

## **Clinical Laboratory Technology Advisory Committee**

Minutes of the Meeting held on June 5, 2015

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

### **CLTAC members participating**

Jonathan Bautista, Richard Bennett, Anthony Butch, Patricia Dadone, Lorri Dean-Yoakum (chair), Elizabeth Dequinia, Kathleen Doty, Lee Hilborne, Daniel Leighton, Daniel Molden, Armand Parada, Jennifer Schiffgens, Fred Ung.

### **Former CLTAC members participating**

Imre Fischer, Robert Footlik, Tim Hamill, Jerry Hurst, Carmen Maldonado.

### **CDPH staff participating**

Alan Ankerstar, Elsa Eleco, Elaine Flores, Ronald Harkey, Robert Hunter, Paul Kimsey, Tina Kruthoff, Nema Lintag, Victoria Maxwell, Donna McCallum, Don Miyamoto, Martha Obeso, Beatrice O'Keefe, Jan Otey, Tammy Pahland, Judy Schlosser, Robert Thomas, Kathy Williams, Mary Wogec, Ellen Yasumura.

### **Public members participating**

Bob Achermann, Geraldine Albee, Mila Braganza, Barbara Brunell, Yvonne Carter, Rafael Cassata, Marian Castillo, Irene Chen, Neng Chen, Anna Choi, Behnaz Dardashti, Dan Dominguez, Heather Goldberg, Dora Goto, Dan Habecker, Carola Howe, Julie Kingery, Margaret Knapp, Peggy Kollars, Shiu-Land Kwong, Lois Langs, Kathy Martin, Iris Miu, Valerie Ng, Karen Nickel, Jim Rash, James Riding, Dwayne Rivadeneira, Rodney Roath, Doug Roth, Karen Rupke, Ozzy Santiago, Matthew Schulze, Barbara Sevilla, Kim Skala, Margaret Tavares, Phyllis Walker, Maureen Weber, Jay Wilkerson, Debbie Wilson-Ferguson, Annie Yang, Tammy Zinsmeister.

### **Welcome and general announcements**

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:00 a.m. Ms. Dean-Yoakum thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

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

### **Introduction of New Board Member**

Ms. Dean-Yoakum introduced three new members of the CLTAC board, Daniel Leighton, Dr. Daniel Molden, and Dr. John Geisse.

Mr. Leighton was nominated by the California Association of Bioanalysts to serve the remaining term of Robert Footlik, who has resigned from the board. He is a licensed clinical laboratory bioanalyst who has worked in numerous hospital and independent clinical laboratories, and also as an independent laboratory consultant. He is currently laboratory director for four laboratories in southern California. He has served as president and secretary for the California Association of Bioanalysts and currently serves as Director at Large for that organization. He also serves as

Western Region Education Coordinator for the American Association of Bioanalysts.

Dr. Molden was nominated by the California Medical Association to serve the remaining term of Dr. Anne Igbokwe, who has resigned from the board. Dr. Molden is a pathologist who is board certified in anatomic and clinical pathology, immunopathology, and cytopathology. Dr. Molden has over 30 years of experience as a pathologist working in anatomic and clinical pathology in a number of hospital and independent clinical laboratories. He currently serves as medical director for the Promise Hospital Laboratory and is a pathologist at the Analytic Pathology Medical Group. He is a member of the American Society of Clinical Pathologists, the College of American Pathologists, and the California Society of Pathologists.

Dr. Geisse was nominated by the California Medical Association. Dr. Geisse is a dermatologist who is board certified by the National Board of Medical Examiners, the American Board of Dermatology, and the American Board of Pathology in Dermatology. Dr. Geisse has over 25 years of experience in clinical laboratory science, having worked as a dermatologist in various hospitals and as a clinical professor in the Departments of Pathology and Dermatology at the University of California, San Francisco. In addition to his position as clinical professor he conducts a private practice in dermatologic surgery and dermatopathology in Vallejo, California, and serves as a consultant to Solano Dermatology Associates and National Heritage Insurance Company, and as an expert reviewer for the Medical Board of California. Dr. Geisse is an editor for the journal Dermatologic Surgery and has authored five book chapters on skin cancer and skin surgery, in addition to numerous clinical research papers. He is an active member of numerous medical and professional societies.

### **Approval of the March 2015 meeting minutes**

Robert Hunter and Robert Footlik submitted corrections to the minutes from the March 2015 meeting. Dr. Lee Hilborne moved that the minutes from the March 2015 meeting be approved as corrected. Elizabeth Dequinia seconded the motion and the minutes as amended were approved by unanimous vote.

### **Department update**

Dr. Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), gave an update the California Department of Public Health (CDPH). He reported that Governor Brown appointed Dr. Karen Smith to succeed Dr. Ron Chapman as Director of CDPH and State Public Health Officer.

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

Smith has indicated an interest in the laboratories at the Richmond Campus and hopes to make frequent visits to the campus.

Dr. Kimsey also announced the appointment of two new deputies by Governor Brown. Claudia Crist, RN, has been appointed Chief Deputy Director of Policy and Programs, and Brandon Nunes has been appointed Chief Deputy Director of Operations.

Ms. Crist will be sworn in as Chief Deputy Director of Policy and Programs in June 2015. She has served as deputy director of health care delivery systems at the California Department of Health Care Services since January 2015. She held several positions at Sutter Health from 2000 to 2014. She was a multicultural health and healthcare delivery systems lecturer at California State University, Chico from 2013 to 2014, a charge nurse at Mercy General Hospital from 1999 to 2000, a staff registered nurse at the California Department of Corrections and Rehabilitation from 1999 to 2000, a charge nurse at Southern Inyo Hospital from 1998 to 2000, and a staff registered nurse at Lancaster Community Hospital from 1997 to 1998, where she was a clinical laboratory assistant from 1993 to 1997.

