

## **CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE**

Minutes of the June 24, 2011 Meeting

Meeting held by videoconference from Richmond campus, CDPH

KP Regional Laboratory, North Hollywood and

Telephone Bridge

### **CLTAC members participating**

Laurie Armour, Michael Borok, Anthony Butch, Elizabeth Dequinia, Vickie Finson, Lee Hilborne, Jerry Hurst, Lin Kassouni, Donna Kirven, Carmen Maldonado, Salim Rafidi, Les Revier, Michael Terry, Peggy O'Toole, Fred Ung, Lori Dean-Yoakum, Mary York.

### **Former CLTAC members participating**

Morton Field, Jim Ottosen

### **Interested parties participating**

Rodney Roath, Karen Denby, Michelle So, Maric Castillo, Rebecca Rosser

### **DPH staff participating**

Frank Barnes, Grace Byers, Maria DeSousa, Bob Hunter, Donna McCallum, Don Miyamoto, Karen Nickel, Bea O'Keefe, Jan Otey, Tom Tempske, Robert Thomas, Kathy Williams.

### **Welcome and general announcements**

The meeting was called to order by CLTAC chairperson-elect Lori Dean-Yoakum. She thanked Kaiser Permanente for providing the videoconference center in North Hollywood and the telephone bridge. A roll call was conducted of CLTAC members and other participants, and Ms. Dean-Yoakum noted a quorum was present.

### **Approval of the June 3, 2011 meeting minutes**

Ms. Dean-Yoakum asked if there were any corrections to the June 3, 2011 minutes and a number of corrections were made. After these corrections were made, Salim Rafidi moved that they be accepted as corrected, Elizabeth Dequinia seconded, and the CLTAC voted to approve the minutes as corrected.

### **Department news**

Ms. Pam Dickfoss, Acting Deputy Director of the Center for Health Care Quality, said there was new leadership in the department effective June 13. Dr. Ronald Chapman is the new director, Ms. Kathleen Billingsley is chief deputy of policy and programs and Mr. Daniel Kim is chief deputy of department operations.

Ms. Dickfoss said that on August 13, 2010, the department filed regulations, DPH-08-001. They went out for public comment, and the 45 day comment period ended September 27, 2010. LFS received comments from over 300 parties which included over 15,000 individual comments. Ms. Dickfoss stated these were the most comments CDPH has received for regulations. LFS worked hard to review the comments, make

amendments to the regulations and prepared responses. Because of the number of comments and the complexity of the issues, together with LFS staff shortages, the department has decided to withdraw the regulations. This is being done to improve the quality of the regulations. The concerns raised in the comments will be addressed in a new regulation package. She said it is more important to be right than to meet the deadline. Changes are still being made to reformat and clarify the issues so we can meet the Office of Administrative Law guidelines. Ms. Dickfoss said she would look forward to working with the CLTAC and the Office of Regulations, and thinks everyone will be pleased with the new package. She asked if there were any questions or comments.

Joseph Musallum asked whether the whole regulation package had to be rewritten since it was being withdrawn. Ms. Dickfoss said they would be resubmitted with amendments. Mr. Musallum asked what the timeline would be and Ms. Dickfoss said there would be another 45 day comment period in September 2011.

Tom Tempske asked what the CLTAC role would be with the new package. Could the CLTAC give advice on the new regulations? Ms. Dickfoss said the regulations would be posted on the website.

Jim Ottosen said BPC 1228 stated the CLTAC should "assist and advise" on regulations. He asked how the CLTAC could be involved between now and September. He said the next regular CLTAC meeting would be too late to comment before the 45 day comment period. He asked if there should be an earlier meeting. Ms. Dean-Yoakum said there had been no CLTAC input on the previous package. Mr. Rafidi said the subcommittee had worked hard on reviewing the current package and asked what their role was and what direction they should take. Ms. Dickfoss said the CLTAC would be given a draft of the new regulation package prior to website publication. Ms. O'Keefe said the subcommittee report could be used. She said the CLTAC has recommended changes and these will be taken into consideration. Jim Ottosen said the CLTAC would be reactive in that case, not proactive. He asked how soon the CLTAC would see the new draft regulations. Ms. Dickfoss said the new regulation draft would be released to the CLTAC sometime in late August, before the website publication. Mr. Ottosen said he would appreciate that. Salim Rafidi asked whether there would be time for input before publication. Ms. Dickfoss thought yes there would be time.

Tom Tempske asked about the confidentiality of the regulation package, and the mechanism for the release to the CLTAC. Ms. O'Keefe said LFS would need direction from the Office of Regulations. Ms. Dickfoss said the regulations would be considered confidential prior to filing. Mr. Ottosen said this would be different than the current regulations if the CLTAC were truly involved.

