

**Title 17. California Code of Regulations
Division 1. State Department of Health Services
Chapter 2. Laboratories
Subchapter 1. Service Laboratories
Group 2. Clinical Laboratory Regulations
ARTICLE 1. DEFINITIONS**

Section 1029. General Definitions.

“Accreditation body” means an approved accreditation organization for laboratories, as defined in section 493.2 of title 42, Code of Federal Regulations.

~~“Accredited college or university” means an educational institution accredited by the Middle States Commission on Higher Education, the New England Association of Schools and Colleges Commission on Institutions of Higher Education, the North Central Association of Colleges and Schools Higher Learning Commission, the Northwest Commission on Colleges and Universities, the Southern Association of Colleges and Schools Commission on Colleges, the Western Association of Schools and Colleges Accrediting Commission for Community and Junior Colleges, or the Western Association of Schools and Colleges Senior Colleges and University Commission~~ a post-secondary educational institution accredited by a regional association recognized by the U.S. Department of Education or the Council for Higher Education Accreditation (CHEA) or its successor organization. ~~A degree from a non-United States college or university that is not accredited by one of these accreditation associations shall be evaluated for comparability by a current member of the National Association of Credential Evaluation Services or endorsed member of the Association of International Credential Evaluators, Inc., or another organization approved by the Department.~~

“Accredited institution” has the same meaning as given in section 493.2 of title 42, Code of Federal Regulations.

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“Antigen” means any viral component including, but not limited to, proteins and nucleic acids.

“Approved certifying organization,” also called a national accreditation or accrediting board or agency, means an organization, agency, or body that creates competency examinations that measure the skill, knowledge, and aptitude required of a person in a profession, occupation, or discipline, and is approved by the Department to administer examinations acceptable to the Department for purposes of licensure and certification under Chapter 3.

“Approved NAACLS-accredited training program” means a training program that meets accreditation standards of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) and meets training requirements for clinical laboratory personnel licensure in California.

“Approved public health laboratory” means a laboratory that has been issued a certificate of approval by the Department after its determination that the public health laboratory, as defined in Business and Professions Code section 1206(a)(11), is in conformity with chapter 7 (commencing with section 1000) of part 2 of division 1 of the Health and Safety Code and the regulations adopted thereunder.

“Arterial puncture” means the penetration of an artery with a needle to withdraw blood for clinical laboratory test or examination purposes.

“Certified phlebotomy technician I” means a person who has completed the education, training, experience, and examination requirements pursuant to Section 40341030 and is certified by the department to perform skin punctures and venipunctures.

“Certified phlebotomy technician II” means a person who has completed education, training, experience, and examination requirements pursuant to Section 40341030 and is certified by the department to perform skin punctures, venipunctures, and arterial punctures.

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~~“Certifying organization,” also called a national accreditation or accrediting board or agency, means an organization, agency, or body that creates competency examinations that measure the skill, knowledge, and aptitude required of a person in a profession, occupation, or discipline.~~

“Chapter 3” means chapter 3 (commencing with section 1200) of division 2 of the Business and Professions Code.

“Civil money penalties” means the civil money penalties imposed by the Department under the procedures identified in section 1067.5.

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“Condition level requirement” means any of the requirements specified in section 1066.

“Credit hour” means a measure of college or university level instruction that is evaluated by duly qualified faculty.

(a) “Quarter hour, unit, or credit” means at least 10 hours of college or university level instruction during a 10-week or longer quarter plus additional time outside of instruction that the student must devote to preparation for the course.

(b) “Semester hour, unit, or credit” means at least 15 hours of college or university level instruction during a 15-week or longer semester plus additional time outside of instruction that the student must devote to preparation for the course.

“Critical review of trainee laboratory test results” means evaluation of clinical laboratory test results recorded by a licensed trainee as specified in sections 1035.1, 1035.2, and 1035.3 by a person licensed under Chapter 3 or chapter 5 of the Business and Professions Code who has demonstrated competency to perform clinical laboratory tests or examinations in the category for which the person is authorized to review tests, using established quality control parameters to determine acceptability by assessing

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analytic quality, correlating results with other pertinent patient data, and confirming compliance with laboratory standards in state and federal law.

~~“Department” means the California Department of Public Health.~~

“Deficiency” or “Violation” means noncompliance with one or more of the requirements in chapter 3, division 2 of the Business and Professions Code (commencing with section 1200) or any rule or regulation adopted thereunder.

“Department” means the California Department of Public Health.

“Direct and constant supervision,” as defined in section 1206 of the Business and Professions Code, means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under ~~this e~~ Chapter 3 other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in section 1269.

“Direct and responsible supervision,” as defined in section 1206 of the Business and Professions Code, means both:

(a) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under ~~this e~~ Chapter 3 other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations;
and

(b) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

“Direct patient care” means medical, psychiatric, nursing, or other health care that is legally provided by a care giver or healthcare provider directly to a patient, and that includes observation of the patient's physical or mental condition to enable the care giver or healthcare provider to report changes in the patient's condition.

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“Electrolytes” means ionized calcium, sodium, potassium, and/or chloride.

“Equivalent degree,” for purposes of clinical laboratory licensure, means a credential granted by a college or university located outside the United States that attests to an individual’s completion of an academic degree and that has been evaluated by a current member of the National Association of Credential Evaluation Services or endorsed member of the Association of International Credential Evaluators, Inc., or another organization approved by the Department, as comparable to a corresponding academic degree issued by an accredited college or university in the United States.

“Evidence of satisfactory performance” means a copy of a document issued to an examinee by the Department for satisfactory performance on a Department-administered licensing examination, or by a certifying board or organization indicating satisfactory performance by the examinee on a written certifying examination approved by the Department for a license or certificate category.

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“Licensed surgical clinic” means a facility as defined in section 1204(b)(1) of the Health and Safety Code that has been licensed pursuant to chapter 1 (commencing with section 1200) of division 2 of the Health and Safety Code.

