



# ELAP PROGRAM MANAGEMENT REVIEW – A COMMERCIAL LAB PERSPECTIVE



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# Disclaimer



- While I have solicited a lot of input from other commercial labs (mainly large), ultimately the remarks are my own.
- Commercial labs do not represent a single entity.
  - Some are multi-site and very large
  - Others are single site and very small
  - Some perform work in multiple states
  - Others work only in California
- All however **should** produce data of known, documented quality and **be expected** to meet specific standards.

# Relevant Observations



- There are a LOT more commercial labs certified in CA than municipal labs. But ALL provide compliance data that has the same importance.
- There are also a LOT more in-state than out of state labs.
- Program changes and the evaluation need to be responsive to these statistics.

| Laboratories Currently Receiving ELAP Accreditation Services |                        |
|--|------------------------|
| Type of Laboratory   | Number of Laboratories |
| In-State   | 626                    |
| Out-Of-State   | 108                    |
| Municipal  | 137                    |
| Private  | 597                    |



# COMMERCIAL LAB NEEDS AND PERCEIVED RELATED ELAP PROBLEMS

# Costs Must Be Realistic and Fees Must Match Value



- When ELAP had NELAP status, the NELAP labs subsidized the ELAP labs.

CA NELAP certification fees were essentially the highest in the country.

ELAP needs to really evaluate the costs of the accreditation. Basic ELAP fees are likely too low.

Thus ELAP now has a significant budgetary problem.

# We Need A Single Stringent Transparent Standard



- All labs should be accredited to a **single documented standard**, based on a validated quality system (ISO17025) and adherence to method requirements.

Accredit **commercial** and **municipal** labs to the **same** minimum standards (at least the lab Cert Manual?); those standards must result in data of known and documented quality.

If the minimum standard is “below” TNI, any labs with TNI accreditation should automatically meet.

# We Need Timeliness in All Aspects of Accreditation



- Lack of timeliness can directly impact our business in a competitive environment.
  - Frequency of audits (ELAP)
  - Deadlines for audit reports (ELAP),
  - Deadlines for corrective action reports (lab),
  - Deadlines for response (ELAP),
  - Deadline for final certificate (ELAP)

ELAP has a “**well deserved**” reputation for not paying attention to most of these deadlines. **That is a management and systems issue.**

# We Need Thorough, Accurate and Consistent Assessments



- Lack of thorough, accurate, consistent assessments means no level playing field.

The nature of an audit in California appears to depend almost entirely on the auditor, and **not on the standard** to which the assessment is supposed to be made.

This reflects both lack of a clear standard and poorly trained staff.



# We Need Better Standards and Training



- **ELAP currently uses no consistent standard.** This is evident from anecdotal stories of auditors and their findings in one lab and not in another.
- **Auditors are poorly trained.** Many have not even been through the Cincinnati DW training program, a requirement for primacy. They also often have minimal bench experience, particularly in the “real world”.
- **There is a great deal of subjectivity** on the part of auditors.

# We Need A Ready Mechanism to Revoke Accreditation



- If a standard/program does not have a clear path for revocation of accreditation, it has no teeth.

Revocation needs to be “easy” to do and have clear guidelines that ELAP can enforce (e.g. it needs to be in statute and regulation).

Revocation should be possible based on PT performance, consistent failure to follow method requirements, or repeated violations of standards.

# ELAP Needs Performance Benchmarks



- Benchmark performance (costs, FTEs, # of inspections, etc) against other states and be accountable to those benchmarks.
- Historically, there is a poor management system with no accountability. Good performance is **not rewarded** and poor performance **is not punished**.
- There is no **effective program to prevent retaliation** for complaints about auditors, or even to encourage confidential complaints.

# We Need Consistent Good Customer Service



## ➤ Timing/customer service is non-existent.

We know of labs that paid fees almost a year ago and only in the last month got even feedback from ELAP, let alone accreditation.

## ➤ There is limited professionalism with respect to confidentiality.

Some auditors freely talk about other labs' findings.



