

Clinical Laboratory Technology Advisory Committee  
Minutes of the December 5, 2008 Meeting

Meeting held by videoconference from Richmond campus, CDPH,  
KP Regional Laboratory, North Hollywood and  
Telephone Bridge Line

CLTAC Members Participating: Laurie Armour, Michael Borok, Tony Butch, Leonard David, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Lin Kassouni, Donna Kirven, Peggy OToole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung, David Yong, Mary York.

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

DPH Staff Participating: Zahwa Amad, Alan Ankerstar, Frank Barnes, Norma Barocio, Kathy Billingsley, Linda Bryant, Grace Byers, Ann Chandler, Maria DeSousa, Pam Farrell, Ron Harkey, Robert Hunter, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Shahrzad Radahd, Judy Schlosser, Joanne Sparhawk, Genie Tang, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams, Ellen Yasumura.

Welcome and General Announcements: The meeting was called to order by Chairman Dr. Tim Hamill. He welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He noted that there was a quorum of CLTAC members present.

Approval of the September 5, 2008 meeting minutes: The minutes of the previous meeting were reviewed, amended and approved.

Department news: Kathleen Billingsley, Deputy Director of the Center for Health Care Quality said the economy was having a serious effect on state government. The legislature needs to take action because budget shortfalls are impacting many programs, particularly General Funded programs. LFS and Licensing and Certification are license fee-supported, special fund and Federal Grant supported, but still are being asked to monitor funds and reduce spending. Ms. Billingsley said she spoke with legislative staff about the BSA audit of LFS and the 60-day response was reviewed. LFS needs to leverage existing resources for important program activities, notwithstanding LFS' desires to do everything required. Ms. Billingsley said Karen Nickel will retire after the March CLTAC meeting, indicating how important she feels the advisory committee to be. She said communication will be important to help during the transition until a new chief is hired. Dr. Borok asked whether LFS' expenses and revenue information was public information. Dr. Hamill thanked Dr. Nickel for her contribution to the CLTAC.

Laboratory Field Services Update: Karen Nickel welcomed the participants and thanked Kaiser Permanente for providing the videoconference site in North Hollywood and for Fred Ung's work down there. She thanked Dennis Tavares and Don Miyamoto in Richmond for set up and welcomed the CLTAC members from southern California. Dr. Nickel reminded the CLTAC that Dr. Hamill was elected to another term as Chair at the last meeting, and thanked him for his willingness to serve in this role. Dr. Nickel presented a certificate of appreciation to Curtis Johnson for his service on the CLTAC. She encouraged everyone to look at LFS' website for updates on HIV informed consent, referral of proficiency testing, and updates on infectious disease reporting, topics that were discussed last meeting. She thanked Dona Lynch, Kathy Williams and Maria DeSousa for their work ongoing on the LFS website.

Dr. Nickel said that civil service exams were held in November for Examiners I and II and hopefully, interviews will be held soon. LFS currently has 8 Examiner vacancies in two offices. Another exam will be given in February 2009, and she encouraged interested qualified persons to apply.

LFS is working on approval of certification exams for licensure purposes and hopes to complete review of ABCC for doctorate level chemists and toxicologists. LFS gave licensing exams for BS-level immunohematologists and hematologists the first of November and hopes to not give exams again.

Dr. Nickel discussed the BSA audit and said LFS' activities are being monitored closely to make sure it maximizes its resources to be more efficient and get more inspections done, complaints handled and enforcement actions taken. The CLTAC asked questions about how LFS could recruit more staff and asked how salaries could be improved.

