



August 28, 2009

Mr. Robert Thomas
Personnel Licensing Section
Section Chief
California Department of Public Health
Laboratory Field Services
850 Marina Bay Parkway
Richmond, CA 94804-6403

Mr. Thomas,

On behalf of the California Association for Medical Laboratory Technology, I am submitting the following comments regarding the California Lab Personnel Licensing Regulations discussed at the Stakeholders meeting on August 24, 2009.

While we are now commenting on the items as listed, we reserve the right to revise or update those comments when the regulations are released for public comment.

We are also very concerned that there are other portions of the proposed regulations that have not been presented to the stakeholders that may require input and discussion.

As always, the members of CAMLTL are excited to be involved in this process and are willing and able to work closely with the Department on these regulations. Thank you for allowing us to be a part of this process.

Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink that reads 'Rebecca Rosser'.

Rebecca Rosser
President, CAMLTL



**California Lab Personnel Law Issues:
Lab Field Services, CDPH**

Please provide written email feedback (organized by and in the order of each Specific Issue number, see below 1-14) to fsrecep@cdph.ca.gov.

Special Note: Comments for each of the numbered items below cannot exceed 500 characters in length. The first 500 characters will be used and the remaining text discarded.

- (1) NAACLS*-accredited training programs are not accepted for licensure in CA.

Proposal: Accept NAACLS.

Impact: Facilitate approval of training for some applicants in and outside CA. Concern about length of training.

CAMLT – NO. Should not abrogate State authority to a private agency who could make changes at will. NAACLS programs are not uniform nor are required courses specified. Programs are as short as 6 months. Can recognize NAACLS graduates if they meet standards defined by California.

Concern that core competencies may not be met, thus placing a burden on employers.

Institutions applying for state accreditation should not be required to obtain NAACLS certification. Their process is extremely laborious and costly.

- (2) The four-year look back of certification exam approval requires older certificants to take the exam again.

Proposal: Retain look back which was based on public comments to regs.

Impact: Applicants thereby demonstrate current, broad knowledge of specialties.

CAMLT – Retain. However, there must be a mechanism in place, at minimum, to review exams every four years thereby making this a true four year look back. This will assure that the applicants seeking licensure can demonstrate that they have appropriate current knowledge to practice their profession.



- (3) The ratio of MLT to supervisor is 4:1.

Proposal: Retain as this was established based on public comments to regs.

Impact: MLTs can work without CLS supervision for Waived tests, but need supervision for Moderate tests.

CAMLMT: Retain. As in other professional hierarchies [i.e. Nursing] there needs to be a hierarchy from Pathologist to CLS to MLT to CPT to assure patient safety. By retaining this ratio employers will ensure that optimal coverage in all areas of the hierarchy will be maintained. To burden the CLS with a higher ratio would not be in the best interest of the patient, just as having no supervision would have the same effect.

- (4) Recognition of post doctorate trainees in CA is difficult

Proposal: Adopt post doctoral trainee license to allow testing, position recognition.

Impact: Streamlines and clarifies pathway of post doctorates to licensure in CA.

CAMLMT: Neutral at the time of the conference, but need to see the language, and details need to be clarified. OK with trainee license.

- (5) Training for specialist license must be done in a CLIA-certified, LFS-approved lab.

Proposed: ILAC-certification for non-US, retain CLIA-certified requirement for US.

Impact: Increases specialist license applicants from non-US. Does not allow on the job, research or non-clinical lab experience. Restricts applicants from non-traditional sites.

CAMLMT: Same as 1 – do not want to abrogate State authority to a private organization who can change their standards at will. Need to research ILAC more closely.

International candidates should be held to standards that are the same as the ones applied to our national candidates. Whether ILAC and its base requirements meet that goal should be fully investigated.

- (6) An unlicensed person is not authorized to train a licensed trainee.

Proposal: An approved program can designate an unlicensed person to train.

Impact: This shall allow doctoral scientists, vendors, professors to participate in training.

CAMLMT: OK as long as it is can be clearly shown that the individual has special skills and knowledge in the subject being taught (special training, years of experience, etc.). The program director should be required to assure this evaluation is completed and adequate to the teaching goal. Also, the material being taught should fall within the teaching guidelines defined by the learning goals and objectives of the program.

