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# OFFICE OF THE ATTORNEY GENERAL State of California

## KAMALA D. HARRIS Attorney General

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OPINION : No. 10-501

of : December 27, 2011

KAMALA D. HARRIS Attorney General

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MARC J. NOLAN Deputy Attorney General

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THE HONORABLE ISADORE HALL, III, MEMBER OF THE STATE ASSEMBLY, has requested an opinion on the following questions:

- 1. What powers does the Department of Public Health have to enforce the Forensic Alcohol Program?
- 2. Given that laboratories performing forensic alcohol tests "shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing," and that the required proficiency tests must be obtained from an ASCLD/LAB-approved test provider, may the Department of Public Health nevertheless (a) require a laboratory to also perform separate proficiency tests under Department of Public Health regulations using samples not obtained from an ASCLD/LAB-approved provider, and (b) discipline a laboratory for failing to perform those additional tests?

#### CONCLUSIONS

- 1. The Department of Public Health may seek mandamus or injunctive relief from a court to enforce compliance with the Forensic Alcohol Program.
- 2. Although laboratories engaged in performing forensic alcohol tests must follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing, and must obtain the required proficiency tests from an ASCLD/LAB-approved test provider, the Department of Public Health may nevertheless (a) require a laboratory to also perform separate proficiency tests under Department of Public Health regulations using samples not obtained from an ASCLD/LAB-approved provider, and (b) discipline a laboratory for failing to perform these additional tests.

#### **ANALYSIS**

In 1969, the Legislature made the former Department of Health, now the Department of Public Health (Department),<sup>1</sup> responsible for establishing a program to ensure the competency of laboratories that perform alcohol testing of persons involved in suspected drunk driving incidents.<sup>2</sup> The conviction and removal of drunk drivers from California's streets and highways provides important public health and safety benefits, and chemical testing to determine the concentration of alcohol in the blood of persons involved in suspected drunk-driving incidents is a critical component of the state's efforts to control drunk driving.<sup>3</sup> Because forensic alcohol tests are key evidence in drunk-driving prosecutions, their reliability is essential to ensuring "that drunk drivers are properly convicted and innocent drivers are not prosecuted unjustly because of faulty

In 1978, the former Department of Health became known as the Department of Health Services (DHS). Health & Safety Code § 100150. In 2007, the responsibilities of DHS were divided between a new Department of Health Care Services and a new Department of Public Health. 2006 Stat. ch. 241 §§ 1, 13. The Department of Public Health "succeed[ed] to and [was] vested with all the duties, powers, functions, jurisdiction, and responsibilities" of the former DHS regarding various functions, including the Forensic Alcohol Program that is the subject of this legal opinion. Health & Safety Code §§ 131050(a)(1), 131051(a)(7)(O).

<sup>&</sup>lt;sup>2</sup> 1969 Stat. ch. 1421 § 1; former Health & Safety Code §§ 436.50-436.63 (West 1994); former Health & Safety Code §§ 100700-100775 (West 2004).

<sup>&</sup>lt;sup>3</sup> See www.cdph.ca.gov/programs/DFDRS/Pages/FDLB-ForensicAlcoholProgram.

laboratory testing."<sup>4</sup> The Department's Forensic Alcohol Program (FAP) regulates some 40 California laboratories that perform forensic alcohol testing to ensure the validity of the tests.<sup>5</sup>

The Department has adopted regulations to implement the Forensic Alcohol Program.<sup>6</sup> Among other things, the regulations govern methods of analysis of blood samples, urine samples, and breath alcohol readings; procedures for sample collection and retention;<sup>7</sup> and maintenance of records.<sup>8</sup> The regulations also establish an oversight program, which includes site inspections;<sup>9</sup> personnel qualifications including proficiency tests and written examinations;<sup>10</sup> periodic proficiency testing of laboratories;<sup>11</sup> and review of laboratories' training programs.<sup>12</sup>

For many years, in accordance with then-existing statutes,<sup>13</sup> the Department issued licenses to those laboratories that met the Department's regulatory requirements.<sup>14</sup> In 2004, amendments to the FAP statutes eliminated the Department's licensing authority

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> Cal. Code Regs. tit. 17 §§ 1215-1222.2. All further section references are to Title 17 of the California Code of Regulations, unless otherwise specified.