She earned a Master of Health Administration degree from the University of Southern California's Sol Price School of Public Policy, a Bachelor of Science degree in Healthcare Administration from Bellevue University, and an Associate of Science Degree in Nursing from College of the Canyons. She served as a registered nurse in a variety of clinical settings from 1997-2000, and as a physician assistant in Miesbach, Germany.

She is a member of the American College of Healthcare Executives and the California Association of Healthcare Leaders, and was named Woman of the Year in 2011 by the Greater Sacramento chapter of the Leukemia and Lymphoma Society.

Mr. Nunes will be sworn in as Chief Deputy Director of Operations at CDPH in June 2105 and will also serve as the acting deputy director for the Office of Compliance. Nunes has served as principal program budget analyst at the California Department of Finance (DOF) since 2010, where he has held several positions since 1999.

He worked closely with CDPH staff from 2010 – 2013, overseeing the development and administration of the CDPH budget. He also oversaw budget development of the CalWORKs, In-Home Supportive Services, and CalFresh programs within the Department of Social Services. He spent eight years in DOF's Office of State Audits and Evaluations in various staff and management roles, focusing on fiscal, programmatic, and internal control reviews of state programs, including those administered by the Department of Corrections and Rehabilitation, the Department of State Hospitals, and the California Highway Patrol.

Dr. Kimsey announced that Susan Fanelli has been appointed Assistant Director of CDPH. This new position in the Director's office has been established to provide management and coordination of public health projects involving intra-departmental collaboration.

Ms. Fanelli will be sworn in as Assistant Director for CDPH in June 2015. She will continue as the deputy director of the Office of Emergency Preparedness Office for CDPH, a post she has held since 2013. Prior to that, she served in several positions in that office since 2006, including acting deputy director and assistant deputy. She was a key collaborator working with public and private stakeholders to develop the comprehensive statewide survey of hospitals, the Statewide Public Health and Medical Care Surge Plan, and the Standards and Guidelines for Healthcare Delivery when a surge of demand must be met by a surge in capabilities and capacities. She served in several positions at the California Department of Health Services from 2002 - 2006. She also served as the chief of the Program Support Section, managing the financial aspects of the Public Health Emergency Preparedness Office and overseeing the Hospital Preparedness Program.

Prior to working for the state of California, Ms. Fanelli was director of information services at the Institute for Fiduciary Education from 1996 – 2001. She was vice president and co-owner of Capitol Weekly, a newspaper dedicated to reporting on the state of California, and was president and instructor at Capitol Seminars and Consulting. She has a Master of Arts degree in Political Science/Public Service from the University of California, Davis and a Bachelor of Arts degree in Political Science, with a minor in Psychology.

Dr. Kimsey noted that LFS is now in the process of a new audit by the California State Auditor, following up on an original audit in September 2008. The audit is expected to be finished by the end of the summer.

Dr. Kimsey discussed a trailer bill, Assembly Bill (AB) 94, introduced by the Assembly Committee on Budget chaired by Assemblymember Weber. Existing law at Section 1220 of the California Business and Professions Code (BPC) requires a clinical laboratory that performs tests or examinations that are not classified as waived under CLIA to establish and maintain a quality control program that meets specified CLIA standards. This bill amends BPC section 1220 to provide that the quality control program may include the clinical laboratory's use of an alternative quality testing procedure recognized by the Centers for Medicare and Medicaid Services, including equivalent quality control procedures (EQC) or an Individual Quality Control Plan (IQCP). It is anticipated that this bill will pass and become law in July 2015.

Dr. Kimsey acknowledged the contributions to LFS and CDPH made by Beatrice O'Keefe, who has resigned her position as chief of LFS. He spoke of his appreciation for Ms. O'Keefe's dedication, sense of history, and experience in the field, and thanked her for her dedication to the department and program during difficult times.

Karen Nickel asked how AB 94 will affect the deeming status of accrediting organizations that are accredited for EQC, and whether these organizations would have to be approved again for the new EQC. Dr. Kimsey said that the Department will work with the accrediting organizations and will be in touch with them once AB 94 is passed.

### **Update from legal counsel**

Tammy Pahland, staff counsel for LFS, reported on the status of the draft regulations package DPH-11-012 on personnel licensing regulations. She reported that the package is nearing completion, and the Office of Regulations will soon review the final draft.

She announced that a new attorney will join the program by the end of April, whose task will be to assist the program with writing regulations, and anticipated that this will improve the speed and efficiency with which the program's regulations packages will be handled. She noted that the Office of Legal Services (OLS) has hired six new attorneys, who will rotate duties depending on the needs of various programs, and this will also help to move regulations packages through the process of development and approval.

Ms. Pahland discussed the issue of non-compliance inducements. She quoted BPC section 650, which states that the “. . . offer, delivery, receipt, or acceptance by any person licensed under this division of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration . . . as . . . compensation or inducement for referring patients . . . to any person . . . is unlawful.” She noted that LFS has been conducting investigations into various situations, and referred to a notice regarding non-compliance inducements issued by LFS that outlines various scenarios of arrangements between physician office laboratories (POLs) and laboratories, which has been posted on the LFS website. She said that OLS does not have jurisdiction over these situations, but refers suspected inducements to the Office of the Attorney General, and advised people to visit the website of the Office of the Attorney General for official opinions on such arrangements. She noted that LFS also works with the Office of Consumer Affairs in some situations.

Dr. Hilborne asked how LFS plans to make physicians aware of this notice. Ms. Pahland said that it was available at this meeting as a handout, and that it will be posted on the LFS website. She noted that OLS is also initiating an outreach program with emails to laboratories and other efforts to follow. Dr. Hilborne suggested that it is important such outreach be proactive and educational rather than only punitive.

