

**Clinical Laboratory Technology Advisory Committee**  
Minutes of the Meeting held on March 7, 2014  
Meeting held by videoconference from Richmond campus, CDPH,  
KP Regional Laboratory, North Hollywood and  
Telephone Bridge Line

**CLTAC members participating**

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

**Former CLTAC members participating**

Michael Borok, Tim Hamill, Jerry Hurst, Curtis Johnson, Carmen Maldonado, Jim Ottosen, Les Revier.

**CDPH staff participating**

Zahwa Amad, Alan Ankerstar, Gillian Edwards, Elsa Eleco, Elaine Flores, Ron Harkey, Tina Hashemi, Robert Hunter, Shideh Khashe, Paul Kimsey, Nema Lintag, Yangzhu Long, Donna McCallum, Don Miyamoto, Karen Nickel, Martha Obeso, Jan Otey, Tammy Pahland, Joanne Rowan, Gabriele Sabino, Judith Schlosser, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

**Public members participating**

Michael Aidan, Kama Brockman, Marian Castillo, Irene Chen, Ann Chenoweth, Alice Crisci, Kathy Davis, Debbie Ferguson, Lisa Forslund, Nancy Fraize, David Gomez, Dora Goto, Mike Janda, Erica Klein, Peggy Kollars, Shiu-Land Kwong, Lois Langs, Dan Leighton, Jill MacAfee, Jamie Marks, Valerie Ng, Rose Palo, Jim Philips, Rodney Roath, Diane Schillinger, Gene Scott, Barbara Sevilla, Shannon Smith-Crowley, Tom Tempske, Ann Tonini, Christine Vernusky, Phyllis Walker, Shirley Wong-Jose, Tammy Zinsmeister.

**Welcome and general announcements**

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:08 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.

**Approval of the December 6, 2013 meeting minutes**

A motion was made to approve the minutes from the December 2013 meeting with corrections as submitted. The motion was seconded and the minutes were approved.

**Department update**

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

Dr. Kimsey reported on the application of CDPH for accreditation by the Public Health Accreditation Board (PHAB). On February 8, 2014, Director Dr. Ron Chapman submitted an accreditation package of over 19,000 pages, comprising approximately 1,100 documents. 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, twelve Domain Teams were created by CDPH 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.

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 team will meet in the summer of 2014.

Dr. Kimsey stated that a report was received in late February giving the results of the federal select agent inspection conducted in December 2013. 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. The report was received approximately two weeks ago, and Dr. Kimsey said that he was in the process of finalizing the response to the inspection report.

Dr. Kimsey noted that the legislative session is now in progress, and that there are a few bills in process. He expects that CDPH and Laboratory Field Services (LFS) may see more bills related to laboratory issues come forward during the session.

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

Tammy Pahland, Staff Counsel for LFS, updated the meeting on the draft personnel regulations package DPH-11-012. She noted that the process is now nearing the end of the initial phase and has produced a package that includes almost 300 pages of regulations and more than 100 pages of the Initial Statement of Reasons (ISOR), which presents the reasoning behind the regulations. The LFS committee completed the final review of the draft of the regulations and the ISOR and prepared the necessary financial documentation. The package has now been sent forward to the Office of Regulations (OR), where it is being reviewed for clarity, consistency, and compliance with the Administrative Procedures Act (APA).

While the package is under review by OR, Ms. Pahland will meet with the Office of Budgets. At the same time, a Regulations Process Team (RPT) will be convened to discuss overall strategy and to review the financial documents. Once the package has been reviewed by OR, it will be forwarded to the Health and Human Services Agency (HHS) for review. It is hoped that the regulations will be available for public comment early next year.

Asked when the package will be released for public comment, Ms. Pahland said that it would happen after the HHS review, and so the date of release depends on how

long the reviews by OR and HHS take. She hopes to be able to say more at the next CLTAC meeting.

Ms. Pahland noted that the process for writing regulations is a complex one, involving many departments as well as review by HHS. Ms. Pahland added that in her opinion the LFS team has done an excellent job and has produced a very good package.

Tom Tempske asked if the package will go to the Office of Administrative Law (OAL) after it is reviewed by OR. Ms. Pahland responded that after the package has been approved by the OR it will be sent to HHS for review and approval. OAL will take over the process at that point, review it, and release it for public comment. The package will be given to OAL as a courtesy before it is sent forward by HHS. Ms. Pahland noted that OAL will review the package and either approve or deny it, but will not recommend or make changes.

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

#### **CLIA Crosswalk Subcommittee update**

Ms. Dean-Yoakum handed the meeting over to Robert Footlik, Chair of the CLTAC subcommittee on the CLIA crosswalk, who reported that the subcommittee was nearing the end of its work. He reported that the subcommittee met in February. They have concluded the review process and will meet once more to assemble their findings. They hope to present their findings and make their final recommendations at the June meeting of CLTAC. Ms. Dean-Yoakum thanked Mr. Footlik, LFS, especially Kathy Williams, and all the members of the subcommittee for their work.

Michael Borok asked if the committee had discussed anatomic pathology yet, and Mr. Footlik answered that they had covered all the specialties.

