

Clinical Laboratory Technology Advisory Committee
Minutes of the Meeting held on September 5, 2014
Meeting held by videoconference from Richmond campus, CDPH,
KP Regional Laboratory, North Hollywood and
Telephone Bridge Line

CLTAC members participating

John Basile, Rhonda Becker, Richard Bennett, Marjorie Braasch, Patricia Dadone, Lorri Dean-Yoakum (chair), Kathleen Doty, Robert Footlik, Lee Hilborne, Anne Igbokwe, Armand Parada, Rebecca Rosser, Fred Ung.

Former CLTAC members participating

Sam Chafin, Imre Fischer, Carmen Maldonado.

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Ron Harkey, Tina Hashemi, Robert Hunter, Nema Lintag, Victoria Maxwell, Donna McCallum, Don Miyamoto, Beatrice O'Keefe, Jan Otey, Tammy Pahland, Judy Schlosser, Dale Statley, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

Public members participating

Angela Aguiluz, Michael Aidan, Lara Baden, Barbara Brunell, Irene Chen, Anna Choi, John Cardoza, Kathy Davis, Debbie Ferguson, Nancy Fraize, Diane Giles, David Gomez, Dora Goto, Carola Howe, Shiu-Land Kwong, Lois Langs, Dan Leighton, Jamie Marks, Iris Miu, Valerie Ng, Polly Rapp, Rodney Roath, Gerald Schultz, Shannon Smith-Crowley, Christine Vernusky, Phyllis Walker, Gary Yamamoto, Annie Yang, Tammy Zinsmeister.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:05 a.m. Ms. Dean-Yoakum 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 June 6, 2014 meeting minutes

Robert Footlik and Lorri Dean-Yoakum submitted corrections to the minutes. Rhonda Becker moved that the minutes from the June 2014 meeting be approved as corrected. Ms. Dean-Yoakum asked if any CLTAC board members had joined the meeting since the roll call was taken, and three more members were present. It was established that a quorum of CLTAC members was present, and Robert Footlik seconded the motion. The minutes were approved as amended by unanimous vote.

Department update

Beatrice O'Keefe, chief of Laboratory Field Services (LFS), gave an update for the Office of the State Public Health Laboratory Director (OSPHLD) in the California Department of Public Health (CDPH).

Ms. O’Keefe gave an update on the Department’s application for accreditation by the Public Health Accreditation Board (PHAB). The application process began in 2012, when the Department began the process of documentation to demonstrate the Department’s advancements in quality and performance. A strategic map was developed, and over 20,000 pages of documentation were assembled. 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 a visit 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 how to facilitate the Act’s success, engaging the private sector, the development and use of metrics to track progress and success, training and development of the work force, succession planning in the face of an aging work force, and the use of social media to advertise open positions. Overall the team’s response was positive.

In the next step, the team will develop and submit a report to the PHAB accreditation committee, which will meet in December 2014.

Update from legal counsel

Tammy Pahland, staff counsel for LFS, reported on the requirement that all CLTAC board members submit a Form 700 Conflict of Interest report. Rhonda Becker asked if this is the first time that CLTAC board members have been required to submit this form. Ms. Pahland said that this is the first time, although the issue has been under discussion for some time. Ms. O’Keefe said that CLTAC is covered under category 11, and board members must disclose any interest or income from any clinical laboratory that is regulated by CDPH. She noted that this does not include research laboratories, and encouraged any board member who has questions to consult with Tim Ford, who is directing the Form 700 process. She added that income earned for work for a government laboratory need not be disclosed. The Form 700 is only one part of the Conflict of Interest program. Ms. Pahland encouraged people to consult the Fair Political Practices Commission’s website at <http://fppc.ca.gov/>, as well as the CDPH webpage regarding the Fair Political Practices Commission at <http://www.cdph.ca.gov/services/DPOPP/regs/Pages/DPH-11-018ConflictofInterestCode.aspx>. She noted that a wet signature is required on the form, and that it must be mailed by September 19, 2014. There are penalties for non-filing of \$10.00 per day up to \$100.00.

Ms. Pahland explained that this matter has been discussed at length over the course of several years, and it was determined that if a committee helps the Department to make decisions with financial implications for laboratory interests, for example the processes with regard to the CLIA crosswalk and regulations that could affect the Department or the regulated community, members of the committee must disclose

their financial interests. Thirteen committees within CDPH are now being required to make these disclosures. She noted that any questions should be forwarded to Mary Wogec. She also said that the form is a public document, so she advised members to provide a business address and contact information rather than personal information.

