CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)

Minutes of the Meeting held on March 2, 2018
Meeting held on videoconference from CDPH Richmond campus, KP Regional Laboratory, North Hollywood, and the Telephone Bridge Line

CLTAC Members Participating

Former CLTAC Members Participating
Lorri Dean-Yoakum, Carmen Maldonado

California Department of Public Health (CDPH) Staff Participating
Dolapo Afolayan, Elsa Eleco, Robert Hunter, Paul Kimsey, Tina Kruthoff, Ted Lee, Nema Lintag, Donna McCallum, Donald Miyamoto, Martha Obeso, Jan Otey, Nga Tran, Aaron Webb, Emily Wei, Mary Wogec, Jenny Yun

Public Members Participating
Anna Choi, Amy Daniels, Nicole Green, Brett Holmquist, Carola Howe, Shiu-Land Kwong, Lois Langs, Katya Ledin, Cecilia Mui, Karen Nickel, Debbie Wilson-Ferguson, Preston “Cinco” Plumb, Irene Tran, Tammy Zinsmeister

Welcome and General Announcements (Rebecca Rosser)
- Meeting opened at 9:15AM.
- Rebecca Rosser conducted roll call and determined that a quorum was present.
- Dr. Zenda Berrada was introduced as the newest CLTAC member; she will be representing the public health sector.
- Representation Reminder
  - CLTAC members represent the constituents of the organization that nominated them. They do not represent the organization itself.

Approval of December 1, 2017 CLTAC Minutes (Rebecca Rosser)
- No changes suggested.
- Marjorie Braasch moved to approve minutes. Dora Goto seconded.

Department News (Dr. Paul Kimsey)
- Thanked Southern California Kaiser Permanente in making this videoconference possible.
• Announced that Jahmal Miller, Deputy Director of the Office Health Equity, is moving to Blue Cross Blue Shield.
• Announced that Claudia Crist, Chief Deputy Director of Policy and Programs, is moving to Sutter Health.
• Apologized for issues and inconveniences associated with PERL 2 and announced that Aaron Webb will go into more detail later in the meeting.

LFS Update
• Branch Report (Martha Obeso)
  o Dolapo Afolayan, Examiner III, Section Chief for the Personnel Licensing Section, was introduced (effective January 31, 2018).
  o Jenny Yun, Attorney III to support LFS, was introduced (effective November 27, 2017).
• Laboratory Infectious Disease Reporting (Martha Obeso)
  o LFS is working with the Division of Communicable Disease Control to formalize a system to reduce the number of non-reporting incidents.
  o Reminder: Report all infectious disease incidents to local health department using either CalREDIE or an established electronic system.
• Charge for Subcommittee on Public Health Lab Regulations (Martha Obeso)
  o LFS thanked the CLTAC Regulations Subcommittee for completing their original charge and going above and beyond.
  o Martha Obeso read:
    ▪ “LFS has a current need for assistance from CLTAC for a subcommittee to review laws and regulations relating to county and municipal laboratories, generally known as public health laboratories. Although these laboratories are designated as public health laboratories, they are also clinical laboratories that do additional testing on food, water, and rabies. These regulations are in the California Health and Safety Codes and some parts of the California Code of Regulations, so LFS would like to form a new regulations subcommittee composed of people who have expertise in these areas. These regulations are decades old and deal with personnel requirements, lab director requirements, and facility operational requirements. These regulations are in need of updating and therefore, we are issuing a new charge.
    ▪ LFS is requesting a motion to create an ongoing subcommittee to assist with public health laboratory regulations. The purpose of this subcommittee is to evaluate changes that may include changes in public health laboratory practices and technology, and also provide any recommended updates. This subcommittee will provide a position paper to the full CLTAC for recommendations regarding suggested changes to the existing laws and regulations related to county and municipal public health regulations.”
Rebecca Rosser stated that CLTAC has a motion on the table to create a new Public Health Lab Regulations Subcommittee.

Dr. Zenda Berrada moved to create the Public Health Lab Regulations Subcommittee. Jonathan Bautista seconded.

