

**Clinical Laboratory Technology Advisory Committee**  
Minutes of the December 2, 2011 Meeting  
Meeting held by videoconference from Richmond campus, CDPH  
KP Regional Laboratory, North Hollywood and  
Telephone Bridge

**CLTAC members participating**

Laurie Armour (Fuller), Michael Borok, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Jerry Hurst, Lin Kassouni, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung.

**Former CLTAC members participating**

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

**DPH staff participating**

Zahwa Amad, Alan Ankerstar, Norma Barocio, Grace Byers, Pam Farrell, Bob Hunter, Nema Lintag, Victoria Maxwell, Donna McCallum, Cassie McTaggart, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Judy Schlosser, Sharon Simms, Robert Thomas, Kathy Williams.

**Welcome and general announcements**

The meeting was called to order by CLTAC chairperson Lorri Dean-Yoakum. She welcomed the participants and thanked Kaiser Permanente for providing the video conference center in North Hollywood and the telephone bridge. A roll call was conducted of CLTAC members and other participants, and Ms Dean-Yoakum noted a quorum was present.

**Approval of the September 9, 2011 meeting minutes**

Ms Dean-Yoakum asked if there were any corrections to the September 9, 2011 minutes and a number of corrections were made. After these corrections were made, Tim Hamill moved that they be accepted as corrected, Elizabeth Dequinia seconded, and the CLTAC voted to approve the minutes as amended.

**Department news**

Ms Pam Dickfoss, Acting Deputy Director of the Center for Health Care Quality, had a meeting conflict and was not able to participate. Bea OKeefe said she would give an update of department news during her update.

**Role of the advisory committee**

Sharon Simms, Senior Counsel in the Office of Legal Services, DPH, said she served as attorney for both LFS and Licensing and Certification under Belinda Whitsett, Assistant Chief Counsel for DPH. She said that Business and Professions Code Section 1228 authorized DPH to have an advisory committee to advise on development of regulations and policy. She said her office was also advisory to the department, and programs can accept, or not, advice from its attorneys. Both staff attorneys and the CLTAC help LFS make the best decisions, and the CLTAC serves at the pleasure of the

Director. The CLTAC is protected from lawsuit through state immunity and meeting minutes are subject to public record request. Therefore, the CLTAC is free to serve without restraint, to advise on rules and regulations and help develop policy.

Tim Hamill asked why the CLTAC was not involved during the development of the current regulations. He said the CLTAC was treated no differently than any public entity. How does the state differentiate? Sharon Simms said she had no history of these regulations until yesterday. She thinks LFS may have gotten some advice that there would be a conflict between CLTAC and LFS, but this did not come from attorneys. Belinda Whitsett agrees that this could have been done with no conflict. The process is fuzzy, confusing and sometimes inconsistent.

Salim Rafidi asked who could not look at the regulations under development. Is that limited to the CLTAC? Sharon Simms said CLTAC meetings were not subject to Bagley-Keene (B-K) Act for open public meetings. The subject of the meeting is not relevant; it should be open except when certain investigations are underway or sanction activities. The public has a right to know. The regulations need to be discussed openly in an open process. "Sunshine" Ms Simms thought there is a finite list of committees for which Bagley-Keene applies and as of April 2009, CLTAC was not on the list. However, open meetings are much better than closed meetings. Ms Simms said she was going to investigate to determine [for sure] whether Bagley-Keene applies to CLTAC meetings and report back to CLTAC during the March 2012 meeting.

Jerry Hurst asked about subcommittees of the CLTAC. Are they also subject to B-K? He said he was on the subcommittee, but the information from LFS on the regulations was said to be not publicly available. Sharon Simms said this may not be covered, by B-K, but there should be no secrets. She asked whether the CLTAC by-laws allow public member participation on subcommittees. She said they usually said public members "may" participate.

Jerry Hurst asked if public members had the right to vote on positions of the subcommittee. Sharon Simms said she would need to see the by-laws to see whether ex-officio persons could participate but not vote. She thinks this is discretionary but will check.