LFS update

Beatrice O'Keefe, chief of LFS, reported that LFS has submitted the regulations package DPH-11-012, which deals with personnel licensing regulations, to the Office of Regulations. This is a huge package that makes revisions to all the personnel license categories and training schools. The new regulations broaden the college degrees that would allow limited scientists and generalists to qualify for licensure. They also broaden the scope of practice elements that can be changed by regulations.

A report received from the Office of Regulations outlined a number of revisions that must be made before the package can be submitted to the Health and Human Services (HHS) agency. These revisions will improve the clarity and consistency, reduce duplication, and clarify the necessity and benefit of the new regulations and facilitate the approval of the package. The report from the Office of Regulations noted that HHS is requesting LFS to consolidate duplicative sections, for example sections for the Clinical Laboratory Scientist specialties, to produce a leaner document.

Ms. O'Keefe reported that LFS is also working on a transition to a new licensing software platform for personnel licensing and eventually for facilities licensing. This transition is required by a mandate from the State to bring all information technology services in-house, which means that the system supplied by an independent contractor must be replaced by new software that can be maintained by CDPH staff. There is one year remaining on the old contract, during which time the transition must be completed.

There are three phases to the implementation of the PEGA platform. The first phase will introduce an in-house online application and payment system. It must be completed by June, 2015. The second phase will bring online the personnel licensing renewal process, and the third and fourth phases will make similar changes in initial applications and renewals to the facility licensing process and bring it online.

Ms. O'Keefe also reported that an examination for the position of Examiner III is expected to be announced soon. The final filing date for this examination is October 2, 2014. She encouraged interested persons to visit the State personnel webpage (<http://www.calhr.ca.gov/Pages/home.aspx>) or contact Mary Wogec for further information.

Robert Footlik asked in regard to the regulations package if there is any chance that LFS will add back embryologists and biogeneticists, which were removed from the previous personnel regulations package. Ms. O'Keefe responded that it is not possible to add new sections, which would require starting over with a new regulations package, but she added that she would ask the Office of Regulations if it might be possible.

Mr. Footlik asked when the new draft of the regulations would be available. Ms. O'Keefe said that it depends to a large extent on the staff of the Office of Regulations. LFS is working to make the requested revisions, and this is a high priority for LFS staff.

Robert Thomas said that for five categories, embryologist scientist, embryologist director, biochemical geneticist scientist, biochemical geneticist director, and immunologist director, there is no authority for charging a licensing fee, and for this reason the Office of Regulations told LFS that these categories could not be included in the new regulations package.

CLIA Crosswalk Subcommittee update

Lorri Dean-Yoakum said that Robert Footlik, chair of the CLTAC subcommittee on the CLIA crosswalk, reported that the subcommittee has no report at this time. She said that the board could ask Mr. Footlik to give a verbal summary at today's meeting and vote on it, or wait for a written report and vote on it in December. Rhonda Becker asked if Mr. Footlik had additions to the minutes from the last meeting.

Mr. Footlik noted that he wanted to make some clarifications with regard to Equivalent Quality Control (EQC) and the Individualized Quality Control Plan (IQCP). He noted that as far as he is aware, neither of them is part of a final CLIA rule. He said that the subcommittee must review the final CLIA rules that have been adopted. These are part of the interpretive guidelines. Since 1993, CLIA stipulates that there is an alternate quality control method and a laboratory can choose to use the alternate method rather than EQC or IQCP in the regulations. This was adopted as California state law in January, 1994. Both EQC and IQCP are part of the interpretive guidelines. The interpretive guidelines are not regulation, so it cannot be accepted in California law. Mr. Footlik said that he does not agree with this, but he pointed out that the subcommittee has no control over that. Kathy Williams was asked if she had anything to add. She said that she asked for guidance and was told that the Office of Legal Affairs doesn't permit anticipatory regulations and so LFS cannot accept or incorporate it. Thus, no alternative quality control method could be accepted at this time.

Donna McCallum noted that IQCP will be published in the interpretive guidelines. Kathy Williams remarked that for this reason California IQCP must be adopted in federal regulations. Lorri Dean-Yoakum noted that this is guidance for the regulated community, and restated LFS guidance that there is no plan to implement IQCP in California at this time.

