

Clinical Laboratory Technology Advisory Committee
Minutes of the September 10, 2004 Meeting
Held by Videoconference from Oakland and North Hollywood, California

CLTAC members participating: Michael Borok, Terry Bryant, Carolyn Days, Paul Fu, Tim Hamill, Curtis Johnson, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Michael Terry, Peggy Tessier, David Yong, Mary York

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

DHS staff present: Alan Ankerstar, Ron Harkey, Jim Howard, Paul Kimsey, Shiu Land Kwong, Cindy Lloyd, Howard Manipis, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Shahrzad Radahd, Tom Tempske, Bob Thomas, Pat Toomer.

Public members: About 70 other persons participated by phone or in person at the videoconference sites.

Introductions and general announcements. In the absence of Cherie Evans, Terry Bryant presided at the CLTAC meeting. Ms. Bryant opened the meeting, welcomed the participants and noted that there was voting quorum. She 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, then the others. She also noted that the telephone bridge participants were all on "mute" and could only access the meeting thru the operator. This was done to eliminate background noise of phones left on.

Approval of the minutes of the June 11, 2004 meeting. The minutes had been made available to the CLTAC members in advance of the meeting. A member noted that these minutes should be put on the website and Karen Nickel agreed. Morton Field asked that the minutes be corrected to list him as a CLTAC member. Dr. Nickel said this could not be done, and then the minutes were approved as written.

Department news. Dr. Paul Kimsey said the Office of Emergency Preparedness has a new administrator, Betsy Lyman. She will be administering a \$60 million federal grant and will report to Dr. Jackson, State Health Officer. Dr. Kimsey discussed the California Performance Review prepared for Governor Schwarzenegger. The large document was a result of drills and information gathered by a working group. It recommends a reorganization of state government and would split DHS into 3 groups, Medical care, Licensing and certification and Public health, and there would be lots of other changes. The CPR would require legislative changes or ballot initiatives, and will take a year or more to implement. Dr. Kimsey said the previous administration's determination

to repeal clinical lab law, has not been continued under the current administration. The whole issue is on hold.

LFS update. Dr. Karen Nickel welcomed the CLTAC and public members, and thanked Kaiser Permanente for providing both the videoconference sites in North Hollywood and Oakland, and the new and improved telephone bridge. She noted that the audio system seems to be much better, and she said she was pleased with the large number of participants (over 100?). Dr. Nickel reminded the CLTAC that the next meeting would be face-to-face in Oakland and she encouraged everyone to come.

Karen Nickel said that LFS was continuing to struggle with severe staff shortages, lots of backlogs, people calling to complain about poor services. She said there are especially problems with phlebotomy certification and MediCal application backlogs. Being done with the legislative session in September shall remove some workload, but LFS is still doing lots of work in response to the CPR that Dr. Kimsey discussed.

Karen Nickel said she was encouraged by a report entitled "Regional Plan to Increase the Supply of Workers in High Demand Healthcare Occupations", put out by the Bay Area Works on June 9, 2004. Dr. Nickel said their aims included swift implementation of MLT licensing, online or summer courses needed for biology graduates to get courses necessary for CLS training, financial assistance to facilities to increase number of students, increase the number of MLT training programs, expand the number of employers and vendors supporting CLS/MLT programs, develop strategies to attract good new students to MLT and CLS majors and strategies to retain existing CLS staff in hospitals.

Several CLTAC members commented on problems with training, asked where the training programs were, and when Section 1032 for CLS training would be updated. Robert Thomas responded to the questions and comments.

Legislation affecting clinical laboratories.

Ron Harkey discussed the two cytology bills. SB 1355 would increase the automated Pap screens to what the manufacturer recommended which is 200 per day. Any that had to be re-screened manually would count toward the 80 limit. He said a literature review was required on or before June 2007 to evaluate patient outcomes and then the bill could sunset. SB 1913 would require labs to do look backs only for high-grade dysplasias. Current law requires cytology labs to do look backs for all abnormal Pap smears and this is unnecessary.

Deanna Iverson asked if the 80 and 200 were additive, that is, would be tallied independently (No). Robert Footlik said the literature review should be done by an independent contractor to avoid bias and should not be a burden on LFS. Kathy Rees said it would be unique to have the manufacturer pay for the study.

Deanna Iverson said she did not understand the anxiety about this bill. It was needed to keep cytology testing in California.

Mary York made a motion and Carolyn Days seconded, that the "CLTAC recommends the following amendment to SB 1355, rather than have DHS do a literature review, an independent consultant hired by any manufacturer of an automated cytotechnology instrument, do a review of the testing (published and not published) to determine if the workload stated in the package insert is reasonable for cytotechnologists. The choice of consultant shall require prior approval from DHS to assure that there is neutrality in the evaluation." The CLTAC unanimously voted to support the motion.

