

Clinical Laboratory Technology Advisory Committee
Minutes of the March 26, 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, Vicki Finson, Tim Hamill, Lee Hilborne, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Michael Terry, Elizabeth Dequinia, Fred Ung, Lorri Dean Yoakum, Mary York.

Former CLTAC members participating: Vickie Bello, Imre Fischer, Robert Footlik, Solomon Notrica, Jim Ottosen.

DPH staff participating: Zahwa Amad, Alan Ankerstar, Kathleen Billingsley, Norma Barocio, Linda Bryant, Grace Byers, Maria DeSousa, Pamela Farrell, Ron Harkey, Robert Hunter, Paul Kimsey, Clay Larson, Nema Lintag, Dona Lynch, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Bea OKeefe, Jan Otey, Judy Schlosser, Genie Tang, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable.

Welcome, general announcements: Chairman Tim Hamill opened the meeting, assured the North Hollywood video site and telephone bridge were functioning, welcomed the 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.

Call for nominations for CLTAC chair: Dr. Hamill asked for nominations for the position of CLTAC chair. He said the election would be held at the June meeting and the chair would take office at the first meeting in 2011. Donna Kirven nominated Lin Kassouni, and she accepted the nomination. Liz Dequinia nominated Tim Hamill and he accepted the nomination. Lin Kassouni then withdrew as a nominee for the position. Dr. Hamill said other nominations would be accepted at the June meeting before the election, and hearing no further nominations, he closed the nominations.

Department news: Kathleen Billingsley apologized for not being able to attend in person and said the meeting appeared to have good attendance and an interesting agenda. She said there were several issues she wanted to address. First, was the problem with the furloughs and its impact on LFS. The impact has been felt in every program but especially in personnel licensing. She was unsure how the judge's ruling for Alameda County would impact state workers, if salaries would be restored, and the furlough ended. The second issue is the ongoing concern about the state budget. The Governor wants federal funding to help the state, but without a budget in July, there will

be delayed reimbursement for travel. Out-of-state travel, for example, is very restrictive and must be approved at the governor's office level. Third, the new legislative session has started and there are going to be important new bills. Ms Billingsley said she had testified on the need for criminal background checks for healthcare applicants. She said there will be a change of administration, continuing fiscal constraints impacting services and budget cuts.

Question: Michael Borok asked whether the Governor can take surplus funds from LFS in a budget emergency. Ms Billingsley said she did not know if the governor had such authority and would check, but would expect public outcry. Bea OKeefe said that SB 744 that authorized more funding for LFS stated that lab funds could only be used for laboratory oversight. Ms Billingsley said most funds that that same language.

News and update on LFS: Bea OKeefe said the last nine months as acting Chief have been exciting. She said there was some positive news. Karen Nickel worked for three years to increase LFS funding and get more positions, and the need was also noted in the BSA audit. SB 744 and the accompanying Budget Change Proposal has been approved that will allow LFS to hire 35.5 positions starting in 2010-11, but not until after the next budget is signed. LFS hopes to start recruitment for vacancies and new positions in Richmond and Los Angeles including another Examiner III in Los Angeles. Ms OKeefe said she has found it very rewarding to work for LFS and encouraged others to consider the change.

Ms OKeefe said LFS had responded on one year progress to meeting the deficiencies cited in the BSA audit. She said LFS has made tremendous progress without new staffing, but still had deficiencies and needs to document corrections, just like laboratories. The furloughs and vacancies have added to the difficulty.

Ms. OKeefe said LFS was working with other programs in DPH to develop online licensing and renewals to replace its antiquated HALS system. The new system is called "EOL". When initiated, hopefully in 2014, there will be online applications, renewals and fee payments, and all new forms. Ms OKeefe said the contract with CPS in Sacramento which processes online personnel license applications, ends June 30 and Bob Thomas was working hard to renew that contract until EOL is going.