<sup>&</sup>lt;sup>7</sup> §§ 1219-1219.3.

<sup>&</sup>lt;sup>8</sup> §§ 1222-1222.2.

<sup>&</sup>lt;sup>9</sup> § 1217.6(b). The Department informs us that it previously conducted periodic on-site inspections as a matter of routine, but that it currently conducts inspections only for cause. Dept. of Pub. Health Memo. to Dep. Atty. Gen. Marc J. Nolan (July 29, 2010) 2.

<sup>&</sup>lt;sup>10</sup> §§ 1216(a), 1216.1(e)(3) & (f)(4). Proficiency testing typically involves having a technician test a sample that contains a known concentration of alcohol, in order to evaluate the accuracy of the test. *See* www.cdph.ca.gov/programs/DFDRS/Pages/FDLB-ForensicAlcoholProgram.

<sup>&</sup>lt;sup>11</sup> §§ 1217(a), 1217.7.

<sup>&</sup>lt;sup>12</sup> §§ 1218-1218.2.

<sup>&</sup>lt;sup>13</sup> Former Health & Safety Code § 100720.

<sup>&</sup>lt;sup>14</sup> §§ 1217, 1217.1.

over forensic alcohol laboratories.<sup>15</sup> Concomitantly, the Department was required to establish a non-governmental review committee composed of specified stakeholders,<sup>16</sup> the purpose of which was to determine how the Department's regulations should be revised in light of the 2004 statutory changes. The review committee has not yet completed its work, so the Department's regulations have not yet been revised. In the meantime, one provision of the Health and Safety Code continues to require the FAP laboratories to comply with the Department's regulations "as they exist[ed] on December 31, 2004,"<sup>17</sup> and another continues to require the Department to enforce both the FAP statutes and its own regulations.<sup>18</sup>

Thus, the questions presented here come to us during a period of transition for the Department and for the laboratories which, until 2004, had been licensed under the Department's regulations. Differing views have evolved as to what enforcement authority the Department currently has over the laboratories it formerly licensed. Some argue that the Department lost all power to discipline laboratories when it lost its licensing authority. Others, including the Department, argue that the Department may initiate court actions seeking to enforce laboratories' compliance with the Department's regulations. A specific point of dispute concerns the ASCLD/LAB-approved proficiency tests that laboratories are now required to perform annually, and whether the Department may still require laboratories to perform additional proficiency tests not specified in the 2004 statutes.

### 1. The Department's enforcement authority

Because the Department's regulations have not yet been revised in accordance with the 2004 statutes, the existing regulations still include provisions that purport to enable the Department to grant and renew licenses to FAP laboratories.<sup>19</sup> Of course, regulations that conflict with their enabling statutes are generally invalid and

<sup>15 2004</sup> Stat. ch. 337 (Sen. 1623) § 3; Health & Safety Code § 100700(b).

<sup>&</sup>lt;sup>16</sup> The committee consists of representatives from law enforcement; prosecuting and defense attorneys; coroners, pathologists, or medical examiners; criminalists; toxicologists; crime laboratory directors; and the Department. Health & Safety Code § 100703(b).

<sup>&</sup>lt;sup>17</sup> Health & Safety Code § 100700(a).

<sup>18</sup> Id. at § 100725.

<sup>&</sup>lt;sup>19</sup> E.g., §§ 1216(a), 1217, 1217.1.

unenforceable.<sup>20</sup> No one claims, though, that the Department is attempting to enforce the repealed licensing scheme.<sup>21</sup> Rather, the claim is that the Department now lacks *any* means of enforcing the FAP since its licensing authority has been removed. For the reasons that follow, we conclude that the Department does still have enforcement authority, by way of court actions seeking to enforce compliance with FAP rules.

