

Clinical Laboratory Technology Advisory Committee

Minutes of the June 7, 2013 Meeting

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

CLTAC members participating

Rhonda Becker, Richard Bennett, Anthony Butch, Lorri Dean-Yoakum (chair), Elizabeth Dequinia, Kathleen Doty, Robert Footlik, Lee Hilborne, Jerry Hurst, Anne Igbokwe, Anthony Mills, Rebecca Rosser, Fred Ung.

Former CLTAC members participating

Michael Borok, Sam Chafin, Imre Fischer, Sol Notricia, Jim Ottosen, Salim Rafidj.

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Grace Byers, Elaine Flores, Ron Harkey, Tina Hashemi, Robert Hunter, Paul Kimsey, Yangzhu Long, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Beatrice O'Keefe, Jan Otey, Joanne Rowan, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

Public members participating

Michael Aidan, Geraldine Albee, Yvonne Carter, Marian Castillo, Kathy Davis, Diana Dupuy, Kathleen Faraday, Nancy Fraize, Diane Giles, Dora Goto, Carola Howe, Erica Klein, Peggy Kollar, Lois Langs, Armand Parada, Rodney Roath, Gene Scott, Barbara Sevilla, Tom Tempske, Ann Tonini, Phyllis Walker, Shirley Wong-Jose, Tammy Zinsmeister.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:02 a.m. Ms. Dean-Yoakum thanked Kaiser Permanente for sponsoring 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 March 1, 2013 meeting minutes

There were no additions or corrections to the minutes from the March 2013 meeting. Rhonda Becker moved that the minutes be accepted as submitted, Jerry Hurst seconded the motion, and the board approved the minutes as submitted.

Department update

Dr. Paul Kimsey, Deputy Director of the Office of State Public Health Laboratory Directors (OSPHLD), gave an update for the department.

He noted that the state legislature still had 10 days to produce a budget, and expressed cautious optimism that this would happen. None of the proposed changes to the budget were expected to affect Laboratory Field Services.

He then discussed the department's plans for gaining accreditation. The Public

Health Accreditation Board (PHAB), which is sponsored by the Centers for Disease Control and Prevention and the Robert Wood Johnson Foundation, is a non-profit entity that implements and oversees national public health department accreditation. It has identified 12 domains, each with a set of standards and measures, which characterize the ideal public health department. It has also established a seven-step accreditation process. Dr. Ron Chapman, the Director of the CDPH, has been involved with PHAB for approximately 6 years, and CDPH has been engaged in the process of application for accreditation for approximately 6 months.

He also discussed the implementation of the Affordable Care Act (ACA), which he described as a massive undertaking. California is in the forefront of this process. CDPH is still researching the effects the ACA will have on its programs. "Covered California" is the California ACA program. Open enrollment is scheduled for October 2013, with coverage taking effect in January 2014.

Dr. Kimsey addressed the issue of the federal government's budgetary "sequestration" on CDPH, and noted that the federal CLIA program has not been affected.

He also discussed his participation in a meeting with the Governor's Office of Economic Development and various licensing and regulatory programs, in which he represented LFS, Licensing and Certification (L & C), and other programs. The meeting was called to address the needs of state programs for online licensing and regulation systems, and the possibilities of working with IT services to make such systems available to California government agencies.

Status of the regulation package, DPH-11-012

In the absence of Tammy Pahland, Staff Counsel for LFS, Beatrice O'Keefe updated the CLTAC on the draft regulations. It has been sent to the Office of Regulations, and although minor revisions are expected, the package is nearing publication for public comment. Ms. O'Keefe thanked Karen Nickel for her work on the initial regulations and on the Initial Statement of Reasons (ISOR). The financial report remains to be written, reviewed, and sent forward to the Office of Budget and Finance for approval, but the regulation package is nearing the end of the process at LFS, and Ms. O'Keefe again thanked Dr. Nickel, Robert Thomas, Zahwa Amad, Kathy Williams, and Tammy Pahland for their dedication in preparing the new regulations.

