

Minutes of the CLTAC subcommittee to review DPH-11-012  
January 11, 2013  
Meeting held by teleconference between  
DPH Richmond and Kaiser Permanente North Hollywood

## **Opening**

Chairman Robert Footlik called the meeting to order at 9:00 AM. He said the purpose of this meeting was to recommend changes on behalf of the CLTAC to department regulations, DPH-11-012, which propose to amend clinical laboratory personnel regulations. He said the recommendations of the subcommittee would be presented to the next CLTAC meeting on March 1, 2013 for full committee approval.

Mr. Footlik said the meeting was open to the public and notices had been sent to all the persons who are normally noticed about CLTAC activities. He said time was limited and discussion would be limited to subcommittee members only and the public could add comments if there was time. He said there would be a midmorning break and a one hour lunch break. He asked other persons on the phone bridge to keep their phones muted. He thanked Kaiser Permanente for providing the facilities for the meeting.

## **Introduction**

Mr. Footlik conducted a roll call of participants. Subcommittee members were Robert Footlik (chair), Lorri Dean-Yoakum (ex-officio as CLTAC chair), Kathleen Doty, Jerry Hurst, Jim Ottosen, Salim Rafidi, Les Revier, and Becky Rosser. Also participating were LFS staff Zahwa Amad, Nema Lintag, Karen Nickel, Bea OKeefe, Robert Thomas, and Mary Wogec. Public members participating (at the beginning) were Joseph Musallam (Richmond), Deb Lial (phone), Diane Tyson (phone) and Geri Albee (phone).

Mr. Footlik thanked Laboratory Field Services for their hard work on the regulation package and asked Dr. Nickel to take notes of the meeting.

## **Meeting summary**

The meeting summary will be divided into two parts; the first part is an overview of the issues discussed by the subcommittee and the second, a tabulation of specific recommendations for changes.

## **Issues**

(1) Agency required for transcript review. The subcommittee suggested broadening the transcript review agency from AACRAO alone to include others. Some commented that AACRAO is inflexible and the agency is said to have poor customer service.

(2) Degrees or courses to meet educational requirements for licensure. DPH-11-012 would broaden course and degree requirements to ease licensure of qualified persons who have the necessary coursework but might not have the required degree. The subcommittee made a number of recommendations to eliminate or substitute some courses.

(3) Explanation of critical review. The subcommittee thought it unnecessary to define what entailed critical review of a trainee's laboratory results and would eliminate much of the definition.

(4) Definition of clinical laboratory practice. The subcommittee recommended deletion of the definition of clinical laboratory practice since it was already defined at BPC 1206(a)(6). The subcommittee recommended clarification of the definition within the regulatory text by stating “engage in clinical lab practices related to the work scope of the license category.” This phrase would be used for every license category in the regulations.

(5) Licensed doctoral scientist versus licensed laboratory director. DPH-11-012 uses the phrase “licensed doctoral scientist” throughout the package, but this term is not found in BPC. Mr. Footlik recommended changing all those references to “licensed laboratory director” and defining that at Section 1029. He will propose a definition.

(6) Consistency of language. The subcommittee noted inconsistent language in the regulations and recommended uniformity, such as “has demonstrated competency in...”, “has documented satisfactory performance in...”, has completed 10 “successful” skin punctures..., and “self-administered” examination.

(7) Supervision of CPTs. The subcommittee recommended that if a CPT is designated as supervisor of other CPTs, they must have at least three (or five??) years of experience from date of certification.

(8) Posting of CPT certificate copies. The subcommittee opposes the DPH-11-012 provision that CPTs working at multiple sites for the same employer be allowed to copy and post their certificate copies at other locations. They said that carrying an identification card should be adequate.

(9) Authority of CPTs to process blood specimens. What supervision is required when they do so? The subcommittee noted that CPTs are authorized to draw blood specimens but are not authorized to centrifuge or otherwise process the samples. This is routinely done by CPTs at patient service centers.

(10) Licensure and supervision of MLTs. The subcommittee recommended changes to their education, supervision, experience requirements outside California, ratio of supervisor, experience in a physician office laboratory. They agreed that onsite supervision was not needed.

