

Clinical Laboratory Technology Advisory Committee  
Minutes of the September 8, 2006 Meeting  
Meeting held by videoconference from CDHS Richmond Campus and  
North Hollywood Kaiser Permanente, and by telephone bridge

CLTAC members participating: Michael Borok, Curtis Johnson, Lin Kassouni, Carmen Maldonado, Salim Rafidi, David Yong, David Zingmond.

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

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

Public members participating: 26 persons attended in Richmond, 23 persons attended in North Hollywood and 46 persons called in on the telephone bridge.

Introduction and general announcements: Karen Nickel opened the meeting at 9:05AM, stated that the chair, Tim Hamill was unable to come to the meeting today and said that Curtis Johnson had kindly agreed to chair the meeting. Mr. Johnson called the meeting to order, welcomed the participants 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. He asked all participants on the telephone bridge to mute their phones to eliminate background noise.

Approval of the June 9, 2006 meeting minutes: Because there was not a quorum of CLTAC members, the June 9, 2006 minutes could not be approved. They will be held over until the next meeting.

Department news: Dr. Paul Kimsey, Division of Laboratory Science, gave the report for the department. He said that an outcome of the governor's California Performance Review was consideration of a split of the Department of Health Services. This was authorized in Senate Bill 162 which will split DHS into the Department of Public Health and Department of Health Care Services. All programs related to licensing, disease control, tobacco control, bioterrorism, will be in the new DPH, including Lab Field Services. MediCal and managed care will be put in the new DHCS. It will take one year to accomplish the split which is supposed to be budget neutral. Nothing happens between now and July 1, 2007 except planning and figuring out how administrative services will be split.

LFS update: Dr. Karen Nickel thanked Kaiser Permanente for providing the videoconference site in North Hollywood and the telephone bridge. She also thanked Curtis Johnson for ably filling in for Dr. Hamill as Chair of CLTAC today.

The next meeting of the CLTAC will be on December 1, 2006. Six members will be completing their terms and they will be recognized at that meeting. Any CLTAC members who want to come to Richmond for that meeting can submit trip requests and their expenses shall be paid. Dr. Nickel said she was also working on an email contact list and encouraged everyone to get on that list to ease communication and save mailing costs. Dr. Nickel said LFS is starting to fill some of its vacancies and encouraged qualified persons to apply for openings in the Los Angeles and Richmond offices.

Legislative update:

AB 2156 (Niello): Robert Thomas reported on this bill which covers 3 different issues, the scope of practice of Histocompatibility lab directors, conditions under which autoverification can be used in California and scope of practice of pathologists' assistants and histotechnicians. (1) Histocompatibility lab directors must be board certified, pass an oral exam if licensed after January 1, 2007 and may direct an immunology lab as well as a histocompatibility lab. (2) Autoverification is defined and is authorized when the lab director is responsible for setting the algorithm parameters, a licensed person is available onsite during the time autoverification is being used, and the licensed person is competent in the testing being autoverified. (3) Pathologists' assistants when certified and with documented competency may perform gross dissections and autopsies when working under the supervision and control of a qualified pathologist who does not need to be onsite. Uncertified pathologists' assistants and histotechs may prepare specimens and do many of the duties of a certified person only when they are directly supervised by a pathologist who is onsite while they are working. The Department may adopt regulations in 2011 if further clarification is needed.

Mr. Thomas answered many questions on these issues. What are the educational requirements for a histotech? Grossing pathology is considered high complexity testing and CLIA requires a person to have an AA as a minimum. If a histotech has national certification, will DHS allow them to work without licensure? Yes, this bill does not recognize certification of histotechs, but authorizes them to work. What about proficiency testing with autoverification? Proficiency testing must be done using autoverification if that is the way testing is routinely done in the lab. How does a lab develop an algorithm, is it public knowledge? It must be developed by the lab director or designee. Can the results be challenged? Any result can be. The algorithm needs to be fully validated and signed by the director. How does a pathologist provide direct supervision? Direct, onsite supervision is required for uncertified personnel, putting the responsibility for activity on the pathologist. Lin Kassouni thanked DHS and CCLA for their work in getting this bill through.

SB 1785 (Figueroa) regulation of mother's milk storage: Ron Harkey said this bill would exempt hospitals that store mother's milk from tissue bank licensure. Mothers donating milk to her own child would be exempt from infectious disease screening.

