

# **Clinical Laboratory Technology Advisory Committee**

## **Minutes of the January 26, 2011 Meeting**

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

### CLTAC Subcommittee Members Participating

Laurie Armour, Michael Borok, Maryann Castillo, Sam Chaffin, Elizabeth Dequinia, Lee Hilborne, Jerry Hurst, Lin Kassouni, Ronnie Lott, Diana Martin, Field Morton, Joseph Musallum, Shahrzad Radahd, Salim Rafidi, Elizabeth Revier, Rebecca Rossen, Jim Ottosen, Peggy O'Toole, Michelle So.

### DPH Staff Participating

Zahwa Amad, Don Miyamoto, Robert Thomas, Bea O'Keefe

### Welcome and General Announcements

The meeting was called to order by Salim Rafidi Chair. He thanked Kaiser for providing the telephone bridge for the meeting.

### Regulation Discussion

Salim wants to have something to bring back in March. Hope we can come to some conclusion. Sharhzad wants committee to be assigned specific areas.

1029.7 Joseph Musallum and Diana Martin did not think anything was wrong with the old legislation. They agree with the except for accredited college oversees. Need statement "evaluated & found to be equivalent". ACCRO is OK or those listed in the world list of colleges should be added. Why don't we put the word "equivalent" in here?

1029.53 Jerry definition covers just about every analyte. He thinks definition is too broad. Joseph seconded that. Jerry would narrow it to SWP and genotyping analysis. Genomic expression, RNA translation, he would not consider a genetic test. Peggy O'Toole thinks it is reasonable; however, to leave it open for future testing. Salim agreed the definition is too broad. Jerry thinks it is to limit the person who does the test. The term "significant" is not clear as to what it means. Salim made a motion to have a more specific and accurate definition. Jerry seconded that motion. Vote 11 agreed, motion was passed.

1029.200 Salim likes this definition. Some of NAACLS standards for training are too loose. There are very few weeks in a clinical lab. Joseph wants the definition to state how long the training will be. Salim said the standards will be coming later. Question: Diana Martin asked are we going to be restricting NACCLS in California? She also asked do we move forward with the state approving all programs or not as there is a shortage of personnel? Salim stated that the state should approve. If NACCLS folds, then the department will be left without anything. Ottosen stated he does not want to appropriate the department's role. Jerry made a motion to accept as is and was seconded by Maryann Castillo. Vote 9 approved. Motion passed

1029.205 Jerry said it is too broad, can mean any lab test. Michelle So agreed. Salim said he did not have an opinion about this. Jerry said he does not see the definition has anything to do with genetics. Peggy O'Toole doesn't think it is appropriate for a person working in the lab. Jim Ottosen moved to have more specific & accurate definition.

Peggy O'Toole seconded that motion. Vote 13 agreed, motion was passed.

1029.210 Jerry, definition is too broad, they can do anything. Question: Jerry asked what is the purpose of this definition? Diana Martin answered it proposes to license clinical embryologists. Jerry said that the definition is too broad & would allow embryologists to do anything. He thinks it is almost the definition of andrology. Peggy O'Toole recommended that a more specific definition be made. Joseph seconded that motion. Vote 11 yes, motion was passed.

1029.215 Salim likes it the way it is. Michelle So moved to approve as written and Jerry seconded that motion. Vote 10 yes, motion was passed.

1029.220 Peggy O'Toole limits future biological science degree or major not as necessary as the course work. Diana Martin limits the candidate pool. The person may have a degree or major in English but have the required course work. Joseph said the specialty requires degree in the sciences and course work. Jerry said that the degree is specified in the federal law as to a science degree. Question: Diana are we going to restrict the candidate pool? Question: Salim Do we want to have specific course work or degree? Jerry, if we are going not to specify degrees, it would be ok for testing personnel but not supervisors. Diana agreed with Jerry. Jim Ottosen said there needs to be a definition in here. Joseph made a motion to keep the definition as is but in the section 1032 & 1031 and subsections allow us to visit course requirements, meet the degree or course requirements. Salim agreed and the motion was seconded by Laurie Armour. Vote 10 yes, motion was passed.

1029.225 Joseph and Salim agreed with the section. Diana wants as provision to obtain other evidence of transcript. A motion was made by Michelle So. Question: Sharhrzad What are you do if there is someone who can not get the transcripts? Joseph thinks that a policy can not be made based on a few applicants. Jerry does not think there is a problem with the definition Salim agreed and the motion was second by Laurie Armour. Vote 13 yes, motion passed.

1029.230 there is a typo in nuclides. Jerry, the definition is too broad. Salim asked if we remove the word protein is that OK. Jerry said it is difficult to anticipate further molecular techniques. Diana and Lee agreed. Jerry said that molecular biology could be a lot of things. Jerry made a motion that the definition has to be rewritten. Peggy O'Toole seconded that motion. Vote 11 yes, 1 abstain, motion was carried.

