

Clinical Laboratory Technology Advisory Committee

Minutes of the December 7, 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, Elizabeth Dequinia, Vickie Finson, Laurie Fuller, Tim Hamill, Lee Hilborne, Lin Kassouni, Carmen Maldonado, Les Revier, Salim Rafidi, Fred Ung, Lorri Dean-Yoakum (chair).

Former CLTAC members participating

Sam Chafin, Imre Fischer, Robert Footlik, Sol Notrica, Jim Ottosen, Fred Struve.

DPH staff participating

Zahwa Amad, Alan Ankerstar, Grace Byers, Pam Farrell, Ron Harkey, Tina Hashemi, Robert Hunter, Eul Hurley, Paul Kimsey, Nema Lintag, Yangzhu Long, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Bea O'Keefe, Jan Otey, Tammy Pahland, Judy Schlosser, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams, Mary Wogec.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum. 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.

Approval of the September 7, 2012 meeting minutes

One addition was made to the minutes from the September 7, 2012 meeting. Tim Hamill moved for approval as amended, Salim Rafidi seconded, CLTAC approved the minutes as amended.

CLTAC Nominations and Election of Chair

Chairperson Lorri Dean-Yoakum explained that the By Laws require a new CLTAC chair to be elected at the December meeting and to begin his/her term the following June. Tim Hamill nominated Ms. Dean-Yoakum, Lee Hilborne seconded and moved the nominations close. Ms. Dean-Yoakum was elected unanimously to another term.

Bea O'Keefe, Chief of LFS, said she was still working on the CLTAC nominations for 2012. She had received nominations from the CSRCP, CAMLT, Blood Centers of California, CAB, CMA, CHCA and ASCLS. She said she still needs a nomination for internal medicine. There are more nominations than vacancies. Dr. Borok asked if the CMA had nominated a POL representative. Ms. O'Keefe said she was looking for three from the CMA: pathologist, POL, and internal medicine.

Lorri Dean-Yoakum asked if subcommittee members needed to be nominated

officially. Ms. O’Keefe said anyone can be appointed.

Department news

Dr. Paul Kimsey, Deputy Director of the Office of State Public Health Laboratory Directors (OSPHLD), gave an update for the department. He welcomed the former CLTAC chairs to the meeting, Fred Struve, Robert Footlik, Sam Chafin, and Lee Hilborne, as well as Jim Ottosen, former CLTAC member. Dr. Kimsey said he would “walk” the CLTAC nominations to the Director as soon as they are ready to expedite.

Dr. Kimsey said there is a lot of interest on how the Supreme Court will rule on the constitutionality of the federal healthcare reform law. He said there was concern how the new act would affect the Department of Public Health. Dr. Kimsey said the Department is working on a Strategic Plan for Dr. Chapman and mapping program activities as the first step. This will lead to a statewide health plan reviewing its processes and relationships. He said Prop. 30 passed and should be of some help with budget shortfalls. CDPH will not be impacted too much but California may still be \$1.9 billion in the red despite Prop. 30.

Dr. Kimsey said there used to be 38 county public health laboratories, but that number is declining as the services are being outsourced by the counties. The new healthcare reform bill (ACA) will put new pressures on services and may create revenue problems. Dr. Nickel asked if the law required county public health laboratories. Dr. Kimsey said populations exceeding 50,000 persons were required to have services available but not necessarily in the county.

Tom Tempske asked if the counties can’t provide services, does testing default to state public health labs. Dr. Kimsey said state labs are the default laboratory, but the state labs may not be able to provide services either.

Lorri Dean-Yoakum asked what are the advantages of the Department being accredited. Dr. Kimsey said such accreditation is not routinely available, but the CDC favors dealing with accredited laboratories. Ms. Dean-Yoakum asked what the cost of accreditation is. Dr. Kimsey said he wasn’t sure, but it would have to be funded with special funds, not general funds.

Robert Thomas asked if the state would be getting any fiscal cliff money. Dr. Kimsey thought that it would, through the CDC and EPA.

Hanta Virus Survey

Dr. Jason Wilken, Epidemic Intelligence Service officer assigned to CDPH, reported on an employee survey of Hanta virus conducted in Yosemite. There was a cluster of infections with 3 deaths among visitors in Yosemite. This seemed to be located only in the signature tent cabins in Curry Village, and arose from deer mice feces. The symptom of infection is acute respiratory disease.

There were 3,000 employees working in Yosemite in the summer and none of them had symptoms of Hanta virus. CDPH and CDC were not aware of any cases among Yosemite employees. CDPH did a pilot study of 95 employees. This was expanded to a full study in October and 477 employees were tested. The limiting step in the collection was phlebotomy. Nurses were contracted from surrounding areas. The

department is completing testing of the employees now.