#### **LFS update**

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

Ron Harkey, Section Chief of the Biologics and Tissue Bank Section, reported on proposed legislation being analyzed by his program. Assembly Bill (AB) 1822, proposed by Assemblyman Rob Bonta, deals with the storage of tissue for implantation into or application onto patients, and would exempt a person who is licensed to provide health care services from the FDA tissue bank licensing requirement for storage of such tissue when the tissue was obtained from a licensed tissue bank, stored in strict accordance with FDA regulations, and used for implantation into or application to a patient. Mr. Harkey reported that he had obtained the fact sheet from Assemblyman Bonta's office, and although he was unable to comment extensively on his analysis, he had noted a few inaccuracies in the fact sheet. He explained that he was not at liberty to discuss the department's deliberations while they are ongoing, but will answer questions at a later date. He remarked that anyone involved in blood banking is aware of the importance of proper collection and storage methods.

Jan Otey reported on Senate Bill (SB) 492, proposed by Senator Ed Hernandez. This bill was introduced last year and is still active as a two-year bill. It would

expand the scope of practice parameters of optometrists who are certified to use therapeutic pharmaceutical agents by removing certain limitations on their practice and adding certain responsibilities, including the ability to immunize and treat certain diseases, and deleting the specified drugs the optometrist would be authorized to use, and authorizing the optometrist to use all therapeutic pharmaceutical agents approved by the United States Food and Drug Administration. Of specific concern to LFS is the provision that would authorize optometrists to direct laboratories. Ms. Otey noted that her calls and emails to Senator Hernandez's office regarding this bill have gone unanswered, and there is nothing on Senator Hernandez's official website concerning this bill. The last action on this bill took place when the bill was amended on August 6, 2013.

Dora Goto of the California Association of Medical Laboratory Technology (CAMLT) called attention to AB 2143, which was amended to add duly licensed chiropractors as directors of waived laboratories. She reported that this spot bill, introduced by Assemblyman Das Williams, serves to hold a place for chiropractors, who are looking for an author for a bill that would allow them to act as waived laboratory directors. She noted that representatives from CAMLT had spoken with the chiropractors' professional organization about an amendment to the California Business and Professions Code (B&PC) that would add chiropractors who are duly licensed for the purpose of specific tests to practice as laboratory directors for waived laboratories doing drug testing for pre-employment physicals and urine dipsticks for the national driver's license physical exam, as well as allowing them to use the urine dipstick for diagnostic purposes. She added that California law does not allow chiropractors to diagnose.

#### **HLWI update**

Rebecca Rozen, Regional Vice President for the Hospital Council, introduced Dr. Tim Hamill, Professor and Vice Chair of the UCSF Department of Laboratory Medicine and Director of UCSF Clinical Laboratories at Parnassus & China Basin, and a former chair of CLTAC, and Sue Foltz, co-chairs of the HLWI Advisory Group, Leadership for the Healthcare Laboratory Workforce Initiative.

They reported on the work of the advisory group, which was created to find innovative solutions to the laboratory workforce shortage facing California and the nation. The goal of the HLWI is to increase the number of licensed Clinical Laboratory Scientists (CLS) and Medical Laboratory Technicians (MLT) in California in order to meet the demand for such workers across industry sectors. To accomplish this goal the HLWI has launched the "Creating a Future Laboratory Workforce" campaign. Earlier this year the HLWI surveyed 100 California MLT license holders in order to obtain current information about the job market for MLTs and their perception of how well they are accepted in the workplace. Fifty-two MLTs responded to the survey, providing a snapshot of the current marketplace for this new profession.

Ms. Foltz noted that she had worked in other states with MLTs. Due to limitations on the MLT scope of practice in California, small laboratories have encountered difficulties with hiring MLTs because of the limited scope of practice and consequent need for supervision. This is frustrating for both the laboratories, which have a difficult time filling laboratory personnel positions, and for the MLTs who want to

work in California. She said that the advisory group has been working together for about nine months and is now seeking the feedback of CLTAC on this issue.

A brief slide show highlighted the aging of California's laboratory workforce, which has resulted in a shortage of laboratory personnel, especially CLSs, of whom 40% are 56 or older and can be expected to retire within the next five or six years. Ms. Foltz noted that as a group, MLTs have a strong interest in becoming CLSs, but that the limited scope of practice, lack of acceptance, and scarcity of job openings in California represent a barrier to job satisfaction and discourage job seekers from outside the state.

Dr. Hamill thanked CLTAC for inviting representatives of the workgroup to address the meeting and reiterated that the advisory group is seeking advice and guidance from CLTAC. He noted that the initiative is a preliminary step to legislative change to the MLT scope of practice, because the scope of practice of MLTs is defined by statute. The goal of the workgroup's initiative is to allow MLTs to do additional work in California laboratories. A number of options are being considered. One is a workforce pilot project sponsored jointly by OSPHD and the Health Workforce Pilot Project (HWPP) that would allow MLTs to perform tasks in a study setting, with a CLS and an MLT reading the same materials, the CLS for purposes of reporting, and the MLT for purposes of the research study with the UCSF Center for Health Professions. Another option is to go to a location where MLTs are already employed to do a comparison study. He emphasized that all clinical reporting would be done by CLSs, and the work of MLTs would be used only for purposes of research studies. He stated that the advisory group is eager to have feedback from interested parties, including the CLTAC board and its public members, and asked that anyone who has thoughts or suggestions for approaching this topic report them to himself, Sue Foltz, or Rebecca Rozen.

Dr. Hamill explained that the workgroup is considering tests that would have a measurable impact on relieving the workforce shortage in laboratories, understanding that statutes and regulations limit MLTs to moderate complexity testing. A preliminary list of such tests includes blood smear tests, urinalysis, and moderate complexity automated tests. He assured the meeting that MLTs involved in the research project will operate within the scope of practice as defined in current California law and that MLTs will not have direct contact with patients and that their results will not be released for clinical purposes. Only CLSs will release results for clinical purposes, and the results obtained by MLTs can only be used for purposes of comparison.