We begin by taking a closer look at the relevant statutes. Health and Safety Code section 100700 provides:

- (a) Laboratories engaged in the performance of forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath for the purposes of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations *shall comply* with Group 8 (commencing with Section 1215) of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations, as they exist on December 31, 2004, until the time when those regulations are revised pursuant to Section 100703.
- (b) Notwithstanding subdivision (a), the [D]epartment *shall not require* laboratories to be licensed.<sup>22</sup>

Health and Safety Code section 100725 states that, "On or after January 1, 1971, the [D]epartment *shall enforce* this chapter and regulations adopted by the [D]epartment."<sup>23</sup>

Where, as here, we are called upon to interpret the meaning of a statute, our primary task is to determine the Legislature's intent.<sup>24</sup> In doing so, we "look first to the words of the statute themselves, giving to the language its usual, ordinary import and according significance, if possible, to every word, phrase and sentence in pursuance of the legislative purpose."<sup>25</sup> If there is no ambiguity in the statute's text, "we may presume

<sup>&</sup>lt;sup>20</sup> Govt. Code § 11342.2; *Yamaha Corp. of America v. State Bd. of Equalization*, 19 Cal. 4th 1, 9-10 (1998); *Woods v. Super. Ct.*, 28 Cal. 3d 668, 679 (1981).

<sup>&</sup>lt;sup>21</sup> See Health & Safety Code § 100700(b).

<sup>&</sup>lt;sup>22</sup> Emphases added.

<sup>&</sup>lt;sup>23</sup> Emphasis added.

<sup>&</sup>lt;sup>24</sup> Freedom Newsps., Inc. v. Orange Co. Employees Ret. Sys., 6 Cal. 4th 821, 826 (1993).

<sup>&</sup>lt;sup>25</sup> Dyna-Med, Inc. v. Fair Empl. & Hous. Commn., 43 Cal. 3d 1379, 1386-1387

that the Legislature meant what it said and the statute's plain language governs."<sup>26</sup> While the statutory scheme in this case clearly contemplates that further changes are to come, we believe that the statutory language as it exists is purposeful and unambiguous, and we see no reason to deviate from its plain meaning.

Crucial, we think, is the language that says FAP laboratories "shall comply" with existing Department regulations, and that the Department "shall enforce" those regulations (except that it "shall not require" that laboratories be licensed). The word "shall" ordinarily connotes a mandatory duty.<sup>27</sup> Although the word "shall" may, in special circumstances, be interpreted as permissive rather than mandatory, such a construction is not available when it would render a statutory command ineffective, meaningless, or absurd.<sup>28</sup> In this case, a permissive construction of "shall" would mean that FAP laboratories had the option of not complying with Department regulations, and the Department had the option of not enforcing them, notwithstanding the Legislature's specific direction that the regulations remain in force until new ones are put in place. Even more nonsensically, a permissive reading of "shall [not]" here would mean that the Department could still require laboratories to be licensed. 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.<sup>29</sup>

(1987).

<sup>&</sup>lt;sup>26</sup> People v. Snook, 16 Cal. 4th 1210, 1215 (1997).

<sup>&</sup>lt;sup>27</sup> Common Cause v. Bd. of Supervisors, 49 Cal. 3d 432, 443 (1989); see People v. Heisler, 192 Cal. App. 3d 504, 506-507 (1987); Hogya v. Super. Ct., 75 Cal. App. 3d 122, 133 n. 8 (1977); Cannizzo v. Guarantee Ins. Co., 245 Cal. App. 2d 70, 73 (1966); 92 Ops.Cal.Atty.Gen. 30, 32 (2009); see also Webster's New International Unabridged Dictionary 2085 (3d ed., Merriam-Webster 2002) (the word "shall" is "used in laws, regulations, or directives to express what is mandatory").

<sup>&</sup>lt;sup>28</sup> People v. Heisler, 192 Cal. App. 3d at 506-507; Governing Bd. v. Felt, 55 Cal. App. 3d 156, 161-163 (1976); People v. Mun. Ct., 145 Cal. App. 2d 767, 775 (1956); 92 Ops.Cal.Atty.Gen. at 33.

<sup>&</sup>lt;sup>29</sup> Because the plain meaning of the relevant language is unambiguous, we need not examine the statutes' legislative history. *Diamond Multimedia Sys. v. Super. Ct.*, 19 Cal. 4th 1036, 1047 (1999); *Snook*, 16 Cal. 4th at 1215. Nonetheless, we have reviewed that history, and have found nothing in it to contradict our conclusion concerning the Legislature's intent.

