CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE (CLTAC)  
Minutes of the Meeting held on December 7, 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  
Robert Footlik, Tim Hamill

California Department of Public Health (CDPH) Staff Participating  
Dolapo Afolayan, Yu-Chen Chang, Karen Demby, Elsa Eleco, Jinong Feng, Tamara Hennessy-Burt, Robert Hunter, Paul Kimsey, Katya Ledin, Ted Lee, Nema Lintag, Yangzhu Long, Donna McCallum, Donald Miyamoto, Greta Nash, Martha Obeso, Jan Otey, Robert Thomas, Armando Tiong, Asraf Tootla, Nga Tran, Hugo von Bernath, Emily Wei, Mary Wogec

Public Members Participating  
Danny Arimboanga, Lisa Broughton, Anna Choi, Denise Driscoll, Diana Dupuy, Nancy Fraize, Lee Hilborne, Brett Holmquist, Carola Howe, Elma Kamari Bidkorpeh, Shiu-Land Kwong, Jamie Marks, Cecilia Mui, Erica Padilla, Cinco Plumb, Rodney Roath, Debbie Wilson-Ferguson

Welcome and General Announcements (Rebecca Rosser)  
- Meeting opened at 9:07AM.
- Rebecca Rosser conducted roll call and determined that a quorum was present.

Approval of September 7, 2018, CLTAC Minutes (Rebecca Rosser)  
- Minor changes were suggested.
- Kathleen Doty proposed to approve meeting minutes as amended. Dora Goto seconded.

Department News (Paul Kimsey)  
- Thanked Southern California Kaiser Permanente for making this videoconference possible.
- Announced the appointment of Charity Dean, MD, MPH, to the position of Assistant Director for the California Department of Public Health.
• Announced the appointment of Heidi Steinecker to the position of Deputy Director of the Center for Health Care Quality.
• Stated that in an effort to improve customer service, LFS will create a call center which will go live December 2018.
• Announced consolidation of public health laboratories.

LFS Update
• Branch Report (Robert Thomas)
  o Announced guest speakers:
    ▪ Tamara Hennessy-Burt from the Division of Communicable Disease Control will discuss CalREDIE.
    ▪ Dr. Richard Bennett will discuss Current CLIA Law and Mohs Micrographic Surgery.
  o Stated that LFS will be monitoring situations where laboratories are not meeting Title 17 Section 2505 laboratory reporting requirements. The goal is to improve compliance with requirements for infectious disease reporting to local health departments.
  o Recognized Aaron Webb, Staff Services Analyst in LFS, for his work on PERL 2.
  o Recognized Rebecca Rosser for her service as CLTAC Chair.
  o Welcomed Jonathan Bautista as the new CLTAC Chair effective January 1, 2019.
• Administrative Items (Ted Lee)
  o Announced creation of call center which will address a need, simplify the current phone tree, and add more staff.
  o There are no vacancies in the Examiner classification.
  o The creation of the call center will impact the budget.

Electronic Updates
• ELLFS (Nga Tran)
  o Completed fourth user acceptance testing two weeks ago. Internal users were able to test system functionalities such as:
    ▪ Creating new applications using sample applications.
    ▪ Renewing applications.
    ▪ Making online payments.
    ▪ Reviewing and approving submitted applications.
  o First beta testing with external participants is scheduled for December 18, 2018.
  o Questions: Nga.Tran@cdph.ca.gov.
• **Certificates, Licenses, Permits and Registrations Portal (CLPR) (Dolapo Afolayan)**
  o Overview of CLPR:
    ▪ Formerly named Utility Profile Management (UPM) portal
    ▪ Central hub for electronic CDPH programs
    ▪ Has key demographic functionality
    ▪ Is the direct log-in to the PERL landing page
    ▪ Provides access to PERL
  o Future releases:
    ▪ Integration of quiz on California state law into PERL
    ▪ Redesign of PERL landing page
    ▪ Addition of continuing education providers
    ▪ Enhancements to initial applications and renewals
  o Questions: Aaron.Webb@cdph.ca.gov