Bea OKeefe said the furlough had a cumulative effect on LFS since the checks are cashiered in Sacramento. The delay in processing checks there further delayed LFS' ability to provide timely service with the furloughs. This particularly impacted phlebotomists.

Question: Mary York asked if the 35 new positions included a raise in salary. She said LFS would not fill the new positions without raises. Bea OKeefe said LFS was working on that.

Question: Michael Borok asked what types of positions were included in the 35. He asked that this information be posted on the LFS website. Ms OKeefe said that was a good idea and would work on that.

Question: An unidentified public participant asked about molecular biologist scientist licensure. Bob Thomas got his phone number and will call him after the meeting.

Legislation impacting clinical laboratories:

AB 549 (Furatani). Bob Thomas said this bill was introduced in 2009 and held over to this year. It deals with licensure of doctoral level genetic scientists. This bill may be waiting for DPH regulations (DPH-08-001) which cover the same issues.

AB 2786 (Committee on Health). Bea OKeefe reported for Kathy Williams. She said this bill would extend the authority for DPH to expand the list of reportable diseases without going through regulatory process. It would reduce sanctions for non-compliance.

SB 482(Padilla). Bea OKeefe said this bill died in January 2010, but was very interesting. It wanted to exclude bio data services that provided algorithms for interpretation of genetic information from oversight. It also would have allowed direct-to-consumer ordering of genetic tests. This bill was sponsored by 23andMe, and was withdrawn because of privacy, not technical, concerns.

SB 1246 (Negrete McLeod). Bea OKeefe said this bill would authorize licensed naturopathic physicians to direct a laboratory and perform waived tests. It would also authorize a naturopathic medical assistant to draw blood and perform waived tests.

Question: Tim Hamill asked in a naturopathic medical assistant would need a phlebotomy certificate. Bea OKeefe, said no, that would be in the scope of work.

Question: Michael Borok asked if a naturopathic physician would need to get a CLIA certificate of waiver to do tests. Bea OKeefe, said yes. State standards are higher than CLIA in this case as only MD, Bioanalysts, and PhD Board Certified scientists can direct waived laboratories now. This would add naturopathic physicians.

SB 975 (Price). Ron Harkey said this industry-sponsored bill would adopt AATB standards for all tissue banks licensed by LFS.

Question: Michael Borok asked about tissues stored in formaldehyde. Ron Harkey said these standards only regulated tissues for human transplantation.

AB 995(Block). Ron Harkey said this bill would exempt podiatrists who used synthetic material for wounds from tissue bank licensure requirements.

Personnel licensing regulations: Bob Thomas said LFS had been working on two sets of regulations as discussed here.

DPH-09-019. This regulation would make a non-substantive change to licensure requirements for cytogenetic and genetic molecular biologist scientists. The NCA was acquired by ASCP in October 2009, and the NCA examinations required for licensure of these categories are no longer available. LFS has communicated with both the ASCP and the NCA and the examinations are not changed, just the name of the organization administering the examinations. Therefore, LFS could justify replacement in current regulations of NCA with ASCP. LFS expects a decision on the request for regulation change by April 10 by the Office of Administrative Law. Anyone passing the NCA examinations before October 2009 can still apply for licensure. After DPH-09-019 is filed into law, applicants can take the ASCP examinations for CA licensure purposes.

DPH-08-001. LFS has worked hard to finish up the personnel licensing regulations. The goal is to have them ready for public review and comment this summer, hopefully June 2010. These regulations make comprehensive changes in education, training and experience requirements for licensure in all categories and adds new categories as discussed at the Stakeholders' meeting in August.

Question: Mary York asked if the regulation package would be emailed to the CLTAC when it was out. Bob Thomas said it would be mailed to the CLTAC, stakeholders and interested public, and would be available online. Mary York asked about the timeframe. Mr. Thomas said there would be a 45 day comment period and possibly a 15 day comment period if changes were made. Bea OKeefe urged everyone to comment, good or bad, as we needed both kinds of input. Persons commenting within the 45 day period would be sent any changes for a 15 day review, so it is important to stay involved.

