

## **Clinical Laboratory Technology Advisory Committee**

Minutes of the Meeting held on December 6, 2013

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

### **CLTAC members participating**

Rhonda Becker, Richard Bennett, Marjorie Braasch, Anthony Butch, Patricia Dadone, Lorri Dean-Yoakum (chair), Elizabeth Dequinia, Kathleen Doty, Vicki Finson, Robert Footlik, Laurie Fuller, Anne Igbokwe, Anthony Mills, Armand Parada, Rebecca Rosser, Jennifer Schiffgens, Fred Ung.

### **Former CLTAC members participating**

Imre Fischer, Curtis Johnson, Sol Notricia, Jim Ottosen, Les Revier.

### **CDPH staff participating**

Zahwa Amad, Alan Ankerstar, Grace Byers, Gillian Edwards, Pamela Farrell, Ron Harkey, Tina Hashemi, Robert Hunter, Paul Kimsey, Nema Lintag, Yangzhu Long, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Beatrice O'Keefe, Jan Otey, Tammy Pahland, Joanne Rowan, Judith Schlosser, Dale Statley, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

### **Public members participating**

Joyce Bladel, Barbara Brunell, Marian Castillo, Ann Chenoweth, Rosie Cohen, Kathy Davis, Debbie Ferguson, Nancy Fraize, Diane Giles, David Gomez, Dora Goto, Brett Holmquist, Peggy Kollars, Dan Leighton, Jamie Marks, Anthony Millena, Valerie Ng, Shahrzad Radahd, Rodney Roath, Diane Schillinger, Diana Schulze, Barbara Sevilla, Vicki Simpson, Tom Tempske, Ann Tonini, Tammy Zinsmeister.

### **Welcome and general announcements**

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:04 a.m. Ms. Dean-Yoakum thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge. Ms. Dean-Yoakum introduced a new board member, Mr. Armand Parada, who was nominated by the American Society for Clinical Laboratory Science (ASCLS) to replace Diane Tyson, who has resigned from the committee. Mr. Parada has served as a licensed clinical laboratory scientist for over 50 years, and has worked at Kaiser-Permanente for over 20 years. He is a member of the California Association of Medical Laboratory Technology (CAMLT) and the American Society of Medical Technicians (ASMT) and has served as president of ASCLS of California.

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

### **Approval of the September 6, 2013 meeting minutes**

Rhonda Becker moved to approve the minutes from the September 2013 meeting with corrections as submitted by Jim Ottosen. Jennifer Schiffgens seconded the

motion and the minutes were approved.

### **Election of officers**

Lorri Dean-Yoakum announced the election of a chairperson, who will take office after the June 2014 meeting, and asked for nominations. Robert Footlik nominated Lorri Dean-Yoakum. Ms. Dean-Yoakum was asked if she was willing to serve another term as chair, and Ms. Dean-Yoakum said that she was. Ms. Dean-Yoakum was re-elected by a unanimous voice vote.

### **Department update**

Dr. Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), gave an update for the department. He announced the recent appointment of Karin Schwartz as deputy director and chief counsel in the Office of Legal Services. Prior to that, she served as a supervising deputy attorney general at the Health, Education, and Welfare section of the California Attorney General's Office. While at the Attorney General's Office, Ms. Schwartz represented CDPH and other agencies in numerous cases, including Douglas v. Independent Living Center, a case she argued in the U.S. Supreme Court. Dr. Kimsey also announced the appointment of William Jahmal Miller as deputy director of the newly formed Office of Health Equity. Mr. Miller was a communications manager in brand communication for national community benefit, research and health policy at Kaiser Permanente and has held multiple positions at Sutter Health in Sacramento, including hospital administration resident and regional manager of strategic marketing and communications.

Dr. Kimsey reported on the application of CDPH for accreditation by the Public Health Accreditation Board (PHAB). The intent to seek accreditation was submitted in March 2013, and the application was submitted in October 2013. Mirroring the twelve domains within the PHAB Standards and Measures, and based on the ten Essential Public Health Services, CDPH created twelve Domain Teams to identify and review documentation from throughout CDPH to show compliance with the PHAB standards and measures. Each domain contains standards and measures against which a health department is evaluated. The standards describe the required level of achievement, while the measures provide a way of measuring if the standard is met.

In December, CDPH submitted nearly 2,000 documents, each of which has gone through several layers of review. This documentation constitutes evidence that CDPH meets or exceeds national standards and is in compliance with 105 measures across the twelve domains.

