

DUTY STATEMENT

Employee Name:	Position Number: 580-750-7949-002
Classification: Examiner I	Tenure/Time Base: Permanent / Full-time
Working Title: Clinical Laboratory Licensing Examiner	Work Location: 850 Marina Bay Parkway, P-1 Richmond, CA 94804
Collective Bargaining Unit: R10	Position Eligible for Telework (Yes/No): Yes
Center/Office/Division: Center for Laboratory Sciences	Branch/Section/Unit: Laboratory Field Services/Laboratory Licensing and Registration Section

All employees shall possess the general qualifications, as described in California Code of Regulations Title 2, Section 172, which include, but are not limited to integrity, honesty, dependability, thoroughness, accuracy, good judgment, initiative, resourcefulness, and the ability to work cooperatively with others.

This position requires the incumbent to maintain consistent and regular attendance; communicate effectively (orally and in writing) in dealing with the public and/or other employees; develop and maintain knowledge and skill related to specific tasks, methodologies, materials, tools, and equipment; complete assignments in a timely and efficient manner; and adhere to departmental policies and procedures.

All California Department of Public Health (CDPH) employees perform work that is of the utmost importance, where each employee is important in supporting and promoting an environment of equity, diversity, and inclusivity, essential to the delivery of the department's mission. All employees are valued and should understand that their contributions and the contributions of their team members derive from different cultures, backgrounds, and life experiences, supporting innovations in public health services and programs for California.

Competencies

The competencies required for this position are found on the classification specification for the classification noted above. Classification specifications are located on the [California Department of Human Resource's Job Descriptions webpage](#).

Job Summary

This position supports the California Department of Public Health's (CDPH) mission and strategic plan by ensuring quality standards in clinical and public health laboratories, tissue and blood banks, the production of biologics, and laboratory scientists through licensing, examination, inspection, education, and proficiency testing.

Under the direction of the Examiner III, the Examiner I evaluates and approves licensing and registration for the Clinical Laboratory Licensing Program and the Clinical Laboratory Proficiency Testing (PT) program. Evaluates and approves initial and renewal facility license applications. Conducts independent reviews of analysts' work to determine technical compliance. Provides technical assistance and research to resolve complex issues. Conducts surveys and investigations of laboratory facilities to ensure adherence to Departmental policies and procedures, and state and federal laws. Investigates laboratory-related complaints and maintains accurate electronic and paper

records. Travel is required both in and out of state up to 30% of the time.

Special Requirements

- Conflict of Interest (COI)
- Background Check and/or Fingerprinting Clearance
- Medical Clearance
- Travel: 30%
- Bilingual: Pass a State written and/or verbal proficiency exam in
- License/Certification: Clinical Laboratory Scientist license or Public Health Microbiologist certification
- Other:

Essential Functions (including percentage of time)

30% Evaluates and approves initial and renewal facility license and registration applications from clinical laboratories seeking to perform clinical laboratory tests and examinations on biological specimens originating in California (CA) to determine equivalence with state clinical laboratory requirements and clinical laboratory licensing standards. Evaluates and approves facility operational policies and procedures, test procedures, method validations, proficiency testing performance, corrective actions, records, and survey reports to determine compliance with out-of-state laboratory licensing, Medi-Cal Provider eligibility requirements, and federal laws. Communicates with applicants regarding documentation needed; and assists applicant during the application process.

Approves, denies, or issues revocation notices to licensed or registered clinical laboratories that test and examine human specimens originating in CA. Evaluates and approves in-state and out-of-state clinical laboratories approved for Medi-Cal reimbursement. Performs audits and reviews quality system activities on at least 10 percent of all clinical laboratory applications and other licenses issued. Authorizes notices of approval of in-state and out-of-state clinical laboratories to the Medi-Cal Provider Enrollment program.

Provides consultation and assistance to LFS staff, client applicants, regulated community, and legislature on laboratory licensing and registration-related issues.

30% Conducts desk surveys, and/or complaint investigations. Fully documents all evidence relating to non-compliance for legal actions, while ensuring patient confidentiality. Independently, or as part of a team, makes a determination of compliance with state and federal laws and regulations based on findings and observations. Prepares written comprehensive narrative reports of findings including conclusions and recommendations. Prepares written statement of deficiencies when deemed appropriate and maintains these records. Communicates with the complainant, the Clinical Laboratory Improvement Amendment (CLIA) program, Centers for Medicare and Medicaid Services (CMS), and partner agencies. Maintains accurate written and electronic records, and updates information in the state and federal databases and facility files.

Travel is required for in and out of state to perform inspections, attend work-related meetings, and receive or provide training.

- 25% Assists with the operations of the Proficiency Testing (PT) program; evaluates and approves proficiency testing dates regarding participation and performance of licensed and unlicensed clinical laboratories to determine compliance with state and federal standards; approves correspondence to interpret requirements, cite deficiencies, and requests and reviews corrective action; negotiates with officials administering proficiency testing services to develop agreements on scoring and grading methods and criteria for determining acceptable performance.

Monitors changes in performance data for patterns and trends that indicate substandard methodology or instrumentation and recommends appropriate remedial action to be taken by participant laboratories; develops modifications and additions to the computerized data system to accommodate changes in laboratory technology and program requirements. Follows up with facilities on proficiency testing failures; reviews and approves plans of correction.

Provides assistance in oversight of license and registration programs under advisement from Examiner II and as assigned by Examiner III or Branch Chief. Provides excellent customer service and expert technical assistance through all methods of communication including email, letter, and telephone by responding to applicants, the regulated community, the legislature, the Governor's office, the public, the media, and others. Reviews and updates work procedures and correspondence templates. Approves correspondence prepared by staff. Prepares and gives presentations, researches, writes reports as needed. Conducts workshops and training programs on licensing or certification topics as needed.

Serves as liaison to the Department's Clinical Laboratory Technology Advisory Committee on issues related to laboratory licensure. Serves on various committees at LFS as assigned.

- 10% Works with Supervising Program Technician(s) and analysts to ensure timely processing of all applications. Develops policies and procedures for approval and implementation. Ensures database updating is done correctly and efficiently, and applications and communication are processed in a timely manner. Participates in and/or leads quality improvement activities.

Testifies at licensure hearings on behalf of the Department and participates in researching and developing regulations and legislation. Acts as subject matter expert on statewide regulations and legislative bill analyses. Works with section's analysts to draft and review regulations as needed.

Marginal Functions (including percentage of time)

- 5% Performs other job-related duties as assigned. Provides follow-up and back-up to assist the personnel licensing section, including surveys and investigations.

I certify this duty statement represents an accurate description of the essential functions of this position. I have discussed the duties and have provided a copy of this duty statement to the employee named above.

I have read and understand the duties and requirements listed above and am able to perform these duties with or without reasonable accommodation. (If you believe reasonable accommodation may be necessary, or if unsure of a need for reasonable accommodation, inform the hiring supervisor.)

Supervisor's Name:	Date	Employee's Name:	Date
Supervisor's Signature	Date	Employee's Signature	Date

HRD Use Only:

Approved By: CO

Date: 4/11/24