

**Clinical Laboratory Technology Advisory Committee**  
Minutes of the June 12, 2009 Meeting

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

**CLTAC Members Participating:** Laurie Armour, Michael Borok, Leonard David, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Lee Hilborne, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung.

**Former CLTAC Members Participating:** Sam Chafin, Morton Field, Imre Fisher, Robert Footlik, Jim Ottosen.

**DPH Staff Participating:** Zahwa Amad, Frank Barnes, Norma Barocio, Kathleen Billingsley, Grace Byers, Maria DeSousa, Pam Farrell, Ron Harkey, Nema Lintag, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Judy Schlosser, Lilia Shumaker, Genie Tang, Tom Tempske, Robert Thomas, Clint Venable, 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 said due to the fairly large agenda that we may jump around on agenda items and not strictly follow the order of items. Note: For flow purposes; these minutes are documented in the order in which they appeared on the agenda, and not in the order discussed.

**Approval of the March 13, 2009 meeting minutes:** Dr. Hamill asked members if there were any additions, deletions, or corrections. One member said that June 12 needed to be added to next meeting dates. It was also noted that there were a few typos that needed correction and these changes were said to be non-substantial. There was a motion and a second for approval. The minutes were accepted.

**Department News:**

Ms. Billingsley said she has been very actively involved with LFS; even more so with Karen Nickel's departure as chief. She said that she can assure everyone that LFS is in good hands. They have been doing a great job. The prevailing thought is with the current fiscal crisis. Some programs in CDPH as L&C and Drinking Water are funded by grants and general fund dollars. Programs have been evaluated in CDPH and by agency as well as education to look for overall cuts. It is difficult when you hear about cuts as they have an impact on delivery of healthcare to so many Californians. At the capitol they have had sessions where several consumers have come in to provide input. Now, we have just heard through a budget committee where proposed cuts have been made for healthy families.

This has resulted in the senate & assembly going back to the department of finance to gather more information to make cuts within a program rather than to eliminate a program. Another interesting aspect is when we put forth state funds for a program we look for a federal match. Sometimes, the federal match can exceed state funds. So, there are times when a cut is made to state funding and the result is loss of federal funds. Therefore, a careful review is made due to potential loss of those federal funds.

CDPH is currently required to take two furlough days per month. This is disruptive to programs especially when we look at the work that needs to get done. There is another proposed reduction that is moving forward. These cuts have an effect on state employees and their families.

This year has been a busy legislation session. The Center for Health Care Quality has had 45 bills. We are looking for what stimulus or grant money may be available and can be brought in for our programs; including for IT services. Another item that may affect all of us is H1N1. The joint operations center is in Sacramento. There is also an active presence in Richmond. Currently, there is an operational look back as there is concern that we will see a resurrection of H1N1 in the fall. There is work going on to determine what type of outreach we should have. At times, more than 1,000 facilities such as hospitals, skilled nursing centers, and others have been participating.

The biggest message I have today is that we all are looking at programs and needs to be sure that we are prioritizing things correctly so that we can protect California patient's safety. It is a tough fiscal climate and if we can keep in mind the importance of what we do and the effect to patient care; I think we will maintain the resolution to move forward on all the good work we do in the department.

The following question was discussed;

**Question:** Can the state appropriate special funds? **Answer:** The legislature can appropriate special funds, but it is not likely to occur for sometime.

- Ms. Billingsley said L&C has savings of about 7-8 million dollars. Rather than have the legislature take that money and see how it would be used it was decided to use that money to maintain the fees providers pay. In consideration when looking at fees for the next year the savings was used to stabilize the fees. LFS is not a program that has enormous savings. There have been some good things to see; such as, how we have been able to work with legislature and also the Governor's office on budget and work force issues. Ms. Billingsley said she does not foresee a situation when SB 744 is passed where special funds will be appropriated from LFS. It is more likely that this would occur in L & C because they have over 1,000 employees.
- Dr, Hamill commented that one of the concerns with SB744 is the amendment for continuous appropriation had been removed. He said that the community would want to see that these funds are not removed from Laboratory Field Services because this is where the funds were increased to help Laboratory Field Services to meet its mandates. Ms. Billingsley said the Governor's office wants more from this program. Legislation appropriation would be more of a concern from larger fee programs as DMV.

