

Clinical Laboratory Technology Advisory Committee

Minutes of the March 7, 2008 Meeting

Meeting held by videoconference from CDPH Richmond Campus and North Hollywood Kaiser Permanente Regional Laboratory.

[CLTAC Members Participating:](#) Laurie Armour, Michael Borok, Lorri Dean-Yoakum, Elizabeth Dequinia, Tim Hamill, Curtis Johnson, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Michael Terry, Fred Ung, David Yong, Mary York.

[Former CLTAC Members Participating:](#) Sam Chafin, Morton Field, Imre Fischer, Deanna Iverson, Robert Footlik, Solomon Notrica, James Ottosen.

[DPH Staff Participating:](#) Zahwa Amad, Frank Barnes, Norma Barocio, Kathleen Billingsley, Grace Byers, Maria DeSousa, Victoria Edwards, Ron Harkey, Robert Hunter, Nema Lintag, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Bea OKeefe, Jan Otey, Shahrzad Radahd, Judy Schlosser, Joanne Sparhawk, Genie Tang, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams, Ellen Yasumura.

[Welcome and General Announcements:](#) The meeting was called to order by Chairman Dr. Tim Hamill. He welcomed the participants and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He noted that there was a quorum of CLTAC members present.

Karen Nickel welcomed the participants and thanked Kaiser Permanente for providing the videoconference site in North Hollywood and for providing the telephone bridge. She introduced Kathleen Billingsley, Deputy Director of the Center for Healthcare Quality (CHQ). Since the reorganization of the Department of Health Services to the Department of Public Health last July, Lab Field Services is now part of this new Center.

[Department News:](#) Kathleen Billingsley thanked Dr. Nickel for the invitation to speak to the CLTAC. She gave the background on the CHQ, saying it was comprised of 3 programs. Licensing and Certification has 1000 employees who inspect hospitals and skilled nursing facilities, licenses certified nurse assistants, hemodialysis techs and nursing home administrators. Lab Field Services is the second program and is responsible for inspecting and licensing laboratories and laboratory people, blood banks and tissue banks. The third program is the Office of Patient Safety, a new program tied to healthcare reform. These programs parallel each other and all face operational challenges as staff resources and new technology. Ms. Billingsley said she had graduated from UCB and is a registered nurse with healthcare administration experience.

[LFS Update:](#) Karen Nickel updated the CLTAC on issues related to Lab Field Services. The recent Governor's Executive Order about cost reductions does not impact LFS directly since LFS is a fee-supported program with revenue going into a protected special fund for use by LFS only. However, LFS is being asked to restrict travel and spending along with the General-funded programs.

Dr. Nickel said LFS has auditors from the Bureau of State Audits, 4-5 persons almost daily in our office now. This is in response to AB 1807, legislation which required an audit of LFS' practices and procedures for enforcing state laws regarding laboratories. The auditors have complete access to any records. This shall result in a report to the legislature with recommendations for improvement. LFS shall also have an audit from the Department of Finance about handling of its license fees this summer.

LFS is closely watching what's happening with genetic testing in California. We are concerned about direct-to-consumer advertising of genetic tests. We get calls from manufacturers who want to sell genetic testing equipment and from labs who want to start testing. We get calls from the public concerned about reliability of the tests and the costs. LFS does not consider genetic tests any different than any other clinical lab test. If it is being used to predict or diagnose a dysfunction, it should be subject to clinical lab law. Dr. Nickel said LFS was following what the federal government was going to do about genetic testing. The SACGHS recently reported that any facility getting reimbursement for genetic testing must have CLIA certification and must enroll in proficiency testing.

Special Presentation: Robert Thomas and Shahrzad Radahd asked that they interrupt the program to make a special presentation. They explained that the new Medical Laboratory Technician (MLT) program had started on December 19, 2007, and four of the first licensees were going to be introduced in Richmond and North Hollywood. They recognized Tania Puro (Hartnell College program director) and Debbie Wagner (DeAnza College program director) as leaders in starting MLT training programs. Recent licensees were recognized: Cynthia Sallabedra and Dat Bui in Richmond. Donna McCallum introduced Vinh (Steven) Le and Dawn Craft in North Hollywood as recent MLT licensees.

