)(A) | <p>Section 1220.2 (a)(1)(A)</p> <p>Clarity/Necessity – The committee proposes here to add the statement that the definition of the secondary alcohol standard, “applies to prepared or purchased solutions.” This amendment is unnecessary since the current regulations do not preclude the use of a “purchased” material. In fact, the subsequent section, current Section 1220.2 (a)(1)(B) refers to “secondary alcohol standards...whether prepared or acquired...” The added phrase, “which, for the purposes of these regulations...” is awkward and adds nothing to the requirements of the regulations. Also, the terminology “secondary standard” here implies the existence of a “primary standard,” but as discussed below under the comments to Section 1220.2 (a)(1)(B), the revisions proposed by the committee would apparently provide the laboratory with an option that eliminates the primary standard. As a consequence, the reference to a “secondary” standard here creates clarity issues. Finally, there is a punctuation problem in that the comma should precede the word “which.”</p> <p>The committee has not demonstrated by substantial evidence the need</p> | <p>The language is sufficiently clear. Language was modified in the amendment and the additional language as proposed is needed to ensure that laboratories understand they can prepare secondary alcohol standards or purchase them.</p> |

|              |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                             |
|--------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                          | for the proposed revision to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                             |
| <b>1:102</b> | Section 1220.2 (a)(1)(B) | <p>Section 1220.2 (a)(1)(B)</p> <p>Clarity – The committee proposes here to add language allowing a laboratory to “purchase (NIST)88 traceable secondary alcohol standards.” This creates clarity issues. The term “NIST traceable secondary alcohol standard” is inherently unclear. First, the terminology here combines a term, “secondary alcohol standard” that is probably used only in California regulations, with the term “NIST traceable.” No vendor produces “NIST traceable secondary alcohol standards.” Commercial NIST traceable alcohol reference materials are available.<sup>89</sup> However, NIST (National Institute of Standards and Technology) currently does not have any specific criteria or protocol to define, “NIST traceability” for aqueous alcohol materials. Vendors may sell “NIST traceable” products, but there are no procedures or standards in place to check or verify the vendor's' claims of traceability. In order to include provisions in the regulations that permit the use of “NIST traceable” reference materials without independently determining the concentrations of these materials, the regulations would have to set forth procedures and standards to authenticate the claim of NIST traceability. [See also comments under Section 1215 (p)].</p> <p>There is another significant clarity issue with the committee’s amendments. The proposed language that describes the option to “prepare a secondary alcohol standard using a direct oxidimetric method, which employs a primary standard, such as the NIST potassium dichromate” is incorrect. The secondary alcohol standard solutions are not “prepared” by an oxidimetric method. They are prepared by dilution of pure alcohol standards. When a regulation uses language incorrectly it does not comply with the clarity standard under</p> | <p>It is correct that no vendor retails a NIST traceable “secondary alcohol standard.” However, water alcohol solutions that are NIST traceable are readily available for purchase. The regulation defines “secondary alcohol standards in 1220.2 (a) (1) (A).</p> <p>Jennifer Shen to answer. Proposed language requires modification.</p> |

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

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>personnel” (an undefined term) verifying the secondary standard, the criteria for verification, or even what “verify” means.</p> <p>Based on the committee’s discussions, it seems likely that the committee was referring to NIST aqueous alcohol standard reference materials analyzed using the laboratory’s forensic alcohol method. All forensic alcohol methods are relative methods. They require calibration based on a comparison of method responses for an unknown sample and a known standard. Accordingly, the proposal here to verify the concentration of a new secondary standard, using the forensic alcohol method would necessarily involve a comparison of two aqueous alcohol samples.</p> <p>However, aqueous alcohol solutions, whether prepared or purchased are labile, subject to evaporative losses. As a result, using one aqueous standard to verify another can introduce errors. The current regulations address this issue by requiring that each new lot of secondary standard must be referenced back to a true primary standard using the direct oxidimetric method (hence the name “secondary” alcohol standard). In terms of the analytical chemistry involved here, the direct oxidimetric method is an absolute method. The concentration of the secondary standard is determined directly based on the mass of the primary standard used and known reaction stoichiometry. The primary standard must have several critical characteristics. It must be very pure, very stable, have a relatively high molecular weight, and can be easily weighed.</p> <p>The primary standard NIST potassium dichromate possesses all four characteristics. Alcohol is not a suitable primary standard. Primary standards are commonly employed in analytical chemistry to ensure the highest levels of accuracy. While there could be value in requiring the analysis of a NIST SRM ethanol standard or a commercial certified</p> |  |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>reference material to evaluate method bias, analyzing each lot of secondary standard against a primary standard using the direct oxidimetric method ensures greater accuracy than any forensic alcohol method.