

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
February 11, 2013
Meeting held by telephone bridge

Opening, January 11, 2013

Chairman Robert Footlik called the meeting to order at 9:00 am. He said the purpose of this meeting was to recommend changes to the CLTAC for 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, Becky Rosser. Also participating were LFS staff Zahwa Amad, Nema Lintag, Karen Nickel, Bea OKeefe, Robert Thomas. Public members participating (at the beginning) were Joseph Musallum (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 strongly urged broadening the transcript review agency from AACRAO alone to include others. They said requiring only AACRAO was inflexible and the agency was 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 with unusual education. The subcommittee made a number of recommendations to narrow the requirements by eliminating or substituting 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). LFS felt the statutory definition was inadequate. The subcommittee recommended clarification of the definition within the regulatory text by stating "engage in clinical lab practices related to the workscope 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 recommends 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, as "has demonstrated competency in...", "has documented satisfactory performance in..", has completed 10 "successful" skin punctures...., "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 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. Dr. Nickel said she would consider how to add this into the regulation package.

(10) Licensure and supervision of MLTs. DPH-11-012 made changes to lighten the regulatory oversight of MLTs. The subcommittee did not agree and recommended changes to their education, supervision, experience requirements outside California, ratio of supervisor, experience in a physician office laboratory. They did agree 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. This was done to ease licensing requirements of qualified persons outside California. The subcommittee opposes this action, saying an applicant must complete training in their state, then be licensed (if applicable). If their training was for less than one year, then the applicant should be required to work for another year within the previous five years to gain practical experience in all areas of the specialty before they would be eligible to apply. Dr. Nickel said she would draft such language for the subcommittee. 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 says 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, 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 workscope. The subcommittee asked that a subsection be added to the new unlicensed person section that states that a person working outside the workscope of their 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 the workscope 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. This may accommodate NAACLS programs which complete a 52 week program with student laboratories. The subcommittee strongly urges expanding 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. Lorri Dean-Yoakum and Becky Rosser were directed to prepare draft language to amend this requirement. The subcommittee also recommended that training in blood specimen preparation for storage and transportation be added.

(21) Additional license categories. The subcommittee urged that licensure and workscope 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 chem" 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, proceed 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) worksopes 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 workscope 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 three places.
1030.2(a)(2)(D) (ii) and (E)(ii)	26	Add "practical" to work experience. Change 10 yrs. To 5 yrs. In Subsection f(ii) add "practical" Add "a total of at least" to 640 hours performing tests.
1030.2(a)(2)(F) (ii)	27	Insert "waived and moderate complexity" after "performing." Change 480 to "140 hours each" In F change ten yrs to 5 yrs.
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 workscope 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 F will provide a definition of laboratory director for new section in 1029. Bob F 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" in second reference
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. Karen asked to draft proposed language and give to subcommittee.
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 F to draft amendment requiring licensed lab director to meet only state law requirements rather than CLIA.
1030.6.2(a)(2)	76	Wherever "clinical microscopy" is used, also mention "urinalysis" for

(B)		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 F 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 workscope 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 workscope 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 phlebo.
1035.1(a)	141	Add “hematology” to list of license categories. Consider adding training in W and Mod in specialties outside workscope and phlebo.
1035.2(d)	151	Add “Didactic” to Practical experience instructors in title. (b) should be replaced with C(6)c
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 F will draft 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 F 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.

Close on January 11, 2013

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

Opening, February 11, 2013

Chairman Robert Footlik called the meeting to order at 3:05PM. He said the purpose of this meeting was to further discuss suggested revisions to DPH-11-012. He asked Karen Nickel to take minutes of this meeting, make corrections to the minutes of the previous meeting and to send both by email to the subcommittee. These would then be presented to the full CLTAC.

Introduction

Mr. Footlik conducted a roll call of participants. Subcommittee members participating were Robert Footlik (chair), Kathleen Doty, Jerry Hurst, Jim Ottosen, Salim Rafidi, Les Revier and Becky Rosser. Lorri Dean-Yoakum (ex-officio as CLTAC chair) was unavailable. Also participating were LFS staff members, Zahwa Amad, Nema Lintag, Karen Nickel, Bea O’Keefe, Robert Thomas and Mary Wogec. Public members on the phone bridge were Lee Hilborne, Peggy Kollars, Lois Langs, Rodney Roath and Barbara Sevilla.

Approval of minute of previous meeting

A number of corrections were made to the draft minutes of the previous meeting and these were incorporated above by Karen Nickel. The subcommittee approved the minutes as corrected.

Remaining unresolved issues

Mr. Footlik said he wanted the subcommittee to discuss some remaining unresolved issues, as follows.

(1) CLS training outside California. Jim Ottosen said he felt it was imperative that persons applying for licensure who had training outside California have one year training. He said he felt that if they had less than one year, even if they met licensing requirements in that state and had passed the certification examination, that they not be accepted for licensure until they had at least one year of practical experience in all specialties outside California. Currently the draft regulations at Section 1030.3.1 (a) (2) (C) and throughout the regulations would accept one year of experience outside California regardless of training there.

