

Clinical Laboratory Technology Advisory Committee
Minutes of the December 5, 2003 Meeting
Held in Oakland, California

CLTAC members participating: Ellen Jo Baron, Vickie Bello, Terry Bryant, Morton Field, Robert Footlik, Robert Freedman, Deanna Iverson, Curtis Johnson, Lin Kassouni, Patricia Ovalle, Les Revier, Tony Van Kessel, David Yong.

Past CLTAC members participating: Sam Chafin, Jim Ottosen, Fred Struve.

DHS staff participating: Linda Bryant, Shiu Land Kwong, Cindy Lloyd, Howard Manipis, Donna McCallum, Don Miyamoto, John Molnar, Karen Nickel, Jan Otey, Paul Kimsey, Shahrzad Radahd, Tom Tempske, Robert Thomas, Pat Toomer, Kathy Williams.

Public members participating: Leticia Acosta, Michael Aidan, Lauie Armour, Rhonda Becker, Bill Bigler, Grace Byers, Michelle Carbone, Christine Darmanian, Lori Dean-Yoakum, Kathleen Doty, Denise Facaros-Armolea, Stephanie Higgins, Dora Goto, Carola Howe, Jerry Hurst, Donna Kirven, Howard Koo, Ken Kuramoto, Karen McRae, Joseph Musallam, John Shillcock, Michelle So, Mel Solis, Diane Thomas, Fred Ung, David Valesquez, Phyllis Walker, Mara Williams, Joyce Weinkauff, Mary York.

In the absence of Chair Cherie Evans, Past-chair Robert Footlik opened the meeting, gave the rules of the meeting, and noted that since the meeting lacked a quorum, the approval of the minutes and election of the new CLTAC chair would be deferred until later in the meeting.

Dr. Paul Kimsey gave an update of Department of Health Services news related to clinical laboratories. He said a new administration was coming to Sacramento. Health and Human Services Secretary Kimberly Belshe was recently appointed. Ms Belshe formerly was Director of DHS. Joe Munso is UnderSecretary of HHS and Mike Genest is Chief Deputy Director of Finance. Dr. Kimsey said DHS continues to have budget woes with a recent 16% budget cut drill and the budget is still not approved. A recent vacancy sweep took 16 more positions and there may be midyear cuts of 20-25%. In order to keep the program functioning, a number of reductions have taken place in complaint investigations, travel, examinations, furloughed retired annuitants, redirection of Division staff, and generalized reduced services. In the announced effort to repeal state lab law, the transition documents are under review and the financial issues of LFS need to be resolved. The CLTAC leaders met with Ms. Bonta and it is hoped that she will talk with Ms. Belshe. Perhaps the CLTAC can meet with the new director when he/she is appointed. Dr. Kimsey was called away for a telephone call.

Mr. Footlik noted that a quorum was present and called for motions to approve the minutes of June 2003 and September 2003, as distributed at the meeting. These minutes were approved without change. Mr. Footlik asked for nominations for a new chair of the CLTAC. Ellen Jo Baron nominated Cherie Evans, Les Revier seconded, the vote was unanimous that Dr. Evans be continued as chair of the CLTAC.

Dr. Karen Nickel gave the LFS update. She officially said farewell to those CLTAC members who were leaving, Ellen Jo Baron, Vickie Bello, Morton Field, Robert Footlik, Robert Freedman, Diane Hedler, Deanna Iverson, Arthur Lurvey, Sol Notrica, Connie Smith and Tony VanKessel. Certificates of appreciation were given to these persons. Those continuing their appointments were also recognized, Terry Bryant, Greg Clark, Cherie Evans, Paul Fu, Tim Huston, Curtis Johnson, Lin Kassouni, Patricia Ovalle, Les Revier, David Yong and Lou Dunka. She noted that nominations had been submitted for new members to the CLTAC and it appears that the qualifications of the candidates are very good.

Dr. Nickel noted that Cherie Evans was very ill and hoped for her speedy recovery. She said that DHS appreciates Robert Footlik's willingness to substitute for Dr. Evans as chair of this meeting. Dr. Nickel noted that the upcoming meetings would be held by videoconference using the facilities kindly donated by Kaiser Permanente in North Hollywood and Oakland. A telephone bridge would also be made available.

Dr. Nickel continued that because of severe staff shortages, LFS is unable to carry out vital functions. The May 2004 exam will have to be canceled and all personnel licensing applications will be held for review until after March 1, 2004. The lab license renewals are late going out and LFS is installing a new call router system to help handle the phone calls without staff. Karen Nickel is very concerned that LFS has had a 3-year freeze in hiring and has not been able to replace any persons leaving in that time. With many staff approaching retirement age, there will be a management crisis in LFS soon.

There has been no further word on repeal of lab law, and this has apparently not been on the agendas of Governor Schwarzenegger or Secretary Belshe. However, LFS is continuing to postpone collection of fees and operating in the red, and it will take years for LFS to regain its staff.

Dr. Paul Kimsey returned to continue the DHS update. He said transition documents had been prepared to explain to the new administration the unresolved problem about collection of lab fees. The previous administration made the decision to repeal lab law, but this is still up in the air. He said the CLTAC appointments had been submitted in October and had not been acted upon yet.

Patricia Ovalle asked about online licensure as a means to accommodate staff shortages. Dr. Kimsey said it was used in other programs, as Licensing and Certification, and we had been working on it in LFS. However, that has been put on hold since the Oracle problem. Robert Footlik acknowledged the effort Dr. Kimsey had made to get permission for the face-to-face meeting in Oakland in December for the CLTAC.