Jennifer Schiffgens noted that in her experience in many other states, MLTs are exceptional workers, and asked if the advisory group could partner with other states to obtain data on the work of MLTs. Dr. Hamill agreed that would be a good idea, and added that 48 other states allow MLTs to review peripheral smears, with some restrictions

Marjorie Braasch noted that there are not many MLTs in California and asked if this initiative was an attempt to recruit MLTs to the state. She questioned the relevance of the survey conducted by the Hospital Council in light of the small number of MLTs working in California. Dr. Hamill responded that MLT training programs in California

are closing because graduates cannot find jobs, which he considers to be a step in the wrong direction. He noted that this also creates a bottleneck for MLTs coming from other states because they cannot do in California what they have been doing in other states. The advisory group is hoping to increase the number of MLTs working in California by expanding training programs and creating a more positive situation for MLTs coming from other states. Ms. Foltz added that the number of MLTs has fallen due to limitations on their scope of practice, because people are reluctant to train for a position with such a limited scope of practice, which means fewer applicants for schools, which in turn leads to the closure of schools.

Robert Footlik suggested that the chair address CLTAC members first before asking the public for input. Regarding the review of peripheral smears, he noted that such testing is only classified as moderate complexity if there are no abnormal cells, and that once abnormal cells are present the test becomes high complexity. He pointed out that it was the difficulty in discerning between the two instances that led to the rule that MLTs in California cannot do microscopy, and asked how the workgroup proposes to deal with the issue of microscopy.

Dr. Hamill said that moderate complexity testing is the highest level that an MLT can perform under California law. He suggested that one solution might be a legislative solution that would carve out microscopy as a separate area.

Jim Ottosen said that, with regard to peripheral smears and microscopy, people need knowledge and expertise to perform such work, but according to regulations MLTs do not have this training, and he asked how they will obtain the necessary expertise without the proper training. Dr. Hamill responded that MLTs in California do receive the training to read peripheral smears, pointing out that MLTs trained in California go to other states and do this. He added that NAACLS-approved programs allow this. Mr. Ottosen stated that such training is not in the MLT curriculum. Lorri Dean-Yoakum asked Les Revier, who has long experience in MLT training programs, if MLTs receive the training necessary for doing peripheral blood smears. Mr. Revier answered that in his program they do.

Tom Tempske noted that he had worked at the bench for many years, and said that as a practical matter, most slide reviews in acute care hospitals are conducted because automated instruments flag specimens for review, and that around 80% of reviews are normal. Robert Footlik said that in a hospital setting, many more abnormal slides could be expected than in an outpatient clinic, due to the acute status of hospital patients. Marjorie Braasch said that she works at the bench in an acute care hospital and that most reviews (60-70%) are abnormal, other than platelet review.

Michael Aidan, whose union (IFPTE #20) represents both CLSs and MLTs, acknowledged the shortage of CLSs. He said that he would prefer to see an increase in the number of CLSs, and that he doesn't think that a dilution of CLS standards is the answer to the problem. He said that he would prefer to work to increase the number of CLSs and CLS training programs. He said that in his opinion increasing the MLT scope of practice while continuing to pay them less is not going to attract MLTs to California. Ms. Foltz pointed out that that the hospital initiative was founded over nine years ago to address the shortage, and that there are more

CLSs now as a result of their work on this issue. Dr. Hamill remarked that the HLWI initiative was not an attempt to dilute CLS standards, and noted that HLWI has been working for a long time to increase the number of CLSs. He added that a combination of both MLTs and CLSs is needed to support the needs of the future.

Lorri Dean-Yoakum pointed out that 80% of testing is of moderate complexity, and suggested assigning this testing to MLTs while giving high complexity testing to CLSs. She thanked Ms. Rozen, Dr. Hamill, and Ms. Foltz for attending the meeting and thanked everyone for their suggestions.

### **Guest Speakers**

#### **Dr. Kama Brockmann**

Lorrie Dean-Yoakum introduced Dr. Kama Brockmann, a Specialist for HIV Prevention and Surveillance Integration in the Office of AIDS (OA) at the California Department of Public Health. She currently coordinates the CDC-funded Expanded HIV Testing in Healthcare Settings Project, and has worked extensively with families affected by AIDS and HIV.

Dr. Brockmann noted that the Office of Aids has enjoyed a good relationship with LFS, and that it had resulted in a fruitful collaboration over a long period of time. She pointed to the movement forward with the new testing algorithm as an example of the collaboration.

Dr. Brockmann reported on a new diagnostic algorithm for HIV testing. She explained that a regulation change effective June 26, 2013 allows California laboratories to use any HIV testing algorithm recommended by the CDC, Association of Public Health Laboratories, Clinical and Laboratory Standards Institute (CLSI), and U.S. Dept. of Health and Human Services. This regulation is expected to become permanent by March 23, 2014. She noted that it is an emergency regulation, and thanked LFS for substantial help, along with the Office of Legal Services (OLS). She explained that because the CLSI recommends algorithm it is permitted for use in California. The CDC is expected to recommend the algorithm by fall of 2014.

