

SAC/ELTAC Feedback to ELAP on WorkPlan Progress

Presented by

Andy Eaton, PhD, BCES
Eurofins Eaton Analytical, Inc

SAC Chair/ELTAC Chair

Disclaimer – These views may not represent everyone on the SAC but I have tried to reflect input from all who provided it.

ELTAC has certainly been reinvigorated and has extensive support from ELAP

- SAC members (and ELTAC members) uniformly feel this has been positive.
- ELTAC has had full agendas at every meeting (**too full?**)
- Initial interpretation of Bagley-Keene requirements severely hampered the ability of ELTAC to provide meaningful assistance. (no effective subcommittees). **That has been fixed.**

ELTAC is perhaps not playing the role it was envisioned to play (advisory panel)

- ELAP is relying on ELTAC for **detailed technical support** and **not just input on policy**
- ELTAC has turned **into a technical resource for ELAP (FOTs, Checklists)** because ELAP still lacks technical depth. That **creates concern about ELAP's abilities to move forward without adding more technical expertise.**

ELAP is Still Lacking Technical Depth

- The level of expertise within the ELAP team on the details of methods from a training perspective and the requirements of a lab accreditation program is still lacking and **ELAP recognized this.**
- We **applaud the decision to get extensive outside training quickly.**
- This should get **extensive publicity via LYRIS** so that labs and the public know that ELAP is on a path to technical knowledge.

There is Still Confusion Amongst Stakeholders on the “Select a Standard” Issue

- On the positive side, ELAP has indeed **moved forward vigorously with establishing a new management system** which seems to be working better than before and ELAP is partnering with ELTAC.
- But there is a perception that there has been insufficient information available about the various options for accreditation standards, even what an accreditation standard might constitute. **There is still a great deal of confusion as to what the possible options are.**

Perception Amongst Many Stakeholders (smaller labs) that TNI is the Preferred Direction

- There is still a lot of concern within the lab community (mainly from smaller labs who represent a majority of the CA lab community) that ELAP is focused on TNI and **TNI is particularly challenging for them.**
- ELAP is asking ELTAC for discussion of lab accreditation standards, but **really needs to convey what the regulators want** to allow ELTAC to be realistic.
- ELAP's recent **establishment of a regulatory advisory body should clarify this issue.**

Other Issues of Concern to Smaller Labs

- Is a 2 tier system an option? (Need input from the regulatory community)
- Did ELAP really do a thorough gap analysis amongst the options?
 - Sharing more details (via ELTAC?) on what has actually been done may help to alleviate concerns (or could of course open more concerns)

Management System

- Stakeholders would like more information on the internal management system to ensure that ELAP is moving towards ISO 17011 or equivalent
 - All indications are that ELAP is indeed moving forward on this front.
 - ELAP has referred to SOPs, **but a simple list of those that are in place (and in process) might increase the confidence** in the management system improvements.

Communications

- Communication has improved, but there are still a lot of stakeholders (especially those who do not operate labs directly such as utility managers) who are not sufficiently aware of activity. ELAP should not rely solely on ELTAC to get that information out.
 - Recommend **more frequent LYRIS communications.**
 - Verify that LYRIS listserve on ELAP issues is reaching the intended audience (**opt-out instead of opt-in?**)

Conclusions from SAC Perspective

- ELTAC is a much more vigorous entity than at any time in the past. 
- ELAP needs to build internal technical expertise, and has started down that path. 
- The discussion of standards is fraught with challenges, and fees may be similarly difficult. ELAP needs to make the options clear. 
- Communications to the community have improved but there are ways to make it better. 