

**Assembly Bill No. 3475**

CHAPTER 747

An act to amend Sections 100850, 100855, 100860, and 100885 of, and to add Section 100837 to, the Health and Safety Code, relating to environmental laboratories.

[Approved by Governor September 21, 1996. Filed  
with Secretary of State September 23, 1996.]

LEGISLATIVE COUNSEL'S DIGEST

AB 3475, Committee on Environmental Safety and Toxic Materials. Environmental laboratories.

(1) Existing law authorizes the State Department of Health Services to certify environmental laboratories that perform various analyses. Existing law authorizes the department to adopt specific regulations for this purpose.

This bill, in addition, would require the department to adopt regulations governing the application criteria for the acceptance and approval of 3rd-party laboratory accreditation organizations, for purposes of certifying environmental laboratories. The bill would require the department to adopt regulations that establish fees for laboratories that obtain certification under 3rd-party laboratory accreditation and contain procedures for the inspection and auditing of these laboratories. The bill would require the department to propose the regulations on or before June 30, 1998, and to recognize 3rd-party laboratory accreditation on or before December 31, 1998.

(2) Existing law requires the department to issue a certificate in various fields of testing if the owner of an environmental laboratory files an application for certification and the department finds there is full compliance with the certification provisions and related regulations.

This bill would provide that evidence of the satisfactory completion of accreditation by a 3rd-party laboratory accreditation organization approved by the department pursuant to regulations shall be forwarded to the department for review and approval prior to issuance of a certificate by the department to the owner of a laboratory accredited by a 3rd-party laboratory accreditation organization. The bill would require the automatic revocation by the department of a certificate of a laboratory accredited by a 3rd-party laboratory accreditation organization whenever that laboratory is no longer accredited by the organization and would set forth a process for immediate recertification in this case. It would permit the department to adopt related regulations.



(3) Existing law sets forth notice and hearing procedures that apply whenever an application for certification of an environmental laboratory is denied or a certificate is revoked.

This bill would extend these notice and hearing procedures to apply when the department denies or revokes the approval of a 3rd-party laboratory accreditation organization.

(4) Existing law requires that an environmental laboratory pay an annual certification fee, consisting of a basic nonrefundable fee and an additional fee for certification in each one of certain designated fields of testing for which accreditation is sought.

This bill would require an environmental laboratory that is applying for or has received certification pursuant to provisions authorizing 3rd-party laboratory accreditation to pay an initial fee at the time of application and an annual fee thereafter.

(5) Existing law provides that any person who operates a laboratory that performs work that requires certification under prescribed provisions, who is not certified to do so, may be enjoined from so doing by any court of competent jurisdiction upon suit by the department. Existing law also provides that when the department determines that any person has engaged in, or is engaged in, any act or practice that constitutes a violation of the provisions regulating the certification of environmental laboratories, or any regulation or order adopted thereunder, the state may bring an action in the superior court for an order enjoining these practices or for an order directing compliance and affording any further relief that may be required to ensure compliance with these provisions.

This bill would provide that any organization that represents itself as a state-approved 3rd-party laboratory accreditation organization without being granted approval by the department would be in violation of the provisions regulating the certification of environmental laboratories and could be enjoined from making those representations by any court of competent jurisdiction at the suit of the department. The bill would provide that nothing in this provision would limit the department from exercising any other remedy for a violation of the provisions. The bill also would provide that nothing in this provision would limit the activities of any 3rd-party laboratory accreditation organization within the state, whether or not approved pursuant to these provisions, if the purpose is not to obtain state environmental testing laboratory certification.

*The people of the State of California do enact as follows:*

SECTION 1. Section 100837 is added to the Health and Safety Code, to read:

100837. (a) The department shall adopt regulations governing the application criteria for acceptance and approval of third-party



laboratory accreditation organizations. The regulations adopted pursuant to this section shall meet the following standards.

(1) Applicants may be any private or public entity, whether or not for profit, that demonstrates to the department's satisfaction compliance with the criteria set forth in the regulations adopted pursuant to this section at the time of application and thereafter as provided in the department's regulations.

(2) Minimum requirements shall be established for the applicant accreditation organizations and objective criteria shall be established for department approval that assure accreditation examinations comparable to those conducted by the department for purposes of environmental laboratories pursuant to this article.

(3) (A) Criteria for the minimum content of accreditation examination and laboratory performance level shall be established that assure, to the extent feasible, criteria comparable to department accreditation practices and procedures that apply to environmental laboratories pursuant to this article and to assure that environmental laboratories are operating in accordance with minimum standards adopted by the department.

