

Clinical Laboratory Technology Advisory Committee
Minutes of the March 13, 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, Michael Terry, Fred Ung, David Yong, Jan Schwartz, Les Revier.

Former CLTAC Members Participating: Sam Chafin, Morton Field, Imre Fischer, Robert Footlik, Jim Ottosen, Curtis Johnson,

DPH Staff Participating: Zahwa Amad, Alan Ankerstar, Frank Barnes, Norma Barocio, Kathy Billingsley, Linda Bryant, Grace Byers, Maria DeSousa, Pam Farrell, Robert Hunter, Nema Lintag, Dona Lynch, Howard Manipis, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Shahrzad Radahd, Jennifer Simoes, Judy Schlosser, Joanne Sparhawk, Genie Tang, Tom Tempske, Robert Thomas, Pat Toomer, Monica Wagner, Kathy Williams.

Welcome and General Announcements: The meeting was called to order by Chairman Dr. Tim Hamill. He went off agenda to recognize and say good bye to Dr. Karen Nickel stating appreciation and recognizing her achievements as LFS Branch Chief. Dr. Hamill welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He called the role and noted that there was a quorum of CLTAC members present.

Approval of the March 13, 2009 meeting minutes: The minutes of the previous meeting were reviewed and approved.

Department News:

Kathleen Billingsley, Deputy Director of the Center for Health Care Quality attended the meeting in person. She started off by saying that the CA Department of Public Health is undergoing budget challenges, fiscal challenges, and constrains in state government.

However, there has been incredible progress since the department split with attention to programs at every department level including the director's office. Ms. Billingsley stated that the department has been receiving input from a wide range of sources.

From a financial standpoint we are in uncharted waters, no predictability. We continue to have a 16 hours of furlough each month, as a self directed program. Some employees can bank their furlough time. We still continue to have a pay reduction and programs are feeling pressure to keep up with work. Also, there are delays in staff travel re-imburement and this has had effects on programs. The travel issue has been resolved last week.

Everyone is working very hard to be able to maximize all the work that they have been doing. As a result of the Laboratory Field Services (LFS) Audit by the Bureau of State Audits (BSA), there had been challenges that have been brought to light. LFS can not exceed their funding within their special fund. LFS faces operational challenges, but they remain very committed to the work they are doing.

Ms. Billingsley announced Dr. Karen Nickel's retirement and appointed Beatrice O'Keefe as the Acting LFS Chief. Ms. Billingsley expressed appreciation in working with LFS Section Chiefs Bob Thomas, Ron Harkey and Donna McCallum who will serve as a strong team with Bea O'Keefe.

Question: Tom Tempske asked if there was disconnect between fees and spending authority. **Response:** Ms. Billingsley said, in general, that it is up to programs to seek an appropriation and demonstrate the rationale for the fees being charged, and this is sometimes difficult to do.

State of the State Program:

Dr. Nickel thanked Ms. Billingsley for attending this CLTAC meeting in person. Also, Dr. Nickel thanked Kaiser Permanente for offering the Southern California meeting location and providing the telephone bridge availability to interested persons who are unable to attend CLTAC in person.

Dr. Karen Nickel said her goodbyes to the CLTAC stating that she had postponed retirement to get important work completed and other important issues in progress. However, she added that a time comes for each of us to retire. Summary of activities over the last sixteen years are:

- 1993** The continuing education regulations were finalized.
- 1996** Senate Bill 113 was enacted. Emergency regulations postponed licensure.
- 1999** Gained authorization for CLIA exemption
- 2000** CLIA exemption was turned down due high overhead fees, and LFS enacted on regulations to license genetic lab directors, BS hematologists and histocompatibility scientists
- 2001** Changes in B&P Code to strengthen lab enforcement
- 2002** Broaden self ordered tests; home kit extension
- 2003**
 - Labs billing medical needed to have a license or registration
 - Phlebotomy regulations were implemented
 - MLT licensure enacted September 2005
 - CLIA final rule regulations enacted
- 2004**
 - Genetic scientist licensure regulations enacted
 - Cytotech workload expanded
 - Labs billing MediCal needed to be registered or licensed
- 2005**
 - MLT licensure regulations were enacted
 - Health fair bill relating to drug stores
- 2006**
 - Phlebotomy technician certification deadline extended to 1/1/07
 - Online application and verification started for new applicants
 - LFS started approval of certification exams in place of state administered exams
- 2007**
 - Autoverification law
 - Pathologists' Assistant, histotechs placed under direct supervision
 - Direct billing for pathology
- 2008**
 - LFS BSA Audit
- 2009**
 - LFS has proposed changes to the B&P code and H&S Code in SB 744