That said, the question remains what enforcement authority the Department retains. Although the Department now lacks authority to "deny a license or renewal thereof," existing regulations still grant the Department authority to "take disciplinary action" against laboratories for failure to meet FAP standards. Thus, the question boils down to what methods the Department might use to "discipline" a laboratory which, for example, failed to use personnel, equipment, methodology, or procedures satisfying the Department's standards. By statute, the Department "may commence and maintain all proper and necessary actions and proceedings" to enforce its regulations. Therefore, in the unlikely event that a forensic alcohol laboratory refused to comply with the Department's regulations, 4 we believe that it would be proper for the Department to seek mandamus or injunctive relief to enforce compliance.

"[O]ver the more than 30 years that the Department has operated the program, there has been a high degree of voluntary compliance among the laboratories. On those occasions that the Department has found that a laboratory is not in compliance with the regulations, it sends reports and correspondence to the laboratory documenting the noncompliance (e.g., failed proficiency tests, disapproved training programs, disapproval of the qualifications of laboratory personnel, etc.) and the laboratories have generally taken the appropriate corrective actions. In the past, the Department has rarely, if ever, had to take formal disciplinary action against a laboratory. This high level of voluntary compliance has continued in the five years since the Department lost its authority to issue laboratory licenses."

Dept. of Pub. Health Memo. 2.

<sup>&</sup>lt;sup>30</sup> § 1216.1(c).

<sup>&</sup>lt;sup>31</sup> *Id*.

 $<sup>^{32}</sup>$  *Id*.

<sup>&</sup>lt;sup>33</sup> Health & Safety Code § 100170(a)(1). Although the "department" mentioned in this statute refers to the former Department of Health Services, the Department "succeed[ed] to and [was] vested with all the duties, powers, functions, jurisdiction, and responsibilities" of the former DHS regarding various functions, including the FAP. Health & Safety Code §§ 131050(a)(1), 131051(a)(7)(O); *see also* Health & Safety Code § 100100.

<sup>&</sup>lt;sup>34</sup> The Department informs us that:

Analogous, in our view, is the Court of Appeal's decision in *Agricultural Labor Relations Board v. Exeter Packers*, in which it was held that "a writ of mandate was a proper procedure to enforce Board regulations promulgated pursuant to the Board's legislative power," despite the fact that the Board had other legal enforcement mechanisms, and despite Exeter's contention that the regulations at issue—requiring employers to disclose the names of agricultural land owners, the location of work crews, and other information—were invalid. The opinion concluded that the Board's legal alternatives (an unfair labor practices action, or pursuit of the information through an administrative subpoena process) were unduly cumbersome under the circumstances. In addition, the appellate court upheld the trial court's determination that the challenged regulations were valid. We think that the *Exeter* case offers strong support for the proposition that mandamus would be an appropriate legal avenue of relief for the Department, if it were needed in a given case.

<sup>&</sup>lt;sup>35</sup> Code Civ. Proc. § 1085(a).

<sup>&</sup>lt;sup>36</sup> *Id.* at §§ 1085, 1086; *Payne v. Super. Ct.*, 17 Cal. 3d 908, 925 (1976); *Agric. Labor Relations Bd. v. Exeter Packers, Inc.*, 184 Cal. App. 3d 483, 489-490 (1986).

<sup>&</sup>lt;sup>37</sup> Exeter Packers, 184 Cal. App. 3d at 490.

<sup>&</sup>lt;sup>38</sup> *Id.* at 490-491.

<sup>&</sup>lt;sup>39</sup> *Id.* at 491-495.

Similarly, we believe that the Department could properly seek injunctive relief to enforce compliance with its regulations. An injunction may be granted "when it appears by the complaint that the plaintiff is entitled to the relief demanded, and the relief, or any part thereof, consists in restraining the commission or continuance of the act complained of, either for a limited period or perpetually," or "when pecuniary compensation would not afford adequate relief." A laboratory that failed to comply with Department regulations might well present a continuing harm to effective law enforcement—and, by extension, public safety—which could not adequately be compensated through money damages. And, again, the Department's absence of licensing authority might further tip the scales in favor of injunctive relief in an appropriate case.

For these reasons, we conclude that the Department of Public Health may seek mandamus or injunctive relief from a court in order to enforce compliance with the Forensic Alcohol Program.