Among the benefits of this new algorithm is the early detection of acute HIV infection. The new algorithm allows detection of infection within two to eight weeks, when people are at their most infectious because the virus is increasing in the blood but the antibody has not yet activated well enough to decrease the virus. The test also differentiates between HIV1 and HIV2; HIV2 is not prevalent in California at the present time, but incidence is increasing. The new test is cheaper than the western blot test, and also offers a very fast turnaround time, about 20 minutes. By contrast, the western blot test, a much more complex test, is usually batched and run once or twice a week. She noted that Siemens ADVIA Centaur is expected to submit a fourth generation assay to the FDA which will not require control bracketing. She also noted that the new algorithm is only approved for RNA qualitative viral load testing, which tests positive or negative for the presence of virus in the blood, and which is not as widely available as RNA quantitative viral load testing. RNA-quantitative viral load testing can be ordered after a second test and diagnosis for the third step of the algorithm with a physician's standing order.

She next discussed the Alere Determine HIV 1/2 Ag/Ab Combo test, a new product that meets the requirements of the new algorithm for HIV testing and is coming soon to the market. Dr. Brockmann explained that this test is a rapid point-of-care (POC) test that differentiates the p24 antigen from the HIV 1/2 antibody. If the antigen appears without an antibody, it will indicate that a patient is in the initial, highly infectious stage of illness. The test was approved by the FDA in January, 2014, as a moderate complexity test. CLIA waiver is expected around July 1, 2014. This test is not as sensitive as laboratory-based fourth generation testing, but the Office of AIDS is interested in it because it is better than current POC testing technology, and would enable the early identification of acutely infectious people. In particular, this test could be useful in programs for people who engage in high risk behavior, because it has the potential to help identify acutely infected patients in the early stages of infection and get them into care, and perhaps encourage them to change their behavior in order to lower the risk to others.

Rhonda Becker asked about a price comparison. Dr. Brockmann stated that laboratory testing is cheaper and better than POC testing, but she pointed out that there are times when laboratory testing cannot be done. She said that the representatives of Alere claim that it will be competitively priced at around \$10.00 per kit; this is comparable with the price of current laboratory testing, which is between \$3.00 and \$5.00 for first step screening. She noted that the Alere test may be a game-changer for HIV antigen/antibody testing. The test does require a blood sample of 50 microliters, which is five times the amount required by most POC tests, and this raises a training issue. It is a chromogenic (color change) test.

Lee Hilborne raised the issue of the CPT panel that was discussed at the last (CLTAC) meeting and asked about the coding of the Alere test. Dr. Brockmann said that the Alere test will have its own code, and will not use the CPT lab code. She noted that some payers are reluctant to pay for fourth generation testing because their patients are not at risk for acute infection. She asked attendees to encourage people with questions about reimbursement to contact her. She said that she wants examples of reimbursement decisions in order to know how such decisions are being made. There are questions about cost effectiveness, and she is interested to know how people are thinking about the test in this regard.

Lorri Dean-Yoakum thanked Dr. Brockmann for her informative presentation.

### **Dr. Duc Vugia**

Lorri Dean-Yoakum introduced the second guest speaker, Dr. Duc Vugia, chief of the Infectious Disease Branch, Division of Communicable Disease Control in the California Department of Public Health.

Dr. Vugia addressed the meeting on the implementation of AB 186 on laboratory specimen collection. This bill was introduced by Assemblyman Das Williams on January 25, 2011, and was sponsored by the Health Officer Association of California. It passed both houses of the legislature and was approved by the governor and chaptered in October 2011. The bill allows CDPH to establish a list of diseases or conditions for which clinical laboratories must submit a culture or specimen to the local or state public health laboratory. With input from local public health partners, CDPH can modify the list at any time without going through the

formal regulatory process.

After passage of the bill, the AB 186 Implementation Workgroup was formed, with representatives from the California Conference of Local Health Directors (CCLHO), the California Association of Public Health Laboratory Directors (CAPHLD), the California Association of Communicable Disease Controllers (CACDC), and the Division of Communicable Disease (DCDC) branches at the CDPH Richmond campus, in particular the Microbial Disease Laboratory (MDL) and the Viral and Rickettsial Disease Laboratory (VRDL) branches. In 2012, the workgroup held three teleconferences to propose diseases and specimens to be included in the first listing, bearing in mind limited laboratory resources and the need to impose minimal cost and minimal burden.

The initial list included *Salmonella* isolates, *Mycobacterium tuberculosis* isolates, malaria smears, meningococcal isolates from sterile sites, Shiga toxin-producing *E. coli* (STEC) O157 and non-O157 isolates and Shiga Toxin (ST)-positive fecal broths, *Listeria monocytogenes* isolates, and Measles IgM-positive sera. Of these, *Salmonella* isolates, *Mycobacterium tuberculosis* isolates, and malaria smears were already listed in the California Code of Regulations, and meningococcal isolates from sterile sites, Shiga toxin-producing *E. coli* (STEC) O157 and non-O157 isolates and ST-positive fecal broths were already being submitted on a voluntary basis, as local public health and clinical laboratories have been asked to submit them for the past three or four years. *Listeria monocytogenes* isolates were listed because they are foodborne and are present in commercial products that need to be identified immediately so that they can be removed from circulation, they can cause severe disease or death in affected populations, rapid detection and investigation may save lives, and there are a small number of isolates, so reporting does not constitute a major burden. Measles IgM-positive sera were listed because they may be falsely positive in clinical laboratories, rapid confirmation may save public health resources that are required for follow-up, and there are a small number of sera. Dr. Vugia noted that there are many cases of measles.

