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

Former CLTAC members participating
Lori Dean-Yoakum, Robert Footlik, Carmen Maldonado

CDPH staff participating
Dana Botello, Paul Duffey, Diana Dupuy, Elsa Eleco, Shohreh Ershadi, Ron Harkey, Bob Hunter, Paul Kimsey, Ted Lee, Donna McCallum, Don Miyamoto, Kim Nachazel, Martha Obeso, Lynnea Rappe, Nai Saechao, Robert Thomas, Nga Tran, Mary Wogec

Public members participating
Michael Aiden, Charity Avena, Marian Castillo, Anna Choi, Amy Daniels, Behnaz Dardashti, Ilene Dickman, Denise Driscoll, Leah Ferrier, Kathleen Fitzgerald, Nancy Fraize, Albert Gold, David Gomez, Brett Holmquist, Carola Howe, Cynthia Hurst, Brian Kim, Julie Kingery, Margaret Knapp, Shiu-Land Kwong, Lois Langs, Valeria Ng, Michelle Paganini, Rosandra Parada, Gabriel Pineda, Shahrzad Radahd, Rodney Roath, Ozzie Santiago, Audrey Soulette, Tom Tempske, Phyllis Walker, Maureen Weber

Welcome and general announcements
The meeting was called to order by CLTAC Chairperson Rebecca Rosser. Ms. Rosser thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Rosser conducted a roll call of CLTAC members and other participants, and noted that a quorum was present.

Approval of minutes
Dora Goto submitted corrections to the minutes. She corrected the spelling of Barbara Brunell’s name on page one. She changed the word “appointed” to “appointment” She changed “Mr. Kruthoff” to “Ms. Kruthoff” on page eight.

Gabriel Pineda asked if a public member has access to the meeting minutes. Robert Thomas replied that the minutes are posted on the LFS website. They are also sent through e-mail. Please send Mr. Thomas an email at Robert.Thomas@cdph.ca.gov to be placed on the mailing list.

Jon Bautista moved to approve the December 2, 2016, meeting minutes as amended;
Dora Goto seconded. The motion passed without opposition.

Department Update
Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), thanked Kaiser-Permanente for their assistance with the video conference. He also thanked Ms. Rosser for taking on the role of the Chair.

Dr. Kimsey said that CLTAC is discussing sections of the Health and Safety Code (H&SC) with the department, some of them dating to the early 1900s. He encouraged the CLTAC Bylaws Subcommittee to consider adding a public health microbiologist to the CLTAC board.

Dr. Kimsey also addressed section 650 of the Business and Professions Code (B&PC). LFS has posted educational information on inducements in violation of section 650 on the website and has hired staff to oversee compliance with this section of the B&PC. He has proposed a discussion of the Department’s enforcement of 650 as an agenda item at the next CLTAC meeting.

Dr. Kimsey reported that the Department has been working for the past several months on improving the CDPH website to modernize it and make it ADA compliant. The soft launch will begin April 17, 2017. CDPH is requesting feedback on the new website, as the Department views the website as a major avenue of communication with the public, and LFS has been working hard to improve its web pages.

A question was raised regarding the availability of the current website once the new website goes live.

Dr. Kimsey responded it is his understanding that when the hard launch takes place on May 1, 2017, the old website will still be available via the archives until October 2017. New information will be posted to the new website. If old URLs are used in a search engine they will go to the archived website or to the new website, where a link to the archives is available.

Robert Footlik commented that section 650 is a statute and asked if the department had adopted regulations to that statute.

Dr. Kimsey asked Mr. Thomas to comment, and Mr. Thomas said that CDPH has enforcement authority in this area according to house counsel, and regulations are not necessary for enforcement of section 650.

Dr. Kimsey responded that that sounded correct to him but that CDPH will provide further clarification of the inducement issues at the next meeting.

