

**Clinical Laboratory Technology Advisory Committee**  
Minutes of the January 14, 2011 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, Anthony Butch, Leonard David, Elizabeth Dequinia, Tim Hamill, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Fred Ung, Lori Dean-Yoakum.

**Former CLTAC members participating**

Victoria Bello, Sam Chafin, Morton Field, Imre Fischer, Robert Footlik, Sol Notrica, Jim Ottosen.

**DPH staff participating**

Zahwa Amad, Norma Barocio, Grace Byers, Maria DeSousa, Pam Dickfoss, Ron Harkey, Robert Hunter, Nema Lintag, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Janet Otey, Judy Schlosser, Tom Tempske, Robert Thomas, Clint Venable, Kathy Williams.

**Welcome and general announcements**

The meeting was called to order by CLTAC Chairperson Tim Hamill. Dr. Hamill apologized for missing the last meeting and thanked Donna Kirven for chairing the meeting in his absence. A roll call was conducted of CLTAC members and Dr. Hamill noted that a quorum was present for the meeting.

**Approval of the October 1, 2010 meeting minutes**

Dr. Hamill asked participants if there were any additions, deletions, or corrections to the minutes. Jim Ottosen said that his name and those of Dr. Lee Hilborne, Liz Dequinia, Sol Notrica and Imre Fischer were not listed as participants at the last meeting, and these additions were made. For the CLIA update, Donna McCallum said "recents" should be "recerts" and "20 follow ups" should be changed to "20 waived lab follow ups" Maria DeSousa said the reference to 99 approved training programs should be changed to 109. Jim Ottosen asked that the minutes be amended to change his comment that there has never been a response from the CLTAC to "there has never been a response from the CLTAC regarding the new DPH 08-001 regulation package." These changes were made. Salim Rafidi moved that the minutes be approved as amended, Jerry Hurst seconded, and the minutes were approved. accepted.

**Department news**

Ms Pam Dickfoss was introduced as Acting Deputy Director of the Center for Health Care Quality, replacing Ms Kathleen Billingsley who took another position in CalPERS. Ms Dickfoss said that Lori DeMartini was also working on managing the Center during the transition and Cheryl Muniz was Acting Deputy Director, Administrative Director of L&C Field Operations.

Ms Dickfoss announced that Diane Dooley will replace Kim Belshe as Secretary of Health and Human Services and David Maxwell-Jolly shall be Undersecretary. She said the state budget is still a problem and there is a hiring freeze for all programs. Even though SB 744 authorized new positions for LFS, the program is not allowed to hire at this time.

The new "EOL" program is still under development after two years. Electronic Online Licensing shall standardize licensing for the Department and improve efficiency.

Question: Dr. Borok asked whether furloughs impacted all department staff. Ms. Dickfoss said furloughs were reduced to one day per month but some bargaining units are still negotiating and have three days. Donna McCallum said the furloughs are impacting the CLIA surveyors being able to meet their targets. Dr. Hamill said if Friday furloughs were gone, CLTAC meetings should be moved back to first Fridays.

### **News and update on LFS**

Bea OKeefe, Chief of LFS, said that LFS had been authorized 35.5 new positions and, despite the hiring freeze, is conducting interviews to be ready to hire when authorized. Currently LFS is interviewing Examiner IIIs, section chiefs for Richmond and Los Angeles, replacing her position and Bob Thomas' in personnel licensing, plus a new Examiner III in Los Angeles for state inspections. Zahwa Amad is currently Acting Section Chief of Personnel Licensing and Kathy Williams, for Laboratory Licensing. She said it is critical that these positions be filled and also Program Technicians, clerical staff performing licensing duties. As soon as possible, LFS would like to interview and hire Examiners I and II. There are about 20 candidates on the civil service list.

Ms OKeefe said work was backlogged in LFS, impacting laboratories and laboratory personnel, especially phlebotomists. The backlog is due to unfilled vacancies and furloughed staff. She is concerned that the contract with CPS is still incomplete and that agency is working without a contract. CPS provides online applications and license verification technology.

SB 744 authorized laboratories to designate inspections by accrediting organizations approved by the department. No agency has been approved yet, but two have expressed interest.

Dr. Horton wants all hospitals linked on an emergency contact system called California Health Alert Network, CAHAN, and that work is underway.

Question: Dr. Hamill asked which two accrediting organizations had applied. Ms OKeefe said none had applied yet, but two had inquired about the process.

Question: Dr. Borok asked how many state lab inspectors LFS had now. Ms OKeefe said LFS had 3 now and approval for 10 more. In addition, the CLIA program had funding for 8 inspectors. She noted that the BSA audit several years ago cited the department for not doing inspections and gave a mandate that have adequate staff to do inspections and complaint investigations.