“Limited phlebotomy technician” means a person who has completed the education, training, and experience requirements pursuant to Section ~~4034~~1030 and is certified by the department to perform skin punctures.

“Master’s or doctoral degree specialist” means a person licensed under section 1209.1 or 1264 of the California Business and Professions Code to engage in clinical laboratory practice and direction of a clinical laboratory, including a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist, clinical laboratory

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geneticist, clinical reproductive biologist, clinical cytogeneticist, clinical histocompatibility laboratory director, and oral and maxillofacial pathologist.

“Medical laboratory technician” means a person who has completed education, training or experience, and examination requirements pursuant to Section ~~1032.5(a)~~1030.6(a), and who is authorized to perform clinical laboratory tests and examinations specified in Section ~~1032.5(b)~~1030.6(b).

“Moderate complexity laboratory technical consultant” means a person who meets the qualifications of section 493.1411 of title 42, Code of Federal Regulations, as published October 1, 1994, and who provides technical oversight in accordance with section 1036.2 of this title and section 493.1413 of title 42, Code of Federal Regulations, as published October 1, 1994.

“Moderate complexity tests or examinations” mean those clinical laboratory tests or examinations classified as moderate complexity under CLIA.

“Notice of Defense” means a document signed by or on behalf of the person, entity, or laboratory, that states the mailing address of the person, entity, or laboratory, and may:

- (a) Request a hearing.
- (b) Object to the accusation upon the ground that it does not state acts or omissions upon which the agency may proceed.
- (c) Object to the form of the accusation on the ground that it is so indefinite or uncertain that the person, entity, or laboratory cannot identify the transaction or prepare a defense.
- (d) Admit the accusation in whole or in part.
- (e) Present new matter by way of defense.

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(f) Object to the accusation upon the ground that, under the circumstances, compliance with the requirements of a regulation would result in material violation of another regulation enacted by another department affecting substantive rights.

“Official school transcript” means a copy of a student's permanent academic record issued by a school, college, or university identifying the student and attesting to the student's completion of specific courses with grades, credit hours, dates of attendance, academic major(s), degree or diploma granted, if any, including date of graduation, and any awards or honors. The hard copy official school transcript shall bear an official seal, unique identifier of the school, or signature of the registrar, dean, or other authorized official. An official transcript shall be received by the Department:

(a) Directly from the school, college, or university registrar, dean, or other person responsible for issuing transcripts in a sealed envelope that bears a tamper-proof mark or seal attached by the school; or

(b) By secure electronic submission directly from the school, college, or university registrar, dean, or other person responsible for issuing transcripts.

“On-site monitoring” means the on-site monitoring imposed by the Department under the procedures identified in section 1067.10.

“On-the-job experience in phlebotomy” means employment as a phlebotomist in a clinical laboratory performing the techniques pursuant to Section ~~4035.4(f)~~1035(f).

“Oral and maxillofacial pathology laboratory director” means a dentist who possesses a valid, unexpired California license to direct an oral pathology laboratory in all areas of anatomic and clinical pathology related to the oral and maxillofacial region.

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“Phlebotomy” means the process of collecting blood by venipuncture, arterial puncture, or skin puncture for the purpose of obtaining blood for clinical laboratory test or examination purposes.

“Practical experience” means ~~hands-on, direct-on-the-job work experience~~ in clinical laboratory science and ~~phlebotomy techniques on real patients while licensed by the state in which the laboratory is located, if such licensure is required, in a clinical laboratory certified by under CLIA or accredited by an international agency as specified in Section 1034, or in any branch of the Armed Forces of the United States as specified in Section 1261 of the Business and Professions Code~~, using equipment, instruments, kits, and materials routinely found in clinical laboratories performing clinical laboratory tests or examinations categorized as moderate or high complexity tests or examinations, under CLIA. ~~and does not include~~ Practical experience excludes work done in academic, research, forensic, pharmaceutical, or veterinary laboratories.

“Preceptor” means:

(a) The laboratory director or the technical consultant of the laboratory, as that term is defined under CLIA; or

(b) A person who:

(1) Meets the qualifications of a technical consultant under CLIA and of Chapter 3 to perform clinical laboratory tests or examinations classified as moderate complexity; and

(2) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor; or

(c) Any person listed in subdivision (b) of section 1206.5 of the Business and Professions Code, except for those persons listed in subsections (10), (11), or (12) of subdivision (b), and who:

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- (1) Has two years of experience performing moderate complexity tests upon the instrument(s) for which she or he will act as a preceptor; and
- (2) Meets any CLIA requirements necessary to perform his or her duties and responsibilities in a preceptor program; and
- (3) Is assigned by the laboratory director or the technical consultant of the laboratory to act as a preceptor.

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“Testing event” means the performance of the pre-analytical, analytical, and post-analytical activities related to performing a clinical laboratory test or examination on a biological specimen.

“Trainee” means an individual training in a licensed clinical laboratory for licensure as a clinical laboratory scientist, a clinical laboratory scientist limited to a specialty or subspecialty, or a medical laboratory technician, who meets the academic requirements specified in section 1030.5.

“Training school” or “training program” means a school or program established to train and prepare persons for licensure or certification in clinical laboratory science.

“Transcript evaluation” or “credential evaluation,” for purposes of clinical laboratory licensure, means a written report of a review of a degree or educational credential from a non-United States high school, college, or university not accredited by an accreditation association as specified in this section, to determine the equivalency of the non-United States degree or credential in terms of educational records issued by a high school, or an accredited college or university in the United States; the evaluation must be obtained from a current member of the National Association of Credential Evaluation Services or endorsed member of the Association of International Credential Evaluators, Inc., or another transcript evaluation or credential evaluation organization approved by the Department.

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“Unprofessional conduct,” pursuant to the provisions of section 1320(m) of the Business and Professions Code, means:

(a) Acts of gross negligence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code;

(b) Acts of gross incompetence in the performance of duties authorized by the license under chapter 3, division 2, Business and Professions Code.

