

Clinical Laboratory Technology Advisory Committee

Minutes of the Meeting held on March 6, 2015

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

CLTAC members participating

Jonathan Bautista, Rhonda Becker, Richard Bennett, Marjorie Braasch, Patricia Dadone, Lorri Dean-Yoakum (chair), Elizabeth Dequinia, Kathleen Doty, Robert Footlik, Lee Hilborne, Armand Parada, Rebecca Rosser, Jennifer Schiffgens, Fred Ung.

Former CLTAC members participating

Michael Borok, Sam Chafin, Imre Fischer, Carmen Maldonado.

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Pamela Farrell, Elaine Flores, Ronald Harkey, Robert Hunter, Paul Kimsey, Nema Lintag, Yangzhu Long, Victoria Maxwell, Donna McCallum, Don Miyamoto, Martha Obeso, Beatrice O'Keefe, Jan Otey, Tammy Pahland, Joanne Rowan, Judy Schlosser, Pat Toomer, Kathy Williams, Mary Wogec.

Public members participating

Bob Achermann, Michael Aidan, Geraldine Albee, Barbara Brunell, Yvonne Carter, Rafael Cassata, Behnaz Dardashti, Ilene Dickman, Karen Fuller, David Gomez, Carola Howe, Peggy Kollars, Shiu-Land Kwong, Lois Langs, Dan Leighton, Jill MacAfee, Iris Miu, Valerie Ng, Karen Nickel, Rodney Roath, Thomas Tempske, David Topp, Alicia Triplett, Christine Vernusky, Phyllis Walker, Maureen Weber, Debbie Wilson-Ferguson, Gary Yamamoto, Annie Yang, 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.

Ms. Dean-Yoakum conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was present for the meeting.

Introduction of New Board Member

Ms. Dean-Yoakum introduced a new member of the CLTAC board, Jonathan Bautista. Mr. Bautista was nominated by Blood Centers of California to serve the remaining term of Vicki Finson, who has resigned from the committee. He is a licensed clinical laboratory scientist who has worked in numerous research and clinical laboratories, including Chiron Diagnostics, Roche Diagnostics, The Blood Center, and Stanford Blood Center, where he currently serves as the Chief Operating Officer.

Approval of the September, 2014 meeting minutes

Robert Footlik and Lorri Dean-Yoakum submitted corrections to the minutes from the

September meeting, but due to lack of a quorum at the December 2014 meeting the September meeting minutes were not approved. Rhonda Becker moved that the minutes from the September 2014 meeting be approved as corrected. Marjorie Braasch seconded the motion and the September minutes as amended at the December 2014 meeting were approved by unanimous vote.

Approval of the December, 2014 meeting minutes

Mary Wogec submitted one correction to the minutes from the December meeting. Rhonda Becker moved that the minutes from the December 2014 meeting be approved as corrected. Jennifer Schiffgens seconded the motion and the minutes as amended were approved by unanimous vote.

Election of officers

Lorri Dean-Yoakum invited nominations for chair. She explained 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 of 2015. The term of the newly elected chairperson will end in June of 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 called for a vote and Ms. Becker was unanimously elected. Ms. Dean-Yoakum congratulated Ms. Becker and wished her success in her tenure as chairperson. Ms. Becker will be installed as chairperson at the June meeting.

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 reported 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. Dr. Kimsey announced that Governor Brown appointed Dr. Karen Smith to succeed Dr. Chapman as Director of CDPH and State Public Health Officer.

Prior to her appointment Dr. Smith, a physician specializing in infectious disease and public health, served as public health officer and deputy director at the Napa County Health and Human Services Agency. She has served on the medical staff for infectious disease at Queen of the Valley Medical Center in Napa since 2012 and as a faculty consultant for the Francis J. Curry International Tuberculosis Center at the University of California at San Francisco since 1997. Dr. Smith completed her medical training and infectious diseases fellowship at Stanford University after having obtained a Master of Public Health degree in International Health at Johns Hopkins School of Hygiene and Public health. Prior to her medical training she worked in communicable disease control for the Peace Corp in Morocco, Thailand, and Nepal. Dr. Smith will be sworn in on March 23, 2015. Dr. Kimsey noted that Dr. Smith has indicated an interest in the laboratories at the Richmond Campus and hopes to make frequent visits to the campus.

Dr. Kimsey reported that until Dr. Smith takes office, the Governor has appointed Michael Wilkening to serve as Acting Director of CDPH and Dr. James Watt, Chief of

the Division of Communicable Disease Control in the Center for Infectious Diseases at CDPH, as Acting State Public Health Officer.

Dr. Kimsey also announced the resignation of Kathleen Billingsley from her position as Deputy Director of Policy and Programs at CDPH. Ms. Billingsley has joined Blue Shield of California as vice president of California Public Employees Retirement System (CalPERS) and the University of California sector, responsible for the program, product, and account management teams.

