

Clinical Laboratory Technology Advisory Committee
Minutes of the **October 1, 2010** Meeting
Meeting held by videoconference from Richmond campus, CDPH,
KP Regional Laboratory, North Hollywood and
Telephone Bridge Line

Note: For flow purposes; these minutes are documented in the order in which they appeared on the agenda, and not necessarily in the order discussed.

CLTAC Members Participating

Michael Borok, Leonard David, Lorri Dean-Yoakum, Timothy Hamill, Jerry Hurst, Lin Kassauni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung, Mary York, Lee Hilborne, Elizabeth Dequinia.

Former CLTAC Members Participating

Robert Footlik, Sol Notrica, Imre Fischer, Jim Ottosen.

DPH Staff Participating

Zahwa Amad, Ron Harkey, Robert Hunter, Donna McCallum, Karen Nickel, Bea O'Keefe, Joann Sparkhawk, Tom Tempske, Robert Thomas, Kathleen Williams

Welcome and General Announcements

The meeting was called to order by the CLTAC Chair Dr. Tim Hamill.

Approval of the June 26, 2010 meeting minutes

Tim Hamill asked CLTAC members if there were any additions, deletions, or corrections to the minutes. There was a motion for approval by Salim Rafidi and a second for approval by Donna Kirven. The minutes were accepted.

Department News

Ms. Billingsley said that the state had been without a budget for 93-94 days. The furlough program was on, then off, now back on again. She said there was now a hiring freeze and it was hard to predict actions between now and the end of this year. She said that there is new legislation that might impact clinical laboratories. The state is in the preliminary transition phase between governors and there will probably be major changes in the administration. Ms. Billingsley applauded LFS for managing the program under difficult circumstances.

Question: Dr. Borok asked, when the budget is signed, will that affect the hiring freeze?

Answer: Ms. Billingsley said she can't predict what will happen. Activity on the part of the unions regarding the furloughs may affect the outcome.

News and Update on LFS

Bea O'Keefe announced that Bob Thomas has agreed to come back as a retired annuitant and is currently helping with personnel regulations. She also announced that Zahwa Amad has been appointed Acting Section Chief of the personnel Licensing Section. Most recently, Zahwa worked in the personnel licensing section of LFS on the Clinical laboratory Scientist licensure. On the Budget, Bea reported that LFS was authorized 35.5 new positions when the budget is approved. An examination was given for the Examiner I and II positions in Richmond and Los Angeles. 20 candidates took the examination. Currently, however, there is freeze on hiring... On the Enterprise Online Licensing (EOL) project, Bea reported that the project was put on hold during the summer. The Information Technology Office that oversees all information technology

in the state requested that a review be made of the data system that Consumer Affairs is using so that there is not a duplication of effort and expense. The review appears to be completed and

the EOL project is now proceeding as planned. Requests for Proposals will be proceeding in the near future. On Work Backlogs, LFS continues to have a backlog of applications for laboratory registration and licensure as well as initial licensure of personnel due to the furloughs and staff shortages. On complaint investigations, one of our examiners participated in a search of a clinical laboratory in southern California by the Department of Justice. During the search two automatic assault weapons and two hand guns were found. Deficiencies were also found in quality of testing. On Genetic Testing, UC Berkeley was planning to offer DNA testing to the incoming freshmen class. UC was informed that of the laboratory requirements for testing, an authorized person must order the test, the test must be performed by licensed personnel, the director must qualify under state law and all quality control and other regulatory requirements must be met. After a meeting by UC officials with the department, the University modified the project so that individual tests would not be released to the students. On Public Health laboratories, Bea reported that she met with the President of the California Public Health Laboratory Directors and the past president. They want to foster better communication between the public health laboratory directors and Laboratory Field Services.

Question: Tom Tempske asked about the regulation's process.

Answer: Bea O'Keefe responded that normally there is a 45 day comment period. There can be more than one comment period.

Current Status of Legislation Impacting Clinical Laboratories

AB 549 (Furutani) Clinical Biochemical Genetics License:

Robert Thomas spoke on AB 549 – Licensure of clinical laboratory personnel. The governor vetoed the bill. (See Statements)

AB 2541 (Portantino) Electronic reporting for HIV:

Kathy Williams spoke on AB 2541 – Repealed exemption of electronic reporting for HIV. The governor signed the bill. This maintains the ability to obtain Ryan White Funds.

AB 2786 (Committee on Health) Reportable Diseases:

Kathy Williams spoke on AB 2786 - Allows public health to add or delete reportable diseases without rulemaking process. The governor vetoed the bill stating it was overly broad & unnecessary.