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“Waived tests” mean those clinical laboratory tests or examinations classified as waived under CLIA.

Credits

NOTE: Authority cited: Sections 1208 and 1224, Business and Professions Code; Sections 100275 and 131200, Health and Safety Code; ~~Stats. 1995, c. 510, Section 1; and Section 14105, Welfare and Institutions Code.~~ Reference: Sections 23.7, 1202.5, 1203, 1204, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1212, 1213, 1220, ~~1222, 1222.5, 1223, 1224, 1225, 1227,~~ 1241, 1242, 1242.5, 1242.6, 1243, 1244, 1246, 1246.5, 1260, 1260.1, 1260.3, 1261, 1261.5, 1262, 1263, 1264, 1265, 1267, 1269, 1269.3, ~~1269.5,~~ 1270, ~~1275,~~ 1280, 1281, 1282, 1282.2, 1285, 1286, ~~1288,~~ 1288.5, 1289, 1300, 1301, ~~1301.1,~~ 1310, and 1320, ~~1322, 1323, 1324, 1325 and 1326,~~ Business and Professions Code; ~~Sections 1002, 120580, 120775, 131050, 131051 and 131052, Health and Safety Code; Section 14123, Welfare and Institutions Code;~~ Sections 11503 and 11504, Government Code; Stats. 1995, c.510, Section 1; Stats. 1995, c. 510 (SB 113) Section 1(a)(6); ~~42 United States Code, Section 1395w-2 (Section 1846 of the federal Social Security Act); and 42 United States Code, Section 1396a(a)(9) (Section 1902(a)(9)(C) of the federal Social Security Act).~~

ARTICLE 1.5. LICENSURE AND CERTIFICATION OF CLINICAL LABORATORY PERSONNEL.

Section 1030. Certification of Phlebotomy Technicians.

(a) The education, training, and experience required for certification in phlebotomy shall be as follows:

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(1) For a person to be eligible for certification as a Limited Phlebotomy Technician, he or she shall:

...

(B) Have completed a minimum of 20 hours basic didactic instruction pursuant to Section 1035.4(e)(1) from a phlebotomy training program approved by the department; and

...

(2) For a person with no on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

...

(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section 1035.4(e) from a phlebotomy training program approved by the department; and

(C) Have completed a minimum of 40 hours practical instruction from a phlebotomy training program approved by the department pursuant to Section 1035.4(f), which instruction shall include completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

...

(3) For a person who has less than 1040 hours on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

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(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section 1035.4(e) from a phlebotomy training program approved by the department; and

(C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years, which shall include the activities listed in Section 1035.4(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

...

(4) For a person who has 1040 hours or more of on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

...

(B) Have completed a minimum of 20 hours advanced didactic instruction pursuant to Section 1035.4(e)(2) from a phlebotomy training program approved by the department; and

(C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years which shall include the activities listed in Section 1035.4(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to

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the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

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Credits

NOTE: Authority cited: ~~Section~~ Sections 1224 and 1246, Business and Professions Code; and ~~Section~~ Sections 100275 and 131200, Health and Safety Code. Reference: Sections ~~1206, 1208, 1212, 1220, 1242, 1242.5, and 1246 and 1269~~, Business and Professions Code; and Section 120580, Health and Safety Code.

**Section 1030.5. Trainee Requirements—Licensure and Work Scope of a Clinical
Laboratory Trainee.**

~~In addition to the requirements for licensure as specified in Section 1263 of the Business and Professions Code, the prerequisites for licensure as a trainee shall be as follows:~~

~~(a) Clinical Laboratory Technologist Trainee. Applicants shall have graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent agency with a baccalaureate and a major in clinical laboratory science, or a baccalaureate and courses pertinent to the clinical laboratory field as may be determined by the department. An individual who is not a graduate but possesses at least 90 semester hours or equivalent quarter hours of university or college work may be licensed as a clinical laboratory technologist trainee, provided he will be granted a baccalaureate at the conclusion of 12 months of training, and have completed at least 90 semester hours or equivalent quarter hours, must have included in the college work the following courses or essential equivalent as may be determined by the department: general inorganic chemistry—8; quantitative analysis—3; basic biological sciences—8; bacteriology—4; provided, however, that university or college work completed after July 1, 1973, must include at least:~~

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~~(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;~~

~~(3) 3 semester or equivalent quarter hours of physics including instruction in principles of light and electricity.~~

~~(b) Limited Technologist Trainee. Applicants shall have graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency with a baccalaureate and a major in the specialty for which licensure is sought. If the major is not designated by the college or university as one of those required under this chapter for limited technologist licenses in clinical chemistry, clinical microbiology, immunohematology, or toxicology, the department may determine the essentially equivalent major.~~

(a) Licensure requirements and work scope for a medical laboratory technician (MLT) trainee are follows:

(1) On and after January 1, 2026, a person performing clinical laboratory tests or examinations as a trainee for medical laboratory technician (MLT) licensure must hold a valid and current MLT trainee license.

(2) To be licensed as an MLT trainee, a person must satisfy each of the following requirements:

(A) Apply for an MLT trainee license as specified in section 1031; and

(B) Document successful completion of an associate degree, or equivalent education of at least 60 semester or equivalent quarter credit hours of coursework, from an

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accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; and

(C) Complete at least 36 semester or equivalent quarter credit hours in chemical and biological sciences with an emphasis on applied clinical laboratory science, medical laboratory science, or medical laboratory technology, including at least:

1. 6 semester or equivalent quarter credit hours in chemistry; and

2. 6 semester or equivalent quarter credit hours in biology.

(D) If an applicant has completed at least 6 semester or equivalent quarter credit hours in chemistry and 6 semester or equivalent quarter credit hours in biology, as specified in paragraph (C), the Department is authorized to issue the applicant a trainee license, in which case the applicant must complete the remaining required credit hours concurrently with the practical training.