Dr. Kimsey reported that the Department received its formal letter of accreditation from the Public Health Accreditation Board (PHAB) on December 9, 2014. This letter marked the culmination of the Department's two and a half year journey to accreditation.

Dr. Kimsey addressed issues raised in a letter to the Governor and legislative leaders by State Auditor Elaine Howle dated March 3, 2015. He noted that CDPH has over 200 programs, and only two have outstanding audit findings. LFS originally had 20 outstanding findings from the audit mentioned in the letter, which have been consolidated down to nine. Dr. Kimsey noted the high number of vacancies in the program as the main factor contributing to the program's inability to resolve the outstanding findings, but reported that LFS is working diligently and is making good progress toward resolving the remaining findings.

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. She reported that the package is nearing completion. Comments from the public submitted during the pre-comment period last year and comments from the CLTAC subcommittee have been considered and incorporated, queries and comments from the Office of Regulations have been answered and incorporated, and final edits are now being made. The draft package will be released for a second short pre-comment period when the package is ready. Once comments received during that period are considered and incorporated as appropriate, the package will be forwarded to Dr. Kimsey for approval, and then to the Office of Regulations. The formal process will then begin, with review by the director of CDPH, the director of the Department of Health and Human Services, and the Office of Finance, followed by publication and release for the 15-day public comment period.

Ms. Pahland explained that the draft was initially 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 was instructed by the CDPH Office of Regulations to streamline the package and eliminate duplications, with special attention to inconsistencies of language in duplicated sections, which would have entailed a large and time-consuming editing task. LFS explained that the reason for the original formatting was to enhance ease of use by the regulated public and LFS staff, and the Office of Regulations agreed that the original approach was appropriate.

Rhonda Becker asked if the decision to use the original format meant that LFS

would no longer need to hire another attorney to assist with the writing process. Ms. Pahland said that she would continue to work with LFS staff on this process, but that a second full-time attorney will be hired to assist with the drafting of other regulations packages.

Lorri Dean-Yoakum asked the members of the CLTAC subcommittee on this regulations package to be ready to reconvene when the package is released for comment, and asked Robert Footlik to continue as chair of that subcommittee. She expressed her willingness to chair the subcommittee in the event that he is unavailable. Mr. Footlik said that he would be happy to have Ms. Dean-Yoakum serve as chair. Marjorie Braasch and Jennifer Schiffgens said they would be willing to serve on the subcommittee. Mr. Footlik moved that Ms. Dean-Yoakum be named as chair of the CLTAC subcommittee on the DPH-11-012 regulations package, and Lee Hilborne seconded the motion, which was unanimously passed.

LFS update

Beatrice O'Keefe, chief of LFS, reported that examinations for Examiner I and Examiner II were held recently, and that LFS will hold interviews soon for several positions that are currently open. She invited applications from people who would like to use their knowledge and experience as clinical laboratory scientists in a new career in regulation. She noted that applications are now online, with continuous filing, and said that the written examination will also be available online eventually, so people will be able to complete the examination without travelling to a specific location. She also noted that State personnel rules require an examination process for civil service applicants.

Ms. O'Keefe reported that the bill analysis season has started and LFS has received four bills to review and analyze. LFS staff members will report later in the meeting on the bills they are reviewing.

Ms. O'Keefe reported that members of the personnel licensing section have been meeting regularly with Pega, the vendor for the new personnel licensing software system, and work is progressing well on the new online application system for initial licenses and certificates. LFS has reviewed the processes for the 32 categories of licenses issued by LFS and Pega is now working on programming the software to tailor it to the needs of LFS. There are still several issues to be resolved, in particular, the question of how much data can be transferred from the current CPS HR Consulting system to the new Pega system.

Ms. O'Keefe reminded the CLTAC board members that they must complete the annual Form 700 and submit their forms to LFS by March 27 for review, as the forms are due on April 1. Information about filing was sent to board members, but if they have any questions they can email Mary Wogec or Tim Ford, who is in charge of Form 700 filing for CDPH. She noted that new board members must file an "Assuming Office Form 700."

Ms. O'Keefe announced that Joanne Rowan section chief for facilities licensing in the Southern California office of LFS, will be retiring at the end of March. She thanked Ms. Rowan for doing a great job working with the State surveyors in the Los Angeles office, and wished her the best in her retirement.

Discussion of IQCP and EQC

Beatrice O'Keefe invited Robert Footlik to lead a discussion of the issue of Equivalent Quality Control (EQC) and the Individualized Quality Control Plan (IQCP).

Mr. Footlik said that he is waiting for a determination from Tammy Pahland of the State's position whether or not California will continue to take the position that EQC and therefore IQCP is lawful in this state. Mr. Footlik said that it is his position that EQC is current law, and that IQCP is a replacement of EQC, and therefore is also current law. But, he added, the decision was not his to make, and he stated that if there was no further information, he had nothing to say.

