

Clinical Laboratory Technology Advisory Committee
Minutes of the Meeting held on September 6, 2013
Meeting held by videoconference from Richmond campus, CDPH,
KP Regional Laboratory, North Hollywood and
Telephone Bridge Line

CLTAC members participating

Rhonda Becker, Richard Bennett, Marjorie Braasch, Patricia Dadone, Lorri Dean-Yoakum (chair), Elizabeth Dequinia, Kathleen Doty, Lee Hilborne, Jerry Hurst, Margie Morgan, Rebecca Rosser, Jennifer Schiffgens, Diane Tyson, Fred Ung.

Former CLTAC members participating

Michael Borok, Imre Fischer, Carmen Maldonado, Sol Notricia, Jim Ottosen, Salim Rafidi, Les Revier

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Gillian Edwards, Elsa Eleco, Pamela Farrell, Ron Harkey, Tina Hashemi, Robert Hunter, Nema Lintag, Yangzhu Long, Don Miyamoto, Karen Nickel, Martha Obeso, Beatrice O'Keefe, Jan Otey, Tammy Pahland, Joanne Rowan, Judith Schlosser, Robert Thomas, Pat Toomer, Kathy Williams, Mary Wogec.

Public members participating

Michael Aidan, Joyce Bladel, Barbara Brunell, Yvonne Carter, Marian Castillo, Kathy Davis, Kathleen Faraday, Concepcion Gomez, David Gomez, Dora Goto, Carola Howe, Lin Kassouni, Lois Langs, Dan Leighton, Valerie Ng, Rodney Roath, Frances Sturtevant, Tom Tempske, Christine Vernusky, Phyllis Walker, Tammy Zinsmeister.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Lorri Dean-Yoakum at 9:05 a.m. Ms. Dean-Yoakum thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge. A roll call was conducted of CLTAC members and other participants, and Ms. Dean-Yoakum noted that a quorum was not present for the meeting. The meeting proceeded with the qualification that no votes could be taken. She introduced a new board member, Marjorie Braasch, who was nominated by Engineers and Scientists of California, Local 20 of the International Federation of Professional and Technical Engineers to replace retiring member Leonard David.

Approval of the June 7, 2013 meeting minutes

Additions and corrections to the minutes from the June 2013 meeting were submitted by Lee Hilborne and Karen Nickel. When the roll was called later in the meeting, a quorum was noted, and Rhonda Becker moved to approve the minutes with the changes submitted. Elizabeth Dequinia seconded the motion and the minutes were approved.

Department update

Dr. Paul Kimsey, Deputy Director of the Office of State Public Health Laboratory

Directors (OSPHLD), was not available to give an update for the department.

Status of the regulation package, DPH-11-012

Tammy Pahland, Staff Counsel for LFS, updated the CLTAC on the draft personnel regulations. The LFS committee is reviewing the Initial Statement of Reasons (ISOR), which presents the reasoning behind the regulations. The Office of Regulations has completed an initial reading of the draft regulations. When the draft regulations and the ISOR have been completed and sent forward to the Office of Regulations, the committee will prepare the necessary financial documentation. It is hoped that the regulations will be available for public comment early in next year. Ms. Pahland noted that the process for writing regulations is a complex one, involving many departments as well as review by agency.

LFS Update

Beatrice O'Keefe reported on issues and events in LFS. Examinations for the position of Examiner were administered in July. There are 10 candidates for Los Angeles and 10 for northern California. Interviews are scheduled for the end of September.

Ms. O'Keefe is also working on a Recruitment and Retention Proposal, which she hopes will make it possible to attract more entry level Examiners. The proposal documents comparative salaries for government and private industry.

She reported on ongoing attempts to update the HALS data system currently used by LFS. At present, IT support of personnel licensing is contracted out, but LFS is exploring the possibility of an internal system that will service both facilities and personnel licensing. This would include fillable online forms for initial applications and renewals, the capacity for uploading supporting documentation, online payment by credit card, and automatic generation of renewal notices. The system would also allow LFS to transfer its current databases and spread sheets. The LFS proposal, which is being formulated by the IT department, is only one of four in CDPH.

As previously reported, LFS has received applications for deeming authority from COLA, the College of American Pathologists (CAP), and The Joint Commission (JC, formerly JCAHO). Ms. O'Keefe reported that the American Association of Blood Banks (AABB) has also submitted an application. LFS has already prepared a prototype for the certificates that will be issued for laboratories that are accredited by accrediting agencies approved by LFS. LFS has also developed a procedure for the transition of accredited laboratories from the CDPH license to a certificate of deemed status.