The next step in the accreditation process is a site visit, which will be conducted by a team of peers who are selected and trained by PHAB. At the end of the site visit a report will be developed and submitted to the PHAB Board. If all goes as planned, the onsite evaluation will occur in the spring of 2014.

Dr. Kimsey reported that a federal select agent inspection was in progress on the same day as the CLTAC meeting. This is a federal regulatory program that oversees and enforces increased security around the transportation of microorganisms which can be used as weapons of mass destruction. He noted that

CDPH has always been in compliance with these federal standards.

### **Status of the regulation package, DPH-11-012**

Tammy Pahland, Staff Counsel for Laboratory Field Services (LFS), updated the CLTAC on the draft personnel regulations package. She noted that the process is now in the initial phase, which is nearing an end. The LFS committee is making a final review of the draft of the regulations and the Initial Statement of Reasons (ISOR), which presents the reasoning behind the regulations. When the draft regulations and the ISOR have been completed, the committee will prepare the necessary financial documentation, and the package will be sent forward to the Office of Regulations, where it will be reviewed for clarity, consistency, and compliance with the Administrative Procedures Act (APA). It is hoped that the regulations will be available for public comment early next year. Ms. Pahland noted that the process for writing regulations is a complex one, involving many departments as well as review by Health and Human Services Agency (HHS). Ms. Pahland added that in her opinion the LFS team has done an excellent job at producing a very good package. Ms. Dean-Yoakum asked when the regulations will be available to the public. Ms. Pahland responded that it is hard to give a date, since there are still a few details that the LFS team needs to finalize, after which the package will be sent to the Office of Regulations, and then to HHS for review.

Ms. Dean-Yoakum thanked the LFS committee and staff for their work on the new regulations.

### **CLIA Crosswalk Subcommittee update**

Robert Footlik, Chair of the CLTAC subcommittee on the CLIA Crosswalk, reported that the subcommittee had not met since the last report. They are still working on the CLIA Individualized Quality Control Plan (IQCP), and are waiting for additional information. Once the subcommittee has considered all information, they will make a final recommendation. Mr. Footlik hopes to have this by the March CLTAC meeting. Ms. Dean-Yoakum thanked Mr. Footlik, Kathy Williams from LFS, and all the members of the subcommittee, for their work.

### **LFS update**

Beatrice O'Keefe, Chief of LFS, reported on issues and events in LFS. Examinations for the position of examiner were administered in July. There are ten candidates for Los Angeles and ten for northern California. Interviews of the candidates are in process. An examiner has been hired to fill the position vacated by Kathy Williams when she became section chief for Facilities Licensing. This examiner handles the examinations for the public health microbiologist certificate and serves as liaison to the public health laboratories, and also licenses out-of-state laboratories that perform tests on patients from California.

Ms. O'Keefe reported that LFS is now in the process of hiring an examiner to handle complaints. This position has been vacant for over a year, during which time complaints have been handled by an LFS surveyor. There are over 200 complaints per year.

LFS is also planning to hire two examiners for the southern California office, one for the CLIA program and another to perform state surveys in southern California.

This still leaves six vacant examiner positions. LFS is working with the examination program to schedule examinations twice a year. Postcard announcements will be sent to clinical laboratory scientists in the San Francisco Bay Area, as the positions in the Richmond office are especially hard to fill.

Ms. O'Keefe is continuing to work on a Recruitment and Retention Proposal that is in the process of finalization before being submitted for approval.

She reported that LFS continues to receive complaints about the use of unlicensed personnel to perform clinical laboratory testing. In almost every case the complaint has been substantiated. Laboratories that use unlicensed personnel inappropriately may be subject to sanctions that range from revocation of licensure to a directed plan of correction or civil money penalties.

LFS has also received questions regarding who can order laboratory tests. The California Business & Professions Code (BPC) section 1288 specifies that those who are licensed under the healing arts are authorized to order laboratory tests. This includes licensed chiropractors, acupuncturists, and many others. A laboratory, however, may make business decisions as to whether to accept clients or not.

Ms. O'Keefe addressed news reports that the FDA sent a letter to the Silicon Valley company 23andMe for allegedly marketing its products without proper federal approval. The company offers a genetic testing product directly to consumers, which is used to analyze and predict the likelihood of developing various health conditions or traits. The FDA contends that the company's saliva collection kit and personal genome service constitute a medical device under the Federal Food and Cosmetics Act and is subject to FDA approval or clearance. Of particular concern is the use of the personal genome service to assess BRCA-related genetic risk and drug response because of the potential health consequences that could result from false positive or false negative assessment.