Tim Hamill said the persons infected were visitors, not employees, and asked what efforts were made to test visitors. Dr. Wilken said the CDC had tried to contact Yosemite visitors from outside the US and was unaware of any with Hanta virus symptoms.

Tim Hamill asked why certified phlebotomists were used since it was done on federal land, outside state purview requiring supervision. There was a question of liability and this was a study conducted by the CDC. Bea O'Keefe said that the CPTs needed to be under the responsibility of a laboratory and its director.

Jim Ottosen asked whether the test was for IgG or IgM Hanta virus. Dr. Wilken said both. Was centrifugation required before transport to state lab? No.

Robert Footlik said he agreed with Dr. Hamill that state law would not apply in a national park, and that CPTs would not be limited by their work scope.

Tom Tempske questioned why other categories of persons could not have drawn the blood, such as CLSs, RCPs, or EMTs.

Dora Goto asked if the infection arose from one particular tent or was it random. Dr. Wilken did not know whether only one tent was involved. She asked why the outbreak had occurred now, since mice have always been there. Dr. Wilken said it had been a milder winter and more mice may have survived.

Michael Borok asked what the results were. No employees had been sick and no test results. What is the issue here? Dr. Wilken replied that the results were not yet available.

Zahwa Amad asked about the effect of environmental temperature and Dr. Wilkin responded that he did not know what effect the environment may have played other than that it was a milder winter than usual.

Lorri Dean-Yoakum thanked Dr. Wilken for his presentation.

LFS Update

Bea O'Keefe said a team of persons had been working hard on the new personnel licensing regulations and mentioned Karen Nickel, Kathy Williams, Robert Thomas, Zahwa Amad, Tammy Pahland, and herself as the team members. LFS wanted to meet the timeframe for release of the draft to the CLTAC for preliminary review prior to or at this CLTAC meeting. The package will be emailed early next week.

Ms. O'Keefe said LFS was able to make some new hires after 1½ years of a hiring freeze. She said there were 3 examiner vacancies in the Los Angeles office that LFS hoped to fill.

Robert Footlik asked if the vacancies in Los Angeles were state-funded or CLIA positions. Ms. O'Keefe said they were state funded for state activities.

Ms. O’Keefe said there is concern about existing MLT training programs at DeAnza College and Diablo Valley College. The problem is low enrollments, high costs, and low employability of graduates once they are licensed. She said the MLT licensing program was implemented in 2005 and LFS expected 5,000 licensed MLTs within a few years, but as of now, there are only about 275 licensed. LFS is doing what it can to support the 2 college programs (above) but the MLT work scope is limited, and the work scope of unlicensed persons is thought to interfere. LFS will try to address this in the new regulations. We are interested in how the new Affordable Care Act may impact the need for MLTs. The unions are also concerned about MLTs competing for CLS jobs.

Michael Borok asked about supervisor requirements for MLTs. Ms. O’Keefe said it was onsite and at a 4 to 1 ratio. Robert Footlik added that no supervision was required for a MLT performing waived testing.

Kathleen Faraday of Diablo Valley College said low enrollment at her school was not a problem as she had 18 well qualified students for spring semester. She said funding was the problem.

Salim Rafidi said community colleges generally need 30 students per class to break even. Karen Nickel said when the MLT regulations were being developed, LFS did not foresee the link between community colleges and training locations. LFS thought there would be mostly independent training sites since there are already so many well-educated persons. Salim Rafidi suggested the problem was with the unions. Ms. O’Keefe said that some MLTs were being hired as lab assistants despite their education and training. Robert Thomas said that there is “low utilization,” no jobs for MLTs, so colleges don’t want the programs. Elizabeth Dequina said the unions support MLT licensure, but the problem is where do the students train after college? Ms. O’Keefe asked if labs would be training MLTs for their future staff needs. Salim Rafidi said there are lots of well-educated, unlicensed persons working as lab aides who should train as MLTs if that would be an advantage for them. Joseph Musallam said LFS should approve more MLT training programs and Nema Lintag felt that there was no hiring problem for new MLTs. Dora Goto said the problem in the Bay Area causing low hiring is the concern about the MLT work scope.

Status of the regulation package, DPH-11-012

Tammy Pahland, Staff Counsel for LFS, said LFS had made its deadline to get a draft of the new regulations ready by this meeting. It would be sent out next week to the CLTAC, the CLTAC subcommittee, and the CLTAC interested parties on the email distribution list. She said Dr. Nickel will go over the regulations in broad terms at this meeting.