</p> <p>There are several errors in the committee's ISOR, which individually may be minor, but taken together suggest a fundamental lack of understating of the regulations and science behind the calibration of a forensic alcohol method. As noted in the comments under Section 1220.2 (a)(1)(B), the statement in the ISOR that "secondary standards are then utilized to check the calibration of the instruments used for forensic alcohol analysis" suggests that there is some prior, independent calibration procedure. This is not correct. As required by regulations [Section 1220.2 (a)(1)], the secondary alcohol standards are used to calibrate the method. As discussed above in the comments under Section 1220.2 (a)(1)(B), the statement, "Currently, laboratories make their own secondary standards using a direct oxidimetric method." is incorrect. The standards are not "made" by an oxidimetric method. They are prepared by dilution of pure alcohol. The statement, "the regulations currently allow for a 5% error rate in the preparation of these solutions" is completely incorrect. The regulations do not set forth any "error rate" requirements for the preparation of the standards used to calibrate the method. The regulations [Section 1220.1 (a)(1)] do require the forensic alcohol method to be accurate and precise within plus or minus 5%. This standard of performance requirement applies to the entire method including aliquoting the biological sample, sample dilution, sample transfer, instrumental analysis, calculating, and reporting. The uncertainty in the concentration of the secondary standards contributes to the total error, but certainly much less than 5%. The ISOR then contrasts the fictitious "5% error rate" with "established error rate of less than 1.2% for all concentration levels" for the NIST ethanol-water SRMs.</p> |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>Here it can be noted that listed NIST uncertainties are based on gravimetric preparation. More importantly, the critical issue is not the uncertainty of the NIST SRM, but rather the uncertainty of the forensic alcohol method used to “verify” the secondary alcohol standards. Here, the ISOR claims that the analysis of the secondary standard by the forensic alcohol method represents “a final verification and most accurate test of the secondary standards”. The accuracy of the forensic alcohol method depends on the accuracy of the standards, but then introduces many additional sources of uncertainty. Again, Section 1220.1 (a)(1) sets the accuracy requirements for the entire method at plus or minus 5%. Laboratory staff should establish uncertainty budgets for each laboratory method, but the 5% figure can be used as an estimate and this would indicate that the relative uncertainty in the verification of the secondary standard using the method for forensic alcohol analysis would be no better than 5%. The Department’s uncertainty budget for the direct oxidimetric method of analysis indicates an expanded uncertainty of 2%. This clearly shows that the direct oxidimetric method is the more accurate test of the secondary standards.</p> <p>Finally, the ISOR notes that the SRM “produced by NIST is clearly of a higher quality, and is much more accurate than any of the secondary standards the state, city, or private laboratories currently produce.” This may or may not be true,<sup>90</sup> but it’s not a meaningful comparison. Secondary alcohol standards are used to calibrate the method. The regulations as revised by the committee do not require or even permit<sup>91</sup> a laboratory to use the NIST SRM as the secondary alcohol standard used to calibrate the method. The role of the NIST SRM is limited to “verifying” the laboratory’s secondary standards, whatever that means.</p> <p>The committee has not demonstrated by substantial evidence how the</p> |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|              |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                    |
|--------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                       | amendment adding the requirement to “verify” the concentration of the secondary standards eliminates the need to establish the concentration based on a primary standard using the direct oxidimetric method [cf. current Section 1220.2 (a)(1)(B)] or how the proposed revision will effectuate the purpose of the statutes which are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                    |
| <b>1:104</b> | Section 1220.2 (a)(2) | <p>Section 1220.2 (a)(2)</p> <p>Clarity/Necessity – The committee apparently intended here to “clarify” the requirements for the analysis of a blank and secondary standard. The ISOR states that the subsection was amended because “the original language is vague as to when the blank and secondary standard can be analyzed in a given day, and does not address situations where multiple instruments are in use.” The review committee did not discuss any situations where the current language caused any actual confusion here and in any case, the committee’s proposed amendments introduce new clarity problems. The reference to the analysis of standards “concurrently or prior to analysis of subject samples” is vague. In all methods, individual samples are analyzed one at a time in serial fashion. It is impossible to analyze samples “concurrently.” In practice, most laboratories’ methods include the analysis of standards at the beginning of the run, but some laboratories’ methods describe the analysis of additional standards at the conclusion of the run. The later practice would apparently be prohibited with the committee’s proposed revisions. The reference to the analysis of standards on “any instrument used” is vague especially in view of the fact that the regulations no longer define the word, “instrument.” (Note: with the Department’s current regulatory program, each instrument is treated as a separate method, i.e., the use of two instruments would mean the laboratory had two methods.)</p> | The language is sufficiently clear. Language was modified in the amendment and the additional language as proposed is needed to ensure that laboratories understand they can prepare secondary alcohol standards or purchase them. |