She noted that LFS first became aware of companies that were offering this type of risk assessment in 2008. The test consists of DNA analysis and application of a software algorithm to determine risk. The algorithm is usually based on cohort studies, generally those performed in Europe, that correlate certain DNA single nucleotide polymorphisms (SNPs) with a variety of diseases. LFS determined that this type of test was subject to California clinical laboratory law and notified 15 companies in 2008 that they were required to have a state license, an order by an authorized person such as a physician, and a director who meets California qualifications as a director for genetic testing. The Center for Medicare and Medicaid Services (CMS) does not currently require a CLIA certificate for this type of risk analysis assessment, so this is a unique situation where California requires a license but there is no CLIA certificate. New York and Maryland have followed California's lead and also require facilities performing this type of risk analysis to possess a state license. 23andMe has stopped all of its advertising on TV, radio, and the Internet. It is also facing a class-action lawsuit alleging that the company misled customers with advertising for its personalized DNA test. There are three types of companies: those that perform only risk analysis based on DNA sequences, those that perform both DNA analysis and risk analysis, and those that perform only

DNA analysis. It remains to be seen whether CMS will determine that companies that only perform the risk analysis are subject to regulation under CLIA.

Rhonda Becker asked if 23andMe deals only with SNPs, and not the whole DNA sequence, and Ms. O'Keefe responded that 23andMe deals only with SNPs associated with a specific disease, and does not provide a whole genome analysis.

Ms. O'Keefe reported on Covered California, the state of California's exchange for health insurance coverage. Unlike the federal exchange, the California program has been operating smoothly. As of the end of November, a total of 431,756 applications had been initiated. Although this is an impressive number, there are approximately 3.5 million uninsured persons in California that need to be enrolled by the end of March 2014, so much work remains to be done.

Ms. O'Keefe reported that COLA has been approved as an accrediting organization by LFS to provide deemed status to the laboratories they accredit, and said that she would be meeting with COLA representatives after this meeting to work on the process. Donna McCallum asked if COLA applied for deemed status for histopathology. Ms. O'Keefe answered that they did not. Debbie Ferguson asked what other organizations have applied for deemed status. Ms. O'Keefe said that CAP, the Joint Commission, and AABB have also applied.

### **Guest Speaker**

Lorrie Dean-Yoakum introduced Dr. James Watt, MD, MPH, Chief of the Division of Communicable Diseases in CDPH, who spoke on Electronic Laboratory Reporting, Health Information Technology, and the Future of Communicable Disease Surveillance. Dr. Watt noted the importance of communicable disease control, and of the partnership of his division with the laboratories which play a critical role in identifying and reporting communicable diseases. This information is critical for designing an effective response. He explained that the process of surveillance involves two steps: submissions sent to local health departments and submissions from local health departments to CDPH. This process usually involves paper reporting and is not standardized, and consequently it can be inefficient and slow, with many opportunities for the introduction of errors. When confronted with the emergence of Hepatitis C, with a huge volume of information that was difficult to handle, the traditional system revealed the extent of its vulnerabilities. A reassessment of the traditional system led to the development of a new vision of the possibilities. Recent advances in information technology and data standardization make it possible for all systems to communicate in a common language and to share accurate and complete information in a timely manner. Moreover, hospitals and laboratories can share information electronically, utilizing resources more efficiently.

Dr. Watt compared current developments in disease surveillance with the development of railroads in the 19<sup>th</sup> century. When they were first introduced, many small railroad systems built tracks with widely divergent gauges, each with its own advantages. When these systems began to link together, it became apparent that standardization would allow unimpeded movement and the use of standardized equipment across systems. In the same way, a switch to standardized electronic data systems and creation of a single data repository will modernize the communicable disease surveillance system in California.

Dr. Watt explained the CDPH Health Information Exchange (HIE) Gateway. The Gateway allows different reporters to send several different types of data. By employing common data standards, the system leverages technologies, enables system interoperability, and facilitates data submission from a variety of sources, including electronic laboratory reporting systems (ELRs), other health information exchanges (HIEs), laboratory information management systems (LIMS), and the California Reportable Disease Information Exchange (CalREDIE).