Dr. Nickel said that this was an important issue 20 years ago, and when LFS was alerted by whistleblowers LFS examiners forwarded evidence to the Office of the Attorney General.

Ms. Dean-Yoakum asked if it was necessary for all three situations in the first scenario outlined in the notice to be present. Ms. Pahland said that only one would be sufficient to categorize a situation as an inducement.

### **LFS update**

Robert Thomas, the acting branch chief of LFS, opened his report by thanking Beatrice O'Keefe for her leadership of LFS for over the last five years. He also recognized the efforts made by the CLTAC chair, members, and attendees in assisting LFS by providing advice on many complex clinical laboratory, biologic, tissue bank, and clinical personnel issues.

Mr. Thomas noted that this is a time of opportunity for staff at LFS and persons who would like to apply their skills and knowledge to advance and broaden their government career or to begin a career regulating clinical laboratories, clinical laboratory personnel, biologics, and tissue banks. He announced that LFS is currently recruiting for a wide range of professional and support positions. LFS is recruiting for examiner I and II positions in Richmond and Los Angeles. State personnel rules require an examination process for civil service applicants. The Examiner I and Examiner II examinations are continuous examinations and are administered biannually. LFS will probably administer these examinations sometime in late July or early August.

He said that in the near future LFS will also fill the Examiner III position in Los Angeles left vacant by the retirement of Joanne Rowan, and is recruiting for positions in Richmond including an associate government program analyst (AGPA) to serve as personnel liaison to Human Resources, an office technician (OT) who will serve as the Branch Chief's administrative assistant, and program technicians (PT I and PT II) who will work in the Facilities Section. He referred questions to Ellen Yasumura, the LFS Assistant Chief, with a copy to Mary Wogec.

He said that LFS has been receiving questions on the availability of the minutes for this CLTAC meeting, and announced that we will be trying out new procedures for CLTAC meetings in order to expedite preparation of the minutes and also to aid in following statistical reports given during the meetings. Section chiefs have been requested to provide statistics on their programs at least one week prior to the meeting so that handouts with current information will be available during the meeting. In addition, any staff member giving reports will provide their paper or electronic report to Ms. Wogec by the end of the next business day following the meeting. This should provide more time for Ms. Wogec to clarify any questions and complete the minutes for distribution to members prior to the next meeting. It has been suggested that there are items on the agenda that roll over from one meeting to the next. He will work with the CLTAC chair to request suggestions from members to determine if there are topics that should appear routinely or at periodic times.

He noted that there has been a robust legislative session this year and LFS has received four bills to review and analyze. LFS staff members will report later in the meeting on the bills they are reviewing. He also pointed out that LFS has no public position on a bill unless it has been sponsored by the department.

He discussed the progress on the new licensing online application system under development at LFS. Eventually, this new system will provide for initial and renewal applications for personnel licensure and certification and renewal for facility licensure and registration. The project has begun with initial applications for personnel licensing. Members of the personnel licensing section continue to meet regularly with Pega, the vendor for the new licensing software system. In December it was reported that the first phase would be completed by June 30, 2015. Due to data transfer technical issues between the current CPS HR Consulting system and the Pega platform that will replace it, the first phase is now scheduled for completion on August 18, 2015. The CPS system will continue to be available until the end of August, which should allow sufficient cross-over time.

He reported that Mary Wogec has been working on providing updates to the LFS website at [www.cdph.ca.gov/programs/LFS](http://www.cdph.ca.gov/programs/LFS) and invited people to visit the website and review it for new postings.

He addressed the issue of personnel licensure renewals, noting that Ms. O'Keefe discussed the processing time-lines for renewal of phlebotomy certificates at the December 2014 CLTAC meeting. In spite of efforts to notify applicants of pending renewal and the encouragement by many employers to their staff to submit biennial certificate renewal paperwork and fees in a timely manner, this continues to be an issue with many phlebotomy technicians. LFS reception and renewal processing staff are being bombarded by multiple emails and phone calls, many from the same applicant on the same day. This is taking away vital resources from reviewing and approving other applications. He asked employers to assist LFS as it acknowledges the issue and works share to improve processing time.

He explained that LFS receives about 12,000 phlebotomy renewals per year, and on average approves about 1000 applications per month. An automated renewal notice is sent to phlebotomists 120 days before certificates expire. The notice includes the renewal form (LAB 177) and information needed to complete the renewal process. Mr. Thomas noted that applications are currently accepted only by mail. There is no drop off or walk up option due to previous threats to LFS staff. Applications are processed in the order they are received.

However, every day LFS receives urgent pleas from applicants who have submitted their paperwork within days of expiration demanding they be processed before others who sent their applications in months before. In fairness, LFS cannot make exceptions to the procedure requiring that applications be processed in order of receipt. If LFS has made an error, then it is fixed and the application is processed immediately. Occasionally someone submits an incomplete application which results in LFS sending a deficiency notice informing the applicant that additional information is needed. This creates additional delays. In addition, phlebotomists are required to inform LFS within 30 days of an address change. Many applicants don't receive their renewal notice or deficiency notice due to failure to notify LFS of their current address.

He reminded people that the renewal website containing useful information on renewal applications is available at <https://www.cdph.ca.gov/programs/lfs/Pages/ContinuingEducation.aspx>. You can also reach this page by visiting the LFS website at <http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx> and clicking on "California Laboratory Facility and Personnel Licenses" and then on "Continuing Education and Renewal."

LFS has been receiving the renewal paperwork from applicants in the following ways:

- CDPH Accounting in Sacramento receives the applications and the checks. They record and deposit the checks, then forward the applications to LFS in Richmond to process.

- LFS in Richmond receives the applications and the checks. The checks are forwarded to CDPH Accounting in Sacramento and the applications stay in Richmond.