|              |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                             |
|--------------|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                          | <p>The ISOR also states, that “requiring blank and secondary sample analysis (sic) be performed on each instrument used for analysis...provides the most accurate approach to determining an instrument’s accuracy.” The references here to “secondary sample analysis” and “determining an instrument’s accuracy” again suggest a lack of understanding of the science behind the calibration of a forensic alcohol method. As required by Section 1220.2 (a)(1), the analysis of the secondary alcohol standard is used to calibrate the method, not to determine an instrument’s accuracy.</p> <p>The committee has not demonstrated by substantial evidence how the revisions proposed for this section will effectuate the purpose of the statutes which are intended to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).</p> |                                                                                                                                                                                                                                                                                                             |
| <b>1:105</b> | Section 1220.2 (a)(2)(A) | <p>Section 1220.2 (a)(2)(A)</p> <p>Necessity – The committee proposes to repeal this section, which requires that the blank and secondary alcohol standard samples shall be taken through all steps of the method used for the forensic alcohol analysis of samples. The ISOR claimed that the same requirements are provided under Section 1220.2 (a)(2). However, the cited section requires only that a “blank and secondary standard shall be analyzed...”; it doesn’t specifically require that that a “blank and secondary alcohol standard samples shall be taken through all steps of the method.</p> <p>Accordingly, it is appropriate to retain requirements of Section 1220.2 (a)(2)(A).</p>                                                                                                                                                                                      | <p>The Section should be updated to read, “A blank and secondary standard(s) shall be analyzed concurrently or prior to analysis of subject samples on each day of analysis and on any instrument used. All blank(s), secondary standards) and samples shall be taken through all steps of the method.”</p> |

|              |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                       | The committee has not demonstrated by substantial evidence how the repeal of his section will effectuate the purpose of the statutes, which is to ensure the competence of the laboratories and employees as required by Health and Safety Code §100703 (d).                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>1:106</b> | Section 1220.2 (a)(3) | Section 1220.2 (a)(3)<br><br>Clarity – The committee proposed no changes to this section. There is a clarity issue with the current language. This section imposes two completely separate requirements (i.e., the analysis of a quality control reference material and the duplicate analyses of unknown case samples).<br><br>These two requirements are not related and for clarity, the two different requirements should be stated under separate sections. Also, the word “section” should be shown in lowercase, since this is consistent with the current format used in the California Code of Regulations. | 1220.2 (a)(3) should be updated to reflect the comments concern. The section does detail two entirely different concepts. 1220.2 (a)(3) should be updated to say, “The procedure shall also include analysis of quality control reference samples as described in section 1220.3.<br><br>An addition should be made as 1220.3 (a)(5) that shall say, “ All samples shall minimally be analyzed in duplicate.” |
| <b>1:107</b> | Section 1220.2 (a)(4) | Section 1220.2 (a)(4)<br><br>Clarity - The committee proposed no changes to this section. This section should probably be revised to substitute “forensic alcohol analysis” for “alcohol analysis” for clarity and to be consistent with the terminology employed throughout these regulations.                                                                                                                                                                                                                                                                                                                      | Committee should discuss. If lab is using GC/MS technology, they cannot adhere to this standard.                                                                                                                                                                                                                                                                                                              |
