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**Topic:** Laboratories with a California Clinical Laboratory License  
Frequently Asked Questions

**Date:** August 21, 2017

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**GENERAL QUESTIONS**

**1. Where can I find the new checklist requirements for laboratories with a California Clinical Laboratory License?**

The new requirements are located in the Laboratory General Checklist beginning in the 2017 checklist edition. They are included in customized checklists for laboratories that report to the CAP that they have a California clinical laboratory license. In addition, there are two revised requirements in the Cytopathology Checklist, CYP.08500 and CYP.08550, for cytopathology workload recording.

**2. Which laboratories do these requirements apply to?**

The requirements apply to all laboratories that have a California clinical laboratory license. This includes laboratories located in the state of California, as well as those outside of the state that test patient specimens originating from California. The following types of laboratories are not required to obtain a clinical laboratory license and are exempt from California laboratory law:

- Laboratories owned by the US government
- Public health laboratories
- Forensic laboratories
- Research and teaching laboratories that do not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of the health of individual patients.

**3. Why did the CAP add these requirements? Why aren't there specific requirements for other states in the checklist?**

The CAP was granted deeming authority with the state of California in spring 2016 to inspect laboratories for compliance with California laboratory law. This means that a CAP inspection can be used to demonstrate compliance with both the CLIA regulations and California laboratory laws. When the CAP was first approved in 2016 it began including a specific letter to inspectors alerting them to areas where unique requirements exist in California law. With the inclusion of these requirements in the checklist, the CAP is streamlining its inspection tools to have all of the requirements in one location.

While the CAP has agreements with other states (e.g. Florida), there have been other mechanisms used to assess compliance with state laws in those states.

**4. My laboratory has a California clinical laboratory license. Why aren't these new requirements appearing in my laboratory's customized checklist?**

The requirements may not be appearing in your customized checklist for one of two reasons: 1) the laboratory is using an older checklist edition (e.g. 2015 or 2016 edition); or 2) the laboratory did not report its relationship with the state to the CAP on its last accreditation application.



This section of requirements will only appear in the 2017 checklist edition and subsequent editions. If your laboratory is being inspected with an older edition, it will have these specific requirements in the version provided with the self-inspection materials.

If the laboratory is using the 2017 checklist edition and the requirements are not present in the customized checklist, contact the CAP at 800-323-4040, option 1 to correct the information.

**5. If my next inspection is not until 2018, do I need to take any action now?**

Since these requirements are aimed at ensuring that laboratories are following the applicable state laws, the CAP encourages all laboratories subject to California clinical laboratory licensure requirements to download the updated checklist edition now to ensure that they are in compliance with these requirements. The laboratory will be assessed for ongoing compliance with these requirements at their next on-site inspection.

**6. Do laboratory personnel licensure requirements apply to personnel working in a physician's office laboratory in California?**

Physician office laboratories with five or fewer physicians that perform tests only on their own patients are exempt from personnel licensure requirements, but must meet the CLIA regulations for the complexity of testing performed (refer to GEN.54750). If high complexity testing is performed by unlicensed individuals, the physician must be present on-site when testing is performed. If testing is performed by California-licensed clinical laboratory scientists, the requirements for on-site supervision by the laboratory director do not apply.

**7. Can medical laboratory technicians (MLT) with an associate's degree perform high complexity testing in a laboratory with a California license?**

With the exception of physician office laboratories with five or fewer physicians that perform tests only on their own patients (refer to # 5) and individuals with specific types of military training, an MLT would not qualify to perform high complexity testing. The personnel qualifications in the California Business and Professions code for high complexity testing personnel are more stringent than the Clinical Laboratory Improvement Amendments (CLIA). High complexity testing must be performed by individuals with the following types of qualifications (refer to GEN.78250):

1. California licensed physician;
2. Individual licensed to direct a clinical laboratory (limited to testing performed in the licensed specialty);
3. Individual licensed as a clinical laboratory scientist generalist; **or**
4. Individual with a limited laboratory scientist license (limited to the specialty of the license).

Information on qualifications to obtain licensure, including specific exceptions allowed for military trained individuals may be found on the California Department of Public Health website and in the California Business and Professions Code §1261. In laboratories located outside the state of California with a clinical laboratory license, personnel are not required to obtain licensure, but there must be records showing that personnel meet equivalent qualifications.

**8. What can a lab assistant do? What kind of supervision is required?**

Laboratory assistants are typically unlicensed laboratory personnel that can perform limited duties in the laboratory only under appropriate supervision. The qualifications, limitations on duties, and types of supervision required are detailed in the Laboratory General Checklist requirement GEN.78300 (Unlicensed Laboratory Personnel).

## LABORATORIES LOCATED OUTSIDE OF THE STATE OF CALIFORNIA

**9. My laboratory has a California clinical laboratory license, but my laboratory is located in a different state. Do these new requirements apply to my laboratory?**

Yes, the requirements apply to all laboratories with a California Clinical Laboratory License, but are limited to the testing performed on patient specimens originating from the state of California.

**10. Do personnel working in laboratories with a California clinical laboratory license located outside of the state of California need to have California personnel licensure?**

Personnel performing laboratory testing on patients specimens originated from the state of California must meet qualifications equivalent to those required for California personnel licensure. The laboratory must retain records demonstrating the equivalence of the individual's qualifications to those required for licensure. The personnel qualifications for different laboratory roles and test complexities are defined in GEN.78250.

**11. Does a pathologist in another state directing a laboratory or reviewing cases from specimens originating in California need to have a medical license from the state of CA?**

No, directors of laboratories located outside of the state of California with a California clinical laboratory license must meet qualifications equivalent to those required for licensure. MDs may be licensed to practice medicine in their own state.

## ADDITIONAL RESOURCES

**12. Where can I find more information?**

Additional resources include the following:

- Laboratory General Checklist
- California Business and Professions Code (BPC)
- California Code of Regulations (CCR)
- California Department of Public Health website