Robert Thomas asked if LFS could write its own regulations package. Ms. Williams said that it would be necessary to seek counsel on this question. Ms. O'Keefe observed that there are limits to the number of regulation packages that CDPH can submit each year and consequently to the number that the program can submit. Kathy Williams said that she asked Tammy Pahland about the process for publishing the crosswalk in the California register, and when she receives an answer she will rewrite the report document in the format required for publication.

Lorri Dean-Yoakum said that the board will wait until the report is received in December to vote.

Guest Speakers

Dr. Carol Ann Glaser

Lorri Dean-Yoakum introduced Dr. Carol Ann Glaser. Dr. Glaser is Acting Chief of the Immunization Branch in the Division of Infectious Disease Control in the Center for Infectious Diseases in the California Department of Public Health. She has also served CDPH as Chief of the Encephalitis and Special Investigations Section of the Emergency Preparedness and Response Branch, Chief and Medical Officer of the Viral and Rickettsial Disease Laboratory Branch of the Division of Communicable Disease Control and Chief of the Encephalitis and Special Investigations Section of the Emergency Preparedness and Response Branch, in addition to other positions outside the Department.

Dr. Glaser introduced her associates Kathleen Harriman, Channing Sheets, and Jill Hacker, who worked with her on the presentation about Ebola virus disease and the laboratory issues raised by the current outbreak.

Dr. Glaser opened with a brief background to the current outbreak in Africa, explaining that Ebola virus disease (EVD) is one of the viral hemorrhagic fevers (VHF), which are characterized by severe multi-organ damage, damage to the overall vascular system, and symptoms often accompanied by hemorrhage such as conjunctivitis, petechiae, and ecchymosis. The Ebola virus is one member of a viral family that includes Hantavirus, Yellow Fever, Dengue, and a number of other viruses that cause such fevers. These are RNA viruses, which are characterized by an enveloping lipid coating and which depend for survival on an animal or insect host as their natural reservoir.

Dr. Glaser explained that the Ebola virus was identified in 1976 and is named for the Ebola River in the Democratic Republic of the Congo (formerly Zaire) in central Africa, where the disease was first identified. She noted in a brief history of previous outbreaks of EVD that since 1976, approximately 50 outbreaks of EVD have occurred. The largest such outbreak before the current one involved around 425 cases, while most involved fewer than 100 cases. Epidemiological studies implicate bats as the reservoir hosts for the Ebola viruses. From bats, the viruses spread to other wild animals, with human infection developing through contact with infected animals, which then triggers waves of human to human transmission that can develop into epidemics.

Ebola virus disease is transmitted via direct contact with the blood or bodily fluids of infected animals or humans, or by contaminated medical equipment, particularly needles and syringes, as well as processes involved in the embalming of infected dead persons. The disease is spread only by direct contact with bodily fluids of persons who show signs of infection. Airborne spread has not been documented among humans in a real-world setting, although it has been documented under research conditions in a Canadian study that involved pigs and macaques.

Ebola virus disease is particularly dangerous due to the high viral load in body fluids of infected persons, including the bodies of the deceased and the semen of

survivors for up to 50 days, the low dose required for infection, and the highly pathogenic nature of the disease, which has a mortality rate of around 79%.

The disease has an incubation period of 2 to 21 days, typically 8-10 days. Initial symptoms include fever, chills, myalgia, malaise, and asthenia. By day 5, the symptoms progress to include watery diarrhea, nausea, vomiting, abdominal pain, shortness of breath, hiccups, conjunctival infection, seizures, cerebral edema, confusion, and in some patients diffuse erythematous maculopapular rash on the face, neck, trunk, and arms. On days 6 through 16 the disease may progress to multiorgan failure, septic shock, and hemorrhage. Case fatality rates range from 55% to 75%.

Laboratory findings include leukopenia, frequently with lymphopenia, which may be followed by elevated neutrophils and a left shift, decreased platelet counts (50,000 – 100,000), elevated hepatic transaminases, prolonged prothrombin and partial thromboplastin times and elevated fibrin degradation products, and in some cases proteinuria.

There are no approved treatments available for EVD, although ZMapp is being evaluated. Patient care is limited to supportive care of complications, such as hypovolemia, electrolyte abnormalities, refractory shock, hypoxia, and septic shock. Experimental trials of a vaccine were started in September 2014.