| <b>1:108</b> | Section 1220.2 (a)(5) | Section 1220.2 (a)(5)<br><br>Necessity – The committee has proposed to repeal the requirement that all instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision. The ISOR claims that                                                                                                                                                                                                                                                                                                                                                                   | The comment carries merit. The revised regulation under 1220.1 (a)(1), 1220.1 (b), 1220.2 (a)(1), 1220.2 (a)(1)(C) and 1220.3 sufficiently demonstrate routine checks of accuracy and precision and this component of                                                                                                                                                                                         |

|                     |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                    |
|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                              | <p>the requirements here are “redundant and unnecessary given the provisions above. These provisions will ensure instruments are in good working order and checked for precision.” The committee’s earlier comments<sup>92</sup> clarified that the “provisions above” are the other procedural standards under Section 1220.2. The committee’s conclusion that the referenced procedural standards will ensure that instruments are in good working order and routinely checked is unwarranted. Even when a laboratory follows the proper procedural steps (i.e., analysis of blanks and standards, analysis of quality control samples, duplicate analyses of samples, etc.), the instruments and equipment still obviously need to be in good working order. This status should be routinely checked. Requirements for instrument maintenance and periodic checks are commonly included in lab regulations and in the ISO-IEC 17025 standards.<sup>93</sup> They are included in the CLIA<sup>94</sup> regulations. The Department currently requires laboratories to include descriptions of maintenance and accuracy check procedures in their written method descriptions. These requirements should be spelled out in the regulations. The committee has not demonstrated by substantial evidence how the repeal of this section will effectuate the purpose of the statutes [H&amp;S Code § 100703 (d)], which requires the regulations to ensure the competence of the laboratories to perform forensic alcohol analysis.</p> | <p>the removed text is redundant and unnecessary. However, the text stating, “All instruments used should be in good working order,” should remain. The assertion that preventative maintenance, and maintenance recommendations are included in accreditation standards is correct and should be considered by the committee.</p> |
| <p><b>1:109</b></p> | <p>Section 1220.3 (a)(1)</p> | <p>Section 1220.3 (a)(1)</p> <p>Clarity/Necessity - The committee’s proposed revision to change the lower limit of the concentrations allowed for the quality control material is consistent with the changes in the per se and presumptive blood alcohol concentrations in the Vehicle Code. There are still clarity issues in the section. The reference to a “suitable” quality control material is inherently vague in that the regulations do not specify what is suitable</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>The language is clear, unambiguous and requires no revision.</p>                                                                                                                                                                                                                                                                |

|              |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                       | and what is not. There are also the continuing place entity issues here with the requirement that a laboratory (a place) “shall make or acquire” and then “analyze” a quality control reference material. <sup>95</sup> The place/entity issue must be addressed in the regulations in order to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>1:110</b> | Section 1220.3 (a)(2) | Section 1220.3 (a)(2)<br><br>Clarity/Necessity – The intent of the committee’s proposed revision, which is to clarify that the concentration of the quality control sample should be determined to three decimal places, is appropriate, however, the proposed language is awkward and again, there are place entity issues associated with the requirement that a laboratory (a place) “shall determine a mean value...”.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | The language is clear, unambiguous and requires no revision.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>1:111</b> | Section 1220.3 (a)(4) | Section 1220.3 (a)(4)<br><br>Clarity/Necessity – The committee here proposes to revise the requirement for the analysis of a quality control material to include analyses of the material at the beginning and the end of the run. There are clarity and necessity issues with the committee’s proposed revisions. Since under Section 1215.1 (h), a sample is defined as a representative portion (singular) of the material being analyzed, the reference here to a sample (singular) being analyzed twice is awkward and probably not clear. Also, while the forensic alcohol methods employed by California laboratories often include the analyses of at least two replicates of a quality control reference material, this is not always the case. Increasing the required frequency of the analyses of a quality control reference material will need justification, since there were no reported problems with the current regulations, which require only a single analysis of the quality control reference material. The committee | The revision improves the quality of forensic alcohol analysis in the state by mandating that a quality control reference material be run at the beginning and the end, covering the entire set of samples. This ensures that the instrument’s calibration is maintained throughout the entire analytical process. This is common scientific practice in both forensic and clinical toxicology,<br><br>The wording of at least one sample permits laboratories to determine whether they use analytical instrumentation capabilities to source from a singular source/vial or to use a separately prepared source/vial of the quality control reference material. |

