

William Ray

William Ray Consulting, LLC

# LESSONS FROM THE CALIFORNIA EXPERIENCE

Lessons for all from the California Experience

**YOU MAY NOT BE IN  
CALIFORNIA, BUT...**

# Issues likely due to

- ⦿ A lack process oversight
- ⦿ Use of standards outside regulations
- ⦿ Assessing to improve the quality system
- ⦿ Other factors such as hiring rules, travel restrictions, and budget shortfalls

Process oversight

**YOU'RE NOT THE BOSS  
OF ME**

# Assessor Independence

- Each assessor was responsible for all facets of the process for each laboratory they took on
- The assessor set the tone of the audit including what were the standards
- The assessor made the final determination of whether to grant accreditation with no management oversight

# As a Result

- Inconsistent assessments
- Assessors would fail to conduct parts of the assessment such as exit interviews
- Assessors failed to look at or would gloss over PT failures including failures to participate
- Assessors would “deny” based on their personal assessment of problems
- Management simply signed accreditations

A question of legality

**BADGES, WE DON'T  
NEED BADGES**

# ELAP and Its Law

- ⦿ Assessment standards include elements from references not in regulations
- ⦿ Did not offer accreditation for methods required by State law but not by Federal law
- ⦿ Has “approved/disapproved” methods



# As a Result

- ⦿ The State is not in a position to take adverse action
- ⦿ Some laboratories have operated without accreditation contrary to State law
- ⦿ Some labs have had to give up methods for which they were otherwise entitled to
- ⦿ Some “adverse actions” not conducted by required process

Assessing vs. Consulting

**THIS WILL IMPROVE  
QUALITY**

# Assessment Findings

- Findings sometimes based on necessity to improve data quality or “legal defensibility”
- Some express a mission to protect human health
- Findings tend to be more than an assessment of compliance

# As a Result

- ⦿ Personal opinion as to how things should be done become findings
- ⦿ Required unnecessary or useless actions
- ⦿ Would disagree with other assessor's findings

Contribution by California Laboratories

I GO ALONG SO THAT WE  
CAN GET ALONG

# CA Laboratories Have Helped

- Did not understand their legal obligations and rights
- Went along with any demand no matter how nonsensical
- Although discussed issues among themselves, did not bring the issues forward

Take away from the California Experience

**COULD IT HAPPEN  
HERE??**

# These could be your issues too

- ⦿ Is there an oversight or review process?
- ⦿ Is the program visible and all standards available?
- ⦿ Is the program operating within its legal bounds?
- ⦿ Do Assessors tend to act more as consultants than “eyes and ears”?



Bill Ray  
William Ray Consulting, LLC

[bill\\_ray@williamrayllc.com](mailto:bill_ray@williamrayllc.com)  
[www.williamrayllc.com](http://www.williamrayllc.com)  
(925) 300-3350