

Clinical Laboratory Technology Advisory Committee

Minutes of the Meeting held on December 5, 2014

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

CLTAC members participating

John Basile, Rhonda Becker, Marjorie Braasch, Patricia Dadone, Lorri Dean-Yoakum (chair), Kathleen Doty, Robert Footlik, Jennifer Schiffgens, Fred Ung.

Former CLTAC members participating

Sam Chafin, Imre Fischer, Carmen Maldonado.

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Tina Hashemi, Robert Hunter, Paul Kimsey, Nema Lintag, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Beatrice O'Keefe, Tammy Pahland, Joanne Rowan, Judy Schlosser, Dale Statley, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

Public members participating

Rafael Cassata, Marian Castillo, Behnaz Dardashti, Karen Fuller, Diane Giles, David Gomez, Dora Goto, Carola Howe, Lin Kassouni, Peggy Kollars, Shiu-Land Kwong, Dan Leighton, Jill MacAfee, Jamie Marks, Cathy Martin, Rodney Roath, Matthew Schulze, Barbara Stizilla, Phyllis Walker, Annie Wang, Maureen Weber, Debbie Wilson-Ferguson, Gary Yamamoto, Annie Yang.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:08 a.m. Ms. Dean-Yoakum noted that the start of the meeting was delayed due to heavy rain, and thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Dean-Yoakum conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was not present for the meeting.

Approval of the September, 2014 meeting minutes

Robert Footlik and Lorri Dean-Yoakum submitted corrections to the minutes from the September meeting. Rhonda Becker moved that the minutes from the September 2014 meeting be approved as corrected. Because a quorum of CLTAC members was not present, the vote was delayed until such time as a quorum was present.

Election of officers

Lorri Dean-Yoakum invited nominations for chair. She noted that according to the by-laws she is not eligible for nomination. She has served two terms on the board, and her tenure will end in December, 2015. The term of the newly elected chairperson will end in June, 2016. Therefore Ms. Dean-Yoakum cannot serve another term as chairperson because her term on the board will end before her new term as chairperson would end. She asked for nominations. Ms. Dean-Yoakum

nominated Rhonda Becker, who accepted the nomination. Ms. Dean-Yoakum stated that a vote will be taken at the March 2015 meeting if a quorum is present.

Department update

Dr. Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), gave an update the California Department of Public Health (CDPH). He thanked Kaiser Permanente for making their infrastructure available to CLTAC and CLTAC members for their time and effort.

Dr. Kimsey gave a progress report on the Department's application for accreditation by the Public Health Accreditation Board (PHAB). The application process was initiated in 2012, when the Department began the process of documentation to demonstrate the Department's advancements in quality and performance. On February 8, 2014, CDPH Director Dr. Ron Chapman submitted the accreditation package. A site visit was conducted by a team of peers selected and trained by PHAB between August 19 and August 21, 2014, which included visits to the Sacramento and Richmond campuses. During the exit interview with CDPH the team commended CDPH on several strengths, including the strategic map and the planning that looked at the health of the Department in all its policies, quality, partnership, research, science-based publications, quality of leadership, and transparency. The team also mentioned challenges that CDPH must bear in mind, including the impact of the Affordable Care Act (ACA) and plans to facilitate the Act's success, engagement of the private sector, the development and use of metrics to track progress and success, training and development of the Department's work force, succession planning in the face of an aging work force, and the use of social media to advertise open positions.

In the next step, the team will develop and submit a report to the PHAB accreditation committee, which will meet in December, 2014. Dr. Kimsey said that the final decision will be announced in December, and noted that all signs point to the Department achieving accreditation.

Dr. Kimsey addressed the issue of Ebola Virus Disease, and advised interested persons to visit the CDPH website, which has a new section on the homepage for Ebola information featuring a number of links to news items and information about the newly established CDPH Ebola hotline as well as a link to the CDC Ebola information page.

Dr. Kimsey announced that at the executive staff meeting of CDPH in early December Dr. Ron Chapman, Director of CDPH and State Public Health Officer, announced his resignation, effective January 31, 2015. He noted that Dr. Chapman has served as Director since June, 2011, and has led the Department through a particularly difficult period. He said that Dr. Chapman did not state his plans for the future. An acting director has not yet been named, and there is as yet no timeline for appointing a replacement director, but a national search is being conducted for a director of CDPH and a director of the Department of Health Care Services, which oversees Medi-Cal, California's Medicaid program.