|              |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                          |
|--------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                       | has not demonstrated by substantial evidence the need for the proposed revision to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                          |
| <b>1:112</b> | Section 1220.4 (a)    | <p>Section 1220.4 (a)</p> <p>Consistency – The committee proposed no changes to this section. This creates a significant consistency issue. Section 1220.4 (a) requires that “all analytical results shall be expressed in terms of the alcohol concentration in blood”. This requirement is not consistent with the proposed new provisions under Sections 1220.4 (a)(1) and 1220.4 (f), which will permit the expression of breath test results as breath alcohol concentrations. The committee must resolve this inconsistency.</p>                                                                                                                                                                                                                                                                                                                                                                                                                   | The section should be modified to read, “All analytical results shall be expressed in terms of the alcohol concentration in blood, based on the number of grams of alcohol per 100 milliliters of blood, with the exception of tissue analysis and breath test results.” |
| <b>1:113</b> | Section 1220.4 (a)(1) | <p>Section 1220.4 (a)(1)</p> <p>Clarity/Consistency – The committee proposes here to define the symbols grams %, %, and % (W/V) as abbreviations of “grams per 100 milliliters of blood” instead of the current “grams per 100 milliliters of liquid.” The ISOR states that, “The word “liquid” was changed to “blood” to be consistent with the Vehicle Code.” In fact, the Vehicle Code does not employ a symbol to represent grams of alcohol per 100 mL of blood. Instead, it describes blood alcohol concentrations using the words percent by weight of alcohol in his or her blood.</p> <p>The change in the definition of the symbols creates a consistency issue. The symbol “grams %” is used in Section 1221.2 (a)(2)(A) to set concentration limits for “alcohol water concentrations and/or dry-gas reference samples of alcohol.” While as discussed below in the comments for Article 6 (current Article 7), the committee’s proposed</p> | <p>The modification should be removed to ensure consistency with change made in 1220.4 (c)</p> <p>Additionally, or grams per 210 liters of breath should be removed as the expression of breath alcohol results is defined in 1220.4 (f).</p>                            |

|                     |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                           |
|---------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                     |                           | <p>revisions to Section 1221.2 (a)(2)(A) create clarity issues, it is still clear that the “water concentrations” or “dry-gas reference samples of alcohol” are not concentrations of alcohol in blood. Redefining the symbol “grams %,” as a blood concentration unit creates a consistency issue.</p> <p>The committee also proposes to allow the use of the symbols grams %, %, and % (W/V) to represent units of grams per 210 liters of breath. The use of the percent symbol (“%”) to represent units of grams per 210 liters appears to be dimensionally incorrect since percent literally means parts per hundred. It would appear to be preferable to provide distinct units for abbreviating the distinct quantity, grams per 210 liters of alveolar breath.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                           |
| <p><b>1:114</b></p> | <p>Section 1220.4 (c)</p> | <p>Section 1220.4 (c)</p> <p>Clarity/Necessity – Section 1220.4 (c), provides that blood alcohol results less than 0.01% for samples from living subjects may be reported as “negative.” The committee proposes to eliminate the qualifier “blood”, thus permitting any alcohol concentration in living subjects less than 0.01% to be reported as negative. It is not clear that this revision is necessary. The regulations describe four types of samples: blood, breath, urine, and tissue. The provision of Section 1220.4 (c) would not apply to tissue samples, which are reported in units of weight amount of alcohol per unit weight of the specimen [cf. Section 1220.4 (g) and urine alcohol results must be converted to blood alcohol concentrations before reporting [cf. Section 1220.4 (e)]. Accordingly, the provisions of this section would apply to only blood or breath samples. As was discussed in the comments under Section 1220.4 (a)(1), there are clarity issues associated with using the % abbreviation (i.e., parts per 100) to report breath alcohol concentration units, which are in units of in parts per 210,000. The same concerns would apply here. Based on this, the special provisions for reporting results less than 0.01% level</p> | <p>The proposed revision is more inclusive and prohibits interpretation that the reporting criteria only apply to blood samples. The comment assumes that it is well understood that this reporting criteria applies to other sample types that have been converted to a blood alcohol concentration.</p> |

|       |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                     |