It should be disclosed in the program packet and approved by the state.



- (7) The ratio of licensed trainee to licensed trainer is 2:1.

Proposal: Is this necessary??

Impact: Current requirement may limit training programs.

CAML: Yes, it is necessary to keep a 2:1 ratio. Anymore might dilute the training or cause quality issues. Business and Professions Code 1205 requires direct and responsible supervision. By increasing the ratio it can become difficult to balance the training relationship and still maintain any required workload. In many institutions, the bench trainer is also assigned to a portion of the regular workload so increasing the ratio could jeopardize patient safety.

- (8) There is no transition for MLTs to CLS licensure.

Proposal: BS degree required and 6-month additional training program.

Impact: This may facilitate articulation of MLTs to CLS licensure.

CAML: Agree. Articulation should occur. Must see actual language. Disagree with arbitrary 6 months training. Must evaluate each MLT program for equivalency. Standard criteria must be set. CLS must meet Statutory requirements, thus MLT must meet same upon moving to CLS. Result of becoming a CLS should be equal core competencies and learning. What content would the 6 months cover? Would more training be needed if the MLT works in 1 section? How long must an MLT wait before moving to a CLS?

- (9) A licensed cytotechnologist is limited to gyn and non-gyn cytology.

Proposal: Expand their work scope to include FISH, HPV, Immunohisto- chemical staining by microscopic analysis.

Impact: Expands work scope for qualified cytotechs.

CAML: NO. Scope of practice issues. Not trained or licensed for those techniques or tests. If a Cytology Technologist learns FISH or PCR, would they then be allowed to go into Microbiology or Genetics to perform those techniques? If Cytology Technologists wish to perform these other techniques or tests, there should be a new training route for high complexity testing, dual licensure or become a CLS.

- (10) A licensed clinical genetic molecular biologist is limited to genetic tests on humans.

Proposal: Redefine "clinical genetic molecular biology tests" to include infectious diseases, metabolic tests and others.

Impact: Expanded work scope.

CAML: NO. Same issue as #9. As the discipline title implies, this is "genetics." Why should they be allowed to do infectious disease testing? A Microbiology Specialist could not perform Genetic testing. Again, if they wish to increase their scope of practice into other areas, then they should have the training and education to perform generalist work and become a CLS.



(11) Persons with specialist licenses have designated work scopes.

Proposal: Continue to require approved training and second license. On the job training in another specialty is not practical.

Impact: Difficulty in expanding work scopes. Retains quality of training.

CAMLTL: Yes. Keep scope and second license

(12) Certification of histotechs is not recognized.

Proposal: Recognize certification with less required supervision.

Impact: Certified histotechs will be able to work under general rather than direct supervision.

CAMLTL: Agree, but establish State requirements which include a review and adoption of standard processes to adhere to set competency standards.

(13) A CPT who works at multiple locations for the same employer must post the certificate at each location.

Proposal: Certificate posted at primary location, copies authorized elsewhere for same employer. Duplicates for second employer.

Impact: Reduce cost while providing proof of certification.

CAMLTL: Concerns with possible forgery and how to identify yourself to clients in homes. Why can't they go back to wallet cards? It would be the responsibility of the Laboratory Director to verify that the CPT had a current certification which could be done by matching the card with the information in the LFS database. Doctors and nurses don't have posted licenses, only wallet card licenses.

(14) Doctoral embryologists cannot perform lab tests in CA.

Proposal: Establish licensing standards for clinical embryologists doing clinical lab tests.

Impact: Improved employability of qualified persons in CA.

CAMLTL: OK with proper standards and limited to the profession of Assisted Reproductive Technology. As long as they meet similar established standards as other limited specialties.

15. At the current time only CLS' are required to take a ten question test on California Law when they apply for licensure. We would request that all applicants for licensure or certification including specialists take the online ten question test on Laboratory Law.

16. The Department should consider the notion of creating silos and specialists as being inflexible in the future when trying to accommodate new technologies. There should be a structure and method in place to ensure that people are properly educated and trained to deal with emerging technologies without having to always create a new specialty.