Dr. Watt discussed one of the components of the system, the California Reportable Disease Information Exchange (CalREDIE). In this secure, web-based system, data received via the CalREDIE provider portal and the CalREDIE ELR is fed into the Master Person Index, which routes it to the Data Warehouse. From there it is accessible through the CalREDIE Data Distribution Portal. Three large laboratories are already using the system, sending approximately 3,000 reports a week, along with 13 hospitals, sending 1,000 reports a week.

Quality control is an important component of the system. When the CalREDIE ELR receives information from laboratories at the state and local level, this information is reviewed by CDPH staff members, who validate the sender, perform quality analysis, and ensure that CalREDIE is configured to handle messages from the laboratory. When the validation has been completed, the laboratory's live feed is sent to the ELR test environment. Upon confirmation, the live feed is connected to CalREDIE Production, where CDPH staff members continue to review exception messages and conduct analyses to identify lapses in the submitter's regular reporting pattern.

Dr. Watt reported that all 61 of California's local health jurisdictions are currently using CalREDIE, and 57 of these jurisdictions are using it for communicable disease reporting, with a total of 2,100 active users reporting 520,900 disease incidents. The result is a better supply of data to the CDC, increased efficiency of data management, more high volume reports transmitted electronically, and better real time data for response to outbreaks. This in turn eliminates the need for faxing of forms and lists, ensures improved coordination and tracking of communicable diseases and enhances situational awareness.

Dr. Watt anticipates the expansion of the CalREDIE network to include more local health jurisdictions, laboratories, and providers. The department is also working on creating data linkages with other electronic health record (EHR) and HIE systems, for example, cancer registries, to enable more accurate identification of risk factors, more complete demographic information, and automated provider reporting.

In closing, he outlined the common goals of disease prevention and promotion of public health, noting that surveillance is a collaborative effort involving many partners contributing data to serve these common goals. He emphasized the importance of partnership in CalREDIE, and welcomed input from users in identifying and reporting problems, ensuring the quality of data, and identifying ways for CalREDIE to add value. He thanked partners in CDPH and in the private sector for their partnership in surveillance and disease control as part of the effort to prevent disease and protect public health. In particular, he thanked laboratories for their interest in participation in electronic data reporting.

Ron Harkey noted the increase in chronic diseases and asked if electronic data reporting would enable a better understanding of this increase. Dr. Watt responded that the increase may be due in part to increased awareness and new tests that can identify previously unknown problems. He added that electronic data reporting may enable coordination between chronic diseases and other conditions and other complications or linkages to communicable diseases.

Robert Hunter asked if electronic data reporting will replace paper forms to do case reports for things like vital signs, symptoms, and medical histories. Dr. Watt said that it eventually would move forward, but he noted that such forms represent a large volume of information and a wide range of types of information, and this is complicated by a lack of standardization between systems.

Mr. Hunter asked about the delay in implementing electronic data reporting in Los Angeles County. Dr. Watt replied that LA County uses the same software as CalREDIE, but they have made local changes, and need to find a way to transfer from their software to that of CalREDIE. He explained that most counties did not have an existing system, so they did not encounter this problem, but Los Angeles and San Diego Counties had existing systems that require working out an electronic exchange that preserves local systems.

Mr. Hunter asked if LFS would have access to CalREDIE soon, citing both the usefulness of analyzing surveillance data that resides in the CalREDIE data bank and the potential difficulty of finding a way to provide information while preserving confidentiality. Dr. Watt replied that CalREDIE is trying to build an application that provides de-identified data with appropriate levels of confidentiality. He asked Mr. Hunter to send him information about the types of data he needs as well as other needs.

Ms. O'Keefe asked about compliance in laboratories reporting reportable diseases. Dr. Watt said that laboratory reporting is often better than provider reporting, and he thanked laboratories for the quality and timeliness of their reporting. He noted that electronic reporting should make this work easier. Because electronic reporting automatically sends data without adding extra work, he expects that it will increase compliance and timeliness.

Ms. Dean-Yoakum complimented the CalREDIE team for their help to her laboratory.

### **Personnel Licensing Update**

Zahwa Amad, Section Chief of Personnel Licensing, deferred her report on statistics to the next meeting to allow time at this meeting for a report on clinical laboratory scientist (CLS) training programs by Martha Obeso, the examiner in the Personnel Licensing section who handles the CLS training programs.