Update from legal counsel

Tammy Pahland, staff counsel for LFS, reported on the status of the draft

regulations package DPH-11-012 on personnel licensing regulations, noting a new approach to the package. She explained that the draft was written with all the regulations for each type of licensure treated in separate sections. This entailed a certain amount of repetition, since some stipulations apply to more than one type of license, but resulted in a package that was easier to use. LFS has now been instructed by the CDPH Office of Regulations to streamline the package and eliminate duplications, with special attention to inconsistencies of language in duplicated sections. This represents a large and time-consuming editing task. LFS is in the process of hiring an attorney to assist with the drafting of regulations, which will facilitate the process. The new directions to LFS are part of a state-wide undertaking to expedite and streamline the process of drafting and implementing new regulations.

Ms. Pahland noted that she is working with Kathy Williams, chief of the LFS Northern California facilities licensing section, on the CLIA crosswalk.

LFS update

Beatrice O'Keefe, chief of LFS, reported on the project to replace the LFS personnel online licensing system with a new, in-house system, which is necessitated by legislation that mandates state agencies to use in-house IT providers whenever possible. A bid to replace the existing online application system with a system based on a platform developed by Pega has recently been approved. The transition will be made in several phases, the first of which must be completed by June 30, 2015. The first phase of the project, designated PERL (Personnel Licensing), will replace the online system that currently handles initial applications for personnel licenses and certificates. The second phase, due for completion in June, 2016, will introduce the online renewal of personnel licenses and certificates. The third and fourth phases, which will be completed in June, 2017, and June, 2018, will bring facilities licensing and renewals online. Ms. O'Keefe reported that LFS staff attended a demonstration of a similar project engineered by Pega, and said that LFS staff expects the new system to speed up the application process by introducing a process in which all application data will be entered and payment will be submitted online. It is hoped that the new system will eventually replace the LFS complaints database and make it searchable, and will include facilities license verification capabilities, thus bringing LFS databases into the 21st century.

Rhonda Becker asked if this will meet the mandate to use in-house IT providers, and Ms. O'Keefe said that it would. CDPH IT staff will work with Pega and LFS staff and will eventually take over the administration and will be able to make adaptations to the system. Dr. Kimsey added that the Department has contracted with Pega, and that the PERL project will adapt the software developed by Pega, tailoring it to enable the LFS licensing system to utilize the Pega platform. The Department is seeking consistency by having all programs in the Department use the Pega platform. Because the system already exists the task is easier than developing an entire new system. Ms. O'Keefe observed that the Pega platform is a robust and adaptable system, and other states are working with Pega to design similar systems.

Robert Hunter asked if there will be training for staff. Dr. Kimsey said that there will be training, and added that the system is designed for ease of use by both LFS and other CDPH staff and the public. Ms. O'Keefe noted that there will be a help desk as

well.

Robert Thomas asked if the Department will own the system. Dr. Kimsey said that while the Department will be using a platform designed by an outside company, the Department has purchased the Pega system and will own it and support it.

Peggy Kollars asked if people will have the option of paying by check. Ms. O'Keefe said that LFS could explore that possibility. The goal is to accept both forms of payment, but currently payment must be made by credit card.

Ms. O'Keefe addressed a question raised by Jill MacAfee at the December meeting about online ordering of tests. She noted that approximately 50 tests can be self-ordered in California. California law does not specify the manner of testing or ordering such tests, which can be ordered at a laboratory or online. She pointed out that a laboratory can refuse to accept self-ordered tests, which is a business decision, and that any FDA-approved over-the-counter test can be self-ordered in California. LFS has a list of such tests and anyone who wants a copy of the list is invited to contact Mary Wogec at mary.wogec@cdph.ca.gov to request it.

Ms. MacAfee said that her question concerned websites that offer any test, without requiring a doctor to be involved. She noted that many such websites include a disclaimer that in certain states, certain tests cannot be ordered, but California is not included in the list of states. California law requires that requests for tests other than over-the-counter tests at laboratories must be made by a doctor, but it appears that people can go online and order any test from certain websites, and she was interested in knowing the opinion of the Medical Board of California on this issue.

Ms. O'Keefe said that the Medical Board of California was consulted on this question by LFS some years ago, at which time the board stated that there need not be a one-to-one physician-patient relationship. A physician must be associated with a website, but that physician need not see a patient in person or consult with the patient. Furthermore, laboratories outside California must be licensed by the State of California to operate in the state or to test on specimens originating in California. Ms. O'Keefe asked Ms. MacAfee to report websites about which she has questions, and said that LFS may need to consult the Medical Board of California again for an opinion about this issue.