(3) A licensed MLT trainee is authorized to train in an approved training program performing clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate complexity under CLIA in the specialties of chemistry, microbiology, diagnostic immunology, hematology, and immunohematology, as specified in section 1035.1.

(4) An MLT trainee must work under the direct and responsible supervision of a licensed physician and surgeon or a clinical laboratory bioanalyst, master's or doctoral degree specialist, clinical laboratory scientist, or clinical laboratory scientist limited to a specialty or subspecialty licensed under Chapter 3 as specified in section 1035.1.

(b) Licensure requirements and work scope for a clinical laboratory scientist (CLS) trainee are as follows:

(1) To be licensed as a CLS trainee, a person must satisfy each of the following requirements:

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(A) Apply for a CLS trainee license as specified in section 1031; and

(B) Document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; or, if the applicant will be granted a baccalaureate degree upon completion of training, document successful completion of at least 90 semester or equivalent quarter credit hours of college or university courses from an accredited college or university; and

(C) Complete at least:

1. 16 semester or equivalent quarter credit hours in chemistry, including:

a. Quantitative analysis or analytical chemistry; and

b. Clinical chemistry or biochemistry; and

2. 16 semester or equivalent quarter credit hours in biology, including medical, clinical, or pathogenic microbiology, hematology, and immunology; and

3. 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics.

(2) A licensed CLS trainee is authorized to train in an approved training program performing clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate or high complexity under CLIA in the specialties and subspecialties of chemistry, microbiology, diagnostic immunology, immunochemistry, immunohematology, hematology, histocompatibility, and other areas as specified in section 1035.2.

(3) A CLS trainee must work under the direct and responsible supervision of a licensed physician and surgeon or a clinical laboratory bioanalyst, master's or doctoral degree specialist, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3 as specified in section 1035.2.

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(c) Licensure requirements and work scope for a clinical laboratory scientist (CLS) trainee who meets California requirements for licensure as a medical laboratory technician (MLT) are as follows:

(1) To be licensed as a CLS trainee, a person who meets California requirements for licensure as an MLT must satisfy each of the following requirements:

(A) Apply for a CLS trainee license as specified in section 1031; and

(B) Hold a current license, or meet requirements for licensure, as an MLT pursuant to Chapter 3; and

(C) Document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; or, if the applicant will be granted a baccalaureate degree upon completion of training, document successful completion of at least 90 semester or equivalent quarter credit hours of college or university courses from an accredited college or university; and

(D) Complete at least:

1. 16 semester or equivalent quarter credit hours in chemistry, including:

a. Quantitative analysis or analytical chemistry; and

b. Clinical chemistry or biochemistry; and

2. 16 semester or equivalent quarter credit hours in biology, including medical, clinical, or pathogenic microbiology, hematology, and immunology; and

3. 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics.

(2) A licensed CLS trainee is authorized to train in an approved training program performing clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate or high complexity under CLIA in the specialties

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and subspecialties of chemistry, microbiology, diagnostic immunology, immunoematology, hematology, histocompatibility, and other areas, as specified in section 1035.3.

(3) A CLS trainee must work under the direct and responsible supervision of a licensed physician and surgeon or a clinical laboratory bioanalyst, master's or doctoral degree specialist, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3 as specified in section 1035.3.

(d) Licensure requirements and work scope for a clinical laboratory scientist (CLS) trainee limited to a specialty or subspecialty are as follows:

(1) To be licensed as a CLS trainee limited to a specialty or subspecialty, a person must satisfy each of the following requirements:

(A) Apply for a CLS trainee license limited to a specialty or subspecialty as specified in section 1031; and

(B) Document successful completion of a baccalaureate or equivalent degree as defined in section 1029 from an accredited college or university as follows:

1. For an applicant for a CLS trainee license in the specialty of chemistry, microbiology, immunoematology, hematology, or histocompatibility, or the subspecialty of toxicology, document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; and

2. For an applicant for a CLS trainee license in the subspecialty of genetic molecular biology or cytogenetics, document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses pertinent to clinical laboratory science or a field related to genetics as specified in Section 1032; and

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(C) Complete coursework appropriate to the license for which the applicant is applying as follows:

1. For the specialty of chemistry: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in chemistry, including:

a. Quantitative analysis or analytical chemistry; and

b. Clinical chemistry or biochemistry;

2. For the specialty of microbiology: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in a biological science, including medical, clinical, or pathogenic microbiology;

3. For the specialty of immunohematology: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in a biological science, including immunology;

4. For the subspecialty of toxicology: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in chemistry;

5. For the specialty of hematology: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in a biological science, including hematology;

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6. For the specialty of histocompatibility: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in a biological science, including immunology or genetics;

7. For the subspecialties of genetic molecular biology and cytogenetics: 23 semester or equivalent quarter credit hours of science courses, including at least 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics and at least 16 semester or equivalent quarter credit hours in a biological or chemical science, including genetics.

(2) A licensed CLS trainee limited to a specialty or subspecialty is authorized to train in an approved training program performing clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate or high complexity under CLIA in the specialties and appropriate to the license for which the applicant is applying as specified in section 1035.2.

(3) A CLS trainee limited to a specialty or subspecialty must work under the direct and responsible supervision of a licensed physician and surgeon or a clinical laboratory bioanalyst, master's or doctoral degree specialist, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3 as specified in section 1035.2.

(e) The director of the clinical laboratory in which a trainee performs tests or examinations must ensure that a qualified person conducts a critical review of the trainee's test results pursuant to section 1029 before the release of those results.

(f) A licensed clinical laboratory trainee as specified in subsections (a) through (d) must maintain current licensure with the Department as a clinical laboratory trainee during the entire period the trainee is performing tests or examinations in a clinical laboratory located in California.

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(1) The trainee must possess a current license issued by the Department attesting to the trainee's name, license type, and effective dates of licensure as a clinical laboratory trainee.

(2) The trainee's current clinical laboratory trainee license issued by the Department must be posted in the clinical laboratory in which the trainee performs clinical laboratory tests or examinations.

