

Clinical Laboratory Technology Advisory Committee
Minutes of the March 2, 2007 Meeting
Meeting held by videoconference from CDHS Richmond Campus and
North Hollywood Kaiser Permanente, and by telephone bridge

CLTAC members participating: Michael Borok, Liz Dequinia, Curtis Johnson, Tim Hamill, Christine Hsu, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Les Revier, Salim Rafidi, Michael Terry, David Yong, Mary York, David Zingmond.

Former CLTAC members participating: Ellen Jo Baron, Sam Chafin, Morton Field, Robert Footlik, Jim Ottosen, Imre Fischer.

CDHS staff participating: Alan Ankerstar, Grace Byers, Maria DeSousa, Robert Hunter, Paul Kimsey, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Bea OKeefe, Jan Otey, Shahrzad Radahd, Steve Rubin, Robert Thomas, Pat Toomer, Kathy Williams.

Public members participating: 23 persons attended in Richmond, 33 persons attended in North Hollywood, 35 persons called in on the telephone bridge and 10 accessed the digital replay of the meeting.

Introduction and general announcements: Chairman Tim Hamill opened the meeting at in North Hollywood at 9:03AM. He welcomed the attendees and asked persons to identify themselves at both videoconference sites and on the telephone bridge. He reminded the audience that CLTAC members would be heard first, then the others. Dr. Hamill asked all participants on the telephone bridge to mute their phones to eliminate background noise.

Approval of the December 1, 2006 meeting minutes: Dr. Hamill acknowledged that there was a quorum of the CLTAC present, and asked that the minutes of the December 1 meeting be approved. Mary York asked that an amendment be made to the discussion on infectious disease reporting, as follows:

“Mary York asked that Dr. Boetani send infectious disease reporting information to the CLTAC, explain whether the alb or physician was primarily responsible, and that changes be made only with an opportunity for public input. She questioned some of the infectious disease reporting requirements, saying there were ineffective mixed diseases and organisms on the same list and added some organisms to the lab reporting requirement that cause similar diseases but omitted others.”

Motion was seconded, and the minutes shall be amended.

Frank Barnes asked that the discussion on CLS training programs be amended to say the number of approved programs is now 79 and not 81, as stated in the minutes. This change shall also be made.

Department news: Dr. Paul Kimsey, Division of Laboratory Science, gave the report for the department. He thanked Kaiser Permanente for sharing their facilities and the phone bridge. He said the upcoming re-organization of DHS has everyone in Sacramento preoccupied. It seems progress is slow and there is some criticism. No appointments have been made at the high positions but Dr. Mark Horton is expected to be the new Director of DPH. Persons are being appointed to the DPH advisory committee, 9 appointed by the governor and 3 from each legislative house. Dr. Kimsey also mentioned the Association of Public Health Laboratories was sponsoring a public health lab assessment on March 38 in Richmond. New performance standards for public health programs were underway and CA may be the pilot test.

LFS update: Dr. Karen Nickel thanked Kaiser Permanente for providing the videoconference site in North Hollywood and the telephone bridge. She said Dr. Hamill and she had traveled to North Hollywood for this meeting and may try alternating sites. She said the CLTAC appointments should be going through for the 6 new members who shall join the current 13 members. One CLTAC position remains unfilled because no nominations had been received. Someone asked what this position was and Dr. Nickel responded that it was the non-voting, non-reimbursed position nominated by the instrument manufacturers starting in about 1996.

Dr. Nickel introduced Barbara Wieskamp, her new administrative assistant. She said that meeting notices should be more timely now that she has help. Dr. Nickel said DHS re-organization was impacting support from administration in Sacramento as support groups are split and reassigned. This has impacted timely renewals of licenses, hiring, and mistakes in accounting. She said she regretted the problems and how this impacted the people.

CLIA exemption is a high-profile issue now in LFS. The goal is to achieve this in 2008-09 and several efforts are underway. First, the CLIA 2003 subcommittee is reviewing state law with federal to see what parts of state law must be changed to achieve exemption. Second, LFS is working to improve its infrastructure by making database and document handling improvements. Finally, LFS is working hard to improve salaries, recruitment of qualified staff and business operations.