Policy requires checks to be cashed within a few days of receipt. However, applications must be evaluated by LFS staff. This means it takes longer for an application to be reviewed than for the check to be cashed. Title 17 of the California Code of Regulations (17 CCR) section 1031.5 (c) requires that renewal applications be submitted 60 days in advance of the expiration date. Until recently LFS had been approving completed renewal applications around a 30 day average, but that time has grown to 45 days. As of June 1, renewal staff were working on applications received on April 17. While this is within the limits of the law, we try to provide better customer service than the legal minimum as we recognize this is impacting both individuals and employers.

He announced that LFS is taking the following short-term steps to remediate this issue:

1. Revise the automated renewal notice sent to applicants to ensure the checks and the applications are being handled consistently, with all applications being sent first to Sacramento, and we are working with ITSD to implement this.
2. Temporarily re-allocate personnel within LFS to reduce the processing time of renewal applications and reduce any perceived backlog.
3. Work with a vendor to upgrade our telephone lines to handle an influx of phone calls.
4. Review policies and procedures and update them for clarity and efficiency.
5. Implement a new tracking system to track individual applications.
6. Place a notice on the renewal website that shows the date of receipt that LFS is currently processing. This refers to the date LFS receives the application.

LFS is also working on a longer term solution:

1. Continue to work with ITSD on moving the current paper-based system to an online application process.
2. Explore other technological solutions, such as scanning to reduce the need for manual data entry.
3. Currently, the law does not permit a grace period for phlebotomists, nor do phlebotomists pay a delinquency fee. LFS is looking into adopting a grace period into law for those renewal applicants who submit a complete renewal application prior to 60 days before expiration of the certificate.
4. The LFS website has already been updated for clarity and consistency.

Mr. Thomas noted that these actions may not resolve all renewal issues. For example, some applicants are subject to a background check for conviction of misdemeanors or felonies other than minor traffic violations in the two years prior to certificate expiration and this obviously slows the process. Other applicants wait until the last minute to submit their renewals, and LFS has no control over their decision to delay submission.

He stated that LFS is requesting CLTAC's assistance in this matter. He suggested that laboratory directors and employers encourage phlebotomy employees to do the following:

- When moving, update the change of address to LFS within 30 days. This ensures that renewal forms are received by the applicant in a timely manner. Instructions on updating address changes can be found at <https://www.cdph.ca.gov/programs/lfs/Pages/ContinuingEducation.aspx>.
- Track their own expiration date and contact LFS if a renewal notice is not received. The renewal form and instructions for renewing can be downloaded from the LFS website renewal page at <https://www.cdph.ca.gov/programs/lfs/Pages/ContinuingEducation.aspx>.
- Once a renewal notice is received, submit the completed renewal application as soon as possible.
- Double check the application to ensure accurate, complete information prior to submitting.
- Do not call or email LFS more than once per day to check on status of the application.
- If you are given an estimated date of completion, do not contact LFS before that date.
- Check the license verification website weekly to see when an application has been approved.
- Put the phlebotomy technician's certificate number on the check and ensure that there are sufficient funds for the check to clear the bank.
- Send both the check and the application to the following address:

California Department of Public Health  
Accounting Section / Cashiering Unit  
MS 1601, P.O. Box 997376  
Sacramento, CA 95899-7376

Dr. Hilborne suggested that LFS aim for a five-day turnaround time, because the fewer applications in the queue, the fewer calls will come in.

Dr. Tim Hamill asked if the LFS verification website could be updated more frequently than once a week. Mr. Thomas said that LFS is working with IT on this issue.

Jennifer Schiffgens stressed the importance of licensed personnel taking responsibility for timely renewal. She noted the importance of a grace period for phlebotomists, so that they would have a full two years to complete their continuing education units. Mr. Thomas noted that phlebotomists are only required to complete 6 hours of continuing education, which is less than the 24 units required for other license categories that have a grace period.

Ms. Dequinia asked if LFS notifies license holders that renewals need to be submitted 60 days in advance. Mr. Thomas said that the renewal notice sent by LFS encourages people to submit renewals 90 days in advance.

Ms. Dean-Yoakum encouraged everyone to commit to doing their part to work with LFS to improve the efficiency of the renewal process. Ms. Wogec will post the bullet points from Mr. Thomas's presentation on the LFS website. And email them to the CLTAC mailing list to make them available to those who need them.

Fred Ung asked if an application is processed sooner if it is sent to Richmond. Jan Otey said that applications are processed according to the date the fee is date-stamped in the Sacramento accounting office, so sending applications to Richmond will not speed the process.

Tina Kruthoff addressed the issue of electronic processing. She said that the Pega online application program will go live in July. LFS will then turn attention to the electronic renewal phase of the project. Workflows and policies and procedures are already available, so the online personnel licensing renewal phase should go live within the next 18 months. This will expedite the renewal process because it will sidestep the need for check processing and eliminate the delay between check processing in Sacramento and application review and approval in Richmond. She noted that the reallocation of staff resources is a short-term solution, and mentioned the plan to include a grace period for phlebotomists in the new personnel regulations package.

Debbie Wilson-Ferguson suggested that clinical laboratory scientists (CLS) be included in the mailing to phlebotomists.

Barbara Brunell asked if it would help to switch phlebotomist renewals from the date of issuance to the birthday, as was done a few years ago for CLS licenses. She suggested that would help people remember their renewal date and would help LFS to spread out the renewals. Mr. Thomas welcomed her suggestions and said that LFS will be happy to entertain all suggestions.

Geraldine Albee asked if CLS trainee licenses will also switch to online renewal. Mr. Thomas said that trainee licenses are different from other licenses in that they are not renewals. Ms. Albee suggested that LFS try to work on improving the processing time for trainee licenses.

