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ACLL 16-01 – LABORATORY REQUIREMENTS

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

NOTICE OF FINAL ACTION

Subject: This is the Final Action on the Notice of Proposed Changes posted as ACLL 16-01 on March 1, 2016, at:
<http://www.cdph.ca.gov/programs/lfs/Documents/ACLL%2016-01.pdf>.

Date of Adoption: The Final Action was effective April 21, 2016.

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).

You may contact Laboratory Field Services (LFS) about this ACLL at LFSaccorg@cdph.ca.gov. Please 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. All laboratories seeking California licensure must apply to LFS.

Laboratories choosing deemed status must meet the requirements listed below.

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.~~
1. A laboratory may choose deemed status only once a year, as an initial applicant or at the time of ~~annual~~ renewal of its licensure, provided that the laboratory's California license or registration, deemed status, or CLIA certificate is in condition-level compliance with California and CLIA and State requirements.
2. The Department may conduct validation surveys of laboratories with deemed status.
3. The Department retains authority to investigate complaints against a laboratory with deemed status.
- ~~2.~~ If the Department determines during a validation survey or complaint investigation 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.~~laboratories deemed by the organization.
4. If the Department withdraws approval of an accrediting organization, a laboratory deemed by the organization will have 45 days from the date of notification to choose deemed status by another ~~approved~~ accrediting organization approved by the Department or revert to ~~state~~ licensure by the Department.
5. A deemed status laboratory must submit changes (change of ownership, change of director, change of address) to both the accrediting organization and the Department within 30 days.

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 by the Department 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. Changes include 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 issued by the Department annually.

c. Application Process

1. To apply for a certificate of 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.~~
 - B. Submit a completed Department application to LFS. If a laboratory's license is in the process of revocation or has been revoked, the laboratory may not apply for a certificate of 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.~~
- F. Pay the application or renewal fee required by the Department.
- 2. A laboratory currently accredited by an approved accrediting organization can apply for a certificate of deemed status at their next license renewal period.
The laboratory must:
 - A. Provide the Department with a copy of the laboratory's current certificate of accreditation.
 - B. Provide the Department with a copy of the most recent decisions and findings of the accrediting organization based on an on-site survey performed within the 24-month period preceding the request for deemed status.
 - C. Pay the renewal fee required by the Department.
- 3. A laboratory applying for a certificate of deemed status not yet enrolled with an approved accrediting organization must
 - A. Complete the accrediting organization's application and provide the Department with documented evidence that the laboratory has applied to the accrediting organizations in the form of an acknowledgment from the accrediting organization that the laboratory has applied.
 - B. Once it has been accepted by the accrediting organization for deemed status, the laboratory must submit to the Department:
 - ~~i. A written request to be considered for deemed status.~~
 - ~~ii. Documentation of acceptance by an approved accrediting organization, including the unique ID number assigned by the accrediting organization.~~
 - ~~iii. A copy of the decisions and findings of the accrediting organization based on an on-site survey.~~
 - ~~iv. Pay the application or renewal fee required by the Department.~~
- ~~4. 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.~~
- ~~5. 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 laboratory documents of produced by 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.