CLTAC Subcommittee Report
On Regulation DPH-08-001
June 24, 2011

A CLTAC subcommittee was formed during CLTAC meeting on January 14th, 2011, and charged to review the next version of DPH-08-001 when it released for public comment, prepare comments on the proposed regulations and return them to the CLTAC for committee review and vote prior to the close of the comment period.

The subcommittee met on January 26, 2011, February 9, 2011, February 23, 2011 and March 16, 2011 for a total of 17 hours. The first two meeting we had quorum with 20 subcommittee member participating in the first meeting and 15-subcommittee member participating in the second meeting. The third meeting we had 9 -subcommittee members participating. The March meeting we had quorum with 10 members participating. Many-interested stakeholder attended all four meetings.

Section 1029.7

The subcommittee agrees with this section, except for accredited foreign colleges. Need statement "evaluated & found to be equivalent". AACRAO is OK or those listed in the world list of colleges should be added.

Section 1029.53

The subcommittee agrees that the definition is too broad and direct LFS to come up with more specific and accurate definition.

Section 1029.200

The subcommittee accepts this section as is, and like the fact that LFS will approve NAACLS approved program.

Section 1029.205

The subcommittee agrees that the definition is too broad and direct LFS to come up with more specific and accurate definition

Section 1029.210

The subcommittee agrees that the definition is too broad and direct LFS to come up with more specific and accurate definition.

Section 1029.215

The subcommittee approved this section as written.

Section 1029.220

The subcommittee agrees to keep the definition as is, but in sections 1032 & 1031 and subsections the subcommittee will visit course requirements.

Section 1029.225

The subcommittee approved this section as written.

Section 1029.230
The subcommittee agrees that the definition is too broad and direct LFS to come up with more specific and accurate definition

Section 1029.235
The subcommittee likes to remove the word microscopic from the definition.

Section 1030
The subcommittee had a long discussion about the oral exam, and concluded to keep the oral exam requirement.
The subcommittee likes to add ISO certified laboratory to the approved laboratory outside the United States.
The subcommittee likes to add "clinical embryology" to Section 1030(b)(1)

Section 1030.1
There was discussion about the merit of National certification agencies approval, and the subcommittee decided to keep this section as is.
The subcommittee agreed to add ISO certification to sections 1030.1(b)(2) & 1030.1(b)(3).

Section 1030.2
The subcommittee agreed to add a limited grandfather provision. With a 2-4 years limitation

The subcommittee had a long discussion about sections 1030.2, 1030.3, 1030.5, 1030.6, 1030.7. The majority of the subcommittee members and public attendees like to keep these sections as is. However, there was a small and very vocal minority that likes to do away with LFS approval and give this authority to the national certification agencies.

The subcommittee agreed 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.

The subcommittee had a discussion about section 1031.4(c) and decided to strike this section.

The subcommittee agreed to amend sections 1031.6(d)(5) a to c. The time for processing should be minimum 30 days, Median 60 days and Maximum 90 days.

The subcommittee agreed to strike the word "experience" for sections1031.11 (a) and 1031.11(b).

The subcommittee agreed that they want the oral exam be given more frequently. 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".

The subcommittee agreed to revise section 1032(a)(2)(A) to read on line 3 one course in organic chemistry and one course in either clinical chemistry or biochemistry

The subcommittee agreed to amend section 1032(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.

The subcommittee agreed to revise section 1032(a)(2)(C). 3 semester hours or equivalent quarter hours of physics, college algebra or higher mathematics or statistics

Section 1033

The subcommittee agreed to change on page 82 section (d). The words "degree in biology" should be changed to "related degree in biological, chemical and/or clinical science"

The subcommittee agreed to change section 1033(b) from "under the supervision of baccalaureate- or doctorate –level persons licensed under chapter 3". To "under the supervision of baccalaureate, *master*, or doctorate –level persons licensed under chapter 3"

The subcommittee agreed to add the same language (ie add master) to section 1033(d) as to the person who can supervise trainee.

The subcommittee agreed to change section 1033(e) (page 83 line 19) by striking out "technical supervisor, technical consultant, general supervisor & clinical consultant"

The subcommittee agreed to change section 1033(a) by Striking after 1031.6 "and shall document completion of education requirements specified in 1032.5(a)(i)"

The subcommittee agreed to change 1033(b) back to originally language in 1033(a) on page 79 change 1033(b) to read after 1031.6(c) "…. in section 1032(a) add "or at least 90 semester hours or equivalent quarter hours from an accredited university or college provided he/she will be granted a baccalaureate at the conclusion of 12 months of training".

The subcommittee agreed to change 1033(b) "related" degree to "biological, chemical and or clinical science".

Section 1034

The subcommittee agreed to change section 1034 (C) by inserting "successful" anywhere it says puncture. To read "successful puncture"

Section 1035

The subcommittee agreed to change 1035(c)(5) to read "phlebotomy to include 40 hours of practical experience, histocompatibility, …."

The subcommittee agreed to add "4 weeks in a CLIA approved clinical laboratory" to the end of 1035(c)(1) through 1035 (c)(5) and "a minimum of one/half of the 48 weeks in a CLIA approved laboratory"

The subcommittee agreed to change training requirements in section 1035 as follows:

1035(c)(1) Microbiology minimum of 12 weeks practical experience. Page 100
c(2) Chemistry minimum of 12 weeks practical experience
c (3) Immunology and Immunohematology 4 weeks each practical experience
c (4) Hematology minimum 8 weeks practical experience
c (5) Phlebotomy, and elective minimum 8 weeks practical experience

Section 1035.1 d
The subcommittee agreed to add a requirement for the phlebotomy instructors to pass the phlebotomy written examination.

Section 1035.3(b)(5)(E)
The subcommittee agreed to delete this section. The rationale is that it is beyond the scope of the MLT.

Section 1036(b)
The subcommittee agreed to delete everything that is underlined.

Section 1039.2(c)
The subcommittee agreed to delete this section

Section 1031.7
The subcommittee agreed to change the wording for the CLS & MLT licensee that cannot practice 60 days from the expiration date of the license. Change the wording such as "…can continue to practice if submitting paper work prior to the expiration date of the license". For Phlebotomy-allow then to continue to perform duties if renewal paperwork is submitted prior to the expiration date of their certificate.

The subcommittee agreed to delete references to ILAC everywhere it appears in the regulations.