• **ArcGIS (Hugo von Bernath)**
  o Live demonstration of ArcGIS
    ▪ Illustrates the active laboratories in California
    ▪ Provides information about each facility
  o Questions: Hugo.vonBernath@cdph.ca.gov

**Legislation Update** (Mary Wogec)

• **Legislation Summary – Bills Signed into Law in 2018**
  o **AB 613 (Total Protein Refractometer Testing)**
    ▪ Would authorize people who have specified qualifications to perform total protein refractometer testing in licensed plasma collection facilities.
    ▪ Effective for a two-year trial period (2019-2021).
    ▪ Introduced on February 14, 2017.
    ▪ Effective on January 1, 2019.
  o **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.
    ▪ Effective on January 1, 2019.
  o **AB 2684 (Parent Child Relationship)**
    ▪ Revises the presumptions and procedures for establishing and challenging parentage based on a genetic or nongenetic relationship with a child and requires gamete banks to collect and maintain records of donor information for release to children born of the donations.
- Introduced on February 15, 2018.
- Effective on January 1, 2019.

- **AB 2281 (Irwin)**
  - MLTs CAN perform:
    - Moderate-complexity microscopic urinalysis
    - Moderate-complexity blood typing, such as automated ABO/Rh testing and antibody screen testing
    - Moderate-complexity blood smear reviews, except for manual leukocyte differentials
  - MLTs CANNOT perform:
    - Manual leukocyte differentials of any complexity
    - Any high-complexity testing

**CLTAC Subcommittee Reports**

- **Public Health Lab Regulations (Zenda Berrada)**
  - The last call of the Subcommittee was November 29, 2018, and the next call is December 20, 2018.
  - The subcommittee has completed its review and is compiling recommendations into a report format that is on schedule to be submitted to the CLTAC at the beginning of February 2019 for discussion at the March 2019 CLTAC meeting.
  - The CLTAC subcommittee chair will present significant recommendations to one of the main stakeholders impacted by any regulatory change, the California Association of Public Health Laboratory Directors (CAPHL), at the December 14, 2018 business meeting.
  - Thank you to Rebecca Rosser and our partners at LFS (Dolapo Afolayan, Mary Wogec, Robert Thomas, and Nema Lintag) for their continued participation in the subcommittee.

- **Regulations Subcommittee Documents (Shiu-Land Kwong)**
  - Subcommittee reconvened since the previous CLTAC meeting to revise the Laboratory Director Fact Sheet based on feedback received from CLTAC and LFS.
  - Revision includes the following:
    - Question 14 on page 6 of 11: The definition of “nominal director” from public resources has been deleted.
    - Note 2 on page 9 of 11: Sentences that do not adequately address compliance with California lab law have been deleted.
    - Note 3 on page 9 of 11: CDPH is encouraged either to define the term “co-director” in future regulations proposal, or discontinue its use.
    - The duplicate question 15 has been renumbered as question 16.
Question 16 on page 10 of 11: Addition of a paragraph to require lab director’s compliance with both CLIA and California law. Examples of California requirements are included in the paragraph, such as lab director’s name must be on lab report, and compliance with disease reporting requirements under Title 17 CCR section 2505.

- Shiu-Land Kwong submitted revised Laboratory Director Fact Sheet to the full CLTAC board for approval.
- CLTAC board approved the revised document.

**CalREDIE** (Tamara Hennessy-Burt)

- California Reportable Disease Information Exchange (CalREDIE) is California’s integrated, secure, electronic system that CDPH has implemented for electronic communicable disease reporting and surveillance.
- CalREDIE has improved the efficiency of surveillance activities and the early detection of public health events through the collection of complete and timely surveillance information on a state wide basis.
  - Local Health Departments (LHD) and the State Health Department have access to disease and laboratory reports in near real-time for disease surveillance, public health investigation, and case management activities.
  - General communicable diseases, including vaccine-preventable diseases, tuberculosis, sexually transmitted diseases, pesticide illness, binational infectious disease cases, and Parkinson’s Disease are all reported in CalREDIE.
    - Currently working with HIV/AIDS colleagues to implement HIV reporting in CalREDIE.
- CalREDIE application is composed of the following modules:
  - Electronic lab reporting (ELR) is the electronic transmission of laboratory reports that identify a notifiable condition from laboratories to public health.
    - ELR replaces traditional paper-based methods of laboratory reporting for many reportable conditions in jurisdictions using CalREDIE.
  - Provider portal (PP) provides secure access for healthcare providers to electronically submit reports of communicable diseases directly to the LHDs.
  - Altering and notifications (ARNOLD) allows users to sign up to receive email alerts for cases and outbreaks that have been entered or updated in CalREDIE.
  - Data warehouse (DW)
- Technical configuration:
  - HL7 is the message format that ELR is sent in.
LOINC is a standard numeric coding system used in the electronic exchange of health information and with HL7. The LOINC coding system is used to classify the laboratory test used to directly or indirectly identify an organism associated with an infection. The LOINC coding system ensures that all laboratories are using the same name for each type of test.