# POTENTIAL FIXES: A COMMERCIAL LAB PERSPECTIVE

# There are Short, Medium, and Long Term Fixes Needed



- Short term fixes should bring the program back to a minimal baseline as an effective program and should be focused on < 12 months.
- Medium term fixes would require more resources and potential systemic changes
- Long term fixes should be based on a vision of where the program needs to be and are probably difficult to achieve, but **without a long term vision** the program will continue to stumble.

# Accept NELAP from Other States



- Officially recognize NELAP accredited labs, **regardless of who audited them**, and charge a fee **ONLY commensurate with the amount of work required** to produce the paperwork and provide oversight.

Historically CA recognized NELAP/TNI as a rigorous standard, so even without being a NELAP AB, **accept the accreditation.**

Nearly all former NELAP labs ended up with accreditation from another state.

# Expand State Auditing “Capacity”



➤ Approve the use of 3<sup>rd</sup> party auditors in CA.

This **assumes there is a standard to audit against.**

ELAP can still provide oversight.

ELAP fees should be commensurate with the level of effort.

**Does not however address the issue of ELAP auditor competence,** as it is unlikely ALL certified labs would go the 3<sup>rd</sup> party route.



# Demonstrate Lab Method Competence During Audits



- Auditors must **watch analysts performing tests** to demonstrate competence and document that competence. (It is **not** just a quality system)
- This also means **developing checklists** for most methods and having those checklists reviewed by people familiar with the methods, **if necessary on a contract basis.**

Reach out to other states as needed.

**Auditors still need actual method experience.**

# Update Regulations (Critical!)



- Write **new regulations in conjunction with ELTAC** that are based on a consensus standard (TNI, ISO, Lab Cert Manual) and address the concerns we have already raised.
- A dual standard **is not a good alternative**, as many clients (municipalities, dischargers, and even many consultants) consider “accreditation” as the only hurdle.

# Address the “Innocently Incompetent” Problem With Better Outreach



- Not all labs are equally knowledgeable, and there **is a difference** between **deliberate short cuts/fraud** and **lack of knowledge**. In the long run, lack of knowledge on the part of labs is no excuse for poor performance.

An effective program should be a resource for labs to improve **and** to make labs adhere to methods. **Look at AZ info updates as an example..**

**Be sure the tools reach everyone impacted.**

# Other Short Term Fixes to Address, While You are at It....



- The only way to truly assess lab adherence to a standard is to incorporate **periodic unannounced audits** in the program/regulations.
  - But if auditors aren't trained, it's moot.
- **Maintain and monitor** the PT database to ensure timely action based on performance.
  - Conscientious labs police themselves on this, but what about the rest....?
- Use Region 9 as a technical resource.
  - Too much reliance on the State lab

# Expand ELAP Accreditation Scopes to Support Regulations



- ELAP currently does not routinely accredit for analytes until they are regulated, even if the Regional Boards are requiring monitoring; this creates a Catch-22 in that you **can base a regulation** on data of **unknown, undocumented** quality.

This needs **to be flipped to require** that labs be accredited for parameters that **MAY** be regulated.

# Miscellaneous Observations



- Municipal labs **do not seem to be held to the same standards** as SOME commercial labs.
- There is **inconsistent enforcement** of regulatory requirements. This reflects the lack of enforceable regulations **and** the auditor training.
- Auditors **seem to be too focused on drinking water** requirements even when auditing WW/HW only labs. This likely reflects their primary experience, even though there are a lot more HW/WW labs that are certified.

# General Commercial Labs Concern



- We have a concern that ELAP may be **“too broke to fix”** with systemic program/staff issues.
- If the short term fixes can’t be implemented, in particular the ones that impact program and staff accountability, **it is unlikely that the program can truly survive as anything that is meaningful** to ensure quality.
- This would leave a **conundrum for the state and labs**, so the panel needs to be prepared with alternative “end game” scenarios.

# Any Questions?



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