

California ELAP Regulations

Frequently Asked Questions

September 3, 2020

On May 5, 2020, the California State Water Resources Control Board adopted comprehensive regulations for the Environmental Laboratory Accreditation Program (ELAP) to modernize the program and elevate data quality for California communities.

1. The State Water Board adopted new regulations on May 5, 2020. Are these regulations now in effect?

The regulations adopted at the May 5th meeting do not go into effect until January 1, 2021.

2. Does my laboratory have to be TNI-compliant by January 1, 2021?

No. Many of the adopted regulations provide a three-year window for becoming compliant with the 2016 TNI Standard. Your laboratory will have to adhere to the TNI Standard once your laboratory's certificate expires after January 1, 2024. During the 3- year transition period, labs will continue being held to the quality assurance requirements in the outgoing or previous regulations.

ELAP is encouraging laboratories to adopt the various changes at a deliberate pace to allow for a smooth transition.

3. Where do I begin?

Transitioning a quality management system to a new standard can seem like a daunting task. IAS recommends performing a gap analysis to identify areas of greatest concern.

Begin by making changes pertaining to proficiency testing (PT) since these are the first regulatory changes to take effect. The regulations stipulate what a laboratory must do when it receives a "not acceptable" score from the PT provider. The regulations also provide timelines for notifying ELAP, performing corrective action, and obtaining an "acceptable" score. Start making changes here.

4. How do I perform a gap analysis?

Laboratories typically go one of two routes.

- 1) If your laboratory has the quality assurance resources necessary to perform a gap analysis, begin with making a schedule to assess all quality system and technical aspects of your operations. Or,
- 2) Have an experienced consultant perform a gap analysis on behalf of your laboratory. In addition to identifying aspects in need of change, consultants can offer solutions which have been shown to

work in similar labs. This can also be used in conjunction to complete the mandatory annual internal audit and data integrity training.

5. Does my Technical Manager have to adhere to the qualifications in the TNI Standard?

No. ELAP regulations specify several alternatives to achieve approval of Technical Managers. These include various educational and work experience, certain Water Quality Analyst certifications, grandfathered positions, and other specific circumstances.

6. What are the requirements for my ELAP application?

It depends on when your certificate is set to expire. ELAP is waiving this application requirement for labs expiring in 2020 and 2021. ELAP has a helpful [Roadmap to ELAP Accreditation](#) graphic on their website.

7. Does my lab have to use a third-party assessment agency (TPA)?

If your laboratory requires assessment to fields of accreditation utilizing sophisticated technologies, yes, TPA must be used. Laboratories not utilizing sophisticated technologies can still use a TPA to assess their lab.

8. Do I have a choice which TPA to use?

Yes, ELAP will not assign your assessment provider. IAS has educated, experienced assessors that work with the laboratory in scheduling and performing impartial and efficient assessments. IAS as a TPA has experience in assessing large and small, municipal and commercial laboratories to the 2016 TNI Standard.

9. How do I get started in using a TPA?

Contact IAS to schedule an assessment date that works best for your laboratory. IAS recommends beginning the process 9 months from when your laboratory needs to have the process completed. Labs must have the assessment process completed (a) within one year from an initial application or amendment, or (b) during the two-year accreditation window for renewals.

Take home message:

The newly adopted ELAP regulations will require a more robust quality management system for California laboratories. While the changes are numerous and can be, at times, confusing, the time frame is generous to give laboratories an opportunity to make a smooth transition. If you have further questions refer to the regulations themselves. If additional questions remain, contact Mohan Sabaratnam at iasinfo@iasonline.org.

This FAQ sheet is not meant to be a comprehensive list of requirements for accreditation.

About IAS The International Accreditation Service is a non-profit, globally recognized accreditation body. IAS is a NELAP recognized Non-Governmental Accreditation body and ELAP TPA. Established in 1975, the IAS headquarters is in Brea, California. IAS is a signatory to the International Laboratory Accreditation Cooperation (ILAC) for testing laboratories, calibration laboratories and inspection agencies. Some of the federal agencies that accept IAS accreditation programs include the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency.