

Clinical Laboratory Technology Advisory Committee

Minutes of the June 3, 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, Salim Rafidi, Les Revier, Fred Ung, Lori Dean-Yoakum, Mary York.

Former CLTAC members participating

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

DPH staff participating

Zahwa Amad, Alan Ankerstar, Frank Barnes, Karen Demby, Maria DeSousa, Ron Harkey, Robert Hunter, Nema Lintag, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Judy Schlosser, Lilia Shumaker, Joanne Sparhawk, Robert Thomas, Shernae Thompson, Pat Toomer, Kathy Williams.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Tim Hamill. He thanked Kaiser Permanente for providing the videoconference center in North Hollywood. A roll call was conducted of CLTAC members and other participants, and Dr. Hamill noted that a quorum was present for the meeting.

Approval of the January 14, 2011 and March 4, 2011 meeting minutes

Minutes from the January 14 and March 4, 2011 meetings were corrected and approved.

Department news

Ms. Pam Dickfoss, Acting Deputy Director of the Center for Health Care Quality, was unable to participate in the meeting today.

Regular meeting of the CLTAC was adjourned temporarily and the meeting of the CLTAC subcommittee on personnel regulations was convened.

Salim Rafidi, Chair of the CLTAC subcommittee on personnel regulations, opened the subcommittee meeting. He recognized the members of the subcommittee including Lori Dean-Yoakum, Jerry Hurst, Michelle So, Marian Castillo, Rebecca Rosser, Morton Field, Michael Borok, Jim Ottosen, Robert Footlik, Liz Dequinia, Les Review and Joseph Musallum. He said many public members also participated as there was much interest in the proposed regulations. This group met 4 times for a total of 17 hours to review the DPH-08-001, clinical laboratory personnel, regulations. The subcommittee report was difficult to prepare because of the different opinions, but a report was prepared for this meeting of the full CLTAC.

Morton Field questioned whether there was a quorum of the subcommittee and whether this report could be presented to the CLTAC.

Jim Ottosen said he had just received the report electronically last evening and had not had a chance to review it.

Lori Dean-Yoakum said some of the issues discussed at the end of the last meeting were not included in the report. Salim Rafidi said it had been difficult to capture all the intent of the subcommittee.

Rebecca Rosser asked that Section 1033 (b) be returned to original language, that is, CLS training can be initiated when a trainee has completed 90 semester hours prior to training with a baccalaureate completed concurrently with training.

Mary York and Les Revier questioned the accuracy of the subcommittee report presented today.

Robert Footlik said the report should be held back and the subcommittee be reconvened. He made this motion, Morton Field seconded, subcommittee voted (9 to 7) to withdraw the report and continue to the next meeting of the subcommittee.

Salim Rafidi said he would reconvene public meetings of the subcommittee to develop a report that was acceptable to the majority of the subcommittee.

Jim Ottosen said the CLTAC could agree or disagree with the subcommittee report but it was still a report to the CLTAC.

Jerry Hurst said the comment period to the regulations was closed and what was LFS going to do with the report. Bea O'Keefe said the comments were under review and the CLTAC input was important if there is another comment period.

Tim Hamill directed the subcommittee to continue meeting and hold teleconferences of the subcommittee and full CLTAC to get an acceptable report for public record. Dr. Hamill thanked Salim Rafidi for his leadership and hard work on this important matter. He said the complexity was "incredible". Salim Rafidi adjourned the subcommittee meeting.

The CLTAC meeting was reconvened.

Chairman Tim Hamill reconvened the CLTAC meeting.

News and update on LFS.

Bea O'Keefe said the state budget situation is still difficult with continuous drills. There is a hiring freeze. Fifty percent of state cell phones have been recalled, affecting field inspectors. The one LFS state car was eliminated.

The Department of Public Health has a new Director, Dr. Ronald Carlson replacing Dr. Howard Bacher who was interim director. Michael Borok asked about Dr. Carlson's background. Ms. O'Keefe said he was an MD, former county health director in Sonoma County. Kathleen Billingsley, former Deputy Director of the CHCQ, has been appointed Deputy Director of Policy and Programs for the Department. Ms. Billingsley is familiar with LFS so this should help communication.

Ms. O'Keefe said the 3 furlough days have been replaced with one unpaid personal leave day per month and 2 professional development days per year.