## 2. Proficiency testing

We turn now to the topic of proficiency testing. As mentioned earlier, proficiency testing typically involves submitting samples with known concentrations of ethyl alcohol for analysis so that the accuracy and reliability of the analyses may be evaluated. Health and Safety Code section 100702 (added in 2004<sup>42</sup>) provides as follows:

- (a) All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The required proficiency test must be obtained from any ASCLD/LAB approved test provider.
- (b) Each laboratory shall participate annually in an external proficiency test for alcohol analysis.
- (c) Each examiner shall successfully complete at least one proficiency test annually.

<sup>&</sup>lt;sup>40</sup> Code Civ. Proc. § 526(a)(1).

<sup>&</sup>lt;sup>41</sup> *Id.* at § 526(a)(4).

<sup>&</sup>lt;sup>42</sup> 2004 Stat. ch. 337 § 5.

(d) Each laboratory shall have a procedure in writing that describes a review of proficiency test results, and, if applicable, the corrective action taken when proficiency test results are inconsistent with expected test results.

In light of this language, we are asked (a) whether the Department may require a laboratory also to perform a separate proficiency test under Department regulations, using samples not obtained from an ASCLD/LAB-approved provider and (b), if so, whether the Department may discipline a laboratory for failing to perform these additional tests. Again, there is no claim that the Department is ignoring section 100702's mandate to adopt external proficiency testing. Rather, the argument is that the new requirement for annual ASCLD/LAB-approved proficiency testing supplants, or impliedly repeals, the Department's own proficiency testing methods. For the reasons that follow, we disagree.

As discussed above, the amended FAP statutes require laboratories to comply with Department regulations as they existed on December 31, 2004,<sup>43</sup> and require the Department to continue to enforce those regulations (except that the Department shall not require the laboratories to be licensed).<sup>44</sup> The existing regulations require laboratories to participate in the Department's own proficiency tests,<sup>45</sup> and require the Department to evaluate the competency of laboratories' testing methods using results from those proficiency tests.<sup>46</sup> The regulations also require the Department to conduct proficiency testing to qualify laboratory staff.<sup>47</sup> "A regulation is impermissible only if it exceeds the scope granted by the relevant enacting legislation or if it conflicts with any act of the Legislature."<sup>48</sup> In this case, the alleged conflict is between the regulations as they existed on December 31, 2004 (and still exist) on the one hand, and the 2004 amendments embodied in Health and Safety Code section 100702 on the other. But the 2004 statute, which imposes a new requirement that laboratories participate in *external* proficiency testing, does not on its face eliminate the Department's existing program of *internal* proficiency testing. In light of the Legislature's 2004 determination that laboratories

<sup>&</sup>lt;sup>43</sup> Health & Safety Code § 100700(a) & (b).

<sup>44</sup> Id. at §100725.

<sup>&</sup>lt;sup>45</sup> §§ 1216.1(a)(3), 1217(a), 1217.7(a), 1222.1(a)(5).

 $<sup>^{46}</sup>$  § 1220.1.

<sup>&</sup>lt;sup>47</sup> § 1216.1(e)(3) & (f)(4).

<sup>&</sup>lt;sup>48</sup> Robin J. v. Super. Ct., 124 Cal. App. 4th 414, 423 (2004), internal citations omitted.

must continue to comply with the old regulations until new ones are put in place,<sup>49</sup> we cannot infer that the Legislature intended to override the very regulations that it has directed shall remain in force.

Our conclusion finds further support in the legislative files associated with the Legislature's 2009 attempt to pass Assembly Bill 599, which would have added the following provision to section 100702:

(e) Prior to the effective date of the revisions to the regulations made pursuant to Section 100703 that are adopted and take effect after January 1, 2010, for laboratories accredited in the forensic alcohol analysis discipline or subdiscipline by the ASCLD/LAB, compliance with the standards of that accrediting body shall satisfy the requirements of this section.<sup>50</sup>

The Governor, however, vetoed the bill, stating:

This bill is a premature delegation of regulatory oversight from a state department to a private entity. If there is a more efficient manner to provide oversight for forensic alcohol laboratories, I encourage the stakeholders to work with the Department of Public Health on a solution that does not eliminate important state functions.<sup>51</sup>

The fact that a particular bill has not been enacted is generally of little value in determining legislative intent,<sup>52</sup> but the progress of Assembly Bill 599 leaves little doubt that reasonable people read the existing language of Health and Safety Code section 100702 as continuing authorization for the Department to administer its own proficiency testing in addition to the ASCLD/LAB-approved testing. Committee and floor analyses of the bill<sup>53</sup> uniformly assumed that the Department has a continuing duty to enforce its

<sup>&</sup>lt;sup>49</sup> Health & Safety Code § 100700(a).