Ms. O'Keefe said that Mr. Footlik had mentioned previously that hospitals are currently using EQC, and that this was saving them money on quality control (QC) materials. She asked how this fits in with IQCP as that moves forward with the CLIA program, and asked also if Mr. Footlik could elaborate on what hospitals are doing.

Mr. Footlik said that EQC is being used in hospitals, and that particularly in regard to point-of-care testing programs, EQC is an important tool and will probably be incorporated as part of a limited IQCP program if it is determined to be legal when IQCP replaces EQC next year. If it is determined that it is not lawful it will cost the hospital industry alone millions of dollars and present a difficult challenge to train nurses in how to use the new controls as prescribed in the regulations. He said that is why there is an alternative under subpart K of CLIA, which is California law.

Ms. O'Keefe asked Mr. Footlik if it was his understanding that when hospitals are using multiple point-of-care instruments, they are using electronic controls to control quality for each of these instruments. Mr. Footlik said that they are using such controls, according to manufacturer instructions. He noted that if electronic controls are not run when they are supposed to be, or if an instrument is out of range of the electronic instruments, the instrument will not let the operator continue. Donna McCallum said that what Mr. Footlik was talking about is following manufacturer instructions, and that even under IQCP there is no option to do less than what is recommended by the manufacturer.

Tammy Pahland said that no determination has been made either for or against the assumption that the Interpretive Guidelines are within California law at this point. She stated that she is not ready to make a determination, and added that it is not her decision alone, but is a public-health-wide decision. She said that she welcomes any input in writing to help in her presentation on this issue to authorities higher up in the agency in CDPH, so that she can give as complete a picture as possible to those who will make the final decision. She asked people to send any comments to her at Tammy.pahland@cdph.ca.gov.

Joanne Rowan said that until a decision is made LFS examiners are enforcing default QC in California when they survey laboratories.

Jennifer Schiffgens stated that this is a huge issue for most laboratories, and suggested that CLTAC as an advisory board put together their recommendations for those who will be making the decision. Mr. Footlik said that in his opinion California

law is clear, and that CLTAC cannot change it. Only the state legislature can make changes to the law, and the Department cannot adopt regulations that supersede statute.

Ms. O'Keefe said that one issue is the use of liquid controls versus the use of electronic controls, and she recalled that electronic controls were only agreed upon by CMS through a state agency letter, which had nothing to do with the Interpretive Guidelines. Ms. McCallum said that there is something in the Interpretive Guidelines that addresses this issue but she had not yet reviewed the new guidelines. She said she would review them and report back on what the newly published guidelines say on this issue and what the cross references are.

Ms. O'Keefe said that there are other issues about electronic controls. Ms. McCallum asked if the issue was the Interpretive Guidelines, because a lot of enforcement of the law is in the Interpretive Guidelines. Ms. Rowan said that this was true only with regard to EQC procedure, which is the only part that was adopted into regulation because of one section of the Interpretive Guidelines that allows the Department to refer to Appendix C for EQC. She said that if CMS comes up with an EQC protocol, that protocol can be utilized as regulation. Ms. McCallum said that it has not yet been adopted, and there is an educational period because IQCP came in, but nothing has been finally decided and nothing will be decided until January 1, 2016.

Mr. Footlik encouraged people to look at BCP section 1220, which says that each clinical laboratory shall establish and maintain a quality control program that meets the requirements of CLIA as it was January 1, 1994. He noted that Subpart K section 493.1201 of Title 42 of the Code of Federal Regulations (CFR) says that one can either follow the stipulations of the regulations or, if the State Operations Manual (SOM) has published an alternative program, one can use that. He pointed out that no alternative program was published in the SOM until 2004, when EQC first appeared as an alternative program in state law.

Ms. O'Keefe observed that this is obviously a very complex issue, further complicated by state agency letters that issue guidance and modify even the Interpretive Guidelines.

Robert Hunter said that he will email Ms. O'Keefe a section of one of the pieces that LFS examiners use in fulfilling the requirements when reviewing QC, which shows clearly that a facility must have a QC program that shows that reagents, equipment, and processes need to be sufficiently comprehensive to show that.

Ms. Dean-Yoakum thanked Mr. Footlik and his colleagues for raising the concerns and sharing information about CLIA and California laws and regulations, because this issue has a large financial impact and it also affects quality of care.

Guest speaker
Dr. James Watt

Lorri Dean-Yoakum introduced James Watt, MD, MPH, Chief of the Division of Communicable Diseases in CDPH, and acting State Public Health Officer, who spoke on "Something Old, Something New: Update on Measles and Ebola (and a

Few Others).”

