

Clinical Laboratory Technology Advisory Committee  
Minutes of the December 2, 2005 Meeting  
Meeting held by videoconference from Kaiser Permanente Oakland and  
North Hollywood, and by telephone bridge.

CLTAC members participating: Michael Borok, Teresa Bryant, Carolyn Days, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado; Peggy O'Toole, Salim Rafidi, Les Revier; Michael Terry; David Yong, Mary York.

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

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

Public Members: 48 persons signed in in Oakland, 14 persons, in North Hollywood, 32 lines called in on the telephone bridge.

Introduction and General Announcements: Teresa Bryant opened the CLTAC meeting, 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 September 9, 2005 Meeting Minutes: The reading and approval of the minutes was postponed until a quorum was achieved.

Department News: Paul Kimsey, Division Chief of Laboratory Science, thanked everyone for attending. He welcomed everyone to the Richmond campus of the Department of Health Services in the bay area. He said there were 6 labs in Richmond with their move in dates occurring 2001-2005. There is also an Administration Building where Lab Field Services is housed. He said there would be a tour of the labs after the meeting for people who could stay over in Richmond. Dr. Kimsey said the new state health officer, Dr. Mark Horton was now in place and getting oriented, replacing Dr. Howard Bacher who had served as interim since July 2005. He mentioned the California Performance Review which was underway requesting all licensing programs to conduct criminal background checks of applicants. Dr. Kimsey said a bust of Dr. Lennett, long-term director of the state lab, had been dedicated at the entrance to the auditorium in Richmond. Dr. Lennett is considered the father of clinical virology. Dr. Kimsey said internal administrative measures were being taken to get more staff for LFS which is currently suffering from staff shortages.

LFS Update: Karen Nickel welcomed the CLTAC and public members, and thanked Kaiser Permanente for the kind use of their videoconferencing center. Dr. Nickel said the big news at LFS is the pressure caused by staff shortages. The backlogs of activities are precipitating lots of phone calls and public anxiety. The worst backlog now is phlebotomy and Maria deSousa will talk about that more. Letters are going to the director and governor complaining, but as Dr. Kimsey said, work is underway to get some more staff for LFS. In anticipation of this, LFS is recruiting Examiners I and II candidates to fill vacancies. Dr. Nickel encouraged people attending the meeting to consider applying.

Update on phlebotomy certification: Maria deSousa said there was a current backlog of about 5,000 applications and a total of 9674 had been received. Her program had recently lost a Program Tech so is down to 2 people, but other people have been redirected to help. Having to do criminal background checks on phlebotomy applicants is an added burden since 5-10% have convictions of DUI, petty theft, drugs, etc, mostly when they are in their early 20's. Other, more serious convictions as manslaughter, lewd behavior, have led to denials of certification, appeals and hearing. Ms. DeSouosa reminded the CLTAC that there were 3 types of certificates, LPT, CPT-1 and -2, with most applying for CPT-1. Those working on or before April 2003 have the 3-year grandfather time to keep working, but new applicants cant be grandfathered.

Questions from the CLTAC, can foreign applicants be exempted from high school requirement (no), will applications received by December 1 be approved by the April 2006 deadline (probably not), how does the online process work (person applies online, does own key data entry, pays by credit card, the signed attestation page and documents come to LFS), do you appreciate that lack of certified phlebotomists after April 2006 will pose a risk to patients in hospitals (yes), can the deadline be pushed back (it would take legislation), are there delays in processing phlebotomist renewals (yes).

Update on MLT licensure: Robert Thomas reported on MLT licensure. He said the regulations were finalized on September 12, 2005, several years after urgency legislation required DHS to implement by emergency regulations. He said it would take one year to get the program going and this year LFS wants to approve MLT certifying exams since not state MLT licensing exam is possible, and approve MLT training schools. Mr. Thomas reiterated the training options that would be available to CA candidates, but said more staff would be needed before licensure could begin.

