

Clinical Laboratory Technology Advisory Committee

Sub Committee On DPH-008-001
Minutes of the February 9, 2011 Meeting

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

CLTAC Subcommittee Members Participating

Michael Aidan, Laurie Armour, Michael Borok, Maryann Castillo, Sam Chaffin, Kathy Davis, Elizabeth Dequinia, Jerry Hurst, Shiu-Land Kwong, Field Morton, Joseph Musallum, Salim Rafidi, Elizabeth Revier, Rodney Roath, James Ottosen, Peggy O'Toole, Rebecca Rosser, Caroline Satyadi, Michelle So.

DPH Staff Participating

Zahwa Amad, Grace Byers, Nema Lintag, Don Miyamoto, Robert Thomas, Bea O'Keefe, Kathy Williams.

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.

Minutes discussion of the January 26, 2011 meeting.

James Ottosen said there are problems with the minutes as there are many errors. However he stated that in the interest of time we should move on. Rebecca Rosser said her name was misspelled. Salim Rafidi asked LFS for comment.

Robert Thomas responded that Mr. Salim Rafidi had announced that his intent as chair was to produce a position paper together to submit to the full CLTAC by the March 4, 2011 meeting. The position needs to accurately reflect the motion, subcommittee record of passing or not passing and recommendations to the CLTAC. The minutes are secondary.

Regulation Discussion

Salim Rafidi

Salim Rafidi moved on with sections 1030.2, 1030.3, 1030.5, 1030.6, 1030.7. There was a lively and engaged discussion on these subsections. Shiu-Land Kwong summarized three issues that she had forwarded from Diana Martin in an e-mail of February 7, 2011 at 3:43pm. The issues were

- Problem 1: Unnecessary requirement for DPH approval of post-graduate programs that are already nationally accredited.
- Problem 2: Requirement for 2 years of experience in the same DPH-approved postgraduate two years training program despite lack of finding to support trainees for 4 years.
- Problem 3: Lack of grandfathering clause leaves current and recent well-qualified trainees with no path to licensure.

These issues were commented on by Morton Field, Robert Footlik, Lori Dean Yoakum, Carolyn Yunsaki, Salim Rafidi, Jerry Hurst, Jim Ottosen and Carolyn Hoke.

Salim Rafidi stated that they need to look back at grandfathering. LFS needs to approve post doc training programs and he also stated that post doctoral experience is important for directing personnel. Although Ph.D's are loaded with academics, experience is needed.

Robert Footlik

Robert Footlik moved to discuss the sections under discussion: 1030 – 1030.7 are licenses that allow the licensee to serve as a laboratory director. Other licenses issued by LFS are licenses to allow the person to engage in clinical laboratory practice. Most of all of these licenses in section 1030 – 1030.74 were not meant to validate a degree or passing a board examination. It is a license to qualify a person to direct a laboratory. Hospital laboratories must have a pathologist. The clinical laboratory scientist license is not merely a baccalaureate degree license. It is a CLS license and this license is mainly the one the person needs for performing high complexity testing, overseeing or supervising laboratory personnel. The license is there to protect the public. Experience is needed to direct personnel. We should not relinquish responsibility to an accreditation agency.

Lorri Dean-Yoakum stated that 1443 CLIA states that the laboratory director must have two years of experience.

Question: Shiu-Land Kwong asked what guidelines are there for laboratory director training. Does LFS has requirements in regulations for CLS training?

Robert Footlik said there is a misunderstanding what the license is about. The training is in clinical laboratory science; not training for laboratory director.

Lorri Dean Yoakum said that it seems a person can get a CLS license to gain experience. Jerry Hurst said this training has to have experience before a person can direct a laboratory. Robert Footlik said that this is right. Go to any website of certifying or accreditation boards and you will see that this prepares a person to be a technical supervisor; there is no laboratory director training. We are talking about legal requirements versus a job title. Also, legally there is no such thing as medical director. The legal term is laboratory director.

Salim Rafidi and Jerry Hurst stated that there are many diametrically opposed to Diana Martin's comments and issues. It was requested by James Ottosen that a motion be postponed until we get two motions: one from Diana Martin and one from Robert Footlik.