Ms. O'Keefe addressed a problem regarding the renewal of phlebotomy certificates. Noting that LFS receives daily telephone calls from phlebotomists asking for expedited renewal of certificates that are about to expire, she explained that LFS sends renewal notices to licensed and certified personnel 120 days before the date of expiration. The renewal notice advises recipients that the median time for reviewing and processing a renewal application once a complete application has been received by LFS is 90 days, and the minimum time is 30 days. She explained that in fairness to all applicants, LFS processes applications in the order in which complete applications are received. If an incomplete or incorrect application is received, LFS sends a letter requesting missing or incomplete documents or information. She asked how laboratories are dealing with the renewal of certification, and if they are notifying employees in advance of the expiration of their certification or licensure. She noted that there is no grace period for phlebotomists.

Jennifer Schiffgens said that her laboratory sends a renewal reminder 90 days in advance of expiration, but she noted that it is the employee's responsibility to submit a renewal application.

Rhonda Becker said that her laboratory does the same, and reiterated that it is the responsibility of the employee to ensure timely renewal.

Ms. O'Keefe said that LFS sees this as an issue of fairness. Robert Thomas said that when LFS set the regulations, it set the timing of renewal notices to make sure that licensed personnel would have sufficient time to obtain continuing education credits and submit their renewal before expiration. He noted that some people do not receive their renewal notices due to a change of address without notifying LFS of the change. Tina Hashemi said that some people do not obtain continuing education credits from a provider approved by the Department, and suggested that phlebotomy schools should make the Department's requirements clear to their students to prevent this happening.

Dora Goto said that it sounds as if the main problem is communication, and encouraged employers in the regulated community to inform their employees of Department renewal requirements. She also suggested that employers check with their phlebotomy staff to make sure they have received their renewal notices, and inform them that replacement forms can be downloaded from the LFS website.

Peggy Kollars asked if the new PERL system will send automatic renewal notices. Ms. O'Keefe said that the interface between the Department's HALS system and the database will not change, and it is the HALS system that generates renewal notices, which are sent by mail. There is no capacity at present for sending an electronic reminder.

Dr. Imre Fischer announced the sad news of the death of Sol Notricia, a former CLTAC board member and active participant in CLTAC for many years.

CLIA Crosswalk Subcommittee update

Kathy Williams reported that she was unable to complete the item-by-item report.

Robert Footlik thanked Ms. Williams for her extensive work in documenting the crosswalk.

Mr. Footlik made some clarifications with regard to Item 8, addressing the issue of Equivalent Quality Control (EQC) and the Individualized Quality Control Plan (IQCP).

Reviewing the history of the issue, he explained that 25 years ago the California legislature adopted a law to set standards for blood banks, adopting the 13th edition of the American Association of Blood Banks (AABB) manual and subsequent editions as the standards by which blood banks should operate. When CLIA was implemented in 1992, the federal government said that laboratories must meet the standards in the regulations unless there was an alternative Quality Control (QC) procedure in the State Operations Manual, also known as the Interpretive Guidelines. At the time, there was no alternative QC program.

In 1995, State Senator Maddy authored Senate Bill (SB) 113, which was sponsored by the Department, to align California to be exempt from the CLIA program without jeopardizing or altering standards. The governor signed this legislation adopting CLIA and it went into effect on January 1, 1996. The regulation in Business and Professions Code (B&PC) Section 1220 specified that California statute was what CLIA specified in the regulations. There was no alternative program for QC at that time. In January 2003 CLIA adopted a new final rule, in which the provision regarding QC remained unchanged, and the relevant section remained intact. In 2004 a new edition of the State Operations Manual was published that included EQC. At that point CLIA laboratories in California had the option to follow either the State Operations Manual or California regulations, which allowed them to follow the State Operations Manual. For some reason, it was perceived as not being legal or as underground regulations or as less stringent. But nothing had changed and EQC was not a new final rule under CLIA. He said that in his opinion EQC should not have been evaluated or commented on by the subcommittee because it was already State law and there was no change in the law or the final rule.