Robert Footlik thanked Ms Simms for the information. He said B-K should be beyond politics and any committee or subcommittee should be open. He said CLTAC should be included in that. Sharon Simms agreed that the intention was that all advisory committees be open. Openness is better. There should be public meeting notices with published agendas.

Tom Tempske asked why the recent regulations by LFS were quarantined and the CLTAC was not able to advise. Sharon Simms said the regulations should not be quarantined and the stakeholders should be involved early.

Lorri Dean-Yoakum thanked Ms Simms for attending the meeting and providing this information.

### **Nomination and Election of CLTAC Chair**

Lorri Dean-Yoakum said that Jim Ottosen had pointed out that the by-laws specify the new chair is elected in December and starts serving in June, so the CLTAC needs to elect a new chair for next year. Tim Hamill nominated Ms Dean-Yoakum, Jerry Hurst, seconded. No further nominations were heard, so Ms Dean-Yoakum was re-elected for 2012.

### **By-Laws Change, Article III, Membership and Term**

Lorri Dean-Yoakum said the issue under discussion is whether a CLTAC member term should be limited to two partial or complete terms with a wait of four years before he or she could be reappointed to CLTAC.

Michael Borok asked what happens when a replacement cannot be found. Can a member continue until the member organization nominates a replacement? Can the member continue in the interim? Does a person need a letter to extend his or her term? Bea OKeefe said it has been the policy that a person would continue beyond his or her term until replaced. It may take months for a nomination to be signed off by the Director.

Tim Hamill said if an organization does not provide a nominee, ask another organization. Karen Nickel said LFS has gone to professional organizations to avoid bias in selections. Jerry Hurst said if there was no response by one year the position should be filled with another organization's nomination. Jim Ottosen said the subcommittee took out professional constituencies and replaced it with membership categories. If one organization does not respond, go to a similar one. Lorri Dean-Yoakum thought that no one organization should have the absolute right to have one of its members appointed to CLTAC.

Michael Borok asked whether CLTAC could make changes in its members. Bea OKeefe said revisions of the by-laws should be reviewed by the Office of Legal Services. Tim Hamill asked whether both the CLTAC and OLS need to approve its by-laws. Kathy Williams said the previous by laws subcommittee had OLS as a member of the subcommittee.

Salim Rafidi said failure of an organization to submit a new nominee may occur because they want the current member to continue. Bea OKeefe said CDPH had three different directors in one year and a nomination might not be handled expeditiously because of the changes.

Salim Rafidi asked if the CLTAC should change the composition of its members. Lorri Dean-Yoakum said that was a different subject. Today's discussion is to focus on term limits.

Michael Borok said he was being termed out and his slot should not go empty. He said he should be allowed to continue for up to one year. He asked who could nominate his replacement. He suggested the ACP and the ACOG as well as the CMA. Morton Field asked how member solicitations were made. Karen Nickel said she used to contact the organizations directly in July preceding term expiration for up to three nominations. LFS would recommend one to the Director. Donna McCallum suggested a CLTAC member now leaving his/her position could ask his/her organization for another nomination. Robert Footlik said he thought if there were no nominees within one year, the person serving should continue indefinitely.

Lorri Dean-Yoakum suggested the issue go back to the by-laws subcommittee for fine tuning. Jerry Hurst made the motion that the issue go back, Lin Kassouni seconded but the motion failed. Ms Dean-Yoakum said she would speak with Jim Ottosen about the issue before the next CLTAC meeting.

Salim Rafidi said he wanted to discuss the composition of the CLTAC at the next meeting.

### **CLTAC Subcommittee on Personnel Licensing Regulations**

Lorri Dean-Yoakum thanked Salim Rafidi and Jim Ottosen for co-chairing this subcommittee.

Salim Rafidi said the subcommittee met on November 21 to decide how to proceed with the draft regulations sent to them in September. The subcommittee felt the draft was inadequate, difficult to read and understand. The subcommittee will give the draft back to LFS without corrections. The subcommittee wants to ensure the CLTAC position paper given to LFS is incorporated in the regulations.

