

Clinical Laboratory Technology Advisory Committee

Minutes of the March 4, 2011 Meeting

Meeting held by videoconference from Richmond campus, CDPH,
KP Regional Laboratory, North Hollywood and
Telephone bridge Line

CLTAC members participating

Michael Borok, Anthony Butch, Elizabeth Dequinia, Tim Hamill, Lin Kassouni, Donna Kirven, Carmen Maldonado, Peggy O'Toole, Salim Rafidi, Les Revier, Fred Ung, Lori Dean-Yoakum, Mary York.

Former CLTAC members participating

Morton Field, Imre Fischer, Robert Footlik, Sol Notrica, Jim Ottosen.

DPH staff participating

Zahwa Amad, Norma Barocio, Grace Byers, Maria DeSousa, Pam Dickfoss, Ron Harkey, Robert Hunter, Nema Lintag, Victoria Maxwell, Donna McCallum, Don Miyamoto, Karen Nickel, Judy Schlosser, Tom Tempske, Pat Toomer, Kathy Williams.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Tim Hamill. A roll call was conducted of CLTAC members and other participants, and Dr. Hamill noted that a quorum was present for the meeting.

Approval of the January 14, 2011 meeting minutes

Dr. Hamill said that LFS had not completed minutes of the last meeting, but would email them when they were completed.

Department news

Ms. Pam Dickfoss, Acting Deputy Director of the Center for Health Care Quality, said that she had addressed the CLTAC at their last meeting. She said that since that meeting Howard Bacher, MD had replaced Dr. Mark Horton as Acting Director of the Department of Public Health. She said that a new director would be appointed soon.

Ms. Dickfoss said the state budget is still a problem and there is a hiring freeze for all programs. She said it was important that LFS fill its key positions but the freeze prevents new hires at this time. Out of state travel is highly restricted and all must be approved by HHS agency, even if it is paid by a grant, and only one person is approved for any trip. Cell phone usage must be reduced by 50% and LFS has given up 14 of its 30 cell phones. Ms. Dickfoss says she knows that LFS has been working hard on the personnel regulations and there will be an update later in the meeting.

Question: Tom Tempske asked why LFS cannot travel to inspect labs outside California when the law says the costs must be borne by the laboratory. Ms. Dickfoss said she knew of that law and L&C has the same authorization but neither program is allowed to travel outside California.

New legislation impacting clinical laboratories

Kathy Williams, Acting Section Chief of Facility Licensing, reported on several newly

introduced bills that may impact clinical laboratories.

AB 186 (Williams) is a repeat bill of one that was vetoed by Governor Schwarzenegger last year. This bill, sponsored by the Council of County Health Officers would allow them to make changes in which diseases or conditions must be reported to the state. Regulations would not be needed to make these changes, which would be communicated by a notice letter to laboratories.

SB 761 (Hernandez) would add optometrists to those who can direct waived labs and perform waived lab testing.

SB 594 (Wolk) is sponsored by the CA Association of Public Health Laboratory Directors, would bring language from B&P Code for personnel licensing into H&S Code, would prevent any fees for licensure and would not allow outsourcing of the Public Health Microbiology exam administered by LFS.

Question: Tom Tempske asked if the licensing standards in SB 594 would limit PHM workscope to the specialty of microbiology and its subspecialties. Ms. Williams said it would for high complexity but would add waived and moderate complexity in any other specialty, just like in B&P Code.

Facility licensing section.

Kathy William, Acting Section Chief, reported that laboratory licensing was backlogged to the first of December. This has resulted in laboratories getting delinquency notices when they have really paid on time which is frustrating both to the laboratory and to LFS. The section is hampered with vacancies and furloughs like all of LFS. Currently LFS is getting about 50 new applications a month along with renewals

Question: Michael Borok asked if there is a plan for electronic applications and renewals. Ms. Williams said this was part of the EOL project slated for 2014 and is not in our control.

Personnel licensing section.

Zahwa Amad, Acting Section Chief, said LFS is working to facilitate licensure of CLS trainees in California. Actions taken include allowing the trainee to apply for CLS licensure one month prior to completing training, asking the training program to notify LFS 45 days prior to completion of training with the names of those completing training, LFS preparing a qualification letter for admission to a certification examination and admission to the online quiz. The candidate is asked to remind AAB or ASCP that they need to verify their passing the exam to LFS. The goal of doing this is to speed licensure of new CLS' to within 2-3 weeks. Dr. Amad reminded the CLTAC that trainee licenses are still one year and need to be renewed, if necessary. The Weber College (online) students need to train in CA, but they need a trainee license. They cannot just go to any lab and work for training. Dr. Amad noted that there still is no CPS contract and this may impact online applications.

