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ACLL 16-01  
ALL CLINICAL LABORATORIES LETTER REGARDING  
REQUIREMENTS FOR APPROVAL OF LABORATORIES TO OPT FOR  
A CERTIFICATE OF DEEMED STATUS ISSUED BY  
AN ACCREDITING ORGANIZATION

This All Clinical Laboratories Letter (ACLL) informs clinical laboratories of the requirements they must meet to be deemed in compliance with California clinical laboratory law by private, nonprofit accrediting organizations approved by the California Department of Public Health (CDPH).

An ACLL is a letter from Laboratory Field Services (LFS) to facilities that are licensed or registered by the department to address the standards the department is imposing, allow the public to observe which California laws are more stringent than federal standards, or specify which accrediting organizations have been approved to conduct inspections. ACLLs are posted on the LFS website at <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/All-Clinical-Laboratories-Letters.aspx>

Public comment on this ACLL will be received and considered by LFS for 30 days after posting online. The ACLL becomes final 45 days after posting, after which time it has the force of regulations. Please address your comments about this ACLL to LFS at [LFSaccorg@cdph.ca.gov](mailto:LFSaccorg@cdph.ca.gov) and refer to ACLL 16-01 in the subject line.

Section 1223 of the California Business and Professions Code (BPC) requires the department to approve accrediting organizations to inspect laboratories for the purpose of deeming them in compliance with California clinical laboratory law. Laboratories licensed by the department have the option to choose licensure or registration by the department or certification of deemed status by an accrediting organization approved by the department. Please refer to [BPC §1223](#) for the complete statute and see the notice regarding criteria for the approval of accrediting organizations on the LFS website at <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/All-Clinical-Laboratories-Letters.aspx>.



a. General Requirements

1. A laboratory may not apply for deemed status for its initial license or the survey conducted during the initial licensure period.
2. A laboratory may choose deemed status only once a year at the time of annual renewal of its licensure, provided that the laboratory's deemed status or CLIA certificate is in condition-level compliance with CLIA and State requirements.
3. The department may conduct validation surveys of laboratories with deemed status.
4. The department retains authority to investigate complaints against a laboratory with deemed status.
5. If the department determines that the survey standards of an accrediting organization do not meet the requirements of California law, the department will notify affected licensees with
  - A. a detailed description of the deficiencies found in the validation survey process.
  - B. an explanation concerning the risk to consumers.
6. If the department withdraws approval of the accrediting organization, a laboratory deemed by the organization will have 45 days to choose deemed status by another approved accrediting organization or revert to state licensure.
7. A deemed status laboratory must submit changes (change of ownership, change of director, change of address) to both the accrediting organization and the department.

b. Approval Requirements

A laboratory must meet the following requirements to be approved for a certificate of deemed status:

1. Meet the accreditation standards of the accrediting organization, which must be approved by the federal Center for Medicare and Medicaid Services (CMS) and the department.
2. Authorize the accrediting organization to provide any records or other information to the department, including complaint and inspection reports.
3. Pay the applicable fees.
4. Authorize its proficiency testing organization to furnish to the department and the accrediting organization the results of the laboratory's participation in a proficiency testing program approved by CMS, along with explanatory information needed to interpret the proficiency testing results, upon request of the department or the accrediting organization.

5. Authorize the accrediting organization to release to the department a notification of every violation of condition-level requirements, including the actions taken by the accrediting organization as a result of the violation.
6. Authorize the accrediting organization to give notice to the department of any withdrawal or termination of the laboratory's accreditation.  
If the accrediting organization withdraws or revokes a laboratory's accreditation
  - a. the laboratory will retain its certificate of deemed status for 45 days after it receives notice of revocation of accreditation or the effective date of any action taken by the department, whichever is earlier.
  - b. the laboratory will revert to State licensure and must apply to LFS for licensure application. The application process shall be followed as outlined in regulations and statutes.
7. Notify the department of any change in deemed status within 30 days.  
Change includes withdrawal, revocation, termination, or any action taken by the accrediting organization against the laboratory's deemed status.
8. Authorize the accrediting organization to release documents to the department pursuant to an investigation or complaint.
9. Renew certification of deemed status annually.

c. Application Process

1. To apply for deemed status a laboratory must:
  - A. Have a current, valid CLIA certificate.
  - B. Be licensed by the department for at least one year and be in condition-level compliance with CLIA and State requirements.
    - i. A laboratory may not request deemed status for an initial license or the survey conducted during the initial licensure period.
    - ii. If a laboratory's license is in the process of revocation or has been revoked, the laboratory may not apply for deemed status.
  - C. Enroll with an approved accrediting organization.
  - D. Submit to the accrediting organization a written request to be considered for deemed status and meet the requirements of the accrediting organization for deemed status.
  - E. Within 30 days of being accepted by the accrediting organization for deemed status, submit to the department the following:
    - i. A written request to be considered for deemed status.
    - ii. Documentation of accreditation by an approved accrediting organization (certification of approval).

- iii. A copy of the decisions and findings of the accrediting organization based on an on-site survey within the 24 month period preceding the request for deemed status.
    - iv. The fee required by the department.
  2. Within 30 days of accepting the laboratory for deemed status, the accrediting organization must also inform the department in writing that the laboratory has been approved for deemed status. The accrediting organization will issue a certificate of approval with its approval number within 30 days.
  3. When LFS receives and approves the laboratory's request for deemed status it will issue a certificate of deemed status with the laboratory's state license number within 30 days.

Please note: LFS does not maintain documents of accrediting organizations. As a private entity, an accrediting organization is not subject to the California Public Records Act (PRA), and its application and inspection reports are not subject to PRA disclosures. Any requests for the documents of an accrediting organization must be sent directly to the accrediting organization.

The provisions of this ACLL do not modify or otherwise affect existing law and do not modify the Department's authority to enforce its laws.