Questions from the CLTAC, when LFS reviews certification exam applications, how are you going to be able to give all applications equal consideration (LFS anticipates it will receive applications from the major providers and some minor providers, but would try to be fair in considering those approved first. We anticipate approving 2 MLT and 2 CLS certifying exams first with the others to follow).

Report on November 2, 2005 licensing exam: Robert Thomas presented the statistics of the examination performance that indicated this exam was comparable with previous exams with a preliminary 44% pass rate.

Questions from the CLTAC, why is the 2004 exam different? (we do not know because the statistics indicate the parameters are within acceptable performance), what are the plans for returning to giving the exam twice a year (no plans, as we are converting to certifying exams which can be taken at any time), how is the California licensing exam prepared? (subject matter experts and a contractor develop and review questions, weight questions, then they are used according to a blueprint based on job task analyses. The statistics of each question is monitored), how are questions on state law going to be done? (10-question self administered exams will be given, requiring at least 7 correct answers), is the MLT exam the only one that has a different work scope from other states? (we think so), why is LFS doing all the exams the same? (the law allows LFS to approve all categories), what are certifying exam pass rates? (someone suggested ASCP used >74%), how often are the exams approved (every 4 years), how can LFS issue temporary licenses when it switches to certifying exams (we cant), temporary licenses may not be necessary if certifying exams are available (LFS agrees), how can LFS track when applicants fail a certifying exam (we cant), cant the certifying organization be required to tell LFS when someone fails an exam (too difficult to track), how many CLS do not renew each year (about 500-1000).

Approval of the minutes from September 9, 2005: Teresa Bryant noted that extra pages were accidentally included with minutes and should be deleted. Morton Field said he should be identified as a CLTAC member. Donna Kirven said she attended the meeting and was not listed as a participant. With these corrections, the minutes were approved (motion Carolyn Days, second Tim Hamill).

Update on CLIA exemption: Bea O'Keefe updated the CLTAC on LFS' progress to CLIA exemption. She said a letter from Director Sandra Shewry in June 2005 announced DHS' intent to seek CLIA exemption again. In order to do this, all labs must be in compliance with state law and state law must be consistent with CLIA. LFS is working on this now. Ms. O'keefe mentioned the Speier bill, SB 857, in 2004 that required all labs participating in MediCal to be licensed or registered by DHS. This has increased the numbers of labs licensed, and lessened the number that would additionally need to be licensed/registered with CLIA exemption. She said in October 2005, LFS started phase 2 of the implementation plan, sending notices to labs not subject to emergency regulation exemption, that they needed to be registered or licensed. This will continue. Most of these labs are accredited and have never been inspected by DHS, so this is daunting.

Questions from the CLTAC, will there be new personnel requirements for physician office labs? (that law has not changed that exempts laboratories owned and operated by 5 or fewer physicians from the same personnel requirements of other labs), of the POLs inspection, how many had compliance problems (20 of 50), what is the breakdown of these non-compliant POLs? (many were run by contractors, many used

out-of-state persons to validate the methods, many used unqualified persons to do testing), a POL is defined differently in state law than federal (we agree), these 50 labs that had never been inspected, what were they (POLs), how do you assure the qualifications of persons doing testing outside California? (arduous evaluation of documents), how are the 5 physicians counted? (physicians seeing patients, ordering and performing tests onsite, all with ownership interest in lab), is license fee the same for labs outside CA as inside? (yes), is accreditation accepted outside CA (no).

Accreditation of labs in California, effect on licensure: Karen Nickel reported that there are 6 accrediting organizations (AO) given deeming authority by CMS pursuant to 42 CFR 493.501. Deemed status is conferred on a lab that has been accredited by a private, non-profit AO approved by CMS. In order to be approved by CMS, the AO must have provided reasonable assurance that a lab accredited by them has met all requirements equivalent to condition-level requirements. The approved AO are AABB, AOA, ASHI, COLA, CAP and JCAHO. Dr. Nickel said accreditation is a voluntary decision that about 1450 labs in CA have chosen. These labs are inspected by their AO, not inspected for compliance with state law, only CLIA. Accredited labs must still meet state law, qualify for state licensure and be inspected by DHS. How can accredited labs in CA use their accreditation to replace license requirements? Their AO must be given deeming authority by DHS, and there are many requirements that must be met pursuant to BPC 1223.

