

Environmental Laboratory Technical Advisory Committee

December 12, 2008

10:00 AM to 3:00 PM

ELTAC Members in Richmond: Ken Osborn, Dave Sandusky, Al Verstuyft, Pamela Schemmer for Scott Hoatson.

ELTAC Members video via conference: Andy Eaton, Socorro Baldonado for Betsy Shepherd; Betsy Shepherd.

ELTAC Member by phone Tony Pirondini, Mark Banuelos, Gerry Guibert, Terry Powers

DPH Members in Richmond: Gary Yamamoto, George Kulasingam, Jane Jensen, Fred Choske

Guests:

In Richmond: Bill Ray SWRCB

DPH Members by phone: Dave Spath, Cathy Ewing, Steve Book

Not present: Miriam Cardenas, Robert Bolton, Steve Meyer,

1. Welcome (10:11 AM) quorum is 7 (Ken, Dave, Al, Andy, Tony, Mark, Gerry; Betsy joined after vote)
2. Minutes – cannot approve minutes without quorum. Chair calls for changes or discussion. Other than misspelled names no changes.
3. Announcement, Current Vacancies in ELAP
 - a. Vacancies – six positions open three supervisors one south (replace Spinner) and two north. ELAP has tentatively offered positions to likely successful candidates. Further processing including funding and a “needs assessment” can take two to three months in Sacramento. Other vacancies (3-4) need posting. Another staff position is open.
 - b. Rufus has been appointed as Director, and Gary is now the Division Chief.
 - c. Nomination of Pamela Schemmer for Scott Hoatson and Socorro Baldonado for Betsy Shepherd as replacements. Move (Eaton) open for nomination second (Pirondini). Eaton nominated Pam/Dave seconds. 7-Y; Eaton nominates Socorro/Dave seconds. Nominations will be forwarded to Director of Public Health through Gary Yamamoto. Pam and Socorro will send contact info and CV to Ken who will forward to Gary with a request to submit the information to confirm the nominations and appoint Pamela and Socorro as members of ELTAC.
4. NELAC Updates
 - a. ELAP has received a recent review by the Accrediting Authority (AA) staff, who accompanied ELAP during an on-site audit. A corrective action (CA) report has been filed addressing issues for level of staffing, training, documentation and timely renewal.
 - b. The next implementation of TNI standards will be for 2010. It is necessary to assure there will be 12 AB by 2010 because there are changes from 2003 NELAC standard. The PT Studies program is another issue for TNI.

5. PT Updates

- a. There is no consensus on replacing the current requirement to pass two studies per year with one required study per year. J. Morgan is surveying 1000 labs on NELAC issues including PT. Andy Eaton speculated it is 50:50 whether there will be any changes.

6. Draft Regulations

- a. George Kulasingam discussed CDPH ELAP email from Shine Park on webpage update.
- b. ELAP draft regulations have been posted on the ELAP website at <http://www.cdph.ca.gov/certlic/labs/Documents/ELAPdraftregulations-12-05-2008.pdf>. Steve Book (steven.book@cdph.ca.gov) and Catherine Ewing (Catherine.ewing@cdph.ca.gov) are the designated recipients for comments from the laboratory community to ELAP. The anticipated delivery date of the regulations package to the Office of Administrative Law is June 2009 with promulgation sometime in 2010. The schedule for additional reviews by Finance and Health & Human Services is not known at this time. Ken will copy Steve, Gary, George and others on comments that he receives. Tony recommended that a statement of reasons be made available for reviewers to understand changes. Gary noted that this would delay the process but agreed it would be useful. It was noted that there is a need for an ELTAC version with tracking changes. This is the 8 revision since 2003. Who initiated the changes and why will help the reviewers. The June version had strike out and changes. This is like a published version and not the office of regs version. Ken suggests reading this as lab professionals and a first comment without a statement of reason. Tony was interested in the legal focus of document. Document went from environmental to environmental, clinical and food. Need to understand the legal influence; Cathy Ewing (legal) explained role in terms of Office of Regulations and Administrative Law. Tony noted that it appears that the scope has expanded with concurrence from Cathy. There has been input in the past from clinical labs. The current version is ONLY environmental labs. Steve Book noted that we need to focus on this version. Ken will send a link to ELTAC members.
- c. Gerry stated that on page 32, the regulatory reporting requirement is ambiguous: the 24 hour reporting requirement for some analytes does not specify when the clock starts. Responsibility is also not clear when the work has been conducted by a sub-contract laboratory. It was noted that the primary laboratory cannot pass the responsibility to the sub-contract laboratory: the primary lab has the responsibility (Ken and Andy) and for small laboratories there is an onus is on the system operator who may not always be fully trained on the protocols (Tony). Notification can be e-mail, voice or hardcopy. Some discussion of liabilities without a consensus or closure. The current language is from the perchlorate review. How is the drinking water process reviewed, what is the intent and what is the practice? Reporting to the client with a sense of urgency.