**State Budget Crisis and Effect on LFS:** Bea O'Keefe discussed the budget crisis in California and how it continues to affect LFS. For example, LFS was directed to eliminate some general-funded positions about two weeks ago. LFS has 6 general-funded positions; 5 filled and one vacant. We were directed to eliminate 2 positions. As a result LFS transferred 2 general-funded positions into vacant special-funded positions. Four positions remain general-funded. If the state budget issues get worse, it may mean those positions will get transferred. The problem for LFS is when positions are transferred there can be a reduction in funding due to an inter-agency agreement LFS has with MediCal. Transfer of these general-fund positions to special-funding means about \$150,000 loss in revenue to the LFS program.

Dr. Borok asked the following;

**Question:** Is this temporary and does LFS have authority to go back and recover these positions later? **Answer:** Bea O’Keefe said when we loose positions we also loose position authority because the positions were eliminated. Therefore, to get the positions back we would have to go through a process to re-justify them. She stated that it’s complicated.

**Legislation Impacting Clinical Laboratories:**  
**SB 744(Strickland)**

Bea O’Keefe said that LFS discussed information at the last CLTAC meeting in March and is providing an update today. This bill gives LFS the fees and revenues to do the work that was identified as deficient in the Bureau of State Audits (BSA) report. This bill has passed three committees hearings. Currently, it is our understanding that it is in the assembly committee and in conference to reconcile differences between the two houses. Various changes and amendments have occurred. One of last changes aligned more with SB113 to ensure that the state can pursue exemption from the federal government CLIA program.

- The bill will recognize accrediting organizations to be approved by California that will also have to be recognized by CMS.
- The accrediting organization must give to LFS their inspection process, describe how they will do the proficiency testing review, and if a lab loses accreditation, the organization must notify LFS.
- The lab must apply to the state within 45 days of loss of accreditation.
- Labs can choose to be either licensed or accredited.
- In all cases enforcement would be done by the state.
- The fees are the same whether the laboratory is accredited or not accredited.
- Deemed status means the state would accept the accrediting agency inspection.
- The “all clinical laboratory letter” is a new concept to communicate changes to laboratories. It would explain what would be acceptable to CDPH and avoid the need for new regulations that would usually require a lengthy process. The lab community would still be able to comment on changes. This would streamline and expedite changes.
- There is a provision that gives LFS authority to inspect accredited status labs for validation or for other reasons such as proficiency testing failures.
- It imposes new fees based on the service provided to cover investigations and complaints. This is needed to respond to comments made by the Bureau of State Audits.
- There was a recent amendment that would put a cap on fees at 15 million tests.
- Current new license fees are \$1323. The new fees would range from \$270 to \$5,260 + \$350 for every 500,000 tests over one million tests.
- The bill requires a legislative report starting in July 13, 2013 and annually.
- Activities we provide to the licensed labs are:
  - We maintain client databases
  - Ongoing consultation
  - Perform validation reviews
  - Follow-up on complaints
  - Enforcement of labs
  - Fees
    - ❖ Waived Labs                   \$62 changes to - \$100
    - ❖ Registered Labs               \$92 changes to- \$150
- On an initial inspection, we often find deficiencies and need to come back for a revisit on-site. This can be costly considering travel, additional time, and report writing and review.

- We must also spend additional time on labs that have multiple sites under one CLIA certificate; as an example, when SB 744 passes if there are 25 sites under one CLIA certificate, LFS would charge \$25 for each additional site.
- This bill includes a delinquency fee which could be up to 25% of the license fee if the lab did not renew on time.
- This bill proposes personnel fee changes on certified phlebotomy technicians. Those fees would be raised from \$54 to \$100 for a 2 year certification.
- In addition, there would be a fee to cover the cost of conducting oral exams for director license categories. Currently, there is no exam fee. A \$200 fee will be imposed for candidates to help with the cost to the department of administering oral licensing examinations.
- Dr. Borok stated that the report would have required the Department to report on achieving CLIA exemption, anything that would prevent us from obtaining exemption, and whether HHS is accepting exception. Also, included would be the overhead costs to achieve exemption. This would have been an annual report to legislature until CLIA exception is achieved. The May 14, 2009 version of the bill included this report which does not appear in the May 21, 2009 version.

