

Clinical Laboratory Technology Advisory Committee
Minutes of the March 3, 2006 Meeting
Meeting held by videoconference from DHS Richmond Campus and
North Hollywood Kaiser Permanente, and by telephone bridge.

CLTAC members participating: Michael Borok, Teresa Bryant, Curtis Johnson, Tim Hamill, Lin Kassouni, Arthur Lurvey, Carmen Maldonado; Peggy O'Toole, Salim Rafidi, Les Revier; David Yong, Mary York, David Zingmond.

Former CLTAC members: Victoria Bello, Sam Chafin, Morton Field, Imre Fischer, Robert Footlik, Deanna Iverson, Jim Ottosen.

DHS staff present: Alan Ankerstar, Frank Barnes, Grace Byers, Wenn Chen, Maria de Sousa, Pam Farrell, Ron Harkey, Robert Hunter, Paul Kimsey, ShiuLand Kwong, Howard Manipis, Donna McCallum; Don Miyamoto; Karen Nickel, Bea O'Keefe, Jan Otey, Judy Schlosser, Tom Tempske, Robert Thomas, Pat Toomer, Clint Venable, Kathy Williams

Public Members: 38 persons signed in in Oakland, 22 persons, in North Hollywood, 63 lines called in on the telephone bridge.

Introduction and General Announcements: Teresa Bryant opened the CLTAC meeting at 9:05AM, called the meeting to order, welcomed the participants and asked the participants to identify themselves at both videoconference sites and on the telephone bridge. She reminded the audience that CLTAC members would be heard first, than the others. She also noted that the telephone bridge participants were all on "mute" and could only access the meeting through the operator. This was done to eliminate background noise of phones left on.

Approval of December 2, 2005 Meeting Minutes: Approval of the minutes of the December 2, 2005 meeting was postponed because four CLTAC members on the telephone bridge had not received copies yet.

Department News: Paul Kimsey, Division Chief of Laboratory Science, thanked everyone for attending. He said that Lab Field Services is suffering with staff shortages and backlogs, and they were in the process of evaluating courses of action. He said the Governor's California Performance Review, the licensing reform proposal, was still on the table. This would make changes to modernize government, maximize services and support. Michael Borok asked why LFS was so short staffed, did they have vacancies that they were unable to fill? Paul Kimsey said there was a ceiling on LFS spending, some vacancies could not be filled, and the workload exceeds approved staffing levels.

LFS Update: Karen Nickel welcomed the CLTAC and public members, and thanked Kaiser Permanente for the kind use of their videoconferencing center. She said that Wenn Chen would be transferring from Manager of Continuing Education (CE) in Richmond to the CLIA inspection team in Los Angeles and Shahrzad was returning as

CE Manager after a year in Nigeria testing people for HIV for Doctor's Without Borders. Karen Nickel mentioned several promotions in LFS, Steve Ruben to Examiner II, blood bank inspector, ShiuLand Kwong, to Examiner II lab licensing, Maria deSousa, Examiner II, phlebotomy certification. She encouraged qualified people to apply for Examiner I and II to fill current vacancies and new positions coming in July 2006.

Karen Nickel said the big news at LFS is the horrendous backlogs in all areas, staff shortages, problems with license renewals, printer problems, mail problems, demands for license verifications. People are upset with all the problems and it is hard to deal with all this. We have hired many retired annuitants who work part time to help until we can fill the vacancies with permanent staff. We apologize for the problems this has created for people.

Dr. Nickel said that today we are going to focus on phlebotomy and its backlog, and the scope of practice of phlebotomists because of the many phone calls we are getting. We are going to talk about SB 169, the legislation that would push the phlebotomy deadline back. We are going to talk about the new MLT licensure program and on our progress toward CLIA exemption.

Karen Nickel spoke on plans to adopt certification exams in lieu of state-administered licensing exams. This was made possible with adoption of title 17 CCR 1031.8 and 1031.9 with the MLT regulations last September. The application form has been developed and very soon the certifying organizations will be notified that LFS will be accepting applications for CLS exam approvals. Karen Nickel discussed the information that the regulations require the certifying organization to provide in order to gain approval. One approved, the exams can be used for licensure purposes for 4 years and there is a 4-year look back for persons recently taking the exam. She said that LFS would try to approve 2 CLS exams in summer 2006, then 2 MLT exams in fall 2006, then go back for another CLS or MLT before it starts on the minor categories.

