

CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)

Minutes of the Meeting held on December 6, 2019

Meeting held on the Telephone Bridge Line

CLTAC Members Participating

Jonathan Bautista, Zenda Berrada, Richard Bennett, Marjorie Braasch, Kathleen Doty, Daniel Dominguez, S. Robert Freedman, William Gardner, Dora Goto, Daniel Leighton, Tula Nieva, Armand Parada, Rebecca Rosser, Fred Ung

Former CLTAC Members Participating

Carmen Maldonado, Lee Hilborne

California Department of Public Health (CDPH) Staff Participating

Dolapo Afolayan, Megan Cornejo, Elsa Eleco, Allison Jacobsen, Paul Kimsey, Katya Ledin, Nema Lintag, Donna McCallum, Martha Obeso, Mai Phan, Robert Thomas, Armando Tiong, Nga Tran, Clint Venable III, Hugo von Bernath, Emily Wei, Mary Wogec

Public Members Participating

Michael Aiden, Nathan Cron, Lydia Bourne, Amy Daniels, Brett Holmquist, Margaret Knapp, Shiu-Land Kwong, Lois Langs, Henry Lee, Elizabeth Lucas, Cecilia Mui, Erica Padilla, Cinco Plumb, Stacy Ralston, Rodney Roath, Salustiano Ribeiro, Osvaldo Santiago, Laura Tucker

Welcome and General Announcements (Jonathan Bautista)

- Meeting opened at 9:04 AM.
- Jonathan Bautista conducted roll call and determined that a quorum was present.

Approval of September 6, 2019, CLTAC Minutes (Jonathan Bautista)

- Minor changes made:
 - Page 1 “Shui-Land Kwong” → “Shiu-Land Kwong” (name)
- Motion to approve by S. Robert Freedman
- Seconded by Zenda Berrada

Department News (Paul Kimsey)

- Dr. Sonia Angell became the Director of CDPH effective October, 2019.
- Office of the State Public Health Laboratory Director (OSPHLD) now reports to Dr. Charity Dean.
- Under the laboratory reorganization project, OSPHLD will be renamed Center for Laboratory Science.

LFS Update

Branch Report (Robert Thomas)

- Announced the passing of Sam Chafin.
 - Sam Chafin was 91 years old.
 - He was an active advocate for clinical laboratory science education.
 - Since 1975, Mr. Chafin held a Clinical Laboratory Scientist (Generalist) License.
 - He worked for many years at Loma Linda Medical Center.
 - He served on several sub-committees of the CLTAC and worked towards improved examination development and clinical laboratory training.
 - Sam Chafin always presented himself professionally and was a wonderful gentleman.
- Announced the promotion of Nga Tran to the Research Data Analyst II (RDA II) position effective October 31, 2019.
 - This is a new position in LFS working on data assignments.
 - Nga's responsibilities include serving as a systems program specialist for online applications systems, system data applications, and performance trends.
 - Nga is a lead specialist charged to establish and maintain well-functioning online application systems and serve in a network of quality improvement committees that oversee improvement activities, performance and evaluation systems, and communication plans.
- CLTAC Update
 - As of December 31, 2019, the CLTAC board will have three new position openings.
 - A Licensed Clinical Laboratory Scientist, Union Member.
 - A Licensed Clinical Microbiologist.
 - A Licensed Clinical Laboratory Scientist.
 - Organizations that have previously nominated candidates and other organizations are asked to submit nominations for these positions.
 - Nominations should be submitted to Megan Cornejo, assistant to Robert Thomas, Branch Chief of LFS, at megan.cornejo@cdph.ca.gov.
- During the fall of 2019, LFS staff attended three conferences.
 - The California Association of Bioanalysts.
 - The California Association for Public Health Laboratory Directors.
 - The California Clinical Laboratory Association.
- LFS hosted a meeting on October 3, 2019, with the California approved accrediting organizations, AABB, CAP, COLA, and the Joint Commission.
 - The California requirements were reviewed and discussed.

- The new Clinical Laboratory License and Registration electronic application system went live for internal users in LFS on October 17, 2019.
 - We continue to move away from paper and modernize the application process with on-line electronic systems.
- LFS held a public meeting on October 23, 2019, as a follow-up to the request by Blood Centers of California for regulations change.
- LFS continues to partner with the Department's Food and Drug Branch and the federal Food and Drug Administration on activities related to tissue-derived therapeutics.