|-------|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       |                    | <p>would apply only to blood alcohol results and consequently the proposed revision is unnecessary.</p> <p>The ISOR claimed that the word “may” was retained because, “Different laboratories may be able to satisfy greater reliability of analysis at lower levels. Also as technical advances occur, more laboratories may have a greater capacity to test for smaller levels, and this language would apply.” The comments here again evidence a misunderstanding of the science and the regulations. Section 1220.4 (b) requires that analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present. Based on this provision of the regulations, a result less than 0.01 grams%, would be reported as 0.00 grams%. Section 1220.4 (c) provides the option (i.e., “may be reported”) of reporting such a result as “negative.” These are the only two choices. A laboratory’s ability “to test for smaller levels” is not an issue here. The committee may at some point wish to address measurement issues such as limits of detection and limits of quantification, but to date it has not done so and this should not be part of the discussion of the revisions proposed for this section.</p> |                                                                                                                                                                                                                                                                                                                                                     |
| 1:115 | Section 1220.4 (d) | <p>Section 1220.4 (d)</p> <p>Clarity/Necessity – This section provides that blood alcohol results less than 0.02% for samples from post-mortem subjects may be reported as “negative.” The committee proposes to remove the qualifier “blood.” The ISOR explains that the intent here was “to make this section inclusive of all sample types as is appropriate.” The proposed change is unnecessary. As discussed in the comments to Section 1219.2 (a), which describes the collection of urine samples from living subjects, there are no provisions in the regulations for the collection of post</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>The comment makes assumptions that postmortem urine samples and other postmortem fluids are not analyzed for ethyl alcohol content. Vitreous humor is a fluid and is routinely analyzed for ethanol content and it would be inappropriate to consider this sample type a tissue and reported as such. The modification should be maintained.</p> |

|              |                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                      |
|--------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                                    | <p>mortem urine samples. Obviously, there are no provisions for the collection of breath samples post-mortem. The provisions of Section 1220.4 (d) would not apply to post-mortem tissue samples, since again the results here are reported in units of the weight amount of alcohol per unit weight of the specimen [cf. Section 1220.4 (g)]. Accordingly, Section 1220.4 (d) can only refer post-mortem blood samples and consequently the committee's proposed revision is unnecessary.</p>                                                  |                                                                                                                                                                                                                                                      |
| <b>1:116</b> | Section 1220.4 (e)                 | <p>Section 1220.4 (e)</p> <p>Clarity – The committee proposed no changes to this section. There is a minor clarity issue with the current language. The two separate (although related) requirements to: 1) convert a urine alcohol result to a blood concentration; and 2) employ a specific calculation to accomplish this conversion should be presented as two separate sentences.</p>                                                                                                                                                      | <p>Change should be made to read, “ A urine alcohol concentration shall be converted and expressed as a blood alcohol concentration. The converted blood alcohol concentration is determined by dividing the urine alcohol concentration by 1.3.</p> |
| <b>1:117</b> | Section 1220.4 (f)                 | <p>Section 1220.4 (f)</p> <p>Clarity – The committee's proposed revision is intended to eliminate the requirement to convert a breath alcohol concentration to an equivalent blood alcohol concentration. This is consistent with the changes to Vehicle Code Section 23152 (b). The committee's proposed language here, “Analytical results for breath shall be based...” is not clear. Since Section 1220.4 is titled Expression of Results,” it would appear to be preferable to replace “based” with “expressed” or perhaps “reported.”</p> | <p>Change should be made to read, “A breath alcohol concentration shall be expressed as the number of grams of alcohol per 210 liters of breath.”</p>                                                                                                |
| <b>1:118</b> | Article 6. Requirements for Breath | <p>Article 6. Requirements for Breath Alcohol Testing (Current Article 7)96</p> <p>Necessity - The proposed change in the article title from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since as noted in</p>                                                                                                                                                                                                                                                                                                        | <p>The proposed change from analysis to testing is to ensure language consistency between the regulation and Health and Safety Code § 100701 which specifically states, “All</p>                                                                     |