Ms. Obeso reported that each year there are approximately 700 available training spots in approved training programs, of which 500 are for generalists and 200 are for specialists, although most training programs do not operate at capacity. At present there are 102 CLS generalists and 51 CLS specialist training programs in operation. Of the specialists, most are training in genetic molecular biology (GMB) (21) and

cytogenetics (10). There are also 5 in chemistry, 5 in histocompatibility, 5 in microbiology, 3 in immunohematology, 1 in hematology, and 1 in toxicology. Program approvals in 2013 include 7 generalist programs and 2 GMB programs. Two programs have requested that they be placed on inactive status in order to update and modify their programs. Five programs have been requested to modify their programs before accepting a new class of trainees. Some did not meet the ratio of 2:1 licensed personnel to trainee, and some GMB programs were directed to modify their focus to include more activities regarding the testing of human genetic disorders. Two programs released trainees to other approved programs: one program due to reorganization, and one because the company moved out of California. Four programs have closed and are no longer training.

Ms. Obeso noted that the current turn-around time for review of training program applications is between two and three months. Applications are available electronically in a PDF format. The website is updated three times a year. She also asked that programs notify LFS and secure approval for major changes, including modifications to the program, requests to increase the number of trainees, change in laboratory director or program coordinator, or updates to contact information.

Ms. O'Keefe commented that LFS needs laboratories to step up and train at capacity. Five hundred trainees are needed each year for the next five years to meet the demand for laboratory personnel.

Dr. Amad commended Ms. Obeso on her work with the CLS training programs.

### **HLWI update**

Robert Thomas reported on the Health Care Laboratory Workforce Initiative (HLWI) meeting that was held on November 20, 2013.

Discussion at this meeting covered three main issues:

1. Best practices for integrating MLTs into the laboratory workforce
2. Recommendations for MLT Scope of Practice expansion under parameters of the OSHPD Health Workforce Pilot Projects Program (HWPP).
3. Development for a Regional Training Laboratory for Clinical Laboratory Scientists.

Mr. Thomas reported that HLWI has convened a subgroup to work on the expansion of the scope of practice for medical laboratory technicians (MLT), and to explore ways to integrate MLTs into the clinical laboratory workforce. This issue has been studied by the Center for Health Professions at UCSF, using data on turnovers and vacancies for allied health positions in hospitals that was collected by the California Hospital Association in cooperation with the UCSF Center for Health Professions. Sixty-three percent of the hospitals surveyed expressed an interest in using MLTs, but the reliability of the data was questioned because survey respondents may have confused MLTs with CLSs. In response to this concern, the survey was reworked to include a case-study approach. The UCSF Center visited five sites. They interviewed various staff, including MLTs, CLSs, and laboratory managers on challenges and successes of integrating MLTs into each of their laboratories. They also interviewed educators. The goal of the study is to educate directors and facilities about successful strategies for integrating MLTs into California's laboratory

workforce. The UCSF Center has incorporated their experiences into a PowerPoint presentation. The presentation goes beyond findings to discuss challenges encountered, lessons learned, success factors, benefits, and perspectives. Rebecca Rozen, Regional Vice President for the Hospital Council, is checking on approval to distribute the Center's PowerPoint presentation. The UCSF group also offered to make a presentation on their program at a future CLTAC meeting.

Mr. Thomas reported that the second area under discussion was the determination of parameters for designing a pilot project study on the expansion of the MLT scope of practice as authorized under authority signed by Governor Reagan. It usually takes from one to three years for a pilot program to be conducted under an approved outline and for findings to be presented to legislators, who may or may not agree on the findings or recommendations.

Mr. Thomas said that Ms. Rozen reported that the members of HLWI have formed an MLT Scope of Practice subcommittee to develop criteria and a project outline. The subcommittee has decided on three main criteria for selecting laboratory tests to be included in the MLT pilot expansion study. They are as follows:

- They are high volume tests that would have a measurable impact on relieving the workforce shortages in the lab.
- They are categorized as moderately complex under CLIA, and therefore within the scope of practice for MLTs outside of California.
- The instrumentation used to perform the test is also categorized as moderately complex.