Dr. Nickel announced that CLTAC has a new member Dr. Lee Hilborne. He has been with UCLA since 1982 and in 2008 became Medical Director for Quest. Dr. Lee Hilborne was a CLTAC member from 1993 to 2002. He chaired the committee from 1997 to 2001. Dr. He has been a Director of Quality Management Services and Director of Patient Safety Quality. Dr. Hilborne was nominated by the California Medical Association.

She gave a brief summary of SB 113 and provisions of the bill that took effect on January 1, 1996. The number of labs under state oversight has increased from about 1200 to 19,000. This bill made many law changes to strengthen requirements for state oversight including bringing test complexity into state law; however, it did not give proper authorized funding. We are excited now because there is pending legislation in **SB 744** to address fees so LFS can add staff necessary to build a strong facility licensing program and strengthen the phlebotomy program that has had a mammoth effect with over 35,000 phlebotomy technicians now certified. She mentioned this is exciting legislation which will be discussed during today's meeting

Dr. Nickel indicated there is more to do in the area of tissue banks. This area will be discussed in more detail at the next CLTAC regarding Assisted Reproductive Technology (ART). Currently, LFS oversees about 450 tissue banks and CDPH has sponsored legislation this year in AB 995 which will also be discussed today.

LFS has licensed about 150 out-of-state labs currently.

Registration of California labs now totals about 7400.

Regulatory standards are being considered for health care personnel in the areas of training schools, genetics personnel, and revised academic coursework requirements.

LFS staffing is not adequate to carry out all functions and mandates. Dr. Nickel referred to language in a published Physician Office Laboratory study using language for quality and reliable clinical lab test results.

Questions and responses followed as;

Question: Michael Borok asked how does CLIA exemption play into SB 744 since it appears to now be on a back burner? Dr. Borok summarized the Departments effort to achieve exemption as setting up a system for duplicative fees. He would like a proposal to reduce POL fees as fees affect every lab. He stated complaints today are being done today. **Response:** Dr. Nickel responded that revenue is needed for positions to do the work required to service 18,900 labs. If LFS does not have enough revenue, positions can not be filled.

Question from Jim Ottosen: Once funds come in, what assurance is there that they will be used to support the LFS program? **Response:** The new law provides for continuous revenues that are needed to support salaries to support staff and to pay for improved document storage systems.

Comment and question from Lee Hilborne: There was a provision as part of SB 113 that the state could not charge any more then under CLIA. The assumption is being that raising fees may force labs out of the state. **Question:** How do we make sure that does not adversely impact California and labs? **Response:** Ms. Billingsley said that the administration has not appropriated monies from special funds. She added that it is important to communicate on how funds are being used. As an example, you minimize replicating what you do. Don't send two teams to look at the same thing. Be thoughtful

in using resources. This is why the cross-walk is necessary as it assists in identifying efforts toward improving program efficiency.

Bea O’Keefe reminded all that lab businesses leaving California are still subject to California licensure when testing specimens originating in California.

Three observations and question from Bob Footlik:

- A. Regarding the CLIA sliding fee scale, there is a cap at one million tests with incremental adjustments. There is an additional \$350 fee for every 500,000 tests.
- B. For labs performing isoteric tests, their volume is usually small; however, the cost to perform these tests may be high resulting in a high charge by the lab. Therefore, some feel charging by volume may lead to inequity in fees.
- C. Accrediting organizations may be unwilling to deal with separate check-lists.

Mr. Footlik asked the following **question**. What is the financial advantage of charging labs by a sliding fee schedule based on test volume versus charging on a dollar volume?

Response Karen Nickel stated that usually LFS consultations and time spent per lab is more for larger labs.

Lin Kassouni asked the **question**: How much money is in reserves, Is it 2.7 million?

Response Karen Nickel said yes.