### **CLTAC member term limits**

Dr. Hamill noted that a number of CLTAC members were completing their terms effective the end of last year. He thinks that seven members' terms expired on December 31, 2010 and they may be eligible for renewal of appointment. These persons are: Armour, Butch, Dean-Yoakum, Dequinia, Finson, Swartz and Ung. He asked these persons to apply for reappointment, if willing or eligible, or supply a replacement nomination. He asked them to contact Bea OKeefe. Dr. Hamill said it appears that the following persons' terms expire the end of 2011, Borok, Hamill, Kassouni, Kirven, Maldonado, OToole, Rafidi, Revier, Terry and York. Some of these members may be completing their second term and be ineligible for renewal of

appointment. They are asked to consider a candidate for nomination of their position.

Question: Jim Ottosen said the CLTAC bylaws state that the CLTAC Chairman is elected in December and starts serving in June, so the election of Tim Hamill at the last meeting is invalid since he cannot serve beyond this year. Dr. Hamill agreed that a new chairperson should be elected and asked that the nominations be opened. Les Revier nominated Lori Dean-Yoakum, seconded by Donna Kirven. Ms Dean-Yoakum agreed to stand for the election. Dr. Borok asked how a person from southern California could serve as chair. Would they have to fly to Richmond each time? Bea OKeefe said the LFS Chief could go to North Hollywood and the CLTAC chair in southern California could come north, but the two individuals would have to be at the same location. Dr. Hamill opened the nominations again. Laurie Armour nominated Jerry Hurst, seconded by Salim Rafidi. Mr. Hurst agreed to the nomination. Hearing no further nominations, Dr. Hamill closed the nominations and a vote of the CLTAC was held. Lori Dean-Yoakum was elected new chair of CLTAC, for one year starting July 2011.

### **Subcommittee Selection for Personnel Regulations**

Dr. Hamill said there had been a request that the CLTAC form a special subcommittee to have input on the personnel regulations, DPH-08-001. He solicited persons who would serve on the subcommittee and a number of persons volunteered, including Hilborne, Rafidi, Ottosen, Revier, Dean-Yoakum, OToole, Borok, Footlik, Armour, Hurst, Maldonado, Joseph Musallam, Michele So, Field, Kassouni, Dequinia, Becky Rosser, Mora Williams, Hamill.

Question: Salim Rafidi said there were only 15 days to meet, this was a big committee and questioned how it would work. Jerry Hurst said the group should be limited to 10 persons, 5 CLTAC and 5 public members. Les Revier suggested 11 persons, 7 CLTAC and 4 public. Dr. Field said the CLIA crosswalk committee has many members but not all participate, so many members are needed. Bea OKeefe asked whether LFS should be involved. Michael Aiden said the public should be represented. Dr. Borok said everyone should be allowed. Liz Dequinia asked how a committee would be chosen. Dr. Field made a motion that a physician be allowed and Bea OKeefe said the motion was out of order. Dr. Borok repeated the motion and it failed to pass. Lin Kassouni made a motion that anyone could participate in the subcommittee, seconded by Les Revier and Michael Borok, motion passed with 19 persons identified as interested in participating in the subcommittee.

Salim Rafidi volunteered to chair the subcommittee on DPH-08-001 review. He said he would organize it, generate a report and report back to the CLTAC. Bea OKeefe said a special meeting of the CLTAC may be necessary to review and approve the report. Mr. Rafidi was concerned that this could be done in 15 day and suggested some dates for meetings. Dr. Hamill noted that any meeting of the subcommittee would be open to the public.

### **Midwife ordering laboratory tests**

Leticia Robinson of the Midwifery Board said there has been a problem with laboratories not accepting test requests from licensed midwives. These persons are licensed under the healing arts through the Medical Board of California and work under the supervision of a licensed physician. They are authorized to open

accounts with a laboratory, collect samples, and order tests limited to the birthing process. There is nothing in laboratory law at B&P Code to prohibit their ordering tests.

Question: Jim Ottosen asked if there was a list of tests that midwives could order. Ms. Robinson said there was not. Les Revier asked whether the lab needed an informed consent from the patient. The answer was, no. Testing does not require informed consent as it is part of the pre- and postnatal care. Dora Goto asked whether lab tests ordered by a midwife are reimbursable by insurance and Ms Robinson said this was a problem sometimes. Dr. Field said that once a lab sets up an account with a client, they accept all tests.

