

Clinical Laboratory Technology Advisory Committee
Minutes of the Meeting held on March 4, 2016
Meeting held by videoconference from CDPH Richmond campus,
KP Regional Laboratory, North Hollywood, and
Telephone Bridge Line

CLTAC members participating

Marjorie Braasch, Rhonda Becker, Patricia Dadone, Dan Dominguez, William Gardner, John Geisse, Lee Hilborne, Dan Leighton, Anthony Mills, Robert Parada, Rebecca Rosser, Lu Song, Fred Ung, Kathleen Doty,

Former CLTAC members participating

Lorri Dean-Yoakum, Imre Fischer, Robert Footlik, Carmen Maldonado

CDPH staff participating

Zahwa Amad, Alan Ankerstar, Elsa Eleco, Ron Harkey, Robert Hunter, Bridget Jones, Paul Kimsey, Donna McCallum, Desiri Moret-Blyden, Don Miyamoto, Tammy Pahland, Nai Saechao, Robert Thomas, Kathy Williams, Mary Wogec, Ellen Yasumura

Public members participating

Michael Aidan, Cloe Basilo, Barbara Brunelle, Marian Castillo, Irene Chen, Anna Choi, Amy Daniels, Behnaz Dardashti, Nancy Freys, Karen Fuller, Gus Gaona, Dora Goto, Brett Holmquist, Matthew Jones, Shiu-Land Kwong, Julie Kingery, Jamie Marks, Valerie Ng, Erica Padilla, Laura Perry, Rodney Roath, Ozzy Santiago, Christine Vernusky, Phyllis Walker, Maureen Webber, Deborah Wilson-Ferguson, Kathy Yanoka, Tammy Zinsmeister

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Rhonda Becker. Ms. Becker thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Becker amended the agenda to include the approval of the December 4, 2016, minutes. She also noted that a change in the order of some items would be needed to accommodate presenters who could not be available for the entire meeting.

Ms. Becker conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was present for the meeting.

Approval of minutes

Robert Hunter noted a change to page 13, in the report on Tissue Banking and Biologics, "he reiterated that ... in reference to the Paul Gann Act."

Lee Hilborne motioned to approve the minutes as amended, John Geisse seconded the motion. The motion passed.

Department update

Paul Kimsey, Director of the Office of the State Public Health Laboratory Director (OSPHLD), reported that the Department was dealing with issues associated with Zika virus and directed those interested in finding out more to the Department's website.

He reported that the Division of Communicable Disease Control (DCDC) wished to speak to the CLTAC about the Electronic Laboratory Reporting system, which they have implemented on a state-wide basis for reporting certain communicable diseases. DCDC's Division Chief, James Watt, MD, would like to update the CLTAC and get its input on the system.

He commented that the CDPH Director's confirmation hearing, which occurred in February, seemed to go well.

He reported that he participated in a hearing of the State Senate Budget Fiscal Review Subcommittee number 3. Laboratory Field Services (LFS) California State Auditor's (CSA) report was on that Subcommittee's agenda. He attended the meeting and presented an update on the CSA audit. On the handout provided to the CLTAC are the questions asked of the Department by the Subcommittee. The six month progress report was also due the following week, which was reported to be on track.

Answering a question, he noted that it was the first time the Department had reported to the Subcommittee about the progress on the audit and timeframes, and that the Department was taking it seriously. The Subcommittee had reiterated that the audit was serious and also pointed out that there was legislation—although they did not get into the details of the legislation.

He noted that the legislative season was just beginning and the Department would keep the CLTAC updated, but new bills were still coming in and more information would be available for the June meeting.

Introduction of new members

Rhonda Becker introduced and welcomed three new members, Lu Song from the American Association of Clinical Chemists, Danilo Dominguez from the Philippine American Medical Technologists, and William Gardner from the CCLA.

Legal update

Tammy Pahland, House Counsel for LFS, reported that the Regulation Process Team met in February to begin the process of starting tissue bank regulations. It was an informative meeting and the Regulations Subcommittee will be included in some of those processes.

Regarding the CLIA Crosswalk, she reported that three documents were provided to the CLTAC for the meeting to give an overview and background, expanded spreadsheet and two page document that had previously been discussed, and a 28 page document on the revisions and documentation of the Crosswalk. Although there would not be a vote, there could be a discussion on the items.

Ms. Becker noted that the CLTAC would skip ahead on the agenda to item #8 and discuss the Crosswalk.

Kathy Williams, Facility Licensing, Section Chief, noted that she hoped that everyone had the opportunity to read over the documents. She thanked Ms. Pahland and her team for their work on the Crosswalk and for breaking out items in the documents. There were some changes in the stringency requirements, and those are colored red in the documents.

Ms. Becker reported she was happy and appreciative for the thorough and detailed report as the CLTAC had wanted specific citations and justifications for the actions to be taken, and she felt that was fulfilled. She noted a couple of typos.

She noted that in many fields in the final column of the chart, there was a note, “added”, and asked regarding item #9 on the third page, which said “same determination” instead of “added”.