H1N1 Flu ("swine flu"): Bela Matyas, MD, Epidemiologist for DPH, gave an update on H1N1 flu. He said the second wave of the epidemic was past. It had a vast impact since persons in 213 countries were known to have the flu. There were over 16,000 deaths worldwide, 550 in CA. DPH has been tracking the flu week by week to plot the trend and have determined that it has stabilized. The flu season is December to March each year. The persons catching the flu were mostly young and there were fewer fatalities than if elderly persons also contracted this flu. Dr. Matyas' slides shall be put on the LFS website for participants.

Question: Karen Nickel asked what was the confirmatory test for H1N1 and which labs were going it? Dr. Matya said it was an infective PCR with a subtype specific PCR. This test was performed by 24 labs in the Respiratory Lab Network and by the state's VRDL.

Question: Bob Hunter asked what are the viral components of the H1N1? Dr. Matya said there were two swine, one human and one avian component.

Question: Mary York said there was a commercial test, not high complexity, approved for emergency use until April 1, 2010. Can CA labs continue to use that? Bea OKeefe said it was not FDA approved, would be treated as high complexity with full validation before use.

Question: Michael Borok asked why seasonal flu was down while H1N1 was high. Dr. Matya said children were not the usual vectors for other flus.

Question: Lin Kassouni asked how many CA cases were confirmed. Dr. Matya said 8800 were tested and confirmed but probably many others had the virus and were not tested.

Comment: Tom Tempske said the disease started in Mexico where it had a higher death rate in young people. Bob Thomas asked how many people in the US died of a secondary infection. Bea OKeefe said seniors were protected from H1N1 due to an immunity gained in a flu outbreak in the 1950s.

Question: Bea OKeefe asked how the new national health care bill will impact public health epidemic tracking. Dr. Matya thought it would not since it impacted testing covered by insurance companies, not public health labs.

Question: Dr. Moradian asked why H1N1 showed such a low rate of response to antiviral treatment. Dr. Matya said he did not know but it may have a genetic bearing.

CLIA requirements—Public Health Lab Director: Dr. Hamill said at the last meeting Ms. Billingsley had said she wanted the CLTAC to review and comment on a proposal that impacted public health lab directors. Material was sent to the CLTAC that showed a request by the CA Public Health Lab Directors for federal legislation which would allow non-doctorate Public Health Microbiologists (PHM) to direct public health labs (PHL) performing high complexity testing. This would alleviate a shortage of doctorate-level directors for the 38 county laboratories in CA.

Question: Michael Borok asked what the current requirement for PHL directors was. Bea OKeefe said prior to 1992, PHL directors needed a BS degree, 6 months training, a PHM certificate and four years experience to direct a PHL. After CLIA was implemented in 1992, anyone not grandfathered needed a doctorate degree, board certification, four years experience. State law adds that they must have a PHM certificate.

Comment: Donna McCallum, supervisor of the CLIA program in CA, said CA is a leader in personnel requirements in the US, requiring an MD to direct waived labs in CA. She said unlicensed PhDs can develop a high complexity test but cannot perform it unless licensed. She asked why high standards should be held for all labs except PHL. Why should federal law be changed? We should expect PHL to also comply. In her experience with inspections of PHL, they do not keep up with state or federal regulations and have other problems.

Question: Michael Borok asked if an MD could direct a PHL or do they need a PHM certificate? Bea OKeefe said they would need a PHM, also.

Comment: Dennis Ferraro, representing CAPHLD, disagreed with the comments made by Donna McCallum. The PHL system has been in place for 70 years and there have only been five board certified directors in that time and there has been no problem. There are economic constraints for hiring doctorate directors. The PHL perform different tests than CLIA labs. They provide epidemiology service and environmental testing. The lab in Mendocino has been closed and consolidating labs has been considered by the others. PHL serve as the reference lab for rabies, west Nile virus, surveillance. Most PHM have 10-15 years experience. CAPHLD wants to change federal law until more doctorate scientists are available to serve as directors.