|              |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | Alcohol Testing (Current Article 7)96 | the comments under Section 1215 (c), the words “analysis” and “testing” are synonymous. The review committee claimed that the proposed change here was intended to distinguish the analysis of blood samples in a laboratory setting from the testing of breath samples by law enforcement, but the committee has not demonstrated by substantial evidence how the proposed change accomplishes this purpose. As a consequence the committee has not shown that the proposed change is necessary to effectuate the purpose of any statute.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | laboratories that are subject to the requirements of Section 100700 shall ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation (DOT).                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>1:120</b> | Section 1221.                         | <p>Section 1221.</p> <p>Necessity/Consistency - The proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since as noted previously, the words analysis and testing are synonymous and do not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples.</p> <p>Section 1221 should be revised to include a requirement that laboratories prepare detailed, up- to-date written descriptions of the procedures employed in support of breath alcohol analysis performed by law enforcement agencies. These descriptions would include procedures for periodically determining the accuracy of the instruments and procedures for training instrument operators. The requirement here would be consistent with the requirement under Section 1220 (b) for a laboratory to prepare written descriptions of its methods for forensic alcohol analysis.<sup>97</sup></p> <p>These written descriptions should be filed with the Department to ensure proper accountability. The regulations under Article 6 (current Article 7) would need to clarify the specific requirements for the contents of these</p> | <p>The proposed change from analysis to testing is to ensure language consistency between the regulation and Health and Safety Code § 100701 which specifically states, “All laboratories that are subject to the requirements of Section 100700 shall ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation (DOT).</p> <p>The regulation remains mostly unchanged. Only modification from original was the substitution of the word testing from analysis for consistency with Health and Safety Code § 100701. Additional requirements would expand Department’s role beyond current regulation.</p> |

|              |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                    | written descriptions. The review committee must consider the need for these requirements in order to effectuate the purpose of the statutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>1:121</b> | Section 1221.1 (a) | <p>Section 1221.1 (a)</p> <p>Necessity/Clarity/Consistency/Authority/Reference – As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary. The committee also proposed a revision here that would require breath alcohol testing to be performed only with instruments which “meet the requirements specified in Health and Safety Code §100701.” The problem here is that the cited Health and Safety Code Section does not directly establish any performance requirements for instruments. The referenced statute requires laboratories to ensure that breath alcohol instruments and calibrating devices used in testing are listed in the Conforming Products Lists published by the US Department of Transportation (DOT). As such the cited statute imposes a requirement on laboratories not on the instruments used. This creates a consistency issue.</p> <p>There are also significant scope and authority problems with the proposed amendment. Breath alcohol analysis is typically performed by law enforcement personnel away from the laboratory. The proposed revisions here would impose requirements on law enforcement by specifying the equipment that must be used when performing breath alcohol analysis. It does not appear that the Department of Public Health has the statutory authority and reference to impose regulatory requirements on law enforcement when performing breath alcohol analysis either directly or indirectly by authorizing a laboratory to impose these requirements. This authority was formerly provided by H&amp;S Code §100715,98 which authorized the Department to adopt regulations describing the procedures used by law enforcement agencies when</p> | <p>The proposed change from analysis to testing is to ensure language consistency between the regulation and Health and Safety Code § 100701 which specifically states, “All laboratories that are subject to the requirements of Section 100700 shall ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation (DOT).</p> <p>The committee removed duplicative language which stated instruments used for testing must meet requirements for standards of performance which were dictated and continue to be dictated in the new version by the DOT.</p> <p>The new language still requires the same standard for laboratories and for breath test instruments; they must conform to DOT conforming product requirements.</p> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>analyzing breath samples and required law enforcement to follow these procedures. This statute was repealed with the 2004 legislation (SB 1623, Johnson, Chapter 337). The aforementioned H&amp;S Code §10070199 appears to give the Department the authority to regulate laboratories, but not law enforcement agencies or personnel.</p> <p>The Department's Office of Legal Services (OLS) reviewed the Department's authority to regulate law enforcement personnel performing breath alcohol analysis and concluded that as a result of the 2004 revisions to the statutes, the Department's authority is strictly limited to the regulation of laboratories. OLS presented its findings to the review committee at its January 28, 2008 meeting.