COMMENTS ON ERP REPORT

STAKEHOLDER ADVISORY COMMITTEE (SAC) PERSPECTIVE

Disclaimer (per Usual)

➢ **While I have solicited input from the rest of the SAC, ultimately the remarks are my own.**

Relevant Statistics

> ➢ **About 48% of the certified labs are commercial and about 50% are non commercial (public agencies, etc).**
>
> > ▪ **Any final standards must therefore respond to the needs of both types of labs.**
>
> ➢ **The more important statistic in terms of setting a standard is the number of FOTs by lab type.**
>
> > ▪ **This would likely show a much greater preponderance of commercial labs in CA.**

In General the Recommendations Are What We Expected

➢ **ELAP had a lot of problems, many self generated**

➢ **There is a new sheriff in town and there are opportunities for improvement.**

- ▪ **Establish a viable management system**
- ▪ **Adopt a standard**
- ▪ **Ensure updated methods**
- ▪ **Expand resources**
- ▪ **Enhance communication**

The Biggest Caveat to the Recommendations

➢ **ELAP's regulations are outdated and until there are new regs, it will be a challenge for ELAP to truly embrace change.**

➢ **We recommend that the report focus a bit more on the challenge of regulations in general.**

- **How will ELAP get buy in to the recommendations without new regulations?**

Management System (3.1)

➢ **The report is good in identifying a number of specific areas for improvement, and providing specific approaches that ELAP could adopt quickly.**

- ■ **Internal adoption of the TNI or ISO standard for accreditation bodies gives ELAP a roadmap for a solid internal management plan that is consistent with accreditation services.**

- ■ **It also gives ELAP a way to draw on numerous resources outside of CA for help, rather than learning on it's own**

Management System (3.1.2)

➢ **Pointing out the deficiencies in ELAP's internal protocols with specifics (document control, record keeping, an internal quality system, better PT review, enforcement, and complaints) offers another roadmap.**

➢ **We agree that 1 PT per year is adequate, especially since ELAP is only now establishing a system for timely review of existing PTs.**

Management System (3.1.2)

➤ **We agree that the GENERAL goal of enforcement should be progressive compliance.**

   ■ **Having said that, there ARE labs who are unlikely to respond to progressive guidance.**

   ■ **ELAP has indicated they are focused on enforcement.**

➤ **We agree that there is a strong need for a complaint process.   ELAP is moving in that direction, but there is no guidance on the website for how to submit complaints.   We suggest the panel recommend such transparency.**

Internal Review (3.1.2.2)

- ➢ **We applaud the emphasis on ELAP establishing internal procedures similar to what should be expected of certified labs**
  - ▪ **Internal audits**
  - ▪ **Periodic program review**

- ➢ **The panel should ideally determine whether ELAP has staff capable of conducting such reviews.**

Establishment of Lab Standards (3.2)

> **There are certainly differences of opinion within the SAC on this question. The ERP should provide additional guidance in the final version of the report to assuage the concerns of the smaller labs that the TNI standard, which is essentially what the ERP is suggesting for expediency, is unworkable for smaller labs.**

- **While the webinar helped, the recommendation for an ongoing training program on this is critical for acceptance if ELAP does move this way.**

- **It would be useful if the panel pointed ELAP towards specific resources for this.**

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Ensure Relevant Methods (3.3)

➢ **We like it that the ERP has pointed out HOW ELAP can accept current analytical methods.**

- ■ **Caveat: As noted by the ERP, ELAP auditors may not have the capability to evaluate newer methods. Again it's a matter of internal training… or external auditors.**

- ■ **It is important to note that methods must be consistent with federal regulations if applicable.**

➢ **The line in the regs about performance based methods is likely not relevant (it was put into the regs in the era when PBMS was in vogue).**

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Expand Resources (3.4)

➢ **This is certainly the most controversial for many labs, as ELAP's fees are already amongst the highest in the nation.**

▪ **We are in agreement that ELAP should separate licensing fees from accreditation fees.**

▪ **We would like to see the ERP weigh in with specific recommendations in response to some of what ELAP is currently surveying labs about.**

▪ **We would also like to see the ERP weigh in on the issue of the overall budget for ELAP.**

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Enhance Communication (3.5)

➢ **We again applaud the specific suggestions on ELAP actions as far as communication. As we noted in our earlier presentation, ELAP has made a start but needs to be much more effective.**

➢ **We agree with the recommendations re ELTAC, but want to remind the committee that ELAP should be sure they also focus on the lab community as a whole.**

➢ **Given ELAP's performance problems in the past, and the fact that ELAP will be asking labs to implement it, we think the development of internal auditing functions should be expedited.**

Adopt Accreditation Standards For Labs (4.2)

➢ **We think a 1 year timeline is likely unworkable, given that it would require new regulations. We believe the ERP may want to discuss with State legal staff the feasibility of doing this.**

➢ **It is also clear that it would require a lot of education and training of non TNI labs to new standards, and that means that the new standard can't really come into place until 18 months to 2 years from now, even if ELAP could move rapidly.**

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- ➢ **We are in agreement with the timelines for these activities; there is no need for delays and they are easy to modify.**

- ➢ **You already heard our concerns about what has gone on with ELTAC over the last 6 months.   We hope we are now over the hump on that with ELAP's decision to temporarily use the SAC has a surrogate ELTAC**

Accept Other Accreditations (4.4)

➢ **We strongly support allowing this option, but it still boils down to what the standard is and how ELAP legally can accept it.**

➢ **Ultimately this is an issue that also has a lot of budget implications (licensing vs accreditation).**

➢ **If this is considered legal, there is no reason not to allow it going forward; it would not require a 3 year time frame.   If it is of questionable legality, that is an entirely different time frame.**

Establish Enforcement Mechanisms (4.5) and Accept Newer Methods (4.6)

➢ **We agree that the timeline for enforcement mechanisms really depends on the status of regulations. You can't enforce without regs.**

➢ **We don't think it should take any significant amount of time for ELAP to start accepting current analytical methods, given that ERP has proposed a road map to accomplish it.**

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Improve PT Program Enforcement (4.7)

- ➢ **While we agree strongly that this would help ELAP in evaluation, we think the overall ELAP budget issues may extend the timeline.**

- ➢ **It is worth pointing out that ALL of the PT providers (to the best of our knowledge) can send the state an Exception report already, which does offer a software solution to greatly facilitate review.   That kind of software solution would take almost no time to implement.**

ELAP Fee Structure (4.8)

➢ **Round one of this is already in place, and we recognize that there is little choice in the need for changes, whether we feel they are service justified or not.**

➢ **We also agree that it will likely take a year or more to implement a new truly equitable fee structure and it will require a lot of EARLY community involvement.**

Any Questions?

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