Replying to Ms. Becker’s question, Ms. Williams said “same determination” refers to what was originally discussed by the CLTAC Subcommittee and during CLTAC meetings—it means that the California and CLIA determinations are the same.

Ms. Pahland thanked Evan Sznol, who had done most of the work on the document, for his work. She noted that the report would need to be published and the Department wanted a more comprehensive report to be published than just the two page chart, even if the report was long.

Ms. Becker noted that she was in agreement on the determinations of stringency. Lee Hilborne noted that he had not yet reviewed the documents, but remembered that there were issues previously. Ms. Becker responded that the new documents were very thorough.

Ms. Becker asked regarding timelines as the document titled “Overview and Background” mentioned that a Department proposed that the CLTAC arrange a phone vote in January, but that it was already March.

Ms. Pahland replied that she would like to give the CLTAC members enough time to review the documents, and the Department would like to have a telephone vote prior to the next meeting in June.

Ms. Becker reported that a vote would be possible well before the next meeting in June. She would send an email and an email vote would be taken.

Ms. Pahland asked if the end of March would be too aggressive. Ms. Becker reported that it would be possible as no others have commented.

Marjorie Braasch asked if it would be possible to share comments on the documents at a later time. Ms. Becker said that if anyone had comments, they could email them to her in following two weeks and she would compile and forward them to the members before the vote would be taken.

Bridget Jones, Attorney in the Office of Legal Services, reported that the personnel regulations package group has been meeting twice a week. The CLTAC had stressed

the importance of this package and she wished to report that the group understood the importance of the package to the regulated community and that the group was making progress.

Dr. Kimsey added that at the Senate Finance Subcommittee meeting, there were two questions about regulations, one about the personnel regulations package and another more general question. He updated the subcommittee on the timeline of the personnel regulations--that the package started in 2008 and went out for comment in 2010; it had received 15,000 comments and the Department had to pull it back. He reported to the Finance Subcommittee that the Department had dedicated two attorneys to writing regulations and they were moving along to the best of their ability.

LFS update

Robert Thomas, Acting Branch Chief of Laboratory Field Services, wanted to take a moment to recognize Rhonda Becker for her recent award from the American Association for Clinical Chemistry for outstanding educational activities. He reported that Ms. Becker had served on the CLTAC since 2013, having been nominated by California Association for Medical Laboratory Technology (CAMLT) and has since been a vital member and partner of the CLTAC. He asked everyone to join him in congratulating her on the award.

Mr. Thomas reported that the official notice announcing that accrediting organizations (AO) are a choice in California had been posted on the LFS website and an order was placed to the Office of State Printing for a mailing to go out to the more than 20,000 laboratories that LFS oversees around March 15, 2016.

This notice informs California licensed or registered clinical laboratories that Section 1223 of the California Business and Professions Code (BPC) requires the California Department of Public Health (CDPH) to approve private non-profit accrediting organizations to inspect laboratories that operate in California or laboratories outside California that process biological specimens originating in California for the purpose of deeming them in compliance with California clinical laboratory law. The statute provides for an inspection process that includes state-based inspection components and determines compliance with federal and state requirements for clinical laboratories.

He reported that LFS has already approved one AO and anticipates approving others that have applied for deeming authority after posting All Clinical Laboratory Letters (ACLL) on its website for comment prior to implementation. ACLLs are a special rule-making process that does not go through the normal regulations process and can be used only for AOs. LFS does not anticipate mailing future ACLL notices; the website postings will serve as notification.

LFS posted the first ACLL notice (16-01) on its website on February 29, 2016. ACLL 16-01 explains deemed status certification comprising two components. This notice also explains that an ACLL from LFS to labs is to address the standards of the component parts. The first ACLL specifies requirements and procedures for a laboratory if it chooses certification of deemed status by a CA approved AO. The second ACLL (16-02) was expected to go out in the two weeks after, and would set requirements that an AO must meet to be approved by the Department to inspect labs, issues certificates of deemed status, and provide continuing oversight to ensure compliance with CA law.

Public comment would be received and considered by the Department for 30 days after its posting on the LFS website (<http://www.cdph.ca.gov/programs/lfs/Pages/AllClinicalLaboratoriesLetters.aspx>). The ACLL would become final 45 days after its initial posting, after which time, it will have the force of regulations. Future ACLLs would be posted in a dedicated section on the main page of the LFS website, under the heading, "Statutes and Regulations."

He noted that as AOs are private organizations and they are not subject to the California Public Records Act (PRA), their application and inspection reports are not subject to PRA requests made of the Department. Any requests for records would need to go directly to the AO.

He reported that he appreciated that the CLTAC had requested that the Department document Crosswalk comparisons as a result of CLTAC Subcommittee meetings prior to the CLTAC voting on the report. This request for written report was made in September 2014 and this item has been the subject of many revisions and discussions. LFS appreciates that the CLTAC was willing to vote on the Crosswalk.

