

Clinical Laboratory Technology Advisory Committee
Minutes of the September 10, 2009 Meeting

Meeting held by videoconference from Richmond campus, CDPH,
KP Regional Laboratory, North Hollywood and
Telephone Bridge Line

Note: For flow purposes; these minutes are documented in the order in which they appeared on the agenda, and not in the order discussed.

CLTAC Members Participating

Laurie Armour, Michael Borok, Leonard David, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Jan Schwartz, Michael Terry, Fred Ung, Mary York.

Former CLTAC Members Participating

Morton Field, Imre Fisher, Robert Footlik, Jim Ottosen.

DPH Staff Participating

Zahwa Amad, Norma Barocio, Kathleen Billingsley, Linda Bryant, Grace Byers, Maria DeSousa, Pam Farrell, Ron Harkey, Robert Hunter, Nema Lintag, Cindy Lloyd, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Bea O'Keefe, Janet Otey, Judy Schlosser, Dale, Statley, Genie Tang, Tom Tempske, Robert Thomas, Kathy Williams.

Welcome and General Announcements

The meeting was called to order by the CLTAC Chair Dr. Tim Hamill. He thanked Kaiser for providing the telephone bridge for the meeting. Dr. Hamill introduced the new CLTAC member Jerry Hurst who is representing the California Association of Public Health Directors.

Approval of the September 10, 2009 meeting minutes

Dr. Hamill asked members if there were any additions, deletions, or corrections. There was a motion and a second for approval. The minutes were accepted.

Department News

Ms. Billingsley apologized for not being physically present at the CLTAC meeting due to other duties in Sacramento. She stated that she was looking forward to participating in the next CLTAC meeting. Ms. Billingsley went on to say that on August 24th the stake holders meeting looked at the key factors for the personnel regulations. Some representatives from the Governors office attended the stakeholders meeting. The center is doing some preparation with the H1N1 flu season coming up. Furthermore, Ms. Billingsley added that the Lab in Richmond should take pride that the Governor visited the Lab. The department faces budget constraints and three furlough days. This is having an impact financially on the state employees and has affected their availability to do the work. The work has to be done in 4 days instead of 5. The Center for Health Care Quality has set up a series of metrics to measure the impacts of the furloughs. The 12 month Bureau of State Audits report was submitted on time last August. There is an amended budget in place.

Question: Does the medical board have some sort of surplus that was grabbed by the governor to offset the budget deficit?

Answer: Ms. Billingsley was not aware of that. She offered to check into that.

News and Update on LFS

Bea O'Keefe said that the CLTAC might want to consider moving the meeting to the fourth Friday of each month since LFS has furloughs the First, Second and third Fridays of each month. We are in a transition period with the retirement of Dr. Karen Nickel. She thanked the LFS staff for being very dedicated despite 15% cut in their salary and furloughs. Bea also recognized Kathy Williams as an acting section chief. We have three furloughs that will continue until July 2010. We do not know if there will be additional furlough days or if the furlough will continue beyond July 2010. Bea stated the furloughs have impacted LFS's reception desk in the number of voice mails received over the weekend. LFS received 150 voice mails without counting the voice mails that went on employee's voice mail boxes. Also, the mail is not being opened as quickly. Bea added that there are backlogs in the personnel and licensing section. The loss of two general fund positions has caused a loss in revenue of about \$150,000 dollars. She is hopeful to fill some vacancies. HAL data system is very antiquated. LFS will be participating in the Enterprise-Wide On Line Licensing System (EOL). In October LFS will be meeting with the consultants about the new system which will be in place by 2013. The goal is that the new system will provide online applications, licensing and renewals for both personnel and facilities. LFS had budget drills dealing with contracts. There was a 15% reduction in contracts. The only contract that LFS has is the CPS for personnel licensing, which is the application process for phlebotomists, certification for phlebotomists, applications for CLS and verification of CLS licenses.

LFS was able to keep the CPS contract due to the number of Phlebotomy applications not dropping. The BSA Audit report was completed on time. LFS was able to do 158 validations of accredited laboratories, leverage CLIA surveyors and utilize cytology surveyors to perform surveys of pathology laboratories. Bill analysis was very busy this year. LFS had 15 bills and almost all required a bill analysis by section chiefs or acting section chief. Some of the bills had as many as five different amendments. Some bills were converted into a two year bills. The stakeholders meeting was very successful, LFS received comments which have being reviewed.

Question: Since the mail is not opened three days a month, are date lines adjusted for receipt of various payments or are they like the federal government the day of postmark?

Answer: The mail has an official post mark from the postal office and is stamped at LFS when its received that will not create a problem.