<sup>&</sup>lt;sup>50</sup> Assembly 599, 2009-2010 Reg. Sess., § 1, as enrolled (Sep. 4, 2009).

<sup>&</sup>lt;sup>51</sup> Veto message of Gov. Arnold Schwarzenegger re Assembly 599 (Oct. 12, 2009).

<sup>&</sup>lt;sup>52</sup> *DaVita v. Co. of Napa*, 9 Cal. 4th 763, 795 (1995); *see Grupe Dev. Co. v. Super. Ct.*, 4 Cal. 4th 911, 922-923 (1993).

<sup>&</sup>lt;sup>53</sup> A legislative staff analysis may be a useful indicator of legislative intent. *Hassan v. American River Mercy Hosp.*, 31 Cal. 4th 709, 717-718 (2003); *Coburn v. Sievert*, 133 Cal. App. 4th 1483, 1500 (2005).

proficiency-testing regulations, and described the proposed legislation as eliminating the need for additional proficiency testing of laboratories that comply with ASCLD/LAB procedures.<sup>54</sup>

We understand that some laboratory directors object to the Department's internal proficiency testing as duplicative of the ASCLD/LAB-approved tests.<sup>55</sup> For its part, however, the Department maintains that it continues to impose its own proficiency testing both to fulfill its mandate under the current regulations,<sup>56</sup> and because it is "unable to rely completely" on ASCLD/LAB-approved tests "because of several shortcomings in [their] testing protocols."<sup>57</sup>

For the foregoing reasons, we conclude as to the second question that, although laboratories engaged in performing forensic alcohol tests must follow the ASCLD/LAB guidelines for proficiency testing, and must obtain the required proficiency tests from an ASCLD/LAB-approved provider, the Department may nevertheless (a) require a laboratory to also perform separate proficiency tests under Department regulations using samples not obtained from an ASCLD/LAB-approved provider, and (b) discipline a laboratory for failing to perform those additional tests.

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<sup>&</sup>lt;sup>54</sup> Assembly Health Comm. Rpt. Assembly 599, 2009-2010 Reg. Sess. (Apr. 20, 2009) at 4-5; Assembly Appropriations Comm. Rpt. Assembly 599, 2009-2010 Reg. Sess. (May 5, 2009) at 1; Assembly Floor Analysis Assembly 599, 3d reading, 2009-2010 Reg. Sess. (May 15, 2009) at 3; Sen. Health Comm. Rpt. Assembly 599, 2009-2010 Reg. Sess. (Jun. 16, 2009) at 2-3; Sen. Health Comm. Rpt. Assembly 599, 2009-2010 Reg. Sess. (Jul. 7, 2009) at 2-3, 8; Sen. Rules Comm. Rpt. Assembly 599, 2009-2010 Reg. Sess. (Aug. 19, 2009) at 1-2; Assembly Floor Analysis Assembly 599, Conc. in Sen. Amends., 2009-2010 Reg. Sess. (Sep. 1, 2009) at 1-2.

<sup>&</sup>lt;sup>55</sup> Cal. Assn. of Crime Lab Dirs. Memo. to Dep. Atty. Gen. Marc J. Nolan (July 17, 2010) 5-7, 10-11; *see also* Cal. Assn. of Criminalists' Ltr. to Dep. Atty. Gen. Marc J. Nolan (July 17, 2010) 1-2.

<sup>&</sup>lt;sup>56</sup> § 1217.1(e)(3) & (f)(4).

<sup>&</sup>lt;sup>57</sup> Dept. of Pub. Health Memo. 4. Specifically, the Department asserts that ASCLD/LAB-approved sample providers "frequently prepare test samples with target concentrations outside the range where California's +/- 5% accuracy requirements apply," and that the "acceptable limits" for the evaluation of participant results on the external tests "are much wider than those set by California regulations." *Id.*; *see* § 1220.1(a)(1).