Ms. O'Keefe discussed the impact of the Affordable Care Act (ACA) on CDPH and LFS. Covered California is the state's program for implementing the ACA, which is expected to expand access to health care to between 4 and 6 million Californians by January 2014. The first phase of the advertising and marketing campaigns began the first week of September to promote the new insurance marketplace. A six-month open enrollment period will extend from October 1, 2013, to March 31, 2014, with coverage beginning January 1, 2014. The Covered California website will help consumers to compare insurance plans and choose the plan that works best for their health care needs and budget. LFS anticipates that when fully implemented, the

ACA will increase the need for clinical laboratory tests by between 15% and 25%, which will have a corresponding impact on the LFS workload.

At the June meeting, CLTAC approved a motion encouraging CDPH to oppose SB 492 as currently written. When she checked with the legislative office, Ms. O'Keefe was informed that although CLTAC has made this recommendation, CDPH does not comment on the Department's proposed positions until they are approved by the Governor. The Department prepares an analysis of a bill and submits it to the Office of Legislative Affairs. Input from CLTAC can be included in the analysis, but it is the Governor who makes the final decision to approve or not approve the Department's position. She noted further that SB 492 is now a two-year bill, and will not be moving forward this year.

In response to a request made at the June CLTAC meeting, Ms. O'Keefe contacted Rebecca Rozen of HLWI and asked her to make a presentation at this meeting on the HLWI's Subcommittee on the MLT Scope of Practice. Ms. Rozen thanked CLTAC for their interest in the work of the subcommittee, explaining that the subcommittee was formed for the purpose of exploring the idea of a pilot through OSHPD's Health Workforce Pilot Projects Program on expanded scope of practice for MLTs. She explained that to date they have had only one meeting and have not made a decision about whether to move forward or not, so she does not have anything to present at this time. She invited Ms. O'Keefe to check back with her before the next CLTAC meeting, as she might have more to report then. Ms. O'Keefe invited anyone who is interested in serving on the subcommittee to email her or Mary Wogec, who will alert Ms. Rozen to their interest.

Richard Bennett asked if the JC inspects every laboratory at a given facility, pointing out that they do not inspect every operating room. Ms. O'Keefe said that if there are multiple laboratories at a facility, LFS expects the JC to inspect all of them. She noted that if anyone has a complaint, LFS is open to them. She also noted that LFS will pose this question to the JC.

Lee Hilborne questioned the extent of the inspection process, asking if CAP inspects all laboratories operating within a facility where the JC is the accrediting organization. They are expected to require compliance for all laboratory facilities under the certificate.

Jennifer Schiffgens asked, if CAP, COLA, and the JC work with a different version of CLIA, how does LFS reconcile this with the state's version of CLIA (CLIA 1994). Ms. O'Keefe responded that LFS gives them the 1994 version of CLIA, and they are expected to require compliance with that version. She noted that a CLTAC subcommittee is currently working on the incorporation of some or all of CLIA 2003 into state law. Ms. Schiffgens asked if accrediting organizations would have a separate set of guidelines for California laboratories. Ms. O'Keefe said that at least one of the accrediting organizations does have such guidelines, and LFS hopes that the others will prepare something similar, such as a separate checklist to ensure that a laboratory meets California guidelines.

Jim Ottosen suggested that a provision be made to give provisional accreditation, then conduct an inspection with a CDPH inspector accompanying an inspector from

the accrediting organization to ensure that the inspector is doing what California requires. Ms. O'Keefe said that is a good idea, but is not authorized in SB 744 and Business and Profession Code (BPC) 1223. Ms. Dean-Yoakum asked if CDPH inspectors in the Los Angeles office conduct validation surveys. Ms. O'Keefe said that they do, but only a small percentage of the accredited laboratories are surveyed. Karen Nickel noted that laboratories are already licensed by CDPH before transitioning to deemed status. Ms. Dean-Yoakum said that in her experience, CAP inspectors do not ask about compliance with California law. Ms. Schiffgens said that in her experience, none of the accrediting organizations (COLA, CAP, or JC) has ever asked about California law. Ms. O'Keefe said that accredited laboratories are still subject to state sanctions.