B&PC Section 1208 states that any CLIA regulations adopted by what is now the Center for Medicare and Medicaid Services (CMS) as a final rule after January 1, 1994, shall be evaluated by the Department in consultation with CLTAC. On January 1, 2016, IQCP will go into effect, to be published in the State Operations Manual in 2016. Laboratories can adopt it. Mr. Footlik noted that it is a risk-based program that requires laboratories to perform risk assessment when developing their QC rule. He said that in his view this is fine for a CLIA laboratory but not in California, because California law does not extend to anything that is not yet published in the State Operations Manual. In summary, EQC is currently legal in California and IQCP is not legal in California. As of 2016, EQC will disappear and IQCP will take its place. Mr. Footlik said that if a laboratory is using EQC in electronic form or in an internal control system, he thinks that those can be incorporated into an IQCP program, or IQCP can be limited to one part of a laboratory, but he feels that it is wrong to deny a laboratory the use of EQC, that the costs for a large laboratory could run into billions of dollars, and that he fails to understand how the State can consider EQC as not being a regulation or as being an underground regulation. He thinks that EQC should be allowed because that is what is stated in California statute.

Karen Nickel explained that the legislation that allowed the Department to adopt AABB standards provided a mechanism for addressing changes to those standards each year, but that is not the mechanism the Department has for CLIA. Mr. Footlik said that B&PC 1208(b) says that the Department can re-evaluate and choose to adopt a new final rule or not. Dr. Nickel said that an interpretive guideline is not a regulation. Mr. Footlik said that CLIA regulations say that interpretive guidelines can be used as alternatives.

Lorri Dean-Yoakum asked if Mr. Footlik was referring to fact that when California adopted the CLIA regulations as written in 1994, they made reference to the State Operations Manual. The State Operations Manual was introduced in 2004, and it included EQC. When California adopted CLIA subpart A in 1994, the State accepted the State Operations Manual. Therefore EQC could be understood to be approved in California because the State approved CLIA 1994 and the subsequent State

Operations Manual under SB 113. Mr. Footlik said that was his understanding. Ms. Dean-Yoakum offered the assistance of CLTAC and thanked Mr. Footlik, Tammy Pahland, and the CLIA Crosswalk Sub-committee for their work.

Ms. Dean-Yoakum deferred a discussion of digital pathology to follow up on the presentation of Dr. Jared Schwartz at the December CLTAC meeting, due to the unanticipated absence of Dr. Lee Hilborne at today's meeting.

HLWI update

Robert Thomas reported on the Health Care Laboratory Workforce Initiative (HLWI) meeting that was held on November 19, 2014, which he attended.

He reported on an update on California Medical Laboratory Technician (MLT) clinical laboratory utilization, and the possible impact of the MLT scope of practice on clinical laboratories. Previously the HLWI looked at three areas of moderate complexity testing to expand the scope of MLT practice. Those areas were microscopy urinalysis, blood smear reviews, and immunohematology.

Mr. Thomas reported on the discussion of a Medical Laboratory Technician (MLT) scope of practice study proposal now being conducted through the Office of Statewide Health Planning and Development (OSHPD) to assess the impact of the current scope of practice regulations for MLTs. The study includes information on the supply of MLTs, workforce shortages in laboratories, quality, and costs. OSHPD has authority to make temporary changes for a trial period for the purpose of rendering a report to the Legislature. On the basis of such a report, it is possible that the California legislature will make changes in current law.

A review of the OSHPD program processes indicated that the procedures would be rigorous, requiring public hearings and resulting in a report of about 400 pages. The HLWI has decided to not pursue the OSHPD approach at this time. Various alternative approaches to conducting research and reporting to the Legislature were discussed. The possibilities include:

1. Collection of data on the scope of practice in each state. Information about the scope of practice and restrictions for MLTs would be compiled, paying careful attention to any changes in regulations over the past five years.
2. An analysis of workforce data. Multiple data sources could be used to assess whether the supply of laboratory scientists and personnel is lower in California than in other states. This data analysis would rely upon federal data sources, such as the Census Bureau American Community Survey and the Integrated Postsecondary Education Data System, to measure current supply for each state and the numbers of graduates from specified training programs each year. The hypothesis is that California will have both lower supply and a smaller number of new entrants per year.
3. A literature review. A brief survey of Google Scholar did not reveal many papers examining the impact of MLTs on efficiency, supply, quality, or costs. A formal, structured literature review that includes the gray literature should be conducted.
4. Key informant interviews. Interviews with laboratory directors in California and in other states would help discern employers' experiences with staffing their laboratories, and their perceptions of the quality and efficiency of work when MLTs

are utilized. If any states have changed MLT scope of practice in the past five years, interviews should be conducted in those states. The number of interviews could be scaled to align with the resources available for this portion of research.