Phlebotomy backlog, how did it happen? Karen Nickel said currently there was a backlog of about 7,000 phlebotomy applications and that LFS expected that to increase to about 8,000 by April 3, 2006, the phlebotomy deadline. How did this backlog happen? (1) Most people waited until the third year to apply for certification, 2,200 in 2003-04, 4,200 in 2004-05 and an estimated 12,200 in 2005-06 with 2,200 renewals coming in. (2) LFS has inadequate staff. Because the program got a slow start, LFS was not authorized to hire more positions until too late. (3) Phlebotomy applications are difficult to process because of language problems, lack of computer access, inability to get proof of HS education, inability to follow instructions, high criminal conviction rate.

SB 169 to extend the phlebotomy deadline. Bob Thomas reported on SB 169 which would extend the certification deadline from April 3, 2006 to January 1, 2007 for grandfathered phlebotomist who had submitted an application on or before July 1, 2006. This urgency legislation would take effect as soon as signed by the governor if it passes. The CLTAC had questions about this issue. One asked, why not extend the deadline for everyone, not just for the grandfathered persons? Paul Kimsey said DHS

does not have a position on the bill, but the amendments did not relate to non-grandfathered applicants. Maria deSousa said there is no deadline for new applicants. They cannot work without certification. Someone asked why not sort the applications to separate the grandfathered from the non-grandfathered? Bob Thomas said that would take too much time. Someone asked how LFS was going to notify the labs. Bob Thomas said LFS would notify phlebotomy training programs directly and put a notice on LFS website. Bob Footlik said the bill was sponsored by the CCLA and impacted only those employed as phlebotomists on or before April 3, 2003. That was the intent of the legislation. Tom Tempske said the Live Scan criminal background checks were taking extra time. Milt Kelly asked how many applicants would be affected by this bill. Karen Nickel estimated that 3,500 of the pending applications were from grandfathered phlebotomists, the rest were new. Barbara Brunell asked how a lab could have proof that their phlebotomist had applied and could continue working past July 1. Bob Thomas said if they apply online, they could make a copy of their attestation page. If they mail in their application, LFS will send a letter back.

Phlebotomy scope of practice. Maria deSousa discussed who was authorized to perform phlebotomy and the scope of practice of certified phlebotomists. Those who can be authorized to perform skin puncture, venipuncture and arterial puncture for diagnostic purposes include, licensed physicians, registered nurses, physician assistants, clinical lab scientists, hemodialysis techs, vocational nurses, respiratory care practitioners, and certified phlebotomists (CPT-2). Medical assistants may perform skin puncture and venipuncture in a physician office or clinic when supervised by a physician, a pharmacist can do skin puncture only, paramedics and EMTs are limited to skin puncture in emergency services. Forensic and insurance company phlebotomists must be certified phlebotomists. Health fairs must employ certified phlebotomists, while non-diagnostic health assessment programs can employ limited phlebotomy techs only for skin puncture draws.

The scope of practice in the law for phlebotomists does not authorize them to do any testing including dipsticks, point-of-care or waived testing. This is a frequent question in LFS.

Maria deSousa answered questions about phlebotomy certification. When can a phlebotomist do testing? They cannot, as a phlebotomist. If also qualified as a nurse assistant providing direct patient care, they could be trained to do waived POC testing, for example, but not as a phlebotomist. Someone asked if applying several times for certification would speed approval. Ms. DeSousa asked that persons not apply twice, as mail-in and online, as that confuses the process with duplicates. Someone asked if applicants could work if they have received a postcard. Maria deSousa said no unless they are grandfathered. The postcard just means the application has been received. Someone asked if phlebotomy renewals could be done online. Ms. DeSousa said no, not yet. Someone asked about the denial rate due to criminal convictions. She said there are many convictions, some denials and hearings. Most are approved.

Other clinical laboratory legislation.

SB 169 (Migden) was discussed before and would extend the deadline for phlebotomy certification to January 1, 2007.

SB 699 (Soto) would require a clinical lab to report POS HIV results to county health officers by patient name and then to Department of Health Services. ShiuLand Kwong said that the counties would continue to offer confidential HIV testing, and there would be penalties for willful disclosure of patient HIV results. This would displace no-name HIV reporting implemented several years ago. Someone asked why the urgency in this legislation? ShiuLand said CA uses no-name reporting and this impacts CDC support of AIDs program. Currently reporting is anonymous, but this bill would make it only "confidential". Patients can go to county health programs for testing but not for treatment.

