

**Clinical Laboratory Technology Advisory Committee**  
Minutes of the June 25, 2010 meeting

Meeting held by videoconference from the Richmond Campus, CDPH  
KP Regional Laboratory, North Hollywood and  
By Telephone Bridge

CLTAC Members Participating: Laurie Armour, Michael Borok, Anthony Butch, Elizabeth Dequinia, Vicki Finson, Tim Hamill, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Les Revier, Fred Ung, Lorri Dean Yoakum, Mary York.

Former CLTAC Members Participating: Morton Field, Imre Fischer, Robert Footlik, Sol Notrica, Jim Ottosen.

DPH Staff Participating: Zahwa Amad, Kathleen Billingsley, Maria DeSousa, Robert Hunter, Nema Lintag, Howard Manipis, Don Miyamoto, Karen Nickel, Bea OKeefe, Jan Otey, Judy Schlosser, Genie Tang, Tom Tempske, Robert Thomas, Kathy Williams.

Public Participating at Richmond, North Hollywood and on telephone bridge.

Welcome, General Announcements: Chairman Tim Hamill opened the meeting, assured the North Hollywood video site and telephone bridge were functioning, welcomed participants and thanked KP for providing the videoconference site in southern California.

Roll Call of CLTAC Members and Introduction of Participants: Dr. Hamill initiated a roll call of CLTAC members and participants in Richmond, North Hollywood and on the telephone bridge. He asked that the telephone bridge mute their phones until the line is opened for discussion.

Approval of March 26, 2010 Minutes: Several changes for made to the minutes as prepared for the meeting. Salim Rafidi moved that the amended minutes be approved, Donna Kirven seconded and the CLTAC approved the minutes as amended. Mary York asked that a copy of the amended minutes be emailed to the CLTAC. Bea OKeefe said this would be done.

Nomination and Election of CLTAC Chair: Dr. Hamill opened the floor to any nominations for CLTAC Chair. Hearing none, the nominations were closed. The only nominee, Dr. Tim Hamill, was elected by consensus of the CLTAC and will officially continue his position in January 2011. Dr. Hamill thanked the CLTAC for their confidence in him.

Department News: Ms Kathleen Billingsley, Deputy Director of the Center for Health Care Quality, DPH, apologized for not attending the meeting. She said she had met recently with Bea OKeefe and Robert Thomas, and appreciated the update from them.

Ms Billingsley said she wanted to tell what's happening in Sacramento. She said this is a challenging time for the administration with no budget likely on July 1 again. Dr. Horton, Department Chief, is keeping everyone informed, as possible. First, as the furloughs end, there is concern they may be continued. Another disturbing news item said with no budget, state salaries may default to the federal minimum wage in July, as proposed in the past. The State Controller is protesting this and Ms Billingsley does not think this will happen. Also proposed is a short time 15% salary reduction, permanent 5% salary reduction, 1 day unpaid leave, 5% increase to retirement contribution. There are 1500 employees in the Center, all impacted. LFS managers are working to keep morale up. Second, this is a busy time of year with legislation and those challenges.

*Question:* Tim Hamill asked if the governor could take LFS' license fee revenue. Ms Billingsley said this was a concern, but he would probably take from other, larger fund, but she has not heard of any sweep.

*Question:* Tim Hamill said that LFS was supported by license fees, so a salary reduction should not impact LFS staff, only those from general fund. Ms Billingsley said bargaining units negotiate exemption for special groups, as firemen and police.

*Question:* Michael Borok asked when LFS will know if furloughs shall continue. Ms Billingsley said she thought the first week of July.

*Question:* Robert Footlik said LFS staff provides necessary public service and how can the state retain and recruit quality employees if the salaries are reduced further? Ms Billingsley said this was difficult and impacts current employees who don't feel valued. LFS is looking at compensation and the current cuts impact recruitment.

*Question:* Michael Borok said LFS is supposed to get new positions with the new budget. LFS currently only has 3 inspectors for the whole state. Maybe LFS should offer higher salaries for fewer slots. Ms Billingsley said the salary ranges for positions are fixed and can be adjusted easily. LFS is working to increase salary ranges. Bea OKeefe said the minimum requirements for the Examiner series are too tough and hard to fill. She would like to establish an entry level position for Examiners that would ease recruitment.

News and Update on LFS: Bea OKeefe thanked everyone for coming and said, after 9 months as Acting Chief and now a few months of Chief, she finds the job daunting and appreciates everyone's support.