Asked when the package would be released for public comment, Ms. O'Keefe responded that she cannot say, because once LFS has completed its review, the package still awaits review and approval by the Office of Regulations, CDPH, and the Department of Finance.

Ms. Dean-Yoakum thanked the CLTAC subcommittee and LFS, and especially Dr. Nickel, for their work on the regulations package. Ms. O'Keefe also thanked the CLTAC subcommittee, and assured them that their recommendations and comments have been carefully reviewed and considered by LFS in its review of the package.

LFS Update

Beatrice O'Keefe reported on issues and events in LFS.

She discussed the effect of sequestration on the operations of LFS, noting that the federal government is considering a 5% reduction in grants. This would be significant for Licensing and Certification, as well as the CLIA program, but noted further that the federal government has said that they would absorb 2% of these costs, leaving 3% to be absorbed by the affected programs. She said that Judy Yost at CLIA has told her that there will be no cuts to that program at the present time.

With regard to recruitment and retention, LFS has sent recruiting postcards to people eligible for employment as examiners. The examination for examiners will be held in July. She noted that LFS currently has several examiner vacancies to fill.

She reported that LFS has received applications for deeming authority from COLA, College of American Pathologists (CAP), and The Joint Commission (formerly JCAHO). LFS compared their crosswalk packages with California law and has sent an initial response. LFS is currently awaiting return responses.

Robert Footlik asked how these organizations intend to accommodate California regulations. Ms. O'Keefe responded that some have separate binders for issues unique to California law. LFS is working with the organizations on their plans for compliance with California regulations. Mr. Footlik noted that CAP has an old list of California regulations, and asked if LFS has a plan to bring them up to date. Ms. O'Keefe assured him that all three organizations had been given current information on California law and that LFS will ensure that they are compliant with current California law.

Ms. O'Keefe reported on Hepatitis C Virus (HCV) infection. Because it is estimated that more than 4.1 million persons are infected with this virus, the CDC has suggested that anyone at risk of infection should be tested for HCV. Most people become infected by sharing needles or other drug injection equipment, or from blood transfusions and organ transplants before 1992, when widespread screening for HCV was instituted. Since 2012, the CDC has suggested that anyone born between 1945 and 1965 should be tested at least once. Over-the-counter tests are now available for collecting blood samples, which must be sent to a laboratory for testing, and the laboratory community should expect that clinicians will be recommending these to their patients.

She discussed the federal government's promotion of electronic health records, noting that more than half of US doctors have adopted them. In California, more than 27,000 providers have signed up for the program. They have received \$1.2 billion from the federal government to fund implementation, with results far in excess of initial expectations.

She also discussed concerns raised in Europe about direct-to-consumer genetic testing (performed without consultation with medical professionals), especially about privacy issues.

Zahwa Amad noted that as of June 30, state employees are no longer subject to the Personal Leave “furlough” that reduced the number of hours worked by one day per month, and that as of July 1, LFS staff will be back to full time work with full pay.

Legislative Update

Various LFS staff members reported on legislation that is being monitored by LFS.

Robert Thomas reported on AB 213, introduced by Assemblyman Logue. Known as the Veterans Health Care Workforce Act of 2013, this bill would require a healing arts board within the Department of Consumer Affairs and the State Department of Public Health, upon the presentation of evidence by an applicant for licensure or certification, to accept education, training, and practical experience completed by an applicant in military service toward the qualifications and requirements to receive a license or certificate if that education, training, or experience is equivalent to the standards of the board or department. The bill addresses concerns about the high unemployment rate among military veterans, and at the same time it addresses concerns about a shortage of health care professionals, including laboratory personnel, that is anticipated to become more acute with the implementation of the ACA. The expansion of health care coverage is expected to result in an increased demand for health care, and, in turn, increased demands for the services of health professionals, including laboratory workers, to provide care and perform laboratory tests. Mr. Thomas said that this bill has been held over for next year. He noted that LFS already accepts military experience toward licensure requirements, so this bill would not have a direct impact on our program.