Ms. Pahland asked the CLTAC to look at the regulation draft as a rough draft, a “fluid” document, needing input. She said this is a “pre-notice” review with no official responses. Comments should be submitted on single pages to Mary Wogec in LFS. LFS needs general comments, not wordsmithing. No explanatory Statement of Reasons is being sent with the regulations. Comments will be gathered, summarized, and included (or not) in the package. The regulation draft is large and complex, and LFS hopes to have the draft regulations ready for official public

comment this summer.

Salim Rafidi asked if this pre-notice was open to all commenters or only the subcommittee. Ms. Pahland said it was open to all. Robert Footlik said in the official public comment period, LFS would have to respond. Michael Borok asked how the public would access the draft regulations. Ms. Pahland said by email. Dora Goto asked when this comment period would be over. Ms. Pahland said comments were needed by LFS by February 15 to make the target of June for release for public comment. Joseph Musallam asked when the regulations might be implemented. Ms. Pahland said, hopefully in 2013.

Lorri Dean-Yoakum, Chair of CLTAC, identified the subcommittee of the CLTAC which would be doing the initial review and feedback of the package as Robert Footlik, subcommittee chair, Kathleen Doty, Jerry Hurst, Jim Ottosen, Salim Rafidi, Les Revier, Rebecca Rosser, and herself as ex-officio chair of CLTAC. All had agreed to serve. Tim Hamill made a motion to limit the subcommittee to these persons, Elizabeth Dequinia seconded, CLTAC approved. Ms. Dean-Yoakum said the charge to the subcommittee is to review and discuss the regulation draft, and make recommendations to the full CLTAC at the March meeting. This would become the official position of the CLTAC. Tammy Pahland reminded the CLTAC that an official public comment period would follow this preliminary review.

Personnel Regulation Package Overview

Karen Nickel gave a short summary of the history of this regulation package. The first regulation package released for public comment in 2010 had 330 respondents with about 10,000 individual comments. LFS was overwhelmed by the comments, and the Department pulled the package back. The Office of Regulations took over the package, renumbered and rewrote it, and the CLTAC got its first look in December 2011. This draft was considered unacceptable by the CLTAC. After support from the CCLA and CAMLT, the regulation package project was returned to LFS in early 2012. LFS set up a team to rework the package consisting of Tammy Pahland, Staff Counsel, Robert Thomas, Zahwa Amad, Kathy Williams, Bea O'Keefe, and Karen Nickel. This team has worked hard on the package with the intent to get it implemented in 2013. The Department legal staff authorized more CLTAC involvement with this package, including a pre-notice review and comments. The team's target was to get the new package to the CLTAC by its December meeting, and we are happy that we made it. Now we are anxious to see what the CLTAC and its subcommittee thinks about the draft.

Dr. Nickel said regulations are "lower level laws" superseded by legislation and the state constitution. Regulations are authorized by statute to clarify and explain how the law will be administered. Many of our clinical laboratory personnel laws are outdated, as they were enacted in the 1970's. The purpose of the new regulations is to update standards, recognize new technologies, and to ease the licensure process both for applicants and for department staff. As you read the draft, you will note that some of current law is amended and this is shown as underlined and struck out. Other sections are new and are shown as totally underlined. The ordering of the regulations has been revised to cluster similar issues. All the licensing and work scopes are now in new Section 1030, unlicensed persons in Section 1031, and training program requirements in Section 1035. The language and format is uniform

in all sections.

Some important changes have been proposed in these regulations. The work scopes of each category have been carefully clarified. Cytotechnologist licensure has been moved to Section 1030 with the other license categories. Changes have been proposed for phlebotomy certification and MLT licensure. LFS has attempted to improve recognition of non-US education and training leading to licensure. LFS proposes to give training programs an approval cycle and grounds for loss of approval to train. LFS received many comments on its previous version about licensure of doctoral scientists and developed postgraduate training programs consistent with state law. One thing that LFS has not done this time is create new license categories for biochemical geneticists and embryologists, because of lack of authority to collect license fees from these new categories.

Robert Footlik questioned the department's inability to collect fees for the new categories and asked whether the department or the community should sponsor legislation to add that to BPC 1300. Bea O'Keefe said there are 25 license categories already, asked if we really need more, and suggested this is a lot of work for a small number. Mr. Footlik said these categories are growing rapidly in the US. Lorri Dean-Yoakum said the CLTAC could suggest such a change to the department.

Tim Hamill thanked LFS for completing the draft and expressed the hope it would clarify who can do what test. Robert Thomas said if he felt this was not adequately addressed, to submit that as a comment.