### **Legislation updates**

Jan Otey of the LFS Biologics and Tissue Bank Section staff reported on Assembly Bill (AB) 258, a bill introduced on February 9, 2015, by Assemblymember Marc Levine and coauthored by State Senator Mark Leno, Assemblymember Bill Quirk, and State Senator Loni Hancock, and sponsored by Americans for Safe Access. She explained that existing law, the Compassionate Use Act of 1996, authorizes the use of marijuana for medical purpose and requires the establishment of a program for the issuance of identification cards to qualified patients so that they may lawfully use marijuana for medical purposes. She noted that currently different transplant centers have different criteria for determining eligibility for transplant recipients, and some exclude cannabis users from consideration. AB 258 would add to the Uniform

Anatomical Gift Act to prohibit a hospital, physician and surgeon, procurement organization, or other person from determining the ultimate recipient of an anatomical gift based solely upon a potential recipient's status as a qualified patient or upon a positive test for the use of medical marijuana by a potential recipient who is a qualified patient, except to the extent that the qualified patient's use of medical marijuana has been found by a physician and surgeon, following a case-by-case evaluation of the potential recipient, to be medically significant to the provision of the anatomical gift. She said that after a few minor technical amendments in the Assembly the bill has moved on to the Senate.

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

Ms. Dean-Yoakum asked Dr. Hilborne for his comments on this bill. He said that he was supportive of the bill with the addition of language regarding the role of laboratory directors. He said that in his opinion recognition of the changes in the profession is a good thing, as long as individuals receive adequate training and are found competent.

Ms. Schiffgens noted that the bill could be broadly interpreted, since cytology could include anything that involved cells. Dr. Hamill pointed out that the language of the bill imposes restrictions by adding the phrase "related to infectious disease or cancer." He stated that the language in the current regulations is out of date. He stated further that most cytotechnologists are able to correlate what they see with the markers, and that who is allowed to perform tests and under which license should be able to change as technology changes.

Dr. Hilborne noted that other states don't have the restrictions imposed by California and there is no evidence that the quality of testing or care in those states suffers as a result.

Dr. Hamill noted that recently educated cytotechnologists are being trained in molecular techniques, and that the key is that the laboratory director must ensure their competence.

Ms. Dean-Yoakum invited Mr. Footlik to comment. He said that with amendments he finds the bill acceptable and agrees with Dr. Hilborne and Dr. Hamill.

Dr. Nickel asked if this bill could be implemented without regulations.

Ms. Otey said that it would be difficult for LFS examiners to know what tests this bill would allow.

Donna McCallum asked what type of equipment would be used. Ms. Otey said that it would be PCR, FISH, and ISH.

Mr. Thomas asked if the bill would allow cytotechnologists to report results. Ms. Otey said that the bill as currently written says only that they may perform tests, not report. She also asked if the bill would allow cytotechnologists to perform all high complexity tests.

Ms. Dequinia asked if the new scope of practice would cause problems with the various unions. Ms. Schiffgens said that would be a matter for employers to work out with the unions.

Mr. Footlik said that reporting is part of performing, and that cytotechnologists currently report negative results, while positive results must go to a pathologist. He said that regulations will be needed to define cytologic specimen, infectious disease, and cancer. Jerry Hurst said that the bill would include genetic testing, so that would also need to be defined. Dr. Hamill said that genetic testing is a technique and not a discipline, and will be used on everything within the next 5 years. It cannot be limited to certain disciplines, and is only going to be used more broadly as new uses for genetic testing are discovered. In his opinion it would be best for patients if genetic testing could be used by anyone competent to use it, and that it should be left up to the laboratory director to ensure the competence of laboratory staff. Mr. Hurst said that licenses are limited by the application of tests, and this creates divisions.

Ms. McCallum pointed out that not all cytotechnologists are at the same level, and a mechanism is needed to ensure competence. Dr. Hilborne and Dr. Hammill said that is the responsibility of the medical director.

Mr. Footlik said that if this legislation is enacted any cytotechnologist doing this testing will have to have his or her workload pro-rated against the time spent doing molecular testing. Ms. Dean-Yoakum asked what the benefit would be if a cytotechnologist would be taken away from reading slides. Dr. Hamill said that there are fewer slides now, so changes in technology would shift the workload in any case.

Mr. Thomas said that the current discussion is important because LFS is working on regulations that will describe the scope of practice, and it is possible at this point to change the draft regulations to broaden that scope.

Robert Hunter of the Biologics and Tissue Bank Section staff reported on AB 757, introduced by Assemblymember Jimmy Gomez on February 25, 2015, and sponsored by Grifols, Inc., a global company that produces and markets plasma-derived medicines, diagnostic systems, and hospital pharmacy products. He explained that bill has been amended since it was introduced. As currently written the bill makes changes to current law that would authorize medical assistants who meet specified criteria to perform a total protein refractometer test analysis in a

licensed plasma collection facility in California. The bill is written to sunset in 2019. There is a potential need for regulations to clarify the content of the bill.

Martha Obeso of the Personnel Licensing Section staff reported on AB 940, introduced by Assemblymember Sebastian Ridley-Thomas on February 26, 2015, and sponsored by the California Clinical Laboratories Association. She explained that existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law also prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 unless the test or examination is performed under the overall operation and administration of a laboratory director. Existing law also defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as any person who, among other things, is licensed to direct a clinical laboratory and who substantially meets the laboratory director qualifications under the CLIA. She explained that this bill would amend eleven sections of the California Business and Professions Code (BPC).

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

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

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

Ms. Obeso pointed out that as written the bill, which has passed the third reading in the Assembly and is now in the Senate, will require CDPH to write regulations to implement some of its provisions.