Zahwa Amad reported on AB 1215, introduced by Assemblyman Hagman. This bill amends Section 1209 of the Business and Professions Code, expanding the definition of “laboratory director” for purposes of a clinical laboratory test or examination classified as waived to include a duly licensed clinical laboratory scientist. It would authorize a person licensed as a clinical laboratory scientist and qualified under CLIA to additionally perform the duties and responsibilities of a waived laboratory director, as specified under CLIA. She noted that optometrists, pharmacist, and naturopaths have recently been added by legislation to be directors of waived laboratories. The bill is sponsored by CAMLT, and supported by Blood Centers of California, AFSCME, the United Nurses Associations of California, and Local 20 of the IFPTE/ESC, among other organizations.

Dora Goto of CAMLT said that the Affordable Care Act will add more waived testing and waived testing laboratories. She reported that CAMLT expects waived laboratories to use licensed CLSs to direct their laboratories in order to reduce the cost of hiring physicians, and thinks that this will attract more CLSs to the field. She added that the bill has a hearing date on June 17 in the BP and ED Committee.

Jerry Hurst asked if the bill provides for limits on the number of waived laboratories per director. Ms. O’Keefe responded that moderate and high complexity tests are limited to 5 per director, but there is no limit on the number of waived laboratories.

Jan Otey reported on AB 1297, introduced by Assemblyman Perez, which would authorize a procurement organization, when specified circumstances are present, to

notify a coroner, prior to the donor's death, that a donor has made or may make an anatomical gift, and would require a coroner to accept that notification, whenever such notification will facilitate the coroner's ability to conduct his or her duties in a manner and within a period compatible with the preservation of the body or part for the purposes of the gift. The bill would also require a coroner to conduct a post mortem investigation in a manner and time period compatible with the preservation of the body or part for the purposes of the gift, thereby imposing a state-mandated local program. This bill was initially assigned to LFS. LFS recommended deferring the bill to Licensing and Certification since it is not within LFS's scope of responsibility.

Ms. Otey also reported on SB 492, introduced by Senator Hernandez. This bill would add the provision of habilitative optometric services to the definition of the practice of optometry. The bill would expand the practice parameters of optometrists who are certified to use therapeutic pharmaceutical agents by removing certain limitations on their practice and adding certain responsibilities, including the ability to immunize and treat certain diseases, and deleting the specified drugs the optometrist would be authorized to use, and authorizing the optometrist to use all therapeutic pharmaceutical agents approved by the United States Food and Drug Administration.

She noted that this is one of several bills that would expand the work scope of non-physicians that have been proposed in the current legislative session.

Robert Thomas pointed out that this bill actually affects not laboratory law but the optometrists' law, and Ms. Otey agreed that it does primarily affect the optometrists' law, but that it works back to laboratory law.

Robert Footlik noted that optometrists have no training in clinical laboratory practice, and moved that CLTAC recommend that CDPH oppose SB 492 as it exists today. Kathleen Doty seconded the motion. Jerry Hurst said that many people are trying to expand their work scopes, and suggested that LFS provide a reference that shows where the work scopes can be found. Ms. O'Keefe responded that LFS has that information, and can provide it. Mr. Footlik continued that the department should oppose these bills as a danger to public health and safety. Tom Tempske offered to look in his current book for the work scopes. Ms. Otey noted SB 491, which expands the scope of practice of nurse practitioners, and SB 493, which does the same for pharmacists. She also pointed out that SB 492 has been amended to include BCP Section 1209.

Ms. O'Keefe pointed out that the department's position is in fact confidential, and suggested that perhaps people should send a letter stating its concerns to Dr. Ron Chapman or to their legislators. Mr. Thomas added that LFS only takes a position when writing a bill analysis. Ms. Otey pointed out that a letter to a legislator must be disclosed as a statement of support or opposition, so a letter to a legislator would be most effective.

The motion was stated that the CLTAC recommend to CDPH that it oppose SB 492 as written today. Eleven members voted to approve the motion, and one member voted to oppose it. The motion carried.