(11) Recognition of out-of-state experience in lieu of CA training. DPH-11-012 proposes to accept one year experience outside California in a license category in lieu of formal training that meets California training requirements. The subcommittee wanted an applicant to complete training in their state, then be licensed (if applicable) and gain one year of practical experience in all areas of the specialty before they would be eligible to apply. This would apply for all license categories if adopted.

(12) Doctoral requirements in state law. DPH-11-012 requires licensed doctoral scientists to comply with CLIA standards in order to serve as laboratory directors. Mr. Footlik said that DPH-11-012 should say they must meet the requirements of BPC 1209, not CLIA. This is part of the definition he will work on.

(13) Unlicensed persons working in microbiology. DPH-11-012 would specify that unlicensed persons are authorized to perform primary inoculations and routine gram staining under supervision and control (which is defined) of a licensed person. The subcommittee opposed this and wants this activity to be allowed only under direct and constant supervision (which is also defined).

(14) Pre-analytical activities of unlicensed persons. DPH-11-012 lists pre-analytical activities that an unlicensed person can do under supervision and control, such as specimen processing and instrument cleanup. The subcommittee wants to add measuring urine samples and reading temperatures of equipment, activities which are currently prohibited. Jerry Hurst will propose language how this could be added and still comply with state law.

(15) Persons working outside their work scope. The subcommittee asked that a subsection be added to the new unlicensed person section that states that a person working outside the work scope of his or her license would be considered an unlicensed person and would need the appropriate supervision. They said this is important when an MLT assists a CLS in performing high complexity testing.

(16) Non-accredited colleges and universities. DPH-11-012 requires transcript review by AACRAO if the university is not accredited. The subcommittee recommends that wherever the term “non-accredited” is used, it be changed to “non-US.”

(17) ISO accreditation of non-CLIA certified laboratories. The subcommittee recommends that the more appropriate ISO accreditation of non-US labs is ISO 15189 and 17025.

(18) Qualification of training instructors. The subcommittee recommends that instructors in any approved training program be limited to instruction in the work scope of their license category.

(19) Rotation schedule for training CLSs. DPH-11-012 proposes 4 weeks of practical experience in each of microbiology, chemistry, immunohematology, hematology, and phlebotomy, and clinical laboratory practices and other areas for a total of 20 required in a 52 week training program. The subcommittee expanded this back to 12 weeks microbiology, 12 weeks chemistry, 4 weeks blood bank, 4 weeks immunohematology, 8 weeks hematology, 4 weeks immunology, and 5 weeks electives including phlebotomy.

(20) Phlebotomy training schools. DPH-11-012 proposes some new requirements for approved phlebotomy training programs. The subcommittee questioned the 50-mile limit for practical experience locations from the didactic site and recommended that training in blood specimen storage and transportation be added.

(21) Additional license categories. The subcommittee urged that licensure and work scope requirements for baccalaureate and doctoral-level biochemical geneticists and clinical embryologists be added back to the regulations. They said the authority for fee collection for these categories (and others) could be added legislatively later.