SB 1369 (Maldonado) pathology billing: Karen Nickel said this bill would have required the lab that performs anatomical pathology reading and reporting to do the billing for the testing. This is a similar requirement in place for cytology reports. However, this bill failed because of concerns about secondary billing of the patient.

SB 162 (Ortiz): Kathy Williams reported on the creation of the new California Department of Public Health. She said the old DHS started out as DPH in the 1950's and now is being reorganized back to DPH! She said the current change was a result of the Little Hoover Commission and the CPR, as Dr. Kimsey had said. Governor Schwarzenegger wants to cut wasteful spending, improve service to clients and remove redundancy. She said there was lots of good information on the internet at the DHS home page including "Rx for Change", "Keeping the Books", "Form Follows Function". The new DPH will be led by a physician, with emphasis on core emergency preparation, environmental health, food safety, water quality, laboratory, hospital and nursing home standards. This implements on July 1, 2007 and is supposed to be budget neutral. Will this impact the county public health laboratories? No, the counties are autonomous.

Personnel licensing issues: Robert Thomas discussed the upcoming staggered license renewals. The notices are supposed to be going out on November 1 for 2007. Those people born in even years will get an extended license date, depending on their birth month. For example a person born in June of an even year will get an 18 month license which expires in June 2008. Then the next license period will be for 2 years. The charge will be prorated but only 12 hours of continuing education will be required. Persons born in odd years will start the staggered renewals in November 2007. When can the CE be taken during the 24 months? Anytime.

Online license verifications is now in test mode and should be done soon. LFS does not want to release any erroneous license information and is concerned because there are 40,000 records in 38 categories of persons. How timely will be the licensing information? Updates will be done once a week. What information will be displayed? Name, license title and number, expiration date will be given. What about the "grace period"? This is a problem because certified phlebotomists and cytotechnologists do not have an official grace period, while CA law allows the others 60 days. This will be explained on the website. What about temporary and trainee licenses? These will not be displayed online. How long is a temporary license valid? It is valid until administration of the next state-administered exam. How will delinquent licenses be shown? For CLS, they will not show as delinquent until after March 1 of the next year, or 60 days after expiration date for staggered renewals.

There is a backlog on training program applications as staff has been redirected to help with review of CLS applications and phlebotomy. After October 1, full effort will be given to training activities to support CLS and MLT licensure.

The next licensing exam will be given on November 1 in Ontario and Oakland this year. A total of 1032 persons have applied, 740 have been approved and 309 have previously failed the exam. Another 261 applications need to provide more documents, proof of

social security number or training in a CLIA-approved laboratory. Why do persons need to have an SSN to take the exam when many other license categories do not require it? California lab regulations require persons to have an SSN to be licensed.

Progress on certification exam approvals for licensure purposes: Karen Nickel reminded the CLTAC that the MLT regulations included Section 1031.8 that set the standards for approval of certifying exams for licensure purposes. Using authority of B&P Code 1261 and 1262, LFS is in the process of reviewing applications from the ASCP BOR, AAB BOR and the AMT medical technologist (CLS) exams. She said LFS hopes to have 2 CLS exams approved for CLS and MLT by the end of the year, and then will start on the other license categories. Which categories need certifying exams to replace state-administered exams? BS-level categories: clinical chemist, immunohematologist, microbiologist, toxicologist, hematologist, public health microbiologist. PhD/MD-level categories: bioanalyst, chemist, microbiologist, toxicologist. It is hoped that in 3 years all licensure categories shall have a certification exam instead of a state exam. How will this impact LFS? LFS must continue to develop the state exam even for a diminishing number of people. LFS will have to process applications from people taking a certification exam and those taking the state exam, adding confusion. How will LFS enforce B&P Code Section 1262.5? This provision requires persons to wait to retake an exam after they fail twice. LFS will have to rely on personal attestation and the deterrent of the cost of retaking the certifying exam.

Phlebotomy certification update: Maria DeSousa said a total of 19,659 persons had applied for certification, 15,432 had been approved, 1,938 have been notified about missing documents or need criminal background check, 2,288 are awaiting review. LFS is surprised by the large number of new applicants. Only 50% are applying online and there is a 2-3 month delay on those mailing in their applications. There are lots of problems with this program, the high criminal convictions, persons applying for CPT-2 without arterial experience, poor language skills. Approval of new phlebotomy training programs is on hold at this time so staff can focus on backlog. How are phlebotomy renewals being handled? These are being sent out routinely from Sacramento based on certification date, and are processed daily. Why is there a delay in issuance of duplicate certificates? There has been a problem with printing of duplicate phlebotomy certificates. The small card was to be used at other locations. Training programs are accepting students without high school and that is a problem.