Dr. Hilborne asked if the horizon for additional AOs is about a quarter, 45 days plus 30 days plus time to get it out.

Mr. Thomas replied that the first ACLL was posted on February 29, 2016; and it could be finalized as early as April 14, 2016. The second ACLL would list the oversight requirements of AOs themselves by LFS. The completion of the processes for both could as early as the end of April. LFS has received additional AO applications for deeming authority, and LFS has proceeded to review those applications but approval would not occur until after the second ACLL was posted and the process for that was completed.

Dr. Hilborne surmised that this would be due to the AOs having to address the oversight requirements of the second ACLL.

Mr. Thomas thanked the CLTAC for stepping up and creating three subcommittees as requested by the Department during the December 4, 2015, meeting; the subcommittees had each met at least once and reports would be given later in the meeting.

7. Legislation update

Mr. Thomas introduced Mary Wogec as the legislative coordinator for LFS.

Ms. Wogec reported that there seemed to be an inundation of bills. There was one left-over bill from the previous year, but the others were new.

AB 1774, introduced by Assembly Member Susan Bonilla on February 24, 2016, is 45 pages long. The CLIA 1998 required CMS to regulate and certify clinical laboratories that perform testing on humans. Complaints against individual laboratories are directed to the state. Existing California law also provides for the licensure, registrations, and regulation of clinical labs and lab personnel by the CDPH. Under existing law, the Department inspects clinical laboratories and assesses a fee for licensure and registration of those laboratories. AB 1774 would repeal the laws requiring clinical

laboratories to be licensed and inspected by the department; they would still be licensed and inspected by the Federal program. It would repeal the sections of law that include laboratory licensing fees; the bill also makes changes to the fees for the personnel program, which was not noted in the legislative digest. So far, LFS has not been able to get a fact sheet from ASM Bonilla's office, nor letters of opposition and support, so those cannot be presented.

She reported that it is an extensive bill, it amends 12 sections of the BPC, repeals 15 sections of the BPC, amends one section of the Food and Agriculture Code, two sections of the Health and Safety Code and one section of the Welfare and Institutions Code. LFS expects to do quite a bit of work on the analysis of the bill.

Rhonda Becker asked if questions could be taken as this was a big piece of legislation and was probably in the forefront of people's minds. She asked Ms. Wogec to elaborate on the effects on the personnel licensing program as alluded to in her presentation; and also, if the bill were to pass and there were no longer a facility licensure program, how would the Department harmonize and enforce personnel licensure.

Mr. Thomas replied that as written, the bill would roll back personnel fees to 1983 to 1991 levels and would reduce those fees that LFS would receive below the level needed to run the Personnel Licensing section. The bill would also remove LFS's ability to adjust fees based on the governor's budget, which would also affect personnel licensing fees. Phlebotomy fees would remain intact and unchanged as the code governing those fees was in a different section. Fees for scientists and other categories would be rolled back 84 percent, with an overall reduction in fees of 37 percent, as phlebotomy fees would not be affected.

Dr. Hilborne asked how long it would take to change as LFS had \$12 million in its account.

Mr. Thomas replied that much of that money was encumbered and the bill did not provide expending authority, so he could not give a definitive answer to that question.

Ms. Becker asked how the State would harmonize or enforce the state's personnel regulations if CLIA was the agency overseeing the facilities.

Dr. Kimsey replied that it would be hard to say at that point as the bill was still fairly new; the Department had not gotten to that point. He added that though it was one of the points the Department would need to consider, it was hard to judge. When asked if the bill was born out of the audit, he replied that it was, adding that the Senate Finance Subcommittee hearing agenda pointed out that AB 1774 was in direct response to the audit.

John Geisse commented that some parts of AB 1774 were directly out of Senator Hernandez's bill from two years ago that stripped self-referral for physician owned labs that was voted down and never got out of subcommittee because there were too many interested parties who had physician owned laboratories.

Bob Footlik, former CLTAC Chair, commented that from his perspective, as clinical laboratory facilities and clinical laboratory personnel are intertwined in existing law, AB

1774 would have a profound impact on the career ladder established by AB 940 that was passed the previous year, especially on laboratory directors, not just bioanalysts but also clinical chemists, microbiologists, Ph.D.'s and MD's who are not listed as CLIA directors. Once the facility license is gone, there is no longer any mechanism to establish multiple laboratory directors in California. There would only be the CLIA laboratory director, and anyone who is not listed as that director, who is currently listed as a director on the state facility license, would be eliminated. AB 1774 was much too drastic a response to the audit and while he understood the rationale, he did not think the legislature understood the fallout that would occur as a result.

Dr. Kimsey noted that he appreciated Ms. Wogec's presentation, but that the Department could not talk about its bill analysis.

Marjorie Braasch asked regarding the reduction of personnel fees, especially for the medical laboratory technician license, which was only created in 2002.

Dr. Kimsey replied that the bill did mention there would be a reduction of fees and everyone would need to look at the bill for more details.