Legislation Impacting Clinical Laboratories

SB 744(Strickland)

This is a department sponsored bill. To get details on SB 744, you can look at the minutes from June 12, 2009 the details which will be posted in the website. This bill went through five committee hearings and Bea attended two of the committees. The bill required a 2/3 vote in both houses to go to the governor. The vote from the senate was 39 to 0 and the assembly vote was 70 to 3. Many amendments were done to SB 744 in order to meet the concerns of the groups such as the Public health lab directors, Public Health Officers, and the Clinical Lab Association and other groups. Most of the oppositions to the bill was removed. This bill has urgency legislation which means that it will go into effect as soon as it is signed. LFS will start implementing it as soon as possible. There will be a letter sent with the renewals for December giving the break down of the various new fees.

Question: Does a laboratory which has one owner and one lab director with multiple testing locations does each individual location needs its own certificate or license and Does each laboratory's own volume determines the fee for that location or do you sum up everything and put it under one big license and sum up the entire volume?

Answer: Each location is site specific. Each location needs a state license, if it's doing moderate or high complex testing and will also need a CLIA certificate. 60% of the laboratories will see a fee reduction. The labs doing less than 2,000 tests per year will see a renewal license fee decrease from \$1,023 to \$170 dollars. The only exception to this rule is laboratories that are not for profit and have multiple locations. The primary location has to have a state license and a CLIA certificate. There will be a fee of \$25 for each multiple site.

Question: Will there be a fee adjustment since the fee is based on volume when the bill goes out in October?

Answer: LFS has the volumes of the laboratories currently in HAL. If your application reflects that the volume has changed, you will get another notice saying that the fees have changed. LFS has a mechanism in place to make the change. If there is any problems the renewal notices will not go out on October 15. They will go out on November 1, 2009 instead.

SB 482(Padilla)

SB 482 is about the biological data service. If you read your minutes for the CLTAC meeting on June 12, 2009 you can get the details for SB 482. This bill was turned into a two year bill. There are several issues with the bill such as, the scientific validity, the ethics aspects, the privacy data act aspects, the economic aspects and others. There is a multitude of information in the internet if you "Google" genetic testing especially direct to consumer testing. There will be more discussion on this bill when it comes up next year.

AB 1045 (John A. Perez)

AB 1045 deals with Reporting those HIV related T-cell results provided that the laboratory can show that the T-cell reports is not related to an HIV case. Most labs can do this very easy because the diagnosis is in the test requisitions. Laboratory Field Services (LFS) looks at reportable when we do laboratory surveys. This bill was chaptered.

Question: Can this be done electronically today?

Answer: This varies by county. There is no state-wide electronic reporting system as of now.

AB 1132(Jones)

Laboratory Field Services (LFS) was only informational on this bill. AB 1132 is a bill that deals with California organ and tissue organ donor registry. Donate Life California is the registry agency currently used by California to register tissue and organ donors. This bill mainly impacts the Department of Motor Vehicles (DMV). Things are done much easier on whether or not you want to be a tissue or organ donor. This information is sent electronically to Donate Life California the process takes about 30 days.

The California transplant donor network is now a full scale OPO where they will be doing recovery. They have done this in cooperation with a number of tissue banks including Tissue Bank International (TBI) and others. They will be working hand on hand so you are not approaching a donor family to ask for permission as a tissue bank for already

registered donors. LFS is dealing with issues that affect the outcomes of the recipients, the patient.

AB 1397 (Hill)

AB 1397 works with facilities that are allowing patients to come in who want to be treated for donation of HIV or HTLV donor for a couple. This can be done with the reduction technique which is, the sperm washing. Sperm washing diminishes the transmission of HIV or HTLV is greatly. The bill made the distinction that an individual which is an expert in the area can receive IDF from some one who is an expert in that area. This bill requires regulations. The American Society of Reproductive Medicine guidelines for sperm washing will be posted in the website. This bill it's on its way to enrollment.

AB 995 (Block)

AB 995 would have introduced the American Association of Tissue Bank (AATB) Standards into law. The assembly was called by a non licensed semen bank, which stated that the AATB standards were prejudicial to gay men and they needed to be dropped from this bill. Block dropped the AATB standards from the bill and inserted language suggested by two tissue bank manufacturer. AB 995 will allow any tissue bank, podiatrist or surgeon practicing in a surgery center to be exempt from the tissue bank license requirement, if they received tissue that is FDA 410k approved as a medical device. This may create a problem due to tissue being subject to contamination. There have been cases reported of the use of the 410k approved tissue that has been contaminated and not being recalled after it has been implanted in a the patient. One of the concerns of Laboratory Field Services (LFS) is that tissue in storage can break down and it can become contaminated with a substance that can cause the product not to be able to be implanted. It can be contaminated in a way that will infect the recipient. This bill is on its way to enrollment.