Dr. Zenda Berrada clarified and moved that the Public Health Lab Regulations Subcommittee will be composed of seven to eight people. Jonathan Bautista seconded.

Rebecca Rosser asked who is in favor of this subcommittee.

- Richmond—all agreed (Jonathan Bautista, Zenda Berrada, Marjorie Braasch, and Dora Goto)
- Los Angeles—all agreed
- Phone bridge—no one disagreed

Rebecca Rosser appointed Dr. Zenda Berrada as chair of the Public Health Lab Regulations Subcommittee.

Rebecca Rosser asked for members for the Public Health Lab Regulations Subcommittee.

- Richmond—Nicole Green, Katya Ledin
- Laboratory Field Services—Dolapo Afolayan
- Los Angeles—no one volunteered
- Phone bridge—no one volunteered

Rebecca Rosser will follow-up with Dr. Zenda Berrada regarding recruitment for the Public Health Lab Regulations Subcommittee.

- **Administrative Items** (Ted Lee)
  - New hires
    - Dolapo Afolayan promoted to Examiner III and Section Chief of Personnel Licensing Section.
    - Karen Demby returned as Examiner II.
    - Program Technician II position is currently pending.
    - LFS continues to promote vertical growth within the department.
  - Student interns
    - LFS contracted with University Enterprises.
    - Goals:
      - Help interns build careers in public health, esp. within LFS.
      - Give interns work experience.
    - Intern positions will be posted on LFS website soon.
  - Training session for LFS staff
    - Past trainings: Customer service, business writing, PERL 2.
    - Future trainings: Business and email writing, and grammar.
  - Strategic planning
    - Continual recruitment
- Dolly Luong is at the American Society for Microbiology meeting.
- Internal discussion regarding strategies to broaden examiner pool.
  - Succession plan
- LFS will send a questionnaire to staff soon to gather updated data for upper management.

**Electronic Updates**

- **PERL 2 Update** (Aaron Webb)
  - Approved applications:
    - 2,413 new applications have been approved.
    - 5,829 renewal applications have been approved.
  - Technical challenges regarding renewal applications
    - Navigating the online application system.
    - Correcting incorrect key demographic information.
    - Uploading Continuing Education (CE) documents.
    - Getting locked out of the application.
    - Receiving errors when matching/associating with previous license/certificate.
    - Receiving errors when entering decimal integers for CE units.
    - Creating multiple renewal applications.
    - Cancelling applications.
    - Receiving physical copy of licenses/certificates in the mail.
  - Technical challenges regarding new applications
    - Navigating the online application system.
    - Creating an account.
    - Correcting incorrect key demographic information.
    - Applying after being abandoned.
    - Viewing application statuses.
  - Technical improvements for renewal applications
    - Provide a systematic (step-by-step) manual (near completion).
    - Prevent the accidental creation of multiple applications.
    - Offer help to cancel applications.
    - Use the Contact Us form (for key demographic changes).
    - Offer a simpler process for matching to a certificate/license.
    - Create a fix for locked applications.
    - Design an enhancement for the use of decimal integers for CE units.
• Provide a fix that will allow licenses/certificates to be mailed out in a timely manner.
  o Technical improvements for new applications:
    ▪ Provide a systematic (step-by-step) manual (near completion).
    ▪ Improve navigation.
    ▪ Aid in account creation.
    ▪ Use the Contact Us form (for key demographic changes).
    ▪ Create a fix for applicants to re-apply after abandonment.
    ▪ Construct a fix for applicants to view application statuses.
  o Contact Us form:
    ▪ Constituents are using the online form to submit program-related inquiries which allows LFS to track and task inquiries more efficiently and thoroughly.
  o Technical (IT) assistance tracking “Cherwell”:
    ▪ Users submit tickets online if assistance is needed with account creation and/or application process.
    ▪ Create ticket through:
      • 1. “Contact Us” link within the application
      • 2. https://accountportal.cdph.ca.gov/ContactUs.aspx
    ▪ LFS/IT staff are assigned tickets and reach out to users to provide assistance.
    ▪ LFS management view metrics to identify areas of quality improvement.
  o Future releases:
    ▪ PERL 2 user manuals.
    ▪ PERL 2 user video walkthrough.
    ▪ Name changes.
    ▪ Training programs.
    ▪ Enhancements to initial applications and renewals.
    ▪ Quiz on California state law integrated into PERL2.
  o Notes from Q&A:
    ▪ We do not have a standard timeline to inquiries. Typically it takes 2-3 days to resolve a key demographic changes inquiry while it may take up to 5-7 days to resolve a more technical inquiry.
    ▪ Renewal notices are sent out 60 days in advance and are not required to renew online; individuals can go to the website directly.
    ▪ LFS is still processing paper applications. Processing time depends on the individual application, but is ideally 30-45 days.
• ELLFS (Nga Tran)
  o Soft launch
- Allows for an opportunity to thoroughly test the system and fix any issues before going live.
- Internal users will start using ELLFS in June.
- External users will start using ELLFS in August.
  - Beta testing
    - Allows volunteers to test the system for functionality and usability
    - Will conduct beta testing around June.
    - Email Nga Tran at nga.tran@cdph.ca.gov if additional clinical laboratories want to volunteer.

