

Change of Laboratory Director(s)

California Business and Professions Code (BPC) section 1265 (e) and (g) require clinical laboratories to notify Laboratory Field Services within 5 days of an interim director and within 30 days of any change in ownership, name, location, or permanent laboratory director.

Pursuant to BPC 1265 (e), a clinical laboratory license will be automatically revoked 30 days after a major change of directorship or ownership. “A major change in laboratory directorship” means a change in laboratory director or directors resulting in the situation where less than 50 percent of the laboratory directors to whom the current laboratory license is issued remain after the change. See BPC 1211 (j). The laboratory must submit a completed application for a new clinical laboratory license within 30 days of a major change of directorship or cease engaging in clinical laboratory practice. For the removal or addition of a director that is not a major change, see required documentation under Minor Change of Director in this section.

Clinical Laboratory License Fee and Required Documents for a Major Change of Director(s):

- **License fee** payable to the State of California Department of Public Health. The fee is non-refundable and subject to change with each fiscal year. View the current fee schedule at <http://www.cdph.ca.gov/programs/lfs/Documents/A-License-FeeSchedules.pdf> .

State forms to complete:

- **LAB 144** – Application for Clinical Laboratory License
- **LAB 144B** – Application for Additional Clinical Laboratory Testing Sites, ONLY if qualified for multiple site exception under California Business and Professions Code 1265 (d).
- **LAB 116** – Laboratory Personnel Report
- **LAB 144A** – Laboratory Testing Declaration, including names of manufacturer(s) and/or equipment(s) and annual volumes
- **LAB 183 - Director’s Attestation of the new director(s)**
- **Resignation letter from the previous director** with effective date and original signature
- **If applicable, LAB 165** – Application for Approval to Perform HIV Tests. Check the box for change of director
- **Original signatures** must be on all forms where signatures are required

Federal forms to complete:

- **CMS 209** – Laboratory Personnel Report (CLIA)
- **CMS 116** – CLIA Application.

State **LAB** forms and **Fee Schedules** can be downloaded from:

<http://www.cdph.ca.gov/pubsforms/forms/Pages/RegulatedLaboratories.aspx>
<http://www.cdph.ca.gov/programs/lfs/Documents/A-License-FeeSchedules.pdf>

Federal forms **CMS 116** and **CMS 209** can be downloaded from

<http://cms.hhs.gov/cmsforms/downloads/cms116.pdf>
<http://cms.hhs.gov/cmsforms/downloads/cms209.pdf>

Required Documents for a Minor Change of Director:

Letter of Resignation (if applicable) including effective date and original signature of the departing director.

Letter of Addition (if applicable) including effective date and the original signature of the incoming director.

- **LAB 183 – Director’s Attestation** (each new director or co-director with original signature).

Submit fee and all required documents for a Major Change or all the required documents for a Minor Change to:

**CDPH - Laboratory Field Services Branch
Facility Licensing Section
850 Marina Bay Parkway Bldg P, 1st Floor
Richmond, CA 94804**