Dr. Nickel said she had decided it was time to retire and was going to miss the interaction with the dedicated staff at LFS, the CLTAC and professional organizations, as CAMLT, CCLA, CLMS, PAMET. She said she had postponed her retirement for 5-6 years so she could work for a stronger state laboratory oversight program. Since 2000 when CA decided to not accept CLIA exemption, LFS has been waiting for an infusion. LFS was counting on CLIA exemption to eliminate duplicate state and federal programs, and when the federal could not be eliminated, some people thought the state program was unnecessary. This has been an issue since 2000. Salaries are a problem for LFS and the program has been short of staff for years, now relying on 22 part time retired people who to help LFS out. LFS has the BSA audit which criticized the program and LFS is hoping that will propel an action to get more staff. Meanwhile, Dr. Nickel does not want to wait any longer. What is LFS going to do? LFS' Examiners III are experienced and will keep their programs going. She said she would like to help part time with regulations or special assignment, but does not want to be chief any more.

Report of the CLIA 2003 Subcommittee. Chairman Robert Footlik said that because of lack of staff liaison availability, this committee has no report.

Legislation impacting clinical laboratories

AB 1060 (Laird, urgency). Ron Harkey reported that this bill had passed and exempted dentists and oral surgeons who use freeze dried bones and dermis from tissue bank licensure. There was concern about patient safety in an unlicensed facility. He said podiatrists were also interested in being exempt from licensure requirements.

Regulations impacting clinical laboratories: Dr. Nickel reported on regulations underway.

DPH-07-010 HIV Screening Testing Standards These regulations will amend 17 CCR 1230 which were enacted in 1986 and which are now outdated. They currently require all labs that screen patients for HIV to be approved by LFS, and that is no longer necessary. Also, these regulations never anticipated waived HIV tests would be approved by the FDA and that this test would be done by minimally trained persons. These standards were markedly changed in this revision, and Dr. Nickel said she was disappointed that none of the CLTAC submitted comments. She said the Department did receive some comments and amendments were made to the regulations based on the comments. The regulations will go out for a second 15-day comment period but only those that commented before will see the revision. Many of the CLTAC said they thought the drafted regulations were good and that they did not need to comment.

There has been no further work on the other regulations since the last meeting of the CLTAC:

DPH-08-01, (amendments to CCR 1030-1061),

DPH-08-02 (amendments to CCR 1050) and

DPH-08-xxx (regulations as mandated in AB 443, Migden, 2007.)

California's Biomonitoring Program (CECBP, SB 1379) Dr. Nickel introduced Dr. Frank Barley, a supervisor of CECBP for the Department. This program is charged with assessing "body burden" of environmental contaminants. The full program will determine baseline levels of contaminants in representative samples of CA residents, establish temporal trends in levels and assess effectiveness of efforts to reduce exposures. This program passed legislature in 2005, was vetoed, passed again in 2006 but was not funded. In 2007 it had limited funding. Blood samples will be analyzed and a CLIA certificate is required.

Personnel Licensing Bob Thomas said the Hospital Council Workgroup had evaluated lab workforce shortages as a threat to patient care resulting in labs not being able to conduct tests onsite. The ratio of CLS to population in CA is low and most labs have at least three CLS vacancies. Mr. Thomas discussed

training programs for phlebotomists, MLTs, BS-level scientists and PhD-level directors. These are listed in the LFS website and it is encouraging to see more interest in training programs. The MLT licensing program is off to a slow start since it started in March 2008. LFS sent out 1000 letters to CLS applicants who failed the CLS licensing exam to encourage them to apply for licensure. The CLTAC discussed MLT licensure. There seems to be interest, but an MLT in a hospital may be a problem because of their limited work scope, lack of flexibility. Can the work scope be broadened? (Not without legislation). The unions originally opposed licensure of MLTs. The regulations have a matriculation route for MLTs to later become licensed as CLSs. How many MLT training programs have been approved? None at this time, but 25 applications have been sent out. Community colleges are cutting back until clinical sites are available.

Mr. Thomas said the Personnel Licensing Section gets 250 phone calls a day, the most of any section in LFS. He said the license fees were increased in November 2008 with the signing of the budget bill. The application fee has doubled because a new license is valid for two years, not one. Mr. Thomas said LFS will use pressure sealed envelopes and new safety paper for licenses. He said LFS receives about 70 CLS applications per month with 40-50 people licensed each month. LFS is having problems with forged licenses and certificates, and urged everyone to check the online verification of licenses.