5. A data analysis performed in partnership with a multi-site organization. In partnership with a health care organization that operates laboratories at multiple sites, the HLWI would collect and analyze data to address the key questions of this study. The types of data to be analyzed could include:

- Staffing data for each laboratory site, with information about the mix of Clinical Laboratory Scientists (CLS), MLTs, and other staff.
- Quality data including information about the accuracy of test results that are routinely collected by the laboratory or have been collected in a special study.
- Cost data including supply costs, which would include both wages and benefits.

A discussion of these issues followed with representatives of the UCSF Center for the Health Professions who took the lead on possible approaches. A study was proposed that could be budgeted and supported by the group. Apparently, there is no study showing MLT scope of practice by state. Occupational classes used by census bureaus do not supply detailed data on work scope. A literature review would be quick but is likely to be limiting.

Of the five approaches listed, numbers four and five appeared to be the most intriguing to this group. It was determined that Kaiser Permanente could be a partner as they have clinical laboratories in California and in other states. Collaboration with other states was suggested, with Colorado and Florida mentioned as possible partners. Other organizations such as ASCP could be contacted for complaint data from states other than California that use MLTs in order to determine if there were a higher number of complaints regarding MLTs compared to CLSs.

Rebecca Rozen, Regional Vice President for the Hospital Council, is checking on possible funding for the study as outlined. Also, team members of the HLWI are reviewing if other test expansion, in addition to the three areas previously discussed, could be considered in the future.

One team member will visit a large hospital in central Florida to look into how MLTs are utilized at the hospital and within the state of Florida. UCSF will also look at the scope of training for MLTs outside of California.

In conclusion, it was suggested that the study should focus on training requirements, competency testing results, and complaint data in addition to the ratio of MLTs to CLSs employed in clinical laboratories in other states.

Lorri Dean-Yoakum thanked Mr. Thomas for his report. Rhonda Becker asked if any research was done when California introduced MLTs. Mr. Thomas said that LFS was limited with regard to regulations to what is in statute. Karen Nickel said that unions opposed legislation unless the work scope was limited. Tammy Pahland said that comments made on legislation before it was passed could be researched online in the bill's history.

Beatrice O'Keefe asked if the Hospital Council had looked at the utilization of MLTs

and CLSs in other states. Mr. Thomas said that utilization of MLTs in Florida is similar to that in California. In Florida, there was an initial concern that MLTs would replace CLSs in laboratories, but it has not happened: the ratio in Florida is roughly 40% MLTs to 60% CLSs. He said that with regard to the question of how MLTs are being utilized in Florida, they do the less complex work and are supervised by CLSs. The proposed study will look at how MLT training in other states compares with training in California.

Ms. O'Keefe asked if the study will look at coursework in Florida in comparison to that offered in California. Mr. Thomas said that the study is focusing on training rather than coursework, and will ask whether other states offer enhanced training that allows MLTs to perform a wider variety of testing.

Ms. Dean-Yoakum asked if the addition of microscopic urinalysis, blood smear reviews, immunohematology, and other moderate complexity tests would attract more MLTs to work in California, noting that in the laboratories with which she is familiar, most testing is moderate complexity.

Mr. Thomas noted that national census bureau data show approximately 300,000 people listed as being employed in the CLS and MLT category. Of these, approximately 160-170,000 are classified as CLSs and 130-140,000 as MLTs, so it appears that more MLTs are working in laboratories in other states than in California laboratories. He suggested that this may be due to a perception in California that restrictions on the MLT scope of practice limit their usefulness in the laboratory.

Legislation updates

Ron Harkey, section chief of the Biologics and Tissue Bank Section, reported on Assembly Bill (AB) 1822. This bill, proposed by Assemblyman Rob Bonta, dealt with the storage of tissue for implantation into or application onto patients, and would have exempted a person or facility licensed to provide health care services from the FDA tissue bank licensing requirement for storage of such tissue when the tissue was obtained from a licensed tissue bank, stored in strict accordance with FDA regulations, and used for implantation into or application onto a patient, returned, discarded, or transferred to hospital storage for later use. If the facility collected tissue from its own donors or engaged in any other tissue bank activity such as collection, processing, or distribution it would not be exempt from licensure.

In its original version the bill made changes to the definition of storage with the intent of saving hospitals the expense of licensure and shipping costs if tissue must be kept for more than one calendar day. Over the course of the legislative session the bill evolved to exempt all hospitals from tissue bank licensure requirements, therefore effectively exempting tissue stored in hospitals from Departmental oversight.