Adoption of CLIA 2003 into state law: Karen Nickel said an important job that DHS needs to do as we prepare for CLIA exemption is to address differences between state law based on CLIA in 1994 and current federal law, CLIA 2003. This will aid in development of a crosswalk comparing state and federal law, and will indicate what parts of state law need to be amended. Any part of state law that is less strict than federal must be changed. Any part of state law that is equivalent or more strict than federal can be retained, or could be amended. LFS needs CLTAC help with this project, to study the 2 laws and recommend changes, probably done by legislation before exemption. Curtis Johnson nominated Robert Footlik to chair this subcommittee

of CLTAC, as he was the chair of the subcommittee that reviewed state and federal law for the first CLIA exemption bid in 1999. He was elected unanimously. Mr. Johnson asked for volunteers for the subcommittee, and Les Revier, Mary York, Jim Ottosen, Morton Field, Tom Tempske, David Yong asked to serve. In addition, Donna McCallum, Bea Okeefe and Kathy Williams of LFS will serve as liaisons. Mr. Footlik will be organizing those persons and perhaps others, to work on this project. Karen Nickel asked that he give a report at the next CLTAC meeting if possible.

Naturopathic doctors and CLIA waived tests: Monique Mazza, ND told the CLTAC about the work scope of naturopathic doctors. She said they were authorized to practice in SB 907 (Burton) in 2003. They are primary care doctors with post graduate degrees. They are 4 accredited naturopathic schools in the US and 2 in Canada. They graduate about 100 persons a year and about 7000 are licensed in the US. Their philosophy is the body can heal itself, so the ND assists in that process. In their training they study physiology, excess analytes, are concerned about toxicity and nutrient interaction. They have 2 board exams covering basic and clinical topics. They learn how to use lab tests and diagnose patients using lab tests. They do venipuncture and microscopics. The ND want to be waived lab directors, and do their own waived and PPMP testing. Bob Footlik noted that ND may be qualified to do waived testing as part of providing direct patient care, but not to direct a lab. Dr. Mazza said licensed medical doctors are not interested in serving as lab director. She said in California ND are called naturopathic doctors while in most states they are called naturopathic physicians. Michael Borok noted that ND do not go through a residency program, treating patients. He said the CMA would equate the ND to a nurse practitioner and both should be able to do waived testing under the supervision of a licensed physician who is also a laboratory director.

Internet ordering of DNA testing: Bea O'Keefe said direct access testing has been an issue since 2000 when LFS started receiving complaints about internet ordering of salivary hormones. In 2002, the law was changed to expand self-ordered tests beyond glucose, pregnancy, glucose, cholesterol and occult blood. LFS has received many complaints since then about internet ordering without a physician order. Now we are seeing genetic testing marketed over the internet for markers for breast and ovarian cancer, as well as obesity and tendency for smoking addiction. There are tests available for hemochromatosis and cystic fibrosis, and nutritional deficits. Of particular concern are nutrigenetic tests that analyze a limited number of genes to give personalized nutritional and lifestyle recommendations for persons. The costs for these tests range from \$89 to \$319 and the Government Accounting Office has investigated. The conclusion of the GAO report was that current regulatory environment only provides limited oversight to those companies marketing new types of genetic tests. In California all genetic tests must be ordered by a licensed physician, even if ordered over the internet, but that is also of concern to LFS. What does the future hold? LFS must assure tests are ordered by qualified person and test done by a licensed lab. Dr. Elissa Levin of DNA Direct asked to speak to the CLTAC saying since this service is offered without seeing a patient, the consumer needs to beware. The genetic tests are validated according to guidelines set by the company.

New business: There was no request for new business.

Setting dates for 2007 meetings: The CLTAC usually meets the first Friday of the third month of each quarter, but may be altered to avoid Labor Day in September and graduation days in June. Karen Nickel suggested the 2007 meeting dates be March 2, June 8, September 14 and December 7, 2007. The CLTAC approved these dates.

With no further business, Acting Chairman Curtis Johnson adjourned the meeting at 12:30 PM. The next meeting will be on December 1, 2006 in Richmond and North Hollywood.