Jim Ottosen noted that Senator Hernandez sits on several committees, and that his bill could be expected to pass.

Ms. O'Keefe asked if optometrists are allowed to do finger sticks or venipunctures. Ms. Otey replied that they are allowed to do so for purposes of diabetes testing.

Ms. Goto noted that CAMLT officially opposes this bill, and is concerned about its breadth. CAMLT feels that passage of this bill would potentially open the door for optometrists to perform other testing, as well as diagnosis and treatment of conditions. It is also concerned because optometrists have neither the training nor education for laboratory sciences. Ms. O'Keefe noted that CLIA recognizes optometrists as directors of waived laboratories.

Kathy Williams reported on SB 222, introduced by Senator Padilla. This bill would enact the Genetic Information Privacy Act, which would declare that an individual's genetic information is protected by the right of privacy. The bill would prohibit any person from collecting, storing, analyzing, or disclosing genetic information without the written authorization of the individual to whom the information pertains, and would include related findings and declarations. It also would prescribe specific circumstances under which genetic information may be collected, stored, analyzed, or disclosed without the authorization. As of May 24, the bill is held in committee under suspension, and is now a 2-year bill, but Ms. Williams recommended that people read the analysis posted on the Leginfo website (www.leginfo.ca.gov) because she expects this bill to return.

Guest Speaker

Zahwa Amad introduced Ed Desmond, PhD, Chief of the Microbial and Mycology Section of the Microbial Diseases Laboratory at CDPH, who made a presentation on the use of molecular methods to detect and guide treatment of multi-drug-resistant tuberculosis (MDRTB).

Dr. Desmond noted that MDRTB is an increasing problem, with an estimated 400,000 cases emerging each year, and a world-wide prevalence between 1 and 1.5 million cases. In addition, an increasing number of MDRTB cases (about 7%) are also resistant to second line drugs, or extensively drug-resistant (XDR). Eighty percent of TB cases in California are in people born outside the United States, and these people also have more cases of MDRTB. He noted that new technologies are emerging, and noted in particular the CEPHEID GeneXpert test, a molecular technology which detects tuberculosis and predicts resistance to rifampin. He explained the procedure for the MTB/RIF test and compared this method, which has a sensitivity of 88%, to the conventional culture method, which has a sensitivity of 98% for smear positive and 68% for smear negative. For detecting rifampin resistance, the GeneXpert technology has a sensitivity of 94% and a specificity of 98%. He pointed out that since TB cultures take from 1 to 3 months, the GeneXpert method can guide therapy until culture-based results can be determined. The WHO has recommended the adoption of the test, which could lead to a three-fold increase in the diagnosis of patients with MDRTB, and in poorer countries will cost a little less than \$10.00 per test. He noted the limitations of the test: it detects only rifampin resistance, and occasionally detects mutations which do not cause drug resistance.

He also discussed pyrosequencing (PSQ) for detection of drug resistance, which is now available as a routine service at the CDPH Microbial Diseases laboratory free of charge. This laboratory-developed test is recommended when drug resistance is suspected. He then discussed the correlation of specific mutations with levels of drug-resistance, noting that while culture-based testing is still useful and desirable, molecular and culture-based testing can confirm and complement each other to detect MDRTB.

Dr. Desmond concluded that new guidelines are needed before replacing skin tests with the newer testing methods, but noted the advantages of molecular methods for diagnosis of drug resistance: a shorter turn-around time, direct application in clinical specimens, lower biohazard risk, and the feasibility of automation. The positive impacts of molecular methods on tuberculosis control and patient management include early detection of drug resistant tuberculosis, early initiation of effective treatment regimens, proper prophylaxis for contacts, resulting in better control of tuberculosis.

Ms. O'Keefe asked if the state is asking for samples for pyrosequencing testing, and Dr. Desmond responded that his lab needs smear-positive samples and a reason to suspect drug resistance before doing pyrosequencing. It is also done in high-risk circumstances, such as pediatric nursing, or, for example, in the case of a grammar school teacher. Specimens should be submitted through the local public health department.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, reported statistics for CLIA for LFS. She noted that her section has been very busy, especially since the promotion of Joanne Rowan, which removed her from routine survey work. Through May, 2013, the section has performed 57 initial surveys, 449 recertification surveys, 11 validations, and 26 PT desk reviews. In May, 54 recertification surveys were performed, 2 validations, and 2 on-site follow-up surveys.