SB 1246 (Negrete-Mcleod) Waived clinical laboratory tests and exams:

Kathy Williams spoke on SB 1246 - Naturopathic doctors can serve as director of waived labs. The bill authorizes naturopathic assistants. This bill was signed.

Question: What is a naturopathic Doctor? Are they separate from Medical?

Answer: Naturopathic Doctors are licensed by a different board and are totally separate from Medical Professions. Unlicensed persons performing this service are called homeopaths.

Michael Borok announced that the video was lost in LA.

Question: Does the bill AB 2786 include faxing?

Answer: The bill prohibits fax. Don't expect system to be implemented for a year or more.

Question: Have to continue with certified mail in the mean time?

Answer: That is advisable.

Question: What waived tests can a patient order themselves? Cholesterol, HDL, Liver function tests?

Answer: The FDA specifies over-the-counter (OTC) tests. Any test available OTC can be self ordered in California.

AB 1487 (Hill) Providing Information to Physician doing insemination

Ron Harkey spoke on AB 1487 – this was chaptered with the secretary of state. Allows donors positive for HIV & HTLV to donate sperm if washed using ASM guidelines. Requires LFS to write regs by 2012.

CLIA Update Report

Donna McCallum spoke on the CLIA Updates – The fiscal year ends in September and she is compiling the final report for the year. COLA no longer accredits histopathology. Labs have to change to certificate of compliance or another accrediting organization. The CLIA surveyors have performed 87 initial surveys, 618 recertification surveys, 2 onsite validations, 3 complaints, 24 PT sanctions, 100 waived onsite and 29 waived followup surveys. Donna announced that Jerry Lash, Examiner, passed away September 11. He will be missed by the laboratory Community. Donna commended the CLIA staff for their hard work.

Dr. Borok asked if COLA can still do the inspection for other than histopathology. Donna answered that they cannot do a partial inspection.

Facility Licensing Report

Kathy Williams spoke on Facility Licensing - 10 License applications and 80-100 registration applications are received each month for Waived or PPMP. The number of licensed labs is currently 2000, Registered 12, 200, Out of State labs (OOS) 200. LFS is receiving numerous requests from OOS. Most applications are for general laboratory services. LFS has experienced delays in processing applications for renewals due to delays in the accounting department in Sacramento in processing the payment fees. EDD has taken over printing of licenses. Staff in facility licensing was thanked by Kathy for their hard work.

Question by Karen Nickel as to what is HALS. Kathy answered it is the state data system where all the laboratory and personnel information is entered.

Personnel Licensing Report

Zahwa Amad spoke on Personnel Licensing – she thanked the personnel licensing section for their work. Approximately 70 Applications for Clinical Laboratory Scientists (CLS) are received each month, and about 40 are issued each month. Oversees applicants must meet current license requirements. CLS trainee programs – 42 applications are received each month, 20 licenses are issued each month. Medical Laboratory Technician (MLT) Program receives approximately six applications per month. Approximately 133 MLTS licensed. Phlebotomy Training Schools – There are 109 approved training schools.

Question by Thomas Tempske – It was originally anticipated that there would be 5000 MLTs in 5 years. Why so few compared to the projection?

Answer by Zahwa Amad – There are 5 training schools. Labs beginning to hire. Questions about scope of practice and union bargaining may have delayed hiring.

Bob Thomas added that projections were based on national numbers. A lot were hesitant to start training programs until they saw employees being hired. We expect as they get in the work force, more would be training. Work is being done for grants for work load enhancement at labs.

Question by Tom Tempske - Are we getting many from out of state?

Answer Zahwa Amad– We are offering OOS applicants MLT license if they don't qualify for CLS.

Question by Donna Kirven – How many licenses are being issued for phlebotomists?.

Answer by Maria DeSousa– Out of 40,410 applications, 37,640 were approved.

Elizabeth Dequinia stated that a lot of unions already have a contract they can not hire MLTs until the union contract is approved.

Salim Rafidi stated that we need training schools. It is at the junior college level and many are not offering programs due to their budgets.

Nema Lintag responded that we have 2 in southern CA approved, and 3 pending.

Bob Thomas reported that there are 150,000 MLTs nationally. CA has 10% of the laboratories historically; therefore, there is potentially a need for 15,000 in CA. Need training schools and labs to accept MLTs to move forward. Nema Lintag commented that out of state applicants must have 3 years experience in a clinical laboratory within the last 5 years as an MLT or comparable experience which may be an impediment.