There is considerable controversy surrounding laboratory practices to be used when testing samples from patients suspected to have EVD, with different guidelines being proposed by the CDC, the American Society for Microbiology (ASM), and others. The CDC recommends that in the laboratory, risk assessments should be conducted by each laboratory to determine potential for sprays, splashes, or aerosols generated by laboratory procedures. PPE requirements, practices, and safety equipment controls should be adjusted as needed to protect laboratorians' skin, eyes, and mucous membranes. Anyone performing phlebotomy procedures should wear PPE. Anyone testing specimens from a patient suspected to have EVD should wear PPE and should use a certified class II biosafety cabinet or plexiglass splash guard with PPE.

The American Society for Microbiology (ASM) recommends that all specimens be labeled "Suspected HFV (Hemorrhagic Fever Virus)" and testing that requires specimen removal from a patient's room and transport to the lab should be kept to a minimum. Pneumatic tube systems should not be used to transport specimens, and all specimen manipulation must be performed in the patient's room or in a biologic safety cabinet in an AFB suite while wearing PPE that includes impermeable gown, double gloves, eye protection, an N-95 mask, and shoe covers. Dr. Glaser pointed out the differences between surgical masks, which are designed to protect the sterile field and the work environment, and respirators, which are designed to protect the wearer from airborne contaminants, and noted that the level of protection afforded by these devices depends on the efficiency of the filter as well as the seal between the face piece and the face of the wearer.

The ASM recommends that diagnostic testing be limited to iSTAT or equivalent POC testing systems and performed in the patient's room. Urinalysis available as dipstick

testing should also be performed in the patient's room. Rapid Malaria antigen testing is preferred, to be performed in the patient's room. Blood cultures should be performed only if required and blood draws should be minimized, using plastic bottles if available. No direct testing should be performed on positive blood cultures. All specimen containers should be wiped with bleach, double-bagged in bags containing pads soaked with bleach, then placed in rigid, impervious plastic containers and isolated until they can be disposed of in an appropriate manner. Long-term storage of specimens from suspected HFV patients is not permitted. All specimens should be autoclaved prior to disposal or, if that is not available on site, the laboratory director should be contacted for procedures for discarding specimens and laboratory waste.

Diagnostic tests to be used differ with the timeline of infection. Within a few days after symptoms become evident, CDC recommends antigen-capture enzyme-linked immunosorbent assay (ELISA) testing, IgM ELISA, polymerase chain reaction (PCR), and virus isolation diagnostic tests. Later in the course of disease or after recovery, IgM and IgG antibodies are recommended. Retrospectively in deceased patients, immunohistochemistry testing, PCR, and virus isolation are used.

The state or local health department should be contacted to determine the proper category for shipment and to obtain guidance and CDC submission documents for suspect patient specimens. Specimens for ruling out EVD will likely fall under Category A, defined as infectious substances that are capable of causing permanent disability or life threatening or fatal disease to humans or animals when exposure occurs.

Dr. Glaser pointed out the CDPH Ebola Virus Information Page, which can be accessed online at <http://cdph.ca.gov/programs/cder/Pages/Ebola.aspx> and is updated regularly. She also suggested that people check the CDC Ebola Virus Disease webpages at <http://www.cdc.gov/vhf/ebola/index.html> and <http://www.cdc.gov/vhf/ebola/hcp/index.html>.

Bea O'Keefe asked about disease transmission, noting the number of trained health care workers being infected by the disease. Dr. Glaser referred to the CDC website, and asked Kathleen Harriman to address the issue of transmission. Ms. Harriman pointed out that the difference between airborne transmission and transmission by droplets is a continuum rather than a sharp distinction, and added that the transmission of EVD is not completely understood. She noted that Médecins sans Frontières teams use respirators with a filter and a tight seal rather than surgical masks, which do not have a tight seal, and they have had no cases of health care worker infection.

Robert Footlik noted with regard to the PPE recommended by ASM that it appears that precautions for airborne transmission are being recommended, and asked if this is an airborne transmissible disease. Dr. Glaser said that judging from her discussions with laboratorians the ASM recommendations seem to be taking extreme cautions. She said that it is not known for certain if the disease is airborne-transmissible, but it is preferable to use an abundance of caution.