(A) If a trainee performs clinical laboratory tests or examinations at one or more locations of a single employer under the same clinical laboratory license, the current clinical laboratory trainee license issued by the Department must be posted at the trainee's primary work location.

(B) If a trainee performs clinical laboratory tests or examinations for more than one employer or at multiple laboratories not under the same clinical laboratory license, the current clinical laboratory trainee license issued by the Department must be posted at the trainee's primary work location at each address of employment.

(3) A trainee license is valid for one year from the date of issue and may be renewed upon expiration as specified in section 1031.1.

Credits

Note: Authority cited: Sections ~~102 and 208~~ 100275 and 131200, Health and Safety Code; and Sections 1208 and 1224, Business and Professions Code. Reference: sections ~~1246~~ Sections 1205, 1261, 1262, 1263, 1264 and 1301, Business and Professions Code.

Section 1030.6. Licensure of Medical Laboratory Technicians and Work Scope of a Medical Laboratory Technician.

~~(a) In order to qualify for licensure as a medical laboratory technician, a person shall apply for a license pursuant to Section 1031(b) and meet the following requirements:~~

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~~(1) Have successfully completed at least 60 semester (90 quarter) units from an accredited college or university. The coursework shall consist of at least 36 semester units of physical and biological sciences with an emphasis on applied clinical science. Coursework shall include 6 semester units of chemistry and 6 semester units of biology appropriate for transfer to a baccalaureate program in science, taken prior to, or concurrently with, training or experience; and~~

~~(2) Have met the following training or experience requirements by documenting one of the following:~~

~~(A) Graduating from a medical laboratory technician training program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or~~

~~(B) Graduating from a medical laboratory technician training program approved by the department pursuant to Section 1035.3; or~~

~~(C) Meeting admission requirements for a clinical laboratory scientist licensing examination, as determined by the department pursuant to Section 1030.7; or~~

~~(D) Completing a minimum of three years on-the-job practical experience within the previous five years, in a clinical laboratory outside California as a medical laboratory technician, with evidence of satisfactory performance on an examination given by a certifying organization for medical laboratory technicians, performing tests in the specialties of chemistry, hematology, microbiology, and immunology. This work experience shall include at least 480 hours in each of these specialties and shall be documented by the laboratory director(s) of the laboratory(ies) employing the applicant pursuant to Section 1031(b)(8); or~~

~~(E) Completing a minimum of three years on-the-job practical experience within the previous five years, in a clinical laboratory outside California as a clinical laboratory scientist, with evidence of satisfactory performance on an examination given by a certifying organization for clinical laboratory scientists, performing tests in the specialties~~

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~~of chemistry, hematology, microbiology, and immunology. This clinical laboratory scientist, also called medical technologist in some states, need not be California licensed pursuant to Business and Professions Code section 1204, but shall have work experience outside California of at least 480 hours in each of these specialties as documented by the laboratory director(s) of the laboratory(ies) employing the applicant pursuant to Section 1031(b)(8); or~~

~~(F) Completing a minimum of three years on the job practical experience within the previous five years, as a medical laboratory technician or clinical laboratory scientist in a California physician office laboratory or in a laboratory owned and operated by the United States of America. This person shall have evidence of satisfactory performance on an examination given by a certifying organization for medical laboratory technicians or clinical laboratory scientists, respectively, and have performed tests in the specialties of chemistry, hematology, microbiology and immunology. This work experience shall include at least 480 hours in each of these specialties, and shall be documented by the physician(s) directing the laboratory(ies) employing the applicant pursuant to Section 1031(b)(8); and~~

~~(3) Have passed a written examination for medical laboratory technicians administered by a certifying organization for medical laboratory technicians approved by the department pursuant to Section 1031.8. The department shall, for licensure purposes, accept evidence of satisfactory performance on examinations taken within the four years previous to department approval of a certifying organization's medical laboratory technician examination. The applicant shall have also passed a separate written, self-administered examination on California clinical laboratory law provided by the department. This self-administered test shall accompany the application. A minimum passage rate of 70 percent shall be required.~~

~~(b) A licensed medical laboratory technician shall be authorized to:~~

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~~(1) Perform tests and examinations classified as waived and moderate complexity by Centers for Disease Control and Prevention in the specialties of chemistry, including routine chemistry, urinalysis, endocrinology and toxicology; hematology including coagulation; microbiology, including bacteriology, mycobacteriology, mycology, parasitology and virology; and immunology, including syphilis serology and general immunology, with the exception of those moderate complexity tests requiring microscopy, or in the specialty of immunohematology.~~

~~(2) Perform phlebotomy, but shall not perform skin tests for specific diseases pursuant to Section 1242 of the Business and Professions Code.~~

~~(3) Perform tests and examinations under the supervision of a licensed physician and surgeon, or a doctoral scientist, clinical laboratory bioanalyst, clinical laboratory scientist, or clinical laboratory specialist licensed under Chapter 3. On-site supervision shall be required during the entire time the medical laboratory technician performs moderate complexity clinical laboratory tests or examinations. The ratio of medical laboratory technician to supervisor at the site of moderate complexity testing shall not exceed four to one.~~

~~(4) Report test results and perform phlebotomy only after competency has been documented by the laboratory director pursuant to Section 1209(e) of the Business and Professions Code.~~

~~(5) Supervise Limited Phlebotomy Technicians or Certified Phlebotomy Technician I's.~~

~~(c) The license application fee and license renewal fee for a medical laboratory technician shall be the same as the license application fee and license renewal fee for a clinical laboratory scientist pursuant to Section 1300(c) and (e) of the Business and Professions Code.~~

~~(d) A medical laboratory technician shall complete twelve hours of continuing education each year as a condition for renewal.~~

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(a) To be licensed as a medical laboratory technician (MLT), a person must satisfy each of the following requirements:

(1) Apply for an MLT license and meet the requirements as specified in section 1031; and

(2) Document successful completion of an associate degree, or equivalent education of at least 60 semester or equivalent quarter credit hours of coursework, from an accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; and