SNOMED is a standard numeric coding system used in the electronic exchange of health information and with HL7. The SNOMED coding system is used to classify the organism or result.

Local codes
- Laboratories often use an internal coding system for test names, organisms and results. In order to exchange data electronically, laboratories must map their internal coding system (local codes) to the standard LOINC and SNOMED codes included in the ELR message. The local codes are often displayed along with the standard LOINC and SNOMED codes in CalREDIE.

transport methods: SOAP and SFTP
- CDPH HIE (health information exchange) Gateway
  - Secure HIE web application developed by CDPH.
  - Administrative tool that allows for public health data exchange management for specific reportable conditions.
  - [http://hie.cdph.ca.gov/](http://hie.cdph.ca.gov/)

Onboarding process
- Prerequisite:
  - Identify the reportable conditions in the submitter’s test compendium.
  - Map the reportable tests, results, and specimens to applicable LOINC and SNOMED codes, including mapping and converting of any local codes.

Registration/enrollment:
- Register at CDPH HIE Gateway and complete the enrollment process.
- Receive instructions and appropriate credentials to submit lab reports to CalREDIE.

Initiate connectivity:
- Work with CalREDIE staff to establish connectivity using SOAP transport method or SFTP connection, as preferred.

Validate message structure:
- Construct filters to ensure that only reportable lab findings are sent to CDPH.
- Ensure that the LIMS produces a message compliant with the HL7 ELR v.2.5.1.
- Perform structural testing for messages without PHI using the developer tool.
  - Validate content and user acceptance testing (UAT):
    - Work with CalREDIE staff to ensure that message content and logical filters are properly formatted to send complete reportable results.
    - Dual report through ELR and traditional means, so that during UAT public health staff may correlate the traditional reports to the ELRs.
  - Transition to production:
    - Upon successful UAT, CDPH will transition a submitter’s ELR feed to Production. This marks the transition to ELR maintenance.
    - Consistently submit production data. CDPH will work with the submitter and the local health jurisdiction to facilitate the decision to cease paper reporting.

**Current CLIA Law and Mohs Micrographic Surgery** (Richard Bennett)
- “Mohs Micrographic Surgery (MMS) is both a surgical and pathologic technique for [systematic] removal of skin cancers performed by dermatologists.”
- MMS requires staining and cutting frozen sections. MMS is usually performed by dermatologists and it takes six to twelve months to learn how to interpret the frozen slides.
- Dermatology residents have limited experience in regards to MMS; there is a one-year post-residency fellowship available to those specializing in MMS.
- The number of Mohs cases per year has drastically increased since 1992.
- In Florida and California the number of Mohs cases performed by fellowship and non-fellowship trained dermatologists are very close.
- Mobile Mohs have a quota which must be met and may lead to many small cases that do not require Mohs surgery.

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
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| - Frozen sections and laboratory review done by experienced Mohs surgeons. CLIA inspections not done by experienced physicians.  
  - Granted equivalency to CAP.  
  - Can assess laboratory requirements unique to Mohs surgery laboratories. | - Burdensome regulation and fees.  
  - Would eliminate availability of Mohs surgery by random labs unable to comply with regulations.  
  - Unsubstantiated that quality would be elevated by requirements and inspection. |
- Can collect and analyze data from laboratories.
- Unique laboratory requirements and fees would ensure that laboratories were run by dedicated Mohs surgeons.
- Increase quality of slide creation and interpretation.
- Creates a unique CLIA number.
- Would decrease unnecessary Mohs surgery.