Lin Kassouni said the version under discussion was written by the Office of Regulations (OR). Jim Ottosen wanted to see another (March 2011) version, written by LFS that OR did not use. He asked that the Department go back to that version. Bea OKeefe said OR had the March version that LFS wrote, but chose to rewrite the regulations into the version that the subcommittee saw. LFS is concerned about the changes and is working with OR to make corrections.

Tim Hamill asked whether LFS is working on the OR version or the LFS version. Bea OKeefe said LFS is working on the OR version. Bob Thomas said that when OR “reformatted” the regulations, many key points were lost and many inaccuracies introduced. Joseph Musallum asked why the subcommittee did not see the March version. Bea OKeefe said OR did not want to release that version.

Salim Rafidi said he wants the subcommittee position paper issues put into the final draft of the regulations.

Bea OKeefe said LFS would do that as much as possible.

Tom Tempske said the CLTAC should see the March version. He mentioned the openness that attorney Sharon Simms said was important. He said OR made many changes beyond format. Bea OKeefe urged the CLTAC to let LFS work with OR on amending the regulations.

Tim Hamill said the subcommittee had completed its work now. He made a motion that the CLTAC accept the subcommittee report that the OR version of the regulations be amended by LFS and that it be repopulated with the previous subcommittee recommendations. Lorri Dean-Yoakum seconded. Discussion ensued.

Jim Ottosen asked that the subcommittee get a chance to review the regulations again before it goes to the full CLTAC and before it goes public.

Lin Kassouni said the subcommittee felt the OR version was unworkable. She had a horrible time following it and wanted to see the LFS version. Karen Nickel said the subcommittee minutes reflected that and that would suffice. Tim Hamill said the OR regulations were the worst piece of material he had ever read. LFS' was better and OR did not do them justice.

The motion made by Tim Hamill (above) was accepted by a majority of the CLTAC.

#### **Announcement of CLTAC appointments**

Lorri Dean-Yoakum said the following persons' terms have been extended to December 2015: Lorri Dean-Yoakum, Liz Dequinia, Fred Ung, Anthony Butch and Laurie Armour Fuller. Mary York would be replaced with Margie Morgan.

Ms Dean-Yoakum said LFS had not received nominations from the CA Healthcare Association, CA Society of Pathologists, American Medical Group Association, CA Association of Bioanalysts, CAMLT, or the CA Society of Internal Medicine. The following members' terms have expired and the members will continue their terms: Lin Kassouni, Tim Hamill, Carmen Maldonado, Peggy OToole and Les Revier. She said those CLTAC members whose terms were ending could continue to serve until replaced or the by-laws amended.

#### **Report of the Healthcare Laboratory Workforce Initiative (HLWI) meeting of November 16, 2011**

Robert Thomas reported on the HLWI meeting of which Tim Hamill is chair. He said this effort is sponsored by the California Hospital Association. It has wide representation and its focus is to review new developments and challenges to clinical laboratory testing. This includes how to improve the workforce, training, education, remove regulatory hurdles, advance MLT licensing, improve scope of practices and give grants for CLS and MLT training.

Mr Thomas said the HLWI was considering legislation to simplify the training program application, to increase number of training programs and move the training program director requirement from the laboratory to the university.

Karen Nickel said this would not be possible for persons entering training outside a university, as specialists. Bob Thomas said there are many different scenarios, as 4+1, 3+1, laboratory affiliations, so any legislation would have to consider those. Karen Nickel said she is encouraged with many new training program affiliations with universities such as CSULA, CSUDH, CSUSJ, CSUSF and upcoming, CSUSD. These programs provide didactic instruction at the university and practical at the affiliated laboratories.

Tim Hamill said the federal training grant is supposed to cover training costs or provide stipends for trainees, but at UCSF, 47% goes to the dean and not to trainees, so the money was given back to the government. Liz Dequinia said the stipend is supposed to be \$10,000 per trainee. Her facility is non-profit, so cannot accept the money. Mr Thomas said there was much effort at several levels. Tim Hamill said the HLWI appreciates LFS' participation in the group.

### **Bugs 'n', Blood 'n' Biologics**

Bob Hunter, Biologics Examiner for LFS, had been asked to speak about an investigation that he had been participating in for LFS. It was decided that this discussion would be postponed until the March CLTAC meeting.