(3) Complete at least 36 semester or equivalent quarter credit hours in chemical and biological sciences with an emphasis on applied clinical laboratory science, medical laboratory science, or medical laboratory technology, including at least:

(A) 6 semester or equivalent quarter credit hours in chemistry; and

(B) 6 semester or equivalent quarter credit hours in biology; and

(4) Complete one of the following training or experience requirements in a clinical laboratory certified under CLIA, or a laboratory accredited by the College of American Pathologists (CAP), COLA, or Joint Commission International (JCI) or certified to meet International Organization for Standardization (ISO) 15189 and International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards or later standards by an international accrediting organization that meets ISO/IEC 17011 standards or later standards, at the time the applicant obtained the training and/or experience:

(A) Six months of MLT training from an approved NAACLS-accredited training program as specified in section 1029 and section 1035.1; or

(B) Six months of MLT training in a program approved by the Department pursuant to section 1035.1 while licensed as an MLT trainee; or

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(C) Two years of training and experience in any branch of the Armed Forces of the United States as a military laboratory specialist that include one year of basic (Phase 1) and advanced (Phase 2) training as a clinical laboratory technician or medical laboratory technician; or

(D) The education and training requirements for clinical laboratory scientist (CLS) licensure pursuant to section 1030.7; or

(E) Three years of on-the-job practical experience as an MLT or a CLS within the ten years immediately prior to application in a clinical laboratory located outside California that meets the requirements specified in section 1032.5 and includes the performance of tests or examinations categorized as moderate complexity under CLIA in the specialties of chemistry, microbiology, diagnostic immunology, hematology, and immunochemistry, and fulfills the following requirements:

1. Achieve satisfactory performance on an examination for MLTs or CLSs provided by a Department-approved certifying organization pursuant to section 1031.8; and

2. Complete 640 hours of practical experience that includes performing at least 60 hours of moderate complexity testing in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of testing in immunology and immunochemistry that includes at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing; and

3. Provide documentation of all practical experience signed by the laboratory director of each laboratory employing the applicant pursuant to section 1031; or

(F) Three years of on-the-job practical experience as an MLT or a CLS within the ten years immediately prior to application in a licensed physician's office laboratory located in California or a laboratory owned and operated by the government of the United States that includes the performance of tests or examinations categorized as moderate complexity under CLIA in the specialties of chemistry, microbiology, diagnostic

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immunology, hematology and immunohematology, and fulfills the following requirements:

1. Achieve satisfactory performance on an examination for MLTs or CLSs provided by a Department-approved certifying organization pursuant to section 1031.8; and

2. Complete 640 hours of practical experience that includes performing at least 160 hours of moderate complexity testing in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of testing in immunology and immunohematology that includes at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing; and

3. Provide documentation of all practical experience signed by the laboratory director of each laboratory employing the applicant pursuant to section 1031; and

(5) Meet the following examination requirements:

(A) Document satisfactory performance on an MLT licensure examination pursuant to section 1031 provided by a Department-approved certifying organization as specified in section 1031.8, completed on or after the date of examination approval by the Department; and

(B) Achieve satisfactory performance on an examination on California clinical laboratory law pursuant to section 1034.

(b) A licensed MLT is authorized to:

(1) Engage in clinical laboratory practices as defined in section 1029 related to the scope of this category; and

(2) Perform clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate complexity under CLIA in the following specialties:

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(A) Chemistry, including routine chemistry, urinalysis, endocrinology, and toxicology; and

(B) Microbiology, including bacteriology, mycobacteriology, mycology, parasitology, and virology; and

(C) Diagnostic immunology, including syphilis serology and general immunology, including microscopic urinalysis; and

(D) Hematology, including coagulation and blood smear reviews other than manual leukocyte differentials; and

(3) Perform blood typing of moderate complexity, such as automated ABO/Rh testing and antibody screen testing; and

(4) Report test results and perform phlebotomy only after competency has been documented and signed by the laboratory director, or by a person who qualifies as a designee under Section 1209 of the Business and Professions Code; and

(5) Supervise a limited phlebotomy technician or a certified phlebotomy technician I.

(c) A licensed MLT must perform clinical laboratory tests or examinations under the supervision of a licensed physician and surgeon or a clinical laboratory bioanalyst, master's or doctoral degree specialist, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3, under the following conditions:

(1) Supervision must be available onsite during the entire time the MLT performs clinical laboratory tests or examinations categorized as moderate complexity under CLIA; and

(2) The ratio of licensed supervisors to MLTs for moderate complexity testing is one supervisor for no more than eight MLTs.

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(d) A licensed MLT must maintain current licensure with the Department as an MLT during the entire period the MLT is performing tests or examinations in a clinical laboratory located in California.

(1) The MLT must possess a current license issued by the Department attesting to the MLT's name, license type, and effective dates of licensure as an MLT.

(2) The MLT's current MLT license issued by the Department must be posted in the clinical laboratory in which the MLT performs clinical laboratory tests or examinations.

(A) If an MLT performs clinical laboratory tests or examinations at one or more locations of a single employer under the same clinical laboratory license, the current MLT license issued by the Department must be posted at the MLT's primary work location.

(B) If an MLT performs clinical laboratory tests or examinations for more than one employer, or at multiple laboratories not under the same clinical laboratory license, the current MLT license issued by the Department must be posted at the MLT's primary work location at each address of employment.

(3) To renew licensure, the MLT must:

(A) Complete at least twelve hours per year, or twenty-four hours every two years, of continuing education in clinical laboratory related courses from an approved provider of continuing education pursuant to Article 2.5; and

(B) Renew the license pursuant to sections 1275 and 1300 of the Business and Professions Code.

(e) The non-refundable license application fee and license renewal fee for an MLT license, pursuant to section 1300, subdivision (q), of the Business and Professions Code, is the same as the license application fee and license renewal fee for a CLS license pursuant to section 1300, subdivisions (c) and (e), of the Business and Professions Code.