**Amendments that occurred:**

- Public health labs and public health microbiologist language was removed from this bill.
- Removes biennial certification of public health microbiologists. No way to track. Currently we have no information on how many microbiologists are in the state, where they live, how to contact them.
- SB 744 must pass by a 2/3 vote of the legislature and would take effect on signing by the governor.
- Provision that all revenue brought in by this legislation would remain in the special fund.
- Continuous appropriation was taken out in the last amendment.

The following was discussed regarding SB 744;

Michael Borok felt that any reference to obtaining CLIA exemption has been obliterated. Page 2 and 17 had this removed. Exemption should be put back in. If CLIA exemption language is not put back in, we will continue with many duplicate activities and fees. Dr. Borok said that whether labs are POC, hospital or other; they will pay more to the State than to the federal government. There should be some adjustment so the lab isn't paying more to the state than the federal government.

The following questions were asked;

**Question:** Does anyone have a better idea of what the fee will be to achieve CLIA exemption? What would the mature fee be? **Answer:** Bea O'Keefe said we do not know what the overhead fee will be.

Bob Footlik stated that he is concerned that increases in fees are significant. He said that down the line in pursuing exemption from the federal program that there will be overhead fees. He said he felt it would be unfair doing it on a sliding scale basis, and the department needs to take this in consideration. His feeling is that the fee should be divided equally among the lab community.

Michael Borok stated that come January 1, there will be reduction in medical reimbursement.

**Question:** Is the fee for phlebotomy only for new application or for renewal.

**Answer:** It is for both.

**Question:** What are the criteria for use on determining a re-inspection? **Answer:** When a lab had a condition level deficiency we would have to go back in.

**Question:** Is the California Public Health Microbiologist (PHM) personnel certification recognized outside California? **Answer:** Kathy Williams said that it is based on a facility by facility basis. She said that LFS was aware of one person that went to Oregon and had the California PHM certificate recognized.

### **SB 482(Padilla)**

This bill sponsors have proposed to exempt biotechnical data from California clinical laboratory oversight. This bill has turned into a 2 year bill.

- New York has a bill that is almost identical to that in CA. We have not had an update on the New York bill.
- Information is that there may be a federal bill to allow for payment of personalized genetic testing.

A discussion began regarding this bill.

**Question:** Dr. Rubio said that he believed that a lavender tube blood draw may need to be performed in addition to other samples. He asked that if blood is involved shouldn't purple top (EDTA) samples for direct to consumer risk analysis be done in a CLIA lab?

**Answer:** Bea O'Keefe said that currently most companies are not using blood samples as companies using software algorithms are using oral specimens at this time.

Donna McCallum said that many of the companies use licensed labs if blood samples are involved, and the licensed labs are dealing with the testing. Bob Footlik said that these companies and their associates argue that they do not deal with a lab sample; therefore, according to them this is not a clinical lab test. He stated that in fact there is a biological sample because you could not get the data unless the results from the analytical phase were obtained from a biological sample. He believes it is a clinical lab test. The sample is a clinical lab specimen in California, but not under CLIA. Bea O'Keefe said she just came back from Washington, D.C. where she attended a scientific meeting and there was discussion on personalized medicine. Somebody from FDA and CMS were there; including representatives of companies doing this type of testing. There is concern on the national level, and she believes we all are awaiting guidance from the FDA. There was an audience participation discussion at the Washington meeting and the group was asked if risk-analysis should be regulated. The majority there agreed that this needs to be regulated. Bob Thomas said that he was at a meeting last week where Judy Yost was discussing many of the issues regarding risk-analysis direct to consumer testing. It was the CMS legal office that gave an opinion that under current CLIA CMS did not have authority to certify these companies. CMS; however, has been watching these companies and there is over 100 now. Ms. Yost mentioned according to Mr. Thomas that different states are handling this differently. There are states that consider within their laws that molecular biology is fully within clinical laboratory practices. Ms. Yost said that regardless of the CMS position, some states may require state licensure. Donna McCallum said that also there is a workgroup that is working on this issue such as the FDA, CDC, and CLIAC. She said that as time goes by we may see new developments. Donna McCallum believes many of these companies would like CLIA certification as it is used as a selling point. One company doing genetics said in the newspaper they were CLIA certified before they were actually certified. They did have a state license but in general these companies want to be regulated.