Robert Footlik said the draft is over 150 pages long, has lots of information for the subcommittee, and can't be rushed. Karen Nickel said it should be an easier read now that it is "harmonized." She said to have any hopes of getting the package ready for public comment by this summer, CLTAC input is needed almost immediately.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, said the federal year ended on September 30, 2012. She said the LFS State Agency Review had just ended yesterday and she thanked all the CLIA staff for their hard work. LFS completed 871 surveys in the last federal year, 34 validations, and took 23 enforcement actions on behalf of CMS for condition-level failures and 48 actions for proficiency testing failures. Already in October, LFS completed 13 initial surveys, 59 re-certifications, 6 proficiency testing failure enforcements, and 1 validation survey.

Ms. McCallum said that eQC at 493.1256(d)(3) had been replaced as explained in a SIEP 23 document and change in Interpretive Guidelines sent to regional office staff. She said also that federal legislation at HR 6118 changed the automatic sanction for PT referral and there was more effort to implement electronic health records at the federal level.

Michael Borok questioned the automatic revocation for PT referral. Robert Footlik asked where in the process was HR 6118, and Tim Hamill said it had been signed already.

Robert Footlik mentioned QC by Risk Management as published by CLSI, and asked how that could be justified in California using CLIA as published in 1994? Donna McCallum said this is in conflict with state law and the more stringent law is enforced.

Facility licensing

Kathy Williams, Section Chief of Facility Licensing, said information had been gathered by the public health laboratories to show that much of the information that should be sent with specimens to public health laboratories is not sent. Many don't provide patient information such as addresses or the referring physician. This will become more critical with the new Affordable Care Act.

Robert Footlik asked why the state does not go after the laboratory for not providing the information. Tim Hamill said that often this information is not available to the laboratory referring the specimen.

Ms. Williams said LFS had 26 complaints against laboratories in the last quarter, mostly about the quality of laboratory tests and phlebotomy. She said her section was tracking new applications from pharmacists and optometrists for certificates of waiver and state registrations based on the laws that went into effect this year.

Diane Tyson asked if optometrists can direct their own labs now in California. Ms. Williams said they can, but they can only perform a limited number of waived tests on their own patients.

Personnel licensing

Zahwa Amad said LFS continues to receive about 75 new applications for CLS licensure each month or about 800 this year. This is up about 10% from last year. Of these CLS applicants, 623 were approved, 243 were trained in California, 228 outside California and 152 outside the US. Of those from outside the US, about 90% are from the Philippines. LFS also received about 155 clinical laboratory specialist applications this year, 33 for cytogenetic scientist, 33 for genetic molecular biologist scientist, 17 for microbiologist scientist, and the rest distributed among the other categories.

Tom Tempske asked how many people are leaving the field each year. Dr. Amad said this is difficult to determine since many persons retain their licenses but maintain inactive status for 5 years, or simply don't work.

Dr. Amad said there were 907 persons licensed as trainees and 20 new training programs approved this year. There is no backlog of CLS training programs and currently it takes 6-8 weeks to approve a program.

For MLT licensure, in 2012, there were 128 applicants for MLT licensure and 82 were licensed. This compares with 88 applicants and 48 licensed in 2011. The total number of MLTs licensed since 2005 is 275. Diablo Valley College was approved for MLT training in 2012. Dr. Amad encouraged laboratories to start MLT training programs.

LFS received 7,339 new phlebotomy certification applications this year, about 611 per month. 98% are for CPT1, <1% is for LPT. This is about 20% fewer applications than last year. LFS has administered 3 oral examinations for director candidates this year, licensing 10 doctoral scientists (3 genetic molecular biologist, 3 cytogeneticist, 1 oral pathology, the rest in other categories).

Biologics and blood bank programs

Ron Harkey, Section Chief, said LFS had met with the technical advisory committee of the Blood Centers of California to discuss the biological standards. The AABB standards are incorporated into California law and are in harmony with FDA standards.

New business

Chairperson Lorri Dean-Yoakum said the meetings of the CLTAC would be March 1, June 7, September 6, and December 6 in 2013.

Ms. Dean-Yoakum asked if there was any new business. She also asked that future agenda items be sent to her before the next meeting.

- Ms. Dean-Yoakum asked for clarification of the phlebotomist work scope other than blood draws.
- Jerry Hurst asked again that genetic testing, laboratory-developed tests, and genetic versus chemistry tests be discussed.
- Robert Hunter had asked for clarification of the waived HIV laboratory test and its ramifications and this was not discussed.
- Ron Harkey said he would speak with Dr. Michael Borok about when a person needs a tissue bank license.

Next meeting

Ms. Dean-Yoakum said the next meeting of the CLTAC would be March 1, 2013.

Adjournment

Tim Hamill made a motion that the meeting be adjourned, Salim Rafidi seconded, and the CLTAC voted to adjourn at 12:20 PM.