

Clinical Laboratory Technology Advisory Committee

Sub Committee On DPH-008-001

Minutes of the February 23, 2011 Meeting

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

CLTAC Subcommittee Members Participating

Michael Borok, Elizabeth Dequinia, Field Morton, Peggy O'Toole, James Ottosen, Salim Rafidi, Les Revier, Rebecca Rosser, Michelle So.

DPH Staff Participating

Zahwa Amad, Nema Lintag, Don Miyamoto, Linda Wraxall.

Welcome and General Announcements

The meeting was called to order by Salim Rafidi Chair. He thanked Kaiser for providing the southern California meeting site in North Hollywood and the telephone bridge. Salim Rafidi noted that they did not have a quorum; therefore no motions could be made on this meeting.

Regulation Discussion

Salim Rafidi

Salim Rafidi stated that the definitions for clinical molecular biologist, clinical biochemical biologist and the embryologist are too broad and this will be left for CLTAC to review.

1033

Salim Rafidi is OK with the section as is. However, James Ottosen wanted some changes. James said that on page 82 section (d). The words "degree in biology" should be changed to say biological sciences and chemical sciences. He also added that under the supervision of doctoral level on page 81 & 82 masters level supervision should be included. James stated that on section E the "post doctoral" language should be changed to read post graduate.

James Ottosen

James stated that under CLIA, a license is needed because a technical supervisor, tech consultant, general supervisor and clinical consultant and the clinical consultant must be a MD, or DO, cannot serve unless licensed. The same applies to a technical consultant. He stated that a licensed post graduate fellow is not a licensed CLS; but a CLS trainee.

Les Revier

Les stated that on section 1032(a) page 80 under the proposed regulations, MLT trainee cannot apply for a trainee license unless he/she has completed an AA degree. Les stated that this regulation will place an increase burden on MLT training schools to be able to serve students. Les also stated that the trainee license is issued at the beginning, but the trainee does not have to complete all course requirements prior to training.

Kathy Davis stated that the trainee license with the existing language is more appropriate. Rebecca Rosser stated that Cal State Dominguez would have huge fiscal impact on the delay of entry students. She said that Dominguez Hills is the only 3+1 program. Rodney Roth from Lora Linda has a 2+2 program & he echoed Rebecca

Rosser's Concerns.

A caller stated that the new proposed regulations must require completion of didactic and academic requirements prior to training.

Elizabeth Dequinia and Salim Rafidi stated that if they fix the language for one category, then it must be fixed for all of the categories such as CLS, MLT etc.

1034

James Ottosen stated that in the certificate of phlebotomy, the language that reads skin puncture arterial completed, should be changed to state successfully completed.

Jim Ottomen

Jim Ottomen stated that on page 90 section E states that when performing skin puncture, to carry ID card at a far location. If they work at different locations, copy the license. Jim Ottomen stated that copying a license is illegal. That the language should read to say copy the card but not copy the license. Salim Rafidi asked Dr. Zahwa Amad regarding ID card. Dr. Amad stated that LFS intends to issue new ID Cards in addition to the phlebotomy certificate. She also added that this question will be asked to LFS legal services.

1035

Diana Martin stated that on page 98 under 1035.B1, it should include licensed medical lab technicians as licensed instructors. Salim Rafidi suggested that the sentence "other persons as designated by program" should be deleted.

Salim Rafidi

Salim Rafidi was not in favor of this section. He stated that if the department opens training to non-licensed personnel; it could then open it to anyone. Salim Rafidi advocated more stringent training with designated licensed trainers. An attendee stated that the labor unions concur with Selim Rafidi in that only licensed personnel conduct training, even though there is a shortage of trainers designated for training. Dr. Borok was against this section due to shortage of trainers. Dr. Borok stated that someone with clinical experience should be able to teach the trainees. He added that the percent time practicing is irrelevant. Dr. Borok wished to leave it the way it is currently.

Question: Diana Martin asked if licensed MLT technicians can be instructors.

1035 C

Salim Rafidi stated that the department should add CLIA approved labs to sections. 1035 C1, 1035 C2, 1035 C3, 1035 C 4 and 1035 C5 which ensures clinical sites rather than student labs. He also added that there is no real substitute for clinical sites. Salim Rafidi suggested that half can train in CLIA certified laboratories and half in student laboratories.

Salim Rafidi went on to say that in page 99 and page 100 that the amount of clinical practical training was drastically reduced in microbiology by 75%, Chemistry and hematology was reduced by 50%. Salim Rafidi wished to change the number of training weeks on page 98. He stated that the proposed 24 weeks of training on page 100 does not add up to the 48 weeks on page 98. Jim Ottosen stated that practical training is too short. Diana Martin added that 4 weeks of training in microbiology is insufficient.

Salim Rafidi was not in favor of decreasing the clinical training to six months or reducing it to 24 weeks. The consensus at the meeting wished to increase the minimum training requirements or it should revert back to the way it currently is.

Dr. Borok wished to leave it at six months training and wished trainees to get a trainee license.