Question from CLTAC, must deeming authority to AO be given at CLIA exemption? (the mechanism for granting deeming authority is under consideration now and we don't know when it would be done).

HIV testing update: ShiuLand Kwong reported on how a lab should report HIV results. A laboratory should treat all lab results confidentially including HIV. HIV reports should not need any special handling by a lab. Regarding how "non-name" HIV results should be handled, all positive HIV results must be reported by the lab to the local health officer, but the name must be scrambled to protect the identity of the person. This is called no-name reporting and only applies to reports to public health labs. A person who wants to know their HIV status can go to his ordering physician and request a copy of the results. These cannot be released electronically, but confidentially. Ms. Kwong also talked about over-the-counter HIV testing which is now being considered by the FDA. LFS is concerned about allowing HIV testing at home without confirmation. The benefits include anonymity and promotion of treatment. Risks include testing done too soon, inaccurate, no counseling for POS, no confirmation, may conflict with state law for reporting. Also, HIV testing of all women at delivery is now required of all patients who have not been tested. If POS, then medication can be given. Of 250 hospitals doing deliveries, 25 already offer rapid HIV testing, but there is a backlog of applications in LFS now.

Questions from CLTAC, is FAXing of HIV results considered electronic? (LFS is unsure, will get back on this issue), who is responsible for reporting HIV to the health officer (lab and referring physician are both required), must repeatedly positive HIV

results be reported (yes), should all viral load be reported (yes), hospitals need a 15-20 turnaround on HIV testing of laboring mothers.

Mother's milk storage: DHS has been licensing tissue banks since 1992 including mother's milk from anonymous donors which must be tested for HIV and other infectious diseases required by tissue bank law. Neonatology units which store milk for use by a mother's own child for less than 24 hours have not been subject to tissue bank standards, but longer than 24 hours, they do. There is concern that milk kept longer may be contaminated, stored at the wrong temperature or given to the wrong baby. Some neonatology units do not want to be subject to tissue bank requirements and may seek a law change.

CLTAC questions, does the FDA regulate tissue banks (yes, but not mother's milk), what about other states? (New York licenses tissue banks but not mother's milk), How can mother's milk be a tissue? (the law says "ingested" and this is the only tissue ingested), how is infectious disease testing done on milk (on the mother), what about autologous (subject to regulations if stored >24 hours)

Teletesting, electronic pathology and split location testing: Bea O'Keefe discussed these issues saying new technology has added complexity to lab testing. Tests may be performed at one location and transmitted to another location for further testing and reporting. This promoted the analytical phase being done by unlicensed persons. Some inquiries have asked if a phlebotomist could draw blood and load an autoanalyzer with a licensed person in the area. Out-of-country software for viral genotypes analyzes data done at another location. Where is the test performed? If done out-of-county, that lab must be state licensed. If done in CA, then the analysis must be validated. Split testing is where the test is started at one location and moved to another for completion. The final report comes from the first location. An example is PCR testing done at two locations, and this would require licensure of both locations. Teletesting is electronic transmission of an image for review and reporting at another location. An example is histopathology which is stained, selected, scanned and transmitted remotely for review.

CLTAC input, this is analogous to microbiology sensitivity testing that uses a literature search to identify organism (initial data derived from clinical studies), how can the out-of-country facility be considered to do a test when there is no specimen, only data, (interesting question), this is a data crunch only but who is responsible, (initiating lab?), the data transfer needs to be quality assured (agreed), the part of the process that does the analysis should be licensed (part or all?), does grossing of pathology require a licensed person (this is high complexity and cannot be done by unlicensed person).