Dr. Watt reported on a recent outbreak of measles, explaining that measles is a highly infectious virus with respiratory spread. Indigenous transmission of measles was eliminated in the United States in 2000 through a vaccination campaign but the disease remains endemic in many other countries, with widespread global transmission. Current controls for measles in the United States include contact investigation, preventive treatment, and quarantine when necessary for active cases. He reported that between January and November of 2014 there were 61 reported cases in the US, the most since 1995. From December 2014 through February 2015 there were 131 cases, at least 80 of which were linked to the Disney theme park exposure widely reported in the news media. With regard to the Disney outbreak Dr. Watt noted that of 80 reported cases, 40 cases developed measles after visiting the park during a single 4-day period, and 40 more developed the disease as a result of secondary exposure, which occurred in multiple settings. The outbreak resulted from an “ideal recipe” for transmission: large numbers of people in a contained space with many international visitors, with transmission amplified by the presence of unvaccinated people.

Dr. Watt reported that the current status of the situation is an ongoing outbreak, with cases reported in 13 counties in California, six states, and Mexico, where 17 cases have been reported linked to exposure at the Disney theme park. There have been at least two additional introductions with different genotypes. Most cases occurred in unvaccinated people. He remarked that this outbreak has required a huge public health investment for containment, and pointed out that vaccination is critical to prevent the spread of this disease.

Dr. Watt also reported on the “old” issue of the ongoing outbreak in West Africa of Ebola Virus Disease (EVD), a severe and highly contagious illness spread by direct contact. To date there have been more than 24,000 cases of the disease, with 10,000 deaths. In the United States, there have been three occurrences of EVD.

A case in Texas presented unexpectedly at a hospital. The diagnosis of EVD was not suspected initially and there was inconsistent infection control. There was a complex contact investigation in response to the initial case, and secondary cases resulted from it. A case in New York with controlled presentation at a prepared hospital was monitored closely by public health officials. The movements of the infected person were known, which simplified investigation, and there was no transmission. Cases at Emory University in Nebraska had no transmission.

Dr. Watt addressed steps being taken to prevent the spread of EVD in the United States: returning travelers are being identified and monitored, hospitals capable of providing treatment have been identified, and emergency medical services are being prepared to respond. There is planning for evaluation of patients if symptoms develop, with early identification of symptoms in travelers who may have been exposed to the disease. Hospitals have been warned and encouraged to practice improved infection control in suspected cases.

He reported that in California travelers who may have been exposed to EVD are being monitored. A major new surveillance system has been implemented and there

are multiple notifications on a daily basis from the CDC, with information being passed to local health departments around the clock. Local health departments monitor suspected cases daily for up to 21 days, and there are regular reporting to the CDC and transfers between jurisdictions. He reported that more than 350 individuals have been monitored for EVD to date, with 30 to 40 people being monitored at any one time. Almost all are at low risk and almost all are returning to metropolitan areas with access to prepared hospitals. In the few cases where people are returning to rural areas special planning takes place to ensure an adequate health care response.

Dr. Watt reported on another “old” problem, pertussis, which is occurring with increasing frequency in California after a drop in incidence from the 1950s through the year 2006. Last year the largest number of cases since the 1940s was reported, with over 11,000 cases in 2014. He noted that the new “normal” of increasing numbers of reported pertussis infections results from a lack of sustained immunity from acellular vaccines, increased laboratory identification, periodic epidemics of increasing size, and widespread transmission that cannot be interrupted in the way measles can be. As a result, there has been a change of focus that attempts to limit the occurrence of the disease in populations at highest risk, with particular attention to prevention of the disease in infants with maternal and early childhood immunizations.

He addressed the issue of outbreaks of foodborne disease, which includes diseases with many etiologies, noting that outbreak detection is increasingly laboratory-based and dependent on the availability of isolates, and that the impact of culture-independent testing is uncertain. He reported on the PulseNet outbreak surveillance system, which involves a national network of laboratories and national comparisons to identify clusters. In California the priority pathogens are Shiga toxin-producing E. coli (STEC), salmonella, and listeria.

Dr. Watt closed with a discussion of the critical role of clinical laboratories in disease control. He thanked laboratories for their contributions, in particular the reporting of diseases and submission of clinical specimens.

Karen Nickel asked Dr. Watt about advances in the treatment of HIV. Dr. Watt said that much work is being done in this area, where the current focus is on the concept of treatment as prevention, because early diagnosis and treatment render HIV-positive patients less infectious. He noted that the next generation of HIV treatments focuses on the ongoing efforts to find effective vaccines and cures.

Judy Schlosser asked about German measles, or rubella. Dr. Watt said that rubella is one of viruses prevented by the measles-mumps-rubella (MMR) vaccine, and that a secondary benefit of the attempts to eliminate measles has been the elimination of indigenous transmission of rubella. He noted that the MMR vaccine is even more effective against rubella than against measles, so cases of rubella are only rarely seen now in the US, and when it is seen, it has almost always been acquired in another country and brought into the US.