Lin Kassouni stated that MLTs cannot do all required tests and this may limit the hiring of MLTs in all but the largest labs.

Bob Thomas commented that the work scope of the MLT is limited in the statute.

Biologics Report

Ron Harkey reported that both blood and tissue banking continue to work with CDC, FDA and the Division of Communicable Disease Control. Most recently corneas were recalled and a cornea was explanted because of an Acanthamoeba infection. Blood and blood products have been found infected with malaria and Chagas. Bacterial contamination of donor blood has also been investigated. Transfusion Related Incidents have included ABO incompatibility and irregular antibody reactions. The licensure of new stem cell banks is increasing. LFS has been able to apply the American Association of Blood Bank Standards relating to Cellular Therapy to these banks. Although AABB has standards for all cellular therapy, legally LFS can only apply the standards to stem cells from umbilical cords and circulating blood. Cytology continues to investigate and enforce screening limits. There continues to be a vacancy in blood banking but that position can only be filled if there is an exemption to the hiring freeze.

Health Resources Services Agency (HRSA) Reporting Requirements

Tom Tempske spoke on HRSA reporting requirements and gave a slide presentation. He also gave a complaints summary. We have received 5 phlebotomy training school complaints. This is not very much when you consider we receive approximately 600 phlebotomy applicants each month. Fraud complaints are referred to the feds. Pharmacy complaints are referred to the pharmacy board. We received a Cytotech complaint that the cytotech was reading 160 slides per day working at 2 locations.

Question by Shiuland Kwong – Do you receive many complaints received about quality of testing.

Answer by Tom Tempske – Yes we do receive some but not that many.

Tom Tempske added that cytotechs cannot exceed 80 slides per day at all of the sites that are worked. He also added the complaint website is on CDPH. The Main portal lists the different complaint categories.

Question by Karen Nickel– Can the LFS complaint form be mailed in?

Tom Tempske– I am not sure but will check the website if it can be mailed.

A presentation was then given by Tom Tempske on the National Practitioner Data Base and Health Care Integrity and Protection Data Bank.

Doctor Linette Scott, of Health Information and Strategic Planning, gave a presentation on Meaningful Use and New laboratory Reporting Requirements. She stated that there was several billions of dollars in federal incentive money for laboratories that met the reporting requirements. The laboratories must use certified Electronic Health Reporting technology. There are also specified requirements and objectives that must be met at specified intervals in order to qualify for the incentive. She presented a series of slides on the subject.

Question by Karen Nickel – How much incentive is there?

Answer by Linette Scott– There are notable differences, hospitals are motivated.

Bea O’Keefe commented that a survey showed that only 40% of physicians currently plan to participate.

Linette Scott commented that they are providing education about the program and out reach, CAL Reach to educate patients; CDPH is working with CMA and family physicians, Questions by Robert Footlik – 1) Labs and Electronic Health Records, certain information must be there. How will medical records interface with Health records? 2) California – in spite of making lab results available to the patients, HIV and anatomic pathology are prohibited from electronic record transmission.

Response by Linette Scott – 1) It depends on how health records are set up. We need to help doctors in how they present their health records. 2). The Privacy Board is trying to tackle the issues and the statutes related to reporting. New statutes or revisions of statutes may be needed.

Question by Bob Hunter about the GIS system.

Linette Scott - We support the GIS and will be of great help and how we use the electronic information.

Question by Bob Tempske – How does GIS work?

Answer by Linette Scott – There are GIS libraries and geocoding. They are working to have more mapped services. GIS is used at county level and in census tracks,

New Business, Open Discussion

Question by Salim Rafidi – Are the By Laws for CLTAC available on the website?

Answer by Tim Hamill – The bylaws are on the website.

Jim Ottosen stated that CLTAC has been involved in many white papers and there has never been a response from CLTAC regarding this regulation package. A subcommittee never formed on the personnel regulations. Karen Nickel stated that LFS has 2 position papers from 10 years ago. Lee Hilborne asked if there is a second comment period, can we have a special meeting? The response was yes, a special meeting can be called and it was noted that subcommittee meetings are also open meetings. Lee Hilborne asked if a second comment period is opened , do we want a subcommittee to meet? This was taken as a motion and seconded by Les Revier. Salim Rafidi said it would be good to have a subcommittee. The motion passed.

Future Items

None brought up.

Next meeting scheduled for December 3rd.

Motion to adjourn by Donna Kirven, second by Salim Rafidi. Meeting adjourned.