The CLIA database (ASPEN) has been updated to ASPEN 10.1.4, with major enhancements including batch billing, maintenance updates, and a tab for directing CLIA fee coupons and certificates to physical, mailing, or corporate addresses. Training in the new process is scheduled for November 2013.

Ms. McCallum also reported that the new CMS CLIA interpretive guidelines are complete and are undergoing final review. These guidelines will include IQCP, Electronic Health Records, and updated PT enforcement guidelines. There are also changes to the statutes concerning reporting of patient results. Release of the guidelines has been delayed to enable release of the entire package at one time.

Facility licensing - Richmond

Kathy Williams, Section Chief of Facility Licensing in Northern California, reported that her section approved a total of 163 new certificates of waived registration. Of these, 149 were from pharmacists, 12 were from optometrists, and 2 were from naturopathic practitioners. The section received 319 new applications for waived

registration, and 38 for other PMPs. Twenty-seven new facility licenses were approved, 13 for CLM, 1 for CLA, and 13 for CLF. Forty-five new registrations and facility licenses are pending.

Ms. Williams also reported on complaints received by her section, of which there were approximately 39. Among the concerns were a test error, a state license, CLIA, an individual CLS, billing problems (2), testing performed by unauthorized persons (4), and phlebotomy (12).

Facility licensing – Los Angeles

Joanne Rowan, Section Chief of Facility Licensing in Southern California, reported that she is trying to monitor and improve her program, and is in the process of gathering information.

The examiners are performing complaint, initial and routine state inspections. For the months of April and May 2013, the inspection statistics were as follows: 33 labs were inspected including 12 initials, 1 complaint and 20 routine inspections. The initial lab inspections included two upgrades (e.g. changing from a Registration/Certificate of Waiver or Provider Performed Microscopy Procedures to a License/Certificate of Compliance or Certificate of Accreditation, and one reinstatement.

Of the 20 routine inspections performed, which were all accredited laboratories, there were 7 TJC, 8 CAP and 5 COLA labs inspected.

The complaint investigation dealt with unlicensed personnel performing high complexity testing in a non-POL setting and is still in progress.

Ms. Rowan stated that her section's goal is to give inspection priority to all initial applications and complaint investigations first. In addition, routine surveys are performed with the focus on accredited labs. These are not validation surveys, as they have not issued any Certificates of Deemed Status yet, but are routine inspections as required under CBPC 1220. Due to staffing constraints, this appears to be the most efficient manner in which to ensure the oversight of all laboratories. The accredited labs are selected primarily because most do not see a representative from the state as often as the non-accredited labs do. In other words, the non-accredited labs are surveyed routinely by the CLIA staff with an eye on state issues. That is, a state checklist is completed by the CLIA surveyor outlining any state personnel or licensure issues that need to be addressed. The checklists are turned in to the state side of the office, where non-compliance issues are subsequently investigated. This requires a coordinated effort between the two programs.

Ms. Rowan feels that by focusing our routine inspections on the accredited labs her section can make sure that the state laws and regulations in those facilities are being followed as well. She noted that another difference in the inspection process between federal and state is the federal regulation set used. The CLIA surveyors are using the final CLIA rule, while the state examiners are using the CLIA former rule. She asked if the committee that was examining the crosswalk between the two sets of regulations would be reinstated to recommend to LFS which federal regulations would be adopted into state law.

She also mentioned that the LA office has a new state examiner, Elaine Flores, who is currently training. Her background is in laboratory management and her final checkout is planned for the end of June.