Lori Dean-Yoakum asked if there were other questions. Dr. Borok asked if LFS would notify the CLTAC when the draft package was ready for CLTAC review prior to publication on the website and start of the 45 day comment period. Ms. O'Keefe said

the CLTAC would be notified by email. Ms. Yoakum thanked Ms. Dickfoss who left the telephone bridge.

### **Report of the CLTAC subcommittee on DPH-08-001**

Salim Rafidi, chair of the subcommittee, said he did not know how to take the news from Ms. Dickfoss. He said the subcommittee had worked hard at four meetings. There was lots of public participation and interest from laboratories, unions, research interests and clinical lab scientists. Not everyone agreed and there was lots of debate. They worked through it and came up with a position paper on the regulations. There were minority opinions, but this represents the laboratory community at large. He hoped the CLTAC could approve the report.

Jim Ottosen said the subcommittee report means nothing now until the new regulations come out. The current regulations have been pulled and the CLTAC should wait for the new regulations. He said the recommendations probably are already in the new version.

Mr. Rafidi said he hopes the CLTAC would approve the report and LFS could use many of the recommendations. Karen Nickel asked if he wanted the CLTAC to “accept” the report or “approve” the report. Mr. Rafidi said that was a good point and asked that the CLTAC accept the report as then it becomes a public document. Les Revier asked if everyone must agree with it. Mr. Rafidi said accept means adopt in this case.

Jerry Hurst said this was unusual and the result of hard work, but is now based on an obsolete proposal. He asked what the relevance of the subcommittee report would be. Ms. Yoakum said if it was adopted, it would be part of the public record and LFS could use the options in its revisions. Mr. Hurst said the responses were based on “old language”. There may be different responses to the new language. Mr. Rafidi urged that it be adopted and used as building stone for the new regulations. If it is not approved, then there is no official response from the laboratory community and no official position. Dr. Rodney Roath said that if the CLTAC accepted the report, then it is on the record, and there should be no argument about obsolete language. Mr. Hurst agreed.

Salim Rafidi moved that the full CLTAC adopt the subcommittee report, Mary York seconded. Mr. Rafidi asked to change his motion that the CLTAC “adopt” the subcommittee report. Mary York seconded and the CLTAC voted unanimously to adopt the report.

Mr. Rafidi asked that the subcommittee be ready for quick meetings with quick turnaround times when the new regulations are given to the CLTAC in August.

### **Open discussion**

Ms. Yoakum asked if there were any other issues of discussion. She said that she and Dr. Hamill had prepared a letter to Governor Brown on the shortage of personnel in LFS, as directed at the last CLTAC meeting. Ms. O’Keefe said that that letter could not be discussed at this meeting since it was not on the agenda ahead of this meeting. The

law (Bagley-Keene Act) requires public meetings of government agencies to post agenda items so anyone interested can participate. Salim Rafidi asked if it could be brought up as new business. Ms. O'Keefe said she was not sure. Mary York said it did not now need CLTAC approval; it had already been approved to be drafted at the June 3<sup>rd</sup> meeting and was a great letter. It did not need a further motion to be sent to the Governor. The content of the letter can be discussed at the next regular CLTAC meeting.

### **New business**

Lori Dean- Yoakum asked that a small subcommittee of about five people look at the CLTAC bylaws and report back to the CLTAC in September on possible changes. Several people volunteered: Michael Borok, Les Revier, Morton Field, Robert Footlik (in absentia), Jim Ottosen and Salim Rafidi. Ms. Yoakum asked who would chair this subcommittee, Jim Ottosen was volunteered, but his eligibility was questioned. Mr. Ottosen read the current bylaws that state a non-CLTAC member can be enlisted to serve on CLTAC subcommittees. Mr. Ottosen was then asked to chair this subcommittee and report back to the September meeting. Kathy Williams asked if someone from legal services should assist. Ms. O'Keefe thought that would not be necessary, and said that she would serve as LFS liaison.

Donna McCallum asked if the LFS section chiefs could work more closely with Ms. Yoakum on the format for the department presentation. Ms. Yoakum said yes.

Mary York asked about the CLTAC nominations. Ms. O'Keefe said the nominations go to the governor. Salim Rafidi said nominations come from professional organizations. Ms. O'Keefe said she needed to contact any organization that had a vacancy and had not yet forwarded a nominee.

Hearing no more new business, Ms. Yoakum asked for a motion to adjourn. Mary York moved, Elizabeth Dequinia seconded and the CLTAC unanimously voted to adjourn the meeting at about 10:40AM.