**Legislation Update** (Mary Wogec)
- **AB 613 (Total Protein Refractometer Testing)**
  - Would authorize people who have specified qualifications to perform total protein refractometer testing in licensed plasma collection facilities.
  - Ordered to inactive file on September 5, 2017.
- **AB 2281 (Medical Laboratory Technicians)**
  - Would expand the work scope of MLTs to include blood smear reviews, microscopic urinalysis, and blood typing of moderate complexity.
  - Introduced on February 13, 2018.
- **AB 2846 (Organ Transplants) (Watch)**
  - Would improve the effectiveness of organ transplantation for the general public and in minority communities and low-income communities in California.
  - Introduced on February 16, 2018.
- **SB 43 (Anti-microbial Resistant Infection Reporting)**
  - Would require specified acute care hospitals and clinical laboratories to submit a report to the department containing an antibiogram of the facility for the previous year.
  - Introduced on December 15, 2016 (two-year bill).
- **SB 1371 (Occupational Licensing) (Watch)**
  - Would establish and maintain a complete list of all occupational licenses required by the State of California.
  - Introduced on February 16, 2018.

**CLTAC Subcommittee Reports**
- **Regulations** (Lorri Dean-Yoakum)
  - Revised the previously submitted FAQs to clarify lab director responsibilities.
  - Completed MLT FAQs.
  - Sent FAQs to LFS for distribution
- Requested LFS review FAQs before next CLTAC meeting.
- No future meetings are scheduled.
- **California State Auditor (CSA) Audit Response** (Fred Ung)
  - No activity since the last CLTAC.
- **Recruitment and Retention** (Jonathan Bautista)
  - No additional updates.

**CLIA Survey Section Updates** (Donna McCallum)
- CLIA has helped improve the quality of testing in the U.S.
  - Total number of quality deficiencies has decreased approx. 40% from the first laboratory survey to their second and further on subsequent surveys.
  - Similar findings were demonstrated on in the review of the PT data.
    - Initial PT failures were addressed with an educational, rather than punitive, approach by CLIA.

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<tr>
<th>Table 1: CLIA Survey Statistics as of January 2018</th>
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<tr>
<td><strong>State:</strong> California</td>
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<td><strong>Initials</strong></td>
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<td><strong>Recertification Surveys</strong></td>
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<td><strong>Total Initial and Recertification Surveys</strong></td>
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<td><strong>On-site Complaints</strong></td>
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<td><strong>PT Desk Reviews and Sanctions</strong></td>
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<td><strong>Total CLIA Surveys</strong></td>
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- Send all requests for information to the Centers for Medicare and Medicaid Services, Department of Health and Human Services.
- Send all public comments to update existing CLIA regulations no later than 5PM on March 12, 2018. Must refer to file code CMS-3326-NC.
  - Electronic comments ([http://www.regulations.gov](http://www.regulations.gov))
    - Follow the “Submit a comment” instructions.
  - Regular mail
    - Centers for Medicare & Medicaid Services
      Department of Health and Human Services
      Attention: CMS–3326–NC
      P.O. Box 8016
      Baltimore, MD 21244–8016
  - Express or overnight mail
    - Centers for Medicare & Medicaid Services
      Department of Health and Human Services
      Attention: CMS–3326–NC
      Mail Stop C4–26–05
Personnel Licensing Section Updates (Dolapo Afolayan)