### **Facility licensing section**

Kathy Williams, Acting Section Chief of Facility Licensing, said LFS is having problems processing fees and has a 30-60 day backlog. Laboratories that pay by the expiration date have a 60 day grace period in which they can continue operating without licensure and without paying a delinquent fee. With the backlog, some laboratories are getting delinquency notices when they paid on time, and this is causing consternation. Ms Williams said LFS is hearing from out-of-state mobile wellness clinics who want to hire middlemen phlebotomists to process samples. LFS is getting applications from franchise labs, as Doctor's Express, which want to do waived testing. Also, she is hearing from "telehelp-telelab" facilities doing testing at one site and reporting offsite.

Question: Tom Tempske said rural clinics in Africa were offering malaria testing. Dora Goto said the PPMP application for state registration is missing director attestation forms. Kathy Williams said these may be eliminated.

### **Personnel licensing section**

Zahwa Amad, Acting Section Chief for Personnel Licensing, thanked her staff for their hard work while short handed and hampered with furloughs. She said that there have been a flood of renewals, especially from phlebotomists. Renewal notices are sent out 90 days prior to expiration and if they are not returned immediately, they are caught in the backlog. There is no grace period for phlebotomists and they are often suspended from work. LFS received 3,000 renewals at the end of the year. Dr. Amad urged persons to send in their changes of address so renewals are not lost. She said LFS was implementing a new process for California CLS trainees, where the program director gives advance notice of completion of training so licensure can be expedited.

Question: Grace Byers told participants to tell their HR departments about the 90 day grace period for CLS'. Robert Thomas said an oral exam was given October 10, 2010 and is scheduled for February 11, 2011. Dr. Borok asked when online renewals would be available. Ms Williams said the EOL should be ready by 2014. A participant asked if the turn around time for specialists is the same as for CLS'. Dr. Amad said the backlog is currently about 3 months.

### **Milk banking and tissue banks in California**

Because of time constraints, this presentation by Jan Otey was postponed until the next meeting.

### **Complaints received by LFS**

Tom Tempske, LFS Complaint Program Manager, reported on complaints, saying fourth quarter 2010, LFS received 63 complaints. LFS received a total of 197 complaints in 2010 compared with 228 in 2009. Of the complaints received in 2010, 106 have been closed and 39 are outside the purview of LFS. Most of the complaints deal with billing, reporting and phlebotomy. Complaints come in by letter or email. Many people are now using the complaint website sponsored by the department ([lab.complaints@cdph.ca.gov](mailto:lab.complaints@cdph.ca.gov)).

### **CLIA update**

Donna McCallum, Section Chief of the CLIA program, said the federal calendar starts October 1 and ends on September 30 of each year. The first quarter 2010, LFS conducted 26 initial surveys, 134 recertification surveys, 2 follow ups, 5 validation and 5 PT sanctions, plus 46 waived lab paper reviews.

Question: Someone asked about the CLIA requirement for physician signature on test requests. The test request must include physician name, tests and patient information. Dr. Hamill said the ruling on the issue is expected in March 2011 with a 3 month phase in. Dr. Field asked whether the lab or the ordering physician should be responsible for assuring a signature is provided. The signature is necessary for reimbursement. Dr. Hamill said an audit of the lab is easier than going to physician offices. Dr. Borok asked about physician office labs, whether a signature is needed.

### **Personalized health information technology**

Kathryn Lowell was unable to attend the meeting so the presentation shall be given at a later meeting.

### **Meeting schedule for 2011**

Dr. Hamill asked that the meeting dates be selected for 2011, assuring that Richmond and Kaiser Permanente North Hollywood facilities were available. The dates selected with March 4, 2011, June 3, 2011, September 2 or 9, 2011 and December 11, 2011.

### **Open discussion**

Salim Rafidi asked to continue discussion on when the DPH-08-001 review subcommittee could meet. He asked about how to contact the public so they would know about the meeting as required. He asked whether videoconference facilities in Richmond and North Hollywood would be available and what kind of support LFS could provide. Several provisional meeting dates were selected. Mr. Rafidi said he would work to get the subcommittee going.

### **New business**

Dr. Hamill asked if there were any new business and there was none.

### **Future agenda items**

CLTAC member (not identified) asked how LFS was responding to the BSA audit for providing improved service to its laboratory clients. Other future agenda items included the status of the CLIA crosswalk subcommittee, milk banking, personalized healthcare information technology. Jim Ottosen asked how the Office of Regulations views the CLTAC and why it was not involved at the beginning of regulation development. Jerry Hurst made a motion that a formal clarification by the Office of

Legal Services and the Office of Regulations on the role of CLTAC be given. This was seconded by Donna Kirven and Salim Rafidi, and the motion was unanimously approved.

Dr. Hamill made a motion that the meeting of the CLTAC be adjourned; the motion was seconded and approved. The meeting was closed at 12:20 PM.