Robert Footlik reported on the CLTAC meeting with Director Diana Bonta. This action was taken based on two motions from the last CLTAC meeting. Mr. Footlik apologized that not every CLTAC member could go, Cherie Evans and he met with Diana Bonta, David Souleles, Kevin Reilly, Paul Kimsey and Sheila Nolan. The meeting was very positive. Ms. Bonta understands the CLTAC concerns. Dr. Kimsey said Dr. Evans and Mr. Footlik had done a good job representing CLTAC and LFS. Martha Kunkel asked if the legislation would go forward in January 2004. Dr. Kimsey said this was an administration call and time was short with much work to be done. Ellen Jo Baron asked Dr. Kimsey whether he supported full fee collection. Dr. Kimsey said he must follow DHS direction on this while pointing out reality and consequences. Robert Footlik said DHS should carry out the intent of SB 113 and seek CLIA exemption. Les Revier challenged that the meeting was really productive, that Ms. Bonta could make the decision despite her support. He asked that CLTAC meet with Secretary Belshe. Robert Footlik said DHS had dropped the ball for a long time for not collecting fees since 1996. He explained that prior to 1996, POLs with 5 or fewer doctors were not exempted from oversight. That came in after SB 113. Dr. Bill Bigler asked what would be the advantage of repealing lab law. The budget problem would remain. Dr. Kimsey said Ms. Bonta planned to meet with Ms Belshe on repeal of lab law.

Les Revier made a motion, seconded by Ellen Jo Baron, as follows, "I move that the CLTAC request a meeting with Kimberly Belshe to discuss the issue of repealing state clinical lab law and recommend other options, as soon as possible." This motion was unanimously approved by CLTAC. The discussion continued with input from Cindy Lloyd, Robert Footlik, Pat Toomer, and Ellen Jo Baron.

The following legislation was discussed by LFS staff:

AB 685, HIV counselors authorized to do finger sticks for Rapid HIV,
AB 1460, Pharmacist as waived lab director,
AB 371, CPTs authorized to work for police agency, drawing DUIs,
AB 1087, CPTs authorized to work for non-diagnostic programs.
SB 165, Lab issues proposed by LFS.

Dr. Nickel discussed the status of regulations under development. She noted there was an executive order to freeze all regulations and we hope that our MLT regulations will be exempted. Dr. Nickel reviewed the regulatory process and Mr. Schwarzenegger's concerns about underground regulations, regulation with

hidden business or financial impact. The MLT regulations (R-13-03E) were submitted for emergency filing in June 2003, and still have not been returned from Sacramento. The Autoverification regulations (R-54-00) remain essentially unstarted. Andrology scientist licensure was split off the genetic scientist licensure package and need to be resubmitted. No other regulation packages are underway at this time.

Robert Thomas discussed personnel licensing examination issues and the delay in application processing. Mr. Thomas said that things continued to be very grim in LFS and this has led to cancellation of the May 2004 exam and delay in processing licensing applications until after March 2004. He said if anyone could volunteer, we could use any help available. He said the remaining LFS staff were dedicated, but could not handle the workload. Mr. Thomas reviewed licensing exam statistics that showed the following:

Year	No taking exam	No passing exam
2000	474	231
2001	570	221
2002	682	261
2003	997	419 + 409 new genetic scientists

The numbers of persons taking the exam has increased dramatically and the number of persons passing has also increased. In 2003 LFS issued 828 new BS-level licenses. There were a number of questions from the CLTAC. Someone said issuing a temporary license was as much work as issuing a permanent license, and may adversely affect health care. Another person said a phlebotomist had been waiting 3 months to be certified, and asked how much longer they would have to wait. Another said phlebo certification has a tremendous business impact and Mr. Thomas said everything was going to take longer. Mr. Footlik said for everyone to write to their legislator about the sad state of affairs.

Dr. Nickel introduced the issue of a discussion on the scope of practice of licensed cytotechnologists. The issue is whether cytotechs should be authorized to perform FISH and ISH tests, as this may be a crossover between cytology, histopathology, immunology and virology. Coding for billing is confusing. Typical tests are non-tissue tests done on urine for bladder cancer or cervical smear test for HPV. Deanna Iverson discussed certification of cytotechs and the ASCP practice analysis underway for cytotechs. Cytotechs basically work in 2 environments, a patient care facility doing FNAs or a non-patient care facility, with no patient contact, doing gyn or non-gyn cytology. There is an overlap with molecular diagnostics with HPVs. There are currently only two cytotech training programs in California, one in greater LA and one at Loma Linda. Cytotechs are trained in gyn and non-gyn cytology. A cytotech without non-gyn experience would not be hired. There are problems for cytotechs with a high backlog of work, turnover of personnel, little opportunity for career advances. Although

autoscreening would help, most cytotechs oppose this. Don Miyamoto of LFS reviewed state law regarding cytotech scope of work, and CLIA at CFR 493.1485. Deanna Iverson said that all non-gyn cytologies are screened by a cytotech but referred to a pathologist for reporting. The same would happen for FISH or ISH tests. The cytotech may screen them but the pathologist would report. Also, the staining for FISH or ISH could be done by anybody, so the cytotech would not be called on to do that. Ms. Iverson concluded that she did not see why a cytotech could not be trained to screen FISH or ISH tests.

Karen McRae of John Muir Hospital, Walnut Creek, asked to address new business. She said a consortium of hospitals in the Walnut Creek area were joining with Diablo Valley College to set up MLT training leading to licensure. There was lots of enthusiasm for this program in that area and concern about delay in MLT licensing regulations.

Robert Footlik asked for any other new business and hearing none, asked for a motion to adjourn the meeting. The next meeting of the CLTAC will be a videoconference and telephone bridge on March 5, 2004.