This list was presented at CCLHO CD committee and CCLHO executive board meetings for discussion and support. The formal request and proposed regulatory language changes were sent forward to the CDPH Office of Regulations, and were given final approval at the end of 2013. The law became effective on January 1, 2014. The final list in the California Code of Regulations (CCR) Title 17, Section 2505, Subsection (l) includes *Listeria monocytogenes* isolates, measles IgM-positive sera, meningococcal isolates from sterile sites, and Shiga toxin-producing *E. coli* (STEC) O157 and non-O157 isolates and ST-positive fecal broths.

The final step in the process involves sending notification to all clinical and public health laboratories in California. The workgroup has prepared a guidance document to clarify the implementation of the bill and also to give further information about the diseases on the list and testing. Laboratories have a six-month grace period from the date of notification to implement the requirement. There will be future additions to the list. The next update to the list will be led by the DCDC Microbial Diseases Laboratory in CDPH along with local and state partners.

Asked if this will entail dual reporting, with physicians reporting as well as

laboratories, Dr. Vugia answered that it would.

### **Blood and Tissue Banking Update**

Ron Harkey, Section Chief of the Blood and Tissue Bank Section, reported that the use of cord stem cells (tissue) and cord blood stem cells (blood) is an issue of increasing concern, and asked Bob Hunter to report on his ongoing investigations in this area. Mr. Hunter reported on a case that occurred two years ago in California involving a cord blood storage company that went out of business. It left a huge inventory of cord blood units at risk in an unregulated facility. LFS was able to arrange for the safe transfer of over 1,000 umbilical cord blood units to other facilities. The decision in the case was a default judgment against the company, and the district attorney is now considering further action against the company.

Mr. Hunter is presently involved in the investigation of another similar case involving more than 500 cord blood units collected within and outside the state of California. LFS is working with the FDA and local authorities on this case. Mr. Hunter is not at liberty to discuss this case because it is still under investigation, other than to say that LFS is trying to get the cord blood units transferred to safe storage.

Mr. Hunter noted another investigation involving a cord blood facility, which resulted in substantial changes in the operation of the organization under investigation.

Another recently concluded case involved a vendor who was distributing contaminated saline products. LFS was successful in making sure that none of the products were distributed for use in licensed plasma centers.

As of March 6, LFS was notified of a case involving transfusion-transmitted disease from a bacterial agent related to infectious organisms. There is no easily available literature about transfusion-related transmission of this particular organism. Investigative work on a sample is being conducted at CDC. Mr. Hunter said that he will share information on this case when he is able to do so.

Tom Tempske asked about problems with the licensure of cord blood facilities. Ron Harkey said that it is not a question of licensure, but rather, of a lack of planning for the return of cords to clients when they want them. Mr. Harkey observed that abandonment of cord blood products appears to be an increasing problem when companies go out of business. This presents the issue of how to return cords to individuals when they want to retrieve them. Some new companies attracted by a good business opportunity do not think through the process.

### **CLIA Update**

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, reported that in February 2014 her section welcomed a new CLIA surveyor, Gabriele Sabino, and lost another examiner to resignation. She noted that the CLIA section is currently understaffed.

Through the end of January 2014, the CLIA section performed 24 initial surveys and 202 recertification surveys. No validation surveys were performed due to a shortage of staff. The proficiency testing desk reviewed ten complaints.

Ms. McCallum reported that as part of an ongoing effort to empower patients to be informed partners with their health care providers, the federal Department of Health and Human Services (HHS) issued a final ruling in February to give a patient or a person designated by the patient a means of direct access to the patient's completed laboratory test reports. The goal of this rule, "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports," is to empower patients to become informed partners in their health care decisions

The final rule as announced by HHS amends the CLIA of 1988 regulations to allow laboratories to give a patient, or a person designated by the patient, his or her "personal representative," access to the patient's completed test reports on the patient's or patient's personal representative's request. At the same time, the final rule eliminates the exception under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to an individual's right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients' privacy. The rule was issued jointly by three agencies within HHS: the Centers for Medicare and Medicaid Services (CMS), which is generally responsible for laboratory regulation under CLIA, the Centers for Disease Control and Prevention (CDC), which provides scientific and technical advice to CMS related to CLIA, and the Office for Civil Rights (OCR), which is responsible for enforcing the HIPAA Privacy Rule. The rule will affect 42 Code of Federal Regulations (CFR) Part 493.129(f) and the California Business and Professions Code (B&PC) 1288.

The newly formulated rule changes the definition of authorized person to include the patient or his or her designated representative, and preempts state laws that limit an individual's access to his or her complete laboratory test results. Laboratories will have 30 days to provide patients with their completed test results. Under HIPAA, laboratories will have 180 days from the effective date of the rule to come into compliance and release test results.

Ms. McCallum pointed out that while laboratories must release test result reports to patients, they are not under obligation to explain the results or diagnosis. It is the responsibility of the healthcare provider to order tests and to explain to the patient the results and the patient's treatment options. She noted that the provider will likely receive test reports before the patient receives the report, allowing time to communicate with and counsel the patient.

Robert Footlik stated that the rule applies to any laboratory defined as a covered entity under HIPAA, but noted that not all laboratories fall under that definition. He explained that a covered entity refers to a health plan, a clearing house, or a laboratory that transmits electronic claims or receives electronic claims for federal reimbursement program. Laboratories that only process paper claims or no claims do not fall under the definition of a covered entity and therefore are not subject to this requirement to provide direct access to laboratory results. This would include laboratories that don't submit any claims, for example hospital laboratories where the hospital, and not the laboratory, submits the claims. Ms. McCallum said that it is not clear how the ruling will play out or what the legal ramifications are. She also

noted that research laboratories are not subject to HIPAA requirements.