Language such as approve or certified data. FL regs is lab director or designee has certified. Positive bacteriological results were in the system without notification. If there is a perceived delay of results, then people will complain (Gary). There could be an expectation that the result should be reported before review. The official reporting should start the clock. Bacteriological tests (coliform) is clearer than chemical (nitrate, perchlorate, etc.). Confirmed is bacteriological whereas validated has a different connotation than final result (Betsy and Andy) etc. Mark says the reality is different between coliform versus chemical tests. Andy point needs to align lab with drinking water regs. Steve indicates this initiates another sampling event and immediacy. Nitrate presence was equated to DBCP situation. When does the clock start, when the sample is approved. Compliance with Fed regs and others (Cathy will review notification requirements in other regs.; restatement of time is not clear in drinking water regs. Mere reference is insufficient(Steve agrees).) If only a few labs do perchlorates then they would/should know reporting requirements. Knowing the reportable perchlorates is an issue for third party lab relationship. Steve discussed difference between reporting to lab and system. Differences between DDWEM regs versus of reg systems.(Eaton). Data receipt is another issue. Total coliform rule req an additional/repeat sample. Andy cited 40 CFR 141 on notification for 24 hours that it is water system and not the lab. Do not want to let lab sit on results. Regs could be redrafted to start the clock. Consistency with Fed regs. Need to define reviewed and approved in SOP or other document as left to the labs. The broad application to all labs may be a challenge. Drinking water cert manual is not helpful as it requires "promptly notify" (1200 noon)

- d. NELAC standards compliance in 2010 will be TNI standards and the draft regulations will be out of date; a placeholder was put into draft(Cathy and Steve). Statute limits State to NELAC. Article 11 refers to NELAC (refer to A. Eaton, who is effected). Article 11 is irrelevant in 2010. Need to change(amendment) statute before changing regulation. Cathy is aware of NELAC standard and change to TNI. Data integrity training does not reference NELAC, whereas Article 12 specifically references EPA Pub #. Cannot easily incorporate 2010 standards. Use language about "subsequent revisions" in the amended statute that might pass legislative counsel office. Do not reference standard in document. There was discussion on how to try to resolve the language. What the program has to adopt by regulation is not clear(Cathy and Jane). EPA provided the original guidance of citing or publishing the reference no. EPA has allowed privatization of accreditation. State is not required by Federal government to provide accreditation. There is not a great deal required by EPA for the State to accredit laboratories(Cathy); the requirement is from administrative law.

- e. Article 7d (p. 25) appears to require SOP with detail (Article 4 only requires list of SOPs). This is open to interpretation. 7d could be a subset of 4. Rewrite 7d to separate lab needs from lawyers needs.
7. ELAP Budget Issues - Budget authority may increase in 2009. There is another set of regs to increase fees to fund sufficient staff. There is a large backlog of reviews, field audits etc that cannot be completed with existing staff. We need to defer on inspections and renewals. Since this is a fee supported program, an increase may be necessary. Existing fees are currently not effected because of reserve. Eaton stated more review than less is needed. There will be a special increase for 2009/2010. The division burden will increase and programs will be in the red. A real hiring freeze may occur. Exemptions are not an easy process. ELAB process could face a small decrease in spending authority/budget.
8. Method Specific Checklists – The State of Florida website was offered as an example of a format that was well organized and readable. It was noted that audit checklists are posted on the Florida website, although it was not recommended that these specific checklists be posted to the ELAP website. Ken strongly encouraged the posting of auditing checklists and was asked by Gary to describe the objectives of posting the checklists. Ken noted that the checklists were the product of an ELTAC appointed sub-committee and that their utility was in providing the environmental laboratory community a mechanism for conducting internal audits, a common set of standards as a means of “focusing” internal QC reviews, and a tool in preparing for audits from ELAP and other external auditing authorities. Ken noted that as a subcommittee report, there was no liability to ELAP if they were posted as a report to ELAP from ELTAC. Scott Hoatson had recommended that the checklists could be posted directly to the ELAP website with qualifier language such as “method audit checklists accessible via this site are posted for informational purposes only. They have not been reviewed or endorsed by ELAP management and thus do not represent an official statement of ELAPs views or policy. Posting these materials does not indicate ELAP adoption or endorsement of the information contained therein.”

It was moved (Al) and seconded (Gary) that a checklist sub-committee report to ELAP is posted on the ELTAC pages of the ELAP website. Ken will forward a sub-committee report to Steven Book for posting. The report will include a discussion of the purposes of the checklists.

9. PT Acceptance Criteria - Where your PT Acceptance criteria are different the lab method criteria 314.0 limits are 85-115%, whereas we got 110% and failed because average was 95% +/- 14% based on regression equation. How is the staff instructed to write SOP and perform the method? Further, how does this affect instrumentation selection. There are two instruments available with 95% and 100% accuracy. Jane mentions there is a dichotomy between QC and PT. PT bias process determination is a problem. The mean is not an accepted reference value. The method provides the min, whereas lab should establish own limits with LCS and QC materials. Lab establishes limits on instruments and

performance. PT reporting process in NELAC requires more specificity on methods. This was discussed at NELAC (TNI PT board) a few years ago with different vendor response. Divide metal sample prep and not be analytical technique was approach used in previous governmental studies. WS limits are hard and firm in EPA-ODW. A 10-30% failure rate is expected.

There was a recommendation to report a verified recommended value. A gravimetric or reference value should be reported. An assigned value is what is put in the sample, ie metals. Where sample stability is an issue that is a mean (accepted reference value) such as BOD. Studies can be invalidated by accrediting authority based on their review. Data pooling at instrument specific levels is challenging. Poor methods are used. A2LA is monitoring vendors who provide vendor oversight.

10. Next Meeting – April 15 or 17, 2009 S. Park will be retiring. She built the website. Shinae Park is recognized by her contributions to the ELAP program.

Action Items

1. Pam and Socorro need to send contact info and CV to Ken.
2. Ken will copy Steve, Gary, George and others on comments.
3. Ken will send a link and an e-mail to serve as new members distribution list
4. ELTAC comments by 31 January
- 5.