- Motion for the CLTAC committee to support the creation of a Mohs surgery laboratory inspection entity, similar to the CAP inspection entity, was denied.

**Tissue and Blood Banks, Biologics, and Cytology Section Update** (Martha Obeso)
- No update.

**Laboratory Licensing and Registration Section Update** (Martha Obeso)
- 2018 personnel changes:
  - New hires:
    - 1 Supervising Program Technician II
    - 1 Program Technician II
    - 1 Examiner I
  - Two promotions
  - Four staff left due to promotions, retirement, etc.
- Introduced Yu-Chen Chang as an Examiner I, effective October 15, 2018.
- Introduced Emily Wei as an Associate Governmental Program Analyst, effective November 30, 2018.

**CLIA Survey Section Update** (Donna McCallum)
- Please see the handout for “CLIA Top 10 Deficiencies in the Nation for Moderate and High Complexity Laboratories as of October 2018.”
- Multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity. They are not to be referred to as “shared laboratories.”
- Multiple laboratories that operate at the same physical location and use the same testing personnel and equipment must meet the following conditions:
  - All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently.
The hours of operation must be specified for each laboratory.
The hours of operation for each laboratory must be separate and distinct.
The times of testing cannot overlap and cannot be simultaneous.

- CLIA Survey Statistics as of September 2018

<table>
<thead>
<tr>
<th>State: California</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Initials</td>
<td>58</td>
</tr>
<tr>
<td>Recertification Surveys</td>
<td>571</td>
</tr>
<tr>
<td>Total Initial and Recertification Surveys</td>
<td>629</td>
</tr>
<tr>
<td>Validation Surveys – Accredited Labs</td>
<td>20</td>
</tr>
<tr>
<td>Onsite follow ups</td>
<td>3</td>
</tr>
<tr>
<td>Onsite complaints</td>
<td>3</td>
</tr>
<tr>
<td>PT desk reviews &amp; sanctions</td>
<td>34</td>
</tr>
<tr>
<td>Total CLIA Surveys</td>
<td>689</td>
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**On-site Licensing Section Update** (Elsa Eleco)
- Introduced Jinong Feng as an Examiner I, effective September 10, 2018.
- BPC Section 650 Update (Asraf Tootla)
  - Examples of violations:
    - The majority of the 650 violations found during 2017 surveys were a result of a laboratory-employed phlebotomist drawing blood at a physician’s office exclusively.
    - Another example of a violation was the physician’s office stated they were open to public. However, no visible signage was posted in the office. Surveyors were informed that the phlebotomist was employed by the laboratory company and most of the samples were sent to the employing lab for testing. The laboratory also provided the physician’s office with supplies and there was no rental agreement in place for the laboratory to use the space.
    - The physician and the laboratory company were issued a report to halt the operation immediately.
  - Random surveys have begun and LFS has developed a criteria for performing random inducement surveys.

**Personnel Licensing Section (PLS) Update** (Dolapo Afolayan)
- Chronology of application review process:
  - Prior to 2004, PLS used a paper-based system.
  - 2004-2005, PLS used the Client Management & Administration System (CMAS).
  - Effective November 14, 2017, PLS has been using PERL 2.
Electronic Personnel licensing systems

<table>
<thead>
<tr>
<th>PERL 1</th>
<th>PERL 2</th>
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<tr>
<td>• Version of PEGA platform designed for the electronic review and approval of initial applications</td>
<td>• Version of PEGA platform designed for the electronic review and approval of both initial and renewal applications</td>
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<tr>
<td>• Renewal applications are manually reviewed, thus longer approval timeframe</td>
<td>• Renewal applications are automatically reviewed, thus shorter approval timeframe</td>
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<tr>
<td></td>
<td>• Renewal applications are randomly selected for quality assurance audit</td>
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**New Business** (Rebecca Rosser)

- **Meeting Dates for 2019**
  - March 1, 2019
  - June 7, 2019
  - September 6, 2019
  - December 6, 2019

**Future Items** (Rebecca Rosser)

- Meeting closed at 12:28pm.