Question: Joseph Musallam asked how many CLS applicants there were each month and whether they were US or foreign trained. Dr. Amad said LFS receives about 80 CLS applications per month, half are licensed, about 20% are foreign

trained, mostly 3+1 students from the Philippines. She said she would give the full statistics at the next meeting.

Question: Robert Footlik asked if LFS was taking legal action against persons training without a license or laboratories training persons without licenses. Dr. Amad says LFS writes a letter to tell them to cease and desist. Tom Tempske said this is a serious matter and violates many aspects of state law.

Question: Elizabeth Dequinia asked how many MLTs apply each month. Dr. Amad said 5-6 per month, mostly from southern California. Dora Goto said Diablo Valley College was starting an MLT program and asked if they had been approved yet. Dr. Amad said they are starting the academic component now and will add the clinical training, requiring approval, later.

Question: Elizabeth Dequinia asked how many phlebotomists are certified each month. Maria DeSousa said as many as 600 per month, sometimes 700. Ms. Dequinia said that was too many. Many schools charge \$5-10,000 for training and there is no place to get their clinical training. Salim Rafidi said this is a problem and asked what LFS can do. Maria DeSousa said phlebotomy training programs are approved for 2 years. Some are approved for the full program, didactic plus clinical, some are approved for didactic only and some for clinical only. Those that are approved for the full program are obligated to provide clinical training. Those that are approved for didactic only, do not need to provide clinical. Mr. Rafidi said most labs can only train a limited number of phlebotomists and students have to look for their own training sites. Maria DeSousa said she is aware of the problem. Ms. Dequinia said that some MLT candidates are looking for training sites. Dr. Hamill said that with a two year renewal for phlebotomy training programs, they should be asked for a list of graduates and how many were certified. Dr. Borok asked how a lab could get approval for training, and Dr. Amad said the standards are in regulation for each license category.

Question: Donna Kirven asked about identification cards for phlebotomists. Dr. Amad said that was still in progress. LFS had reviewed mockups from the contractor. The new cards will be designed like CNA cards.

Question: Robert Footlik asked how phlebotomists can draw blood at remote sites without a card. Salim Rafidi said cards were needed for consumer protection. Dr. Amad agreed and said the laboratory usually provides name badges to identify their staff or they could carry duplicate certificates until the cards are available. Joseph Musallam said LFS should raise phlebotomy fees to pay for cards.

Personnel standards subcommittee report

Salim Rafidi was thanked for his work in calling together three subcommittee meetings to review the regulations, DPH-08-001, since the last meeting of the CLTAC on January 14, 2011. He, in turn, thanked all the participants who showed such spirit and interest in going through the regulations, section by section. He said the CLTAC really needed a 45 day comment period at the next publication of the regulations to allow time to review and comment.

Dr. Hamill made a motion that the CLTAC review and approve the recommendations of the subcommittee as presented today. If the next comment period is only 15

days, then this document shall be submitted as an official response of the CLTAC. It the next comment period is 45 days, then the subcommittee shall reconvene as it has more time to thoroughly review and submit comments on behalf of the CLTAC. Mary York seconded the motion. Discussion ensued.

Question: Jim Ottosen said the subcommittee had not had an opportunity to review and approve the subcommittee report, so the CLTAC could not approve it. Dr. Hamill agreed and asked how the CLTAC subcommittee members could vote and approve it and then present to the full CLTAC before the regulations were released for comment again. Jim Ottosen said the bylaws required a vote in person and that is a problem. Mary York made a motion that the CLTAC approve the subcommittee report and submit it as is if there is a 15 day comment period, and redo it if there is a 45 day comment period coming. Elizabeth Dequinia seconded the motion but there was no vote. Michael Borok asked if the next comment period could be extended from 15 to 45 days because there will be extensive amendments. Tim Hamill said he could write a letter to ask for a longer period. Tom Tempske said the website of the Office of Administrative Law gave information about comment periods. Salim Rafidi said he would try to reconvene a subcommittee meeting via videoconference on March 23-25 assuming the new comment period does not occur in the meantime. The subcommittee could review the report and approve or disapprove it, then present it to CLTAC. Morton Field asked what the timeframe requirement for prior notice for a public meeting. Tom Tempske said he thought it was 72 hours and it was required in the Government Code.

Biologics report

Ron Harkey, Section Chief of Tissue Banks and Biologics, said the freeze exemption is really hurting his sections in LFS as they need to fill current vacancies. He said that Jan Otey would not be able to give the report on human milk banking in California as slated as she was ill today. She will cover that at the next meeting.

