

Clinical Laboratory Technology Advisory Committee
Minutes of the March 2, 2012 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, Lee Hilborne, Jerry Hurst, Lin Kassouni, Carmen Maldonado, Salim Rafidi, Les Revier, Fred Ung, Margie Morgan.

Former CLTAC members participating

Sam Chafin, Morton Field, Imre Fischer, Robert Footlik, Dr. Freedman, 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, Don Miyamoto, Bea O'Keefe, Paul Kimsey, Jan Otey, Tammy Pahland, Debbie Rogers, Judy Schlosser, Robert Thomas, Kathy Williams.

Welcome, general announcements and roll call of CLTAC

The meeting was called to order by CLTAC chair 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 December 2, 2011 meeting minutes

Ms Dean-Yoakum asked if there were any corrections to the December 2, 2011 minutes and a number of corrections were made and documented by LFS. After these corrections were made, Lin Kassouni moved that they be accepted as corrected, Salim Rafidi seconded, and the CLTAC voted to approve the minutes as amended.

Department news

Paul Kimsey, Office of Public Health State Laboratory Director, gave an update on department news. Dr. Kimsey reported that Ron Chapman, Director of CDPH, is interested in Public Health Accreditation through the Centers for Disease Control (CDC). Accreditation is a three year process. As part of this a strategic map (plan) is required. CDPH has a draft plan. However, some programs have not been able to identify themselves on the map. Feedback is being received. It is critical that every employee needs to see where persons fit in. Jerry Hurst asked how the plan and feedback coordinates in the Public Health Accreditation Program and select agents; i.e, between the state and local county process? Dr. Kimsey said it may coordinate but was

not sure. He said the plan has more functionality; e.g., do you track QC. The aspects for labs are not as stringent as CLIA. It includes the Drinking Water and Environmental Health state programs. Jim Ottosen stated that the draft was completed on the 4th of January. He asked why did the CLTAC just get it? Dr. Kimsey said that there was a meeting of the executive staff and it was internal to the department for a while. He added that there is still plenty of time to comment on the plan. Dr. Borok said that to him the bottom line is Medicare patients and making results available to patients.

There have been changes in the Center for Health Care Quality. Debby Rogers is the Deputy Director for the Center. Pam Dickfoss was serving as the Acting Deputy Director for the Center and is now the Assistant Deputy Director. Ms Rogers previously worked for the legislature as a lobbyist. Confirmation of the Director of CDPH is requiring staff to prepare reports for his use in confirmation hearings.

Laboratory Field Services Update

Bea O'Keefe, Chief LFS, gave the following update.

The department's strategic map plan is to leverage key opportunities to define & shape the future of public health in a changing environment. The department wants us to share this with external stakeholders and get their input. The map is on the CDPH website.

The state had frozen the hiring of new personnel for approximately one and one-half years. Since the last meeting in December 2011, the governor has lifted the hiring freeze. LFS has been busy interviewing for many vacant positions. So far, we have hired or in the process of hiring 4 Examiners. In addition, LFS is in the process of hiring 18 program technicians and 2 office technicians. We will be sending out a postcard to CLSs and public health microbiologists in the greater Bay Area and Los Angeles County in March and will be giving the exam in May. We hope to be able to fill our vacant Examiner positions after that time.

The governor has been looking at all boards and commissions as to their usefulness. The CLTAC was identified as a committee for review. Bea said that she prepared a justification citing the legislative creation of the CLTAC, the minimal expense imposed by committee meetings, the important role it plays in advising the department and a recommendation that it be retained.

In regard to the Electronic Health Record Program and the incentive money available for hospitals & physician offices to use certified equipment for reporting lab results electronically, this program has had a slow response. The response has been especially slow by physician offices. Federal officials have released a proposed rule extending Stage 1 until fiscal year 2014. Health care providers could remain in stage 1 for two years.

In regard to genetic testing and the federal government attempts to decide about regulating lab developed tests. Nothing much has moved forward in terms of

regulations. However, the NIH has launched a web resource to provide consumers and healthcare providers with information about the genetic tests on the market. The Genetics Testing Registry was unveiled on February 29th of this year. The registry will provide information on the purpose of the test, its limitations, the name and location of the providers, whether for clinical or research use, what methods are used, and how the results are measured. The NIH will not verify the content but will require the test providers to agree to a code of conduct for accuracy. The registry will also provide details about a test's analytic & clinical validity and clinical utility. It takes about 30 minutes to provide the minimum information and around 2.5 hours to answer more optional questions.

