

Clinical Laboratory Technology Advisory Committee

Minutes of the February 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 all college oversees. Need statement "evaluated & found to be equivalent". ACCRO- ok. Or those listed in the world list of colleges should be added. Why don't we put equivalent in here.

1029.53 Jerry definition covers just about every analyte. He thinks definition is too broad. Joseph seconds that. Jerry would narrow it to SW Panalysis & genotyping. Genomic expression RWA needs translation. He would not consider a genetic test. Peggy O'Toole thinks it is reasonable; however, she thinks you should leave it open for future testing. Salim agrees it is too broad. Jerry thinks limits the person who does the test. The term "significant" is not clear as to what it means. Salim needs to be more specific and accurate, Jerry second that motion. Vote 11 agreed motion was processed.

1029.200 Salim likes this definition. Some of NAACLS standards are training is too loose, 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 late.

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 in personnel?

Salim thinks the state should approve if NACCLS folds, then the department will be left without anything. Salim has found some NACCLS programs have limited clinical training. Ottosen does not want to appropriate the department's role. Jerry motion to accept as is and was second by Maryann Castillo. Vote 9 approved.

1029.205 Jerry said it is too broad. Can mean any lab test. Michelle So agrees. Salim does not have an opinion. Jerry does not see the definition has anything to do with

genetics. Peggy O'Toole does think it is appropriate for person working in the lab. Jim Ottosen love to have more specific & accurate definition. Peggy O'Toole seconds 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 proposes to license clinical embryologist. Jerry said that the definition is too broad & would allow embryologists to do anything. He thinks it is almost the definition of anthology. Peggy O'Toole comment that recommends that a more specific definition be made. Joseph seconds 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 second 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 poole. Salim 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 poole?

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 agrees with Jerry. Jim said this is just a definition. There needs to be a definition in here. Joseph made a motion for the definition as is but in the section 1032 & 1031 substitution allow us to visit course requirements, get into the degree of course requirements. Salim agrees and was second by Laurie Armour. Vote 10 yes motion was passed.

1029.225 Joseph and Salim agree. 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 sudides. Jerry too broad. Salim if we remove the word protein is that ok. Jerry molecular biology could? 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 seconds that motion. Vote 11 yes, 1 abstain motion was carried.

1029.235 Jerry why is limited to microscopic slides. Need to get rid of the limitation. Diana said that the definition does not refer to any technique. Jerry proposed 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, 1 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?

Peggy 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. 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 proposes that ISO be added.

Question: Diana Oral has the department consider an online exam rather than oral?

Jim Oral exam refers out more information and it's a valuable tool. Diana suggests to leave the word oral out and could change it in the future. Joseph applicants become frustrated because of having to take the oral exam. Sharhzad 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 it is not just the knowledge of the law, it is application of the law. The scheduled for the exam is once a quarter. Jerry said not need to discuss the merits of the oral exam. If you take out 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 second by Laurie Armour. Vote 5 yes, no approved motion failed.

Jim Ottosen made a motion to add ISO for outside the country his motion was second by Sharhzad. Vote 13 yes motion passed.

Jim made a motion to add (b)(1) clinical embryology. Peggy O'Toole second that motion. Vote 10 yes, 1 abstain. Motion passed.

1030.1 Joseph word masters is redundant here. Jerry masters 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 substantial definition betral 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 if they took training in California they will not approved a training program that is not approved.

Jerry made a motion to change the language to a program approved by the applicable certifying board and delete approved by the department. Jim stated this will appropagate authority to another agency. Statue says it has to be approved by the department. His

motion was second by Morton Field. Vote 4 yes, 6 No 3 abstain motion fails.

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 was passed.

1030.2 Jim page 19 or acc 1031.10 refers to 1031.11 to histocompatibility agree to correct the typo. Committee agrees. Diana (b)(1)(A) no grandfather clause. CA is treated differently than out of state persons.

Question: Joseph if persons are highly qualified can not continue unless they leave the state?.

Morton field re open the previous vote by saying failure 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 second by Jerry. Vote 7 yes, 1 no 3 abstain. Motion was passed.

Diane 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. Morton field send the motion. Vote 10 yes, 0 no motion was 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 said there is no provision for grandfather in the license categories. Joseph said they should have a look back at grandfather.

Jerry made a motion to add a grandfather provision. Field second that motion and added anyone with a PhD up to regulation implementation. 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 second by Jerry.

Meeting Adjourned: The meeting was adjourned by Salim Rafidi at ?

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