### **AB 1132 (Jones)**

Ron Harkey discussed the following: This bill does not have a direct effect on LFS. When the department of motor vehicles (DMV) receives an application via e-mail an

applicant can select to be an organ donor. This can be hyperlinked to tissue registration that will greatly facilitate an increase in donors. On the hyperlink, a person can choose to be a donor or indicate that he/she has changed their mind. A person can be withdrawn or added in 30 days. Most of the National Organ Networks are not required to be licensed unless they procure tissue. Mr. Harkey said we think this will be a bill that increases both organs and tissue donors.

#### **AB 995 (Block)**

Ron Harkey said this bill will introduce requirements to comply with the American Association of Tissue Banks Standards. This bill allows for changes in requirements once posted on the website after 45 days. Responses are not required from the department, but a hearing can be requested. LFS will have responsibility to determine if everything is met in standards. This includes if the tissue bank is complying with storage standards. This would help to identify who is doing storing. This would include embryos.

#### **The ART dilemma, octuplets and licensed tissue banks**

Ron Harkey discussed the dilemma that resulted in a cross-over in responsibility between medical practice and LFS responsibilities. LFS has responsibility to determine if everything is met in standards regarding tissue banks. The dilemma has to do with the physician having a past good record and then ending up with this case involving eight children. How LFS got involved was the hospital called because they had a tissue bank license. The other involvement is how to regulate the children who come to term in the recent news about octuplets. Mr. Harkey said the issues in this matter did not fall under LFS. The issues involved in this case are primarily medical practice issues.

#### **AB 549 (Furutani)**

Robert Thomas discussed AB549 which has to do with clinical laboratory personnel and workforce issues. This bill was introduced as a spot bill and has since had substantive changes covering about twelve sections of the law for training and licensure requirements. Currently, this bill has been pulled by the legislature carrier this year, but will likely continue into next year. Our understanding is this is to allow time to receive comments from all the different groups that would be affected.

#### **AB 221 (Portantino)**

Robert Thomas also discussed AB 221. This bill has to do with HIV testing counselors and certification requirements. The major issues are training standards for HIV testing counselors which includes their ability to collect blood by skin puncture for waived HIV tests. The Office of Aids within the department and LFS have been working together since this bill was introduced and amendments are expected in the near future.

**Question:** Dr. Borok asked about Bea O'Keefe presentation on HIV testing regulations that will be discussed at item #14. He asked doesn't this go hand in hand with this bill? In other words, if a doctor wants to do a waived HIV test in the office, he still has to be licensed and do proficiency testing. If a HIV counselor did it, would that require proficiency testing? **Answer:** Robert Thomas and Bea O'Keefe said in clarification that HIV testing counselors are working in a state run program under specific counties and have specific exemptions. Also, a POL doing only waived tests would only need to be registered and not licensed. Mr. Thomas said the main purpose of AB 221 has to do with the training of HIV test counselors and not with issues of proficiency testing.

#### **Personnel Licensing Regulations:**

Robert Thomas reported that CLTAC had submitted at least 2 position papers on personnel standards. Mr. Thomas said that recently there has been more

attention by several groups and recently within the Center for Health Care Quality & Agency concerning role out of stimulus money to increase the number of pharmacy technicians, imaging personnel, and lab technicians which has driven this to a new priority.

Mr. Thomas gave a PowerPoint presentation on why changes are felt to be needed. The following outlines this presentation:

- Need for more clinical lab scientists (technologists) in the state and nationally. Some states have recognized requirements for Assisted Reproductive Technology (ART) and assisted reproduction techs for testing.
- Need to repeal outdated requirements.
- Respond to doctoral scientist training needs that lead to a smoother transition to full licensure and recognition as clinical consultants, technical supervisor, and laboratory director.
- Transition requirements need to be defined for MLT to CLS licensure as for articulation routes to address redundancy in education and training.
- Genetic molecular biology is currently narrowly defined in law. With rapid growth in this testing area, there has been community concern to broaden the current definition.
- Since the Margolin legislation in 1993 and further regulations in 2000, there has been public request to add new license categories as biochemical genetics, and gene expression products at the PhD/MD level.

Mr. Thomas described some general areas that LFS has been requested to look at for changes. LFS can not be too specific at this meeting as regulations have not yet been submitted to the office of regulations.