Legislation Impacting Clinical Laboratories:

SB 744(Strickland)

Dr. Nickel said the intent was to ensure lab and personnel standards be maintained to ensure accurate reliable and necessary test results, this language was previously used in the department POL study that was published in JAMA. To meet this mandate to ensure compliance with state and federal law it is necessary to rely on inspections. LFS needs additional staff to perform these inspections. This bill would provide additional fees to provide for a strong state program. Some provisions of the bills are as follows:

- Introduces a new concept called, all laboratories letter. This is a communication tool between the government and public for changes in activities, updates in law via a letter or internet notice. Hopefully this would avoid the need for further regulations on minor activity changes.
- Would authorize continuous appropriation
- Sliding fee schedule
- Would connect funding from HSC to BPC for deposit into CLIF special fund
- Revenue should cover costs of AO approval and validation inspections. If not, report to legislature
 - AO can only decertify labs but nothing else
 - CDPH has the enforcement authority to issue a variety of sanctions
- Would be enacted as urgency legislation to cover serious lab oversight issues due to underfunded program activities.

Dr. Nickel talked about a re-inspection fee due to labs not being ready at the time of initial survey and using the first LFS inspection as consultation.

Issues were discussed for a multiple site inspection fee and the need for a facility license delinquency fee as charged by the Personnel Licensing Section for late filers for a license renewal.

Dr. Nickel also stated that a few changes in personnel licensing are needed and are covered in this bill. One is the need for a fee to cover expenses to conduct a laboratory director oral examination for licensure, and second, the need to increase phlebotomy application and renewal fees from \$54 for every two years to \$100.

Also, the need for Public Health Microbiologist continuing education coursework and renewal on a biennial basis was discussed.

In closing, Dr. Nickel stated if revenue collected by passage of this bill is insufficient for LFS to complete all of its mandated tasks, this would need to be reported to the legislature along with a request for a fee increase. We hope that we will not need to do this.

AB 995 (Block)

- Would require the collection, processing, storage or distribution of human tissue banks and tissue for use in California to comply with the American Association of Tissue Banks Standards.

AB 549 (Furutani)

- The bill does nothing more than to make minor restructuring changes that are nonsubstantive
- Targets Business and Professions Code Section 1264
- 1264 authorizes and establishes standards for the licensing of clinical chemists, microbiologists, toxicologists, molecular biologists, and cytogeneticists
- The bill was converted to a 2yr Bill on 4/28/09

AB 221 (Portantino)

- The bill as introduced would amend Health and Safety Code Section 120917
- It would exempt human immunodeficiency virus (HIV) counselors from certification as limited phlebotomy technicians (LPT) when working under a licensed physician and surgeon.
- They would be trained according to standards that are not clear; but would not meet standards already in law.
- The bill would reduce the current direct supervision and permit general non-direct supervision of persons uncertified

Regulations Impacting Clinical Laboratories:

DPH-07-010 HIV Screening Testing Standards. Dr. Nickel stated that the regs were supposed to have gone out, however they will not be going out until next week for the second comment period. Only those persons that commented the first time will receive the comments. She said next week the DPH website should be able to display these regulations.

Report of CLIA 2003 subcommittee:

Bob Footlik reported that the subcommittee has not met since the last CLTAC. However, in recent conversations with Karen Nickel, Kathy Williams and Bea O'Keefe, he expects to reconvene the subcommittee more regularly.

Six Month Progress of the BSA Audit Recommendations:

Bea O'Keefe discussed the BSA audit which has resulted in concerns regarding LFS' ability to enforce compliance for the following activities:

- Issuing Sanctions
- Imposing sanctions thru fines

- Completing mandates timely as, PT review, enforcement actions and biennial onsite inspections
- Licensing all out of state labs receiving specimens from California
- Writing or updating new regulations as required
- Sufficient legal support to the program

Bea said that LFS is leveraging resources as follows:

- Cytology examiners are inspecting accredited labs
- CLIA inspectors are funded 80% federal 20% state, LFS has been training CLIA staff on identifying additional state processes as state law differs from CLIA in specific areas such as lab personnel requirements

Summary of Complaints received by LFS:

Linda Bryant discussed the following summary as she has been assisting Tom Tempske, Program Manager for Complaints. She said that she has been working on modifications to the Access data base summary which assists in tracking and classifying complaints.