Approval of December 7, 2007 minutes: Chairman Tim Hamill noted that review and approval the previous CLTAC meeting minutes had been overlooked. These minutes had been distributed to the CLTAC and the public members before the meeting. A few corrections were made to these minutes and they were approved.

Report of the CLIA 2003 Subcommittee: Robert Footlik said his committee which is charged with preparing a crosswalk between CLIA as incorporated in state law in 1996 with that enacted by CMS in 2003, is making slow progress. The committee is not yet ready to report to the CLTAC on its recommendations.

Medicare Competitive Bidding Update: Donna McCallum reported on the recent announcement of CMS' intent to conduct a competitive bidding demonstration in the San Diego area for laboratory services. The objective of this demonstration is to bid Medicare reimbursement rates below the current rate, yet maintain quality and access. This 3-year project has a number of exclusions, as labs doing <\$100,000, ESRD tests, labs providing nursing home services. It is expected site selection will start July 2008. A second demonstration is expected at another location in the US next year. The CLTAC had a number of questions about which lab type would be impacted and why San Diego was selected. Bob Footlik said there were 2 federal bills introduced with multiple sponsors to repeal this project. LFS will follow this.

[Update on Reportable Disease Requirements, MRSA:](#) Kathy Williams reported on methicillin-resistant Staph aureus (MRSA). MRSA has been added to the list of diseases that must be reported to local health departments in the state. The new reporting requirement mandates that health care providers report all cases of severe staph infections, including MRSA, to their local health department which reports the infections to the state. Severe cases are those in which there is an infection in a previously healthy person that results in death or admission to a hospital ICU. Dr. Borok questioned how outpatient MRSA patients would be reported. Dr. Field said MRSA were already hospital reported. Jim Ottosen said that outpatient and reference labs are often not provided with information that would allow them to classify Staph cases as severe and therefore would only be able to report those for which they had this specific knowledge.

[Legislation impacting clinical labs, SB 1184 \(Kuehl\):](#) Kathy Williams reported on SB 1184 which proposes to require all CD4 results to be reported to the state. The health officer shall match the CD4 result with known HIV patients, in an attempt to find previously undiagnosed patients. This is required now by the CDC in order for California to get federal funding for AIDS treatment. The CLTAC questioned reporting all CD4 results as burdensome, asked about why the CDC would require this. This is apparently required for federal Ryan White funding.

[Validation of Autoverification:](#) Dr. Nickel said that Autoverification is “use of computer algorithm in conjunction with automated clinical lab tests for accuracy and reliability”. She said that autoverification relies on Boolean logic, series of questions (rules) to eliminate outliers, strings them together, with “And”/”Or” statements, leading to a logical decision. In order for a test system to be eligible for autoverification, the tests should have discrete limits, not titers or qualitative. The sample must not be consumed but must be available for retesting if flagged. There must be a computer system to analyze complex data sets fast. Dr. Nickel also reviewed the lab director responsibilities in autoverification. The lab director must establish reporting criteria, set up validation protocol, authenticate before use and whenever changed, then re-validate annually. He/she, of course, must make sure staff is trained and competent, and make sure documentation is complete.

[Cystic Fibrosis \(CF\) Testing from Thin-Prep Pap Slides:](#) Bea O’Keefe introduced the topic of cystic fibrosis (CF) testing. She said that the American College of Obstetricians and Gynecologists had adopted new guidelines for CF testing. She stated that under the guidelines, it is recommended that health care providers make the CF carrier screening test available to all couples who are considering having a baby. The risk factors for CF are the following: Caucasians 1 in 29, Hispanics 1 in 46, African Americans 1 in 62 and Asian Americans 1 in 90. Bea explained that both parents must be carriers for the child to have CF. She said that the guidelines advise test laboratories to check for the 25 most common mutations. The laboratory should include all of the genes that can be detected in their test system. California law requires that the testing personnel and the technical supervisor must qualify to perform the tests in molecular human genetics. Other qualified individuals include physicians, pathologists, bioanalysts, clinical laboratory scientists and molecular genetic scientists. This test is considered high complexity. Specimens can be blood, oral or vaginal. Validation must follow the requirements for high complexity testing under CLIA and must include accuracy, precision, sensitivity and specificity.