Ms. Wogec continued her report with AB 1864, which was introduced on February 10, 2016. The bill dealt with the performance of autopsies in cases of Sudden Infant Death Syndrome (SIDS), the leading cause of death for children under age one. Existing law requires the coroner to perform an autopsy within 24 hours, or as soon as feasible, in any case where an infant has died suddenly and unexpectedly. LFS responded to the assignment by pointing out that the bill did not pertain to its oversight areas; and though there had not been a response, Ms. Wogec anticipated that LFS would not be assigned to the bill.

Ron Harkey, Tissue Bank, Blood Bank, and Biologics Section Chief, agreed, noting that the bill was in relation to coroners, autopsies, and the area of SIDS, none of which LFS is involved in or regulates. No laws which LFS are charged with enforcing require or allow the program oversight over the matters discussed by AB 1864.

Ms. Wogec continued with AB 2179, authored by Assembly Member Mike Gibson, introduced on February 18, 2016. LFS was assigned secondary analysis. Existing law authorizes an HIV counselor who receives specified training and works in specified counseling and testing sites to perform HIV testing and Hepatitis C and combined HIV-HCV tests, including skin punctures for the purpose of blood collection for these tests. The bill would authorize a Hepatitis C counselor who meets specified requirements comparable to the HIV counselor to perform HCV tests in the manner described above with respect to HCV testing by an HIV counselor. It does not have much to do with LFS, so LFS was assigned secondary analysis. She noted that there were no letters of support or opposition or a fact sheet. LFS was only in the beginning stages of analysis, but it had minor interest in the bill as written.

Ms. Wogec continued with SB 622, which became a two-year bill at the end of the last session. The bill was authored by Senator Ed Hernandez, introduced in February 2015, and would amend ten sections of the BPC deleting current requirements under the Optometrists' Practice Act and replacing those specific requirements with a broader requirement that an optometrist refer any patient when a situation or condition occurs

that is beyond the optometrist's scope of practice. It expands the optometrist's scope of practice to allow minor procedures and the use of certain non-surgical techniques after meeting training requirements and demonstration of competency; it allows optometrists to use therapeutic pharmaceutical agents to collect finger prick blood specimens and perform skin tests to diagnose ocular allergies, and would allow them to initiate and administer vaccines for influenza, herpes, and pneumococcus after they meet certain requirements. The bill also proposes a pilot project to expand roles for optometrists in the performance of management and treatment of diabetes, hypertension and hypercholesterolemia. There is considerable support and opposition to the bill. The bill would amend some sections of the BPC, repeal others, and add sections to the BPC. There were many aspects to the bill, and LFS would only analyze those sections that applied to its code.

Dora Goto, representing CAMLT, pointed out two items. First, the bill allowed optometrists to perform capillary collection of blood for glucose testing which they cannot currently perform—CAMLT is neutral on that section. Second, current law provides a finite list of tests that optometrists can order; they are also allowed to be a laboratory director of a laboratory that performs those selected waived tests. The bill would keep the finite list of tests that they can order, but would expand what they may perform to all waived tests. If they cannot order the test, why would they be allowed to perform it? CAMLT is opposed unless the bill returns this second item to existing law.

Ms. Wogec reiterated that LFS could not speak to its position on a bill; while LFS appreciated Ms. Goto's input, she was speaking of CAMLT's position, not that of LFS.

Ms. Wogec continued with SB 1316, authored by Assembly Member Louis Wolk, co-authored by Assembly Member Christina Garcia, introduced February 19, 2016. Existing law requires a tissue bank operating in California to have a current license from CDPH LFS Tissue Bank Section. A tissue bank, as defined by current California law, is a place, establishment, or institution that collects, processes, stores or distributes tissue for transplantation into human beings. "Tissue" includes human bodily fluid, which includes milk; and "transplantation" includes ingestion, so human milk for ingestion by human babies would fall under LFS's law, which is why it was assigned to the Tissue Bank program. The Department has the authority to suspend or revoke a Tissue Bank license, and a violation of any of the provisions is defined as a misdemeanor.

She reported that this bill would define a human milk tissue bank as one that provides financial compensation to a participating mother for procuring human milk for the purpose of human consumption; a participating mother is defined as a mother who is providing her human milk to a human milk tissue bank in exchange for financial compensation. This bill would establish a new category of tissue bank, human milk tissue banks, which buy and sell human milk for human consumption. This bill would require such tissue banks to work with lactation support groups to provide breast feeding education and lactation support for participating mothers and would also prohibit these banks from procuring milk from a mother within her first 180 days post-partum. LFS was just assigned the bill and did not yet have letters of support or opposition.

Dr. Hilborne commented that the 180 day requirement would address the issues that if one were to produce milk for anyone, it should go to one's own child first. Ms. Wogec

concluded, noting that she believed the language was meant to protect mothers from exploitation by the human milk tissue banks.

Ms. Wogec continued with SB 1418, authored by Senator Kathleen Galgiani, introduced February 19, 2016. The bill would change section 1246.5 of the BPC; and as written, the changes would be minor changes of grammar and formatting, not substantive and would not affect the law.