Administrative Items (Ted Lee)

- The LFS Call Center receives 600 inquiries a week through phone and via email.
- The number of inquiries has not gone down despite tightening the Branch's application processing windows.
 - Two staff members will be added to the Call Center to help reduce the wait times.
- The Call Center can be reached at 510-620-3800, or via email at LFSCC@Cdph.ca.gov.

Electronic Updates

ELLFS (Nga Tran)

- Online system developed to eliminate paper-based laboratory licensing process.
- There is a two-phase implementation plan.
- Phase I has been implemented internally.
 - Launched October 7, 2019.
 - Migrated approximately 30,000 records from the legacy system.
 - Paper applications are now being processed in the new system.
 - PDF license certificates are generated by the new system and issued to the laboratories via email.
 - PDF Certificates' QR code currently directs the user to the LFS website.
 - In the future, the QR code will direct the user to the Laboratory Licensing Registration Section website.
- Phase II will be implemented with Clinical and Public Health Laboratories.
 - This allows the ability for these laboratories to:
 - Access and manage their account.
 - Submit new license applications.
 - Renew licenses annually.
 - Download and print digital certificates.
- Beta testing allows for:

- Creating new applications.
- Renewing licenses.
- Providing feedback.
- Email Nga Tran at nga.tran@cdph.ca.gov for any questions or comments.

PERL (Dolapo Afolayan)

- Effective September 5, 2019, applicants applying for MLT and CLS licensure are able to take the California State Laboratory Law quiz in PERL.
- Quintessential Instructional Archive (QUIA) is no longer an LFS third party vendor.
 - Applicants who applied after September 5, 2019 will take the quiz in PERL.
 - Applicants who applied before September 5, 2019 will take the quiz in QUIA.
- Applicants are only able to proceed with the application process upon passing the quiz.
- The study guide is available to both applicants and educators prior to starting the quiz.

Independent Phlebotomy Subcommittee (Jonathan Bautista)

- Members:
 - Elizabeth Lucas
 - Dan Leighton
 - Cecilia Mui
 - Cinco Plumb
 - Teri Ross
 - Stacy Ralston
 - Jonathan Bautista
 - Mary Wogec
 - Greta Nash
- The charge is for the subcommittee to research phlebotomists operating independent of a clinical laboratory and report the findings.
- The findings will assist LFS in drafting a policy on the issue.
- California law does not allow phlebotomists to work independently.
 - BPC section 1246 refers to the requirements for phlebotomists.
 - Title 17 CCR section 1034 refers to phlebotomist supervision requirements.
- Phlebotomy training programs must be approved by LFS.
- Two subcommittee meetings have been held:
 - November 8, 2019.
 - Discussed research ideas:

- Internet search.
 - Job opportunity listings.
 - Social networks
 - Discussed the distinction between mobile phlebotomists and independent phlebotomists.
 - Mobile phlebotomists are traveling phlebotomists either as a laboratory employee or independent of laboratory employment.
 - Independent phlebotomists are those who are not employed by a licensed clinical laboratory.
 - November 22, 2019.
 - Reviewed data.
 - Discussed risks.
 - Discussed the challenge of confirming the number of independent phlebotomists in California.
- Research methods:
 - Website searches.
 - Social media.
 - Phone interviews.
 - Information provided by public members.
- Data shows there are over 45,000 licensed phlebotomists in California.
- Different types of phlebotomy models:
 - Independent phlebotomy group without CLIA license but supervised and oversight provided by a separate clinical laboratory.
 - Phlebotomy owned and operated by a clinical laboratory.
 - Independent phlebotomy provided by nurses.
 - Online independent phlebotomy using independent contractors, like a registry or clearing house for independent phlebotomists.
 - Concierge phlebotomists.
- Some risks/concerns that have been brought up are:
 - Is the training provided by an approved program?
 - Are proper pre-analytic procedures followed?
 - If proper pre-analytic procedures are not followed, what is the impact to the analytic phase?
 - What are the insurance requirements to cover liability?
 - How is California certification verified?
 - Are there phlebotomists working in California without a license?
 - Are independent phlebotomists collecting at physician's offices?
- Some ideas/solutions considered:

- Including a module in training programs that covers California phlebotomy law.
- Conducting an informational campaign.
- Deciding whether or not independent phlebotomists should be required to post their certificate on their site.
- Amending regulations to align current healthcare needs with current business, administration, and technological capabilities.
- Motion to accept report by Marjorie Braasch.
- Seconded by Dora Goto.

