

Clinical Laboratory Technology Advisory Committee
Minutes of the December 1, 2006 Meeting
Meeting held by videoconference from CDHS Richmond Campus and
North Hollywood Kaiser Permanente, and by telephone bridge

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

Former CLTAC members participating: Sam Chafin, Morton Field, Robert Footlik, Jim Ottosen, Imre Fischer, Deanna Iverson, Fred Struve,

CDHS staff participating: Alan Ankerstar, Grace Byers, Maria DeSousa, Jim Howard, 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: 32 persons attended in Richmond, 20 persons attended in North Hollywood, 36 persons called in on the telephone bridge and 12 accessed the digital replay of the meeting.

Introduction and general announcements: Chairman Tim Hamill opened the meeting at 9:05AM. He thanked Curtis Johnson for chairing the September meeting in his absence. 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.

Recognition of departing CLTAC members: Karen Nickel presented a plaque to Teresa Bryant for her service as chair of CLTAC and member for 8 years. She presented certificates of appreciation to Tim Huston, Paul Fu, Carolyn Days and Gregory Clark, for their service on the CLTAC.

Introduction of new CLTAC members: Karen Nickel introduced 2 new members of CLTAC, Christine Hsu and Elizabeth Dequinia. Christine was nominated by the Engineers & Scientists of CA and works as senior CLS at Kaiser Regional Lab in Berkeley. Elizabeth (Liz) was nominated by the Philippine Association of Medical Technologists and has been Assistant Lab Director at Washington Hospital, Fremont, since 1995. Dr. Nickel said that other nominations have been received for new members of the CLTAC and these are under review.

Approval of the June 9, 2006 meeting minutes: Dr. Hamill acknowledged that there was a quorum of the CLTAC present, and asked that the minutes of the June 9 meeting be approved. Motion was made, seconded, and minutes were approved as written.

Amendment of the March 3, 2006 meeting minutes: Dr. Nickel explained that although the March 3 minutes had been approved by the CLTAC, there has been a request that an addendum be made to clarify whether a LLC can own a clinical laboratory. Bea Okeefe read what the previous minutes had said, what was being added, and explained why the additional statement was needed. Since the CLTAC minutes are a public document, there was concern that these minutes may misrepresent this important issue.

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 explained the upcoming re-organization of the Department of Public Health that begins on July 1, 2007. LFS shall be relocated to Licensing & Certification to consolidate licensing activities. Other programs were being changed, also. He said this was an outcome of the governor's California Performance Review authorized in Senate Bill 162 last year. All programs related to licensing, disease control, tobacco control, bioterrorism, will be in the new DPH. MediCal and managed care will be put in the new DHCS. Dr. Kimsey also mentioned the Association of Public Health Laboratories National Lab Training Network was undergoing redesign in Nashville. New performance standards for public health programs were underway and CA may be the pilot test in March 2007.

LFS update: Dr. Karen Nickel thanked Kaiser Permanente for providing the videoconference site in North Hollywood and the telephone bridge. She encouraged everyone to get on the email list for contacts from LFS to save mailing time and expense. She said LFS is continuing to have backlog problems in all areas and we regret the poor service and frustration. She said LFS was authorized to hire 14 more positions this year but is having trouble filling examiner positions. LFS is preparing a mass mailing and she encouraged people to think about a career at LFS. Dr. Nickel said LFS was interested in what the CLIA 2003 subcommittee was going to do as we prepare for CLIA exemption. She said we would talk about staggered renewals, phlebotomy and MLT updates, and some lab licensing concerns today.

Report of the CLIA 2003 subcommittee: Dr. Nickel explained that 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 the first meeting of the subcommittee would be held in the afternoon. Kathy Williams is serving as LFS staff liaison to the committee. Mr. Footlik said they would consider all changes since 1994. He was previous chair which prepared a crosswalk of changes from 1994 to 1998 for the first CLIA exemption bid. His subcommittee will start from them and consider all changes since. Mary York asked if she were on the committee. Robert Footlik said she could be.

"Doc-in-a-box" and retail center testing: Bea Okeefe said that in the last 20 years there have been many changes in technology making many tests easier to perform and the public is demanding access to medical care and testing. This has led to retail stores

setting up little clinics to treat common illnesses and do lab tests at half the cost that a physician would charge. The clients of these clinics are mostly uninsured. Currently there are only 6 such clinics in CA but other states with less regulation have many more. The two main companies opening these clinics are Wellness Express with 316 in the US and Quick Health with 35 clinics. The proponents of these clinics say they are quick, cheap (\$40 - \$70), accessible to minorities and those without insurance. Opponents say this perpetuates two-tiered health care and isolates these people from traditional care. Many persons asked questions. What is required of these lab facilities in CA? ...A CLIA certificate and state registration or license. Where is the testing done?.. Onsite or at labs offsite. Who draws the blood? Usually the RN who runs the clinic. Is the clinic licensed as a "clinic"? If so, they can employ a medical assistant for testing. How can they operate without a CA-licensed physician? A physician is on the business license but a nurse practitioner runs the clinic. What about businesses coming from outside CA? These companies do not aware of state law requirements. Ms Okeefe said an Oakland clinic is licensed as a clinic and CLIA certified. Asia has lots of retail clinics now which are very popular. Who pays the rent for retail clinics? We assume the clinic does but we heard that Walmart donates the space in its midwest stores. Tim Hamill asked for an update of this at the next meeting.