Joseph Musallum

He stated that LFS responded to the comments and that the comments are not being released. In the mean time new regulations have come in. He suggested that they should move to the next issue since there is much misunderstanding regarding LFS regulations.

1031.0

Salim Rafidi likes it the way it is.

Question: Morton Field questioned why MD must be there.?

1031.2(4)

Jerry Hurst said that scientists are limited to doing molecular tests suitable to specialty. He stated how is this defined for clinical molecular biology tests. Salim Rafidi responded that the problem is in the definition. Rafidi requested members to think about definitions. Dr. Michael Borok suggested to define the word definition.

Joseph Musallum made a comment stating that he cannot identify which specialty does the molecular tests fall under. It is a technique. Morton Field agreed with Joseph Musallum's comment.

1031.2

1031.2 refers to page 19 Clinical Biochemistry Genetics or pathologists or physicians who are board certified by ABMG. Dr. Borok said that the definition needs to be more specific. He stated that everywhere pathology adds a physician.

Lorri Dean-Yoakum said that the purpose for ILAC is to create international trade. That they focus on topics such as promotion, global recognition of labs and others. That it is not clear if this refers to clinical labs or other labs.

Motion #1

Salim Rafidi wants ISO to be added as an approved organization. Lorri Dean-Yoakum made a motion to remove ILAC from the list and replace it with ISO. Her motion was seconded by Joseph Musallum. Joseph made the comment that ISO has already been included in 1031.11.

Votes: 12 Yes and 1 abstain. The motion was passed.

James Ottosen made a comment that he does not want to trade off experience for training. And Lorri Dean-Yoakum said that there is a big difference across the country in experience whether it is a CLIA lab or not. Rafidi Salim agreed with Lorri's comment. Peggy O'Toole added that the training programs in specialties are very specific. Jerry Hurst said that there is a vast number of states without specialty training and added that this will put a limit to people that have 10 yrs of experience.

Motion #2

James Ottosen made a motion which was seconded by Morton Field to move to strike all words after 1035 to the end of page 33, leaving the and, and apply this to all wording for all categories in this section, In addition this would include sections 1031.1, 1031.2, 1031.3.

Votes: 10 Yes and 3 No, motion was passed.

1031.1 thru 1031.5

Salim Rafidi NCA is mentioned several times and it does no longer exists. Borok 1031.4(b) at the bottom of 47 add "or physicians" because there are plenty of gynecologists that should be qualified. Section (C) on page 48 add there again.

Joseph Musallum said that he wanted to add taking classes within the last 5 to 7 years on page 36. 4A 1031 Section clinical chemists addresses academic requirements which is "25 semester units". Borok and Salim stated that this will be too restrictive. Once you earn a degree that's it. One should not have to go back and take classes.

Lorri Dean-Yoakum wanted to go back to page 47 & 48 which discusses CLIA regulations for technical supervisors which are different for cytology than other specialties.

1031.4(c)

Matt Riding

Matt Riding: Cytotechnologist is more qualified than an MT to perform FISH Caps Tests. This needs to be addressed. Cytotechnologist labs must get additional certification. Matt Riding questioned why California has more restrictions on cytotech labs.

James Ottosen responded that this is because statute limits cytotechs to microscopic testing. He also added that he thought that legislation limits the scope of practice. James Ottosen asked LFS to comment. Robert Thomas for LFS said cytotechnologists are authorized by statute to perform microscopic testing. This resulted in a long discussion about what cytotechnologists are allowed to do in other states and the scope of practice of cytotechnologists in California.

Motion #3

A motion was made by Dr. Michael Borok and was seconded by Morton Field to look at 1031.4(b)(c) after the wording board-certified or board-eligible anatomical pathologist and or physician pursuant to chapter 5 holding a CLIA certificate in cytology. Jerry Hurst added that it must be a pathologist per CLIA certification.

Votes: 2 Yes 8 No motion failed.