The HLWI subcommittee reviewed five possible areas of focus for the study:

Under Microscopy

1. Blood Smear reviews; morphology, manual WBC differential
2. Urinalysis
3. Body Fluid analysis: differential, crystals
4. Gram stain

Under Immunohematology (Blood Bank)

5. Moderately complex ABO/Rh testing

Of the five possible areas, the proposed study has been narrowed to three areas, with body fluid analysis and gram stain being deleted. Of the three remaining areas, the current proposal is as follows:

Under Microscopy:

- For blood smear reviews, the proposal is for MLTs to review blood smears and, when normal cells are present, for the MLT to report the results. However, if abnormal cells are present, the MLT would refer the slides to a CLS or pathologist as the test would then elevate to high complexity.
- For urinalysis, the same process would be utilized.

Under immunohematology:

- Any moderately complex test classification would be eligible for performance and reporting by a MLT.

Once the HLWI subcommittee has formulated the required outline for the proposed MLT Scope of Practice Expansion study, the next step will be to design the study.

At a previous CLTAC meeting, LFS was requested to invite a representative from the HLWI to a CLTAC meeting to describe the scope of the proposed study. LFS invited Rebecca Rozen of the Hospital Council to present an update on the MLT pilot project. Ms. Rozen felt it was premature to give a report at this time because the subgroup is still working on the design of the project. LFS will check back with her in February. It is likely that the project outline may still not be completed by that time. Ms. Rozen expects to have sufficient material to make a presentation at the CLTAC meeting in June.

Mr. Thomas said that the third issue discussed at the meeting concerned the possibility of setting up a Regional Training Laboratory for CLSs. Dr. Howard Evans, Dean for the College of the Extended University at CA State Polytechnic, Pomona, and Brian Jersky, Dean and Professor of the College of Science at the same institution, are interested in increasing training capacity. They have 18 student trainees in their program out of over 100 who have applied. They would be interested in taking more students into the program but are limited because they cannot accommodate enough practical training positions. Two ideas were proposed:

- Provide more training at a central facility, such as an academic laboratory working with partners.
- Focus on training at the university without the trainees reporting out results

The group identified several issues with these initial models. For example, there is a requirement for a ratio of licensed clinical laboratory personnel to trainees of no less than 2:1. Also, if the laboratory would not be producing test results there would be a cost challenge. The group decided that this issue would require further discussion and research.

Dr. Amad noted that some applicants for the limited licenses apply with training that occurred outside a CLIA certified laboratory. She asked if an academic training program would be accepted. Mr. Thomas said that the programs probably would not be acceptable unless they partner with CLIA laboratories, placing students in those laboratories for practical training.

Jim Ottosen commented that since Ms. Rozen declined to make a report at the December CLTAC meeting, it is obvious that the subgroup does not want input from CLTAC. Mr. Thomas clarified that Ms. Rozen had declined to report at the December meeting because the subgroup had not made sufficient progress to provide material for a report. He said that they are not rejecting input from CLTAC, and noted that they are open to input at any time.

Karen Nickel asked if the task force is aware that many of their ideas are not in compliance with state law. Mr. Thomas responded that they are aware of this, and are considering ways to comply or to change the relevant statutes.

Dr. Nickel asked how many MLTs have been licensed by LFS. Dr. Amad replied that from 2008 to the present, approximately 300 MLTs have been licensed.

Ms. Dean-Yoakum asked if UCSF would be willing to make a slide presentation. Mr. Thomas said that he thinks they would be willing to do so, and that Ms. Rozen had

asked him to invite them to make a presentation at a future CLTAC meeting. Mr. Thomas said that he would do so.

Armand Parada asked if there is an opinion on autoverification. Ms. Dean-Yoakum said that she thinks it is acceptable, citing Section 1259.5 of the BPC. Mr. Thomas added that Section 1050(h) of Title 17 of the California Code of Regulations (CCR) is still on the books, although changes in statute have occurred since Section 1050(h) was implemented.

Peggy Kollars, who is a participant in the HLWI subcommittee on MLT scope of practice, offered a few clarifications. She noted that the subcommittee needs input from LFS on what would happen to MLTs who have already been licensed. The subcommittee also needs the expertise of LFS on state law as feedback to their ideas.

Ms. O'Keefe noted that MLTs might need additional training if the statute were to be changed.