Report from the Subcommittee on CLIA

In the absence of Robert Footlik, Lorri Dean-Yoakum read his report on the activities of the CLIA subcommittee. The subcommittee, which had been dormant since 2010, met on July 23 to crosswalk existing state law with CLIA analytic systems and quality control requirements for histopathology, cytology, clinical cytogenetics, histocompatibility, and oral pathology. The subcommittee met again on August 22, 2013, and continued with hematology and immunohematology. During this meeting, the subcommittee also worked on a crosswalk of proficiency testing requirements. The subcommittee plans to meet on September 26, 2013.

Jennifer Schiffgens asked what the next step will be. Ms. O'Keefe said that the report will come back to CLTAC for approval, and that LFS can adopt changes without going through the regulation process. The changes must be posted for public comment before being adopted. Ms. Schiffgens asked what impact changes to CLIA would have on the deeming process. Ms. O'Keefe noted that LFS is currently doing crosswalks with accrediting organizations. She said that the first priority for LFS at present is the completion of the personnel regulations, but crosswalks are being done and are considered important.

Guest Speaker

Lorrie Dean-Yoakum introduced Dr. Dongxiang Xia and Dr. David Cottam of the Viral and Rickettsial Disease Laboratory (VRDL) at CDPH. Dr. Xia, who is the new director of VRDL, introduced the presentation, which offered an overview and update of the work of VRDL. He noted that California's VRDL is the oldest public health laboratory in the United States and the largest laboratory in California, and emphasized the importance of collaboration with other domestic and international laboratories in the face of a changing world.

Some of the challenges to public health that have emerged in the twenty-first century include an increase in terrorism, including the weaponization of infectious diseases, emerging and evolving diseases, natural disasters, pollution and global warming, economic recession, and the increasing mobility of the world's population, which facilitates the rapid spread of diseases around the globe. Other concerns include the development of antiviral resistance, an increase in health care associated infections, and a surge in atypical and non-reportable diseases.

In such an environment, global strategies are needed. Laboratorians must think globally, with an eye to the implications of local occurrences and conditions for the

international community, and act locally, identifying problems, responding promptly, reporting outbreaks, and addressing public health issues at the grassroots level, providing education and services to prevent local problems from spreading. It is also important that they collaborate with other health departments and agencies, clinicians, epidemiologists, environmentalists, and law enforcement agencies at the state, national, and international levels.

Dr. David Cottam, PHM Supervisor at the VRDL, has worked for over 40 years at the laboratory. He addressed new developments at the laboratory, including advances in electronic publication and reporting and a new emphasis on epidemiological liaison.

Legislative Update

Various LFS staff members reported on legislation that is being monitored by LFS.

Robert Thomas reported on AB 213, introduced by Assemblyman Logue. Known as the Veterans Health Care Workforce Act of 2013, this bill would require a healing arts board within the Department of Consumer Affairs and the State Department of Public Health, upon the presentation of evidence by an applicant for licensure or certification, to accept education, training, and practical experience completed by an applicant in military service toward the qualifications and requirements to receive a license or certificate if that education, training, or experience is equivalent to the standards of the board or department. The bill addresses concerns about the high unemployment rate among military veterans, and at the same time it addresses concerns about a shortage of health care professionals, including laboratory personnel, that is anticipated to become more acute with the implementation of the ACA. The expansion of health care coverage is expected to result in an increased demand for health care, and, in turn, increased demands for the services of health professionals, including laboratory workers, to provide care and perform laboratory tests. Mr. Thomas said that this bill has been held over for next year. He noted that LFS already accepts military experience toward licensure requirements, so this bill would not have a direct impact on our program.

Bea O'Keefe reported on AB 722, introduced by Assemblywoman Lowenthal. This bill would add a doctor of chiropractic or a certified medical examiner to the list of persons who may make a report of a medical examination of applicants for an original or renewal certificate to drive a school bus, school pupil activity bus, youth bus, general public paratransit vehicle, or a farm labor vehicle. This bill will bring the state into alignment with federal law and ensure consistency amongst providers by requiring all licensed medical examiners that perform physical examination for commercial license applicants to undergo the same federal certification process. Of concern to LFS is the fact that this bill would also allow chiropractors or certified medical examiners to do workplace testing using the tests that would be necessary for completing the DMV forms for these bus drivers, although it would not allow them to direct laboratories. Ms. O'Keefe noted that if abnormal results are obtained in the course of performing an assessment of general health, the patient should be referred to a clinician for diagnosis and treatment. However, LFS would have no way of knowing what these practitioners are doing unless they have CLIA certification and CLS licensure. This bill is a watch bill for LFS, which means that no analysis is required from LFS.

