CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE

Minutes of the Meeting held on May 26, 2017
Meeting held by videoconference from CDPH Richmond campus,
KP Regional Laboratory, North Hollywood, and
Telephone Bridge Line

CLTAC members participating
Johnathan Bautista, Marjorie Braasch, Patricia Dadone, Dan Dominguez, Kathleen
Doty, William Gardner, Dora Goto, Dan Leighton, Tula Nieva, Armand Parada, Rebecca
Rosser, Jennifer Schiffgens, Fred Ung

Former CLTAC members participating
Sam Chaffin, Carmen Maldonado

CDPH staff participating
Dolapo Afolayan, Alan Ankerstar, Melanie Banares, Brandon Carey, Elaine Flores, Gina
Glass, Ron Harkey, Bob Hunter, Paul Kimsey, Tina Kruthoff, Nema Lintag, Dolly Luong,
Donna McCallum, Don Miyamoto, Martha Obeso, Jan Otey, Rocky Pramanik, Lynnea
Rappe, Sarah Rutschmann, Maria Shevchenko, Nai Saechao, Deborah Tan, Asraf
Tootla, Nga Tran, Bob Thomas, Gilberto Wilson, Mary Wogec, Jean Woo

Public members participating
Michael Aidan, Broky Broninee, Brent Chafin, Anna Choi, Amy Daniels, Behnaz
Dardashti, Dianna Dupuy, Leah Ferrier, Nancy Fraize, Karen Fuller, Debbie Ferguson,
Brett Holmquist, Carolyn Howe, Cynthia Hurst, Jerry Hurst, Julie Kingery, Margaret
Knapp, Shiu-Land Kwong, Lois Lang, Cecilia Mui, Francisco Nepacena, Valerie Ng,
Karen Nickel, Erica Padilla, Michelle Paganini, Phyllis Walker, Maureen Weber, Annie
Yang

Welcome and general announcements
Roll was taken. A quorum was present.

Approval of March 3, 2017, minutes
 Corrections were made to the minutes. Jonathan Bautista motioned to approve,
seconded by Jennifer Schiffgens. The minutes were approved as amended.

Department update
Paul Kimsey, Ph.D., Deputy Director of the Office of the State Public Health Laboratory
Director (OSPHLD), reported on three topics:
1. The California Department of Public Health (CDPH) Website
2. Federal Government Grants
   A. Part of the Public Health Emergency grant is being used to set up an assistant
      public health laboratory director program with counties.
   B. Public Health Officers relayed to CDC that the epidemiology capacity grant is
      helping with disease control and surveillance throughout the state, and reiterated
      the importance of grants with CDC upper management.
   C. The CLIA program is funded by fees and no changes are anticipated.
3. CDPH 10 year anniversary
   CDPH will be celebrating ten years as a department with events at the State Capitol
   and in Richmond.
Questions
Q: Should applicants for personnel licensing go through the new or archive website?
A: Applicants can reach the online application site through either the new or archive site.

Q: Can the online license verification page for laboratory personnel be reached through either site?
A: Yes, both the new and archive sites have links that lead to the verification page.

Q: Is the new site’s search function attached to the archive site?
A: No, one would need to search on archive site itself.

LFS Update
Robert Thomas, LFS Branch Chief, gave a branch update.
1. Brandon Carey was hired as the branch chief’s office technician.
2. Several LFS section chiefs could not attend the meeting due to the meeting date change, but their staff will report in their stead.
3. The Bagley Keene Open Meeting Act was discussed.
   B. The Brown Act applies to local legislative bodies.
4. LFS is working to transition pages from the archive site to the new one. New pages are being created to replace the pages on the archive site, and during the transition period we will continue to update the pages on the archive site.
5. LFS has received many questions regarding phlebotomy school requirements.
   A. Requirements for phlebotomy technicians are found under BPC section1246 and 17 CCR section 1034.
   B. Phlebotomy training school requirements are found under BPC section1246 and 17 CCR section1035.1.
6. LFS has several projects underway; staff members will present reports.

Questions
Q: How can the lab personnel and facility lists be obtained?
A: Lab personnel and facility lists can be obtained by submitting form LAB 192 (on the archive site) along with fee. The list is produced once the form and fee are received. The database is updated daily Tuesday through Saturday.