Personnel licensing update Robert Thomas reported on the activities of his section. He said both lab licensing and personnel licensing payments were hampered by aging processes in Sacramento, leading to problems. He said LFS is working with its contractor to start online renewals of personnel licensing, but that will be several years away yet. Personnel Licensing section is in a transition with "continuous licensing" of clinical lab scientists, staggered renewals, and implementation of certification exams. It will take a while for the processes to settle down and staff to be trained. Online license verification is going well. This was driven by public demand and JCAHO need for primary source verification. Many people are using that and if you get an error message, it means too many people are accessing at one time. Mr. Thomas said the background work for MLT licensing has been done, but staff needs to be hired to start the program. Questions from the public: When will LFS start licensing MLTs? ...Next 2-3 months. Will MLTs graduating from NAACLS programs be handled differently? These persons will have their training automatically approved.

2006 Licensing examination update. Shahrzad Radahd thanked the subject matter experts for their hard work in updating the November 2006 exam. She said the total approved to take the exam was 758 with 47% passing. This pass rate is consistent with previous years. Ms Radahd said the social security number requirement was a deterrent for several hundred foreign applicants. LFs had had 800-900 applicants in previous years without this requirement. Questions from the public: When will results be out? Mailed in 1 week to ~300 passing. What is exam breakdown? LFS will update at next meeting.

Staggered renewal update: Shahrzad Radahd reminded the CLTAC about how the staggered renewals were being implemented with even birth years occurring first. She said that even with extended license periods, only 12 hours of continuing education will

be required this time. Questions: When would 24 hours of CE be required? At the second full two-year licensing cycle.

Training program update: Shahrzad Radahd said the number of training programs for clinical lab scientists and specialists had increased to 81 schools now. That is very encouraging.

Phlebotomy certification update: Maria DeSousa said the December 2006 deadline was rapidly coming. She thanked her staff for bearing up to the heavy workload of meeting this deadline. Applications peaked at March 2006 for the first deadline and again in December 2006 for the extended deadline. To date, LFS has received 21,214 applications and have approved 18,255. Of those that applied by July 1, 80% have been approved and 9% have missing documents. Questions: What is status of those in the backlog? Many are awaiting release of criminal conviction report, others have failed to respond to requests for documents. What is status of applications received after July? These are awaiting processing. LFS has a 3-6 month backlog. Making the applicants wait this long makes them lose their phlebotomy skills? LFS knows this is a problem, but the law allows up to 180 days to approve an application. Phlebotomy training programs are a problem, most have waiting list for students and there is problem finding internship sites. LFS know this is a problem, too. There should be a moratorium on new phlebotomy training programs. Many charge \$7-\$10,000 per course? Shouldn't this be controlled? Ms. DeSousa said we cannot prohibit a program from offering training if they meet training requirement in law, and cannot regulate their charges. Someone asked for an explanation of the grandfather clause. When will approval letters be sent to the remaining 20% that are in the backlog? When LFS receives their documents. What happens to labs that employ non-certified phlebotomists who have approval letters after January 1, 2007? The approval letters will be accepted as certification until the certificate is received, hopefully in 3-4 weeks.

Infectious disease reporting update: Dr. Janet Mohle-Boetani, of DHS Division of Communicable Disease Control, reported on changes to infectious disease reporting requirements. She said that changes are made in response to public health needs with provider labs required to report findings to their local public health labs. Dr. Boetani went over the list of reportable diseases. Questions: Are regulations necessary to add diseases? No, changes are made without regulation. How is this communicated to labs? The local public health labs contact the labs in their counties. There is confusion between the hospitals, reference labs and physician. Who is responsible for reporting? The lab that received the original sample must report and the physician must also report.

“Mary York asked that Dr. Boetani send infectious disease reporting information to the CLTAC, explain whether the lab 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.” Added at March 02, 2007 meeting by Dr. York.

Request to change the date of the September 14, 2007 meeting: Karen Nickel said there had been a request to change the meeting date to September 7, 2007. The CLTAC discussed, moved, seconded, that this date be changed. She said she would change the room reservation and contact Kaiser Permanente North Hollywood, and hoped both would still be available.

General discussion: Carmen Maldonado and Salim Rafidi said the CLTAC meetings were now too short and they should be changed back to all day meeting. Karen Nickel said she felt it was much more efficient to have a half day meeting with videoconferences and telephone bridge. She said that more people are participating now than ever, and she hoped to expand the email listing for real time information distribution.

Mary York asked that Dr. Boetani send infectious disease reporting information to the CLTAC, explain whether the lab 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 they were outdated or ineffective.

Chairman Tim Hamill asked for a motion to adjourn, second, and the meeting was adjourned at 12:30 PM.