Jennifer Schiffgens asked about the fact that approximately 25% of the cases in the current measles outbreak involved people who had been vaccinated. Dr. Watt noted

that some of these people had received only one dose of the recommended two doses, resulting in a vaccine effectiveness rate of only about 92%. The full dosage has an effectiveness rate of about 97%. He pointed out that there are always cases of vaccine failure, which accounts for the occurrence of disease in a small number of people who have been vaccinated.

Zahwa Amad asked about legislation to enforce vaccination. Dr. Watt said that California parents can currently opt out of vaccinations for their children on the basis of personal beliefs. He discussed the circulation of misinformation about vaccine safety. He also noted current legislative efforts to limit vaccination exemptions, and the efforts of CDPH to provide doctors and schools with effective tools for providing accurate information about vaccination.

Beatrice O'Keefe asked whether EVD could be transmitted from pregnant women to their fetuses. Dr. Watt said that there is insufficient information to give a decisive answer because EVD during pregnancy tends to be particularly severe and has a very high mortality rate, and therefore there is very little data on such transmission.

Lorri Dean-Yoakum thanked Dr. Watt for his presentation.

Legislation updates

Jan Otey of the LFS staff reported on Assembly Bill (AB) 258, a bill introduced on February 9, 2015, by Assemblymember Marc Levine and coauthored by State Senator Mark Leno, Assemblymember Bill Quirk, and State Senator Loni Hancock, and sponsored by Americans for Safe Access. She explained that existing law, the Compassionate Use Act of 1996, authorizes the use of marijuana for medical purpose and requires the establishment of a program for the issuance of identification cards to qualified patients so that they may lawfully use marijuana for medical purposes. She noted that currently different transplant centers have different criteria for determining eligibility for transplant recipients, and some exclude cannabis users from consideration. AB 258 would add to the Uniform Anatomical Gift Act to prohibit a hospital, physician and surgeon, procurement organization, or other person from determining the ultimate recipient of an anatomical gift based solely upon a potential recipient's status as a qualified patient or upon a positive test for the use of medical marijuana by a potential recipient who is a qualified patient, except to the extent that the qualified patient's use of medical marijuana has been found by a physician and surgeon, following a case-by-case evaluation of the potential recipient, to be medically significant to the provision of the anatomical gift.

Ms. Otey also reported on AB 599, a bill introduced by Assemblymember Susan Bonilla on February 24, 2015, and sponsored by the California Association of Cytotechnologists and the California Society of Pathologists. She explained that existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel, including cytotechnologists, by CDPH, subject to certain exceptions. Under existing law, only a licensed cytotechnologist may perform examinations of cytological slides. This bill would expand the work scope of cytotechnologists to authorize licensed cytotechnologists to perform all tests and procedures pertaining to cytology, including, but not limited to, microscopic and non-microscopic methodologies and tests and procedures that utilize molecular or genetic methodologies that are performed on cytologic

specimens related to infectious disease or cancer diagnosis.

Karen Nickel asked if the bill would require regulations to implement. Ms. Otey said that it would.

Robert Footlik said that cytotechnology is a subspecialty of pathology and asked if the phrase "all tests related to cytology" would include tests in other specialties like microbiology. Ms. Otey said that she did not know what it means beyond what is stated in the bill.

Lee Hilborne said that the purpose of the bill is to allow cytotechnologists to perform all tests, and suggested that the bill would require further amendment. Ms. Otey noted that the bill was introduced only on February 24, and there have not been any hearings or amendments yet, but that she expected that there would be amendments.

Ron Harkey, section chief of the Biologics and Tissue Bank Section, reported on AB 757, introduced by Assemblymember Jimmy Gomez on February 25, 2015, and sponsored by Grifols, Inc., a global company that produces and markets plasma-derived medicines, diagnostic systems, and hospital pharmacy products. He explained that this is an intent bill, with no bill language at the current time, but the intent of the bill is to make changes to current law that would authorize medical assistants who meet specified criteria to perform a total protein refractometer test analysis in a licensed plasma collection facility in California.

Martha Obeso reported on AB 940, introduced by Assemblymember Sebastian Ridley-Thomas on February 26, 2015, and sponsored by the California Clinical Laboratories Association. She has requested but not yet received the fact sheet or letters of support and opposition from the author's office. She explained that existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law also prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 unless the test or examination is performed under the overall operation and administration of a laboratory director. Existing law also defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as any person who, among other things, is licensed to direct a clinical laboratory and who substantially meets the laboratory director qualifications under the CLIA. She explained that this bill would amend five sections of the California Business and Professions Code (BPC).

The bill amends the BPC to authorize LFS to add two new license categories in the specialty of reproductive biology and the subspecialty of biochemical genetics, and would allow LFS to collect fees for applications and renewals of these licenses.

Another provision in the bill would amend current state law to expand and clarify the experience requirement for bioanalyst licensure to include four years of experience in a clinical laboratory certified under CLIA. This bill would provide a career ladder to people from other states who have been performing tests but without a California clinical laboratory scientist (CLS) license.