- Definition for molecular biology, and possibly a new license category for clinical immunologist who can be recognized as a Technical Supervisor.
- Need to address specific types of genetic tests as chromosome analysis, mRNA, Proteomic analysis, gene expression products of proteins.
- Clinical embryology used in ART; ABB gives exams in this area.
- Other changes are requested to make a smoother route for those in post-doctoral program needing 4yrs of training/experience; 2yrs training and 2yrs experience. This is needed to qualify at the lab director level.
- Create & simplify issues on trainee licenses possibly through the novel idea on having one license. The details have not yet been worked out for MLT, CLS and post-doctoral trainees. Suggestions are welcome.
- Repeal old law practical exams, clean up current regulatory language for consistency & clarity.

**Question:** Has LFS considered adding licensure for histo technologists? **Answer:** This group is currently regulated under 1269.3 as unlicensed personnel. This statute allows for additional requirements in 2011.

**Question:** Dr. Hamill asked if LFS was considering applying the 4yr post-doc training requirements for all director level Chapter 3 licensed categories? **Answer:** Robert Thomas said yes that it would be applied for all categories and any new license categories that would be introduced.

**Question:** Maria DeSousa asked if the Clinical Embryologist would need a doctoral degree in a specific area. **Answer:** Mr. Thomas said the details have not been discussed. Comments would be welcome.

**Question:** Jerry Hurst asked a question about the slide presentation and gave his experiences with genetic testing which falls under two areas. He talked about gene

expression, quantitative measurement of RNA and how the community interprets these terms. He talked about genotyping and gene expression. Dr. Hamill commented that under genomic testing general approach details can get worked out for proteomic and genomic terms. **Answer:** Robert Thomas said that mRNA was included in the slide presentation; however, there may be need to further work out on details as LFS receives more information.

**Question:** Dr. Jon ten Bosch of Children's Hospital in Oakland said that in the near future there is likely to be a merging coming between cytogenetic and molecular biology. He asked where does the department see cytogenetic and genetic molecular biology going in the future? **Answer:** Robert Thomas thanked Dr. ten Bosch for his question. He added that the department recognizes this area to be a fast growing and changing area. Also, currently there is not a clear definition for molecular biology. Suggestions on how the department should handle these areas are appreciated because adding more license categories may not be the answer. Dr. Nickel said we also are getting information now on "molecular pathology". Robert Thomas added. We must follow the rules process as we are constantly being reminded that we cannot release the details of a regulation package prior to the comment period. However, anyone can write to us on what you would like to see. This may help us as molecular biology techniques are being used under several different specialties.

A discussion on the above began which included audience participation. Karen Nickel said just this week we are getting information on the whole field of "molecular pathology". New York has this category. Dr. Nickel mentioned and Jerry Hurst commented that this is one area that needs further intervention. Dr. Hamill said that compartmentalizing this area may inhibit growth. Possibly the solution is to de-compartmentalize this area. Direct FISH regulations should be broad enough to simplify categories instead of creating new categories. Dr. Rubio added that there is need for clarification in terminology as these areas represent a changing field. Robert Footlik said that the current regulations have narrow requirements for clinical cytogeneticists and is related to requirements by boards as ABMG. He said there is a need to recognize the issue of who may serve as a clinical consultant.

### **H1N1 Flu (Swine Flu):**

David Schnurr, Ph.D. gave an update report that H1N1 has just been declared a pandemic based primarily on this novel virus' ability to be highly transmissible person to person; currently this virus has demonstrated a relatively low severity. The designation of a pandemic means it is transmitted globally. The 2009 H1N1 virus contains a combination of gene segments that that previously has not been reported in swine or human influenza viruses in the USA or elsewhere. In California surveillance is done as briefly described below and in the PowerPoint slide presentation:

- Virology assays involve PCR testing for typing.
- Strain typing requires live virus.
- This allows for identity of future vaccine strains. Analysis includes data from sentinel labs such as CDC, Kaiser, and public health lab sources
- California respiratory program involves specimen submitted where children have respiratory illness
- Public health labs which offer culture of virus.
- Countries that offer only PCR in blue counties that offer PCR and culture in yellow. 21 counties do culture.
- Result in antigenic shift where the new virus occurs in human population.
- Virus can be introduced from aquatic birds which are the reservoir of or can go from birds to swine.
- Swine can be co-infectious with humans. Under goes process called re-assortment. Where they can migrate and become a completely new virus where