Biologics and Tissue Bank Program update

Section Chief Ron Harkey reported that members of the tissue bank licensing section and LFS's legislative government analyst met with representatives of the American Association of Tissue Banks (AATB) concerning the subject of California's Health and Safety Code storage requirements for human tissue. The AATB requested that LFS remove storage of human tissue as a requirement for licensure. The AATB pointed out that when facilities receive human tissue, the tissue arrives in a shipping container and is kept in its original container until it is used, typically within one calendar day of receipt. In the event the tissue is not used within one calendar day, the tissue is to remain in its original shipping container, unopened. LFS explained that the definition of storage is the retention of tissue over one calendar day. AATB requested that the definition of storage be changed to allow storage of tissue in its original container until it is used, even when the period exceeds one calendar day. AATB requested LFS to develop a specific and legal definition of storage. LFS explained that proper storage of human tissue is very important as storage temperature can affect the integrity of an unopened container and have serious consequences for public health. AATB requested a written and formal definition of storage. It was explained that the Office of Legal Services (OLS) had previously advised LFS that "storage" is a commonly used word, found in the dictionary, and does not require any further definition. Our current OLS attorney, Tammy Pahland, concurs with this previous OLS guidance.

Robert Footlik asked if there are current United States Food and Drug Administration (USFDA) standards, which monitor these concerns. Mr. Harkey responded that there are such standards, but they cannot be enforced under the California law.

Moreover, neither federal (USFDA) nor national accreditation standards, e.g., AATB, may be adopted into California law without legislation.

Mr. Harkey noted other questions on which he is seeking clarification from legal counsel:

- What constitutes ownership in a tissue bank? This may become a matter of concern in the event of a recall.
- What constitutes "processing"?

Robert Hunter reported that he is still working on issues of transfusion-related infections (TRI) with regard to tissue banking and blood banking. He is working with Blood Centers of California (BCC).

HLWI update

Robert Thomas gave an update on the Health Care Laboratory Workforce Initiative (HLWI). HLWI is working with the State Office of Statewide Health Planning and Development (OSHPD) on a pilot project to expand the scope of practice for medical laboratory technicians (MLT) to include performance of urine microscopies, pipetting in molecular tests, subculture of bacteriology colonies after selection of the colony by a CLS, and performance of moderate complexity immunohematology tests. OSHPD has the authority to establish manpower programs. When doing so, it looks at

California's health workforce challenges, including a shortage of health professionals, maldistribution of health professionals, lack of racial and ethnic diversity, an insufficient number of culturally and linguistically competent practitioners, constraints on the capacity of educational programs, delivery models, salary differentials by specialty, the economic recession, and increased demand on health care services.

The Health Workforce Pilot Projects Program (HWPP) provides opportunities to test, demonstrate, and evaluate new or expanded roles for healthcare professionals, or new healthcare delivery alternatives. It also enables California's non-profit education institutions, community hospitals or clinics, and government agencies engaged in health or education activities to demonstrate and evaluate new and expanded health care roles.

The minimum time frame for a program to perform and complete a study is usually at least three years but can be fast tracked to about one-year. HLWI is planning to fast-track the MLT study and hopes to complete it in less than one year.

OSHPD provides the legal framework for the demonstration of new ideas and has the power to waive standards in existing laws to be tested under the proposed pilot project concept. Their role is to set up pilot programs with goals recommended to them by organizations such as the HLWI, to allow people to learn and utilize new skills which are not permitted under existing licensing laws. The outcomes are sent to OSHPD. The function of the project is to generate data, collect and analyze the data, and recommend changes in the statutes to policy makers.

Jim Ottosen asked Mr. Thomas to summarize what HLWI wants to do and how they plan to accomplish it. Mr. Thomas outlined the process whereby HLWI devises a program and submits it to OSPHD. If OSPHD accepts the proposal, they write a recommendation report which is made available to legislators and other interested parties. The proposal then becomes a legal pilot project and they are able to proceed. Any change to statute, for example, a change of work scope, must be accomplished through legislation.