Existing law requires that a laboratory director “substantially” meet the laboratory director qualifications under CLIA. This bill would amend current state law by removing the word “substantially” from BPC section 1209 pertaining to laboratory directors, and would clarify laboratory director requirements by limiting the CLIA qualification requirements to a person serving as the CLIA laboratory director in a laboratory that performs tests classified as moderate or high complexity.

Ms. Obeso pointed out that as written the bill will require CDPH to write regulations to implement some of its provisions.

Personnel Licensing Update

Zahwa Amad, Section Chief of Personnel Licensing, thanked her staff for their service to the public and acknowledged the work of Martha Obeso, Examiner II, who has been assigned to lead the program for licensing laboratory directors in addition to her work on licensing CLS limited to a specialty.

Dr. Amad reported on the progress of the transition to the new PERL licensing system, which will replace the CPS licensing software currently in use. Staff members of the LFS personnel licensing section, especially Martha Obeso, MindaLuz Imbong, and Nyla Daggett, are working with CDPH ITSD staff and Pega staff to design a system that will meet the needs of the LFS Personnel Licensing program. The new system will be available in June 2015. She outlined several features of the new system. New applications will be submitted online. The new program allows staff and applicants to upload documents that must currently be sent through the mail, facilitating record management and retention and shortening application processing times. The new system allows for electronic signatures. The system will provide clear information during the online application process about licensing requirements, enabling applicants to know and meet all requirements before they begin the application process. The system will provide clear, current information online about the status of an application, reducing the need for telephone and email contact between staff and applicants, allowing staff to use their time more efficiently. The system will provide reminders to staff when documents are received from applicants and periodic reports to supervisors, facilitating tracking, and enhancing accountability. The new system will thus improve customer service, reduce the turn-around time for processing applications, and facilitate tracking.

Dr. Amad reported on the statistics for licensing of medical laboratory technicians (MLT), phlebotomists, clinical laboratory scientists (CLS), and clinical laboratory directors. She stated that 554 MLT licenses have been issued since the program was launched in 2007. In 2010, 57 new applications were received and 43 licenses were issued. In 2011, 73 new applications were received and 61 licenses were issued. In 2012, 127 new applications were received and 84 licenses were issued. In 2013, 221 new applications were received and 132 licenses were issued. In 2014, 134 new applications were received and 132 licenses were issued. Approximately 67% (87) of the applicants are from California, 15% (20) of the applicants are from are from out of state, 10% (13) are from the military, and 8% (10) are from outside the United States.

She noted that there are eight schools that train people for MLT licensure, four in

southern California, Southwestern College, Saddleback College, San Diego Miramar College, and College of the Canyons, and three in northern California, Folsom Lake College, De Anza College, and Diablo Valley College. There is one new college, Santa Monica College, which was approved in August 2014 and which has clinical affiliation with UCLA.

She reported that 6,636 new applications for phlebotomy certification were received in 2014, and phlebotomy certificates were issued to 6,585 applicants, compared to 6,287 new applications and 5,838 certificates issued in 2013. She noted that the current turn-around time for processing a new phlebotomy application is approximately two months.

She reported that Robert Thomas, who has been handling the laboratory director program, is currently mentoring Martha Obeso and will leave the program in good hands to concentrate on regulations. Applications for laboratory director licensure have been online since 2011. Four laboratory director oral examinations were held in 2014. Nine new laboratory directors were licensed, three in oral pathology, three in genetic molecular biology, two in histocompatibility, and one in cytogenetics. Three oral examinations were held in 2013, and six laboratory directors were licensed, two in chemistry, two in genetic molecular biology, one in histocompatibility, and one in cytogenetics. Three oral examinations were held in 2012, and eight laboratory directors were licensed, two in histocompatibility, three in genetic molecular biology, two in cytogenetics, and one in oral pathology. An oral examination was held in February 2015 and another is planned for May. The program anticipates offering the oral examination four times a year.

Reporting on the CLS program, Dr. Amad said that in 2012 LFS received 800 new applications for CLS licensure. In 2013 LFS received 1,020 new applications and issued 703 licenses. In 2014 LFS received 1,105 new applications and issued 794 licenses, of which 554 were general licenses and 240 were limited licenses. Of the applicants who applied in 2014, 140 of the limited license applicants trained in California and 100 trained outside California. Of the 554 applicants for the general license, 228 applicants trained in California, 134 applicants trained out of state, 173 applicants trained outside the United States, and 10 applicants trained in the military. Of the 240 applicants for the limited license, 140 applicants trained in California and 100 trained outside California. Seventy-six of the limited CLS license applicants were licensed in genetic molecular biology, 84 in cytogenetics, 41 in microbiology, 21 in chemistry, 4 in immunohematology, 2 in hematology, and 12 in toxicology. She noted that the turn-around time for general CLS licenses and CLS limited licenses is approximately five months.