Administrative Items
Dolly Luong, staff services analyst, reported:
1. Seven new staff have been hired in Richmond and LA.
2. LFS has been meeting regarding succession planning.
3. LFS will also coordinate meetings with the CLTAC subcommittee for LFS Recruitment and Retention on how to expand outreach for examiner positions.

Responding to a question, Tina Kruthoff, Assistant Chief of the OSPHLD, reported that salaries are negotiated by bargaining units and the most recent contract would give examiners an increase of 12 to 15 percent over the next few years.

Legislative Update
Mary Wogec, Associate Governmental Program Analyst (AGPA) for legislative affairs, reported that, unless a bill is sponsored by the department, LFS does not take a position
until the Governor chooses a position. LFS staff members make an internal recommendation in a bill analysis that they send through the Office of Legislative and Governmental Affairs to the legislators and Governor, but the analysis is not shared outside the department. Her report provides an overview of the bills analyzed by LFS in the current year and the status of those bills at the moment. The information presented in the report is publicly available information, which can be found online at http://leginfo.legislature.ca.gov/.

Ms. Wogec reported that LFS has been assigned the following bills:
1. AB 613 – Total Protein Refractometer Testing
2. AB 658 – Clinical Laboratory Licensing Fees
3. SB 43 – Anti-microbial Resistant Infection Reporting
4. SB 608 – Narcotic Treatment Programs

**CLTAC Subcommittee Reports**

Shiu-Land Kwong, reporting for Subcommittee for Regulations, presented three items for consideration by the full CLTAC:
1. High school equivalency - The committee has proposed a definition, as many laws reference the term but there is no definition in law.
2. FAQ for waived testing
3. FAQ for analytical testing

Disclaimer: These Frequently Asked Questions and recommendations are a supplement to help understand existing statutes and regulations and do not replace any actual California laws or regulations.

A vote was taken. The three documents were approved by the CLTAC without opposition and were submitted to LFS for consideration.

Bob Thomas reiterated the dual purpose of the Subcommittee: LFS accepts recommendations for the purpose of inclusion in regulations and for posting on a technical questions page on the LFS website. LFS is working on its review of the CLTAC submissions before submitting them for legal review, and appreciates the work of the CLTAC and this subcommittee.

**Lead Care Recall**

Jean Woo, of the Childhood Lead Poisoning Prevention Branch, which helps to identify children exposed to lead, reported that on May 17, 2017, the FDA and CDC jointly released a CDC advisory warning against using the Magellan Diagnostic LeadCare Blood Lead Testing System. The system may underestimate blood lead levels and give inaccurate results when processing venous blood samples. The FDA recommends discontinuing the use of any LeadCare Blood Lead Testing System (LeadCare, LeadCare II, LeadCare Ultra, LeadCare Plus) with venous blood samples.

The program recommends that hospital providers retest all recently tested persons under the age of 17 years before May 17, who had a result of less than 10 micrograms per deciliter when analyzed by the LeadCare instruments at either an onsite or offsite laboratory. The program also recommends reaching out to currently pregnant or lactating patients who had tests performed on these machines. The CDC recommends that parents discuss retesting with health care providers or the department. More information can be found on the CDC and FDA websites.
Online System Enhancements

PERL II
Tina Kruthoff reported that the Personnel Licensing (PERL) II system will go live sometime in October. LFS is reaching out to the regulated community about the new process in advance in order to reduce the confusion relating to the changes.
1. Renewal notification will be sent to licensees 60 days before expiration explaining how to apply.
2. Licensees will need to create an online account.
3. Once the account is created, the applicants will
   A. Fill out the online application
   B. Upload CE completion certificates (this is a change; currently, applicants declare completion without sending documentation)
   C. Pay online with credit card or electronic check
4. LFS will no longer accept paper applications once PERL II goes live.

ELLFS
Nga Tran, AGPA for Laboratory Licensing and Registration, reported that the Electronic Laboratory Licensing and Registration for Facilities System (ELLFS) has captured requirements for clinical laboratory licensing and registration. These requirements will be used in creating the interface that will cover licensing and registration. She added that programming would begin in July.