### **LFS Update**

Bea OKeefe said there was much interest in setting up a data base for laboratories and laboratory personnel, "electronic health records, EHR". The Department of Health Care Services is implementing electronic health records, in the "California Medical Health Implementation Plan" with \$5 billion to improve electronic health records. It is estimated that 40% of lab work can be electronically stored, and hospitals can send electronic records to public health agencies. Labs and hospitals can be identified using a uniform reporting system. They are looking at LFS' databases and want to access them monthly or more frequently. They also want email addresses that are currently not available in the state database. The benefits of such a system include emergency contact information. The OR says regulations are needed to implement, so LFS may put this into new regulations.

The Assembly Health Committee is also interested in LFS' personnel licensing data base. They want to know the size distribution of the license categories, the counties, and other information. The question was asked, "What are they doing with this information"? Ms OKeefe thinks they are looking for license trends, revenue, need by other programs such as reportable diseases, and need to contact licensed persons.

Changing subjects, Ms OKeefe said LFS was in danger of losing more positions. The Department of Finance says any position vacant more than 6 months should be abolished. But, with a hiring freeze, LFS has many positions vacant for a long time. She is hoping to not lose more positions. LFS can hire from inside the department and made offers for several new examiners in June, but these offers are still on hold. She

thanked LFS staff which has tolerated several years of staff shortages, especially the phlebotomy program.

Someone asked about online license renewals, saying that that would save staff time. Ms OKeefe said there were four attempts in the last 10 years to set this up, and all were scratched due to cost.

Tom Tempske asked about the 35 new positions granted with SB 744, after the BSA audit, for more inspectors. Ms OKeefe said LFS still had those positions but was unable to hire due to the freeze on hiring.

Morton Field asked about Electronic Health Record requirements for POLs. Ms OKeefe said many POLs were not equipped for online reporting and money was available for training and equipment.

### **CLIA Update**

Donna McCallum said electronic health records are covered in CMS 2319-P which addresses 493.1291 (f) and patient access to health records. It was amended to add 493.1291 (l).

Ms McCallum said she was able to get a couple hundred thousand dollars more from CMS for CLIA administration in California next year to cover program needs. The CLIA program in LFS did 934 surveys last year when the target was 841, so the CLIA surveyors did well. The target for this year is 852. She thanked her staff and team for their efforts.

Michael Borok asked if electronic reporting was required of all labs including POLs. Ms McCallum said, yes.

Someone asked if the changes in CLIA were implemented yet. Ms McCallum said she thought they were still in the comment period, although changes in state law had already been made. She said federal law supersedes state law in any state with this change. Bob Footlik noted that changes in CLIA and state law may conflict with HIPAA. BPC 1288 requires physicians to authorize release of test results. Now labs will be able to give them directly to patients (with exceptions). Tom Tempske said where there is a conflict of law; the "states' rights" provision allows states to be stricter.

Michael Borok said if MediCal providers must transmit to a patient, it will cut reimbursement. He asked if there is a financial penalty for non-compliance.

Jerry Hurst said this is a major change for laboratories, a paradigm shift. LFS should notify labs when this is implemented. Donna McCallum indicated that expected implementation would be in mid-2012. Bea OKeefe said labs should also look at the CMS proposed language. Bea OKeefe said she was concerned a patient would not be satisfied with simply a lab result, but would call the lab for an interpretation increasing costs for laboratories.

### **Personnel Licensing Section Update**

Zahwa Amad thanked her staff for their hard work in spite of staff shortages. She said some improvements had been made. Trainee licenses are now valid for one year from issue date and directors can now apply online. That means all license categories can now apply online. A total of 190 MLTs have been licensed. LFS had 507 applications for trainee licenses and 300 have been licensed. A total of 732 CLS or CL Specialist applications have been received with 533 licensed. Of these, 400 were CLS and 133 were specialists. Of the 400, 220 were from CA, 70 from outside CA and 150 from outside the US. The LFS website has an updated list of training programs. Five persons are awaiting an oral examination for licensure.

Peggy Kollars said the trainee license is still problematic since most expire in the middle of training.