She reported that a new cytotechnology program at the University of Nebraska Medical Center was approved by the Council on Accreditation of Applied Health Education Programs. This program has a practicum at UC Davis, which is the first cytotechnology training program in northern California. There are currently approximately 800 licensed cytotechnologists in California.

Karen Nickel asked about the possibility of temporary CLS licensure between the end of the trainee licensure and CLS licensure to ensure that there is no gap in licensure.

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 tissue banking and blood banking seem to be “bill magnets,” and pointed to the example of AB 1822 from the 2014 legislative season, which proposed to reduce hospital expenses when tissue was received by hospitals from tissue banks. Mr. Harkey explained that technological advances have increased the time span for safe storage of tissue, but pointed out that AB 1822 would have exempted most hospitals from any oversight by the Department, and that there is no federal oversight and no oversight by the American Association of Tissue Banks (AATB). The bill was passed by both houses of the state legislature, but Governor Brown returned the bill without signing it, which amounts to a veto. In his veto message the Governor said that while he supports eliminating overly burdensome regulation, he was not convinced that the bill struck the right balance between safety and economy, and he directed CDPH to continue working with interested parties to develop an approach that balances appropriate oversight with cost savings for suppliers.

Mr. Harkey reported that LFS had responded to the Governor’s directive by changing the rule that applies to storage of allograft tissue. The requirement that tissue be stored for no longer than one day has been changed to allow for storage within the parameters set by the shipper, as long as tissue is stored in the unopened shipping container, which must be validated by the shipper and must specify the time span for safe storage. A copy of Mr. Harkey’s letter on this subject was made available to meeting participants and will be posted on the LFS website. The frequently asked questions about tissue banking on the LFS website will also be revised to reflect the new recommendations that use the shipper’s parameters as the time span for safe storage. Mr. Harkey reiterated that a facility must have a storage license from the Department only when the facility removes allograft tissue from the validated shipping container and place it into the facility’s own storage unit.

Mr. Harkey reported on the issue of licenses granted by LFS to tissue banks that his program is considering issuing temporary licenses during the first year of a facility’s operation, with renewal after the first year. The program will monitor complaints and problems.

He said that Robert Hunter is investigating a number of transfusion-related incidents (TRI) and will discuss his work on this issue at this meeting if there is time.

Robert Footlik asked if the tissue bank program is any closer to adopting regulations. Mr. Harkey said that his program is working on regulations. He stated that the last three attempts to issue regulations were blocked by the issue of donors who engage in male-to-male sexual activity. The FDA is changing its rules with regard to male-to-male sexual activity and those changes may affect the progress of LFS regulations.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, announced that Judy Yost, the national director of the CLIA program, retired 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. Ms. McCallum reported that there is an opening for Ms. Yost's position in Baltimore.

Ms. McCallum reported that through the end of February, 2015, the CLIA section performed 10 initial surveys and 52 recertification surveys, three validation surveys, and one onsite complaint investigation, and issued five proficiency testing (PT) desk review sanctions. No waived laboratory surveys were performed due to a lack of sufficient staff. Since the beginning of the federal fiscal year in October the CLIA section has performed 49 initial surveys and 241 recertification surveys, five validation surveys, and one onsite complaint investigation, and issued 20 proficiency testing desk review sanctions.

She reported that a new revision of the State Operations Manual Appendix C was released January 9, 2015, but noted that the changes were those that occurred prior to July 1, 2014. The new revision pertains to proficiency testing referrals and allows for some alternative sanctions where before there was only a principle sanction or revocation. The revision was published in the Federal Registry on May 2, 2014.

She also noted a regulatory exception for Title 42 of the Code of Federal Regulations section 493.1291 (f) regarding patients being able to authorize a person for receiving test results, and noted that this was added to section (f) except as provided in section (l), which refers to a person or his or her designee for receiving the report.

Ms. McCallum also noted that one quarter of a million laboratories have been certified under CLIA. A breakdown of national statistics as of February 12, 2015, shows that there were 17,266 compliance laboratories, 172,707 certificate of waiver laboratories, 15,344 certificate of accreditation laboratories, 35,462 provider-performed microscopy procedures, 2,424 registrations, 4,032 exempt laboratories of NY, and 4,093 exempt laboratories of Washington, for a total of 251,328 laboratories certified under CLIA.

She said that she is still in the process of reviewing the Interpretive Guidelines released February 9, 2015. In response to the frequently asked question why IQCP was not included in these guidelines, she said that it was because IQCP would not become effective until 2016. She noted that guidelines were in preparation, but could not be incorporated until the end of the educational period.

Robert Footlik asked if the new PT rule in the Federal Register is a final rule. Ms. McCallum said that it is a final rule.