Zahwa Amad reported on AB 1215, co-authored by Assemblyman Hagman and Assemblyman Holden, sponsored by the California Association for Medical Laboratory Technology (CAMLT), co-sponsored by the Engineers and Scientists of California and International Federation of Professional and Technical Engineers, Local 20 of the IFPTE, and supported by the United Nurses Association of California/Union of Health Care Professionals, the Western States Council of the United Food & Commercial Workers, AFSCME, Blood Centers of California, and the California Society of Pathologists.

This bill amends Section 1209 of the Business and Professions Code, expanding the definition of “laboratory director” for purposes of a clinical laboratory test or examination classified as waived to include a duly licensed clinical laboratory scientist. It would authorize a person licensed as a clinical laboratory scientist and qualified under CLIA to additionally perform the duties and responsibilities of a waived laboratory director, as specified under CLIA. Ms. Amad noted that optometrists, pharmacist, and naturopaths have recently been added by legislation to be directors of waived laboratories. The bill unanimously passed both the Assembly and the Senate, and was approved and signed into law by the governor and chaptered on August 28, 2013.

Jan Otey reported on AB 1297, introduced by Assemblyman Perez, which would authorize a procurement organization, when specified circumstances are present, to notify a coroner, prior to the donor's death, that a donor has made or may make an anatomical gift, and would require a coroner to accept that notification, whenever such notification will facilitate the coroner's ability to conduct his or her duties in a manner and within a period compatible with the preservation of the body or part for the purposes of the gift. The bill would also require a coroner to conduct a post mortem investigation in a manner and time period compatible with the preservation of the body or part for the purposes of the gift, thereby imposing a state-mandated local program. This bill was initially assigned to LFS. LFS recommended deferring the bill to Licensing and Certification since it is not within LFS's scope of responsibility. AB 1297 passed both houses of the state legislature and was enrolled and presented to the governor for signature on September 3, 2013.

Ms. Otey also reported on SB 492, introduced by Senator Hernandez. This bill would add the provision of habilitative optometric services to the definition of the practice of optometry. The bill would expand the 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. She noted that this is one of three bills authored by Senator Hernandez in the current legislative session that seek to expand the work scope of non-physicians. SB 491 deals with the work scope of nurse practitioners, SB 492, with that of optometrists, and SB 493, with that of pharmacists. She said that LFS is concerned with all these bills because they conflict with Business and Professions Code (BPC) section 1209. All three bills have been held over until next year.

Dora Goto said that changes made by SB 491, 492, and 493 to BPC section 1209 could open the door for amendments allowing these professionals to become general waived laboratory directors. She is concerned that they will try to amend the bills to expand the allowed tests, and that they plan to delegate testing to less qualified persons. Lorri Dean-Yoakum recommended that people who are concerned about this go to professional organizations and facilities and ask them to look at these bills and, if appropriate, to write a letter of opposition. Ms. O'Keefe added that LFS has seen several bills that seek to expand scopes of practice, and expects to see more in the future as a result of the implementation of the ACA. She recommended that everyone be watchful and make sure that testing is being performed by qualified persons.

Kathy Williams reported on SB 222, introduced by Senator Padilla. This bill would enact the Genetic Information Privacy Act, which would declare that an individual's genetic information is protected by the right of privacy. The bill would prohibit any person from collecting, storing, analyzing, or disclosing genetic information without the written authorization of the individual to whom the information pertains, and would include related findings and declarations. It also would prescribe specific circumstances under which genetic information may be collected, stored, analyzed, or disclosed without the authorization. This bill was held in committee under suspension, and is now a 2-year bill, but Ms. Williams recommended that people read the analysis posted on the Leginfo website (www.leginfo.ca.gov) because she expects this bill to return.

Facility licensing - Richmond

Kathy Williams, Section Chief of Facility Licensing in Northern California, reported that processing of new applications remains steady. There is a new facility category, the minute clinic. There were 10 applications for this category in June, and all were approved. In the past three months her section also received 127 applications from pharmacists, 13 from optometrists, and 1 from a naturopathic practitioner. She noted that a higher percentage than usual were from pharmacists. Ms. Williams asks her program technicians to flag any pharmacy application that lists more than three tests and give it to her for review. She checks the Pharmacy Board and facility rosters for the pharmacist-in-charge, because a pharmacist in charge is only allowed to be in charge at two pharmacies, which must be located within 50 miles of each other. On average, her section processes about 50 new laboratory applications per month.