Legislative update:

AB 185 (Dymally): Bob Thomas discussed AB 185 which impacts the work scope and supervision of unlicensed persons in a clinical lab. It defines the analytical phase which is important in setting limits for work activities. This bill also amends B&P Code 1209.5, the autoverification section, to make it permissive rather than mandatory. It amends B&P Code 2069 to make Medical Assistants subject to all B&P requirements when doing testing. It also eliminates trainee licenses and would make training programs responsible for assuring applicants are qualified. Mr. Thomas said he expected amendments to this bill. Peggy O'Toole asked why there needed to be a change in supervision. Mr. Thomas said more supervision would be required during the analytical

phase of testing. Somebody asked what are the qualifications of unlicensed lab assistants? Mr. Thomas said state law requires a high school diploma and competency. Ellen Jo Baron asked if an unlicensed person could prepare the stain for a licensed person to read. Yes. Somebody asked what LFS thought about elimination of trainee licenses. Mr. Thomas said LFS would lose revenue of about \$25,000 per year, but it would give a lab more flexibility in training people. The current situation may inhibit training rather than help. Jim Ottosen said issuing trainee licenses complements the CLS training regulations at CCR 1032 in which LFS is responsible for assuring applicants meet all the education requirements prior to training.

AB 34, 40 (SB 155 last year): Ron Harkey reported on these two bills that both address cord blood use to generate stem cells. Although there are many blood banks in California, there are currently only 4 stem cell banks. This bill would create a cord blood symposium to promote storage of cord blood. However, the problem is, this effort is unfunded and expensive. It costs \$1800 to collect, \$100 per year to maintain, but \$17-\$35,000 to recover stem cells. Mr. Harkey felt use of cord blood for stem cells would be a long time before reality.

AB 1355 (Aanestad, 2004), SB 366 (Aanestad, 2007): Karen Nickel said the AB 1355 which implemented in 2004 authorized cytotechs to perform up to the FDA-approved limited of Pap smears a day when using automated or semi-automated screening devices. That meant that they could read up to 200 slides a day using automation. However, DHS is required to do a literature search to determine whether increasing the number of slides reviewed daily increases the rate of error. If it does increase the error rate, then DHS must issue regulations that limit the number of slides. Dr. Nickel said that LFS was working on this report and expected to have it done on time. SB 366 would remove the 2008 sunset from the earlier bill without waiting for the DHS report.

AB 512 (Richman, 2005): Kathy Williams reported on AB 512 that gave DHS enforcement authority for non reporting of infectious disease findings. Ms. Williams said there had been few violations, but more by out-of-state labs. The CLTAC was critical that there had been no public input on the list of reportable diseases and Ms. Williams said they should work through their local health officer. The CCLHO communicable disease subcommittee changes the list. While notice to the labs is mandated, there is no mechanism to do this. LFS used to do the mailing but the last time was 1996. Dr. Borok suggested the list be put on the LFS website and on the DCDC website. Dr. Baron said the labs need lots of information. He moved and Peggy O'Toole seconded that DHS provide a link to the appropriate organization that has a list of reportable infectious diseases and organisms that need to be reported to the county health officer. The CLTAC approved this motion.

AB 1442 (Feuer): Karen Nickel reported on AB 1442 which would make important changes in inspections of registered labs, would delete the CLIA requirement that laboratories have a comprehensive QA program and would bring into statute special testing requirements for HIV screening tests.

AB 1175 (Niello): Bob Thomas reported on AB 1175 which would make autoverification permissive instead of mandatory.

Report of the CLIA 2003 subcommittee: The CLIA 2003 subcommittee had been charged with reviewing state law as based on CLIA in 1994 with CLIA as published in 2003, to identify parts of the old law that are less stringent, more stringent or without effect in the new law. Chairman Robert Footlik said there had been several meetings and review of General Laboratory Systems, Pre- and Post-Analytical Systems had been done and substantial progress had been made on General Quality Control. The results of this discussion shall be available to the CLTAC and the public after the June meeting. All meetings are open to the public and quite a number of public members are participating. Dr. Nickel explained that the CLTAC would use the subcommittee report to generate a crosswalk and ultimately recommend legislative changes for DHS support.

Update on “Doc-in-a-box” and retail center testing: The CLTAC had asked for an update on this subject. Bea O’Keefe said these are clinics operating in retail centers as Longs Drugs or WalMarts which employ nurse practitioners to see a patient, order tests and prescribe medicine. This is done under a physician protocol. Visits typically cost \$49 to \$59 and often simple tests are performed onsite so a diagnosis can be made quickly. There have been several changes since the last CLTAC meeting. Wellness Express had 4 clinics but has now closed them all, citing inability to get funding to expand or become profitable. Longs Drugs is said to be looking for another company to provide retail clinics in their stores. Meanwhile, Sutter Health opened its first walk-in clinic and 5 more are planned in the Sacramento area. Other clinics in southern California are scheduled. The AMA and AAP continue to raise concerns about quality of care in these clinics.