(2) 50-Mile radius restriction proposed for phlebotomy practical training sites. Becky Rosser said the 50 mile radius restriction for phlebotomy training at Section 1035.2 (f) (1) (B) would pose a real hardship on Kaiser Permanente training in southern California. Ms. Rosser recommended that this section be amended to exclude “hospitals and independent laboratories” from this limitation. Further discussion by the subcommittee would exclude “a California licensed clinical laboratory as specified in Section 1035.2 (b) (6)” from the 50 mile requirement.

(3) Definition of clinical genetic molecular biology. Karen Nickel said this definition at Section 1029.53 had been criticized by the subcommittee. Jerry Hurst had been asked to draft an amended definition and Dr. Nickel felt that definition was too confusing. She asked that the subcommittee look at that again. The issue of genetic testing, cytogenetic testing, changes in technology, limitations in Business and Professions Code Section 1207, and work scopes was discussed at length. Jerry Hurst suggested amended definitions to Section 1029.53, already in the regulation package, plus amended definition to Section 1029.52 for Clinical Cytogenetics. Dr. Nickel discouraged adding yet another definition to DPH-11-012, and urged for clarity.

The amended definitions proposed by Jerry Hurst (shown as underlined) are as follows:

Section 1029.53. Tests or examinations in “clinical genetic molecular biology” means the determination of all aspects of molecular organizations of the nucleic acids of the human genome with respect to genotype and phenotype evaluation of human genetic material by any method which involves a direct analysis of nucleic acids including genotyping, sequencing, gene copy number and genomic expression products to aid in the assessment of physiological conditions or diagnosis of disease or dysfunction and excludes those tests or examinations in other specialties and subspecialties including those defined as cytogenetics.

Section 1029.52. “Clinical cytogenetics” means the techniques used to isolate, replicate and identify whole or parts of human chromosomes including culturing, manipulation, banding, staining and hybridizing, and analysis with respect to genotype and phenotype. (current definition)

“Clinical cytogenetics” means evaluation by any method which involves direct analysis of chromosomes for determination of abnormalities such as aneuploidy and excludes those tests or examinations in other specialties including those defined as “genetic molecular biology”

(4) Laboratory director versus licensed masters or doctoral scientist. Robert Footlik again raised the issue of changing any mention of licensed masters or doctoral scientist to laboratory director. Karen Nickel suggested adding a definition in Section 1029 to explain what we mean when the regulations say “licensed masters or doctoral scientist”. She said the education requirements authorized licensure of masters-level applicants and the worksopes listed laboratory director “when they meet CLIA and state law requirements”. She felt that was adequate. Mr. Footlik said use of this term throughout the

regulations excluded bioanalysts who are licensed to direct a laboratory. He proposed changing any reference of a “licensed masters or doctoral scientist” to “licensed laboratory director” and to make a new definition as follows:

Section 1029.240. Laboratory director category licensure. For purposes of these regulations, laboratory director category licensure means a license issued by the department pursuant to Chapter 3 of the Business and Professions Code to a person who qualifies as a clinical laboratory bioanalyst, or to an individual who qualifies as a clinical chemist, clinical microbiologist, clinical toxicologist, clinical cytogeneticist, clinical genetic molecular biologist, oral or maxillofacial pathologist, or their specialty or subspecialty limited laboratory director category license enacted by the legislature under Chapter 3 of the Business and Professions code or adopted by the Department pursuant to Section 1208 of the Business and Professions code.

(5) Clinical laboratory practice. Bob Thomas said this had been defined in the new regulations at Section 1029.230 and the subcommittee had opposed the need for this definition at the last meeting. He asked for further explanation. Mr. Footlik felt it unnecessary to refine a definition in statute (at BPC 1206 (a) (6)). Dr. Nickel said she thought that definition was inadequate and needed to be expanded for these regulations.

Discussion

Several CLTAC subcommittee members asked why they could not see changes made to these regulations based on their recommendations. Ms. OKeefe said that the subcommittee recommendations had to go to the full CLTAC for approval. Bob Thomas added that LFS was also receiving comments from other members of the public and was also looking at those. After all of the comments have been reviewed and CLTAC has made its recommendation, LFS may or may not make changes based on those recommendations. The regulations, once approved by the department, would go out for public comment. Karen Nickel added that she hoped the official comment period would begin in June 2013. She said their “pre-notice” review of the draft regulations had been a special allowance given by the Office of Regulations legal staff. When released for public comment, if any of the subcommittee recommendations were not accepted, individual members could submit comments. These comments would be addressed in the Statement of Reasons, explaining why they could not be incorporated into the regulations.

Dr Nickel said she would send the updated minutes to the subcommittee on Tuesday, February 12, 2013.

Close of meeting on February 11, 2013

The subcommittee meeting closed at 4:37 PM. Mr. Footlik thanked everyone for their participation.