Joseph Musallum said the state needs 800 new CLSs each year just to balance out those retiring. Bea OKeefe said there is growth in the new specialties. Karen Nickel said that several years ago, the state was losing 1000 CLSs per year and gaining 400 new ones.

Lorri Dean-Yoakum asked about the status of the CPT ID cards. Dr. Amad said they are still working on that and the mock up looks good.

### **Facility Licensing Section**

Kathy Williams says LFS continues to receive about 100 new laboratory registrations each month, plus 4-5 new California laboratory license applications and 4-6 new out-of-state license applications. LFS now has a backlog of applications from outside California. Ms Williams encouraged persons sending in applications to make sure they are complete so as to avoid time wasted by staff trying to get needed information. Ms Williams said LFS has new automated shelving units for laboratory, lab personnel and phlebotomy files now so hopefully that will consolidate space and ease access. LFS also has an electronic scanner and software for processing checks in Richmond.

There are several bills in the legislature that LFS is watching, AB 1328 dealing with CLS licensure and SB 594 dealing with continuing education for public health microbiologists. AB 186 shall allow the Department to add reportable diseases to the list without regulations. Tim Hamill asked how a lab would hear of any additions to the reportable list. Ms Williams suggested they check the website of the infectious disease branch. She said she would put that link in the CLTAC minutes. Ms OKeefe said it would be put also on the LFS website. Ms Williams suggested a lab check every three months at <http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx>

Robert Footlik expressed concerns regarding AB 1328 as it would accept two years of experience without documented training.

Michael Borok asked if the new reportable disease process “is working”. Ms Williams questioned whether it was.

Norma Barocio said laboratories are sending application/renewal documents in separately from their checks, and this is really creating confusion.

Lorri Dean-Yoakum asked that hints for expediting renewals be posted on the LFS website. Bea OKeefe said she would look into it.

Bob Hunter said the biologics section was having similar problems with its renewals. He said LFS needs original documents sent in separately from clinical laboratory documents.

### **Special thanks to Dr. Tim Hamill**

Lorri Dean-Yoakum thanked Dr. Hamill for his eight years of service on the CLTAC and for chairing the CLTAC for four years. She presented him with a plaque. Dr. Hamill thanked Ms Dean-Yoakum, said it was his pleasure to serve and was glad to pass the job on to her.

### **Complaints update**

Tom Tempske reported on complaints. He said in 2007, there were 315 complaints and in 2011, 135 up to this date. The number of complaints has halved, Mr Tempske thinks due to the complaint website which directs consumer complaints to the right agency. This has filtered out many of the complaints that LFS used to get.

In the last quarter, 38 complaints were received. Of these 21 have been closed, 6, referred (hospitals to Licensing and Certification, physicians to California Medical Board and nurses to Board of Registered Nurses). There was no POL complaint last quarter. Phlebotomy makes up 15-20% of all complaints. These include complaints about phlebotomy schools, about entities that contract for home phlebotomy or CPT performance.

Jerry Hurst asked whether contract phlebotomy services should be put on a LAB 116 for laboratory personnel. Bea OKeefe said, no.

### **Meeting dates for 2012**

Lorri Dean-Yoakum said the meeting dates for the CLTAC in 2012 would be March 2, June 1, September 7 and December 7, 2012.

### **New business**

Lorri Dean-Yoakum asked if there was any new business. There was none.

### **Future items**

Ms Dean Yoakum thanked the CLTAC members for their participation in 2011. She said that the last three meetings had a quorum of members. She asked for future items to be discussed by the CLTAC.

- Karen Nickel asked that the CLTAC address a renewal cycle for CLS training programs.
- Jim Ottosen asked for a new list of CLTAC members. Morton Field asked for an email roster of CLTAC.
- Karen Nickel hoped the CLTAC subcommittee would see draft personnel licensing regulations before the March meeting. The CLTAC concurred.
- Jim Ottosen asked that the by law review and revision be continued.

**Meeting adjournment**

Hearing no further discussion, Lorri Dean-Yoakum asked for a motion to adjourn. Tim Hamill moved that the meeting be adjourned, Jerry Hurst, seconded and the CLTAC voted to adjourn the meeting at 12:40PM.