(B) Nothing in this subdivision shall be construed to limit the department's ability to adopt standards applicable to environmental laboratories.

(4) Procedures for the notification of the department when a privately accredited laboratory fails to meet appropriate performance criteria shall be established that would be suitable to initiate enforcement processes available under the law.

(5) Provisions for the department to periodically review performance and procedures of approved third-party laboratory accreditation and enforcement procedures including revocation of approval shall be included in the regulations. The department shall recover the costs of approving and sustaining the approval of the third-party laboratory accreditation organization from the person or entity seeking that approval.

(6) A third-party accreditation organization shall not be prohibited from establishing and implementing, on its own initiative or at the request of a laboratory, standards that exceed the minimum standards established by the department.

(7) The regulations adopted by the department shall contain procedures for inspection and auditing of laboratories, including inspection and auditing by the department, as appropriate.

(8) The regulations adopted by the department may contain procedures for interim certification of laboratories.

(9) The regulations adopted by the department shall establish, for laboratories that obtain certification pursuant to third-party laboratory accreditation, fees that result in a lower fee structure than, but parallel to, that adopted in subdivision (a) of Section 100860. These regulations shall include a basic fee plus an additional fee for



each field of testing that the laboratory performs and the fees shall be sufficient to support the program.

(b) The department may consult with third-party accreditation organizations, laboratories, and other interested parties and consider any national or international guidance for accreditation programs in adopting regulations as set forth in this section.

(c) The regulations adopted pursuant to this section shall be proposed on or before June 30, 1998. Recognition of third-party laboratory accreditation shall commence on or before December 31, 1998.

SEC. 2. Section 100850 of the Health and Safety Code is amended to read:

100850. (a) (1) Upon the filing of an application for certification and after a finding by the department that there is full compliance with this article and regulations adopted under this article, the department shall issue to the owner a certificate in the fields of testing identified in Section 100860.

(2) Evidence of the satisfactory completion of accreditation by a third-party laboratory accreditation organization approved by the department pursuant to regulations or as otherwise provided in Section 100837 shall be forwarded to the department for review and approval prior to issuance of a certificate by the department pursuant to this section to the owner of an accredited laboratory. The department shall retain ultimate authority to decide whether a laboratory shall be certified or decertified. Whenever an accredited laboratory that has been issued a certificate pursuant to this section no longer is accredited by a third-party laboratory accreditation organization, the certificate issued pursuant to this section shall be automatically revoked by the department, pursuant to appropriate administrative due process as may be prescribed by the department by regulation. However, the laboratory may apply to the department for immediate recertification pursuant to this section. Immediate recertification may occur if the department determines that the loss of accreditation does not result in the laboratory's failure to be in compliance with this article and the regulations adopted thereunder.

(b) The department shall deny or revoke a certificate if it finds any of the following:

(1) The laboratory fails to report acceptable results in the analysis of performance evaluation samples.

(2) The laboratory fails to pass an onsite inspection.

(3) The laboratory is not in compliance with any other provision of this article or regulations adopted under this article.

(c) Provided that there is compliance with all other provisions of this article, a certificate may be restricted by the department to the fields of testing of Section 100860 or subgroups thereof as defined by regulation for which acceptable results have been produced and onsite inspection was passed.



(d) Upon the filing of a complete application for a certificate pursuant to subdivision (a), the department may issue an interim certificate pending the completion of onsite inspection and an analysis of performance evaluation samples. An interim certificate shall be nonrenewable and shall remain in effect until a certificate is either granted under subdivision (a) or denied under subdivision (b), but not later than one year after the date of issuance.

SEC. 3. Section 100855 of the Health and Safety Code is amended to read:

100855. Upon the denial of any application for a certificate or the denial of approval as a third-party laboratory accreditation organization, or the revocation of a certificate or the revocation of approval as a third-party laboratory accreditation organization, the department shall immediately notify the applicant or organization by certified mail, return receipt requested, of the denial and the reasons for the denial. Within 20 days of receipt, the applicant or organization may present the department with a written petition for a hearing. Upon receipt in proper form by the department, the petition shall be set for hearing. The proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and the department has all the powers granted in that chapter.