Role of the advisory committee

Jim Ottosen brought up a question regarding feedback that was to be provided by Sharon Simms, Senior Counsel in the Office of Legal Services, regarding whether CLTAC meetings were subject to Bagley-Keene (B-K) Act for open public meetings as it was stated at the last CLTAC meeting that there is a finite list of committees for which Bagley-Keene applies and as of April 2009, CLTAC was not on the list. Mr. Ottosen said that Ms Simms said she was going to investigate to determine whether Bagley-Keene applies to CLTAC meetings and report back to CLTAC during the March 2012 meeting. Instead of Ms Simms reporting back to CLTAC Tammy Pahland, in the Office of Legal Services, will respond by the June 2012 CLTAC meeting.

Continuation of By-Laws Change, Article III, Membership and Term - Discussion

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.

Salim Rafidi had previously asked if the CLTAC should change the composition of its members at the last CLTAC. Lorri Dean-Yoakum had said that was a different subject. Mr. Rafidi, per discussion at the last CLTAC, brought up today that he still would like to discuss the composition of the CLTAC. Ms. Dean-Yoakum said she prefers to wait until a decision on membership terms is made. She did list the current categories for CLTAC as follows:

4 CLS, one bioanalyst, one cytotechnologist, one clinical chemist, one clinical microbiologist, one clinical toxicologist, 2 licensed physicians who are pathologists, one licensed physician internist, one public health microbiologist, one public member, 2 physicians in office based testing, one R.N. in bedside testing, one RCP, one person doing lab testing in a clinic, one healthcare administrator, one CLS member of labor union, and one non-voting member for a total of 21 members.

Continuation of Bylaws discussion was deferred to the June 2012 CLTAC meeting.

Nominations Submitted for CLTAC

Lorri Dean-Yoakum said there are nominees for the CLS and the RCP spots. Lin Kassouni asked how realistic it was to expect they could be seated by June 2012.

Discussion of Draft Language for Training Schools

Bea OKeefe said OR had the March version of the new personnel licensing regulations 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. One of the suggested additions by OR was insertion of QMS-QSE generic language that would be applicable to any training program. A handout was provided covering several points labeled A through L. Bea OKeefe said that she would like to get feedback on the QMS-QSE language and whether this language should be added in regulations. A lengthy discussion on this topic ensued.

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.

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

Joseph Musallam said that the proposal for QMS-QSE should be given to the people involved in training. He said that academia needs to be involved.

Bob Footlik said that the training year would need to be expanded due to the added requirements. He asked how would one test knowledge of these standards.

Becky Rosser commented regarding phlebotomy programs and CLS programs. She said that the course outline is already dictated in phlebotomy. It would be impossible to add these to the phlebotomy program. Also, to implement these requirements into every CLS program would be a lot of work and it is questionable about any added value should these requirements be implemented.

Dr. Borok questioned teaching QSE in the management series and asked for definitions. He said that it is difficult to apply these requirements until a person is in the field.

Salim Rafidi said the phlebotomy training is too short to add this information. Also, he added that it would be difficult to add these requirements to the MLT program. He said that a choice would need to be made to decrease the amount of scientific information provided in the training if this QMS-QSE information were to be added.

Jim Ottosen said this discussion needs to go to the CLTAC regulations subcommittee.

Phyllis Walker said that this information looks like what is required for blood banks. She thought that it could be covered as one lecture in a training program.

Linn Kassouni said that the information would be excellent as part of a degree program rather than as part of a training program.

Bob Footlik said that he does not think this type of curriculum is appropriate for phlebotomy training programs.

Michael Borok made a motion which was seconded by Linn Kassouni; "CLTAC recommends to LFS to send this two page proposal to each training program or to the list of educators for their comments with an appropriate response deadline."

The motion passed with 10 yes votes.

Timeframe for Renewal of CLS Training Programs

Bob Thomas discussed this item which was initiated by Karen Nickel. California requirements in the B&P Code and in regulations Title 17, CCR 1035 do not have a time frame for renewal of approved CLS training programs. There are specified times for phlebotomy and MLT training programs. The question is what should be the time deadline for an approved program to have to apply for renewal?

Joseph Musallam said that 5 or 7 years for renewal would be consistent with NACCLS programs.

Salim Rafidi said that the renewal process for phlebotomy is a lot of work every 2 years. For CLS, he said that every 6 to 8 years would be appropriate if the renewal package was as big as the initial application.

Bob Thomas asked if there should be triggers that could be applied to renew some programs more frequently. What should those triggers be?