Ms. O’Keefe also discussed “pod” or “condo” labs. This is an arrangement in which a pathology lab vendor leases space in a medical building and subdivides it into cubicles that are rented to different group practices. The pathologist performing the professional component of lab services moves from pod to pod. The group practice pays a flat fee to the pathologist that covers the cost of the test and interpretation. The group practice bills Medicare for professional and technical component of the lab work. This pod lab arrangement has been criticized by the federal OIG as violating anti-kickback laws. CMS is considering tightening the rules that govern billing of pathology and ASCP has launched a grass roots campaign to force CMS to block pod labs from abusive billing practices.

Ms O’Keefe said that a recent re-interpretation of 17California Code of Regulations 1050(c)(8) shall cause LFS to enforce the 3 lab director limit in California. CLIA limits non-waived directors to 5 and has no limit on waived labs. The CLTAC protested this ruling saying this limit has only been applied to directors of cytology labs. What happens to those already directing 5? These shall be dealt with on a case-by-case manner as LFS becomes aware of them. Bea Okeefe, said that co-directors were also

impacted by this interpretation. Carmen Maldonado moved that the CLTAC advise DHS to reconsider the 3 lab limit.

The CLTAC passed the following motion, "The Department of Health Services should further research the implications of its legal advice to limit laboratory directors to 3 laboratories."

The CLTAC discussed how this change of practice would negatively impact laboratory directors. Ellen Jo Baron asked if the crosswalk would address this. What about public health labs? What about grandfather provisions. Tim Hamill remembered an earlier legal opinion that explained this. Karen Nickel said she was not aware of this. Bea Okeefe said that her staff had had no complaints or problems from directors who were told they could not direct more than 3 labs.

Update on CLIA in California: Donna McCallum reported on federally-funded activities by LFS staff in 2006-07 and that projected in 2007-08. In 2006-07, LFS was expected to inspect 915 labs but did 984 including 71 initial surveys, 758 re-certifications, 40 validations, 4 onsite complaints and 241 waived labs. In 2007-08 the total laboratories inspected shall decrease to 869. A new emphasis for CMS is penalties for proficiency testing failure. In 2006-07, 110 actions were taken for failed PT, and in 2007-08 already there has been 45. Ms. McCallum is working on a special workgroup with CMS in response to the GAO audit that includes accrediting organizations, exempt states, FDA and CMS. Their goal is to achieve better consistency between accrediting and state agencies inspections. Ms. McCallum said CMS was evaluating oversight of foreign labs, genetic testing and cytology proficiency testing.

Personnel licensing update: Maria DeSousa reported that LFS had received 22,683 phlebotomy applications as of February 28 and had certified 20,212. She said the online verifications were current as of January and LFS was working hard on training program approvals now. Joseph Musallum asked how LFS assured consistent training standards among the programs. Ms DeSousa said LFS was working hard to do this but needed more staff resources to do onsite inspections.

Bob Thomas said LFS was converting to all online license applications and eventually shall have online renewals, also. The staggered renewals are in transitions with many questions continuing about continuing education. The LFS website was updated to help answer questions. Mr. Thomas discussed continuous licensing in which there are no cutoff dates. This shall be possible soon with payment either by credit card or electronic checks. Temporary licenses shall be eliminated with certification exams after March 1, 2007. Mr. Thomas said that MLT licensing is still on hold pending hiring staff. All the infrastructure is ready to go.

There were many questions of Mr. Thomas. How does a lab deal with an applicant who wants to take a certification exam and holds a temporary license? They can take either option at the current time. What about Hartnell MLTs who have been waiting 5 years to get their license? What is the timeline for licensing certified applicants? 150 days is in

regulation, but sooner we hope. Can out-of-state ASCP applicants automatically work? No. How does the 60 day grace period work with biennial renewals? Renewal invoice mailed 60 prior to expiration, then 60 day grace period. Cytotechs and CPTS do not have a grace period in law.

Karen Nickel explained the process of reviewing certification organization applications for approval of their examinations, and the online quiz on state law. She urged the CLTAC to take the quiz by contacting her by email to get their username and pass code. Someone asked how a bioanalyst examination would be given. Bob Footlik said the AAB had a separate bioanalyst examination. Someone asked how long would it take to get a license after an application was submitted. Mr. Thomas reported that on or after April 13, LFS would begin accepting online applications from persons choosing a certifying examination and licensure should begin then.

New business, open discussion: There was no time for new business so the meeting was adjourned at 12:33 PM. The next meeting shall be June 8, 2007.