Ms. Williams also reported on complaints received by her section, of which there were approximately 54. Among the concerns were test result errors (6), individual clinical laboratory scientists (3), testing performed by unauthorized persons (4), billing (3), and phlebotomy (16). Most of the others concerned quality of care, and those were sent to L & C for investigation.

Facility licensing – Los Angeles

Joanne Rowan, Section Chief of Facility Licensing in Southern California, reported that her examiners performed 18 inspections of accredited laboratories, of which 2 were accredited by CAP and 16 were accredited by COLA. They received 18 applications from Richmond for initial inspection and licensure, including an additional 11 received the beginning of September. Of the 29 applications received,

21 were new applications and 8 were upgrades from Registration certificates. Two of these were accredited, 9 were POLs, and 18 were non-POLs. They also investigated 3 complaints.

Ms. Rowan was happy to report that applications are being processed faster these days, thanks to the efforts of Victoria Maglio in the Richmond office, who processes them. She also announced that the new examiner Elaine Flores passed her survey training checkout, and will now be going out to do inspections on her own.

Biologics and Tissue Bank Program update

Section Chief Ron Harkey reported that members of the tissue bank licensing section are working on several investigations, but he deferred reporting on these investigations until they are completed. He noted that his section is also working on an upgrade to the computer system.

CLIA Update

In the absence of Donna McCallum, Section Chief of the CLIA Section in Los Angeles, Elsa Eleco reported for that section. She acknowledged the efforts of the CLIA field examiners, and extended thanks to Pamela Farrell and Daniel Yamasaki, who conduct desk reviews, and the administrative staff who provide office support. She reported that from October 2012 through July 2013 the CLIA section performed 68 initial surveys, 589 recertification surveys, 13 validation surveys, and 31 desk reviews. During the month of August they performed 7 initial surveys and 60 recertification surveys. This means that they are only 57 surveys away from reaching their target of 100 initial surveys and 681 recertification surveys.

She also announced that a new CLIA brochure is now available on the CLIA website, www.cms.hhs.gov/clia. It is brochure #11: CLIA Individualized Quality Control Plan (IQCP) Introduction. She explained that IQCP is the alternative CLIA quality control (QC) option, which will provide for equivalent quality testing to meet the CLIA regulations for nonwaived testing. IQCP considers the entire testing process: pre-analytic, analytic, and post-analytic. A laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements.

Highlights of the IQCP include:

1. IQCP will offer laboratories flexibility in achieving QC compliance with current test systems. It also provides the ability to adapt to new future technologies while still meeting CLIA requirements.
2. IQCP applies to all non-waived testing performed in the laboratory, including existing and new test systems.
3. All CLIA specialties and subspecialties are eligible for IQCP except Pathology.
4. IQCP is voluntary.
5. The laboratory director will be responsible for implementing and approving IQCP procedures in the laboratory.

Karen Nickel noted that IQCP is new to CLIA as published in 1994 and currently cannot be implemented in California.

HLWI update

Robert Thomas will report on the Health Care Laboratory Workforce Initiative (HLWI) at the December CLTAC meeting.

New business

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

Ms. Yoakum asked for recommendations for topics for future discussion. There were several suggestions.

Joanne Rowan will report at the next CLTAC meeting on inspection findings in accredited laboratories.

Kathy Williams suggested that the committee invite someone from CalREDIE (California Reportable Disease Information Exchange) to make a presentation on electronic reporting and digital pathology. CalREDIE is a computer application that the California Department of Public Health (CDPH) is implementing for web-based disease reporting and surveillance.

Bea O'Keefe noted that nominations and elections to the board will be held in December, and asked everyone to consider nominations.

Kathy Williams asked what constitutes digital pathology and how LFS will regulate it. Lee Hilborne said that he would speak with Ms. O'Keefe about people who could make a presentation on this topic.

Don Miyamoto suggested a discussion on the work scope of cytotechnologists.

Next meeting

Lorri Dean-Yoakum announced that the next meeting of the CLTAC would be Friday, December 6, 2013.

Adjournment

Rhonda Becker made a motion that the meeting be adjourned, Diane Tyson seconded, and the CLTAC voted to adjourn at 11:37 AM.