Ms. Wogec reported that an additional bill was received the previous day, AB 2092, introduced on February 29, 2016, submitted by the Committee on Environmental Safety and Toxic Materials. This bill would amend section 105206 of the Health and Safety Code relating to pesticide poisoning. LFS did not get a change to look at it in detail yet, but at a glance, it did not appear that the bill would affect LFS, and LFS would ask for it to be reassigned.

Subcommittee reports

Rhonda Becker reported that the CLTAC was charged at the December 4, 2015, meeting to set up three subcommittees that were created before the end of the holidays; chairs were chosen and members put forth. Each subcommittee had met at least once and the chair for each will give a report.

Fred Ung reported on the Subcommittee to assist with the CSA audit. The Subcommittee met twice and has planned to meet every other week via teleconference. Many of the items in the corrective action report noted that they would either be completed or would be able to show progress either at the end of 2015 or in the early part of 2016. The Subcommittee is awaiting the update to those, once the official responses have been submitted and made public, the Subcommittee would be able to discuss it and give feedback.

Lee Hilborne reported on the Subcommittee assisting with regulations. LFS has provided a list of ten topics or questions that it receives regularly and would like to receive input on. In the Subcommittee’s first meeting, members decided on the length of time it would take to discuss the topics and their priority. Not surprisingly, those topics with the highest priority were also those that would take the longest to resolve. Although the meetings are scheduled to occur via teleconference, some had suggested that face-to-face meetings may be more productive. Although there was a starting list of ten issues, the Department most likely had many more, and the list would probably grow. The goal is to come up with one set of answers, which the whole community would be aware of.

No.	Question	Priority	Discussion time
1	The definition of supervision and control	High	Long
2	What can unlicensed personnel do at collection stations? For example, collection and incubation for Quantiferon Gold test	With #1	With #1
3	Can a phlebotomist supervise another phlebotomist? If so, to what extent does the supervision extend?	High	Medium
4	Issues associated with coursework in conjunction with scientific testing personnel obtaining a Clinical Laboratory Scientist (CLS) generalist license. Are courses viewed as more important than the degree obtained?	High	Medium to Long

5	Issues associated with coursework in conjunction with scientific testing personnel obtaining a limited CLS license. Are courses viewed as more important than the degree obtained?	With #4	With #4
6	Is there a contemplated means available for an MLT to become a CLS without having to complete the same course of training as a traditional trainee (one year)?	Medium	Short to Medium
7	Should a trainee license be required for MLTs?	Low	Short to Medium
8	What type of agency other than CLIA or an international accrediting agency (e.g. ISO/IEC - International Organization for Standardization/ International Electrotechnical Commission) should act as an accrediting organization for individuals who have obtained training or experience outside the United States for the purposes of personnel licensure?	Low	Short
9	Are there different parameters required for hospital labs versus independent labs? For instance: (1) pre-transfusion services (2) unlicensed personnel such as a pathologist's assistant, histologic technician and histotechnologist (see BPC 1269.3) (3) supervision of lab personnel in hospital setting versus an independent lab (many physicians and nurses are available in a hospital lab but this is not the case with independent labs, where physicians are unavailable on site at all times).	Low	Medium
10	What are the parameters for genetic testing among the limited scientist licenses? Should clinical biochemical genetics and pharmacogenetics fall under genetics or chemistry? Should cytogenetic scientists be allowed to perform the work of genetic molecular biologist scientists?	High	Medium to Long

Ellen Yasumura, LFS Assistant Branch Chief, reported on the Subcommittee to assist with Recruitment and Retention in place of the Chair, Jonathan Bautista. She reported that the Subcommittee discussed data gathering to determine the state of CLS in California. The Hospital Laboratory Workforce Initiative group has already identified a CLS shortage; the Subcommittee planned to compare CA CLS requirements to those of other states to see if the state's requirements are more stringent, look at the availability of schools to accommodate CLS students and school capacity, and perhaps come up with a plan to expand capacity, as in some cases there are more students than available schools. The Subcommittee will also consider creating a survey to send to former CLSs to determine why they left the field. Various members had volunteered to work with other groups and gather more information.

Marjorie Braasch reported that she was a member of the Subcommittee, and that her employer, Kaiser Permanente, has a large group on education in Northern California, and she would look at some of the ways they are doing recruitment and retention, and will reach out to Southern California schools. The Subcommittee was working on its charter during the last meeting and would hopefully be able to discuss the issues in the coming meetings.

Ms. Becker commented that she was thrilled at the progress of the subcommittees and thanked everyone for their participation and effort.

Mr. Thomas thanked Ms. Becker for her leadership and the participation of the CLTAC in advising the Department.