Salim Rafidi asked Dr. Zahwa Amad the rationale behind the Department's reducing the number of weeks of clinical training. Dr. Zahwa Amad stated that she was not involved in writing the regulations. However the State of California is perceived as a barrier for licensing out of State CLS applicants as the average national training is 24 weeks or 6 months.

Salim Rafidi asked Dr. Zahwa Amad what are the current options for out of State CLS applicants. Dr. Zahwa Amad responded that they have three options to pursue:

- Apply for CLS trainee license to train for one year in the State of California
- Apply for MLT license
- Work outside the State for 12 months in all areas of the clinical laboratory

Salim Rafidi wished to revert back to original training. He also added that the CLS and MLT scope of practice for training should include phlebotomy as it is in their scope of practice and that CLS manage phlebotomists.

1035.1 D

Salim Rafidi wished to add a requirement for the phlebotomy instructors to pass the phlebotomy written examination. Salim Rafidi stated that when you take the exam, you can prepare students better, and it is also part of the pre-analytical phase. Salim Rafidi added that the nurses training in phlebotomy is weak. He wished to add all instructors in phlebotomy must pass the phlebotomy exam.

James Ottosen

Wished to add the exam back in. He said a written exam of about 150 questions. He added that the instructors should benefit from taking the exam to prepare students better.

1035.1F

Phlebotomy should be part of the 40hrs CLS training. This is because it would give the CLS practice and it would help them in managing the phlebotomists. Salim wants to add phlebotomy training. Salim reminded everyone that they could not make any motions because they did not have a quorum.

James Ottosen wished to add 40hrs of skin puncture and venipuncture. He stated that CLS trainee must be trained in phlebotomy just as phlebotomists and MLT trainees.

1035.2

Diana Martin stated that no regulations exist for curriculum of post graduate training program. She stated that the state should accept accredited national training programs in lieu of state approved training. The current situation creates a significant barrier. The current status favors out of state applicants to California applicants and drive California applicants out of state.

Salim Rafidi stated that this issue was discussed at length for at least one full hour in the last meeting of Feb 09, 2011. That enough time was dedicated to this issue earlier when there were many more members who attended the last meeting. Salim Rafidi emphasized the need for LFS to approve the training programs. He stated that in the last meeting, it was agreed on that a provision of grandfathering should be included within a time frame of 2-4 years for a limited time rather than leaving it open.

Dr. Borok wished to add section where the department can deem an accredited agency as acceptable to state requirements. Salim Rafidi responded that LFS needs to have control over accreditation. He also stated that it is the responsibility of the trainee to make sure that the training they are receiving is approved by the state. Salim Rafidi also made a comment that this should not be left to the hands of the national organizations since they change requirements at their will and might fold like NCA when LFS had to pursue emergency regulations. Dr. Borok added that LFS can withdraw its approval if an agency folded and revert to LFS approval. It is an addition rather than a substitution.

Salim Rafidi suggested to the committee to discuss this issue already in extent to address any additional comments to the CLTAC meeting when he presents his position paper. Diana Martin stated that currently LFS looks into the curriculum of national accrediting agency and thus training should be approved by the national accrediting board. This should be sufficient and provides flexibility. Salim Rafidi maintained that LFS should retain control of approval of training programs in California.

1035.3

James Ottosen stated that on page 117 section E the validation of test method and clinical correlation is very difficult. Laboratories are required by law to their own validations. It is beyond the scope of MLT to validate the tests. Michele So added that MLT can assist but can not work solo to validate. She also added that the word validation should be removed from the moderate complexity testing. She said that validation needs to be changed.

1035.5

Salim Rafidi likes it the way it is. He also added that 1036 (b) on page 124 the clinical consultant should be aligned with CLIA MD or DO & Licensed by the state. The language should read clinical consultant as CLIA MD, podiatrist or pathologists unless licensed by the state of California. They should be one of the two categories; otherwise it will be out of CLIA compliance.

1036.1

Diana Martin noted that there was a grammar error; big A B should have read (a)(b). Another grammar error should read "or specialty they are supervising. "

1038.1

Salim Rafidi stated that 24 CE credits over a period of 2 years. He likes it rather than 12 CE credits over a period of one year. Salim Rafidi also added that he had no comment for section 1038.6 on page 127.

1039.2(c)

Jim Ottosen made a comment that 1039.2(c) on page 128 that they were not going to accept training for experience and that a motion was passed not to accept them. He wanted to strike out the words "training" and "or" .

1060

Diana Martin stated that cytotechnologist license was moved to section 1031.4. Salim Rafidi stated that the committee has decided that the definitions are too broad in the current proposed regulations. He stated that this issue should be brought up in the CLTAC committee.

Dr. Borok wished the definitions of the professional organizations to be looked at. Salim Rafidi stated it was already decided that the definitions are too broad in the proposed regulations. This issue will be referred to the whole CLTAC committee.

James Ottosen suggested to Salim Rafidi to summarize all of the motions and write his position paper and to share his draft at the CLTAC meeting with the CLTAC chair and the whole committee for approval. He made a comment to Salim that he was grateful that they were all able to meet before the revisions were made.

Meeting Adjourned: The meeting was adjourned by Salim Rafidi around 11:30.

Next Meeting Dates: This was the last CLTAC subcommittee meeting.