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Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; and ~~Section Sections 100275 and 131200~~, Health and Safety Code. Reference: Sections ~~1202.5, 1204, 1206, 1206.5, 1208, 1209, 1210, 1242, 1260.3, 1261, 1275, and 1300 and 1320~~, Business and Professions Code.

Section 1030.7. Examination for Clinical Laboratory ~~Technologist's~~ Scientist's License.

With the exception as provided in Section 1262 of the Business and Professions Code, written, oral, or practical examinations shall be conducted by the department to aid it in judging the qualifications of applicants for licensure as clinical laboratory ~~technologists~~ scientists. In addition to the requirements for licensure as specified in Section 1261 of the Business and Professions Code, the prerequisites for entrance into the licensing examination shall be one of the following:

(a) Graduation from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges, or an essentially equivalent accrediting agency, with a baccalaureate, or an equivalent degree as defined in section 1029, and a major in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology, the last year of which course shall have been primarily clinical laboratory procedures in a clinical laboratory training school acceptable to the department; or

(b) Graduation from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Eastern Association of Schools and Colleges, or an essentially equivalent accrediting agency, with a baccalaureate, or an equivalent degree as defined in section 1029, and courses pertinent to ~~the clinical laboratory field~~ science as may be specified in Section 1032, plus one year as a clinical laboratory technologist trainee or the equivalent as

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determined by the department in a clinical laboratory acceptable to the department; provided, however, that a baccalaureate obtained after July 1, 1973, must include at least:

(1) 16 semester or equivalent quarter credit hours of chemistry, including ~~instruction in analytical and biological chemistry;~~

(A) Quantitative analysis or analytical chemistry; and

(B) Clinical chemistry or biochemistry; and

(2) ~~18~~16 semester or equivalent quarter credit hours of biological science, including ~~instruction in medical, clinical, or pathogenic microbiology, hematology, and immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology;~~ and

(3) 3 semester or equivalent quarter credit hours of physics, ~~including instruction in principles of light and electricity~~ math, or statistics; or

(c) A minimum of two years of experience as a licensed trainee or the equivalent as determined by the department doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory acceptable to the department and 90 semester hours or equivalent quarter credit hours of university or college work in which are included the following coursess, or essential equivalent as may be determined by the department: general inorganic chemistry--8; quantitative analysis--3; basic biological sciences--8; bacteriology--4; provided, however, that university or college work completed after July 1, 1973, must include at least:

(1) 16 semester or equivalent quarter credit hours of chemistry, including ~~instruction in analytical and biological chemistry;~~

(A) Quantitative analysis or analytical chemistry; and

(B) Clinical chemistry or biochemistry; and

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(2) ~~18~~16 semester or equivalent quarter credit hours of biological science including ~~instruction in~~ medical, clinical, or pathogenic microbiology, hematology, and immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology; and

(3) 3 semester or equivalent quarter credit hours of physics, ~~including instruction in principles of light and electricity~~ math, or statistics.

Credits

NOTE: Authority cited: ~~Sections 102 and 208, Section 1224, Business and Professions Code, Sections 100275 and 131200, Health and Safety Code.~~ Reference: Sections 1246, 1261, and 1262, 1263, 2164 and 1304, Business and Professions Code.

Section 1030.8. Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure.

(a) To be licensed as a clinical laboratory scientist (CLS), a person who is licensed as a medical laboratory technician (MLT) or who meets requirements for licensure as an MLT must satisfy each of the following requirements:

(1) Apply for a CLS license and meet the requirements as specified in section 1031; and

(2) Hold a current license, or meet the requirements for licensure, as an MLT pursuant to Chapter 3; and

(3) Document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses pertinent to clinical laboratory science as specified in Section 1032; and

(4) Complete at least:

(A) 16 semester or equivalent quarter credit hours in chemistry, including:

1. Quantitative analysis or analytical chemistry; and

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2. Clinical chemistry or biochemistry; and

(B) 16 semester or equivalent quarter credit hours in biology, including medical, clinical, or pathogenic microbiology, hematology, and immunology; and

(C) 3 semester or equivalent quarter credit hours of physics, mathematics, or statistics.

(5) Complete training in a six-month CLS training program approved by the Department as specified in section 1035.3 while licensed as a CLS trainee as specified in section 1030; and

(6) Meet the following examination requirements:

(A) Document satisfactory performance on a CLS licensure examination pursuant to section 1031 provided by a Department-approved certifying organization as specified in section 1031.8, completed on or after the date of examination approval by the Department; and

(B) Achieve satisfactory performance on an examination on California clinical laboratory law pursuant to section 1034.

(b) A licensed CLS is authorized to:

(1) Engage in clinical laboratory practices as defined in section 1029 related to the scope of this category; and

(2) Perform clinical laboratory tests or examinations categorized as waived and tests or examinations categorized as moderate or high complexity under CLIA in the specialties of chemistry, microbiology, diagnostic immunology, immunohematology, hematology, histocompatibility, and genetics; and

(3) Perform any of the following duties:

(A) Serve as general supervisor if the CLS meets the requirements as specified in sections 1029 and 1036.1, and CLIA; and

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(B) Serve as moderate complexity laboratory technical consultant if the CLS meets the requirements as specified in sections 1029 and 1036.2, and CLIA; and

(C) Serve as waived laboratory supervisor if the CLS meets the requirements as specified in sections 1029 and 1036.3; and

(D) Serve as technical supervisor if the CLS meets the requirements as specified in sections 1029 and 1036.4, and CLIA.

(c) A licensed CLS must maintain current licensure with the Department as a CLS during the entire period the CLS is performing tests or examinations in a clinical laboratory located in California.

(1) The CLS must possess a current license issued by the Department attesting to the CLS's name, license type, and effective dates of licensure as a CLS.

(2) The CLS's current CLS license issued by the Department must be posted in the clinical laboratory in which the CLS performs clinical laboratory tests or examinations.