Personnel Licensing Update Section (PLS) Update
Sarah Rutschmann, AGPA for Personnel Licensing, reported for Shohreh Ershadi, Section Chief of Personnel Licensing, that in addition to PERL II, the program has allocated more staff to respond to questions from public. LFS receives a high volume of emails, mostly about renewals.

Public Health Microbiologist (PHM)
Nema Lintag, Examiner II for Personnel Licensing, reported:
1. The PHM certification program has been reassigned from Laboratory Licensing and Registration Section to the PLS.
2. The PHM certification application is currently online through the PERL system.
3. The PHM Trainee application form has been updated; application no longer requires the “pink form,” and will soon be online.
   A. The new application process will assign a trainee number (currently, applicants receive a trainee approval letter).
   B. It is possible that the PHM examination may be administered online or via a certifying organization at some point in the future.
   C. PHM laboratory director applicants will be required to submit form LAB 145 before the start of training and LAB 146 upon completion.
4. Possible updates to regulations
   A. Regulations for PHM are under consideration for updating
   B. The current regulations do not specifically address Technical Supervisor, General Supervisor, or Clinical Consultant as required by CLIA
   C. PH laboratories are exempt from BPC section1241, but they are regulated by the Health and Safety Code.
   D. Regulations state that LFS must inspect PH laboratories but do not state the frequency.
5. LFS invites feedback by the end of June 2017.
Public Health Laboratory Director (PHLD) and Director Trainee
Dolapo Afolayan, Examiner II for Personnel Licensing, reported:
1. PHLD Trainee certificate
   A. Applicants must be Ph.D., M.D., Dr.PH, D.V.M., D.Sc., and meet other education requirements
2. PHLD Certificate—Pathways to Certification
   A. Classic
      i. Education
         a. Ph.D., M.D., Dr.PH, D.V.M., D.Sc.
         b. 24 semester units: microbiology, cellular or molecular biology, chemistry, genetics, physics, epidemiology. At least 6 of those semester units completed in medical or pathogenic microbiology, or bacteriology
      ii. Training
         a. Two years of experience in all aspects of public health microbiology
         b. Experience must be completed in CLIA certified laboratory
         c. PHM certificate required
      iii. Experience
         a. Four years laboratory experience in all aspects of public health microbiology, at least two of them while supervising high complexity testing
         b. Experience must be completed in a CLIA certified laboratory
      iv. Board Certification
         a. Written evidence of satisfactory performance from
            (1) ABB (High Complexity Laboratory Director - General Knowledge, Microbiology, and Public Health Microbiology)
            (2) ABMM (Medical and Public Health Microbiology)
   B. Executive
      i. Same education, training, certification, experience as required for “classic”
      ii. Training and experience accepted from CLIA certified clinical laboratory
      iii. Eligible applicants will sit for an oral examination
      iv. If successful in the oral examination, will take a written LFS examination
   C. Grandfather
      “On or before February 28, 1992, be qualified under State law to direct a laboratory in the state in which the laboratory is located” – 42 CFR § 493.1443

As certain requirements for public health laboratory directorship are written in regulation and not statute, LFS is looking for public input on possible changes to administrative law. LFS requests community review and comment by June 27, 2017.

**Tissue and Blood Banks, Biologics and Cytology Section Update**
Ronald Harkey, Section Chief of Tissue Banks, Blood Blanks and Biologics, and Cytology Section, reported:
1. Tissue Banking has transferred its database to the LFS HAL system.
2. Blood Banking will remain on an independent system until ELFFS goes live.
3. The tissue bank sperm washing regulation package has gone to agency for review.
4. The tissue bank program is working on the ISOR and fiscal and economic impact for a regulation package to partially adopt the AATB guidelines into law.
5. The program is working with constituents to improve the process regarding licensure of a stem cell facility as a tissue and/or blood bank.
6. The program is increasing cytotechnology surveys for those who fail to respond to questionnaire.

