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The Overhaul of California ELAP: The Laboratory/ELTAC Perspective



- Level playing field
- Quality systems based approach in all labs to improve the odds of defensible data
- Good communication of changes in the program so I can respond
- Responsiveness from the program to my needs

Historical Issues That Were Vexing to the Lab Community



THE OLD ELAP

- Inconsistent evaluations
- Opinions instead of standards
- No consistent review of PTs
- No timeliness in response (or in audits)
- No communication of program changes
- Etc....



- Environmental Laboratory Technical Advisory Committee (ELTAC)
- The ERP recommended reinvigorating this entity, which had actually existed for a number of years but was at cross purposes with ELAP.
- ELAP wanted to use ELTAC as a resource to help re-invent and improve the program.





A mix of commercial, public health, municipal and state agency (non voting) representatives

Selected by ELAP to represent various industry sectors, but <u>also tasked with trying to put aside</u> <u>inherent biases</u> and support ELAP

Voting and non-voting members

Current ELTAC Voting Members are Diverse



Name	category	representing	
Mindy Boele	muni	CWEA-small	
Jill Brodt	commercial	small	
Stephen Clark	commercial	bioassay	
Ronald Coss	muni	CWEA-large	
Huy Do	muni	CASA-large	
Andy Eaton-Chair	commercial	multistate	
Miriam Ghabour	muni	large	
Bruce Godfrey	commercial	ACIL- large & small	
Anthony Gonzales	public health	public health	
Rich Gossett	commercial	small specialty	
David Kimbrough	muni	medium	
Mark Koekemoer	muni	small	
Allison Mackenzie	commercial	medium	

ELTAC Was REALLY Busy In the First 18 Months



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- Lab Accreditation Standard Controversial to say the least...
- Proficiency Testing Evaluation Approach ELTAC generally speaks with one mind
- Fields of Testing Worksheets for CA lots of input and some consensus
- Adding new methods for compliance (CA) consensus on approach
- Fee structure punted to stakeholder group



- Check Lists In our bailiwick, then out of our bailiwick
- Enforcement approach also controversial
- Communications approaches consensus on recommendations
- CA DLRs just weighing in directly on that subject now that CA is considering a lower RL for CIO4
- Implementation of the Standard and New Regulations

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- Discussions on this took the better part of a year and there was no consensus.
 - Small lab issues were the greatest area of concern (CA has a LOT of small labs)
 - Smaller muni labs concerned with the large number of requirements.
 - Many wanted something simpler.
 - Even some commercial labs (non TNI) were worried.
- Ultimately the State Agency Partners called the shots with the State Board. Essentially TNI2016.



- Historically ELAP did minimal tracking of PTs.
 - So if a lab didn't participate there was no penalty...
 - But also for methods like VOAs, they did not evaluate individual analytes on their own, but relied on 80% of ALL analytes to "pass".
 - This was a problem for labs that only do short lists like BTEX.
- ELTAC strongly recommended evaluation by analyte (duh...).
- But there are still issues with determining availability of PT samples for some analytes.



- The former FOT set up in CA was not very lab friendly for applications and also not all inclusive of allowable methods
- ELAP asked for ELTAC to come up with alternative models to make it more logical.
- ELAP embraced the changes, but ...
 - The MUR (whenever...) complicates it
 - It overlaps extensively with fee issues.
 - We are now moving towards FOAs (analytes) and not worrying about FOTs per se.