- Director’s Program
  - Personnel licensing section conducted its first oral licensing exam.
    - Five laboratory director applications have been approved for licensure.
  - Approved licensure categories:
    - Clinical Cytogeneticist-1
    - Clinical Genetic Molecular Biologist-3
    - Clinical Toxicologist-1

- Continuing Education (CE) Accrediting Agency Program
  - Deadline for monthly CE participant reports will be the 10th of every month (effective March 2018).
  - All monthly reports can be emailed to LFSclsceprovider@cdph.ca.gov.
  - CE Accrediting Agencies not offering CE courses will need to notify LFS.

Tissue and Blood Banks, Biologics, and Cytology Section Updates

- Tissue Bank Updates (Jan Otey)
  - Last month LFS mailed surveillance letters to laboratory directors of all laboratories certified in the subspecialty of cytology.
    - There were 332 laboratories in 2017.
    - LFS has received the faxed replies from over 50% of the labs.
  - LFS licenses over 850 tissue banks
    - Approx. 25% are located out-of-state.
    - LFS has received 14 new tissue bank applications in 2018.
    - Over 100 hospitals are licensed to store and use donor breast milk.
      - Evidence shows that premature infants tend to do much better when given donor breast milk rather than formula until their mother’s own milk becomes available.

- Bacterial Contamination of Apheresis Platelets (Robert Hunter)
  - Bacterial contamination of platelet components is the second most cause of transfusion-related deaths in the U.S.
  - Platelet components are associated with a higher risk of sepsis and related fatality than any other transfusible blood component, principally due to room temperature storage.
  - Safety measures:
    - FDA has approved a pathogen inactivation (PI) system.
• Apheresis platelets treated with this system are known as PI or PRT platelets and can be obtained from certain suppliers.
  ▪ Culture a greater volume of product.
  ▪ Delay inoculation of culture bottles to allow potential pathogens to proliferate.
  ▪ Practice a “safety or release” test prior to transfusion.
  ▪ Use an anaerobic culture bottle in addition to aerobic culture.
  ▪ Pay more attention to the donors themselves.

**On-site Licensing Section Update** (Elsa Eleco)

- Validation inspections
    ▪ Complaint investigations.
    ▪ Different laboratory types.
    ▪ Different specialties and subspecialties.
    ▪ Geographical location—urban and rural areas.
    ▪ Out-of-state (OOS) labs are included.
      - Conducted within 90 days of the Accrediting Organization (AO) inspection.
      - Sample at least 5% of labs with deemed status certificates.
      - Disparity rate of 20%.
      - Proportionate to number of labs under each approved AO.
      - Approx. 1,216 labs inspected by the AOs from May 2015-June 2017.
        ▪ College of American Pathologists (CAP) = approx. 51%.
        ▪ COLA = approx. 25%.
        ▪ Joint Commission = approx. 24%.
    - 43+ trips were included in the travel blanket approval for SFY 18-19.
      ▪ Across 21 states.
      ▪ At least 120 labs.
    - Mostly routine inspections, but last includes validations and complaints.
    - Additional trips will be added as needed.

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

- License Fee Suspension
  - License fee suspension began on January 1, 2018.
  - The fee suspension will be in effect for two years. This means that all currently licensed labs will not be required to pay any renewal fees for the next two years.
  - All labs are still required to send in their annual renewal applications.

**New Business** (Rebecca Rosser)
• Reminder: Next meeting will be on May 25, 2018.

Future Items (Rebecca Rosser)
• Dora Goto moved to close the meeting. Jonathan Bautista seconded.
• Meeting closed at 12:00PM.