Robert Footlik asked how many of the 275 licensed MLTs were trained in California. He stated that no trainee license currently exists, and there is no statute that allows MLTs to engage in clinical laboratory practice. Dr. Amad responded that LFS is planning to clarify this in the new regulation package for personnel licensing. Mr. Footlik asked what authority exists in California law for an MLT trainee to engage in clinical laboratory practice, and observed that in his opinion this is not being done legally. Mr. Thomas responded for LFS as the past section chief for personnel licensing. He said that there is no mandate requiring a trainee license for any license categories except for persons training for clinical laboratory scientist and for CLS limited license specialists. He said he would check with LFS's legal consultants for exceptions for a trainee who does not report results and is under the direct, responsible supervision of a CLS or licensed physician and surgeon. He noted that LFS could not have licensed these personnel if a trainee license were required, as there was a four-year look-back on acceptance of training for the first MLTs being licensed from Hartnell College and DeAnza College. Mr. Footlik said that he wants to know where in statute is the authorization. He noted that he asked Cindy Lloyd in the CDPH Office of Legal Services for a legal opinion on this issue, and requested that a legal opinion be given at the next CLTAC meeting. Dr. Nickel said that MLTs operate equipment and hand the results to a supervisor for reporting. Ms. O'Keefe said that LFS will respond at the March 2014 meeting on the question.

### **Biologics and Tissue Bank Program update**

Section Chief Ron Harkey asked examiner Bob Hunter to comment on ongoing investigations. Mr. Hunter noted that there has been a decrease in the number of biologic facilities because many have chosen not to collect samples, and because mergers and consolidations have resulted in a smaller number of facilities. There is, however, an increase in the number of businesses dealing with cord blood, plasma, and biologics, and there is also an increase in the number of complaints, and he is working on three investigations at present.

Mr. Hunter noted that tissue banking and biologics are complicated because they involve both donors and recipients. This introduces an opportunity for new business

models. He cited as an example the payment of a donor for human milk, noting that the sale of human milk from one person to another is difficult to monitor. In the same way, payment for reproductive tissues (ova and semen) introduces a new level of concerns. He said that if a semen donor goes beyond ten live births, he is usually cut off from further donation under scope-of-practice provisions. Plasma donation is also limited. In both cases, donors may go to a different facility in order to continue donating, since there is no provision for federal oversight in the law. He is researching new business models that cannot be monitored because they are not regulated by state or federal law.

Jamie Marks asked if there is any response from LFS to the new FDA guidelines on West Nile virus. Mr. Harkey said that the law indicates what must be tested for. There is nothing in tissue bank law that specifies anything about this.

### **CLIA Update**

Donna McCallum, Section Chief of the CLIA section in Los Angeles, reported that in October and November 2013 the CLIA section performed 8 initial surveys and 107 recertification surveys. They also processed two proficiency testing desk review sanctions.

Ms. McCallum announced that the CLIA section is in the process of hiring one new CLIA inspector, and that one of their current inspectors, Ora Griner, has retired. She expressed hopes that the resulting vacancy will soon be filled.

Ms. McCallum reported that CMS has approved a procedure, the CLIA Individualized Quality Control Plan (IQCP) that permits laboratories to develop customized quality control procedures for their healthcare setting. IQCP will be found in the updated Interpretive Guidelines under Sections 493.1256 (d), (d)(1), and (d)(2).

Ms. McCallum noted that quality control (QC) cannot be less than manufacturer's instructions, and that a laboratory must continue to follow calibration and calibration verification as found in Section 493.1267. IQCP cannot be used for histopathology. She said that IQCP is voluntary and must include all three phases of testing, pre-analytic, analytic, and post-analytic. She explained that IQCP is composed of three components:

- Risk Assessment is the identification and evaluation of potential failure and errors in a test process.
- A Quality Control Plan is a laboratory's standard operating procedures that describe the practices, resources, and procedures to control the quality of a particular test process.
- Quality Assessment is the laboratory's policy for ongoing monitoring of the effectiveness of the Individual Quality Control Plan (IQCP).

When the manufacturer's instructions for QC are absent or less stringent than the analytic system control procedures, the laboratory has the flexibility to follow all regulatory requirements as written or to develop their QC using the CLIA IQCP. Ms. McCallum reminded laboratories that Risk Assessment must include a minimum of five components:

1. Specimen

2. Environment
3. Reagent
4. Test System
5. Testing Personnel

Ms. McCallum was asked if the IQCP is intended to reduce quality control in laboratories. She said that it is not. Rather, it allows a laboratory to develop a unique plan customized to address the individual laboratory's environment. She further noted that a laboratory is not allowed to do less control testing than the manufacturer recommends.

She noted that the educational period for the IQCP will extend from January 1, 2014 through January 1, 2016. During the transitional period a laboratory has three options: CLIA QC as written, continuation of equivalent quality control (EQC), or implementation of IQCP. She added that after January 1, 2016 EQC will be discontinued and a laboratory will have only two options.