Karen Nickel asked if any validation surveys had been conducted. Ms. McCallum said that due to the shortage of staff no CLIA validation surveys had been conducted.

### **Facility licensing - Richmond**

Kathy Williams, Section Chief of Facility Licensing in northern California, introduced a new facility licensing Examiner II, Shideh Khashe. Ms. Khashe will be working mainly with the complaint program, but is being trained in all aspects of facilities licensing.

Ms. Williams reported that since January 1, 2014, her section has received 49 major complaints. Three of these involved test errors, two involved state licensing, and 26 were miscellaneous. Thirteen complaints concerned phlebotomists and their techniques. Three involved billing issues. Ms. Williams noted that LFS doesn't usually deal with billing issues, but one case involved collections and she asked her staff to investigate it. She noted that there seems to be an increase in the number of complaints about testing errors.

Ms. Williams reported that in the past three months, from December 2013 through February 2014, her section received 38 new applications for licenses. There were 18 new applications from pharmacists, 18 from optometrists, and 2 from naturopathic practitioners, all of which were approved.

Ms. Williams reported that SB 222 (the Genetic Privacy Act) sponsored by Sen. Alex Padilla is dead. She noted that Sen. Padilla is in the last part of his term and so the bill is not likely to come up again. The bill would have imposed huge costs to laboratories. As an example, Ms. Williams stated that Kaiser and UCSF recently turned over databases of genomic information to the NIH, involving several thousand records. If the bill had passed, they would have been required to go back to all tested persons and get written permission to give their data to the NIH.

In reference to the federal ruling discussed by Donna McCallum, Ms. Williams noted that the rule as recently enacted by HHS overrides state laws, and she encouraged members and interested parties to download the federal register of February 6, 2014, which gives a full discussion of patient access to laboratory results reports. The ruling and discussion can be found at <https://www.federalregister.gov/articles/2014/02/06/2014-02280/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports>.

Ms. Williams reported on recent developments concerning the off-label use of glucometers. The discussion centers on FDA approval of glucometers not intended for diagnosis or screening, but only for monitoring glycemic patients or diabetic patients. New York has revoked permission for the use of screening meters in health fairs, hospital ICUs, and clinics. LFS will research the situation in California. LFS asks health fairs and others using glucometers for screening or other off-label uses to come into compliance with CLIA. LFS will also have to determine how glucometers are being used for screening at corporate wellness testing centers. Ms. Williams urged interested parties to download the guidelines on "Blood Glucose

Monitoring Test Systems for Prescription Point-of-Care Use” from the FDA website at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidanc edocuments/ucm380325.pdf> and to submit comments.

Karen Nickel noted that only waived tests can be used in non-diagnostic settings. Lorri Dean-Yoakum thanked Jim Ottosen for bringing this matter to the attention of LFS.

Robert Footlik stated these glucometers are used as point-of-care tests throughout California, and that this issue never surfaced before now, going back to 2000. He asked why now all of a sudden people are being asked to stop using them, and why nurses can no longer use them as POC tests. Ms. Williams said that this could have a great impact on practice in California and across the country.

Lorri Dean-Yoakum encouraged everyone to comment, and to pass on the information to hospitals and other stakeholders.

Jan Otey asked if glucometers that are specified for use by health care professionals could be used. Ms. Williams said that they could not be used, because in this case the tests are being used not to monitor a glycemic patient or a diabetic patient, but to screen and diagnose.

Jill AcAffee pointed out that a lot of patients may remain untreated as a result of this development, and asked if the AMA and the American Association for Diabetes know about this. Ms. Williams said that the American Association of Diabetes does not endorse the use of glucometers for screening purposes, but only for monitoring purposes.

Jerry Hurst asked if LFS has passed this information on to county facilities. Ms. Williams said that LFS would be doing this soon. She added that the information had only been received last week, but that such notification is part of the project.

Lorri Dean-Yoakum thanked LFS for its quick response and asked Ms. Williams and Ms. McCallum to give updates in June. She noted that other tests done in the context of health fairs may also constitute off-label use, so we can expect to hear more on this subject.

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

Joanne Rowan, Section Chief of Facility Licensing in southern California, reported on findings in accredited labs

The information in her presentation is based on the results of routine state inspections of accredited laboratories by state examiners from February 2013-February 2014. This data does not include any information regarding the findings from “validation” surveys of accredited labs performed by the federal CLIA program, or findings from northern California. The only findings reported were of the validation surveys of accredited labs performed by southern California.

Of the 80 laboratories inspected, 44 were accredited by COLA, 22 by CAP, 9 by

TJC, 3 by AOA, and 2 by AABB. Of these 80 laboratories, 52 (65%) were found to have no deficiencies. The remaining 28 laboratories (35%) had deficiencies as follows:

4 laboratories inspected by TJC (44%)

8 laboratories inspected by CAP (36%)

16 laboratories inspected by COLA (36%)

No laboratories inspected by AOA or AABB had deficiencies.

Four of the 28 laboratories with deficiencies, or 14%, had condition level deficiencies. The conditions cited were for Quality Control (QC), Laboratory Director (LD), Quality Assurance (QA), and Patient Test Management (PTM). All conditions were cited in the laboratories inspected by COLA.