**Laboratory Licensing and Registration Section Update**

Martha Obeso, Section Chief of Laboratory Licensing and Registration Section, reported

1. The section is working to update and migrate web pages.
2. The section has hired a supervisor for renewals and two program technicians.
3. Beginning June 2017, the section will contact laboratories currently classified as exempt to verify status, with the goal of completing the updates by early 2018.
4. Regarding multi-site licenses under BPC section 1265, clinical laboratories are required to be licensed, with the following exceptions:
   A. Health screening fairs, not for profit, local or federal government labs
   B. Laboratories within a hospital located in contiguous buildings on the same campus, and under common directorship
   C. Same street or address, and under common ownership

**On-Site Licensing Section Update**

**Complaints Process**

Gilberto Wilson, Staff Services Analyst for Onsite Licensing, reported:

1. Complaints
   A. After the CSA 2015 audit, new procedures were developed and implemented.
   B. The section has hired two staff dedicated to complaints.
   C. The section has created a SharePoint site to handle tracking and produce management reports
      i. 83 closed, 5 forwarded to other sections/agencies, 8 are awaiting assignment, 21 pending with sections/examiners, 2 in triage waiting for examiner to review. Percentage of facility types
      ii. Closed complaints comprise those forwarded to other organizations/agencies, completed investigations, no further action required
   D. LFS is developing a communication plan, including what information can be released to the public, and how.

**Inducement Investigation Process**

Asraf Tootla, the AGPA working on inducement complaints, reported on the investigation process:

1. The investigator speaks with office manager or in-office phlebotomist to determine business operation: who is drawing, who employs that person, where samples are sent, and why
2. Key factor: who employs the phlebotomist, who may be employed by doctor or clinic; if it is another organization, this warrants further questions
3. If draw station is operated by independent laboratory, signs should be posted that it is open to public
4. The investigator reviews the site visit documents to determine compliance
5. If site is compliant, the investigator sends notice
6. If non-compliant, sends deficiency letter to laboratory and physician office involved
7. The investigator works with both to return to compliance
8. If necessary, forwards to DOJ for further action

Tina Kruthoff advised that the department has received reports of fraudulent letters purporting to be from LFS sent to laboratories regarding inducements. The department is seeking to clarify the inducement complaint investigation process and asks the
community to report any questionable notifications.

**CLIA Survey Section Update**
Donna McCallum, Section Chief CLIA Section, reported:
1. Examiner, Rocky Pramanik, Ph.D., biochemistry, has joined the Section.
2. The total actions for the period Information of October 1, 2016 to April 30, 2017: 435 (55 initial inspections, 328 recertifications, 10 validations, 4 onsite complaints, 38 PT desk review sanctions).
3. Regulatory responsibilities
   A. CMS: approve private accrediting organizations (AO) that perform inspections, approve states exempt from CLIA, collect user fees, conduct inspections, enforce regulatory compliance, issue lab certificates, monitor PT and approve PT programs, and publish CLIA rules and regulations
   B. FDA: categorizes tests based on complexity, develops rules and guidance for CLIA complexity categorization, and reviews requests for waiver by application
   C. CDC: conducts laboratory quality improvement studies, develops and distributes professional information and educational resources, develops technology standards and practice guidelines, manages CLIA advisory committee, monitors PT practice, and provides analysis, research, and technical assistance.
   D. Between these three, collaboration and cooperation ensure consistency in the application of the standards
4. Section staff attended the CMS CLIA Western Consortium in Denver from May 8-12, which involved three different regions: 8, 9, and 10; region 9 is CA, AZ, NV, HI, and the Samoa Islands. Presentations were made by CDC, American Association of Psychology, and other agencies that play a role in laboratory compliance.

**New Business**
1. The CLTAC Bylaws Committee (Lee Hilborne, Kathleen Doty, Lorri Dean-Yoakum) has not met, but may have a report next meeting.
2. Concerns about state-approved AOs not having CA specific guidelines for surveyors and questions
   A. LFS has discussed requirements specific to California with AOs
   B. LFS reviewed and approved AO guidelines
   C. LFS has an upcoming AO meeting and will discuss
3. Change of CLTAC meeting days – to be discussed

**Next Meeting**
September 8, 2017

**Adjournment**
Jonathan Bautista motioned to adjourn and the motion was seconded by Jennifer Schiffgens. The meeting adjourned at 12:41PM.