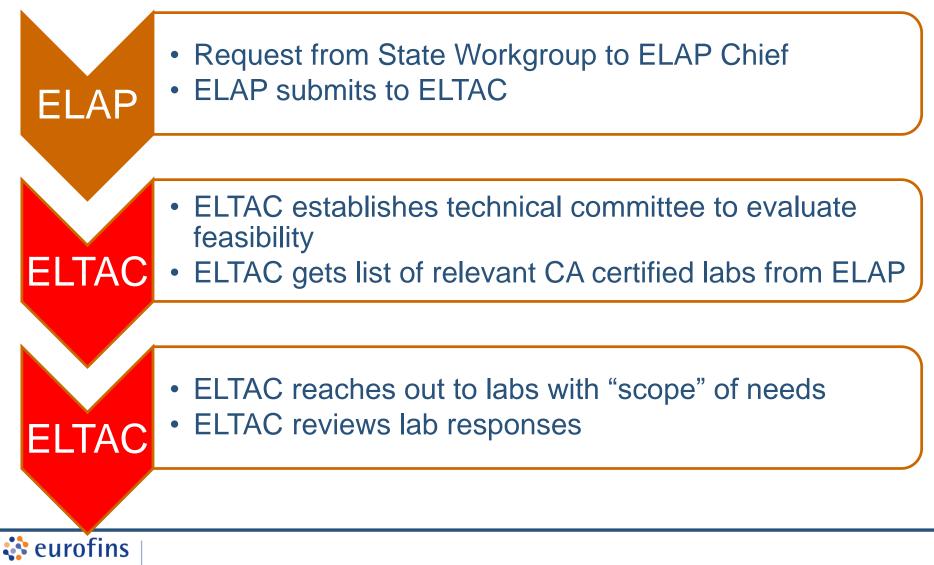
Adding New Methods or Lowering Reporting Limits



- ELTAC developed a "Proposed Framework for State Agency Requests to ELAP for New Analytical Methods and Lowered Reporting Limits"
 - More interagency cooperation encouraged
 - Multi-step process (see next slides) designed to ensure that methods are validated and reporting limits are achievable.
 - ELTAC as a technical resource is the backstop of the process
 - This is ultimately a critical role for ELTAC.

Flow Chart for New Methods Process

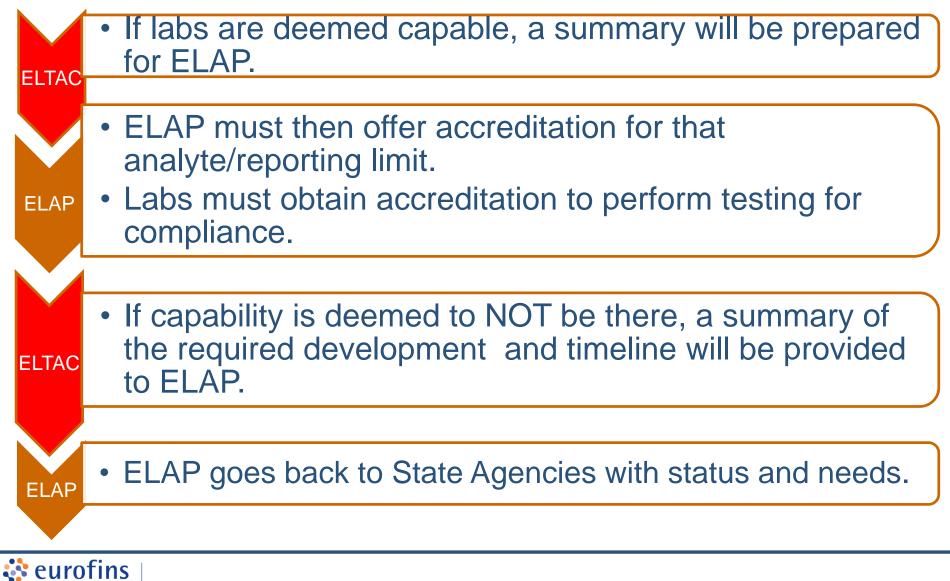




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Flow Chart for New Methods Process (Continued)







- It was originally envisioned that ELTAC would be the primary resource for discussion of fee structures.
- But instead ELTAC members are participants in a broader stakeholder group.
- Work in process, but things are moving fast.
- ELAP Fees have gone up significantly in past two years to account for budget shortfalls, so the plan now is to have a sustainable fair fee structure.

Historical Issues That Were Vexing to the Lab Community



- **THE NEW ELAP**
 - Inconsistent evaluations
 - **Training contract implemented to train auditors**
 - Opinions instead of standards
 - Training contract implemented; there is a standard
 - No consistent review of PTs
 - ELAP is still learning...
 - No timeliness in response (or in audits)
 - Anecdotally this is still a bit problematic
 - No communication of program changes
 - Improved, but more is always needed.

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- ELAP does not have in-house capability for assessing any mass spec methods.
- This will lead to requirements for 3rd party assessments for as many as half the labs in CA.
- ELTAC weighing in on criteria for approving 3rd parties to:
 - Make it easier for smaller labs to have a choice
 - Ensure that TNI/ISO/DOD labs don't need an additional assessment

Any Questions?





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