

Clinical Laboratory Technology Advisory Committee

Minutes of the June 1, 2012 Meeting

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

CLTAC members participating

Michael Borok, Anthony Butch, Tim Hamill, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Les Revier, Fred Ung, Lorri Dean-Yoakum (chair),

Former CLTAC members participating

Imre Fischer, Sol Notrica, Jim Ottosen.

DPH staff participating

Zahwa Amad, Norma Barocio, Ron Harkey, Robert Hunter, Paul Kimsey, Nema Lintag, Yangzhu Long, Vickie Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Bea O'Keefe, Jan Otey, Tammy Pahland, Judy Schlosser, Robert Thomas, Kathy Williams, Gwen Wong.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum. She apologized on behalf of LFS for the meeting notice not going out to everyone as usual. Ms. Dean-Yoakum thanked Kaiser Permanente for providing the videoconference center in North Hollywood and the telephone bridge. A roll call was conducted of CLTAC members and other participants, and Ms. Dean-Yoakum noted that a quorum was present for the meeting. Jim Ottosen questioned the quorum but this was confirmed.

Approval of the March 2, 2012 meeting minutes

Corrections were made to the minutes from the March 2, 2012 meeting minutes. After correction, Lin Kassouni moved for approval, Salim Rafidi seconded, CLTAC approved.

Department news

Debbie Rogers, Deputy Director of the Center for Health Care Quality gave an update for the department. She said the state was still faced with dismal budget issues, with a \$15-16 billion shortfall. The budget "May revision" was still looking for ways to cut costs. This may mean a 5% pay cut for employees, 38 hour work week or 4 day work week with state offices closed on Fridays. This raises concerns about how the department will provide needed services to the public. The governor is working with labor unions to negotiate a 5% salary cut. This can be done by the governor or by the legislature. Some tough decisions need to be made.

Ms. Rogers said the Department of Public Health is working on a strategic plan to guide the department in future activities.

Tim Hamill asked why LFS would be impacted since its revenue is in a special fund. He said the work the LFS does is very important. The labs pay their fees but LFS has reduced work time. Ms. Rogers said all CHCQ programs are special funded but

all are still impacted.

Bagley Keene and status of the regulation package

Tammy Pahland was introduced as new Staff Counsel for LFS. She was asked to address these issues today.

Is the CLTAC subject to Bagley Keene restrictions? As a follow up to the previous discussion by Sharon Simms of CDPH legal staff, it has been determined that since the CLTAC is not specifically named in the Bagley Keene (B-K) legislation, it is not subject to all B-K transparency requirements. However, Ms. Pahland said it was in the best interest of the department that the CLTAC follow the B-K guidelines, such as open meetings, published agendas, and so on.

What is the involvement of the CLTAC on the regulation package revision? The department heard the CLTAC's concerns about the state of the regulation amendments after the CLTAC meeting in March. Ms. Pahland said development of the personnel licensing regulations has been taken back from the Office of Regulations and returned to LFS. LFS is now making good progress on the package, is addressing public comments and CLTAC concerns. It is hoped that a draft will be ready in September.

Lin Kassouni asked when the CLTAC would be able to see the new draft, before release to the public, or at the same time. Ms. Pahland said she would check with administration whether CLTAC would get prior review. Joseph Musallam asked how different the revisions would be from the draft prepared by the Office of Regulations that the CLTAC saw previously. Bea O'Keefe said the effort now is to clarify the language and make it easier to implement. Ms. Pahland said there was lots of collaboration going on now in LFS on the regulations.

LFS Update

Bea O'Keefe said the hiring freeze had been lifted after a 1-1½ year freeze. LFS was in the process of interviewing and hiring new staff, mostly clerical support staff. Hopefully this will improve client services. She encouraged persons to contact LFS staff by email rather than by phone. Ms. O'Keefe said 4 new examiners had been hired, 2 in personnel licensing, 1 in CLIA and 1 in laboratory licensing. She said there would be another civil service examination for Examiners on June 7 and encouraged people to apply and consider a job with state government.