Karen Nickel reported on the health fair bill. AB 2436 would distinguish between health fair testing and non-diagnostic testing authorized since 1990. The latter was enacted in 1990 in response to the NCEP to provide easy access to testing for cholesterol and glucose for persons without physicians. This law preceded SB 113 and currently is inconsistent with complexity, phlebotomy and testing personnel qualification laws which has been more recently enacted. This has allowed health fairs to be offered which did not comply with current law. This bill defines health fairs, requires them to meet all state and federal laws, be licensed and certified.

Robert Thomas discussed AB 2409 regarding cytogenetic scientist licensure. This bill will remove the BS requirement for persons board certified prior to 1991 who have at least 7 years lab experience. Carolyn Days asked if this would be inconsistent with CLIA requirements. Bob Thomas thought not since state law is currently based on CLIA in 1994 which did not require a BS.

Mr. Thomas reviewed AB 2138 which failed to pass the legislature but which was of concern. It would have required DHS to license CLS and Radiologic Techs who were nationally certified or licensed in another state. This would partially duplicate Section 1031.8 in the MLT regulations for certifying exams.

Regulation update: Dr. Nickel reported that the MLT licensing regulations were waiting final signoff by HHS agency and the Department of Finance. Once they are signed off and go to the Office of Administrative Law, they have 10 days to approve or reject them. If approved, they have emergency filing followed by a comment period, maybe some adjustments to the regulations and another comment period, until they are finally filed. The phlebotomy emergency regulations had 4 comment periods and we hope the MLT don't follow suit. No further work had been done on any other regulation packages.

The CLTAC urged DHS to work on regulations to allow autoverification of laboratory test results.

Implementation of MLT licensing. Dr. Nickel said LFS had learned a lot from phlebotomy certification and will apply to MLT licensing. The plans for MLT licensing are as follows: (1) develop internal process and procedures, (2) train LFS staff on procedures, update LFS website, prepare informational material, (3) approve MLT certification exams for licensure purposes, approve MLT training programs, (4) hire new staff after July 2005, (5) initiate MLT licensing after July 2005.

There were lots of questions about MLT licensing. Mara Williams asked if NAACLS- programs had automatic approval. (Yes). Mary York asked if an AA degree were required (No). Bob Footlik asked if exams would be approved 5 years forward (No, 4), look back (Yes). Sam Chafin asked in LLUMC has applied for MLT training program yet (No, none accepted yet).

Implementation of certification exams for licensure. Once the Section 1031.8 regulations are enacted, LFS will start implementation of certification exams for state-administered exams. The goal is to do this over a three-year period as follows: (1) develop checklist, forms, data base, internal processes, (2) update LFS website, prepare informational material, send letters to certifying boards, inform staff, (3) identify contact person and set priorities, (4) approve CLS exams, approve MLT exams as priorities, maintain current, dated list, accessible on website, (5) continue until there at least two exams for each license category, (6) discontinue state-administered exams.

Problems anticipated in switching to certification exams include, (1) how does LFS set priorities for minor categories, (2) how will LFS monitor those failing certification exams for licensure purposes (BPC 1262.5), (3) can LFS issue temporary licenses to those waiting to take a certification exam, (4) how can the change be done smoothly?

Questions about certification exams followed. Joseph Musallam asked whether applicants would have to submit education and training documents before applying for a certification exam (yes, they would be approved for a "California" certification exam for licensure purposes). Dr. Nickel said applicants would have to qualify in all three, education + training + exam before they could be licensed. Mara Williams suggested that applicants be required to give the scores obtained on every certification exam they have taken. Salim Rafidi suggested the certifying organizations be required to tell LFS of who fails and LFS should maintain a database. Carolyn Days said the applicant should self-attest of any failures. Tim Hamill said there would still be a backlog of oral exams for director level licenses. Bob Footlik said there were not two exams possible for each category. Jim Ottosen asked about the separate written exam on state law questions. Mary York suggested doing the easiest exams first, first come, first served with no priorities, to be fair.

Temporary licenses for lab personnel. Robert Thomas discussed the problems with temporary license. This issue arises since applicants have to wait so long to take the state-administered exams, but may go away with certification exams. Currently a temporary license may allow a person to work for nearly a year while they wait for the exam date. If they fail, it impacts the person and the lab where they work. There is concern that unqualified persons may be working with a temporary license and it may be difficult to revoke in a timely manner.