Mr. Harkey said that the bill was enrolled and sent to Governor Brown, who returned the bill without signing it, which is the equivalent of a veto, and quoted the Governor's message, in which he stated, "I am returning Assembly Bill 1822 without my signature. The bill would exempt hospitals, ambulatory surgical centers and other outpatient settings from having to obtain licensure as a tissue bank if the human tissue or cell-based product they receive and store meets specified requirements.

Currently, because hospitals and other outpatient facilities do not want to become licensed tissue banks, they pay expensive courier fees to transport unused products back to tissue banks -- a cost they pass on to the tissue banks themselves. While I support eliminating overly burdensome regulation, I'm not convinced that the bill strikes the right balance between safety and economy. I will direct the Department of Public Health to continue working with interested parties to develop an approach that balances appropriate oversight with cost savings for suppliers.”

Mr. Harkey said that in response to the Governor’s direction to CDPH to continue working with interested parties to develop an approach that balances appropriate oversight with cost saving for suppliers, LFS will revisit the definition of storage and pursue a solution that meets the needs of suppliers as well as the requirement that the Department safeguard public health by exercising oversight. One possible solution would adjust the specified time period for storage based on current technology. Storage of tissue requires tissue bank licensure, but current technology makes it possible to store tissue safely longer than the 24 hours specified in current Department regulations. LFS will be seeking a solution that will maintain oversight of tissue stored in hospitals, but will also lower costs to hospitals by allowing for longer period of time before tissue must be sent to storage, which can be done safely due to changes in technology. He is hopeful that this can be addressed in Frequently Asked Questions on the program’s website.

Robert Footlik asked about the status of the bill, and specifically if it had become law when the Governor failed to sign it. Ron Harkey said that the Governor returned the bill without signing, and it was recorded as the equivalent of a veto, and the bill did not become law.

Facility Licensing – Los Angeles

Joanne Rowan, Section Chief of Facility Licensing in southern California, reported that there were only slight increases in the number of initial and routine surveys in 2014 compared to the numbers for 2013. In 2013 91 initial and 85 routine surveys were performed, and the routine surveys were mostly COLA-accredited laboratories. From January through November of 2014, Ms. Rowan’s section received approximately 109 applications for initial licensure and performed around 98 routine surveys of accredited laboratories, most of which were accredited by CAP and TJC.

The section continues to find deficiencies in both initial and routine surveys. Approximately 43% of the laboratories inspected during initial surveys have deficiencies or problems that need to be corrected before a license can be issued. This can result in licensing delays since LFS must wait for the laboratory to make corrections. About 42% of the routine surveys discover deficiencies, most of which are at the standard level and can be easily corrected.

Ms. Rowan reported that during 2014 her section performed more complaint investigations than in 2013, and resumed out-of-state (OOS) laboratory inspections. The section received approximately 17 complaints to investigate in the Los Angeles area and performed 5 OOS surveys, 2 in Florida, and 3 in Texas. The section is targeting additional OOS laboratories for survey for the continuation of the fiscal year (12 more in total).

Ms. Rowan addressed the issue of timelines, stating that the average time from receipt of an application in Richmond to the on-site survey in Los Angeles is about 61 days. It takes about 26 days for packets to move from Richmond to Los Angeles, and another 35 days to schedule and conduct an inspection, because surveys are scheduled a month in advance. When staff in Los Angeles receives an initial packet, the current month is already booked with existing surveys. In addition, laboratories are sometimes not ready for inspection when contacted, postponing the initial survey. Oftentimes, they are surprised how quickly the inspections are scheduled.

She observed that on more than one occasion a laboratory, following initial inspection and issuance of a license, has failed to initiate patient testing. In such a case, when CLIA inspectors arrive to inspect and find that the laboratory is still not testing patients, the CLIA application and state license are simultaneously terminated and the application process must begin all over again. She encouraged laboratories to bear in mind that they should be ready to test patients after being licensed to prevent this from happening.

She mentioned that her staff is also working on updating their procedure manuals and strengthening existing systems.