AB 2156 (Niello) is entitled "Clinical laboratories" is a placeholder bill with only one word changed in B&P Code Section 1241. CCLA is sponsoring this bill and we expect that more will be forthcoming.

AB 2452 (Richman) would require DHS to automatically license any accredited laboratory.

MLT licensure status. Robert Thomas said he and Karen Nickel were working this year to get the MLT program started, pending new staff coming hopefully in July 2006. There was much to do but priorities were getting MLT training programs and certifying exams approved, setting up the data bases, accounting codes, application forms. If LFS does not get new staff in July, the licensing program cannot be started beyond this. The CLTAC asked questions. Will the MLT license be for 2 years and staggered? Bob Thomas said he hoped both could be done, either by birth date or date of issuance. Will the MLT fee be the same as for CLS? Yes, the application and renewal fees will be the same since the work to review and approve will be the same. How many exams and training programs will be approved? LFS hopes several exams will be approved but does not know how many MLT training programs will be started. Will the application forms be put on the website? Yes.

Verification of lab personnel licenses. Robert Thomas reiterated that JCAHO was requiring labs to verify their staff's licenses through the primary source, LFS. This has been a great workload to LFS and has been impossible to do on a timely manner. LFS has 42 different license categories and several databases, and is working with IT in Sacramento to develop online verifications. It is hoped that this will be done this summer.

Does grossing for pathology require a licensed person? This question came up at a previous meeting. State law does not mention pathologists' assistants (PA) or histotechs, so these persons are not licensed or really authorized to work. Pathology is

a high complexity test requiring licensed persons. Therefore, a person licensed to perform high complexity testing should be doing the grossing, as a pathologist. Deanna Iverson said anatomical pathologists (AP) have a high workload and rely on PA and histotechs to get their work done. She said the state should not take a hard stance on this. Bob Thomas said that CLIA allows persons who were certified prior to 1992 to be grandfathered and continue to do PA work under technical supervision of a pathologist. He said some simple jobs, as skin tags, could be done by a histotech, but this is an unresolved issue in California.

Update on implementation of lab registrations and CLIA exemption. Bea O'Keefe said that her limited staff resources had been partially redirected to assist with phlebotomy, and that was delaying implementation of lab registrations. To make matters worse, the lab renewals were late being mailed from Sacramento and some labs had to wait until the first week in April to get their new license. Her section started sending registration notices to labs that had started testing after 1996 and were not subject to exemption by the emergency regulations. About 300 labs were contacted and >75% are now registered. Those that did not respond were sent 3 successive letters that their CLIA certificates would be cancelled if they did not get a state registration. There was lots of confusion in why they had to be registered.

The path to CLIA exemption started in June 2005 with direction from Governor Schwarzenegger followed by a letter to clinical labs from Director Sandra Shewry. FAQs were listed on our website and a letter of intent sent to CMS. A follow up meeting was held with CMS to talk about CLIA exemption. The implementation plan included getting all CA labs not subject to exemption by emergency regulations in 1996, licensed or registered, identify the labs outside CA that need to be licensed, eventually considering deemed status for accrediting organizations, reviewing the previous CLIA exemption package, adding LFS positions necessary to conduct a CLIA exempt program, repeal the emergency regulations and license/register all labs and then submit exemption package.

The CLTAC has questions about lab licensing and CLIA exemption. Michael Borok asked how DHS would give deemed status to accrediting organizations. How would the organizations apply? Karen Nickel said the process had not been defined yet, but would probably require regulations to set approval standards. David Yong asked how LFS could terminate CLIA certificates if the lab were not registered. Bea O'Keefe said both were required, and one could not operate without the other. Michael Borok asked how many POLs were accredited. Karen Nickel said a total of 1400 labs in CA were accredited and about 600 of those were thought to be POLs. Mary York asked about the status of the administrative overhead fee that was charged before and would be charged again. Will it be renegotiated or borne by the labs? Karen Nickel said all avenues would be attempted to lower these fees or make them less burdensome to the labs. Mary York had questions about research versus diagnostic testing.