LFS Update

Branch Report
Robert Thomas, LFS Branch Chief, stated that LFS is pleased that Rebecca Rosser was nominated and has accepted the position of Chair of the CLTAC. He reported that she is
the Education and Development Consultant at Kaiser Permanente Regional Reference Laboratories in North Hollywood, California, and in this capacity, she is the Education Coordinator for the California State University Dominguez Hills CLS Program and the Administrator for the LFS-approved accrediting agency. She earned a bachelor's degree in clinical science from San Francisco State University, a master's degree in healthcare management from California State University Los Angeles, and an MBA from California Lutheran University. He noted that Ms. Rosser has been an active member of the Clinical Laboratory Management Association at both out of state and national levels, and is an active member of the California Association for Medical Laboratory Technology (CAMLT), for which she has served as President in past years. He added that she has also lectured as part-time faculty at California State University L.A., California State University Dominguez Hills, and at seminars both locally and nationally. She has been active on the CLTAC subcommittee on regulations and has been an exemplary, helpful, enthusiastic, kind, and insightful participant in CLTAC over many years. He stated that this is Ms. Rosser’s first meeting as the Chair of CLTAC, and CLTAC is very happy to welcome her.

Mr. Thomas stated that at the last meeting in December, he announced that he would be recognizing Rhonda Becker for her services as the CLTAC Chair and her previous services with CLTAC. He reported that Ms. Becker told him she would be unavailable to attend the March meeting, so he will defer that to the next meeting to give her proper recognition.

Mr. Thomas reported that since the last CLTAC meeting, LFS has appointed Ted Lee as the Staff Services Manager I over the LFS Administrative Unit. Mr. Lee has a Master’s Degree in Business and a strong budget background and has consulted with OSPHLD on the development of budgetary tracking.

Mr. Thomas stated that LFS continues to address the findings of the California State Audit. LFS continues to work with the OSPHLD on program enhancements. Mr. Thomas and the LFS section chiefs have begun a series of meetings to formulate a strategic plan of evaluating LFS’s mission goals and providing recommendations for review of CDPH’s upper management.

Mr. Thomas said that LFS has a goal of inspecting all licensed laboratories under its oversight by September 2017, including in-state laboratories and out-of-state laboratories.

Mr. Thomas stated that LFS expects to roll out new electronic systems, mainly personnel license renewals, later this year. He noted that although it is still in the early stages, LFS is moving ahead on electronic laboratory licensing and registration for facilities.

Mr. Thomas reported that LFS is also working to revise all of its policies and procedures.

Mr. Thomas reported LFS is working to present a comprehensive report on data for all of LFS’ sections in order to be more transparent, but the report is not ready to be released at this meeting. Section chiefs will report on data in their individual presentations.
Administrative Items
Ted Lee, LFS Staff Services Manager I, reported that he is assuming a lot of the responsibility formerly assumed by Ellen Yasumura, who was the Assistant Branch Chief. Mr. Lee thanked everyone for their support while he learns his position.

Mr. Lee stated that LFS is hiring to fill vacancies both in Los Angeles and Richmond.

Mr. Lee stated that LFS has hired a personnel liaison, Dolly Luong, who has been working to post vacant positions and schedule interviews.

Mr. Lee reported on the strategic planning process. LFS scheduled a series of five meetings, which will run through the first week of May. Mr. Lee said that he and Mr. Thomas will be able to report at the next CLTAC meeting of the progress of these efforts and the direction LFS will be charting.

Mr. Lee stated that if anyone has any questions or feedback on the website please let him know via email at Ted.Lee@cdph.ca.gov.

Legislation Update
Mary Wogec, LFS Associate Governmental Program Analyst (AGPA), reported on current legislation assigned to LFS for analysis. She noted that unless the bill is sponsored by the Department, LFS does not take a position on assigned legislation. LFS is charged with making an internal recommendation that is sent through the CDPH Office of Legislative and Governmental Affairs to the legislators and the governor, but LFS does not share that recommendation outside of the Department. She stated that her report conveys information available to the general public from the website http://leginfo.legislature.ca.gov, which gives information about all legislation for the current season as well as past seasons.

Four bills have been assigned to LFS for analysis:

1. Assembly Bill 613
   This bill concerns total protein refractometer testing. The bill was introduced on February 14, 2017, authored by Assembly Member Adrin Nazarian and coauthored by Assembly Members Cristina Garcia and Jimmy Gomez.