SEC. 4. Section 100860 of the Health and Safety Code is amended to read:

100860. (a) At the time of application and annually thereafter, from the date of the issuance of the certificate, a laboratory shall pay an annual certification fee. The fee shall consist of a basic nonrefundable fee of eight hundred seventy-nine dollars (\$879) and an additional fee of three hundred ninety-six dollars (\$396) for certification in each of the following fields of testing for which accreditation is sought: (1) microbiology of drinking water and waste water; (2) inorganic chemistry and physical properties of drinking water excluding toxic chemical elements; (3) analysis of toxic chemical elements in drinking water; (4) organic chemistry of drinking water (measurement by gc/ms combination); (5) organic chemistry of drinking water (excluding measurements by gc/ms combination); (6) radiochemistry; (7) shellfish sanitation; (8) aquatic toxicity bioassays; (9) physical properties testing of hazardous waste; (10) inorganic chemistry and toxic chemical elements of hazardous waste; (11) extraction tests of hazardous waste; (12) organic chemistry of hazardous waste (measurement by gc/ms combination); (13) organic chemistry of hazardous waste (excluding measurements by gc/ms combination); (14) bulk asbestos analysis; (15) substances regulated under the California Safe Drinking Water and Toxic Enforcement Act and not included in other listed groups; (16) wastewater inorganic chemistry, nutrients, and demand; (17) toxic chemical elements in wastewater; (18)



organic chemistry of wastewater (measurements by gc/ms combination); (19) organic chemistry of wastewater (excluding measurements by gc/ms combination); (20) inorganic chemistry and toxic chemical elements of pesticide residues in food; (21) organic chemistry of pesticide residues in food (measurement by gc/ms combination); (22) organic chemistry of pesticide residues in food (excluding measurement by gc/ms combination); (23) operation of a mobile laboratory in any one of the above fields of testing in addition to activity in the same field of testing in a certified stationary laboratory under the same owner.

Fees for certification in a specified field of testing may be refunded if the department nullifies the application due to failure by the laboratory to complete the application process in the time and manner prescribed by regulation.

(b) In addition to the payment of certification fees, laboratories located outside the State of California shall reimburse the department for travel and per diem necessary to perform onsite inspections.

(c) If reciprocity with another jurisdiction is established by regulation as described in Section 100830, the regulations may provide for the waiver of certification fees for program activities considered equivalent.

(d) Fees collected under this section shall be adjusted annually as specified in Section 100425. The adjustment shall be rounded to the nearest whole dollar. It is the intent of the Legislature that the programs operated under this article be fully fee-supported.

(e) State and local government-owned laboratories in California established under Section 101150 or performing work only in a reference capacity as a reference laboratory are exempt from the payment of the fee prescribed under subdivision (a).

(f) In addition to the payment of certification fees, laboratories certified or applying for certification in fields of testing (20), (21), or (22) under subdivision (a) shall pay the department a fee of four hundred dollars (\$400) for the preparation and handling of each performance evaluation sample set.

(g) For the purpose of this section, a reference laboratory is a laboratory owned and operated by a governmental regulatory agency for the principal purpose of analyzing samples referred by other laboratories for confirmatory analysis. Reference laboratories carry out quality assurance functions for other laboratories and may carry out unusual, highly specialized, and difficult analyses not generally available through commercial laboratories, and a limited number of routine analyses, for regulatory purposes only, and without assessing per-sample fees for the services.

(h) Notwithstanding subdivision (a), a laboratory that is applying for or has received certification pursuant to third-party laboratory accreditation as set forth in paragraph (2) of subdivision (a) of



Section 100850 shall pay an initial fee at the time of application and an annual fee thereafter. The initial and annual fee shall be established by the department in the regulations authorized by paragraph (9) of subdivision (a) of Section 100837. The fees collected under these regulations shall be adjusted annually as specified in Section 100425. The adjustment shall be rounded to the nearest whole dollar. It is the intent of the Legislature that the programs operated under this article be fully fee-supported.

SEC. 5. Section 100885 of the Health and Safety Code is amended to read:

100885. (a) Any person who operates a laboratory that performs work that requires certification under Section 25198, 25298.5, 25358.4, 110490, or 116390 of this code, or Section 13176 of the Water Code, who is not certified to do so, may be enjoined from so doing by any court of competent jurisdiction upon suit by the department.

(b) (1) Any organization that represents itself as a state-approved third-party laboratory accreditation organization without being granted approval pursuant to Section 100837 shall be in violation of this article and may be enjoined from making those representations by any court of competent jurisdiction at the suit of the department. Nothing in this section shall limit the department from exercising any other remedy for a violation of this article.

(2) Nothing in this article shall limit the activities of any third-party laboratory accreditation organization within the state, whether or not approved pursuant to Section 100837, if the purpose is not to obtain state environmental testing laboratory certification.

(c) When the department determines that any person has engaged in, or is engaged in, any act or practice that constitutes a violation of this article, or any regulation or order issued or adopted thereunder, the department may bring an action in the superior court for an order enjoining these practices or for an order directing compliance and affording any further relief that may be required to ensure compliance with this article.