Licensure of labs outside California. So far LFS has licensed about 115 labs outside CA, but thinks there are >400 that need to be licensed based on a survey done to

licensed labs in CA. Bea O'Keefe said the time to process a lab application from a lab outside CA is much longer than in-state labs because it requires exhaustive paper review, including review of testing personnel equivalency. Each person performing testing, supervising or consulting must be evaluated. Previously all labs outside CA billing for MediCal reimbursement had to be licensed. Now all labs doing any CA testing must be licensed. The Occupational Health Branch has notified labs doing occupational lab testing that they must also be licensed. One of the large labs in CA has recently sent letters to their reference labs outside the state that they must be licensed in order for them to continue submitting specimens. LFS anticipates more out-of-state labs getting licensed as LFS gets more staff, but none will be cut off in the interim. Tim Hamill said there should be some mechanism to allow a physician to send a test to labs outside CA when needed so as to not jeopardize patient care. Michael Borok asked what are the fees for licensing labs outside CA? The fees are the same as in-state labs. Robert Footlik asked how could anyone restrict a physician from where he/she send a test, and how would anybody know? Michael Borok said a physician could send the specimen to a lab who in turn refers it out of state, who would know?

Can a limited liability company (LLC) own a clinical lab? Bea O'Keefe said LFS has been getting questions about LLC as owners of a lab. LFS is responsible for reviewing the ownership status of a laboratory applying for licensure, as its corporate status with the Secretary of State. If its corporate status is suspended, the lab license shall not be issued. The owners of a LLC have the liability protection of a corporation where members cannot be held personally liable for debts. But, whereas corporations can go on forever, an LLC is dissolved when a member dies or is bankrupt. Corporation law says an LLC cannot render professional services which are authorized by license, certificate or registration, and this includes doctors and healthcare professionals. Doctors cannot form an LLC and own a laboratory, but a non-physician LLC can own a lab or physicians in other business arrangements can own a lab.

Mother's milk update. This discussion was postponed until the next meeting because of time constraints.

CLIA update. Donna McCallum updated the CLTAC on CLIA activities in CA. She said that LFS staff was scheduled to perform 800 routine follow up CLIA surveys this year plus 38 validation surveys of accredited labs and 198 surveys of waived labs, totaling 1036 inspections. Ms. McCallum discussed the new CLIA complaint system, called ACTS, that was started in March 2006. This provides national data on complaints, and it is hoped that accrediting organizations will enter minimal complaint data on accredited labs, also. CMS will publish the long-awaited proposed rule for genetic testing by the end of 2006 and will solicit public comments. Some recommendations were already incorporated into CLIA 2003 as enhance confidentiality and unidirectional workflow. Donna McCallum discussed the Certificate of Waiver Study conducted by CMS. This is in its final year but may continue. The goal of this study is to see the effect of onsite visits of waived labs on quality of testing. Cytology proficiency testing was started in 2005 with good registration and follow through. The initial data indicates a need for

testing although 91% of those tested, passed. Ms. McCallum said enforcement of PT failures was increasing with monetary sanctions imposed by CMS.

Cytotechnologist (CT) scope of practice. Ron Harkey deferred to Deanna Iverson, CT and former member of CLTAC. She said the scope of practice of CT was changing in large part due to liquid-based Pap testing, GC, Chlamydia, HPV molecular diagnostic testing. A CT is expert in microscopy, cellular differentiation, staining and such, and can add the other skills. Some CT schools are adding training in flow cytometry, immunohistochemistry and molecular diagnostics, and ASCP has a certification specialty in molecular diagnostics for CT. Karen Nickel said LFS would continue to evaluate this as it may require another license type. Maybe there would have to be two CT licenses since not all CT would be impacted, one that included molecular and one that did not, and this would require licensing regulations. Ms Iverson said the CA Association of CT, ASCT and CLTAC should work on this. Ron Harkey said the CT screening must be signed off by pathologist, but not so in molecular testing.

Quality control issues for high complexity testing. This issue was tabled because of lack of time.

New business, open discussion. Karen Nickel apologized that the agenda had been overly optimistic or that they had been too much unanticipated discussion that made it impossible to complete the agenda. She said the unaddressed issues would be held over until next meeting on June 9, 2006.

Chairperson Teresa Bryant asked for motion for adjournment and the meeting was closed at 12:33 PM.