The hiring freeze instated on August 2010 was re-instated on March 2011. LFS has put in freeze exemptions to fill vacant Examiner 1, 2, and 3 and Program Technician positions. The phlebotomy program needs help as it is still getting 700 applications per month. LFS is interviewing candidates and has given civil service qualification examinations to new candidates. It has tentative offers out for 5 Examiner candidates. Vacancies in personnel and facility licensing is hurting LFS. There are vacancies also in tissue bank and the biologics programs. LFS currently has a 40% vacancy rate.

SB 744 in 2007 authorized accrediting organizations to apply for deemed status of the laboratories that it accredits. One organization has applied and is under review and several others have expressed interest. They must document that their standards are equivalent to CA condition-level standards for inspection and proficiency testing enforcement.

Ms. O'Keefe said Dr. Zahwa Amad had been promoted to Section Chief of Personnel Licensing and Kathy Williams, to Section Chief of Facility Licensing in Richmond.

The "EOL" program that has been under development for several years has been shelved. This was scheduled for implementation in 2015 and would have provided online applications and renewals for facilities and personnel, online payment and complaint administration. The Department is looking for a smaller program. LFS is disappointed because its mainframe, HALS, is antiquated and must be replaced.

Karen Nickel suggested Ms. O'Keefe mention the freeze on travel. Ms. O'Keefe said the governor's office had restricted all in-state travel. The CLIA inspections are federally funded. Out-of-state delayed travel approval prevented the LFS CLIA staff from attending a CMS meeting in Denver recently.

Michael Borok asked if there was any data on money collected from POLs and non-POLs and what is happening with the money. Ms. O'Keefe said the CA Clinical Laboratory Association had recently asked the Department about revenue and expenditures of LFS with the new fee schedule, and data was available on overall revenue and expenses.

Robert Footlik asked what happens to the revenue that goes to the CLIF special fund if LFS cannot use it. Ms. O'Keefe said the unspent money goes to reserves and can be spent on one-time expenditures. LFS is getting new storage systems using some of this money, for \$250,000. This will help with paper storage until there is a replacement for the EOL. Mr. Footlik questioned the need to store paper storage records, but Ms. O'Keefe said they were often needed for enforcement actions, especially by the DOJ which needs signatures and dates.

Michael Borok asked when CLTAC members were going to be replaced. He said he had served for 8 years. Ms. O'Keefe apologized for the delay, said she was going to work on it now, and asked current members to continue until replaced. She said that the bylaws had not been looked at for many years and asked the CLTAC to review

and update its bylaws. Dr. Hamill said he would defer that request to the new Chair, Lori Dean-Yoakum.

Ms. O'Keefe reported on the legal response on the request from CLTAC as to the role of the CLTAC. B&PC Section 1228 was read which states the CLTAC is to assist and advise on development of regulations. Tim asked why weren't they involved in the new proposed regulations. Ms. O'Keefe reported that there was a stakeholders meeting with the CLTAC at which they were allowed to provide input. She also stated that perhaps she failed in not suggesting to the CLTAC that they form a committee to review the regulations. Tim Hamill said he still wanted a legal opinion on the role of the CLTAC on development of regulations.

Jerry Hurst asked whether it was the Office of Regulations or the Office of Legal Services' decision to not involve the CLTAC. Ms. O'Keefe said the Office of Regulations said LFS could not discuss the regulations with the CLTAC. Karen Nickel said the regulations had been put on a "fast track" which did not allow time for CLTAC consultation. Dr. Hamill said he still wants an explanation why the CLTAC was left out. Mr. Rafidi said there is no intent to blame, but there needs to be a clarification of the CLTAC function and mission. Ms. O'Keefe said she would make sure someone from the Office of Regulations comes to the next CLTAC meeting.

Mary York asked if there would be a benefit if the CLTAC sent a letter to the Governor, Agency Secretary or Director of Public Health about being excluded. Ms. O'Keefe said the new director takes office mid-June. Dr. Hamill moved, Ms. Dean-Yoakum seconded and the CLTAC voted that a high-level letter be sent regarding this issue.

Milk banking and tissue banks in California

Jan Otey, Examiner II in the Tissue Bank licensing program in California, was asked by Ron Harkey to give the CLTAC a summary of a presentation she made at the FDA public meeting in December and discuss donor milk banking. California, along with New York and Maryland, were invited to speak at the Maryland meeting because these states regulate donor milk.