Ms. O'Keefe reminded the CLTAC that SB 744 several years ago authorized the department to approve accrediting organizations (AO) for deeming authority of laboratories that they accredit. Laboratories choosing AO oversight would be given a certificate of accreditation by the department instead of a license, and would be subject to AO inspections rather than routine state inspections. Alternative sanctions, such as loss of accreditation, would be imposed by the AO and principal sanctions, by the state. Ms. O'Keefe said LFS has received 4 applications already and Dr Nickel is the primary reviewer.

Joseph Musallum asked which AOs had applied and Ms. O'Keefe said that in the interest of confidentiality, she could not say.

Ms. O’Keefe said LFS continues to get questions on the following issues. Can an unlicensed person calibrate an instrument? The answer is NO. Can a radiologic technologist perform laboratory tests or phlebotomy? The answer is NO, they can do injections for contrast media only. Can a phlebotomist perform waived tests and can a certified medical assistant work in a hospital? The answer is NO to both.

Nominations submitted for CLTAC

Lorri Dean-Yoakum said nominations for CLTAC membership had been solicited from professional organizations, and there were more nominations than vacancies. LFS will submit the names to the Director’s office with terms beginning December 31, 2012. These new CLTAC members would continue until December 31, 2016. She thanked current members for their continuing involvement.

Results of Survey on regulation changes for training programs

The CLTAC had asked that LFS conduct a survey of currently approved training programs, asking them about proposed changes to their terms of approval in the new regulations under development. Bea O’Keefe said fifty training programs were surveyed and the results were as follows:

Should training programs be approved for four years and subject to renewal? 21 YES, 12 NO. Comment: renewal cycle should be consistent with NAACLS cycle.

Should training program renewal documentation include a request for information on number trained and number licensed? 25 YES, 8 NO. Comment: LFS has that information. LFS comment: it is difficult to retrieve.

Should the CLSI standards (introduced into the training program regulations and reviewed by CLTAC at their last meeting) be required of all training programs? 15 YES, 19 NO. Comment: maybe a one day seminar on the standards would be appropriate for some training programs.

Michael Borok said an online survey would get broader coverage. Ms. O’Keefe thought that this survey was adequate and a larger one would offer no additional information.

Legislative Bills

AB 761: Jan Otey said this bill would authorize optometrists to direct their own waived laboratories and perform non-waived tests. They currently are only authorized to perform waived tests under existing law.

AB 2356: Jan Otey said this bill defines “sexually intimate partner” and provides immunity for the physician who allows an assisted reproduction technology (ART) recipient of sperm from a known donor to waive repeat sexually transmitted disease (STD) testing of that donor. However, a physician is not required to provide this waiver.

AB 1976: Robert Thomas said this bill would require acceptance of military experience for licensure purposes. The purpose is to help military veterans and alleviate labor shortage in the scientist categories. State law currently accepts

military experience for licensure of CLS and MLT applicants.

SB 975: Robert Thomas said this bill may impact LFS and clinical laboratories. It would bring all licensing boards under the Department of Consumer Affairs. It would not impose any further standards on physicians, pharmacists and others already overseen by Consumer Affairs.

SB 1267: Kathy Williams said SB 1267 was called the Genetic Information Privacy Act. It would add privacy rights to cover genetic testing information. Such results could not be released without written authorization.

Karen Nickel asked how SB 1267 would impact online genetic test orders. Ms. Williams said it would not affect it. Jerry Hurst asked whether a physician was required to get consent to perform. Ms. Williams said the sample would have to be blinded for lab and doctor. Dr. Borok said this goes beyond normal confidentiality. Ms. Williams agreed and said this would impact the state's prenatal and postnatal testing programs. P. Davenport asked why HIPAA would not cover this. Ms. Williams said this bill would extend beyond HIPAA. Dr. Borok said, way beyond HIPAA. Dr. Borok asked whether forensic DNA, paternity testing would be impacted. Robert Hunter said this would impact RBC phenotyping for blood donors. Ms. Williams said, yes, this bill would have no or few exemptions.

SB 1481: Ms. Williams said this bill was sponsored by the California Association of Pharmacists and would exempt pharmacists and pharmacies from clinical lab law entirely. Currently pharmacists are authorized to perform (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived, provided they have a physician and surgeon as their waived laboratory director.