LFS has received a total of 238 contacts with concerns over the last four months. Many of these take less than 5 minutes to resolve and are not classified as actual complaints. There is a wide range of sources that contact us as patients, relatives, lab directors/CEO's, medical providers, lab employees, whistle blowers, state and federal agencies.

Complaints from December 1, 2008 to March 10, 2009

59 complaints received

- 29 are open
- 30 are closed

Total Complaints for 2008

- 230 were received
- 100 were closed

For Personnel Licensing Section, phlebotomy leads the area for complaints as forged certificates, not reporting prior law convictions, issues with phlebotomy training schools.

For Facilities, leading areas of concern involve patient test management, questionable results, and falsifying of records.

Tom Tempske reminded all that license verification can be done by checking the LFS Website at <http://www.cdph.ca.gov/programs/lfs>

Experiences on the CLIAC:

Lee Hilborne discussed his experience on the federal laboratory advisory committee (CLIAC) and some comparisons with California CLTAC. He stated that the CLIAC organization came about after following CLTAC structure and activities. For example, one difference with CLIAC is that it must follow strict federal rules; whereas, CLTAC has more interaction and is more open to networking and discussion.

The following areas were briefly discussed by Dr. Hilborne;

- Genetic testing is on the federal radar. MMWR report on genetics is coming soon.
- There is a focus on laboratory services for all laboratory types to ensure

- appropriate use of tests and services, and enhanced patient safety.
- Promoting collaboration among laboratory medicine stakeholders
- Supplementing research and educational programs provided by other organizations
- Establish and disseminating laboratory medicine evidence-based practices to providers and users
- Maximizing laboratory medicine's contribution to optimal healthcare quality
- Support for research for and use of evidence-based laboratory practices that lead to improvements in patient outcomes
- Facilitate educational materials and research on laboratory services and practices of interest to a broad cross-section of the healthcare community

Personnel Licensing Statistics for 2008:

Bob Thomas discussed issues of concern on workforce issues, Post-doctoral training, and transition between different license category levels. He also discussed the need for articulation of training for persons among different license categories as MLT to CLS to Bioanalyst / Chemist / Microbiologist. Mr. Thomas stated that all training programs have the obligation to identify trainees to LFS at the beginning and the end of training.

Pressures to Expand Phlebotomists' work scope:

Bob Thomas also discussed the confusion on phlebotomy technician activities.

- Prior to 2003, most persons performing phlebotomy for clinical lab testing purposes were unlicensed lab personnel
- Questions came up regarding phlebotomy technicians performing single waived tests as during the administration of glucose tolerance testing using urine dipsticks
- CLTAC recommended that phlebotomists not be considered under the Business and Professions Code Section 1206.5 (a)(12) as other health care personnel providing direct patient care
- CLTAC recommended that phlebotomy technicians would not be authorized to perform tests
- The number of waived tests has increased from about 8 to about 100

One scope of practice issue was discussed by Mr. Thomas regarding specimen collection for the Breath-Tek test for H. pylori. After a good discussion by Mr. Thomas and Dr. Nickel it was decided to table this issue until the next CLTAC meeting in June.

A brief discussion on clinical lab personnel licensing stats was discussed.

2008 Statistics

CLS 838

- 544 Qualified
- 379 Licensed

MLT 151

- 23 Qualified
- 65 Licensed

Trainee 258

- 130 Licensed

Phlebo 7088

- 6648 Licensed

Clarification of Microbiology QC Under Current State Law:

This **question** came from Mary York and involves Appendix C from federal law, CFR 493.1250. In August 2008, federal law incorporated commercial microbial systems guidelines. Can these standards be used under State law? ***Response:*** No.

Problems With Infectious Disease Reporting Requirements:

We have had the California Council of Local Health Office request that we remind labs to complete lab forms in full. This includes the ordering physicians name telephone numbers.

Should LFS Promote CLS Review Courses?:

Dr. Nickel announced LFS will be providing website notices about the CLS review courses along with any study materials that persons may recommend. We will be doing this not to promote any specific organization but to help applicants prepare for the licensing exam.

New Business:

CLTAC asked for the slides to go out with the minutes in the future. Dr. Nickel said that's normal procedure but we were unable to do it for this March CLTAC meeting.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:45 PM.

Next Meeting Dates: June 12, 2009, September 11, 2009 and December 4, 2009.