Phlebotomist scope of practice: Robert Thomas discussed who can perform phlebotomy. Many healthcare professions are interested in performing phlebotomy and LFS get lots of questions. For example, a pharmacist can do fingersticks but not venipunctures unless certified as a CPT. RCPs can draw arterials, and could do phlebotomy for diagnostic purposes. EMTs can do fingersticks and venipunctures when

working outside the hospital in emergency situations, but cannot draw blood on the floor of the hospital. Phlebotomists cannot do glucose tolerance tests, but probably could collect breath for a H pylori test. There are many phlebotomy issues that are confusing, and you must always look at the scope of work of the healthcare provider.

Quality control of allergy testing: Bea O'Keefe continued this discussion from the previous CLTAC meeting. Since CA law is currently based on quality control as listed in CLIA as of 1/1/04, current law would require 2 controls per day for moderate complexity testing, as allergies. In high complexity allergy testing using ASR reagents, their use must be validated and controls run the same as the patient. This makes it difficult for labs to QC high complexity allergy kits. In the BD Chlamydia and GC amplification testing, some labs are repeating all POS or indeterminate. If they get NEG, they report NEG. The kit insert says all POS and indeterminate should be repeated with amplification control, not just repeated. Therefore, labs doing this are violating the FDA approved procedure and it become subject to high complexity QC. Ms O'Keefe said labs can repeat these tests, but must validate the modification. Most labs say they will follow the manufacturer's instructions and risk reporting false POS.

CLTAC input, if the CDC requests labs to repeat all POS by another method, what happens if the lab uses the same method ? (the labs must validate using the same method.)

Election of CLTAC Chair: The new CLTAC chair should be elected at this meeting and will take office in June 2006. Dr. Nickel had sent the CLTAC those people she thought would be eligible to serve as chair (have terms left to serve). Salim Rafidi nominated Dr. Tim Hamill, seconded by Mary York. The CLTAC voted unanimously that Dr. Hamill should chair the CLTAC.

#### New business:

Michael Borok asked about POLs, their frequency of inspection and fees. Dr. Nickel explained that the only special provision for POLs is their exemption from testing personnel requirements for POLs owned and operated by 5 or fewer physicians doing testing on their own patients. All other requirements in law, as frequency of inspection and fees are same for POLs and non-POLs.

Tim Hamill asked why the CLTAC had not been sent a special notice about AB 1161. This bill dealt with unlicensed lab personnel, their supervision and restrictions of work. Dr. Nickel said that bill came and was withdrawn before the CXLTAC could be involved.

Tim Hamill asked about online verification of licensed persons, required by JCAHO in 2006. Robert Thomas said that online verification was not ready yet, and this must be done case-by-case from a FAXed list. He hoped to have online by summer 2006.

Tim Hamill asked how public health labs were subject to state law. Kathy Williams said that although subject to federal law, public health labs were exempt from state lab law.

Terry Bryant asked if a pharmacist compounder could use a patient serum to prepare eye drops for the patient. Dr. Nickel said LFS would check into that.

David Yong said the staff shortage in LFS had a public health impact but nobody was taking any action. Dr. Kimsey said LFS funding was set by the legislature and he would be interested in CLTAC input on this. He suggested a formal letter on behalf of CLTAC. Robert Footlik said why collect lab fees if the Department of Finance wont let LFS spend them. Dr. Kimsey said LFS had to have the money first, before approval to spend. Terry Bryant suggested that David Yong, Tim Hamill, Mary York and Terry, write a letter to DHS about staffing in LFS.

Pat Fornier said there was lots of frustration with LFS, and the LFS website should be updated more frequently.

The meeting was adjourned at 12:15 PM.

The next meeting will be held on Friday, March 3, 2006 at Richmond and North Hollywood with a telephone bridge.