SB 744 positions: LFS was authorized 35.5 new positions under budget authority starting this July or whenever the budget is approved. LFS has advertised the new openings for Examiner positions and has had some applicants. An Examiner written examination will be offered in July and encouraged everyone to consider applying. LFS currently has a large vacancy rate.

BSA audit report: The BSA audit required a 3-year followup for LFS' being cited for failure to perform all legislative mandates. LFS is struggling to conform and provide written documentation as required. Ms Okeefe is hoping that new staff hired after July 2010 will relieve pressure of staff shortages and difficulty in responding to BSA audit recommendations.

EOL: LFS is working with other licensing programs to update its licensing process. The Enterprise Online Licensing system is initially done and now LFS must review each of its licensing applications for data inconsistencies. This is called "data cleansing" and must be done on at least 18 data bases maintained by LFS, besides the HALS mainframe. The new system is supposed to be up in 2014 and LFS has 1 year to get this done.

Furlough impact: LFS has a backlog of applications for laboratories as well as laboratory personnel due to the furlough and staff shortages.

Transparency: The Governor wants any audit of a state program to be available to the public. The federal audit of the CLIA program, called the SAPR, will be posted and the BSA audit was available on the internet.

Bob Thomas' retirement: After 22 years at LFS, Bob Thomas is retiring. His leadership in the personnel licensing section will be sorely missed. He has been involved with the Hospital Council, received the Sustained Superior Performance Reward for CDPH, has worked with our contractor to have online applications and fee payment for lab personnel (first in CDPH). Ms OKeefe hopes that EOL will be as good. She said Bob hopes to come back as a retired annuitant after the end of the year.

#### Legislation impacting clinical laboratories

AB 549 (Furitani) Bob Thomas said this bill was amended again on June 17 and impacts licensure standards for doctoral scientists. It adds a new category, biochemical genetics, would change mandated licensing timelines and period of eligibility to take an examination. It would require LFS to issue temporary licenses or denials 30 days after application. It would also require LFS to accept self attestation of training or experience without documentation.

Question: Tim Hamill said trainee licenses were appropriate for CLS', but for doctoral scientists would not want to be called trainees. Bob Thomas thought the trainee title was a placeholder in the bill, but felt regulations would be necessary to implement.

Question: Jerry Hurst asked who would write and regulations and how long that would take. Bob Thomas said he wanted to mention the personnel licensing regulations, DPH-08-001, that were underway at this time. This high priority package will make significant changes in personnel licensing standards but LFS cannot discuss them publicly until they are released for public comment, hopefully the end of this summer. There will be a 45 day comment period and possibly a second 15 day one. Bea OKeefe

said the Office of Regulations has 700+ persons that will be notified of the regulations. Tim Hamill said there is an overlap of AB 549 and DPH-08-001 with conflicting issues. Bob Footlik said many laboratory groups oppose AB 549. Bea OKeefe asked whether they had registered their opposition with the bill's author and Bob Footlik said he did not know.

Question: Jim Ottosen asked what LFS would do if the bill passes. Bob Thomas said LFS must enforce the new law. Bea OKeefe said DPH-08-001 was consistent with current law and would have to be redone. Bob Thomas said LFS understands the CLTAC concerns and must rely on the public comment period to get input. LFS cannot comment further on the regulations at this time.

Question: A public member said that out-of-state scientists cannot work in California and can they use CLIA regulations for lab director? Bob Thomas asked that he put that question in writing to LFS and it would be put on the agenda of the next meeting for discussion. Bea OKeefe urged him to read DPH-08-001 when it was available, and make comments if warranted.

Question: Michael Borok said DPH-08-001 was very long and asked that an index be given to the CLTAC to aid review. Bob Thomas said he would look into that. (Note, LFS found out later from the Office of Regulations that an index could not be given to the CLTAC as this would be perceived as preferential information not available to the general public.)

AB 2541: Kathy Williams said federal Ryan White funding for HIV treatment requires every state to comply with electronic reporting of HIV results. Two years ago HIV by electronic reporting was added to the reportable disease list in California. So far 36,000 HIV cases have been reported nationwide by patient name.

AB 2786: Kathy Williams said this bill would authorize a health officer to add or delete diseases, specimens or organisms on the reportable list without regulations as regulations take too long to implement.

Question: Tim Hamill gave further information. He said organisms were wanted so they could be processed, tracked and monitored. Mary York questioned the need for "specimens", only organisms. Bob Footlik said Kathy Williams was right, as LA County Public Health laboratory wanted biological specimens for West Nile Virus.

SB 1246 (Negrete-McLeod): Kathy Williams said naturopathic doctors can perform waived tests and be director of a waived lab. This bill would create a "naturopathic assistant" with listed duties and would allow them to consult with other groups before adding more duties.