Asked about shipping, Channing Sheets noted that Ebola is on the select agent list,

and must be destroyed within 7 days. If a laboratory receives a sample of a select agent, it must confirm the sample with the CDC by filling out the proper form, and the sample must be transported or destroyed within 7 days. He noted that the transfer process is labor intensive and encouraged anyone who is interested to contact him for a copy of the ASM guidelines, which can also be viewed online at www.cdc.gov/vhf/ebola/hcp/index.html

Tammy Zinsmeister suggested the possibility of preparing people for dealing with an outbreak of the disease by holding a summit similar to the COLA Leadership Summit that was held in San Francisco on April 28-29, 2014. She arranged to contact Dr. Glaser with information about a similar summit on SARS (Severe Acute Respiratory Syndrome) that she was involved in when there was an outbreak of that disease.

Dr. Glaser warned that the predictions for the current outbreak of EVD are dire, and the end is not in sight. It is not unlikely that there could be more than 20,000 reported cases before the outbreak is brought under control. The situation is exacerbated by the fact that in the countries most severely affected, there is little to no health care infrastructure, people don't believe the disease is caused by a virus and refuse to present for health care, and there are not enough health care workers to deal with the patient population. She noted that what we are seeing is only the tip of what could be a much larger iceberg.

Ms. Dean-Yoakum thanked Dr. Glaser and her colleagues for an informative and timely presentation, and suggested that they be asked to return to a future meeting to give an update.

Dr. Jared Schwartz

After a short break, Lorri Dean-Yoakum introduced the second guest speaker, Dr. Jared Schwartz. Dr. Schwartz received his M.D. degree from Duke University Medical School and his Ph.D. from Duke University Graduate School. He is an independent consultant in pathology and laboratory medicine and has served as president of the College of American Pathologists (CAP), and as a consulting professor in the Department of Pathology at the Stanford University School of Medicine.

Dr. Schwartz was invited by Dr. Lee Hilborne of the CLTAC board to address the meeting on the topic of digital pathology, and presented a webinar from his location in Chicago. Dr. Schwartz explained that electronic transmission of full-slide imaging as it is currently practiced can be cumbersome. A slide must be scanned and then be sent elsewhere, which involves files that, even when zipped, are very large. Technology is changing rapidly, however, with new developments that make long-distance pathology much more convenient. Dr. Schwartz noted that most medical schools are replacing microscopes with iPads and similar digital devices, and remarked that once a slide has been digitized, images can be sharp enough that they can be used to make a diagnosis. The tools used to create the image are different from those used to create glass slides, but the images produced are equally good. Advances in technology have made it possible to use robotics and digital techniques to perform surgery on a patient in a remote location.

“Digital pathology” refers to the creation and use of digitized images using a variety

of digitizing techniques for purposes of diagnosis. Dr. Schwartz noted that although medical schools are making the switch to digital technology, many pathologists are still being trained with microscopes, and said that with regard to regulatory activity, training in digital techniques needs to be made a high priority. He noted the drawbacks of glass slides, including difficulty of storage and retrieval. In some cases it can take as long as 10 days for an individual slide to be located, retrieved, and shipped. With digital technology, a slide can be scanned into a database and from there imported into a patient's electronic medical record (EMR), and is instantly available to anyone with access to that record. Rather than being packed and shipped, it can be transmitted almost instantaneously via a secure, HIPAA-compliant server anywhere in the world. This new technology is safer than the old technology and provides more metrics for quality assurance, and ultimately better patient care.

Dr. Schwartz noted that this technology already exists and is already in extensive use in hospitals and academic medical institutions around the world, though less frequently in the US than elsewhere. He referred interested people to the website of the US Department of Health and Human Services for more information on digital priorities, and noted that digitization may increase the availability and improve the quality of health care and also enhance the ability to recruit and retain a qualified workforce. Digital pathology has been approved by regulatory agencies in the European Union, China, Brazil, and other countries because of the acute shortage of pathologists combined with the difficulty of transporting and receiving pathology reports.

He stated that technology is developing and being utilized rapidly, but pathologists in the US are not being trained to use it. Digital pathology has the capacity to revolutionize medical practice, and it is up to laboratories to understand it and develop the metrics to use it appropriately. He also noted the potential of digital pathology to improve health care in the US as it has elsewhere, offering a patient at a rural 50-bed hospital the same quality of health care that is available to a patient at a major medical center.