[Pathologists' Assistants \(PA\) and Grossing of Pathology Specimens:](#) Dr. Nickel said that she wanted to update the CLTAC on the impact of the new law created with Senate Bill 2156 (2006). She said that this bill recognized Pathologists' Assistants (PA) and Histotechs. These persons do not need a California license to do grossing. Board certified PAs are authorized to do grossing of tissues under the general supervision of a pathologist. Non-board certified PAs can still do grossing of tissue as long as they are being directly supervised by a pathologist. The gross description and dissection of human tissues according to SB 2156 is that done on living humans, not human postmortem exams, autopsies and preparing the body for release. The requirements for board certified PAs include a BS or MS in science and one to two years training leading to certification by ASCP or AAPA.

[DPH-07-010: Standards for Laboratories Performing HIV Screening \(CCR 1230\):](#)

Bea OKeefe said Title 17 of the California Code of Regulations Section 1230 set standards that facilities must meet in order to screen for the presence of HIV. She stated that this section went into effect in 1986 ahead of CLIA which implemented in 1992. Ms OKeefe said there have been technological advances such as simple HIV waived tests that have made testing available to clinics and physicians. There is also growing public health demand for wider HIV testing. Several important changes are proposed to the current regulations. The CLTAC will be sent copies for review and comment when they are ready. LFS proposes to repeal the requirement that LFS approve all laboratories that perform HIV screening. Since all labs are subject to both CLIA and state law, elimination of second approval shall allow more facilities to perform testing and eliminate delays in approval. Another proposed change would be the addition of more specific language as to what confirmation test must be performed. Current language only specifies the use of a more specific test but does not say what that test is. The federal CDC has recommended a specific protocol using the Western Blot or immunofluorescence for confirmation. In a study done by CDC, it was found that patients with reactive waived HIV tests that are confirmed negative by Western Blot or IFA, should be retested 4 weeks later. Another change in the proposed regulations is to allow use of non-FDA approved HIV antibody screening for non-waived tests. There are new tests that might be used to detect antigen rather than antibody. Also some laboratories have been able to modify and validate the use of oral fluid on EIA test kits. The current language does not allow those changes. Proficiency testing is available for waived HIV tests and it is thought that proficiency testing for the HIV waived tests would help to ensure all laboratories are performing HIV testing correctly.

[DPH-08-01, Clinical Laboratory Personnel Standards \(CCR 1030-1061\):](#)

Dr. Nickel said LFS had a big surprise for the CLTAC. LFS has been working on an update of the personnel licensing standards for several months. Using position papers developed by the CLTAC over many years, LFS has made major progress in amending regulations to Sections 1030 to 1061. Many of these standards are 30 years old. The rationale for pushing this through now is to help with new applications, particularly those coming from persons coming from outside California. Our old requirements are a barrier for many qualified persons. Many of these standards are unnecessary, outdated, burdensome and hard to administer. The CLTAC will not be able to review these regulations until they are reviewed and approved by legal staff.

[DPH-08-02: Clinical Laboratory Standards \(CCR 1050\)](#): The second regulation package will amend laboratory standards at CCR 1050. The CLTAC should remember that sections of this regulation prohibited autoverification and limited the number of labs a person can direct to 3. It took new legislation to supersede these requirements in Section 1050, and there are other outdated sections that need to be repealed. Again, LFS will be using a position paper from the CLTAC to justify repeal of this regulation. We hope to have this done in summer of 2008.

[DPH-08-XX: Sperm Donor Standards \(SB 443, Migden\)](#): Ron Harkey reported on regulations mandated by recent legislation. Senate Bill 443 authorized sperm from donors who tested POS for HIV to be used for insemination when informed and mutual consent had been obtained and only after the sperm has been processed to minimize infectiousness. The bill would require the Department (LFS) to adopt regulations by January 1, 2010 regulating facilities that would perform sperm processing from HIV POS donors. Mr. Harkey said developing such standards would require expertise not currently available to LFS, so outside consultation will be needed. He said the American Association for Reproductive Medicine has sperm washing standards.

