

# Clinical Laboratory Technology Advisory Committee

## Minutes of the December 7, 2007 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, Vicki Finson, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Radifi, Les Revier, Michael Terry, Fred Ung, David Yong, Mary York, Phyllis Walker.

Former CLTAC Members Participating: Sam Chafin, Morton Field, Robert Footlik, Jim Ottosen, Fred Struve.

DPH Staff Participating: Zahwa Amad, Frank Barnes, Norma Barocio, Grace Byers, Linda Bryant, Ron Harkey, Robert Hunter, Nema Lintag, Howard Manipis, Donna McCallum, Don Miyamoto, Karen Nickel, Shahrzad Radahd, Judy Schlosser, John Sherwin, 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 welcomes 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.

Laboratory Field Services Update: Karen Nickel welcomed the participants and thanked Kaiser Permanente for providing the videoconference site in North Hollywood and for providing the telephone bridge. Dr. Nickel noted that LFS had been able to fill some of its Examiner vacancy positions. Donna McCallum in Los Angeles office recently added 4 Examiners I who are being trained in CLIA inspections. Bob Thomas in Richmond office added 2 Examiners 2, 1 Examiner I and has filled all his clerical vacancies. Karen Nickel said she would let these persons talk about their new hires. Bea OKeefe is away from this meeting and Dr. Nickel announced that Tom Tempske was recently promoted to Examiner II for complaints and compliance. She said there were still Examiner I vacancies in Richmond and we hoped to have another civil service examination this year.

Dr. Nickel recognized the CLTAC members from southern California who have traveled to Richmond for the meeting and introduced former CLTAC members in attendance. She reminded the audience that LFS had switched to email and website notifications, so if anyone is not getting a meeting notice, to please contact her.

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 Plans for San Diego: 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.

CMS' View of Trends in Accredited Laboratory Oversight. Dr. Nickel introduced Gary Yamamoto, Laboratory Consultant, Region IX of CMS in San Francisco. He was invited to speak about changes in oversight of accredited labs after the GAO audit several years ago. Mr. Yamamoto said CMS is seeing two changes in handling of accredited labs. First, a number have had involuntary loss of accreditation and second, enforcement of improper proficiency testing referral. He said in the first issue, labs can voluntarily give up their accreditation, mainly with CAP accredited labs, and this is not a concern. But, involuntary loss of accreditation, initiated by the accrediting organization (AO) is immediate, before an appeal. When CMS takes action, the action is proposed, imposed, then appealed. In order for an accredited lab to stay open, it must scramble to get re-certified, impacting CMS regional office. The second issue, referral of PT, is being strictly enforced by AO, even when it is done by an employee without director knowledge.

Surprise Introduction of Dr. Mark Horton, Director of Public Health: Dr. Paul Kimsey said that Dr. Mark Horton was in Richmond and would like to speak to the CLTAC. He introduced Dr. Horton and welcomed him to CLTAC. Dr. Horton greeted the CLTAC, said he appreciated the help and advice given CDPH by the CLTAC. He said lab issues were very important to the department, and he urged CLTAC continued involvement.

Public Health Lab Director Shortage: This agenda item was tabled for further review of federal legislation which is pending.

Comparison of Testing Standards—Health Fairs and Non-Diagnostics: Karen Nickel said there was lots of confusion (and phone calls) about health fairs and non-diagnostic (NGHA) testing in California. DHS sponsored AB 2436 several years ago to clarify what health fairs could do, but there is still confusion. The NGHA legislation was enacted in 1992 at B&P Code 1244. NGHA can perform only waived tests, with CLIA certificate of waiver, finger stick, patient ordered, tested onsite by anyone, reported to patient, under control of county where testing done. Health fairs must be state license/registered, CLIA certified, can offer any test as appropriate with or without physician, testing done by authorized persons, onsite or offsite, reported to patient or physician, as appropriate. Dr. Nickel handed out a table contrasting the 2 types of testing locations.

Changes in Infectious Disease Reporting Requirements: Kathy Williams handed out recent mailings sent to labs in California on infectious disease reporting requirements. She highlighted the changes, explained why the changes were necessary, and

reminded the CLTAC how notification should be done by labs in California and outside. Failure to report infectious diseases within the required timeframe or manner may subject a laboratory to sanctions.

Newborn Screening in California, an Update: Karen Nickel introduced Dr. John Sherwin, recently retired Chief of the Genetic Disease Laboratory in Richmond for CDPH. Dr. Sherwin is a former CLTAC member and former president of the AACC. Dr. Sherwin said California screens newborns for 28 disorders now. The screening program started in 1966 with fluorometric PKUs, added hypothyroid tests and galactosemia in 1980, and sickle cell in 1990. Starting in about 2000, many new tests have been added with tandem mass spectrometer capabilities. Currently about 560,000 babies are born in the state each year, and the prevalence of defects varies with demographics, but are typical. Babies with metabolic defects are tracked to assure treatment.

Update on Personnel Licensing Issues: Robert Thomas introduced the new staff members in his section, and said he was encouraged to have most of his vacancies filled. He made a special presentation to Joseph Musallam, UCSF, for all his help in preparing the recent licensing examination for LFS. Robert Thomas said the new MLT licensing program was starting on December 19, 2007 with (only) online applications and 2 certification exams approved. Once LFS gets all documents from an applicant, they will get a qualification letter to take the exam for licensure purposes. Mr. Thomas said we were working hard with training programs, giving Frank Barnes more help. Shahrzad Radahd gave the exam statistics for the November 2007 exam. She said 319 took the exam in southern CA, 231 in northern CA and 127 were “no shows”. Determination of those passing has not been completed. About 150 persons have been licensed through certification exams, 68 CLSs, 43 cytogenetic scientists, 22 genetic molecular biology, 12 histocompatibility scientists. Robert Thomas said LFS may not give exams in 2008 for CLS or MLT, and that announcement may be made in March 2008. Maria DeSousa reported on phlebotomy certification. She said LFS is still receiving about 500 new applications per month. She said 27,279 persons have applied and 25,606 persons, approved, in phlebotomy. LFS is emphasizing training program approvals and continuing education programs for phlebotomists. The CLTAC asked questions about MLT training programs, programs approved by NAACLS, how accrediting organizations know when an MLT applicant is qualified for state licensure, how temporary licenses would be administered (not), and progress on certification exams for specialty licenses.

Bioanalysts as Directors of Moderate Complexity Labs: Peggy OToole asked that LFS recognize that bioanalysts without doctorate degrees and board certification can still direct labs doing moderate complexity testing. Bea Okeefe said she did not think the discussion at the last CLTAC meeting had said otherwise, and the minutes do not reflect that, but, she said this was true.

Phlebotomy Training Program Approval Consistency: Donna Kirven said that she did not ask that this be put on the agenda, but had concerns anyway. Maria DeSousa said she appreciated the input, and said LFS gets lots of complaints from students on the phlebotomy training programs. LFS is working hard to make sure the students are trained properly and that bad programs are eliminated. Ms. DeSousa explained the

reasons why some programs were treated differently than others, and said she was working hard to improve communications on training program standards between Richmond and Los Angeles staff. She hoped there would be no further problem, but would be ready to get any feedback.

Selection of 2008 Meeting Dates: Dr. Tim Hamill queried the CLTAC on 2008 meeting dates, and March 7, June 13, September 5 and December 5, 2008 were selected.

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