Jerry Hurst asked how work can get signed off without a pathologist. Salim Rafidi answered that this will be done by federal law. Caroline Satyadi stated that CA state Downing Hills Cytotechs took all the same classes except on chemistry side by side with CMT's. Training is equivalent to doing work.

Joseph Musallum said that licensed cytotechnologists and molecular pathology is the same as clinical genetic molecular training. We are trying to clarify California law. Matt Riding said that cytotechs are qualified to take the molecular pathology exam.

1031.2(b)(2) and 1031.3 (b)(2)

Jerry Hurst stated that California regulation if less stringent than CLIA, it can not supersede CLIA. The only case is if CA regulations were more stringent than CLIA.

1031.6(c)

Joseph Musallum suggested to remove evaluations by AACRO and include other evaluating agencies in the U.S.A. Many universities send electronic transcripts.

Joseph Musallum asked what are non-accredited colleges. Rafidi Salim said that there are small colleges which are not accredited.

Question: Joseph Musallum asked what if AACRO folds. What does CLIA accept?

Jim Ottosen stated that agency is accepted by CMS under the CLIA program.

Motion #4

1031.6(d)(5)

Salim Rafidi made a motion and was seconded by Joseph Musallum to amend 1031.6(d)(5) a to c. The time for processing should be minimum 30 days, Median 60 days and Maximum 90 days.

Vote: 11 Yes 6 No, motion passed.

1031.11

Refers to training labs outside the U.S.A pages 72 and 73. Joseph Musallum said that training and experience overseas are questionable.

Question: James Ottosen asked why should we accept experience outside the U.S.A Salim Rafidi said because it is in regulations under (a)(1).

Motion # 5

James Ottosen made a motion to strike the word "experience" for 1031.11(a) and 1031.11(b). His motion was seconded by Elizabeth Dequinia.

Vote: 10 Yes 1 No, motion passed.

1031.12

Michael Borok said that the age of oral examination is over. It is cheaper, easier, and better for LFS to eliminate oral examinations for the directors.

Peggy O'Toole said that the oral exam is application of the laws. Responsibility can be better determined by oral examinations. Rafidi Salim said that oral exams apply the law to see how a person will perform. Joseph Musallum added that the idea of an oral exam is not bad but it frustrates the person because oral exam is too long.

Motion #6

Dr. Michael Borok made a motion that the oral exam in Section 1031.12(a) should be amended after the word department to state to be given at least 4 times a year in northern California location and in southern California location. His motion was seconded by Elizabeth Dequinia.

Vote: 7 Yes 1 No, motion was passed.

1032 (A) page 77

Joseph Musallum made a comment of where did organic chemistry come from or is this redundant. Delete organic chemistry.

Lorri Dean-Yoakum worries if not put in it is less clear. She said we need to be able to count it. Jim Ottosen said all you have to have is one course. Biochemistry or clinical chemistry should be included. Salim Rafidi added that if the person does not have biochemistry the training program should do it.

Discussion on organic, biochemistry and clinical chemistry includes the numbers of semester units.

Motion #7

Lorri Dean-Yoakum made a motion to revise 1032(a)(2)(A) to read on line 2 one course in organic chemistry and one course in either clinical chemistry or biochemistry. Her motion was seconded by Joseph Musallum.

Vote: 6 Yes 2 No, Motion passed.

Motion #8

Joseph Musallum made a motion to amend 1032.9(a)(2)(B). in section (B) 18 semester hours or equivalent quarter hours of biology that includes one course in medical or clinical or pathogenic microbiology, one course in immunology or serology and one course in hematology. His motion was seconded by Elizabeth Dequinia

Vote: 9 Yes 0 No, motion passed.

Motion #9

Joseph Musallum made a motion to revise 1032(a)(2)(c). (c) 3 semester hours or equivalent quarter hours of physics, college algebra or higher mathematics or statistics. His motion was seconded by Michelle So.

Votes: 9 Yes 0 No, motion was passed.

1032 (c) discussion was on military with a bachelors exemption. General discussion leave the way it is. 1033 was left for next discussion.

Motion to adjourned by Michael Borok.

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

Next Meeting Dates: Is scheduled for February 23, 2011 from 9:00am – 1:00pm.