Robert Footlik asked if there are any software applications that can assist a pathologist in making a diagnosis. Dr. Schwartz said that this is under development and that software can be used to identify specific patterns. He cited the example of rare event detection software being developed by the military, and noted that although software cannot yet make a diagnosis, it can aid a pathologist to do that.

Ms. Dean-Yoakum thanked Dr. Schwartz for his excellent presentation.

Biologics and Tissue Bank Program update

Ron Harkey, section chief of the Biologics and Tissue Bank Section, reported on proposed legislation being analyzed by his program. Assembly Bill (AB) 1822, proposed by Assemblyman Rob Bonta, deals with the storage of tissue for implantation into or application onto patients, and would exempt 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. This bill has not changed since Mr. Harkey made his report at the March and June meetings except for technical, non-

substantial changes. It has been enrolled and is awaiting a decision by the governor.

Mr. Harkey reported on the work of his section that there are four major investigations underway in the tissue banking program, and that Robert Hunter in Los Angeles is working on three investigations in blood banking. Mr. Hunter said that he would report on his investigations at the December meeting. He said that blood banks and hospital laboratories are acutely aware of the danger of Ebola virus and are taking precautions. Mr. Harkey noted with regard to Dr. Schwartz's presentations on digital pathology that the adoption of digital technology will have a huge impact on the field of cytotechnology.

Facility Licensing - Richmond

Kathy Williams, Section Chief of Facility Licensing in northern California, reported on AB 2143, which has been chaptered and is in effect as emergency legislation. The bill concerns exempting doctors of chiropractic from the requirement of having a state laboratory director for their practice so that they may participate in the Department of Transportation (DOT) physical fitness examination. The single dipstick test that they perform under this exemption includes urine-specific gravity, urine protein, urine blood, and urine sugar tests that are classified as waived clinical laboratory tests under CLIA for the sole purpose of completing the Department of Motor Vehicles Medical Examination Report. They may only be exempt if certified through the DOT and listed on the most current federal DOT and National Registry of Certified Medical Examiners (National Registry). Ms. Williams noted that there is a webpage where certification can be verified. She noted that currently in California 250 medical doctors are certified to administer these examinations, and no chiropractors are certified at present. She added that if doctors of chiropractic want to perform any other waived tests they must follow state requirements and have a qualified director of their laboratories.

Ms. Williams announced the addition of a new employee to her staff, Desiri Moret-Blyden, who will assume some of Jun Mallillin's duties when she has completed orientation.

Ms. Williams reported that between June 1, 2014 and September 1, 2014, her section received 48 complaints. Eleven of these were major: two involved test errors, four involved test management and quality control, one involved state licensing, and four involved tests being performed by unauthorized personnel. LFS also received 29 other complaints. Eighteen were referred to other departments, seven were resolved by LFS staff, and four did not provide sufficient information for investigation.

Jan Otey reported on Senate Bill (SB) 492, proposed by Senator Ed Hernandez. The bill has been withdrawn, and is now dead.

Facility Licensing – Los Angeles

Joanne Rowan, Section Chief of Facility Licensing in southern California, was on vacation and no report was given for her section.

Personnel Licensing Update

Zahwa Amad, Section Chief of Personnel Licensing, reported on the change of policy on walk-in applications for personnel licenses and announced that Laboratory Field Services is no longer serving walk-in clients. She thanked laboratory directors for their cooperation in notifying their employees of the change, and noted that walk-ins have declined from approximately 20 per week to less than 2 per week.

She noted that she has an excellent staff now, and that they are processing applications and renewals very efficiently. She asked that anyone who is experiencing difficulties with personnel licensing issues contact her directly.

Dr. Amad also noted changes to the LFS Personnel section's web pages that will make it easier to use, and thanked Mary Wogec for her work on the website changes. To date, LFS has updated the page on renewal and continuing education, which also includes information on change of name and address, added CLTAC agendas and minutes for all meetings since 2010 to CLTAC webpage, added information about the walk-in policy to the LFS homepage (under News, Hot Topics, and Updates), and updated the contact list (under Contact LFS on the LFS homepage). We are in the process of making new frequently asked questions (FAQs) for the phlebotomy program. These are almost ready, and should be available by the end of September. Once those have been posted, we will make and post new FAQs for other license categories.