Ron announced that Jan Otey has been promoted to an examiner II at LFS and thanked her for her contributions. He also thanked Robert Hunter for his exceptional work in blood banking, since he has been working by himself in this area. He was very concerned in the area of cytology due to Don Miyamoto being the only person available to go out in the field.

AB 221 (Portantino)

AB 221 has to do with HIV counselors exempt from phlebotomy technician certification. This bills sponsor is the AIDS Health Care Foundation and it is urgency legislation. The goal is to increase the number of HIV counselors authorized to collect blood samples and perform HIV tests which would be less expensive than to use an oral fluid HIV test. Currently HIV counselors are limited to using an oral fluid test method instead of a HIV blood method unless they are California certified phlebotomists. This state run program would be run according to rules under the Health and Safety Code; it would be administered by the Office of AIDS.

Question: The HIV counselors are a specified group trained by the California Department of Public Health. This does not apply to anyone calling themselves "HIV counselors" that is not being so trained. Is this correct?.

Answer: That is right the bill refers to them as HIV test counselors that work through a contract, they are not necessarily all department employees. It is a program where the department over sees its operations and they can contract people out and they are responsible for training.

Question: Does this only limit people like a counselor doing a finger stick or someone doing a home glucose test or does it say that they can do a full blood draw?

Answer: This is limited to a skin puncture for a waved HIV test. They will be able to collect the sample and perform the test.

Question: Having an offsite HIV clinic, would we be able to use those HIV counselors to do the blood test on the HIV since we are tied to a medical center?

Answer: This bill really addresses a department run program not programs that are not run by the Office of AIDS. The only one that this bill relates to is those programs that are under the department Office of AIDS through local public health laboratories.

Personnel Licensing Regulations

On August 24th, the Department's Center for Health Care Quality scheduled a stakeholder meeting. At this meeting, LFS discussed 14 specific clinical laboratory regulatory personnel issues. These issues are listed in the LFS website under news hot topics and under updates for California laboratory personnel law issues. The website address is www.cdph.ca.gov/programs/lfs. After the stake holder meeting, there was a dead line to submit comments which were due by September 4th. They were approximately 25 to 30 comments received from organizations and individuals. Modifications were made based on the comments received. When the final review is ready it will be submitted for public review, which consists of 45 days. During this time, anyone will be able to submit official comments. The September 4th comment dead line is for unofficial comments and the department is not required to respond to those comments. However, when the official comment period is announced by the Department's Office of Regulations you will need to comment within the 45 day period even if you previously submitted comments during the unofficial comment period ending September 4th as the department is required to review and respond to all official comments.

Question: Is there any proposed draft that we can review since some of us were not able to attend the meeting and did not know about the comment period dead line?

Answer: No, but if you missed the meeting you can go to the website. The slides that were presented at the meeting lists the 14 main issues that are posted there. There is also a short form review listing covering the issues and the impact that may occur as a result of making changes.

H1N1 Flu (Swine Flu)

Dr. John Talarico reported on H1N1 activities. He said that he wanted to start by discussing a little bit about influenza historically to provide a background to what happened in April 2009. The swine flu was first identified in 1930. At that time, it was endemic in pig herds and 50% to 90% had flu like symptoms such as runny nose, decreased feeding and cough. The herds are commonly vaccinated. Regarding human swine flu, what we knew from 2005 to 2008 was that there were 12 cases identified with mild upper respiratory problems as a result of direct or indirect exposure to pigs. He said that these were triple reassortant viruses. One of the cases required hospitalization in ICU. Eleven of 12 had direct exposure to pigs. From 1976 through 2006, there were 37 human civilian cases reported. The median age of the cases was 24.5 yrs of age. The fatality rate was 35% but they had pneumonia and 3 of the 6 had underlying illnesses. There was no swine flu exposure in about 61%. In April 2009, a patient A a 10 yr old boy in San Diego County California with fever, cough and vomiting for a week. He had no exposure to pigs and no travel history prior to illness. While sick, he traveled to Texas. Mother and brother had similar symptoms. Patient A was screened and identified as having influenza A. His blood sample was sent to CDC and identified as swine flu. CDPH was notified of patient B who was from Imperial County in California with an onset of illness beginning on March 28, 2009. Patient B is a 9 yr old girl who had