Joseph Musallam and Salim Rafidi said that there are questionable schools. They said that sometimes the paper work does not give the whole picture.

Bea OKeefe gave information on BPPE approval rather than registration.

Jerry Hurst said it depends on the renewal documents that are required for renewal. The amount of time and work to fill these out should be considered and that this will assist in determining the renewal cycle.

Dora Goto asked the following question for programs that are NACCLS accredited; would LFS accept that accreditation without doing a LFS separate approval?

Joseph Musallam said that California should retain its standards. Zahwa Amad said that inspections of lab schools would take additional time.

Bea OKeefe said that LFS would like a recommendation so that the regulations would be clear on what is required in regards to a time line for renewal of CLS training programs.

Someone from LA commented that she didn't think the renewal application would be as long as the initial application. For example, she didn't think that equipment has to be listed. She thought 5 years is okay.

Geraldine Albee said that LFS should send out to the schools what time frame would be required. She added that if we are going to require information it should not be overly detailed as the university programs are strained for resources.

Salim Rafidi said the department needs to decide on what time frame they want.

Lin Kassouni said that the department can come out with a recommendation and put it in the letter that is being sent out regarding QMS/QSE standards.

Lee Hillborne asked what do we know about other states and what they do? If it works in other states; for example, NACCLS then we should do it here. Salim Rafadi said the California has more stringent requirements; the rest of the approval process is NACCLS.

Linn Kassouni made a motion to CLTAC and Lorri Dean-Yoakum seconded it. The motion is "LFS will recommend a timeframe and the process for renewal. LFS will solicit input from the appropriate California approved training programs regarding the renewal process for training programs." The motion passed with the following yes votes; Richmond – 5, LA – 4, phone – 1. A total of 10 yes votes.

Salim Rafadi asked if LFS has a position about sharing clinical facilities in a training program.

Joseph Musallam asked about whether LFS would accept a consortium among training schools. Bea OKeefe said that there is no prohibition against a consortium; however, the requirements specify specific approval of each laboratory. Joseph responded with what is the role of LFS? Bob Thomas said that the role of LFS is to approve training as specified in statute and regs. He added that it is required that for any person to operate a school or conduct any course for the purpose of training persons to perform duties as defined in regulations of the department, approval by the department must first be obtained.

Status of Legislative Bills

Kathy Williams reported on legislation for pharmacists.

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. He presented a PowerPoint slide presentation.

Report on Ad Hoc Committee's HWDC-Action Plan Meeting on 2/15/12

Robert Thomas, LFS Personnel Licensing, reported on the California Workforce Investment Board (CA WIB). CA WIB established The Health Workforce Development Council (HWDC) in 2010 as a Special Committee of the State Board and is looking for receiving feedback in several areas. Individuals or the CLTAC as a group may choose to send in recommendations no later than March 15th to:

Cathy Martin
Director, Workforce
California Hospital Association
Tel: (916) 552-7511
email: camartin@calhospital.org

in regards to the following:

The HWDC subcommittee's action plan is in development and covers several areas including:

- Clinical Laboratory Scientist
- Medical Assistant
- Nursing
- Physician Assistant
- Primary Care Physician
- Public Health
- Social Work
- Crosscutting – Data Clearinghouse
- Crosscutting – Education and Recruitment and Retention

The Clinical Laboratory Science Action Plan currently includes three broad strategies as follows:

1. Utilize distance education and other innovative delivery models in order to expand statewide access to special courses required for CLS licensure.
2. Improve MLT to CLS course articulation so that certain science courses taken at a California Community College by MLT students are recognized by the California State University System as upper division; thereby, allowing MLTs to more efficiently earn a bachelor's degree and enter a CLS program.
3. Increase CLS training program capacity by increasing the number of training slots for CLS trainees in California by expanding the number of clinical laboratory practical training sites approved for training; especially, for small and rural hospitals. It would appear to achieve this that a statutory change or regulations would be required to implement B&P Code Section 1222 that says the department may approve schools that are NAACLS accredited.

Another objective was brought up at the February 2012 meeting. This objective is to provide an adequate number of qualified CLS licensees as trainers who have clearance from their employer to participate as trainers to licensed trainees. This is believed to be necessary as CLS training program capacity is increased as each trainer is limited in their ability to provide adequate direct and responsible supervision to trainees for the practical laboratory training. In addition, this issue is complicated in that many employers feel that to invest in training is an added cost. This appears to be confirmed by the fact there are many approved but unfilled training slots each year.