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

Ron Harkey, Section Chief of the Biologics and Tissue Bank Section, noted that his section seems to attract legislation, with three of the four bills currently assigned to LFS dealing with issues that fall under his section's purview. He also noted that bills do not go away even if they are not signed into law, pointing to the example of AB 1822 from the 2014 legislative season, which proposed to reduce hospital expenses when tissue was received by hospitals from tissue banks. Mr. Harkey explained that technological advances have increased the time span for safe storage of tissue, but pointed out that AB 1822 would have exempted most hospitals from any oversight by the Department, and that there is no federal oversight and no oversight by the American Association of Tissue Banks (AATB). The bill was passed by both houses

of the state legislature, but Governor Brown returned the bill without signing it, which amounts to a veto. In his veto message the Governor said that while he supports eliminating overly burdensome regulation, he was not convinced that the bill struck the right balance between safety and economy, and he directed CDPH to continue working with interested parties to develop an approach that balances appropriate oversight with cost savings for suppliers.

Mr. Harkey reported that LFS had responded to Governor Brown's directive by changing the rule that applies to storage of allograft tissue. The requirement that tissue be stored for no longer than one day has been changed to allow for storage within the parameters set by the shipper, as long as tissue is stored in the unopened shipping container, which must be validated by the shipper and must specify the time span for safe storage. A copy of Mr. Harkey's letter on this subject has been posted on the LFS website.

The frequently asked questions about tissue banking on the LFS website have also been revised to reflect the new recommendations that use the shipper's parameters as the time span for safe storage. Mr. Harkey reiterated that a facility must have a storage license from the Department only when the facility removes allograft tissue from the validated shipping container and place it into the facility's own storage unit.

Mr. Harkey noted that researching and writing bill analyses and other legislative documents has taken hundreds of hours of staff time and thanked his team and other LFS staff for their work.

He also reported on the adoption of the standards of the American Association of Tissue Banks (AATB) as well as the Paul Gann Blood Safety Act. He said that his section is working with Blood Centers of California on updating the Paul Gann Blood Safety Act. The update will address the issue of informed consent.

Mr. Harkey thanked members of his staff for their dedication and thanked them for doing an amazing job.

Dora Goto commented that Senate Bill (SB) 492 is back this year as SB 622, which includes a slight expansion. She noted that the California Association for Medical Laboratory Technology (CAMLT) is currently opposing the bill. Mr. Thomas said that LFS would ask the Office of Legislative and Governmental Affairs about this bill to see if LFS should write analysis of this bill and will report on it at the next meeting.

### **CLIA Update**

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, announced that the revised Interpretive Guidelines (IG) were posted on the Centers for Medicare & Medicaid Services (CMS) website on January 9, 2015. Some of the changes are as follows:

#### **Additions**

- New d-tags
- Subpart J - Facility Administration
  - (D-3000) 493.1100 Condition: Facility Administration gives the updated FDA website for test categorization.
- Subpart K - Quality System for Non-waived Testing

- (05427) 493.1253 Standard: Establishment and verification of performance specifications.
- (05660) 493.1257 Standard: Cytology
- (05823) 493.1291 (I) Standard: Test report Subpart Q - Inspections
- (D-8201) 493.1775 (b) Standard: Inspection of laboratories issued a certificate of waiver or provider performed microscopy procedures
- (D-8203) 493.1775 (c) Standard: Inspection of laboratories issued a certificate of waiver or provider performed microscopy procedures
- (D-8301) 493 .1777(a) Inspection of laboratories that have requested or have been issued a certificate of compliance
- (08303) 493.1777(b) Inspection of laboratories that have requested or have been issued a certificate of compliance
- (D-8305) 493. 1777(c) Inspection of laboratories that have requested or have been issued a certificate of compliance
- (D-8307) 493. 1777(d) Inspection of laboratories that have requested or have been issued a certificate of compliance

### Regulations

- Subpart A - General Provisions
  - 493.2 Definitions
    - "Confirmatory Testing"
    - "Distributive Testing"
    - "Reflex Testing"
    - "Repeat Proficiency"

### Revisions

- Testing Proficiency Testing samples
- Test report release
- Reference to accrediting agencies or associations that approve school programs have been removed from the IG
- Testing waived samples
- Laboratory director authorizes release of Proficiency Testing (PHTPV testing laboratories must enroll and successfully participate in a CMS approved PT program for HPV and must include the subspecialty of virology) records to regulatory agencies when he or she signs the CLIA application.
- Laboratory must have a system in place to let personnel know how to file an anonymous complaint to outside agencies.
- Corrected reports must be clearly indicated and sent to all who received the original report.

Ms. McCallum noted that as of January 1, 2016, Equivalent Quality Control (EQC) will not be accepted by CLIA but laboratories will have to adopt an Individual Quality Control Plan (IQCP) or comply with the default regulations. The IQCP workbook can be found on the CLIA website [www.cms.hhs.gov/CLIA](http://www.cms.hhs.gov/CLIA).

She reported that the user of blood glucose meters must follow the manufacturer's instructions. Nova has a system that is approved for use on critically ill patients but it is not to be used with capillary blood samples.

She reported that New York was reapproved for deemed status on March 27, 2015 for six years.

She said that the American Osteopathic Association (AOA)/ Health Facilities Accreditation Program (HFAP) and College of American Pathologists (CAP) were reapproved for deemed status on March 27, 2015 for six years and are subject to validation surveys and complaint investigations.

She noted the following IQCP updates approved by CMS:

- CAP-03/12/15
- COLA-05/20/14
- NY-06/06/14
- WA-02/27/15

Ms. McCallum reported that through the end of April, 2015, the CLIA section performed 11 initial surveys and 80 recertification surveys, 2 validation surveys, and 4 onsite complaint investigations, and issued one proficiency testing (PT) desk review sanction. No waived laboratory surveys were performed due to a lack of sufficient staff. Since the beginning of the federal fiscal year in October the CLIA section has performed 74 initial surveys and 379 recertification surveys, 7 validation surveys, and 6 onsite complaint investigation, and issued 25 proficiency testing desk review sanctions.