Report on CLIA Survey Section

Donna McCallum, CLIA Survey Section Chief, reported on individual quality control plans (IQCP). CA has adopted IQCP comprising three parts: risk assessment, quality control, and quality assessment. Risk assessment has five components, the specimen, the test system, the reagents, the environment, and the test personnel. The new brochure made available October 6, 2015, on the CLIA website provides more information on IQCP, electronic test records, and ordering of tests not previously available. She reported that those seeking more information may obtain brochures number 11, 12, 13 and the IQCP workbook on how to apply IQCP to individual laboratories on the CLIA website; LFS has also posted some information on its site.

She reported the national and state figures as shown in the chart below:

Laboratory Type	National Jan 2016	California Jan 2016	# change in CA from Nov 2015	% change in CA from Nov 2015
Certificate of Compliance	18385	1543	3	0.19 %
Certificate of Waiver	177016	16271	98	0.60 %
PPMP	34808	3213	0	0.00 %
Accreditation	16441	1223	-19	-1.53 %

Regarding the handout on conditional level and standard deficiencies, she reported that the majority of the conditional level deficiencies dealt with personnel; for standard level deficiencies, it was proficiency testing. In terms of how laboratories who fall into these categories, they could find brochures (brochure 7 laboratory director responsibilities, 8 proficiency testing, 10 personnel competency) on the CLIA website that would address some of the issues. The brochures provide clearer language as to the regulations and requirements. This may help physician office laboratories and other smaller laboratories, which may not be as knowledgeable about the laboratory community. For standard level deficiencies, much of it falls on the analytical systems, competency is also listed. There was one item appeared on both lists, laboratory director moderate-complex testing. There is a lot to be done with respect to moderate complexity laboratory directors knowing their responsibilities.

She also noted that the chart showed the number and percentage of laboratories and physician operator laboratories in the nation with the specified deficiency.

Report on Tissue Banks, Blood Banks, and Biologics Section

Ron Harkey reported that the agenda item relating to Quality Improvement (QI) projects was to be removed since it was already discussed; the QI project headed by Jan Otey, Examiner I, also included Mary Wogec and Clint Venable, and related to tissue bank licensure. It is active and working well in the background.

He reported that since the law went into effect in 1992, the program applies the American Association of Blood Bank (AABB) standards as their standards are updated for blood banks that provide services in CA. The other part of blood banking is that all

hospitals involved in transfusion services are also regulated by AABB standards whether or not they have a blood bank. Those facilities are the ones that Bob Hunter, Examiner I for Blood Banks, will report on. They are clinical labs, they are not blood banks unless producing products, and they are involved with transfusion related incidents (TRI), which are very extensive.

Mr. Hunter reported that when he was starting out, LFS wrote all of their own regulations, but it became clear that in order to keep up with scientific and community knowledge, the Department needed to adopt AABB standards as their own. AABB is keeping current with changes and issues new sets of standards (blood bank and transfusion service, cellular therapy) every other year, which the Department incorporates into its laws after review. In the interim time, should something like Zika arise, AABB can react very quickly and make changes to their standards.

He reported that Health and Safety Code §1279, which now requires reporting of all adverse events, has become very important; he had given many presentations to government oversight groups such as Licensing and Certification (L&C) and hospital groups about the requirement, especially the hospitals that may not know they must be part of the mechanism according to the AABB standards. Through the process, some AOs have also started to report incidents found among the facilities they oversee.

The reporting for transfusion-related incidents (TRI) can come from anywhere, often it comes from L&C as a result of their surveys, sometimes media, and from staff in the facility. He noted that a mechanism was needed to enable employees of those facilities to report issues anonymously to government agencies.

He noted that he had reported on the laboratory and nursing side of the TRI process during the previous CLTAC meeting in December 2015, and they can also be found in the handout. The Tissue Bank, Blood Bank, and Biologics Section is involved with Hepatitis C Virus (HCV) items with regards to transfusions and organ transplants, HCV or infectious disease testing on the donor side for blood or bone components, and organ transplants, as those patients typically also have had transfusions. For the blood supplier component, the largest piece was contaminated platelet products that have been distributed and issued at the facility.

He commented that AABB's two year cycle is very beneficial for the biologics program, noting that the FDA recently put something out similar to LFS's CLIA Crosswalk, which began in 2003 but just became effective this year and everyone was still trying to interpret and understand the new rules. He noted that it was a ten to twelve year process.

The Biologics program had investigated 131 cases of complaints or reportables since 2005 and 76 of those were transfusion related.

He concluded by reminding everyone that there is a mechanism for anyone who wanted to report an issue with a blood center, blood bank, or transfusion service (anonymously or otherwise); please email issues to: Biologics@cdph.ca.gov

Facility Licensing Section Update

Kathy Williams, Facilities Licensing Section Chief, reported that the program was still working on many of the business processes that CSA wanted to be improved. One examiner, Pat Toomer has retired, and her duties were being redistributed.

She noted that there was a complaint backlog. Many complaints concerned phlebotomists at draw stations and the conditions at draw stations. There were also many inquiries after the posting of the Non-Compliance Inducement Letter on the LFS website, and the program will be looking into those. There had been a rash of PRA requests; and also requests from laboratories who did not want their documents released to the public, especially accredited laboratories who did not want AO documents released. LFS's attorneys have stated that AOs are private organizations and as such, are not subject to PRA requests; furthermore, LFS is not the custodian of those records.