Biologics and Tissue Bank Program update

Ron Harkey, section chief of the Biologics and Tissue Bank Section, reported on the work of the blood banking, tissue banking, and cytology programs in his section. He noted that there are a number of investigations in process in blood banking and tissue banking, and that Robert Hunter is working on a complex transfusion related incidents (TRI) and general blood bank complaints. Mr. Hunter is seeking to share the TRI protocols with all Licensing and Certification offices. He is also licensing facilities that act as brokers for cord blood stem cell collection and storage. These facilities work with families that want to store their own cord blood stem cells for later use. The broker is responsible for contacting blood banks that store the donor blood when the blood is required by the family.

Mr. Harkey reported that the tissue bank program is also involved with brokers of human stem cells (non-blood) derived from umbilical cords. These brokers are also licensed as tissue banks. A number of facilities act as brokers for arranging for the collection and storage of human ova and their distribution to in-vitro fertilization clinics. These facilities are also licensed as tissue banks. The tissue bank program is currently pursuing two complex tissue bank investigations.

He noted that a major responsibility of the tissue bank program is the analysis of legislative bills that are associated with tissue banking, and remarked that it has taken his staff hundreds of hours to review and respond to issues raised in connection with AB 1822, which he discussed earlier.

Mr. Harkey explained that approximately 750 tissue bank facilities are licensed by the Department, which also receives a number of new applications each year. He noted that it can take between 6 and 9 months to review and process a new application, and said that applications are reviewed and processed in the order of submission. He also noted that his staff is engaged in a large number of complex, ongoing investigations at the moment.

He thanked Don Miyamoto for his diligence in administering the cytology program. Cytology facilities are required to provide the department with lists of the number of cytotechnologists and slides read to ensure that cytotechnologists read no more slides than allowed by law, which ensures that slides are read accurately. Mr. Miyamoto makes routine surveys of cytology laboratories and gathers data through annual cytology questionnaires to accomplish this task.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, announced that Judy Yost, the national director of the CLIA program, will retire on December 31, 2014. Karen Dyer will serve as the interim director until a replacement is named. Ms. Dyer has been in her current position for about one year, so a smooth transition is anticipated.

Ms. McCallum reported that through the end of September, 2014, the CLIA section performed 63 initial surveys and 612 recertification surveys. Twenty validation surveys were completed, 2 onsite follow-ups and 2 complaint investigations were performed, and 36 proficiency testing desk review sanctions were issued. No waived laboratory surveys were performed due to a lack of sufficient staff. In total, Ms. McCallum's section completed 735 surveys as of September 30, 2014, the end of the federal fiscal year.

As of October 31, 2014, the first month of the federal fiscal year, the CLIA section performed 7 initial surveys and 44 recertification surveys. One validation survey and 4 proficiency testing desk reviews were completed, for a total of 56 surveys in the first month of the federal fiscal year.

She reported that the CMS have issued an Ebola State Memorandum for clinical laboratories containing information concerning possible cases of Ebola Virus Disease and giving interim guidance for specimen collection, transport, testing, and submission for persons under investigation for Ebola Virus Disease in the United States. Ms. McCallum noted that the Piccolo and the I-Stat are the test instruments most commonly used for Ebola Virus Disease.

More information about guidance for laboratories handling suspected Ebola Virus Disease specimens is available on the CDC website at <http://www.cdc.gov/vhf/ebola/>. The OSHA Ebola Guidelines can be found at <http://www.osha.gov/SLTC/ebola/>. Information on the FDA Test System can be found at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm>. Questions about the memorandum should be addressed to Karen Dyer (karen.dyer@cms.hhs.gov) or Kathy Todd (kathleen.todd@mcs.hhs.gov).

Beatrice O'Keefe said that LFS encourages people to visit the CDC and CDPH websites for updated information on Ebola Virus Disease. Ms. McCallum said that people can also contact her at donna.mccallum@cdph.ca.gov and she will be happy to send them copies of the CMS handout.

Ms. McCallum addressed the issue of off-label use of blood glucose meters,

explaining that use of a test outside of its Food and Drug Administration (FDA)-approved and cleared intended use, limitations, or precautions as indicated in the manufacturer's instructions is considered "off-label use." The term "off-label use" applies whether the test is waived or non-waived and it means the test is considered modified and therefore defaults to high-complexity classification under CLIA. This requires the laboratory using the device for an "off label" use to meet all applicable CLIA high-complexity requirements. Nova's Stat Strip Glucose Hospital Meter System has FDA approval for use in critically ill patients when venous, arterial, neonatal arterial, and neonatal heel sticks are used.