#### **Facility Licensing - Richmond**

Kathy Williams, Section Chief of Facility Licensing in northern California, reported that between March 1, 2015, and May 30, 2015, her section received 67 new applications for licensure and 503 new applications for registrations. Eight new applications were received from chiropractors, 5 were received from pharmacists, and 6 from optometrists. LFS received 30 new applications from out-of-state laboratories.

Ms. Williams reported that between March 1, 2015, and May 30, 2015, her section received a total of 61 complaints. Three complaints involved test errors, 17 involved test management and quality control, and one involved proficiency testing. Two complaints involved state licensing, 11 involved CLIA certificate laboratories, 4 involved tests being performed by unauthorized personnel, and 16 involved laboratory personnel. LFS received 7 miscellaneous complaints. Sixteen of these complaints were referred to other departments and the remaining complaints were resolved by LFS staff.

Ms. Williams said that she has been assigned an assistant, Desiri Moret-Blyden, to help with putting the CLIA crosswalk into the final format.

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

identify them.

Ms. Williams announced that the complaint examiner for LFS, Ms. Shideh Khashe, is retiring, and invited anyone who might be interested in this position to submit an application.

### **Facility Licensing – Los Angeles**

Victoria Maxwell, acting Section Chief of Facility Licensing in southern California, presented a summary of the section's survey statistics for the calendar year 2014 and the first quarter of 2015.

#### Initial surveys:

For the calendar year 2014, there were 112 new application packets received from Richmond. Fifteen of those applications were denied, cancelled, or downgraded. Of the remaining 97 applications, 89 were surveyed within the calendar year and 8 were pending survey, which were completed in the first quarter of 2015. Of the 89 laboratories surveyed, 42% (37 of 89) of the laboratories have deficiencies and 58% (52 of 89) have no deficiencies. In the first quarter 2015, 12 new applications were received and one was downgraded. Of the 11 remaining laboratories, 5 were surveyed within the first quarter of 2015 and 6 were pending survey, which will be completed by the end of the second quarter of 2015. For the first quarter of 2015, we surveyed a total of 13 new laboratories, 23% have deficiencies and 77% had no deficiencies.

#### Routines:

LFS examiners from the southern California Facilities Licensing Section surveyed a total of 101 accredited laboratories in 2014. Of these laboratories, 50% were accredited by CAP, 24% by TJC, 15% by AOA and ASHI, and 11% by COLA. LFS found 44% of the laboratories to have deficiencies and 56% were found to have no deficiencies. In the first quarter of 2015, the examiners surveyed 18 accredited laboratories. Of these laboratories, 67% were accredited by TJC and 33% by CAP. LFS found 56% of the laboratories surveyed to have deficiencies and 44% were found to have no deficiencies.

#### Complaints:

LFS received a total of 18 complaints in 2014; one was referred to another agency and 17 were investigated. Examiners found that 65% of the complaints were substantiated and 35% were unsubstantiated. In the first quarter of 2015, LFS received 2 complaints; one was referred to Biologics and one was investigated and the complaint was substantiated.

#### Out of State (OOS) Inspections:

LFS conducted 5 OOS surveys in 2014. Of the laboratories investigated, 20% were found to have deficiencies and 80% were found to have no deficiencies. Two of the laboratories were accredited by CAP, 2 were accredited by COLA, and one was accredited by AABB. In the first quarter of 2015 LFS surveyed 6 OOS laboratories, of which 33% were found to have deficiencies and 67% were found to have no deficiencies. Four of these laboratories were accredited by CAP and 2 were accredited by AABB. Ms. Maxwell said that her section expects to survey 18 more OOS labs by the end of 2015.

### **Personnel Licensing Update**

Martha Obeso, Examiner II, reported on renewal statistics for the Personnel Licensing section in the absence of Dr. Zahwa Amad, the section chief. Ms. Obeso reported that between May, 2014, and May, 2015, 103 director licenses were renewed, 1,222 CLS trainee licenses were renewed, 8,113 CLS licenses were renewed, and 14,346 phlebotomy technician certificates were renewed. Between May, 2013, and May, 2014, 94 director licenses were renewed, 815 CLS trainee licenses were renewed, 8,071 CLS licenses were renewed, and 12,203 phlebotomy technician certificates were renewed.

Dr. Hilborne said that he was heartened by the increase in CLS trainees.

Ms. Dequinia said that there are no jobs for phlebotomists and asked if LFS was doing anything about this. She also noted that many of those who completed phlebotomy didactic coursework were unable to obtain placement for practical training to complete the requirements for certification. Mr. Thomas said that when LFS first began certifying phlebotomy technicians it was anticipated that there would be about 30,000 jobs, with high turnover and approximately 40% of initially certified phlebotomists not renewing their certification. He noted that LFS does not have statistics on these numbers. He agreed that there is a problem with training programs that offer didactic instruction but do not provide practical training. Dr. Nickel said that the personnel regulations now under development will address this problem.

### **Report on Biologics Investigations**

Robert Hunter, an examiner in the Biologics and Tissue Bank Section, reported on statistics from the Biologics program from January through June, 2015. He reported that there are 140 licensed blood banks in California, with 136 fixed collection sites. He noted that 8 blood banks have closed or will close this year. There are 21 licensed cord blood banks, with hundreds of fixed collection sites and several different business models. There are 10 stem cell facilities, with 20 fixed collection sites. Mr. Hunter noted that these facilities are associated with a variety of advances in stem cell therapy. There are 14 plasma collection facilities owned by 5 different companies.