Question: Michael Borok asked who can get a waived CLIA certificate. Kathy Williams said CLIA lets anyone. Bea OKeefe said California state law differed from CLIA. Mr.

Krishnan asked if an unlicensed person could direct a waived lab. Bea OKeefe said not in California. He asked if a limited licensed person could direct a laboratory.

Question: Jerry Hurst asked if there was any opposition to this bill. Kathy Williams said yes and directed the CLTAC to the website (?).

Comment: Michael Borok said the CMA is opposed to this bill because naturopathic doctors are not trained in laboratory science in either residency or internship.

AB 1963 (Nava): Kathy Williams said she wanted to mention this bill which deals with pesticide poisoning. This bill would add cholinesterase testing as a reportable “disease” as required by the Department of Pesticide Regulation but CDPH would be expected to enforce this. Ms Williams is concerned that LFS has no authority to enforce this. The penalty related to this bill was dropped at the last amendment. This bill would also require CDPH to write a 3 year report on the impact to health of workers.

AB 1487 (Hill): Jan Otey said this bill would allow assisted reproduction for responsible HIV couples. AB 1397 last year was vetoed by the governor which would have adopted ASM guidelines for sperm washing for HIV positive donors.

IVD-MIA Re-visited, FDA and Congressional Action, SACGHS Task Force: Bea Okeefe said the CLTAC has reviewed this 2 years ago. LFS is following recent federal activity in this regard. In September 2006, draft guidance documents were put forward with new guidelines. Laboratories that had test systems which used an algorithm for diagnosis were exempted to allow time for compliance. The FDA considered laboratory developed tests (“home brew”) as IVD-MIA which combined multi variables to yield single result for a patient. An example is SNP analyses which use gene analyses and an algorithm of lifestyle habits for prediction of risk. In June 2008, LFS became aware of DTC genetic tests and it was determined that risk assessment was subject to state regulation, as did New York and Maryland. CLIA said this was not a clinical laboratory test. There seem to be 3 types of testing, only SNP, SNP + algorithm, or algorithm only. In June 2008, letters were sent to 13 laboratories, telling them they needed to verify their test reporting and be licensed by the state. Current 15 labs using a diagnostic algorithm are licensed. Molecular diagnostic tests are the fastest growing tests and California leads the way for other states. Ms OKeefe said that if the FDA provided regulation to this type of testing, LFS’ job would be easier, but since 2007, the FDA is silent.

UC Berkeley in May 2010 was offering DNA testing of incoming freshmen. There were questions of legality, integrity, reliability, privacy. Stanford U had a similar program, offering DNA testing for new medical students. Pathway Genomics marketed a home collection kit in Walgreens, CVS and Caremark for salivary DNA testing.

The House Committee on Energy and Commerce is questioning information on diseases being testing, counseling, how risk is established and how samples are used. The SACHGT Task Force questions affordability, information on clinical validity, ethical,

legal and social concerns, how data is interpreted, what clinical decisions are made, who pays, how the information is relayed to physicians and consumer education.

The FDA is having a public meeting on July 19-20, 2010 for input on how the FDA should oversee IVD-MIA and laboratory developed tests.

Question: Jerry Hurst asked if LFS had heard from CLIA on how to handle this type of testing. Bea OKeefe said CMS, CDC and FDA want to establish guidelines later. Jerry Hurst said this goes beyond genetic testing alone, but should focus on who is responsible for checking validation, who inspects the tests and what are the director qualifications. Ms OKeefe said the test systems are complex and difficult for LFS inspectors.

Question: Mary York asked if Ms Okeefe had seen an email about a new federal law regarding ASRs. Ms. Okeefe said she had not seen that.

Comment: Tim Hamill said the FDA meeting was only considering risk assessment.

Facility licensing section report: Acting section chief, Kathy Williams said LFS continues to receive about 80-90 new applications from waived labs and 10 applications for laboratory licensure per month. LFS has been dealing with HRSA recently on reporting enforcement actions taken on laboratory directors and personnel. This is part of the National Practitioner database and the Healthcare Integrity and Protection. This agency expects state agencies to report all actions and LFS has been given 30 days to respond and clear its backlog.

Question: Tim Hamill asked, what is the breadth of the adverse action? Kathy Williams said each state defines its own enforcement criteria. Bea OKeefe said LFS would go back to 1996 and report condition-level actions. She said lack of social security numbers prior to 2000 would be a problem. Bob Thomas said this workload was unfunded and required. Mary York asked what happens if LFS does not comply? Ms Williams said CA would be identified in the Federal Register and non-compliant.