She noted that the proposed notice for fecal occult blood (FOB) was released in the Federal Register on November 7, 2014. This notice proposes to add the word "non-automated" to FOB so that only non-automated, or manual, FOB tests are waived by regulations. The notice also proposes to remove the use of the hemoglobin by copper sulfate method from the list of waived tests because possibly it is no longer in use. She asked that if anyone knows of facilities still using the hemoglobin by copper sulfate method, please advise them to send their comments by January 6, 2015. The link for commenting is in the notice, which can be found at <http://www.gpo.gov/fdsys/pkg/FR-2014-11-07/html/2014-26559.htm>.

Robert Hunter asked if the use of copper sulfate by a blood center could cause it to be classified as high complexity. Ms. McCallum said that it could, so she encouraged him to notify such blood centers of the Federal Register notice and website and encourage them to comment.

Debbie Ferguson asked if there is a website where one can check to see if a blood glucose meter is approved for screening purposes. Ms. McCallum said that there is no such website, and said that it is necessary to look at each instrument and check the manufacturer's instructions for each instrument.

Facility Licensing - Richmond

Kathy Williams, Section Chief of Facility Licensing in northern California, reported that between September 1 and November 31, 2014, her section received 41 applications for licensure, of which 7 were incomplete and had to be returned. Two hundred twenty-eight applications for registrations were received. Twenty new applications were received from chiropractors, 5 were received from pharmacists, 9 were received from optometrists, and 1 was from a naturopath. She noted the problem that the pharmacy board is not keeping its roster of pharmacists-in-charge up to date, so LFS staff is unable to verify pharmacists-in-charge for particular sites and must return applications to corporate headquarters to verify such information.

Ms. Williams reported that between June 1, 2014 and December 1, 2014, her section received a total of 66 complaints. Seventeen of these were major complaints: two involved test errors, five involved test management and quality control, one involved state licensing, four involved tests being performed by unauthorized personnel, and five complaints concerned draw stations. LFS received 42 miscellaneous complaints. Twenty-eight were referred to other departments and ten were resolved by LFS staff. Four complaints did not provide sufficient information for investigation. LFS contacted the complainants but received no response. Ms. Williams noted that the operation of phlebotomy draw stations and mobile units by

persons not under the oversight of a laboratory director was becoming an issue.

Shiu-Land Kwong asked if there had been any follow-up enforcement actions as a result of investigations of complaints. Ms. O'Keefe said that there is one case in which an action may be taken as a result of a complaint investigation, but the case is still in process. Ms. Williams stated that Shideh Khashe, the examiner in charge of the complaints program, tracks complaints to ensure that they are followed up and corrective actions are made, requesting plans of correction and making recommendations based on responses to complaints. She noted that LFS has received many requests from phlebotomists wanting to operate mobile draw stations, and said that LFS informs them that they must operate under the supervision of a laboratory director.

New business

Lorri Dean-Yoakum asked if anyone had new business to discuss or if there were suggestions for future business. She noted that the approval of the minutes for the meeting of September 2014 and the nomination of a new chair person must be carried over to the next meeting due to lack of a quorum at the present meeting.

Robert Footlik's questions about EQC were suggested as an item for future discussion.

Lorri Dean-Yoakum will confer with Dr. Lee Hilborne about the possibility of a discussion of digital pathology.

Rhonda Becker suggested that Dr. Carol Glaser be invited to present an update on the Ebola Virus Disease outbreak. Ms. O'Keefe announced that Dr. Glaser had resigned from her position at CDPH, but said that this would not preclude inviting her to speak at CLTAC meetings.

Lorri Dean-Yoakum thanked Fred Ung, Rebecca Rosser, and Kaiser Permanente for making their facilities available for the southern California CLTAC meeting. She also thanked Beatrice O'Keefe, Mary Wogec, Kathy Williams, Don Miyamoto, and Dennis Tavares for their work in preparing for the northern California meeting and ensuring its smooth operation.

It was requested that the September meeting in 2015 be rescheduled from September 4 to September 11, to accommodate the Labor Day holiday weekend. CLTAC meetings in 2015 are scheduled for March 6, June 5, September 11, and December 4.

Ms. Dean-Yoakum asked that if anyone had other suggestions for new business, they be forwarded to herself or to Ms. O'Keefe.

Next meeting

Lorri Dean-Yoakum announced that the next meeting of the CLTAC would be held on Friday, March 6, 2015.

Adjournment

Rhonda Becker moved that the meeting be adjourned, the motion was seconded by

Jennifer Schiffgens, and the CLTAC voted to adjourn at 11:45 PM.