   The bill states the intent of the legislature to enact legislation relating to authorizing a person with specified qualifications to perform a total protein refractometer test using an automatic button-operated total protein refractometer with additional readouts in a licensed plasma collection facility in California under specified circumstances. She commented that some people may remember that in 2015 AB 757 dealt with this topic, and LFS expects that AB 613 will probably include some of the same material. There are no letters of support or opposition on record.

2. Assembly Bill 658
   This bill concerns clinical laboratory licensing fees. The bill was introduced on February 14, 2017, authored by Assembly Member Marie Waldron.
The bill amends, repeals, and adds to Section 1300.1 of the Business and Professions Code. It would temporarily suspend the annual renewal fee for clinical laboratory licenses until January 1, 2020, so it is a two-year suspension of lab renewal license fees. The bill is sponsored by the California Clinical Laboratory Association (CCLA), and at this point there is no opposition on record.

3. Senate Bill 43:
This bill concerns antimicrobial resistance reporting. The bill was introduced on December 15, 2016, and was amended on January 31, 2017, authored by Senator Jerry Hill and coauthored by Senator Nancy Skinner, Assembly Member Cristina Garcia, and Assembly Member Brian Maienschein.

The bill amends Sections 102825 and 102875 and adds Part 5.5 to Division 105 of the Health and Safety Code. Currently there are reporting requirements for the specified diseases or conditions, and this bill would add a requirement that acute care hospitals and clinical laboratories submit an annual report to the Department containing an antibiogram of the specific facility for the previous year and require the Department to publish and post on its website an annual report based on the data reported by hospitals and clinical laboratories and also death certificates when a death is attributed to antimicrobial-resistant infections and will specify a list of those. LFS is one of three programs in the Department assigned to this bill. There are no letters of support or opposition on record.

4. Senate Bill 608:
This bill concerns narcotic treatment programs. The bill was introduced on February 1, 2017, authored by Senator Ed Hernandez. Currently it is a “spot bill,” which means that it is a kind of placeholder, and text will be filled in at a later date. LFS will probably have more information on this bill by the next CLTAC meeting.

Mr. Thomas clarified that AB 658 does not waive initial laboratory license fees, or any laboratory registration fees; it only affects license renewal fees. He also noted that if the bill passes laboratories would still be required to apply for renewal and would be subject to inspection by the Department, complaint investigations, and so forth.

**Online Systems Enhancements Update**

**Electronic Content Management (ECM)**

Kim Nachazel, LFS Research Program Specialist II, reported on behalf of Sarah Rutschmann, LFS AGPA, that the ECM project is nearly implemented. LFS staff has been trained to use scanners to manage the data inventory checkpoints. The ECM project is expected to be fully implemented by April 1, 2017.

**Personnel Licensing (PERL)**
Ms. Nachazel noted that the first phase of PERL 2 is currently scheduled for user acceptance testing by LFS the second week of April.

**Electronic Laboratory Licensing and Registration for Facilities (ELLFS)**
Nga Tran, LFS AGPA, reported that LFS has been working with the Project Management Office to capture the system requirements for licensing and registration as part of the groundwork for the ELLFS project.

Ms. Tran stated that LFS hopes to begin programming the system in August 2017. This system will result in a reduction of paper documents and streamline the submission and processing of applications for laboratory licensing and registration.

**CLTAC Subcommittee Reports**

**California State Auditor (CSA) Audit Response**
Fred Ung, Subcommittee Chair, reported that his CSA Audit Subcommittee has nothing to report at this time.

**Recruitment and Retention**
Jonathan Bautista, Subcommittee Chair, stated that the Recruitment and Retention Subcommittee is reviewing Examiner job descriptions with the focus of expanding the candidate pool for those positions. He stated that he will have a report at the next meeting of the progress.

**Regulations**
Rebecca Rosser resigned as Chair of the Regulations Subcommittee. The new Chair is Lorri Dean-Yoakum. The Subcommittee has developed FAQs for analytic testing and waived testing which will be submitted to the CLTAC for approval at the June meeting.

Ms. Dean-Yoakum reported that the Subcommittee was asked to suggest a definition for high school equivalency, and that definition will also be submitted at the June meeting.