Comment: Mary York said the problem is salaries. They are trying to lower director requirements so a person without a doctorate can work, but most doctorate scientists do not have a PH background.

Comment: Jerry Hurst said a non-doctorate PHM can serve as co-director but can only supervise moderate complexity testing. Most PHL do high complexity tests.

Comment: Valerie Ng, MD wanted to talk from a clinical lab perspective. She said in 1987 she looked into directing a PHL but was told she was not qualified. She needed six months more training. She felt there was fear of PH and epidemiology as not being timely. As in H1N1, PH labs could not respond timely and commercial labs had to come up with the test. There must be a better way to meet the need for PH.

Comment: Dennis Ferraro said board certified doctoral scientists do not need six months more training. They just need to take the PHM state exam.

Facility licensing report: Bea OKeefe said SB 744 which passed on October 11, 2009, implemented new fees for laboratories. LFS made quick changes in response, but there were delays in mailing laboratory renewals in November. Many labs were sent automatic delinquent notices before they had a chance to send in their renewals. However, LFS is not assessing delinquency fines if labs renewed within their 60 day grace period. Ms OKeefe said 800 labs renewed their licenses, and 1500 labs renewed their registrations, in January 2010, and the new fee process seems to be going well.

Question: Tim Hamill asked how the number of tests were calculated, like for a CBC with 6 tests. Ms OKeefe said each of the 6 tests would count toward the total tests.

Question from a participant in North Hollywood: Many of the small labs that she consults for are actually paying more now than before. How does that happen? Ms OKeefe said those labs performing less than 10,000 tests see a reduction, those close to 10,000 pay about the same, those performing more, pay more. More information on this is given on the LFS website.

Question from a participant: Can LFS alert a lab by email that their renewal is in the mail. Many renewals get lost on large campuses. Ms OKeefe said that this was not currently possible, but encouraged labs to change their mailing address to a different site than the laboratory address, one that would not so easily get lost. She said the new EOL system may be capable of more email notices.

Personnel licensing section report: Bob Thomas thanked his section for working hard to solve problems created by the furlough, fielding phone calls, complaints, and upset people.

Mr. Thomas gave statistics for licensing effective March 26, 2010. LFS currently licenses 16,672 clinical lab scientists, 864 clinical lab specialists, 729 clinical genetic specialists, 754 cytotechnologists, 107 medical lab technicians, 1,756 public health microbiologists, 215 doctoral scientists, 467 trainees, and 31,547 certified phlebotomists. He said the hospital council was conducting a survey of licensed MLTs regarding employment and salaries.

Mr. Thomas gave a list of certifying examinations approved for licensure purposes in CA. He said some further changes would be made before it is changed on the LFS website. He said 15,750 persons are expected to renew their phlebotomy certificates this year, and many are waiting too late to renew. This has been a problem since they do not have a grace period. There are 120 phlebotomy training program approved and five are awaiting approval.

Mr. Thomas introduced Maria DeSousa, program manager of phlebotomy. Ms DeSousa and Shahrzad Radahd, former manager of MLT licensure, developed an informational program that was selected for a national award. This award was recognized by Dr. Horton, DPH director. Ms DeSousa described what had been done.

Mr Thomas said another oral director examination would be help on April 30 for 4 candidates. He said SB 744 had authorized a \$200 examination fee which would be assessed for any new candidates.

New applications continue to come in to LFS. On average, LFS has received monthly applications from 587 phlebotomists, 70 CLS, 32 trainees and 2-4 specialist applicants. Mr Thomas said the CPS contract will expire on June 30, 2010 and if it is not renewed in time, LFS will have to switch back to a manual system.

Question: Mary York asked if the oral director examination could be eliminated. The ASM legal office felt it was too subjective, and suggested it be eliminated. Mr. Thomas said no, it was required by law.