### Tabulation of specific recommendations

Section Number	Page Number	Comment
1029.6	1	Don't limit to AACRAO.
1029.7	1	Don't limit to AACRAO.
1029.53	2	Still problematic. Jerry Hurst was asked to draft alternative language.
1029.81	3	Change "identified" to "approved."
1029.134	3-4	Change "on patients" to "on patient samples"; Change "diagnostic purposes" to "diagnostic and treatment purposes and monitoring of patient."
1029.200	4	In Biological Science, remove any mention of "botany"; In Chemical Science, remove "chemical engineering"; In Physical science, remove "pharmaceutical chemistry, chemical engineering, biochemistry, pharmacology or analytical chemistry" and replace with "physics or biophysics"; In Clinical Lab Science, remove "parasitology" and replace with "microbiology."
1029.215	5	Correct title to 1029.215; Delete last four lines. (Note to Karen: Add 1205 to Reference line)
1029.230	7	Delete this entire definition as unnecessary.
1029.XXX	X	Bob Footlik to propose new definition for licensed laboratory director. This will replace any reference to licensed doctoral scientist throughout the text.
1029.235	8	Add "educational" to "educational" program and "educational" training.
1030 (a)	9	Any place competency is addressed, use consistent language, "has demonstrated competency in...."
1030 (d)	10	Add hematology to list of specialties.
1030 (e)(1)	12	Citation 1031.9 should be 1031.8.
1030.1.1(b)(3)	13	Any place that skin or venipunctures are mentioned, precede with "successful", as appropriate.
1030.1.1(c)(3)	14	Add experience requirement for CPT designee supervisor, as "A designee shall be licensed under Chapter 3 or certified under Chapter 3 with three (five?) years of experience from date of initial certification...."
1030.1.1(c)(8)	15	Delete "The photocopy(ies) shall be made of the current, valid certificate and shall be clearly labeled as 'COPY', and shall include the address where the original certificate is posted" from the 3 places proposed.
1030.1.2(c)	18	The CPT-1 (and -2) work scopes does not authorize processing of blood samples. There are different supervision requirements for phlebotomy versus blood processing. Karen to review this and make proposal.
1030.1.2(c)(4)	19	Change "qualified" person to a person "specified in subsection (3)" or similar language.
1030.1.2(c)(6)	19	Add competency in processing venipuncture specimens.
1039.1.3(c), (1) and (3)	22	Clarify CPT-2 work scope to include processing of venipuncture and arterial puncture specimens. (Karen to work on this.)
1030.2(a)(1)(A)	25	Add requirement for 3 hours of math for MLT.

1030.2(a)(2)(D)	25	Change 10 years back to 5 years for OTJ practical experience for MLTs.
1030.2(a)(2)(D) (ii) and (E)(ii)	26	Add "practical" to work experience. Add "a total of at least" to 480 hours performing tests.
1030.2(a)(2)(F)	27	Add "performing waived and moderate complexity tests in chemistry, microbiology, hematology, and immunology" after California physician office laboratory.
1030.2(b)(1)	28	Change here and wherever used in the regulations, "Perform clinical laboratory practices, as defined in Section 1029.230" to "Engage in clinical laboratory practices related to the work scope of the license category." Delete definition at Section 1029.230.
1030.2(b)(4)	29	Remove "a doctoral scientist, clinical laboratory bioanalyst" and replace with licensed "laboratory director" here and throughout the regulations. Bob Footlik will provide a definition of laboratory director for new section in 1029. Bob Footlik wanted to add "or a person with clinical laboratory licensure." I am unsure what he meant.
1030.2(b)(4)(B)	29	Change MLT ratio back to "no less than one supervisor for four MLTs."
1030.3.1(a)(1) (B)(i)	31	Change "in any one of" to "each of the."
1030.3.1(a)(1) (B)(ii)	31	Change "in any one of the" to "each." Change immunology "or" hematology to immunology "and" hematology.
1030.3.1(a)(1) (B)(iii)	31	Change "in any one of the following" to "in one or more courses."
1030.3.1(a)(2) (C)	32	Here again and throughout the regulation package, do not accept out of state experience in lieu of training.
1030.3.1(a)(3) (C)	33	Replace here and throughout regulations, "online" examination and replace with "self-administered examination on state and federal clinical laboratory law" for consistency.
1030.4.5(a)(3) (B)	54	Change clinical "toxicologist" to clinical "hematologist."
1030.4.6(c)(2)	59	Whenever mentioning the specialties of histocompatibility (1029.169), cytogenetics (1029.52) or genetic molecular biology (1029.53) say "as specified in Section 1029.whatever" since these categories are unique to state law.
1030.5(b)(3)	70	Change "80 slides per day" to "80 slides per 24 hours" wherever mentioned.
1030.6.1(b)(3) (A)	73	Change "when this director also meets the requirements of CLIA" to "when this director meets the requirements of Section 1209 (this chapter?)" This should be done for all doctoral scientist categories. Bob Footlik to draft amendment requiring licensed lab director to meet only state law requirements rather than CLIA.
1030.6.2(a)(2) (B)	76	Wherever "clinical microscopy" is used, also mention "urinalysis" for consistency.
1031(a)(1)	99	Change "Has graduated from a high school or its equivalent" to that language used for CPTs on page 23: "Be a high school graduate or have achieved a passing score on the General Education Development examination or have equivalent education as specified in Section 1032.3."