She reported on the Medical Laboratory Technician (MLT) program that the last MLT licensed by LFS had an MLT license number of 512. This program was launched in 2007, and it appears that it is not moving forward as expected. From January through June 2014 LFS received 85 MLT applications, or an average of 15 per month. LFS licensed 75 of the applicants, or 88%. Fifty-six of the licensees were trained in California and 19 were trained out of state. Ten other applicants are awaiting official documents or have not yet passed the exam.

In June 2014 there was one approved MLT training program, Santa Monica College. LFS has recently been notified that Santa Monica College is not accepting new students. Diablo Valley College is also not accepting new students. Currently there are six active MLT training programs: two in northern California, Folsom Lake College and De Anza College, and four in southern California, Southwestern College, Saddleback College, San Diego Miramar College, and College of the Canyons.

She also reported that the 5,115 applications for phlebotomy certification were received from January through August, 2014, compared to 4,451 applications for the same period in 2013. LFS issued phlebotomy certificates to 4,481 applicants from January through August, 2014, compared to 3,432 certificates issued during the same period in 2013. There has been a significant increase in the number of phlebotomy applications and certifications in the past year.

In 2013, LFS received an average of 77 new applications for CLS trainee licenses each month, and licensed an average of 79 CLS trainees each month. In 2014, LFS received an average of 64 applications each month and licensed an average of 64 CLS trainees each month.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, reported that through the end of July 2014, the CLIA section performed 53 initial surveys and 497 recertification surveys. Five validation surveys were completed, one onsite complaint investigation was performed, and 28 proficiency testing desk review sanctions were issued. No waived laboratory surveys were performed due to a lack of sufficient staff.

Ms. McCallum announced that the Centers for Medicare & Medicaid Services (CMS) have approved a new accreditation agency, A2LA (American Association for Laboratory Accreditation), which is approved for all specialties and subspecialties.

Ms. Dean-Yoakum thanked Beatrice O'Keefe and Mary Wogec for arranging for excellent speakers at CLTAC meetings this year, and also thanked Ms. Wogec for her work in arranging the details of meetings and for her outstanding work on the minutes.

She thanked Dr. Lee Hilborne for arranging to have Dr. Schwartz speak on digital pathology.

New business

Lorri Dean-Yoakum asked if anyone had new business to discuss.

Beatrice O'Keefe asked that laboratories encourage phlebotomists in their laboratories to renew their certificates in a timely fashion. She reiterated that LFS will no longer accommodate walk-in applications or renewals, and asked laboratory directors to remind their staff members to renew on time.

Dora Goto asked about the acceptance status of Weber State College's online training course. Zahwa Amad said that the online training course was no longer accepted as of May 2014. LFS received numerous complaints from CLS training coordinators regarding the curriculum of the medical microbiology class offered at Weber State. LFS investigated those concerns and has been in communication with Weber State since March 21, 2014. LFS reviewed the curricula and content of these courses and determined that the course curriculum does not reflect a medical microbiology course content. LFS notified Weber State College personnel regarding the results of our review on March 21, 2014, April 21, 2014, and May 23, 2014.

LFS sent an email on May 08, 2014 to all the educational coordinators of the LFS-approved CLS training programs regarding courses offered at Weber State College, and directed them to accept all courses completed by May 1, 2014. LFS notified Weber State College of the end date of May 1, 2014 as their courses run through April 28, 2014.

LFS and Weber State College are working on a solution to the problems that led LFS to withdraw approval. Once these issues are resolved and LFS receives Weber State College's modified curricula, LFS hopes to be able to approve the courses of the online program.

Ms. Goto pointed out that students are caught in the middle. Dr. Amad said that LFS has not denied any students as a result of this problem and has not requested any student to repeat a course taken at Weber State College, and has informed students of available alternatives. She noted that Weber State College is not the only such problem that LFS is dealing with. She suggested continuing the discussion with Ms. Goto later, and said she would be happy to discuss the quality of course content, instruction, course length, and inconsistency between course title and content.

Ms. Dean-Yoakum asked for further recommendations for topics for future discussion. A discussion of the CLIA crosswalk was requested, and it was requested that Dr. Glaser be invited to the December meeting to give an update on the outbreak of Ebola virus disease. Dr. Hilborne suggested that it would be worthwhile to hold a brief discussion of Dr. Schwartz's presentation on digital pathology.

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, December 5, 2014.

Adjournment

Rhonda Becker moved that the meeting be adjourned, the motion was seconded by Armand Parada, and the CLTAC voted to adjourn at 12:30 PM.