Mr. Ottosen then asked if it is possible to look at a plan before it is accepted by OSHPD. Mr. Thomas replied that he was not sure of the answer, but suggested that anyone can establish criteria and write a proposal for a plan. If OSPHD approves a pilot project, the project can be implemented even if it goes beyond current law. The results obtained in a pilot project, however, cannot be used for diagnosis or treatment of patients, but only for research purposes within the pilot project. If the pilot project is deemed to be successful, legislation can be sponsored and brought forward by a legislator to change current law.

Jerry Hurst asked if OSHPD can override state and federal (CLIA) law. Mr. Thomas replied that he does not yet know the details, but he reiterated that any testing done under the pilot project would be used only for research purposes within the project, and not for diagnosis or treatment of patients. Results of any testing would be compared with results obtained in the usual manner. Ms. O'Keefe noted that LFS has requested of HLWI to be kept abreast of progress on this plan. Ms. Dean-Yoakum noted that HLWI deals primarily with hospitals, and that hospital laboratory

directors are closely involved. Ms. Otey asked if they will not be working for example with MLTs already in their employment, and asked further why they did not do this in another state. Mr. Thomas replied that they are doing it in California because they want to change California law. Robert Hunter asked how CLTAC and LFS can stay abreast of developments. Peggy Kollars said that she is on the HLWI and that she could assure people that there is no question of results obtained by MLTs appearing on patient charts. The work that they do will only be used for the purposes of the study. She added that anyone who is interested can contact Rebecca Rozen at HLWI and ask to be put on the committee. Elizabeth Dequinia asked for the contact information, and Mr. Thomas said that he would email the information to anyone who wants it. Donna McCallum asked if they are doing the study in California because California has a higher number of laboratories, and Mr. Thomas responded that it was not for that reason, but rather because they wanted to change California law. Ms. O'Keefe added that OSHPD is a California state agency, and this is a matter of the state workforce and labor shortage. Mr. Ottosen stated that clinical laboratory scientists (CLS) should be paid more in order to attract more of them.

New business

Lorri Dean-Yoakum asked if anyone had new business to discuss. There was no new business.

She asked for recommendations for topics for future discussion. There were several suggestions.

One was the crosswalk with CLIA. Robert Footlik noted that the CLIA crosswalk subcommittee is still available, and it was decided that the subcommittee would reconvene with Mr. Footlik as chair.

It was suggested that it would be helpful to have more information about the HLWI, with perhaps a guest speaker from HLWI to address the next CLTAC meeting.

Another suggestion was that the CLTAC hold a discussion on the MLT scope of practice and make a recommendation on that issue. Peggy Kollars suggested that such a discussion be kept to a single meeting, rather than convening a subcommittee. Ms. O'Keefe responded that she would have to check with the department's legal counsel, because the current work scope is in statute, and so any changes would have to be made through legislation. Salim Rafidi stated that CLTAC should be involved in this issue because CLTAC represents a variety of stake holders, while HLWI represents only the Hospital Council. He also noted that there are not enough MLTs to make a significant difference in the labor shortage. Mr. Thomas responded that on the national level, there are about as many MLTs as CLSs, and if the scope of practice were to be expanded in California, more MLTs would come to the state. Dora Goto agreed that CLTAC should be involved, to make sure that the data collected by the pilot project study is objective and reliable. Ms. McCallum asked if the pilot project is looking at all hospital laboratory personnel or only MLTs. Mr. Thomas replied that the particular pilot project under discussion is only concerned with MLTs.

Jerry Hurst suggested that more information is needed before deciding how to

proceed, and moved that CLTAC invite someone from HLWI to the next meeting to provide information. Rhonda Becker seconded the motion, and it was passed. Ms. Dean-Yoakum announced that CLTAC will invite a representative of HLWI to the next meeting. Ms. O'Keefe noted that it would be necessary to contact Rebecca Rozen before distributing her email to CLTAC members.

Next meeting

Lorri Dean-Yoakum announced that the next meeting of the CLTAC would be Friday, September 6, 2013.

Adjournment

Rhonda Becker made a motion that the meeting be adjourned, Jerry Hurst seconded, and the CLTAC voted to adjourn at 12:25 PM.