Lee Hilborne asked if the inducement issues were in regards to the letter posted about BPC §650, for which the Department had previously stated that it did not have full enforcement authority, and that it would cooperate with the Medical Board to get the message out.

Ms. Williams reported that the calls were coming from companies and individuals, especially from out of state, who wanted to put phlebotomists in physicians' offices. The Department's standard response has been to direct those individuals to read the Inducement Letter that discusses the issue of an out-of-state laboratory supervising a phlebotomist in California.

Dr. Hilborne followed up by asking regarding a request for a change to parts of the Inducement Letter, which implied that if laboratories paid fair market value to lease space in a physician's office for use by a phlebotomist, it would not be a violation of BPC §650.

The letter and issue in question were responded to by the Department and the recommended changes were made to the Inducement Letter. The new version was posted on January 22, 2016.

On-Site Inspection Section Update

Elsa Eleco, On-Site Inspection Section Chief, reported that the section had been reorganized and renamed. The section is based in Los Angeles and consisted of one Examiner III, one Examiner II, and three Examiner I's. The section is responsible for conducting initial and routine inspections of laboratories in California and routine out-of-state inspection of compliance and accredited laboratories. She thanked the CLIA section for helping with inspection of non-accredited labs. The section would be working on complaint investigations of clinical laboratory facilities. She noted that they will be very visible and project to increase the number of routine in and out-of-state surveys and complaint investigations.

Following up on Ms. McCallum's presentation on IQCP, she noted that LFS did post a notice on IQCP on its website. SB 75 amended sections of the BPC §1220(d)(2)(I)(a), §1220(D)(2)(b) mainly with quality control, and IQCP and §1220(D)(2)(c). Also adopting Subpart J of CLIA 2003 final rule regarding facility administration, previously patient

health management; the whole of Subpart K, not only the individual specialty and subspecialty requirements, but includes general laboratory systems, pre-analytic systems, analytic systems, post-analytic systems; and within those systems, it has incorporated the quality assessment.

She believed that the adoption of these has made things more streamlined and harmonized, and would make it easier in terms of community compliance and state enforcement.

Personnel Licensing Section Update

Zahwa Amad, Ph.D., Personnel Licensing Section Chief, reported that SB 1159 went into effect on January 1, 2016. SB 1159 mandates that state licensing bodies shall require an individual tax payer identification number (ITIN) or social security number (SSN) if the applicant is an individual; and shall provide these numbers for the purpose of matching the names on its certified or licensing lists in response to requests from individuals or child support agencies.

According to the IRS website, the ITIN is a nine digit number beginning with a “9” which is required in order to file taxes; the ITIN does not authorize work in the USA nor does it guarantee benefits or services.

LFS has updated its databases and as of early January, and can now accept either number. LFS has also improved the security of its database systems so that SSNs and ITINs are now masked and cannot be viewed by staff.

She reported that during the period of March 2015 to March 2016, LFS conducted four director licensing oral examinations and licensed 20 directors—each exam typically consists of five examinees and an examination panel of four members, two from the Department and two from outside.

She reported that the most recent director’s exam took place on February 22, 2016, where one oral pathologist, one histocompatibility director, and two bioanalysts were licensed; noting that with the passage of AB 940, two bioanalysts were qualified to be licensed based on their out-of-state experience in CLIA certified laboratories—experience that they would not have been able to use before the passage of AB 940.

She reported that LFS approved two CLS training schools in January, one in Lancaster, and the other in Baldwin Park. In February, LFS approved a clinical microbiologist scientist training school in San Juan Capistrano, and a clinical genetic molecular biologist scientist in Temple City. She noted that the section is also streamlining the training school program and trying to make it more transparent.

She reported that LFS has provided additional administrative support to the examiners reviewing CLS and phlebotomy training school applications, a checklist of required documents has been created and is under review, and tracking logs are being kept in an effort to make the process more efficient and expedient.

She reported that there were eleven complaints, two regarding phlebotomy training schools, one of which was not an LFS approved school; it was an on-line school that was being investigated by multiple agencies. LFS was also investigating other schools,

and planned to do more on-site visits. The other eight complaints regarded phlebotomists, their attire, bruising of patients, and unprofessional behavior—LFS was investigating those, also.

Ms. Becker thanked Dr. Amad for her report and asked if the CLTAC would be able to see statistics and charts again. Dr. Amad replied that those would be forthcoming.

Dr. Hilborne asked when LFS would become all electronic. Ms. Yasumura replied that it would still be several years away. The initial personnel applications were first, renewals will follow, then the facility programs.