Last year LFS received 4 complaints related to transfusion-related incidents, and 4 such complaints so far in 2015. The complaints received this year included one instance of wrong blood contained in the tube, one instance of incompatible platelet pheresis, one concerning special needs, and one related to ABO mistyping and transfusion. Last year there were 4 complaints about plasma centers, and one this year. There were no complaints about blood centers, cord blood facilities, or biologic laboratories last year, but this year so far LFS has received 6 complaints about blood centers, concerning contaminated platelets and potential transfusion-related disease. There was one complaint about a cord blood facility and one complaint about a biologics laboratory. Complaints about cord blood facilities typically relate to fraudulent or deceptive advertising, or threats to destroy stored cords unless payments are not received.

Mr. Hunter also discussed AB 757, which would authorize medical assistants to

perform a total protein refractometer test (TPRT) analysis in a licensed plasma collection center under specified conditions. The conditions established by AB 757 include education, training, direction, supervision, and test reporting. The provisions of this bill would sunset on January 1, 2019. The bill adds a new section 1246.7 to the Business and Professions Code to allow unlicensed medical assistants to perform the moderate complexity total protein refractometer test. It was introduced by Assemblymember Jimmy Gomez and has passed through several subcommittees. It is supported by Grifols, Inc., the sponsor, and Blood Centers of California, and is opposed by the California Society of Pathologists and the Engineers and Scientists of California.

### **Recognition of Beatrice O’Keefe upon her Retirement as Chief of Laboratory Field Services**

Ms. Dean-Yoakum announced that Beatrice O’Keefe has retired from her position as chief of Laboratory Field Services after a long career in State service. Ms. O’Keefe graduated from the University of California at Berkeley, Phi Beta Kappa, with a Bachelor of Science degree and obtained a master’s degree in Business Administration from Golden Gate University in San Francisco. She holds both a California Public Health Microbiologist certificate and a Clinical Laboratory Scientist license.

Ms. O’Keefe entered State service in 1963. She conducted research in the California Department of Public Health, Viral and Rickettsial Disease Laboratory, under the immunologist, Dr. Natalie Cremer, for many years. She coauthored six articles on slow virus research in animals and the results of viral studies on patients afflicted with Sjögren’s syndrome, Amyotrophic lateral sclerosis, and Creutzfeldt-Jakob disease syndrome. She joined Laboratory Field Services (LFS) in the California Department of Public Health (CDPH) as an Examiner, and surveyed over 500 laboratories for compliance with state and federal laws.

As Section Chief for the Special Investigation Unit for LFS, Ms. O’Keefe oversaw the investigation of laboratories for potential MediCal fraud with sanction actions.

Ms. O’Keefe has served as the chief of Laboratory Field Services for the last five years and oversees a staff of 92 employees, with responsibility for facility and personnel licensing of 18,000 laboratories and 60,000 clinical laboratory personnel.

In addition to her service at CDPH, Ms. O’Keefe serves as an elected director of the Stege Sanitary District in El Cerrito, California, and serves on the El Cerrito Planning Commission. She is also president of the Golden State Lily Society and plays percussion with the West County Winds band.

Ms. Dean-Yoakum thanked Ms. O’Keefe for her service to the State of California and also thanked her for her work with the CLTAC board and membership on issues of importance to clinical laboratory science, as well as the assistance she gave during her time as chair of the CLTAC board.

Dr. Kimsey announced that he arranged for a proclamation to be issued by the State legislature recognizing Ms. O’Keefe’s service to the California Department of Public Health and the people of California on the occasion of her retirement. Unfortunately

there was a delay and the proclamation is not ready yet, but staff members from the offices of Ms. O'Keefe's legislative representatives will be coming to Richmond for a formal presentation when it is ready.

Dr. Nickel spoke of her high regard for Ms. O'Keefe and recalled the work she did in Laboratory Field Services, as an examiner, as a section chief, and as chief. Ms. McCallum, Mr. Thomas, Mr. Harkey, Ms. Maxwell, Margaret Knapp, and Ms. Wogec also offered congratulations to Ms. O'Keefe on her retirement and thanked her for her contributions to CDPH, LFS, and to their own work.

Ms. O'Keefe responded that she was grateful for the kind comments. She thanked in particular the section chiefs at LFS and the entire staff for their excellent and committed work. She said that she thinks of herself not as a regulator, but as a public servant whose goal is the improvement of clinical laboratory services in California. She also said that she will still be available to support Mr. Thomas as acting chief during the transition period until LFS has a new chief.

### **New business**

Tammy Zinsmeister referred to the Leadership Summit sponsored by COLA last year in San Francisco in which Dr. Kimsey., Ms. O'Keefe, and Ms. Williams participated, and announced that a new website has been created to share ideas and perspectives from many disciplines in order to expand understanding of the role of laboratory medicine within the larger context of healthcare. The website is envisioned as a social platform and virtual home for the clinical laboratory community as well as a forum for communication between laboratorians, physicians, nurses, administrators, manufacturers, educators, regulators, and allied healthcare professionals. She encouraged people to visit the website at <http://www.labtestingmatters.org/> and to participate in this new online community.

Ms. Dean-Yoakum asked Dr. Hilborne to lead a discussion of digital pathology at the next meeting.

Noting that this was her last meeting as chair, Ms. Dean-Yoakum thanked LFS for the guidance they have provided her in during her tenure, especially Ms. O'Keefe, Dr. Nickel, Mr. Thomas, and Ms. Wogec. She said that she had learned a great deal during her service as chair and congratulated her successor Rhonda Becker, on her election.

### **Future items**

Lorri Dean-Yoakum asked if there were suggestions for future business. She encouraged people to contact Mr. Thomas with items for the next meeting's agenda.

### **Next meeting**

Lorri Dean-Yoakum announced that the next meeting of the CLTAC would be held on Friday, September 11, 2015.

### **Adjournment**

Dr. Hilborne moved that the meeting be adjourned, the motion was seconded by Ms. Schiffgens, and the CLTAC board voted to adjourn at 12:30 p.m.