Facility Licensing - Richmond

Kathy Williams, Section Chief of Facility Licensing in northern California, reported that between December 1, 2014, and February 28, 2015, her section received 47 new applications for licensure and 440 new applications for registrations. Ten new applications were received from chiropractors, 14 were received from pharmacists, 11 from optometrists, and one from a naturopath. LFS received 16 new applications from out-of-state laboratories, of which 11 are pending approval.

Ms. Williams reported that between December 1, 2014, and February 28, 2015, her

section received a total of 33 complaints. Twelve of these were major complaints: one involved test errors, two involved test management and quality control, one involved state licensing, three involved tests being performed by unauthorized personnel, two concerned draw stations, and three were related to biologics. LFS received 21 miscellaneous complaints. Eleven were referred to other departments and nine were resolved by LFS staff. One complaint 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 is a continuing issue.

Ms. Williams discussed a new project on unlicensed laboratories, saying that physician office laboratories were not required to be licensed prior to December 31, 1995. LFS accepted CLIA certification in lieu of licensure until California became exempt from CLIA as long as a laboratory did not change its CLIA certification type. Since January 1, 1996, 5,500 laboratories have availed themselves of this option. Ms. Williams's staff are searching for these laboratories and registering them when they identify them.

Facility Licensing – Los Angeles

Joanne Rowan, Section Chief of Facility Licensing in southern California, reported that there were few changes from her report at the December meeting on the number of initial and routine surveys in 2014 compared to the numbers for 2013. In general, her section performs about 100 inspection and licensing surveys of new facilities in the Los Angeles area, and about 100 routine inspections of accredited facilities each year. The section handles approximately 20 complaints each year.

She noted that her section partners with CLIA in completing inspections and that there are now funds available for inspecting out-of-state facilities. The law requires that all laboratories performing testing on samples from California must be licensed by California and inspected every two years. There are 334 out-of-state laboratories engaged in such testing. Ms. Rowan reported that in fiscal year 2014-2015 nine out-of-state laboratories were inspected, and she anticipates that in the coming year approximately 24 such inspections will be performed. In the course of last year's inspections two deficiencies were reported, both of them minor.

Ms. Rowan announced that she will retire at the end of March. She expressed gratitude for the time she has enjoyed with LFS, and for the challenges her work has provided and the opportunities for learning and growth.

Recognition of Robert Footlik's Service to CLTAC

In honor of Robert Footlik on the occasion of his retirement, Karen Nickel gave a presentation on Mr. Footlik's contributions to CLTAC since he first joined the board in 1995. He served two terms as a board member, as chairperson much of that time, and chaired or served on a number of subcommittees that issued important position papers, including the CLIA 2003 subcommittee. Dr. Nickel thanked Mr. Footlik for his service to CLTAC, LFS, and the people of California, and for being a wonderful colleague and champion of the cause of clinical laboratory science, and wished him well. Donna McCallum then presented Mr. Footlik with a certificate of appreciation from LFS, expressing her thanks to Mr. Footlik for his contributions and wishing him

well as he begins his retirement.

Mr. Footlik expressed his thanks to CLTAC and LFS, his gratitude to the department for the recognition, and for the honor and privilege of being appointed and being allowed to serve on the CLTAC board and subcommittees over the years, and said that he would miss everyone.

Lorri Dean-Yoakum thanked Mr. Footlik for his participation and contributions. Beatrice O'Keefe thanked Mr. Footlik for his many emails, which have challenged her to research California statutes and come up with positions on the many issues that he inquired about.

New business

Lorri Dean-Yoakum thanked Mary Wogec for her work on producing and distributing the meeting minutes and Dennis Tavares for his assistance with preparations for the northern California meeting and support with audio visual communications between the southern California and northern California meetings. She also thanked LFS staff for their work in preparing for meetings.

Lorri Dean-Yoakum asked if anyone had new business to discuss. Robert Hunter said that because there was not enough time at this meeting, he would present his report at the June meeting.

Future items

Lorri Dean-Yoakum asked if there were suggestions for future business.

Karen Nickel suggested a discussion of digital pathology. Ms. Dean-Yoakum asked Lee Hilborne if he would be willing to lead such a discussion at the June meeting.

It was also asked if CLTAC should be proactive about AB 599, the proposed legislation on the work scope of cytotechnologists. Beatrice O'Keefe explained that the Department does not take a public position on legislation, but only offers an opinion to the governor. However, as an advisory committee CLTAC can express an opinion. Donna McCallum said that any bill must meet federal requirements, and noted that requirements on training and experience were missing from the bill as currently written. Lorri Dean-Yoakum asked CLTAC members and participants to read the bill and be prepared to discuss it at the June meeting. She also asked Laurie Fuller to represent cytotechnologists at that meeting.

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, June 5, 2015.

Adjournment

Robert Footlik moved that the meeting be adjourned, the motion was seconded by Rhonda Becker, and the CLTAC board voted to adjourn.