high fever, cough, and no reported direct exposure to pigs. She had attended a state fair but never saw pigs. She had traveled to Mexicali, Mexico two weeks prior to the symptoms and had a 13 yr old brother and a 13yr cousin with respiratory symptoms. The specimen was sent to a different lab and the result came up as swine flu. On April 17, 2009 a conference call was held regarding these two cases. When the genetic results came back for the second case, it was identified as being the same virus as patient A. These two cases occurred approximately 80 miles apart and were un-subtypeable. During the investigation, lab contamination was quickly ruled out. At this point, a health alert was written to request enhanced surveillance. On April 20th, the CDPH emergency operations center was activated. The cases quickly grew from 3 to 4 to 50 to 60 cases by the end of the week. CDC also activated their emergency operations. At this time, there were reports coming out of Mexico of severe cases and some fatalities due to respiratory problems but swine flu had not been identified. A travel advisory alert was given for Mexico. Then Canada reported cases of people who had traveled to Mexico. The flu started to spread very rapidly. WHO called the swine flu a pandemic by the end of May 2009. The spread was rapid and included many school children in Sacramento and New York within a short time, spread was national. What makes this a pandemic? WHO called this a pandemic because this influenza virus was identified as a novel virus in humans and the virus demonstrated ability to quickly replicate and cause disease.

This triple reassortant virus strain had not been seen before in the U.S.A. The situation in California is 63 cumulative hospitalized cases, 134 new cases, 33% were less than 19 yrs of age and 20% of those cases were admitted to the ICU with a medium age of the patient as 33yrs. Four of the deaths reported were pregnant women, the medium days of the onset to death is 11 days. VRDL lab at CDPH has tested 2,100 un-subtypeable specimens and 1,900 or 91% have been confirmed positive for H1N1 flu. VRDL and the Public Health Labs have collectively tested over 20,000 specimens. It is believed that everyone will need two doses of the H1N1 vaccine as we are naïve to this virus. The vaccine will be given to priority groups such as health care workers, pregnant women, people who care for infants under 5yrs old, and children 5 to 18yrs with underlying risk factors. The vaccine will be distributed by CDC and will be under control at the local or state level. The vaccine will be available on early to mid October. This virus will probably increase in activity and CDPH is monitoring for severe cases. New risks groups are perhaps persons with BMI greater than 35 and who are overweight. Regarding surge in H1N1 VRDL is planning on testing 100 specimens per day on a regular basis and up to 150 per day for a limited time.

Question: What is the efficacy data on the vaccine?

Answer: We do not have data at this time. We are doing active and passive studies. Regarding the safety of vaccine, there are formulations that are aerosols. We may have to get an exemption for the aerosol issue early on.

Question: How would that vaccine be rationed among those groups that you are distributing it, and secondly, if there is vaccine left over at what point will it be offered to the general public?

Answer: This will be done by county. Providers are pre-registering with the state. A list of providers is been generated to the local health officers and those jurisdictions. They are prioritizing and deciding which providers will get the vaccine. The providers will have to sign an agreement agreeing that they will give the vaccine according to the recommendations. It is estimated that there will be vaccine left over for anyone who wants it.

Question: What are the current plans to re-activate the H1N1 center in Richmond?

Answer: The center has been reactivated as of the middle of June in a low level. There are plans for expansion and again in ramping up service. This center supports technical staff and proving equipment on need and assists in getting expedited contracts for new staff. They also provide guidance documents.

Question: If you have seasonal flu vaccine, should it be given now?

Answer: There will be an overlap between seasonal flu vaccine and the vaccine for H1N1. Therefore, if you have seasonal flu vaccine it should be given to targeted groups now.

Summary of Complaints received by LFS

- The total for this year is 160 which is less than last year.
- LFS receives 35 complaints this quarter.
- LFS closed 52 complaints last quarter.
- The complaint website keeps being very popular.
- LFS continues to work with Fraud and Medical investigations.

Question: Do you have the complaints subdivided in different categories?

Answer: The complaints that LFS receives are in the subdivision of phlebotomy, laboratory analytical, medical billing and unlicensed personnel especially in phlebotomy and CLS using with false licenses.

Personnel Licensing Section Report

Robert Thomas reported on the following Personnel Licensing Section activities.

Phlebotomy applications

<u>Month</u>	<u>Received</u>	<u>Approved</u>
June	647	505
July	621	535
August	637	412
Total	1,905	1,452

Clinical Laboratory Scientist (CLS)

<u>Month</u>	<u>Received</u>	<u>Qualify</u>	<u>Licensed</u>
June	74	24	13
July	72	39	11
August	66	36	45
Total	212	99	69

Medical Laboratory Technician

<u>Month</u>	<u>Received</u>	<u>Qualify</u>	<u>Licensed</u>
June	5	8	0
July	11	4	2
August	6	2	1
Total	22	14	3

Question: On the CLS licensure what is the average time from the time you receive the exam results to the licensure?