Ms. Otey told about a recent double blind study that showed that mothers' milk, fortified with human milk concentrate as compared when a bovine-based fortifier, helped extremely premature babies survive and thrive. Milk is defined as a tissue in California since implementation of H&SC Sections 1634-1644.5 in 1992. This legislation included the terms "other fluids" and "by ingestion" to purposely include mothers' milk as a tissue. California licenses 5 donor milk screening and collection services, 2 full service centers which pasteurize donor milk and 43 hospitals which store donor milk for use in NIC units. LFS does not generally conduct onsite inspections prior to issuing tissue bank license, but does a paper review of their policies and procedures to assure the donor is screened and tested for the required STD testing. A for-profit mothers' milk bank, Prolacta Bioscience, does DNA testing of the donor mother and her milk to assure donor sources.

Amendments were made to H&SC in 2007 to exempt facilities that only store milk from mothers for their own baby's use from tissue bank licensure requirements. This generally exempts hospitals which only store milk for such use. These hospitals are

inspected as part of their L&C inspection and their policies and procedures must follow the most current HMBANA standards.

Most of the problems or complaints associated with use of mothers' milk involve freezing and thawing. The FDA concluded that casual sharing of milk posed the biggest risk associated with donor milk and felt there may be a need for federal oversight. When the donor mother is not tested for communicable diseases, this is considered inappropriate use of milk. There are currently several internet sites that sell or facilitate sharing of donor milk, such as "Eats on Feet", "Human Milk 4 Human Babies" and "Only the Breast".

Robert Footlik asked how LFS is doing adopting tissue bank regulations. Ron Harkey said LFS has tried several times to adopt AATB standards by modifying H&SC or writing regulations, but has been unsuccessful. He said it is too political. Mr. Footlik asked if the FDA was going to adopt standards. Ms. Otey said "casual sharing" is the worst problem at the federal level.

Personnel licensing section update

Zahwa Amad said the staff in the personnel licensing section is working hard to overcome many vacancies and a high workload. Dr. Amad said the contract with CPS had finally been approved so the online applications and license verification shall continue for another 2 years. LFS is still working on the phlebotomy ID card, reviewing changes. The speed at which CLS and CPT licenses and certificates are being issued has been improved by CPS, as has the time for posting of the online license verification. Licenses are printed each week. However, CPS can no longer process paper applications that they receive. They will only accept online applications.

Dr. Amad said a doctoral oral examination is scheduled June 10 in San Diego for 4 candidates. She said LFS is receiving about 8 MLT applications each month with 4-5 being licensed each month. A total of 150 MLTs are licensed now with about 50 applications pending.

Dr. Amad said someone asked about the number of non-United States (US) CLS applicants. She said she would give an update next month, but in 2010, there were 831 CLS applicants and 500 licensed. Of these, 30-35% were non-US, 40% were from California and 20-30% were US applicants from outside California. Regarding trainee applicants, LFS received 532 applications and licensed 200. In 2010 LFS received 57 MLT applications and licensed 45.

Someone asked why some CLS applicants were not being approved for licensure. Dr. Amad said there were several reasons. Often their training is too short since 32 weeks of practical training is the minimum in our law. They may have not taken a physics course that includes light and electricity, or their foreign academic credentials do not meet US standards as evaluated by AACRAO. Of the 150 non-US applicants in 2010, 140 were from the Philippines. Academic credential problems often occur with applicants from China, India or the Middle East. Someone pointed out that the need for a Social Security Number is also a problem. Dr. Amad said some applicants ask for a letter from LFS justifying their need for a SSN, but this cannot be done.

Robert Footlik asked if LFS gets information about persons failing certification examinations. Dr. Amad said yes, indirectly, since these persons apply but cannot complete their application within 150 days because they have not passed an examination. Nema Lintag of LFS said the ASCP accepts candidates to their exam which may not meet California standards.

Jerry Hurst said the LFS website explaining licensure requirements is not clear. Zahwa Amad said some of the information is in the FAQ. Mr. Hurst said the information should be more readily accessible, upfront. Dr. Amad said that some of the information in the FAQ may be added to the instruction page for licensure requirements so that it is clearer.