Personnel Licensing Section (PLS)

Zahwa Amad, PhD, Section Chief for LFS Personnel Licensing thanked the Personnel Licensing Section staff for working hard to serve the public during this difficult time of staff shortage.

She said that Examiners are still subject to one unpaid day/month. The Governors' executive order of the hiring freeze was lifted in Dec 2011. We are racing to fill the vacant position at PLS before this window is closed. She thanked Corinna Lam, LFS program analyst, for working hard to advertise, recruit, set up interviews, and submit paperwork to fill LFS vacancies.

In the month of Feb, PLS filled two positions for program technician 1 (PT1). We have added two new staff for renewal, Ludelia for phlebotomy renewal and another for CLS renewal, Lin Chen. Currently, PLS has four vacant PT2: We interviewed and selected candidates, the paperwork is with HR. Hopefully they will be on board in a month.

Dr. Amad announced the promotion of Carol LeGuie to a supervisor of Program Technicians II. Carol joined LFS almost four years ago as an office technician. She quickly became the lead staff at PLS working in all areas of PLS including renewal, CE and is the coordinator of CLS trainee applications. She is currently studying information technology at University of Phoenix. Dr. Amad also welcomed back Examiner Frank Barnes after 6 months absence.

PLS filled one Examiner I position. There is still one vacancy for Examiner I.

Dr. Amad said that she wished to introduce Ms. Yangzhu Long. Ms Long joined LFS in Feb, 2012. She is in training in the phlebotomy program. Ms. Long holds a medical technology Bachelor degree from Framingham State College, Massachusetts. She worked for 5 years as medical technologist in the specialty of microbiology. She is ASCP certified since 1994 and held a CLS license in CA for the last 10 years. Prior to joining LFS, Yangzhu worked as a contract staff on the Richmond campus with Genetic Disease on the State newborn screening program using molecular biology tools. Prior to that she worked in the virus lab.

Dr. Amad announced the promotion of Nema Lintag from Examiner I to Examiner II in Feb 2012. Nema joined LFS in 2007 as an Examiner I. She served in the phlebotomy and CLS programs. She became the lead staff for MLT in 2009 and the lead staff for

CLS in 2010. Prior to joining LFS, she was a lab operations manager at Kaiser, Richmond.

Dr. Amad said that LFS was making progress with the backlog accumulated from two years of furloughs 2009-2011. The LFS website was updated with CLS training and MLT training schools. She requested that people send emails to LFS as it was difficult to answer all the telephone calls playing telephone tag.

Dr. Amad said she pointed out additional improvements in the PLS section:

1. The trainee licenses are now on an annual cycle. We adopted your previous recommendation. It is valid for one year from the issue date rather than expiration by 12/31.
2. The Director license application has been online since Nov 07, 2011 through the LFS's online contractor in Sacramento that processes all new online phlebotomy, CLS trainee and CLS applications. This eliminates the wait time for mailing or faxing paper applications to directors. It provides accountability and speeds up the process.
3. The following are some statistics of Jan 2011 through Dec 1st, 2011 about the CLS program/MLT program that the examiner Nema Lintag prepared.
 - The MLT program: PLS licensed a total of 190 as of Nov 29, 2011 since it was launched.
 - The total MLT applications in 2011 was 88, total MLT licensed is 45 (51%). Those not licensed do not meet the MLT qualification requirements.
 - Total CLS trainee applications received this year was 507. Total trainee licensed 286 (56%). The others do not meet the academic requirements.
 - Total CLS applications (general and specialists) received in 2011 was 732. We licensed 533 or 73% of applicants, of those, 400 are generalists and 135 are specialists
 - Of the 400 CLS generalists licensed, 182 were CA trained, 63 were out of CA USA trained, and 153 were foreign trained.

Dr. Amad asked those present to remind their lab professionals to renew their licenses/certificates as soon as they receive their renewal notice as it does take 2 months to process. LFS has been issuing verification letters to applicants to help them. She also asked that the laboratories accept the LFS online verification and verification letters.

Facility Licensing

No report

CLIA Updates

Donna McCallum stated that this year marks the 20th anniversary for implementation of CLIA amendments.

Complaints update

Tom Tempske gave a brief update.

New business

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

Future items

None mentioned.

Meeting adjournment

Hearing no further discussion, Lorri Dean-Yoakum asked for a motion to adjourn. Jerry Hurst made the motion to adjourn the meeting. Lorri Dean-Yoakum seconded.

Next meeting will be Friday, June 1, 2012