CLTAC SUBCOMMITTEE ON CLS EDUCATION AND TRAINING

POSITION PAPER

August 2001

This position paper is prepared by the Subcommittee on Education and Training for presentation to the Clinical Laboratory Technology Advisory Committee (CLTAC).

The charge to the subcommittee was to:

(1) Review authority given in BPC Sections 1261, 1262, 1263 and 1264, review current standards in 17 CCR section 1032 and
   (a) Recommend number of hours of specific coursework and college degrees appropriate for candidates for licensure as a CLS in California and
   (b) Recommend any alternative pathways, if appropriate.

(2) Review authority given in BPC (above); review current standards in 17 CCR Section 1035 and
   (a) Recommend the type of program eligible for CLS training,
   (b) Recommend who should direct and instruct,
   (c) Specify duration and scope of training,
   (d) Specify type of training in analytical skills,
   (e) Specify training in pre- and post-analytical activity, including phlebotomy,
   (f) Make any other recommendations necessary to insure standards of training.

The subcommittee recommends that Sec.1032 (a)(b)(c) be replaced by the following:

> Graduation from a college or university maintaining standards equivalent to those institutions accredited by the Western Association of Schools and Colleges or an equivalent accrediting agency, with a baccalaureate degree as specified under CLIA`88 and completion of a professional program in clinical laboratory practice approved by the Department. The professional program may be completed concurrently with the baccalaureate degree. In addition, before or during the professional program the examinee must have completed:

1.) 16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry;
2.) 18 semester or equivalent quarter hours of biological science, including instruction in immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology; and
3.) 3 semester or equivalent quarter hours of physics, including instruction in principles of light and electricity.

The subcommittee discussed this at length. They agreed that a baccalaureate degree be required for CLS licensure and that there be no option for licensure without it.

Modify Section 1033(a) to read:

Clinical Laboratory Scientist (CLS) trainee applicants shall have graduated from a college or university with a baccalaureate degree as specified in CLIA. A CLS trainee applicant who is not a college graduate but possesses at least the minimum semester hours or equivalent quarter hours of university or college work specified in statute may be licensed as a CLS trainee provided a baccalaureate degree will be granted at the conclusion of training. All CLS trainee applicants must have completed at least 23 semester hours or equivalent quarter hours in chemical, physical or biological Sciences.

Section 1035, Training schools, to be replaced with the following:

A program, school or course eligible for approval by the department to train Clinical Laboratory Scientists shall be accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS).

Licensed Physicians, Surgeons, Bioanalysts or Clinical Laboratory Scientists shall direct the program. Instructors may include those named above, Limited Licensed Clinical Laboratory Scientists and other persons with expertise deemed appropriate by the program director.

The program shall assure that training includes practical application of, and instruction in, phlebotomy to include skin puncture and venipuncture; pertinent anatomy and physiology; choice of equipment; proper technique; care of specimen; hazards and complications; and postpuncture patient care.

The program shall provide at least 52 weeks of practical and didactic training of which at least 32 weeks shall be practical training in chemistry, hematology, microbiology, immunology, immunohematology and molecular biology in a licensed clinical laboratory.

The program shall provide didactic training such that the student demonstrates competency in pre-analytical skills, such as patient preparation, specimen collection, sample labeling, handling, preservation, fixation and processing or preparation for transportation and storage.

The program shall provide didactic training such that the student demonstrates competency in the analytical skills required for performing tests of waived, moderate and high complexity. The didactic training shall include quality control, quality assurance, performance improvement, safety, universal precautions, troubleshooting, documentation and legal requirements, preventive maintenance, reagent control, calibrator material stability and specimen handling and storage.

The program shall provide didactic training assuring that the student demonstrates competency with post-analytical skills required such as knowledge of factors that influence test results and the ability to access and verify the validity of patient test results.

The program shall provide practical training such that the student demonstrates competency in the use of laboratory instruments and information systems including preventive maintenance and problem solving.

The program shall provide practical training such that the student demonstrates competency with instrument and test parameters to assess reasonableness and clinical correlation of test results.

The program shall maintain student records for a minimum of 7 years.

The application for a clinical laboratory scientist program shall include the following:

(1) Name and address of the training program;
(2) Location(s) at which training shall be conducted;
(3) Name(s) and qualifications of the person(s) directing the program;
(4) Name(s) and qualifications of person(s) instructing in the program;
(5) Didactic curriculum showing classes, objectives, topics, instructor and time spent;
(6) Practical training showing objectives, techniques taught, instructor and time spent;
(7) Phlebotomy training meeting the requirements listed above;
(8) Lists of equipment, supplies and materials used for instruction; and
(9) Signature(s) of the program director(s) and date of application.

The approval period to train Clinical Laboratory Scientists shall be consistent with NAACLS reaccreditation cycles not to exceed seven years.

To apply for renewal, the training program shall file an application at least sixty days prior to the end of the approval period providing the following:

(1) Name and address of the training program;

(2) Any changes in directors, instructors, didactic, practical or phlebotomy instruction, equipment, supplies and materials that were made to the program since the previous application;

(3) A list of students who completed its program since the previous approval was granted and those licensed by the department; and

(4) Signature(s) of the program director(s) and date of application for renewal.

Approval for training granted by the Department pursuant to requirements of this Section may be denied, suspended or revoked if the program is unable to meet or maintain these requirements. The Department may withdraw program approval if during any consecutive five-year period, less than sixty percent of the graduates from the program pass the licensing examination on their first examination attempt.

Comments

1. The subcommittee feels strongly that a program, school or course for the purpose of training Clinical Laboratory Scientists should not be assessed a fee by the Department. The Subcommittee feels that levying a fee would be a disincentive to offering training.
2. The subcommittee recommends that Laboratory Field Services allow flexibility under these guidelines in order to allow programs to remain creative and responsive to changes in modern laboratory medicine.

   It is the intent of the subcommittee that regulations regarding the education and training of clinical laboratory scientists provide maximum flexibility while maintaining high standards. To that end, requirements listed in the recommendations are to be completed prior to taking the examination but not in any particular order nor necessarily in a single program.
3. The subcommittee strongly advises that whenever possible, the Department accept the information required for program evaluation in the format that the program provides to NAACLS for accreditation. This may be provided in the format of the NAACLS self-study.

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