Jerry Hurst asked why so few MLTs were being licensed. Some of the reasons heard, according to Dr. Amad, is the unions oppose the MLT position in order to protect CLS jobs, Kaiser Permanent is not hiring them, many laboratories prefer CLSs who are more broadly usable, or unlicensed persons can be used now with autoverification.

Tim Hamill asked if the look back of examinations was an impediment for out-of-state applicants who have passed the ASCP CLS examination. Robert Thomas thought not since the 4 year look back plus 4 years forward has made an 8-9 year window for applicants.

Dora Goto asked how long LFS kept applications, especially foreign transcripts. Dr. Amad said transcripts were kept for at least 3 years, foreign transcripts, 5 years. Ms. Goto said foreign applicants who were re-applying were discouraged because they thought they would have to get their transcripts again.

Geri Albee asked how applicants could put all their colleges and universities in the application since there were only 2 lines on the online application. Dr. Amad said to just put 2 down but have all transcripts sent in anyway. Ms. Albee questioned whether LFS would accept transcripts from unlisted universities, and Dr. Amad said they save all documents sent and put them into the applicants file automatically.

Dr. Roath said that Loma Linda gets many questions from outside applicants on how to apply for CLS licensure in California and feels the LFS website should be clearer. Dr. Amad said they would work on improving it.

Laboratory Licensing Section update

Kathy William, Section Chief, reported that currently LFS is getting about 50 new license applications and 120-150 new registration applications each month. Combining this workload with all the renewals keeps her staff very busy. For the renewals, the paperwork and checks go first to Sacramento accounting, then to Richmond. There is a backlog now to March. The out-of-state licensing program is also backlogged.

On June 6, LFS staff will begin training on an RPS check scanning system which will allow LFS to process the checks in Richmond. Hopefully this will speed things up considerably as checks and renewal documents can be processed at the same location. Ms. Williams said in 2009, LFS issued 153 notices of unsuccessful

proficiency testing and in 2010, 131 notices to accredited laboratories. The most common cause of failure in proficiency testing is human error such as late reporting, mixing samples or transcription errors.

Ms. Williams introduced Karen Demby who was recently hired by the state-funded Lab Aspire program to facilitate public health microbiology certification.

CLIA section update

Donna McCallum, Section Chief of the CLIA program in California, said there is still some confusion on state registration and CLIA certification of laboratories performing waived or PPMP testing. Some laboratories think one renewal does both and let one lapse or confuses one with the other.

Ms. McCallum said in April and May 2011, LFS surveyors performed 77 and 75 onsite surveys respectively and had a year-to-date total of 552 laboratories. In addition, LFS conducted 46 onsite waived laboratory surveys and 10 waived lab follow up surveys.

Meeting schedule for 2011

Chairman Tim Hamill asked that the CLTAC set the dates for the next 2 CLTAC meetings in 2011. This had been a question when LFS staff was on Friday furloughs. Since Labor Day is September 2, the September meeting date was set for September 9 and the December meeting, set for December 2, 2011.

Subcommittee meeting times

The CLTAC subcommittee on the personnel licensing regulations shall meet by telecom on June 7 from 9AM to noon. If they are able to agree on a subcommittee report, a teleconference with the full CLTAC shall be held on June 24, 2011, 9 AM.

New business, open discussion

Michael Borok said he was concerned that he is terming out of CLTAC and no replacement has been made. Bea O'Keefe said she will continue working on that.

Jerry Hurst asked that there be an update from the Office of Regulations (OR) on why the CLTAC was not involved in development of the regulations. Ms. Okeefe stated that she will try to have someone from the OR attend a CLTAC meeting to give their requirements.

Mary York said that a letter should be sent to the governor about CLTAC's non-involvement. Tim Hamill said he and Lori Dean-Yoakum, the incoming chair, would work on that and have it done before the CLTAC teleconference on June 24, 2011.

Tim Hamill said he wanted a presentation from the Office of Legal Services on how legally the CLTAC should be expected to assist and advise the Department.

Someone said there should be a discussion on cellular therapy at the next meeting.

Adjournment

The meeting was adjourned by Chairman Tim Hamill at 12:35PM. Karen Nickel asked that Dr. Hamill be recognized for his 4 years serving as CLTAC chair. Bea O'Keefe said that would be done at the next meeting.