[Will LFS be administering State Licensing Exams in Nov 2008?](#): Robert Thomas said that LFS will not be administering a CLS generalist licensing examination in 2008 or in the future. He also stated that all CLS applicants must pass a California approved certifying organization exam. He said that 16 license categories now have approved certifying exams for licensure in California. Six categories still do not have exams approved, but LFS is working on that. The CLTAC asked several questions. What about doctoral-level examinations? LFS is reviewing these exams, also, but has done the higher volume BS-level exams first. With the ASCPi, who checks the social security number (SSN) of the applicant? LFS has to make sure that any applicant has a valid SSN before they are licensed. This does not prohibit a person outside the US from taking the ASCPi exam. What is the status of the online quiz? Every applicant taking a certification exam for licensure, except phlebotomists, must take and pass the online quiz.

[Update on Personnel Licensing Issues](#): Robert Thomas reviewed progress on certification exam approval. At the high school level, phlebotomists take one of 6 certification exams leading to certification as CPT-1 and -2. At the associate level, there are 2 exams approved for Medical Laboratory Technicians. At the baccalaureate level, clinical lab scientists, clinical chemist scientists, clinical toxicologist scientists, clinical cytogeneticists scientists, cytotechnologists, genetic molecular biologists, histocompatibility scientists, clinical microbiologist scientists have certification exams available. Doctoral level candidates can take certification exams leading to licensure as clinical toxicologists, cytogeneticists, genetic molecular biologist, histocompatibility lab director, oral pathology lab directors.

Mr. Thomas said LFS shall continue to offer examinations to baccalaureate-level clinical hematologists, immunohematologists, public health microbiologists and doctoral-level clinical laboratory bioanalysts, clinical chemist and clinical microbiologist in 2008 unless exams can be approved in these categories by June 2008.

An oral exam on state and federal laboratory law shall continue to be given to doctoral-level applicants or bioanalysts.

Transition Procedure for CLS Trainees to CLS Scientist: Frank Barnes discussed the procedure to speed the transition between California trainee and licensure as a CLS. The applicant must apply on line not less than 45 days prior to the completion of training at www.dhs.ca.gov/lfs and send LFS the signed and dated attestation page immediately after registering. Also, the CLS training program director must send to LFS the verification of training forms (LAB-N-148 or LAB 150) not less than 30 days prior to completion. LFS will send the applicant a qualifying letter one week prior to completion of training so the applicant can apply for a certification examination and take the online quiz. Then when the applicant completes his/her training and passes a certification exam, he/she can be licensed without delay. The license will be issued within 2-3 weeks and the online license verification will be available within 72 hours of license approval.

Clinical Laboratory Scientist (CLS) Examination Statistics for November 2007:

Zahwa Amad reviewed the statistics of the November 2007 licensing examinations given by LFS. She said that 700 persons were qualified to sit for the state-administered exam, 550 took the exam and 280 passed. Of those who took the exam, 56% of examinees passed while 54% failed. Of those that passed, 53 trained in California, 98 trained in the US outside California and 129 trained outside the US. (Note, the CLTAC thought more than 53 California trained persons passed the exam and Dr. Amad will check.) In the specialty exams 40 persons took the exams and 72% passed.

For those persons taking certification exams for California licensure, LFS has licensed 52 clinical lab scientists, 27 clinical cytogenetic scientists, 7 genetic molecular biologist scientists and one each, clinical toxicologist scientist and histocompatibility scientists between December 2007 thru February 2008.

MLT Licensing Report: Shahrzad Radahd reviewed licensure requirements for the new Medical Laboratory Technician (MLT) license. She said the 4 new licensees introduced today reflect different avenues for MLT licensure, college training program, re-entry college, military training and out-of-state certification.

New business and open discussion: The CLTAC would like to discuss the follow items at a later meeting:

- Histotech licensure?
- Email a phone list
- Modernize the public doctorate health microbiologist requirements.
- Can the phlebotomists have a grace period for their renewals?

Next Meeting Dates: Tim Hamill announced the dates of the upcoming meetings as June 13, 2008, September 5, 2008 and December 5, 2008. Dr. Hamill was concerned that he would be unavailable for the June 13 meeting, so Donna Kirven agreed to serve as Acting Chairperson in his absence.

Meeting Adjourned: The meeting was adjourned by Tim Hamill at 12:40 PM.