Ms. McCallum said that more information can be found in a new CLIA brochure available on the CLIA website, [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia). It is brochure #11: CLIA Individualized Quality Control Plan (IQCP) Introduction. She noted that IQCP considers the entire testing process: pre-analytic, analytic, and post-analytic. A laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements.

Ms. McCallum said that IQCP involves more work for the surveyor than the existing QC program, and referred laboratories to CLIA brochures and other websites. She said she will advise people when the website is updated. She noted that IQCP is voluntary. The other option is default regulation. If a laboratory is using multiple devices, they must do testing on all the devices in use, and they must make sure that the IQCP process is maintained. She said that she expects that new information will be published in 2015, but noted that there are constant updates available on the CLIA website.

### **Facility licensing - Richmond**

Kathy Williams, Section Chief of Facility Licensing in northern California, reported that over the past three months her section has received 27 major complaints. She noted that LFS does not oversee billing problems. Those issues should be addressed to Consumer Affairs or the accounting department of the individual laboratory. Complaints of that nature should be addressed to the administrator of the individual laboratory. LFS does not disclose the results and findings of investigations to the individual who made a complaint.

Ms. Williams reported that there were 34 new applications for licenses from September through November. There were 349 new registration applications for those three months. In the past three months her section also received 6 new applications from pharmacists, 12 from optometrists, and 2 from naturopathic practitioners, all of which were approved.

She reported on the number of sites that were added at various multiple-site facilities. In September six different facilities added a total of 118 new sites; in

October, four different facilities added a total of 14 new sites; in November, four different facilities added a total of 13 new sites.

Ms. Williams reminded laboratories that the CDPH form LAB 183 must be returned for renewals at all levels of renewals. This form is being reinstated to verify the qualifications of directors and to remind directors of their responsibilities. She also noted a large increase in the number of requests from outside California to establish draw stations in California.

Ms. Williams reported that the text of the emergency HIV regulations is available on the Office of Regulations website at [http://www.cdph.ca.gov/services/DPOPP/regs/Pages/DPH-13-007E,HumanImmunodeficiencyVirus\(HIV\)ScreeningTestingbyLaboratories.aspx](http://www.cdph.ca.gov/services/DPOPP/regs/Pages/DPH-13-007E,HumanImmunodeficiencyVirus(HIV)ScreeningTestingbyLaboratories.aspx). For information about the HIV testing algorithm, she directed people to the website <http://aids.gov/>, where it is now published instead of being published in the MMWR.

She announced that Karen Demby is a new examiner in the Facilities Licensing section.

Robert Footlik stated that there is no requirement that prohibits a phlebotomist from working in a research laboratory. He said that they must meet the requirements that govern research laboratories, which LFS does not monitor. He requested clarification of Section 1282.2 of the BPC. Beatrice O'Keefe agreed to provide clarification at the next CLTAC meeting.

### **Facility licensing – Los Angeles**

Joanne Rowan, Section Chief of Facility Licensing in southern California, was asked at the last CLTAC meeting to present her findings on accredited laboratory inspections. She reported that 80 laboratories were inspected and of these, 28 labs were found to have deficiencies. Ninety-five (95) deficiencies were cited in total. She worked on grouping the deficiencies into several categories as follows: Personnel, Patient Test Management (PTM), Proficiency Testing (PT), Quality Assurance (QA), Quality Control (QC), State only (CBPC, CCR), and Waived Testing. Ms. Rowan was prepared to present her findings on each category in greater detail, giving examples of each, but due to the limited time remaining in the meeting, her presentation was rescheduled for the March 2014 CLTAC meeting.

### **New business**

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

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

It was asked that Karen Nickel make available a copy of the position paper that was previously prepared when Section 1050 of the current LFS regulations was under discussion in 2001. (The position paper is available on the LFS website at <http://www.cdph.ca.gov/programs/lfs/Documents/Clinical%20Lab%20Standards.pdf>.)

Dr. Nickel will report on the work being done on new regulations regarding sperm-

washing (DPH 11-01).

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 Friday, March 7, 2014. Other meetings in 2014 are scheduled for June 6, September 5, and December 5.

**Adjournment**

Laurie Fuller moved that the meeting be adjourned, Rhonda Becker seconded the motion, and the CLTAC voted to adjourn at 12:28 AM.