Question: Dora Goto as if the CPS contract is not renewed, will LFS lose its online personnel license verification? Mr. Thomas said no, but it would be slower because LFS would have to manually enter all the data, not CPS.

Question: Tim Hamill asked if there was something on the LFS website that stated the license verification there could be used as legal documentation. Mr. Thomas said yes, that was just prior to the verification on the website.

Question: Dora Goto said if 70 persons were applying each month for CLS licensure, how many were getting licensed? She said that sounded high. Mr. Thomas said he would check and get back to the CLTAC next time on that.

Question: Barbara Brunell asked if there is online verification for clinical labs. Bea OKeefe said no, but maybe with the new EOL system. Donna McCallum said it was possible to identify CLIA labs on the CMS website.

Question: Carola Howe said if there were 70 persons applying for trainee licenses each month, where are they? Mr. Thomas said they were retained in the data base and perhaps looking for training sites.

Question: Donna Kirven asked what complaints there had been about training programs? Mr. Thomas said mostly about persons wanting to complete the practical portion of phlebotomy training. There is nothing in the law about timeframes for completing training.

Tissue bank and biologics report: Ron Harkey said these programs were impacted by vacancies. LFS needs another biologics inspector, another cytotechnologist inspector and has 2 new tissue bank positions to fill starting in July 2010. there are 200 blood banks in CA, plus collection sites and 1.4 million red cell units are collected each year at mobile sites and these all need surveillance. SB 744 eliminated the cytology assessment fee, but cytology labs still need cytotech inspectors. The tissue bank program is growing with 550+ facilities.

CLIA update report: Donna McCallum reminded the CLTAC that the federal calendar starts in October and the state's, in July. The activity of the LFS CLIA program since October 2009 included 307 initial or recertification surveys, 4 validation surveys, 1 onsite follow up inspection, 2 complaint investigations, and 10 proficiency testing sanctions. There are 214,875 CLIA labs in the US, 19,596, in CA. Ms McCallum said CMS is continuing with waived lab inspections. Regarding cytology proficiency testing, CMS is accepting comments to new standards and these will be published next year. CMS is working on the top 10 deficiencies cited on inspections, to see if they can work with labs to bring those down, and is considering changes to its proficiency testing referral regulations. CMS has published the waived lab checklist online.

Question: Mary York asked when the new Appendix B would be available. Ms McCallum said the document was currently under review. Completion time is unknown.

Summary of complaints received by LFS: Tom Tempske said LFS has received 50 complaints in the last 3 months. Of these, 12 were referred to other agencies, 18 were

still open and 14 were closed. LFS is still working with Medicare and MediCal on billing fraud, and deals with physician inducements as prohibited at B&P Code 650.

Question: Does LFS get support from DPH legal staff on complaints and enforcement? Ms OKeefe said support is gotten for immediate jeopardy cases and sanctions.

New business, open discussion: Dr. Hamill opened the floor for open discussion and new business.

Mary York asked again about identification of microorganisms in multi-test identification systems. This includes 63 tests per card and provides an algorithm for interpretation. The question is, how to provide a positive and negative control for each test as currently required in state law. The manufacturer provides a test organism for each group, but that adds greatly to the expense. Bea OKeefe said this deals with the cross walk of state law based on CLIA of 1994 and CLIA as adopted in 2003. The test needs to be controlled, but there is a question of how to do it. This is not specifically covered in the cross walk underway, but the state needs to consider this.

Donna McCallum said Judy Yost and CMS and very interested in what CA will do. Mary York said the ASM was also interested. Bea OKeefe said if the issue is not clear in the law then LFS cannot make a decision as it would be an “underground regulation”.

Dr. Hamill announced that the next meetings of the CLTAC would be June 25 and September 24. The date of the December meeting will be set later.

Dr. Hamill announced that the planned meeting of the CLIA crosswalk subcommittee had been cancelled this afternoon and that nominations were still open for Chair of the CLTAC with the election to be held at the June meeting.

The meeting was adjourned at 12:25 by Chairman Tim Hamill.