Ms. Dean-Yoakum reported a summary of what they have accomplished since the Subcommittee began:

1. The Subcommittee has submitted FAQs for laboratory directors, phlebotomy, and unlicensed personnel.

2. The Subcommittee was asked to pose a definition for pre-analytic, analytic, and post-analytic testing, and they did. She stated that they are waiting for feedback from the Department.

**CLIA Survey Section Update**
Donna McCallum, LFS Section Chief, reported that for the fiscal year of 2015-16 her section completed 831 surveys. For this fiscal year the total is about 58 initial surveys, 300 recertification surveys, and 29 validation surveys. The total for out of condition, standard, PT, or condition level surveys is 156.

**Personnel Licensing Section Update**
Shohreh Ershadi, LFS Section Chief, reported that the personnel licensing section has cleared its backlog and all licensing areas are currently up to date. Clinical Laboratory Scientist (CLS) applications are being accepted at a steady rate, with 226 applications in the first quarter, of which 185 were approved. There were fewer applications for Medical
Laboratory Technicians. Certification of Public Health Microbiologists (PHM) was recently reassigned from the facilities licensing section to the personnel licensing section. The number of applications for PHMs has increased. The renewals section is the busiest section, with around 6,000 applications processed in the first quarter.

In response to questions, there was a discussion about applications from people who obtained education outside of the United States and about personnel training and examination requirements.

A question was raised about a list of licensed personnel available for purchase through the website.

Mr. Thomas stated that the nature of the list and the process for obtaining it have changed over time. He said that he would report on the next meeting on the personnel list currently available and the process for purchase.

Tissue Bank, Cytology, Blood Banks, and Biologics Section Update
Ronald Harkey, LFS Section Chief, reported on applications and renewals for his section and discussed complaint investigations. He also discussed the details of blood bank applications, which can be very complicated. He reported that his section is working on a regulation package to ensure coordination with American Association of Tissue Bank standards.

Facility Licensing Section Update
Martha Obeso, LFS Section Chief, reported that she will not be reporting the statistics of the facility license and registration section. She reported that her section is working towards developing new database software, which will allow her to present her section’s data in a more comprehensive form. She hopes to present this report for the CLTAC next meeting.

Ms. Obeso reported positions in her section are rapidly being filled. Three new Program Technician positions were recently filled and two new Examiners were hired.

On-Site Licensing Section Update
Elsa Eleco, LFS Section Chief, reported that she is confident that her inspectors will complete their survey responsibilities for in-state and out-of-state laboratories by June 30, 2017. She noted that the department inspectors are responsible for roughly five percent of California licensed laboratories. Department-approved accrediting organizations are responsible for inspecting ninety-five percent of California laboratories. She stated that the accrediting organizations are on target to complete their inspections.

Ms. Eleco reported LFS completed 181 in-state surveys for fiscal year 2015-16, and for the current fiscal year, about 35 surveys have been completed, which is at 100%.

Ms. Eleco stated that her Section is working on a plan to complete more out-of-state surveys in the current fiscal year and is hopeful it will complete 100%. She explained that for the current fiscal year 94 out-of-state surveys are scheduled, with the goal of completing 100% by September 30, 2017.
In response to questions, Ms. Eleco discussed Department-approved accrediting organizations.

**New Business**

**CLTAC Bylaws Subcommittee**

Rebecca Rosser, CLTAC Chair, reported that a CLTAC Bylaws Subcommittee had been formed and Lee Hilborne had volunteered as one of the members. She stated that they are looking for more volunteers to become part of this subcommittee. Lorri Dean-Yoakum and Kathleen Doty volunteered. Ms. Rosser asked people to let her know if they were interested.

**Future Items**

Ms. Rosser asked for suggestions for future items on the agenda from members of the CLTAC Committee.

Dora Goto requested further discussion of the report on MLTs produced by UCSF and the Healthcare Laboratory Workforce Initiative (HLWI).

Ms. Rosser asked Ms. Goto if she could provide LFS with contact information and Ms. Goto responded that she would forward the information.

Ms. Rosser agreed to include the HLWI in the next meeting’s agenda.

**Next Meeting**

Ms. Rosser stated that the CLTAC June meeting will be held on May 26, 2016.

**Adjournment**

Dora Goto moved to adjourn, and Marjorie Braasch seconded the motion. The meeting adjourned at 12:18 p.m.