Salim Rafidi asked what LFS's role was in advising the department on this bill. Ms. Williams said this was done confidentially via internal communication. Jim Ottosen asked what qualifications would be expected of a pharmacy lab director. Ms. Williams said CLIA does not restrict pharmacists but state law does.

SB 1199: Ms. Williams said radiologic technologists are authorized to do venipuncture and in-line draws for radiologic purposes, but are not authorized to perform phlebotomy. She said this could be part of their scope of practice, but would have to be in their own law, not laboratory law.

New CDC HIV algorithm

Bea O'Keefe handed out a new HIV testing algorithm released by the CDC for confirming HIV screening tests. This new algorithm reflects HIV tests which are very sensitive, but less specific, and are used for screening. There is no confirmation test required, but state law at CCR 1230 makes further requirements, such as FDA approval of kit, confirmation using CDC protocol, a QA program, and competency of testing personnel.

Lorri Dean-Yoakum asked whether the new guidelines would be published in the MMWR. Ms. Williams did not know, but expected they would appear either separately or imbedded. She noted that over-the-counter HIV testing would be authorized by the FDA soon. Bob Hunter asked whether the third and fourth

generation HIV testing would be for HIV antigen or antibody. Ms. O'Keefe thought it would be both.

Hospital Council Meeting

Robert Thomas said there had been a short meeting and he had no report. Dr. Hamill referred the CLTAC to the OSPOD website that gives the EDD summary of the laboratory market in California (EDD.ca.gov).

CLIA section update

Donna McCallum reminded the CLTAC that recent updates of CLIA 2003 do not impact California laboratories as California law is still based on CLIA as of January 1994.

Ms. McCallum said the EP23 publication, called the IQC Plan, replaces EQC. It is voluntary and permits labs to customize their QC. She discussed the top 10 CLIA deficiencies in the US and how this impacts California. Lorri Dean-Yoakum asked what happens if a lab does not adopt IQC. Ms. McCallum said it must go back to the CLIA regulations for QC prior to EQC.

Electronic health record guidelines are open for public comment now, closing on September 11.

Ms. McCallum said that LFS had performed 534 surveys as of the end of April. For April, LFS staff performed 17 initial surveys, 53 re-certifications, 7 validations and 4 proficiency testing sanctions.

Ms. McCallum handed out an update on the CLIA program in the US. In our Region IX, as of January 2012, these are the number of labs in California:

COC	1571 (of 19,387 in US)
COW	14090 (of 159,256)
CPPMP	3494 (of 37,559)
COA	1284 (of 15,697)

Facility licensing section update

Kathy Williams reported that LFS is receiving a steady 100 new registrations and 3-5 new laboratory license applications per month. She said that Tom Tempske had retired and that she would be handling complaints until a replacement was hired. She was busy training new clerical support staff and trying to get the paper documents re-filed in the new file system. Ms. Williams hopes that turnaround times on laboratory licenses and registrations will improve as new staff gets trained.

Complaints Ms. Williams said LFS had received 11 complaints since March 2012, as follows: a laboratory operating without a license (1), draw station with dirty bathroom (1), unauthorized testing (6), unqualified phlebotomy instructor (1), missing test reports (4). There were no specific complaints on the DPH reportable missing requirement.

Out of state licensing Ms. Williams said there was a backlog of 20 new applications and 50 renewals. Gwen Wong is going to assume responsibility for the out of state

licensing program.

Jerry Hurst asked where a laboratory is supposed to mail its license check. Ms. Williams said the check can come to LFS in Richmond. Ms. O'Keefe wants the check to go to Accounting in Sacramento, but it is delayed there. LFS recently obtained RPS equipment to process checks electronically in Richmond and staff is being trained. Robert Hunter asked about where other checks, such as biologics, should go. Ms. O'Keefe said LFS was working on implementing tissue bank, biologics and personnel licensing check processing using the RPS equipment in Richmond.