Answer: We try to do it in 2 weeks but we are finding it takes 4 weeks to 6 weeks. We are getting the results thru snail mail. We are processing new numbers and issuing

licenses every two weeks. Once they are entered in the HAL they can be printed and used as a temporary authorization to work while the hard copy certificate arrives in the mail.

Question: Have you approved any new MLT schools and are there any applications pending approval for MLT.

Answer: LFS approved IME as a new MLT training school and we have two applications pending that are under review. There will be a follow up report at the next CLTAC meeting.

Question: The LFS website lists some MLT schools and are some California approved or NAACLS approved which are those and which are the newest one?

Answer: The first two that were mentioned were Hartnell and DeAnza as those were initially California approved and are now also NAACLS accredited at the time. They were applying for NAACLS and they were going through the NAACLS approval process. Both schools had students that had graduated their training in previous years and to ensure that LFS would recognize those trainees for MLT licensure the schools submitted applications so that they were California approved and also NAACLS. The newest approved MLT program is IME. There are two pending applications which are Southwestern and Saddleback.

Question: How many MLTS are licensed in California?

Answer: 81 MLTS are licensed in California.

Robert Thomas continued his report stating that LFS has been receiving inquiries about the California approved certifying examinations for Clinical Cytogeneticist Scientist and Clinical Genetic Molecular Biologists Scientist. ASCP Board of Registry (BOR) and NCA announced that they formed a single certification agency to be effective on Friday, October 23, 2009. This new certification group is called the ASCP Board of Certification (BOC). It is reported at this time that the NCA will be dissolved as a corporation. So this merger will have an effect on the licensure of California Clinical Cytogeneticist Scientists and Clinical Genetic Molecular Biologist Scientists as California regulations require as this regulations were effective on March 2003 required applicants to pass an exam administered by NCA. LFS has been pro-active on contacting both ASCP and NCA since we heard about this change. In conjunction with the LFS legal office, we have been considering possible solutions as to minimally affect California licensure of applicants. At this time the discussions are ongoing. We are looking at different options. The Cytogenetics exam will be the same exam that is currently given by NCA but it will be given by the new organization. The Molecular Biology exam may not be the same exam when it moves over from NCA to ASCP. LFS is in the process of contacting ASCP to verify the facts regarding changing in exam administration.

Facility Licensing Report

The number of files that we process per month remains about the same for registrations and licenses. Approximately LFS receives 100 applications per month, 10 for licensure and the rest for registrations. There is an increase of podiatrist applying for registration. Since the beginning of the year LFS has licensed 235 new laboratories with a total of close to 2,000 licensed laboratories. LFS gets about 4 to 6 new applications for out of state laboratories per month. As of September 9, the state of California has licensed 176 out of state laboratories. LFS was able to send surveyors to check on some out of state laboratories. During the summer 8 laboratories were inspected by four examiners. The laboratories inspected were in Georgia, Florida, Tennessee and Kansas. The examiners

reviewed the CLIA report from the last survey each laboratory had and then they will concentrate on state issues. They would check on the staff qualifications whether or not they were qualify to do the kind of testing they were doing. The laboratories inspected were found to be in compliance with the California law.

The addition of hepatitis C reporting was expanded to include the signal to cut off range and or they wanted to make sure that it was in the part of the instrument reading that indicated a true positive rather than a waver. The working committee on Hepatitis C surveillance is proposing to drop the requirements of sending the signal to cut off ratio and report only those reactive hepatitis C screenings that have been confirmed with a more sensitive test. Contact Rachel McLean if you have any questions regarding this process. Her e-mail address is Rachel.McLean@cdph.ca.gov .

There is a new Cal/OSHA standard that became effective August 5, 2009. Cal/OSHA board of standards is holding an advisory committee meeting after the effective date. The standard 5199 aerosol transmissible diseases have several pointers similar to the blood borne pathogens standards that need to be implemented in the laboratories. You can go to the department of industrial relations website and scroll down to Cal/OSHA and click on the advisory committee link. www.dir.ca.gov/dosh/DoshReg/advisory_committee.html.

Question: What are they proposing for the laboratories?

Answer: Controlled of any activity that might produce an aerosol of infectious diseases. They have been working on this for about two years.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:15 PM.

Next Meeting Dates: To be announced at the December 3, 2009 CLTAC.