Changes to Title 17 Section 2505 of the California Code of Regulations – Lab Reportable Disease Updates (Allison Jacobsen)

- Title 17, Section 2505 of the California Code of Regulations (CCR) specifies the reporting requirements of laboratories to public health.
- Updated every few years.
 - Due to the file and print authority for this section, changes can be made in an expedited manner.
- The most recent revision cycle started two years ago.
- Changes went into effect October 1, 2019.
- Changes to list of reportable diseases:
 - Added:
 - Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing).
 - Influenza.
 - Latent Tuberculosis Infection identified by a positive laboratory test (including positive interferon gamma release assays).
 - Middle East Respiratory Syndrome Coronavirus (MERS-CoV).
 - Removed:
 - Entamoeba histolytica (not E. dispar).
 - Reworded:
 - Mycobacterium tuberculosis now Tuberculosis, including Mycobacterium tuberculosis complex.
 - Neisseria meningitidis (sterile site isolate) now Neisseria meningitidis (sterile site isolate or eye specimen).
- Changes to 17 CCR section 2505 Isolate and Specimen Submissions:
 - Added:
 - Neisseria meningitidis eye specimens.
 - Removed:
 - Measles immunoglobulin M (IgM)-positive sera.
 - Changed:

- Submission of HIV – ½ antigen or antibody reactive sera or plasma now upon request form CDPH.
- Mycobacterium tuberculosis complex changes:
 - If the complex is identified by molecular testing but no culture isolate is available, a specimen must be submitted to the public health laboratory.
 - Results of molecular assays for drug resistance must be reported.
 - Resistant cultures must be submitted as soon as available.
- Changes to 17 CCR section 2505 Reporting Requirements
 - Initial and subsequent findings must be reported.
 - Molecular and pathologic testing must be reported.
 - Negative results must be reported upon request.
 - Reporting is now based on where the patient resides.
 - Laboratories must report to the state electronic reporting system, CalREDIE.
 - Animal specimens are no longer limited to rabies and plague.
 - Testing now includes anthrax, brucellosis, tularemia, and viral hemorrhagic fever agents.

Legislation Update (Mary Wogec)

- LFS Bill Assignments:
 - AB 476, California Opportunity Act of 2019 (Watch-Vetoed)
 - AB 601, Health Facilities (Two-year)
 - AB 617, Stem Cell Therapies Notice (Watch-Vetoed)
 - AB 785, Gamete Banks (Signed and chaptered)
 - AB 810, Organ and Tissue Transplantation (Two-year)
 - AB 822, Phlebotomy (Two-year)
 - AB 889, Research Animals (Laboratory Central Services) (Two-year)
 - AB 922, Oocyte Donors (Watch – Signed and chaptered)
 - AB 1271, Licensing Examinations (Watch – Two-year)
 - SB 180, Gene Therapy Kits (Watch – Signed and chaptered)
 - SB 334, MLT Articulation to CLS (Signed and chaptered)
- AB 785 (Gamete Banks)
 - Would require a gamete bank to collect and maintain any other contact information provided by the donor at the time of the donation and records of gamete screening and testing.
 - Introduced: February 12, 2019.
 - Amended: March 21 and March 27, 2019.
 - Enrolled August 22, 2019.
 - Signed and Chaptered: October 8, 2019.
 - Effective: January 1, 2020.

- SB 180 (Gene Therapy Kits)
 - Would prohibit a person from selling in state a gene therapy kit, unless the seller indicates to the consumer on their website, and on a label on the package, prior to the point of sale, that the kit is not for self-administration.
 - Introduced: January 28, 2019.
 - Amended: March 27, 2019 and May 2, 2019.
 - Enrolled: July 8, 2019.
 - Signed and Chaptered: July 30, 2019.
 - Effective: January 1, 2020.
- SB 334 (MLT Articulation to CLS)
 - Would require the State Department of Public Health to establish a pathway program that would authorize a licensed medical laboratory technician (MLT) to apply work experience and training from a Department-approved MLT training program towards the completion of a CLS training program. The bill requires the Department to establish a pathway program by January 1, 2022.
 - Introduced: January 19, 2019.
 - Amended May 28, 2019.
 - Signed and chaptered: July 30, 2019.
 - Effective January 1, 2020.
- Regulations packages
 - Clinical Laboratory Personnel Standards
 - DPH-11-012 – Definitions
 - DPH-19-009 – Geneticists and Reproductive Biologists
 - DPH-20-007 – Trainees, MLTs, Cytotechnicians
 - DPH-20-006 – CLS, CLS Limited to a Specialty, CLS Training Programs
 - DPH-20-005 – Bioanalysts, Master’s and Doctoral Degree Specialists
 - DPH-16-019 – Certified Laboratory Personnel, Phlebotomy Training Programs
 - DPH-18-017 – Unlicensed Laboratory Personnel
 - DPH-16-020 – Applications and Clean-Up
 - DPH-15-005- Tissue Bank
 - DPH-16-002- CLIA 2003 Crosswalk Part II
 - DPH-18-018- Public Health Laboratories and Personnel
 - DPH-18-019- Blood Donation Centers