1029.235 Jerry asked why the definition is limited to microscopic slides, need to get rid of the limitation. Diana said that the definition does not refer to any technique. Jerry mad a motion to remove the word microscopic, the motion was second by Sharhrzad. Michelle So believes that by clinical microscopic, not limiting to one technique. Vote 10 yes, I abstain, motion was passed.

Old 1030 Repealed. This section is OK by consensus.

New 1030 Salim likes the section. Peggy O'Toole 1030(a)(2), just because lab is CLIA certified does not mean it would meet state requirements. Question: 1030(a)(3) Peggy asked what if they worked in several labs? If outside the state, would want it to be something that is equivalent to the state. Don't know if the state would hold an oral exam. Diana stated that there is a requirement for examination. Salim summarized the concern about one CLIA lab & others & concern about the oral exam. Joseph thinks the section is clear. Section (a)(4) specifies the oral exam. Salim agrees with that. Jim Ottosen section 5(b)(1) Clinical embryology is left out. Jerry section 3 ISO is not included for international agencies. Jerry proposed that ISO be added.

Question: Diana asked has the department considered an online exam rather than oral? Jim Ottosen answered that the oral exam ferrets out more information and is a valuable tool. Diana suggested to leave the word oral out and could change it in the future. Joseph stated that applicants become frustrated because of the time to take the oral exam. Sharhrzad said there is no need for an oral exam. Question: Salim how soon the oral exam is given. As soon as they are ready? Jim Ottosen stated that it is not just the knowledge of the law, it is application of the law. The schedule for the exam is once a quarter. Jerry said we are not here to discuss the merits of the oral exam. If you take an oral, the department still has decisions to make. Salim said keep the oral exam. Jerry made a motion to delete the word oral. His motion was seconded by Laurie Armour. Vote 5 yes, the motion failed to delete the oral examination. Jim Ottosen made a motion to add ISO for those outside the country. His motion was seconded by Sharhrzad. Vote 13 yes, motion passed. Jim Ottosen made a motion to add (b)(1) clinical embryology. Peggy O'Toole seconded that motion. Vote 10 yes, 1 abstain. Motion passed.

1030.1 Joseph word "masters" is redundant here. Jerry said that those with a master's degree can direct waived or moderate complex labs. Jim Ottosen wants to add ISO. Michelle So wants to add "the department can approve others". Jerry said that a whole set of regulations needs to be added as to approve other agencies. Diane said that there is a substantial difference between national certifying organizations & the CLS. The department should acknowledge training approved by the department or a program of a national certifying board with or without approval of the department. We will accept person with out of state training; however, if they took training in California they would not be approved if the training program was not approved by the state. Jerry made a motion to change the language to a program approved by the applicable certifying board and delete approved by the department. Jim Ottosen stated this will appropriate the authority of the state to another agency. Statute says it has to be approved by the department. Jerry's motion was seconded by Morton Field. Vote 4 yes, 6 No 3 abstain, motion failed. Jim Ottosen made a motion to move section (d)(3) & (b)(2) and add ISO certification. His motion was second by Salim. Vote 13 yes, 0 no, motion passed. Michelle So made a motion to add organization or other approved by the department to section (d)(3) & (b)(2) her motion was second by Laurie Armour. Vote 11 yes, 1 abstain. Motion passed.

1030.2 Jim Ottosen, page 19 or accredited according to 1031.10 refers to 1031.11 to histocompatibility He said it was a typo. The Committee agreed. Diana Martin stated that in (b)(1)(A), there is no grandfather clause. California is treating state persons differently than out of state persons. Question: Joseph Musallum, if persons are highly qualified they cannot continue unless they leave the state? Morton Field asked to reopen the previous vote. Laurie Amour said how is it logical to approve training outside the state but not in CA because it is not approved by CA. Joseph made a motion to add a grandfather provision. The motion was seconded by Jerry. Vote 7 yes, 1 no 3 abstain. Motion was passed. Diane Martin said she is focusing on the post graduate training. Some people will never be able to be licensed in CA because they got their training before approval. Joseph made a motion to write to Salim as to thoughts on this at [cousin89@hotmail.com](mailto:cousin89@hotmail.com). Morton Field seconded the motion. Vote 10 yes, 0 no, motion passed. Jim said that 1031.11 adds ISO so did not need to add that.

1030.3 Salim asked the question why the training is 4 years. Diane Martin said there is no provision for grandfather in the license categories. Joseph said they should have a look back at to grandfather. Jerry made a motion to add a grandfather provision. Field seconded that motion and added that anyone with a PhD up to regulation implementation should be approved. Salim would like to have a limitation. Vote 5 yes, 1 no, 3 abstain. Clarify whether this is approved or not by checking rules.

Motion to adjourned by Michelle So, seconded by Jerry.

**Meeting Adjourned:** The meeting was adjourned by Salim Rafidi.

**Next Meeting Dates:** Scheduled for February 9, 2011 from 9:00am – 1:00pm.