Personnel licensing section update

Zahwa Amad said that examiners in personnel licensing section (PLS) were off furlough effective May 2012 after being subjected to it since February 2009. Her section has several vacancies. Despite adding 6 clerical support staff, personnel licensing section still has 3 vacancies. PLS has lost 9 support staff and 3 examiners in the last 3 years. She is pleased to announce that Martha Obeso has been hired as a new Examiner II. Martha is a licensed clinical microbiologist scientist and certified public health microbiologist. She worked in the San Francisco Department of Public Health for 15 years and the State's Microbial Disease Laboratory for the last 5 years.

Nema Lintag, program manager for CLS/MLT licensure, said the MLT program has grown in the 4 years since its implementation. LFS has received 399 applications, 228 MLTs have been licensed, 87 are currently waiting for their examination, and 27 are awaiting other documents. LFS has received 9 applications for MLT training programs, but 3 have closed (Hartnell, Diamond, IME). In the US, about 166,860 MLTs can perform any test, whereas in California, the 228 licensed MLTs are limited by law.

Michael Aidan said that Kaiser Permanente was starting to hire MLTs in the Bay Area, but UCSF could not hire them because of their limited scope of practice. He said DeAnza College started with 73 students, 24 graduated, 21 were licensed, but only 16 were working. Joseph Musallum asked whether the new regulations could expand the work scope of MLTs. Robert Thomas said their workscope was limited by statute.

Joseph Musallum asked whether there was an increase in CLS applications from outside California. Dr Amad said that number remains quite steady.

Biologics and tissue bank update

Ron Harkey said this program had finally gotten some clerical support. The tissue bank licensing program has experienced modest growth, and the tissue bank and biologics program overlap in technology. He introduced Robert Hunter, Examiner II in the biologics program. Mr Hunter went over some case studies that he had encountered. He said that LFS licenses about 150 blood banks with about 800 collection centers. "Biologics" means any facility that processes blood or blood products for human use. Mr Hunter said there had been 186 complaints in California since 2007 involving blood banks and other biologics facilities. The LFS Biologics Program has been working with the FDA Office of Criminal Investigations, local

district attorneys, as well as local health agencies in the investigations. LFS is currently involved with 7 ongoing investigations. Other complaints about blood banks have involved misidentified antibodies, mislabeling of blood products, unlicensed persons doing testing, and persons with infectious diseases being recruited as donors.

Training programs

Karen Nickel said she had been helping with training programs and has enjoyed the interaction with the programs and universities. She summarized the approved training programs as follows:

CLS training programs approved in California = 92, estimated 242 training positions

San Francisco State University affiliated programs = 34

San Jose State University affiliates = 20

Kaiser Permanente = 19

CL Specialist training programs approved in California = 54

C genetic molecular biologist scientist = 21, estimated 45 positions

C cytogenetic scientist = 12, estimated 65 training positions

Clinical chemist, histocompatibility, microbiologist, scientist = 5 each

Dr Nickel said the list of training programs had been updated on the LFS website effective May 15, 2012, and there were no pending CLS training program applications for the September 2012 start date. LFS has spoken with new CLS programs pending in San Diego, Ventura County and Sonoma, and anticipates receiving these applications soon. California State University Los Angeles is expanding their program to include California Polytechnic University Pomona in September 2012.

New business

Chairperson Lorri Dean-Yoakum asked if there was any new business.

Joseph Musallum asked for clarification of “molecular techniques”. Karen Nickel said this would also hopefully be addressed in the new regulations. Robert Thomas said the issue was “molecular biology”. Jerry Hurst said there needs to be a definition of molecular biology separate from genetic molecular biology. Robert Thomas said molecular biology was a “technique,” not a specialty.

Future items

Ms. Dean-Yoakum asked that future agenda items be sent to her for the next meeting.

Next meeting

Ms. Dean-Yoakum said the next meeting of the CLTAC would be September 7, 2012.

Jim Ottosen said that was a four day work week for many people and the meeting should be changed. Ms. O’Keefe said room reservations had already been made and it would be hard to change.

Adjournment

Donna Kirven made a motion that the meeting be adjourned, Michael Borok, seconded, and the CLTAC voted to adjourn at 12:20 PM