

Environmental Laboratory Technical Advisory Committee

December 12, 2008

10:19 AM to 2:00 PM

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

ELTAC Members video via conference A. Eaton, for B. Shepherd S. Baldonado; B. Shepherd.

ELTAC Member by phone T. Pirondini, M. Banuelos, G. Guibert(AM), T. Powers (PM)

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

Guests:

In Richmond: B. Ray SWRCB

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

Not present: M. Cardenas, R. Bolton, S. 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
 - a. Vacancies – six positions open three supervisors one south (replace Spinner) and two north. We have tentatively offered positions to likely successful candidates. Need screening and clearing that can take two to three months processing in Sacramento. Funding and need must be reviewed and determined. Other vacancies (3-4) need posting. Another staff position is open. George repeated for teleconference colleagues.
 - b. Rufus appointment as director, then Gary as acting division.
 - c. Nomination of P. Schemmer for S. Hoatson and S. Baldonado for B. Shepherd as replacements. Move (Eaton) open for nomination second (Pirondini). Eaton nominates Pam/Dave seconds. 7-Y; Eaton nominates Socorro/Dave seconds. Nominations to director of public health. Pam and Socorro need to send contact info and CV to Ken.
4. NELAC Updates
 - a. Accrediting Authority (AA) review of ELAP was conducted. Two accompanied staff for on-site visit. Corrective action (CA) report filed (level of staffing, training, documentation and timely renewal were issues; address previous CA). AA has responded with request for additional information. Accrediting Body. TNI standards will be for 2010. Need to assure there will be 13 AB by 2010 because there are new changes from 2003 NELAC standard. PT is another issue for TNI. There is a lot of work for full TNI compliance.
5. PT Updates
 - a. Status of one time versus two times remains open. J. Morgan is surveying 1000 labs on NELAC issues including PT. A. Eaton was speculating it is 50:50 whether there is a change from one to two.
6. Draft Regulations
 - a. G. Kulasingam discusses CDPH ELAP email from Shine Park on webpage update.
 - b. ELAP draft regs are posted. Steve Book is point with attorney. Dave Spath has helped on regs. Intent is to move reg forward with a statement of reason. Tentative date for reg package is June 2009 to office of regs with promulgation 2010. Two divisions in CDPH this is half the reg packages. Steve does not have

Dave Kimbrough and Bill Ray's comments. Reviews outside the department like Finance and Health & Human Services adds to the time. Ken will copy Steve, Gary, George and others on comments. Tony recommends the need to have statement of reasons for reviewers to understand changes. Gary does not want to spend time without changes. Need an ELTAC version with tracking changes. This is the 8 revision since 2003. Who initiated the changes and why will help the reviewers. 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 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 Regs and Administrative Law. Appears the scope has expanded according to Tony and this is probably true (Cathy). Cathy tried to look with fresh perspective. There has been input in the past from clinical labs. The current version is ONLY environmental labs. Steve Book points out we need to focus on this version. Ken will send a link.

- c. P. 32 Gerry points out the regulatory reporting requirement (define 24 hours from what (implies analysis but you want review) and by whom; 24 hr from presumptive/confirmed result), ie. Perchlorates, nitrates and bacteriological sent to third party lab reported out by whom. Utility has to provide contract lab info. Notification can be e-mail, voice or hardcopy. Primary lab has responsibility (Ken and Andy) and the onus is on the system operator (Tony). There are liabilities discussions. 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 – FL website is good for format. The ELAP checklists are good for consistency. Labs should be able to go to ELAP website. Checklists are guidelines and not regulation. Checklists could be on ELTAC website where they are guidance. Scott Hoatson’s suggest “method audit checklist 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.”

Gary ELTAC is an advisory committee, however, it is only ELABs website. It must be approved by division and department. Gerry notes ELTAC posts minutes. Could guidelines be posted in minutes. Purpose of checklist is for labs to use for internal audits and use for common talking points. ELTAC cannot have website separate and apart from website. Separate websites within other websites. Committee report on checklists would be another alternative for publishing. Another approach is George as ELAP Manager recommend these to Gary to be approved by the Division. Move(AI) to committee report on checklists second (Gary). George wants clarification of use. Ken recommends these as guidelines to standardize and improve environmental lab practice.Y-8/N-0

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