Standard level deficiencies were cited most often for QC (40 occurrences), followed by Personnel (LD responsibilities and duties) (20 occurrences), PT (12 occurrences), state-specific findings, that is, those unique to state law and not covered by CLIA (11 occurrences), QA (7 occurrences), PTM (4 occurrences) and waived testing (1 occurrence).

In the area of QC, the most common deficiency cited was failure to perform equipment maintenance, followed by lack of performance of Method Verification (MV), and failure to maintain QC records.

In the area of personnel, the deficiency cited most often was the LD's failure to ensure that the competency and performance of staff were evaluated and documented. This was followed by the LD's failure to ensure that QC programs were established and maintained. Other deficiencies in this category included failure to specify in writing the responsibilities and duties of each person engaged in the performance of preanalytic, analytic and postanalytic testing procedures; failure to ensure that all personnel prior to testing had the appropriate education and experience and received the appropriate training for the type and complexity of services offered; and failure to ensure that QA programs were established and maintained.

For proficiency testing, the most common deficiency was not taking remedial action for unacceptable proficiency testing results. Other findings included not reviewing results, having no attestations for the LD or testing personnel, proficiency testing being run more often than patients, and incomplete proficiency testing forms.

State-specific findings included the failure to include the director's name on the test report, the use of unlicensed personnel, failure to display the CLS licenses, and one auto-verification issue involving the lack of specific policies and procedures.

In the area of QA the findings included not performing QA audits, not documenting the audits, not having a QA Policy and procedure, failure to identify QC problems (i.e. lack of monitoring), and not sharing QA findings with the staff.

In the area of PTM most deficiencies had to do with reporting critical values (i.e. not following policies and procedures for reporting) or having outdated policies and procedures for reporting critical values. In the PTM category there was one instance

of failure to include the location of the testing laboratory (i.e. the name and address of the testing facility were not shown, but instead the sister laboratory's address was listed.) There was also one instance in which waived testing was performed but the manufacturer's instructions were not followed.

Ms. Rowan said that as her staff continues to monitor accredited laboratories, the number of COLA inspections will be reduced, because COLA now has deemed status. Ms. Rowan and her staff are focusing on the other accrediting organizations in order to improve the numbers and findings in those facilities as well.

Karen Nickel asked how LFS is ensuring compliance when deficiencies are found. Ms. Rowan said that in such cases deficiency letters are sent.

Jim Ottosen asked when this becomes a problem with the certifying organization and not the entities inspected. Lorri Dean-Yoakum asked if reports with names redacted are sent back to certifying organizations. Ms. Rowan said that lies with those conferring deemed status on certifying organizations. Karen Nickel noted that LFS does not have authority over those not approved. Ms. Rowan said that these are routine state inspections, not CLIA inspections.

### **Personnel Licensing Update**

Zahwa Amad, Section Chief of Personnel Licensing, thanked her staff for their service to the public and thanked especially Mary Wogec for her work on the regulations package and Minda Imbong, supervisor of the phlebotomy program technicians, for a tremendous improvement in the turnaround time for phlebotomy applications and renewals, which now averages two to three months.

She reported the welcome news that she may soon be able to hire intermittent staff to replace the seven retired annuitants whose positions were lost last year.

Dr. Amad announced a new policy on walk-in applications for personnel licenses and asked for the cooperation of CLTAC in disseminating the information to laboratory directors and staff. Dr. Amad explained that walk-in applicants have presented a particular problem for LFS personnel licensing staff, and asked that laboratory supervisors encourage timely renewals of personnel licenses and certificates. She noted that on average a license renewal takes 60 days. In recent months, LFS has experienced an increase in the number of walk-in applicants, which can be as many as 20 a day. Such applicants can become difficult for staff to deal with. Dr. Amad noted that new applicants and licensed and certified laboratory personnel and their employers can contact LFS personnel licensing staff by email ([LFSPersonnel@cdph.ca.gov](mailto:LFSPersonnel@cdph.ca.gov) or LFS [Recep@cdph.ca.gov](mailto:Recep@cdph.ca.gov)) and that the LFS website provides a contact list for LFS staff at <http://www.cdph.ca.gov/programs/lfs/Documents/A-Section-SpecialtyList.pdf>.

Walk-in applicants have been served as a courtesy, but beginning in May, LFS will no longer serve walk-in clients. Information about the policy will be posted on the website, a notice will be sent in the renewal packet mailed to certificate and license holders, and notice will be sent to phlebotomy schools, training programs, and employers.

Dr. Amad reported that walk-in applicants often ask LFS staff to expedite their applications. She explained that LFS staff cannot review and approve any application “on the spot.” When an application is received, whether by hand delivery or through the mail, the renewal fee must be processed, the CE units must be verified, and the complete application must be reviewed and approved. It is then sent to another state agency, which prints and mails the paper copy of the license approximately four weeks from the date of issue. If a person has been convicted of a misdemeanor or a felony other than minor traffic violations, the process includes submission of a live scan to the Department of Justice (DOJ).

Dr. Amad noted that in fairness to the thousands of applicants served by LFS every month, applications are processed in the order in which they are received. A hand-delivered application is date-stamped and must go through the same process as the one that is received by mail. It is not moved ahead of other applications in the processing queue.

Dr. Amad reported that after a renewal has been approved, it is posted on the LFS website within 10 business days. This is the only verification LFS offers. LFS does not issue “temporary” licenses or certificates or verification letters. She encouraged laboratory managers and laboratory personnel to use the LFS verification website to verify licensure or certification of employees and job applicants. A screen print of the verification page can be used for 90 days after the date of renewal as a temporary authorization to work.