- PLS welcomes Mai Phan as an Associate Governmental Program Analyst, effective October 14, 2019.
- New applications:
 - September, October, and November 2019, PLS received more applications than it approved.
- Renewal applications:
 - September, October, and November 2019, PLS received more renewal applications than it approved.

Laboratory Licensing and Registration Section (LLRS) Update (Martha Obeso)

- Phase I of ELLFS was implemented on October 7, 2019.
- Changes and Challenges with the implementation of ELLFS:
 - Name of contact person is required to complete application.
 - Valid email addresses required for PDF certificates, approval notices, and other correspondence through ELLFS.
 - LFS must get in touch with the laboratories to verify the email.
 - Revised annual renewal notices.
 - Renewal notices are mailed out 75 days prior to a laboratory's expiration date.
 - Renewal applications/payments to be mailed to Richmond.
- Laboratories will receive a termination notice if they fail to provide requested documents.
 - Laboratories are advised not to contact CLIA should they receive a termination notice.
- License fee suspension ends on January 1, 2020.

CLIA Survey Section Update (Donna McCallum)

- October 2019 survey report for the CLIA fiscal year:
 - 7 initial surveys.
 - 81 recertification surveys.
 - 1 proficiency testing desk review sanction.
 - 0 on-site follow ups.
- Provider-performed microscopy procedures (PPMP)
 - The laboratory or testing site performing PPMP is not subject to routine biennial inspections.
- CMS Updates:
 - Pilot Project:
 - One state is selected from each region.
 - Nevada was the state selected from our region.
 - The findings will determine the expansion of this project.

- Brochure #2 Verification of Performance Specification.
- Fully staffed CLIA Survey Section to resolve survey backlog.

Tissue and Blood Banks, Biologics, and Cytology Section Update (Martha Obeso)

- 6 inspections since September.
- 1 inspection scheduled in December.
- 7 of 11 Tissue Bank policies and procedures complete.
- 20 of 26 Biologics policies and procedures complete.
- Currently, there are only two examiners assigned to this section.

On-site Licensing Section Update (Elsa Eleco)

- In-state validation process:
 - California will perform validation surveys of laboratories accredited by each of the four California-approved accrediting organizations (AOs).
 - 1193 laboratories were inspected by the four California-approved AOs.
 - Of these 1193 laboratories, 5-6% will be subject to validation inspections for calendar year 2019.
 - Sample sizes will be proportionate to the number of laboratories issued with a license of deemed status.
 - State inspectors will contact the AOs prior to the validation inspection.
 - The state validation inspection should be performed within 90 calendar days of the AO inspection date.
 - State inspectors then contact the laboratories to schedule the validation inspection.
 - Unannounced validation inspections will be conducted by state inspectors if there is a complaint investigation occurring within 90 days of the AO survey date.
 - The AO will be copied when the statement of deficiencies is sent to the laboratory.
 - Frequently asked questions regarding nurses and perfusionists can be answered by referring to the appropriate laws.
 - 42 CFR § 493.1411 Technical Consultant Qualifications (Moderate Complexity).
 - Title 17 CCR § 1036.2 Moderate Complexity Laboratory Technical Consultant.
 - California Business and Professions Code (BPC) Chapter 3- Clinical Laboratory Technology.
 - California BPC Chapter 5- Medicine.
 - California BPC Chapter 6- Nursing
 - California BPC Chapter 5.67 Perfusionists.

- 42 CFR § 493.1449 Technical Supervisor Qualifications (High Complexity).
- Title 17 CCR § 1036.4 Technical Supervisor.

New Business (Jonathan Bautista)

Future Items (Jonathan Bautista)

- Next meeting March 13, 2020.

Adjournment (Jonathan Bautista)

- Motion to adjourn by Dora Goto
- Seconded by Marjorie Braasch
- Meeting closed at 12:17 pm.