<sup>100</sup></p> <p>There are also practical issues here. As provided by the options included under Section 1221.1 (b), the analyses conducted by law enforcement personnel may not even be under the jurisdiction of a forensic alcohol laboratory. Accordingly, it is not clear that the laboratory will have any direct control over breath alcohol analysis. Absent some jurisdictional control of breath testing, there is no way for the laboratory to "ensure" that the breath testing equipment used meets the DOT standards.</p> <p>There is another clarity issue. The text of the committee's proposed revisions reads, "Breath alcohol analysis testing shall be performed only with instruments and related accessories calibrating units/devices which meet the standards of performance set forth in these regulations requirements specified in Health and Safety Code Section 100701." The word "accessories" is included in the current regulations and should not be underlined here. More importantly, the regulations would now refer to "instruments and accessories calibrating units/devices." The noun</p> | <p>The language in 1221.1 (b) remains mostly unchanged by the committee. The only changes made are in analyst classification and substitution of testing for analysis to ensure consistency with other modifications. Substance of regulation is maintained.</p> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|       |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       |                    | <p>“accessories” here is apparently used incorrectly as an adjective. When a regulation uses language incorrectly it does not comply with the clarity requirements under the Office of Administrative Law’s regulations [cf. 1 CCR 16 (a)(4)].</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1:122 | Section 1221.1 (b) | <p>Section 1221.1 (b)</p> <p>Clarity/Necessity/Authority/Reference – As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary, since the words analysis and testing are synonymous and do not serve to distinguish the analysis of breath samples from the analysis of blood, urine, or tissue samples. The provisions of this section that permit a forensic alcohol laboratory to have jurisdiction over breath alcohol analysis when performed by law enforcement personnel create place/entity issues, since a laboratory (a place) can’t have jurisdiction over anything. There would also appear to be additional problems when the laboratory is operated as a non-governmental, private business. The former licensing procedures solved both problems. It transformed a laboratory location into an entity. It also gave the non-governmental laboratory entity an official duty making it comparable to a governmental agency capable of applying the law and assuming jurisdiction over the breath alcohol analysis activities.</p> <p>Besides the place/entity issue, there is also an authority/reference issue. Since breath alcohol analysis is invariably performed by law enforcement personnel, the language here that requires that breath alcohol analysis must be under the jurisdiction of a governmental agency or a forensic alcohol laboratory again appears to impose a requirement on law enforcement. As noted in the comments under Section 1221.1 (a), with the changes in the statutes, it is not clear that the Department has the authority to impose such requirements with its</p> | <p>Licensing authority was removed by SB 1623 and the removal has been maintained by the committee. Licensing is not an option that will be considered by the committee.</p> <p>The regulation remains mostly unchanged. Changes made ensure consistency with other modifications. Only changes made to the text include the removal of analyst classifications and the requirement of licensure of laboratories.</p> |

|              |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                          | regulations either directly or indirectly as proposed here by authorizing a laboratory to impose the requirements. There is also a clarity issue with the phrase “may be used” and the reference to “places other than forensic alcohol laboratories” is not clear especially since virtually all breath alcohol analysis is conducted away from the laboratory.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>1:123</b> | Section 1221.1 (b)(1)101 | <p>Section 1221.1 (b)(1)101</p> <p>Clarity/Necessity - As discussed previously, the proposed change from “breath alcohol analysis” to “breath alcohol testing” is unnecessary. Moreover, the entire section is unnecessary and it should be repealed. The undefined reference to “immediate analysis” (now “immediate testing”) is unclear since there are no references in the regulations to non-immediate analyses or tests. Similarly, the language here limiting the analysis to “samples collected by direct expiration of the subject into the instrument” is also unclear since there are no provisions in the regulations for alternative modes of sample collection for analysis. The language here had meaning at one time when the analysis of a captured breath sample for latter analysis was authorized under the regulations.<sup>102</sup> This authorization was removed in 1985 and the references to “immediate analysis” of a breath sample here and also under Section 1221.1 (b)(2) are now vestigial and should be repealed.</p> | 1221.1 (b)(2) is one of the most critical sections of the document as it relates to breath alcohol testing. It clearly differentiates blood, urine and tissue alcohol testing standards of performance and standards of procedure (Article 5) from requirements for breath alcohol testing. The term immediate, although possible at sometime prior to have had different implications, is now understood to define direct/timely testing of a subject (breath alcohol testing) as being different than collection of a biological sample that will be tested almost always at a different location and at a later time. The section defines what requirements breath alcohol testing is not held to and should be maintained. |