1031(a)(3)(A)	99	Remove “qualified” from supervisor.
1031(a)(3)(A)(i)	100	Use alternate language for “measuring urine volumes using a digital meter” to something else Bob Footlik will provide.
1031(a)(3)(A)(ii)	100	Move “(ii) Pre-analytical phases in microbiology tests or examinations” to be an activity requiring “Direct and constant supervision.”
1031(a)(3)(A)(iii)	100	Add “Recoding temperatures using a digital thermometer.” Jerry Hurst shall provide draft language.
1031(a)(3)(B)(ii)	101	Add “function checks.”
1031(c)	102	Add a new subsection that says “Anyone working outside the work scope authorized his or her license category shall be considered an unlicensed person and is subject to the restrictions of this section.”
1032.1(b)(6)(C)	104	Replace “non-accredited” with “non-US” colleges here and wherever used.
1032.2(a)	107	Add “license” to fee prior to “license” expiration date.
1032.4(a)	113	Add “certificate” to fee prior to “certificate” expiration date.
1033.1(a)(3)	124	Use same language as used on page 129: “Name and address of the certifying organization including street, city, state and zip code.”
1034(a)(1)	133	Add “current” to ISO/IEC... Delete 17011 and replace with 15189 and 17025. Delete “later standards for certifying technical facilities including clinical laboratories” and replace with “related standards for clinical laboratories.”
1034(a)(4)	133	Replace “research purposes” with language on page 4: “academic, research, forensic, pharmaceutical or veterinary” purposes.”
1035(d)	136	Add “Didactic” to Practical experience instructors in title.
1035(d)(2)	136-7	Add “limited to the work scope of his or her license category” to instructors. Change” equivalent licensure” to “equivalent qualifications” for instructors. Change “equivalent certification” to” equivalent qualifications” for instructors. Change training program is “location” to “located.”
1035(f)	137	Four week rotation is too short. Add “practical experience” and require 12 weeks microbiology, 12 weeks chemistry, 4 weeks blood bank, 4 weeks immunohematology, 8 weeks hematology, 4 weeks immunology, 5 weeks electives including phlebotomy.
1035.1(a)	141	Add “hematology” to list of license categories. Consider adding training in W and Mod in specialties outside work scope and phlebotomy.
1035.1(e)	143	Add “Practical” to Didactic instructors in title.
1035.2(d)	151	Add “Didactic” to Practical experience instructors in title. “One of the persons listed in (b) above” is unclear. Where is (b)?
1035.2(x)	152	Are Didactic instructors missing?
1035.2(f)(1)(B)	154	Training within a 50 mile radius of didactic site will be a problem for KP.
1035.2(f)(1)(C)	154	Change “4” years to “5”. Note to Karen, spell out.
1035.2(f)(2)	155	Add requirement for training in “Blood specimen storage and transportation.”
1035.3(b)(3)	159	Change “developed tests or examinations” to US FDA-approved or

		laboratory developed test (LDT) systems.” (Systems??)
1035.4(e)	163	Change “or a person with an earned master’s or doctoral degree” to “or a person with and earned baccalaureate, master’s or doctoral degree in their specialty...” Make this change here and on page 169, 1035.5(e)(2).
1035.5(f)	169	Add “didactic” to the practical experience “and didactic instruction”... Bob Footlik will draft an amendment to require 20% of 26 weeks be didactic instruction.
1035.5(f)(1)(H)	170	Add “federal” to Health Insurance. Add “California Division of” to “Occupational...” and add “of the Department of Industrial Relations” to the end of OSHA. Bob Footlik will send language.
Unspecified	NA	Add license categories for BS and doctoral biochemical genetics and clinical embryologist and let CLTAC work to add license fee language.

### **Adjournment**

The subcommittee meeting closed at 5:15 PM. Mr. Footlik thanked everyone for their thoughtful participation and the meeting was adjourned.