- they can infect humans.
- The virus came from swine to infect humans and became triple re-assortment virus genetic from classic swine virus.
- This one that happened in 2008/2009 and probably entered the USA from southern border of California.
- This one had not been seen before but included genes. Red genes, Eurasian service flu.
- This is a completely new virus that was not seen before transmitted very easily among humans.
- Transmitted efficiently but does not show severity which has led to pandemic designation.
- Occurrence of first offset was on April 15, 2009; second offset was in April 17, 2009.
- Number of cases increased dramatically until we have seen a considerable number.
- Table show testing in California up from seasonal expectations and on June 2<sup>nd</sup> over 11,000 specimens have been tested through the network. Of those tested, about 10% positive for A, 25% typical H1 influenza and 26% typical H3.
- Normally we don't think of influenza in May/June. What we saw was considerable. This could mean influenza going on around the year but we really do not know.
- 1000 cases hospitality are of age under 18 yrs old; oldest reported is 50 yrs old.

**Question:** Isn't typically October to March a peak period? What is going on here with this virus with this out of season peak? **Answer:** We are not sure if this is a seasonal change or if this due to increased surveillance.

**Question:** Where did it start; Mexico or somewhere else? **Answer:** May have circulated in humans up to 10yrs. Where it started no one knows. In Mexico the virus seemed to be much more severe but the numbers are not all in.

**Question:** Why is there concern this is coming back more severe? **Answer:** Experience in 1918 was 30 million deaths. It started with a mild flu and then came back over the summer under going genetic change. There is concern that this could be repeated.

### **Out of State Onsite Lab Inspections:**

Bea OKeefe announced that when she was made acting chief of LFS she needed someone to take care of the Facilities Licensing section. Kathy Williams was asked to serve as the Acting Section Chief for Facilities Licensing A. Kathy accepted and she is doing a terrific job. Ms. Williams reported on the following:

- BSA audit has been with us for a considerable amount of time.
- The audit report indicated that we were not actively seeing ways to go out of state to inspect labs receiving specimens from California.
- Now we have actively gone out of state for inspections & 2 labs have already been inspected.
- Inspections focus on each lab and they are required to provide last inspection results.
- We are looking at special requirements such as for lab director equivalency with California requirements.
- Testing personnel must be equivalent to Bachelor's degree and additional training. Look at reportable diseases compliance.
- Currently, the overall program consists of 169 labs located out of state with a California license.

**Question:** Is there a list available for the 169 out of state labs on the website?

**Answer:** No, it has to be ordered through HALS.

**Summary of Complaints received by LFS:**

Tom Tempske reported on this topic for LFS.

Complaints for the last 3 months	74
Increase over the last year	14% increase

Mr. Tempske reported that the LFS website is up and running and we don't have the figures from these, but likely this is helping on reporting complaints to LFS. There are people that don't know where to complain about health care in the state. However, if you Google complaints California, the first thing that comes is the LFS website. Also, we have observed the Department of Consumer Affairs file which when selected for labs kicks you over. In addition, we get several that are medical care, hospital issues which are referred over, including issues about pedicure, manicure and so on. These are referred to the appropriate group for follow-up. The following outlines some issues and activities;

- A lot of complains about phlebotomists many times is "rude" phlebotomists. Patient trying to tell phlebotomist how to do job and the phlebotomist is just doing what they were taught.
- LFS is doing onsite investigations on several issues to meet the spirit of the report to legislation.
- We are leveraging our resources
- We are adding comments in our HAL database where surveyors may look up comments before they go out and survey.
- We are active on issues where there are Medicare and MediCal billing. Our HAL database is better for looking up owners and directors than their databases.
- Gathering up information on billing hospital charges. We really don't have statutory authority for resolving billing disputes.

**Question:** Is there a report to legislature that is more detailed and categorized?

**Answer:** LFS is not required to give report to legislative branch. We are required to give report to BSA which is due in September.

**Personnel Licensing Section Report:**

Robert Thomas reported that there is a concern over changes in paper used to print licenses. LFS is working with a new vendor to implement printing licenses on security paper. This change is targeted to take effect in December. Until that time, licenses may be printed on different colored paper. The Facility can always verify the license by using the license verification website (LPW) on the LFS website.