Changes in laboratory fees, ICD-10 codes and electronic access. Bea OKeefe reported on the new ICD-10 billing codes which will be effective October 1, 2011. This will include 155,000 codes, 10 times more than now. The reason for the change is the ICD-9 list is outdated. New procedures and diagnoses need to be added. Changing will be hard and there is a risk of payment slow down, so labs are encouraged to start preparation. Dr. Borok said many physicians oppose the change and anticipate many problems.

BSA Audit of LFS: Dr. Nickel said changes have been made in LFS in response to the BSA audit. Some accredited labs may have noticed they are getting state inspections, for example. LFS has expanded its efforts to inspect randomly selected accredited labs, and Bea OKeefe will tell you more about that.

Dr. Nickel reviewed the audit findings. The audit was legislatively mandated. The purpose was to audit LFS' ability to detect and investigate non-compliance, to investigate consumer complaints, to impose sanctions, to assess and collect fees and to limit Medical/Medicare participation as appropriate, all heavy tasks. The 4-5 BSA auditors spent five months auditing LFS' complaint investigations, proficiency testing enforcement, biennial inspections, licensing of labs, regulation writing, enforcement actions, legal support and IT support. The auditors recommended that LFS maximize existing resources and determine additional resources needed, leverage the state program with the CLIA program, explore use of contract inspectors, prioritize complaints for potential patient harm, sanction labs as appropriate, improve proficiency testing monitoring, update

regulations and continue efforts to license and register all labs in California and outside, doing testing on California residents. Dr. Nickel said the key players in getting this done are the section chiefs, Bea OKeefe and Donna McCallum and their respective staffs

Deputy Director Kathleen Billingsley said LFS had prepared a 60-day response to the audit and had done a good job of reassessment, leveraging, developing an action plan, without additional staff. LFS needs to fill its vacancies, consider contracting inspections, and adjusting its fees. There is a lot to be done.

Bea OKeefe discussed inspections of accredited labs. The CLIA program performs validations of about 2.5% of the accredited labs each year. The rest do not ordinarily get state inspections. LFS did a state and federal data base sort and found 540 accredited labs that were certified for CLIA after January 1, 1996. These labs are being randomly selected for a state inspection. So far 35 accredited labs have been inspected since October. Deficiencies found include personnel and phlebotomy violations. These labs are given a state 2567 deficiency statement and would be subject to sanctions under state law. The CLTAC asked that these not be called "validation" surveys as this is confusing with a CLIA validation survey. They also asked why January 1, 1996 was selected as a start date. This is the date after which CLIA labs were not exempted from licensure requirements in the emergency regulations enacted in 1996.

Donna McCallum explained the checklist for state compliance that the CLIA inspectors are using now. In response to the BSA audit, LFS' CLIA inspectors are checking for compliance of 12 key state law issues, including state licensure or registration, qualified lab directors, general supervisor, technical supervisor, technical consultant, testing personnel, phlebotomists, appropriate employment of unlicensed persons, lab owner disclosure, licenses posted, infectious disease reporting, qualified person releasing results, qualified person ordering tests, and lab director identified on the report. Checklists are referred to Bea OKeefe for state enforcement action.

Bea OKeefe explained expanded enforcement of proficiency testing failure underway. The state is reviewing performance of accredited labs and taking enforcement and the CLIA program is overseeing the non-accredited labs.

Tom Tempske said all complaints are prioritized and assigned some type of follow up. The complaint form is on the LFS website and all telephone complaints are directed to him. LFS has received 210 complaints to date, about one third related to phlebotomy and some from whistleblowers. The CLTAC asked what categories of complaints LFS receives and this will be given at the next meeting.

New business:

How can a consumer make a complaint? Is there a hotline for compliance and complaints? CAP requires this. The CLTAC asked that this be discussed at the next meeting.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:45 PM.

Next Meeting Date: March 6, 2009.

DRAFT