Update on phlebotomy certification : Robert Thomas said there was good news about phlebotomy certification. The program was off to a good start despite loss of management staff. The processes have been established, databases set up, forms approved, staff trained. So far 84 training programs and 4 phlebotomy certification exams have been approved, and LFS has received about 2000 applications. About 1100 certificates have been printed and 1000 applications are waiting. Mr. Thomas related 8 problem issues regarding phlebotomy certification, (1) some phlebotomy sticks are being done in classroom, not in clinical setting, (2) foreign applications require translation, interpretation, (3) all instructors must pass certification exam, (4) some applicants are submitting false high school documents, (5) high number of felony/misdemeanor convictions require DOJ background checks, (6) slowness of IT support to upgrade database problems, (7) some many odd exceptions that must be handled consistently by several staff working independently, (8) requests for duplicate certificates are difficult to handle.

Joseph Musallam asked if LFS was going to put pictures on badge (No, not yet). Salim Rafidi asked how instructors could prove they passed the certification exam (certification organization gives notice, not certificate). Donna Kirven asked if the phlebotomy applicants were new or old (both, first come, first served). Mary York said LFS had done a great job getting the program started and was praised in Advance recently.

Update on Medi-Cal contracting. Bea O'Keefe reported that LFS is working with Medi-Cal (MC) on the new contracting process. MC had sent out enrollment packets on September 15 to independent clinical labs with 60 days to respond. Their responses will be rated by MC and scored with a 75% passing score. Re-enrollment of Physician Office Lab (POLs) billing for CM is underway. About 6000 lack either a CLIA certificate or state registration as required by SB 857, and LFS is processing applications from many of these.

There were several questions, including why are hospitals excluded from the process (later), what determines an independent lab (self declared), when will the MC moratorium be lifted (unknown), what about clinics and home health (unknown), what about billing for the professional component (not involved yet), what type of lab will be contracted next (first independent labs, second POLs, third hospitals), how can new labs get MC provider number (moratorium

continues), what if a POL takes referral testing (will be treated as an independent).

November licensing exam. Bob Thomas said there would be no increase in license fees for 2005 and the November 2004 exam would be held in 3 locations, Hayward, Carson and Long Beach. Improvements are underway to change to online applications for phlebotomists and CLS, with ability to pay online, hopefully in Spring 2005. The bad news is that about 1550 CLS applications had been received as of July 15, 2004 and only 650 had been approved for the exam as of this date. LFS may not be able to review the applications of many applying and so they may not be admitted to the exam.

Carola Howe asked if priority was given to graduates of CA programs (no), Joseph Musallam asked if that included persons failing previous exams (no), and would 2 state exams be given next year (probably no), will the 2005 exam need to be updated (yes), will the 2005 be given (yes, hopefully), why not let applicants take the exam and then review their credentials (interesting suggestion, but no), if a person waits a whole year, can they work with a temporary license (maybe yes), can volunteers help proctor exam (no, must be credentialed), would temporary license be continued indefinitely (no, but no regulations to explain process).

Status of public health lab standards. The subcommittee to recommend updated standards for public health labs has been put on hold pending support from the public health lab directors.

New business

(1) Tim Hamill said he was concerned about the requirements put upon labs to re-validate tests when they move. He made the following motion:

“To allow laboratories in California to maximize efficiency and protect the health of our patients, I move that California CLTAC request a written response from Federal CLIAC on the following question:

When a CLIA certified laboratory finds it necessary to move a portion of its testing operations to a new, non-adjacent location and where the testing personnel, test procedures, testing equipment, directorship and ownership do not change it is required by federal regulations that the laboratory re-validate the test that are moved under the new site CLIA? We recognize that 42 CFR 493.1253 requires that any “new” test be validated before reporting patient results. However, we seek clarification on the need for existing tests (previously validated or in use prior to April 2003) to be re-validated if moved to a new physical location. Please cite any regulations that bear upon this issue.”

This motion was seconded and discussed. Karen Nickel said it would not be the CLIAC that would be consulted, but LFS, who would in turn consult CMS. She said this would be discussed at the next meeting of the CLTAC after discussion with CMS, The motion was passed unanimously by the CLTAC.

(2)Tim Hamill made a second motion:

“In light of the acute shortages of qualified clinical laboratory scientists in the State of California and the availability of highly advanced laboratory instrumentation and efficient LIS, we ask the DHS to revisit the auto-verification issue and enact regulation to implement it in this state in a timely manner. Autoverification of laboratory tests will reduce human errors, allow technologists to concentrate on abnormal results, speed up reporting of lab results, improve productivity, reduce costs and shift paradigms. We recommend the repeal of California Code of Regulations, title 17, Section 1050 (a) – (g) and revision of section 1050 (h) to allow autoverification”.

The motion was seconded by Mary York, discussed by the CLTAC and unanimously adopted.

Close of the meeting. Hearing no further new business, Chairperson Terry Bryant asked for a motion to adjourn the meeting at 12:30 PM. The CLTAC moved, seconded and approved close of the meeting.

The next meeting will be in Oakland, California at the Harris State Building, 1515 Clay Street. Dr Nickel encouraged all CLTAC members and the public to attend this meeting as there would be no telephone bridge or videoconference available.