CLIA update

Donna McCallum, Section Chief of the CLIA program in California, said that in February, LFS surveyors conducted 67 recertification surveys, 6 validation surveys of accredited labs, 1 complaint inspection, 10 waived lab follow up surveys for a total of 83. Since the federal fiscal year started on October 1, 2010, LFS has conducted 39 initial surveys, 259 recertification surveys, 12 validations, 1 complaint, 47 waived lab surveys and 9 proficiency testing sanctions for a total of 324.

Question: Michael Borok asked if CLIA allows an ordering physician to have his/her name preprinted on the test requisition. Ms. McCallum said that was acceptable. Dr.. Borok asked about requisitions for testing paid by Medicare or Medicaid. Ms.. McCallum thought this was acceptable for Medicare.

Question: Les Revier asked how many waived labs were found in compliance. Ms. McCallum said of the 47 reviewed this year, ten were sent follow up letters of recommendation. These aren't sanction letters as there is no federal provision for sanctions other than if testing outside certification (that is, performing non-waived tests). Reviewing waived labs is a CMS special project. Ms. McCallum said California could impose sanctions over and above CMS if it wanted to. Mr. Revier asked how many waived labs were out of compliance last year and Ms. McCallum said of about 200 were reviewed last year, 30-40 got letters. LFS uses a checklist of

things to check but not QC, as opposed to non-waived labs have extensive QC requirements. Waived labs use tests with built in QC. (Note that not all waived tests have built in QC.)

CLIA crosswalk subcommittee report

Robert Footlik, Chair of the CLIA crosswalk subcommittee, said this committee first convened in 2006. Its charge was to review CLIA and state law to find areas of inconsistency and recommend whether to adopt CLIA if it is less stringent and/or retain state law if it is more stringent. Mr. Footlik reviewed the sections that had been completed and those that were left. The project has been on hold since its last meeting on July 9, 2010. Private accrediting agencies applying for deeming authority in California need the crosswalk, but it is not completed because of priorities in LFS.

Question: Les Revier asked what progress had been made in accepting applications from accrediting agencies. Karen Nickel said she understood some contact had been made with Bea OKeefe who is not at the meeting today. Kathy Williams said there was information on LFS' website. She said she thought the contacts were just casual from the accrediting organizations.

Question: Mary York asked if the project could be completed in one more meeting. Mr. Footlik thought more than that would be needed.

Regenerative medicine in California

Robert Hunter, Program Manager of Biologics said there was a lot of work going on now in regenerative medicine in California. He said he was at UC Davis last week, reviewing their facility and was very impressed with the work going on. Many were using cadaveric liver and mesenchymal stem cells, avoiding the controversial embryonic source. There are 147 investigators involved there, using stem cells to repair peripheral artery disease, eye and neurological degenerative diseases, kidneys, blood and hearing disorders. He said he would give a further update at the next meeting of the CLTAC.

Question: Robert Footlik said there was similar research going on at Cedars-Sinai in Los Angeles. Tim Hamill said this was also being done at UCSF.

Question: Victoria Maxwell asked if insurance would cover procedures using regenerative medicine. Mr. Hunter said he thought that it does not at this time. Tim Hamill said the CLTAC should stay involved in this work.

New business

Dr. Hamill said that the CLTAC had asked for a formal presentation from the department's legal staff on the role that CLTAC now has with the department, and there was no such presentation put on the agenda this time. He said the CLTAC had no involvement prior to publication of the personnel regulations, and no charge was given to Salim Rafidi, chair of the new subcommittee, to review the regulations. He said he would send a formal letter to the department asking for this, and not rely on simply putting an approved motion in the CLTAC minutes.

Question: Karen Nickel said she was disappointed not to hear anything from the subcommittee. Tim Hamill said that was not possible until the subcommittee report

was approved by the full CLTAC.

Question: Ernie Satyadi asked who is responsible to pay for TB tests done on inmates. Kathy Williams did not know, but suggested she contact Dr. Desmond in the Microbial Disease Lab in Richmond. Karen Nickel thought that testing on inmates was done under contract with outside laboratories, with fixed prices.

Question: Ms. Satyadi asked if training that is acceptable to a nation board is acceptable for licensure in California. Salim Rafidi said this is controversial and the issue needs some compromise.

Next meeting

Chairman Tim Hamill said the next meeting of the CLTAC will be Friday, June 3. The special meeting of the subcommittee shall be March 16 if all arrangements can be made. An email shall be sent out by Salim Rafidi.

The meeting was adjourned at 11:15 AM.