Personnel licensing section report: Robert Thomas said LFS was working on re-doing its issuance of licenses, using pressure sealed envelopes with the licenses and certificates. He said we are working to include CPT cards with their certificates. Mr. Thomas said laboratory director oral examinations were given April 30 and June 17 with 6 of 8 candidates passing. After SB 744, the oral examination fee is now \$200. LFS is working to continue another 3 year contract for online processing of license applications as the current contract expires on June 30, 2010. The number of new CLS licenses continues to hold steady. About 70 new CLS applications per month are received and about 37 per month are issued. Kathy Williams asked why the difference is number applying and issued. Bob Thomas said 10-15% withdraws their applications because of lack of coursework and LFS has a backlog of pending approvals due to furlough time off work. Mr. Thomas said the number of CLS training programs is increasing with 13 new programs pending approval. Grant funds for training and the hospital council are

helping with this. MLT training regulations currently require a licensed person to train MLTs whereas outside CA, the instructor must “substantially meet” licensure requirements. Also, LFS has received questions about MLT supervision, whether the MLT can work in a separate room. Bob Footlik said the CLTAC committee did not want MLTs supervised like an unlicensed person. Bob Thomas said this was not clear in the regulations.

Bob Thomas said he was retiring after working for 18 years in LFS and everyone was invited to his retirement dinner.

Biologics report: Robert Hunter gave an overview of oversight of blood banks and tissue banks as authorized for LFS in Health and Safety Code. He said “biologics” includes blood and blood products. Tissue includes tissue collected, processed, stored for human transplantation. The gray area is broadening and includes placenta blood and dental pulp. Mr. Hunter demonstrated the LFS website with links to federal programs, FAQ, letters of interest and fees. LFS inspects blood banks, blood collection centers, stem cell and cord blood facilities. LFS is responsible for investigating transfusion-related incidents, plasma collection centers, coordinating with the FDA, CDC and CBER for investigations, handles complaints and reports of blood contamination.

Question: Tom Tempske asked when is an unusual pathogen in blood not reported as a reportable disease. Mr. Hunter said if the donor is not tested for that pathogen and the blood recipient becomes infected, then that is reported. Kathy Williams says that report should come directly to the state for action.

CLIA report: There was no CLIA report.

Summary of complaints received by LFS: Tom Tempske summarized the complaints received April to June, 2010. Of these, 30 are closed with one third being referred to other agencies. A tabulation of recent complaints include 13 against phlebotomy schools, 1 injury by a phlebotomist, 5 blood bank-transfusion complaints, 5 patient billing complaints, 2 fraudulent laboratory billing complaints, 1 HIPAA violation, 2 complaints about testing by unlicensed persons, 1 complaint on a pizza delivery man, 1 complaint about a dirty gynecologist office and 1 complaint about an unqualified laboratory person.

Question: Jerry Hurst asked about the HIPAA complaint. Tom Tempske said this was forwarded to the CDPH HIPAA office as it was not a CLIA or LFS issue. Kathy Williams said the Licensing and Certification follows up on HIPAA complaints, too.

New business:

Budget issues: JJerry Hurst asked how budget restrictions on travel were impacting LFS and the CLIA program? Bea OKeefe said it was handicapping LFS because travel

advances are needed and they have to be approved by the HHS Agency in Sacramento.

SB 744: Tim Hamill asked when SB 744 would start that authorized new staff for LFS. Bea Okeefe said after the state has a budget signed for 2010-11. Dr. Hamill asked about the crosswalk between federal and state laws and how this would impact approval of accrediting organizations to inspect clinical laboratories for licensure in CA after January 2011. Bea OKeefe said the crosswalk was still needed and was not completed yet, primarily due to staff pressures in LFS.

AAB exam for CLS candidates: PAMET reported that it was sponsoring a CLS certification examination offered by the AAB at Washington Hospital on August 23, 2010. This is the first time this has been done by an organization in northern California. Liz Dequinia has worked on this for PAMET.

Future items: Tim Hamill discussed the date of the December CLTAC meeting and reminded the CLTAC that September 24 was the date of the next meeting. Michael Borok asked that the CLIA update at the September meeting be presented before 10:30AM.

Meeting adjournment: Tim Hamill asked for a recommendation that the meeting be adjourned, Donna Kirven moved, Liz Dequinia seconded, and the CLTAC voted to close the meeting at 1:20PM.

The next meeting of the CLTAC is scheduled for September 24, 2010.