Dr. Amad reported on the licensing statistics for the MLT and CLS programs, thanking Martha Obeso and Nema Lintag for their work.

Since the inception of the MLT licensing program in 2008, there have been 706 applications. As of February 2014, 441 MLT licenses have been issued.

LFS received 221 applications for new MLT licenses in 2013, an increase of 42% over the total number of applications received in 2012, which was 127. Of these, 132 were licensed, an increase of 36% over the number licensed in 2012, which was 84. Others are still pending documentation.

Of the 132 MLTs newly licensed in 2013, 88 were trained in California, 20 were trained out of state, 14 were from the US military, and 10 were trained outside the US.

In 2010, LFS received 57 applications, of which 43 were licensed.  
In 2011, LFS received 73 applications, of which 61 were licensed.  
In 2012, LFS received 127 applications, of which 84 were licensed.  
In 2013, LFS received 221 applications, of which 132 were licensed.

Three MLT training programs have closed. There are currently seven approved programs in California, four in southern California and three in northern California.

Dr. Amad also reported on the statistics for the CLS licensure program. LFS received a total of 1,020 applications for new CLS licensure (general and limited) in 2013, an increase of 20% over 2012, when LFS received 803 new CLS applications.

LFS issued 703 new CLS licenses in 2013, an increase of 11% over 2012, when LFS issued 623 licenses.

Of the 703 new licenses in 2013, 493 were for generalists and 210 were for limited CLSs.

Of the 493 CLS generalists licensed, 210 were trained in California, 119 were trained out of state, 5 were from the US military, and 159 were trained outside the US.

Of the 210 limited license CLSs, 140 were trained in California and 70 were trained out of state.

Of the 210 limited license CLSs, 84 were licensed for clinical genetic molecular biology, 52 for cytogenetics, 31 for microbiology, 28 for chemistry, 7 for histocompatibility, 4 for immunohematology, 3 for hematology, and 1 for toxicology.

Dr. Amad discussed the applications for laboratory director. She thanked Robert Thomas, a former Section Chief for Personnel Licensing in LFS who continues to serve LFS as a retired annuitant, and Gillian Edwards, an LFS Examiner. Applications for this license category have been processed online since November 2011, through LFS' online contractor in Sacramento, which also processes all new online phlebotomy, CLS trainee, and CLS applications. Online application eliminates the wait time for mailing or faxing paper applications for director licensure, enhances accountability, and speeds up the process.

LFS held three oral examinations for laboratory director licensure in 2013, licensing six directors: two in chemistry, two in clinical genetic molecular biology, one in histocompatibility, and one in cytogenetics.

In 2012, LFS held three oral examinations, licensing eight directors: two in histocompatibility, three in clinical genetic molecular biology, two in cytogenetics, and one in oral pathology.

LFS will hold an oral examination for three candidates in March, 2014, one in clinical genetic molecular biology, one in cytogenetics, and one in oral pathology.

Robert Footlik asked for an update on the progress of implementing online license renewals. Dr. Amad said that LFS has the capacity for online initial applications, and that a contract was submitted six months ago for online renewals. CDPH is looking for a consolidated contract and is hopeful that such a contract will go through this time. She noted that she and members of her team have weekly meetings with the CDPH Information Technology Services Division (ITSD), and that they have been working since June 2013 on the design of an online renewal system. They are hoping to have the capacity to process online renewals by next year. Dr. Amad noted that Dr. Chapman, Director of CDPH and the State Health Officer, and Nabil Fares, Deputy Director of ITSD for CDPH, are supportive of the move to online renewal processing.

Jennifer Schiffgens asked if there is a plan to notify laboratories and schools of this. Dr. Amad answered that there is.

### **Update on Form 700**

Lorri Dean-Yoakum announced that she had received clarification from Beatrice O'Keefe, Chief of LFS, on the requirement that CLTAC board members file a Form 700 Statement of Economic Interest in 2014. The initial announcement from Timothy Ford in the Office of Legal Services, sent in December, 2103, stated that CDPH released a proposed Form 700 code, which would expressly add 13 CDPH advisory groups as needing to file a Form 700.

Notice of this development was forwarded in December by Ms. O'Keefe to each CLTAC committee member, providing the notice, a statement of reasons, and the proposed code. On March 3, 2014, Ms. O'Keefe received another email from Mr. Ford stating that the implementation of the new Form 700 code has been delayed a few weeks. Mr. Ford said that he expects that members of the CLTAC committee will be required to file, but the deadline will be later than the usual date of April 1, probably closer to May 1. Once the deadline is clarified, he will send notification of the new code via email. Ms. O'Keefe will then forward that email notice to CLTAC board members, and will be asked to receive all required forms and submit them as a group to HRB for official filing.

### **New business**

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

Lee Hilborne raised the issue of digital pathology.

Donna McCallum introduced a new examiner in the CLIA section, Gabriele Sabino.

Armand Parada said that he would appreciate a guide to the acronyms in common use at CLTAC.

Ms. Dean-Yoakum asked for recommendations for topics for future discussion. There were no suggestions.

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 6, 2014. Other meetings in 2014 are scheduled for September 5 and December 5.

### **Adjournment**

Lorri Dean-Yoakum moved that the meeting be adjourned, the motion was seconded by Armand Parada, and the CLTAC voted to adjourn at 12:22 PM.