Mobile Phlebotomy

Mr. Thomas reported that the Chair had requested that this item be discussed. The item regards mobile phlebotomy operations, scope of practice, and is related to blood collection, throat swab collection, and breath collection, patient safety, and Medicare and medical billing. On November 17, 2009, LFS put out a document regarding issues unique to California law; item six of that notice, points A-F, discussed phlebotomy, items A-D listed those categories of personnel authorized to perform phlebotomy to collect blood samples for clinical laboratory testing, and item F discussed authorization for certified phlebotomy technicians to work outside of a clinical laboratory to perform phlebotomy to perform phlebotomy for non-diagnostic insurance purposes or for forensic purposes when the certified phlebotomy technician (CPT) follows policies and procedures established by a physician and is supervised by a physician, registered nurse, or person licensed under chapter 3, which would include an MLT. Since 2009, there appears a growing number of questions from persons who want to set up a mobile phlebotomy business. There have been questions regarding supervision and current phlebotomy regulations with the term “accountable to the laboratory director.” This item is also a topic for the Subcommittee for regulations and has been listed as a high priority item.

Dr. Amad added that it was not a new question to LFS. This is laid out in BPC §1246 and 17§ CCR 1034(b)(2)(B), which requires that phlebotomists work under the direction of a laboratory director who would be accountable for the phlebotomist.

This means three things: the phlebotomist who wanted to open their own mobile phlebotomy business would need to be associated or affiliated with a laboratory and laboratory director, there would need to be an actual written agreement provided to LFS, and the monthly supervision requirement had to be met to ensure that the supervision occurred and someone competent was needed to review as the immediate supervisor.

In addition, 17 CCR §1034(b)(1)(E) requires that the CPT’s license be displayed at the work location in the laboratory employing the person.

The facility hiring and having phlebotomists is a clinical laboratory. Those facilities who utilize other personnel such as nurses to perform phlebotomy are separate. There are three instances in BPC§1246 where a CPT may work in mobile stations, in association with clinical laboratory, or for the two authorized non-diagnostic purposes (forensic or insurance purposes, but still under the supervision of licensed persons).

Dr. Hilborne commented that the general issue of whether a phlebotomist may supervise another phlebotomist was going to be taken as a high priority by the Regulations Subcommittee, but if the real question concerns mobile phlebotomy, articulating the question in that manner may help to focus the discussion and would be a better starting point.

Mr. Thomas noted that the current item related not just to phlebotomy but also non-blood specimen collection. The issue is broader and concerns the duties that personnel may be expected to perform in remote sites where licensed personnel may not be available to provide the proper type of supervision in relation to the duties being performed at those remote sites.

Ms. Becker added that it was an important issue that affects a large part of the community.

Lu Song reported that she heard of an issue where a serum tube was received by a lab drawn by a mobile service and the patient could not be located afterwards.

Bob Footlik asked a question with regards to collection of biological specimens other than blood samples, as a license or certification was needed to collect blood. For unlicensed lab personnel, BPC §1269 does permit those with proper education, training, and competency training to collect biological specimens—although it may have to be done under direct and constant supervision, it is permitted by the law. Directing the question to Mr. Thomas and LFS, with regards to breath samples and throat swabs, if it can be done safely for the patient, what would prohibit unlicensed personnel from collecting those types of specimens?

Mr. Thomas replied that LFS had been dealing with those situations with collection stations and phlebotomy outside of the laboratory where direct and constant supervision is not available. The issue the Department had been struggling with was what “supervision and control” actually meant. That was why the Department asked the CLTAC to help. The law was written some time ago and current practice might differ. Answering the question, in remote areas, LFS was concerned about what level of supervision those personnel would need.

Mr. Footlik noted that under BPC §1246(c), biological specimen collection is not listed, so it would require direct and constant supervision; he asked how would that be achieved outside of the laboratory.

Mr. Thomas replied that LFS would need to look at the terms listed in the law and what was being done in the community. If the law needs to be changed, then how so? And in the interim, what would be the policy of the Department with regards to the issue until the law is changed. Once LFS finalized its policy on a given question, the policy would be posted on its site for the entire community.

Ms. Becker noted that the Department’s charge to the CLTAC was made in order to help to create a uniform policy that could be put forth for everyone. Dr. Hilborne added that it would still need to go through channels and review by Office of Legal Services.

New Business

Ms. Becker reminded the CLTAC members about Form 700, which needed to be returned to LFS by March 23, 2016.

Ms. Becker asked that a speaker be provided from the Center for Infectious Diseases, perhaps for an update on the Zika virus as the issue seemed to be broadening.

Future Items

Rhonda Becker asked if there were suggestions for future business. She noted that the next meeting would occur on June 3; and there would be a standing item for the Subcommittees.

Next meeting

Ms. Becker thanked Dennis Tavares, Don Miyamoto, Nai Saechao and everyone at CDPH who helped to arrange the meeting; she thanked Fred Ung and Kaiser in North Hollywood for providing the phone bridge.

Adjournment

Lee Hilborne motioned to adjourn and the motion was seconded by Marjorie Braasch; the CLTAC board voted to adjourn at 12:10pm.

DRAFT