Mr. Thomas also reported that LFS has been working with our Center for Health Care Quality on workforce issues. The Center for Health Care Quality and LFS are working with stakeholder groups on updating current regulations. This upcoming meeting will be an opportunity for LFS to hear from various groups and to clarify our understanding of regulatory issues on post-doctoral training programs, CLS to MLT transition, supervision ratios, the need for new license categories, and re-defining terminology and workforce license scopes of practice. The upcoming meeting date and time have not yet been finalized. Mr. Thomas clarified that the MLT scope of practice is set in statute and cannot be changed through regulation alone.

LFS has been progressing on the approval of certifying organization exams according to Bob. The LFS committee working on this continues to be Karen Nickel, Kathy Williams & Bob Thomas. LFS has just approved the American Board for Medical Microbiology

(ABMM) with an effective date June 1. LFS is looking at the end of June to review ASCP exams for hematology and immunohematology. We are planning on reviewing the American Board of Bioanalysis (ABB) exam after that time.

Regarding a carry-over item from last CLTAC involving H. pylori breath test collection by phlebotomists, Bob Thomas said this can be confusing. He pointed out that Business & Professions Code Section 1269 (d)(2) would prohibit this for unlicensed lab aides and it is not clear that this would be part of duties for a certified phlebotomy technician. He also said that a laboratory sent an email explaining how they accomplish this by mixing the powder and water at the laboratory and sending to the Stat lab on appointment as indicated in their service manual.

### **Facility Licensing Section A Report:**

Kathy Williams reported on activities;

Applications lab for registration	85 – 120
Certification issued about	80/month
Average Total	100/month
Registered Labs	7,500

Application for licensure	10/month
Survey for year	220

There are between 1700 and 2000 licensed labs

**Question:** Are these participants in MediCal or are this all labs? **Answer:** All labs; no distinguishing on whether MediCal or not.

### **Changes to HIV Testing Regulations:**

Bea O'Keefe reported on this regulation;

- Regulations went thru Department 1<sup>st</sup> comment address, 2<sup>nd</sup> comment no comment submitted to office of regulations.
- Apply to any clinical lab, POC, clinic doing testing. Does not apply to dept program.
- Concern over virus in 1980 prepared at that time was to ensure a safe blood supply.
- Wanted to test for agent of aids before transfusion.
- Wanted to ensure all labs perform this test properly before doing HIV.
- They also had to give us monthly reports.
- They had to do confirmation and be enrolled to proficiency testing.
- Only tests availability were moderate complexity.
- Now in 2009 HIV new technology have come out so the regulations want to remove some of these requirements to allow for modification of HIV kits.
- We saw some of the public health labs modify and they were performing validations but not allowed under the older lab regulations.
- PT blind testing or some way for competency testing of personnel may be part of QA procedures.
- There were a lot of redundancies. They already had to do
  - ❖ Proficiency Testing
  - ❖ Approval by LFS
  - ❖ Confidential records
  - ❖ Reports to us we did not what to do
  - ❖ Lab failed to comply would lose approval
  - ❖ Some method to be accurate
  - ❖ There are PT blind samples
  - ❖ Confirmation said needed to be by a more specific test

- New tests require lab confirmation. What is recommended by CDC? Confirmation by western Blot, triple test by rapid but has not being approved
- New test use of any FDA approved it.
- New test use of any FDA approved test with appropriate validation
- Have to establish competency program for those doing testing prior to testing, at six months, annually
- Need to have method to show test is accurate either through proficiency testing
- If they fail person has to be retrained
- Under old requirements if lab failed they lost ability to test
- Under the new requirements allows lab to be subject to full enforcement procedures which could be civil money penalties and revocation of lab licensure or registration
- Update to reflect new technologies for HIV testing and remove redundancies
- Allow modification of FDA-approved HIV kits.
- Require quality assurance procedures for waived HIV tests, as PT, blind testing, split testing and competency testing.
- Update confirmation of screened POS.

**Failure to Comply**

- Old standard authorized loss of HIV approval
- New standard shall subject the lab to full sanctions authorized in B&P Code.

**New Business:**

None discussed.

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

**Next Meeting Dates:** September 10 and December 3, 2009