(A) If a CLS performs clinical laboratory tests or examinations at one or more locations of a single employer under the same clinical laboratory license, the current CLS license issued by the Department must be posted at the CLS's primary work location.

(B) If a CLS performs clinical laboratory tests or examinations for more than one employer or at multiple laboratories not under the same clinical laboratory license, the current CLS license issued by the Department must be posted at the CLS's primary work location at each address of employment.

(3) To renew licensure, the CLS must:

(A) Complete at least twelve hours per year, or twenty-four hours every two years, of continuing education in clinical laboratory related courses from an approved provider of continuing education pursuant to Article 2.5; and

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(B) Renew the license pursuant to sections 1275 and 1300 of the Business and Professions Code.

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1208, 1261, and 1275, Business and Profession Code.

Section 1030.16. Licensure of Clinical Cytogeneticist Scientists.

...

(b) In order to be eligible for licensure as a clinical cytogeneticist scientist, an applicant shall:

...

(2) Provide evidence of satisfactory performance on a written examination in the specialty of cytogenetics administered by the National Credentialing Agency for Laboratory Personnel (NCA), prior to October 23, 2009, or by the American Society for Clinical Pathology (ASCP), on or after October 23, 2009, and either:

(A) On or after March 14, 2003, have completed at least one year of training and/or experience in clinical cytogenetics in a clinical laboratory certified by the Centers for Medicare and Medicaid Services (CMS) in clinical cytogenetics. This training shall be approved by the department pursuant to Section ~~4035~~1035.2 and acceptable for admission to an examination administered by the NCA prior to October 23, 2009, or by the ASCP on or after October 23, 2009, in the specialty of cytogenetics; or

...

Credits

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NOTE: Authority cited: Sections 1224, 1261 and 1261.5, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1203, ~~1205, 1206, 1206.5, 1210, 1222.5, 1261, 1261.5, and 1262, 1282 and 1286,~~ Business and Professions Code; and Sections ~~131050 and 131051,~~ Health and Safety Code.

Section 1030.17. Licensure of Clinical Genetic Molecular Biologist Scientists.

...

(b) In order to be eligible for licensure as a clinical genetic molecular biologist scientist, an applicant shall hold a baccalaureate or an equivalent or higher degree in a biological or clinical laboratory science, or field related to genetics from an accredited college or university; and

(1) Have completed at least one year training and/or experience in clinical genetic molecular biology in a clinical laboratory certified by the Center for Medicare & Medicaid Services (CMS), performing high complexity testing in clinical genetic molecular biology. This training and/or experience shall be acceptable for admission to an examination administered by the National Credentialing Agency for Laboratory Personnel (NCA) or the American Society for Clinical Pathology (ASCP) in the specialty of molecular biology. On or after March 14, 2003, this training shall be approved by the department pursuant to Section ~~4035~~1035.2; and

...

Credits

NOTE: Authority cited: Sections 1224, 1261 and 1261.5, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1203, ~~1205, 1206, 1206.5, 1210, 1222.5, 1261, 1261.5, and 1262, 1282 and 1286,~~ Business and Professions Code; and Sections ~~131050 and 131051,~~ Health and Safety Code.

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Section 1031. Requirements and Timeframes for Applications for Licensure and Certification.

...

(c) An application for certification in phlebotomy shall be considered complete when the following is provided to the department:

...

(7) Certification of the applicant's instruction in phlebotomy as specified in Section 1035-4(h); and

(8) Certification of the applicant's on-the-job experience in phlebotomy, if applicable, including:

(A) Name and address of laboratory where employed, dates of employment, number of hours of experience in techniques specified in Section 1035-4(f) and an estimate of the number of skin punctures, venipunctures or arterial punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfills all the sampling requirements of all clinical laboratory tests or examinations; and

...

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; ~~Section~~ Sections 100275 and 131200, Health and Safety Code; and Section 17520, Family Code.

Reference: Sections ~~1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1220, 1241, 1242, 1242.5, 1246, 1260, 1260.3, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301, 1301.1 and 1320~~, Business and Professions Code; Section 120580, Health and Safety Code; and Section 15376, Government Code.

Section 1032. Examples of Degrees or Courses in a Biological Science, Chemical Science, Physical Science, or Clinical Laboratory Science.

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Examples of degrees or courses in a biological science, chemical science, physical science, or clinical laboratory science may include, but are not limited to, the degrees and courses listed below:

(a) Biological science:

(1) Degrees may include Biology, Microbiology, Animal Science, Botany, Genetics, Physiology, Chemistry, Zoology.

(2) Courses may include Microbiology, Animal Science, Biochemical Engineering, Biomanufacturing, Biotechnology, Botany, Genetics, Molecular Biology, Physiology, Zoology.

(b) Chemical science:

(1) Degrees may include Chemistry, Pharmaceutical Chemistry, Chemical Engineering, Biochemistry, Physical Chemistry, Pharmacology, Analytical Chemistry.

(2) Courses may include Pharmaceutical Chemistry, Chemical Engineering, Physical Chemistry, Biochemistry, Pharmacology, Analytical Chemistry, Quantitative Analysis.

(c) Physical science:

(1) Degrees may include Physics, Physical Chemistry, Biophysics.

(2) Courses may include Physics, Physical Chemistry, Biophysics, Thermodynamics.

(d) Clinical laboratory science:

(1) Degrees may include Clinical Laboratory Science, Medical Laboratory Science, Medical Laboratory Technology.

(2) Courses may include Cytology, Hematology, Immunology, Clinical Chemistry, Immunohematology, Parasitology, Histology, Medical Microbiology, Clinical Microbiology, Pathogenic Microbiology, Pathogenic Bacteriology.

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; Sections-100275 and 131200, Health and Safety Code. Reference: Sections 1261, 1261.5, 1262, 1263, and 1264, Business and Professions Code.

Section 1032.5. Acceptance of Training or Experience Obtained in a Laboratory Outside the United States.

(a) The training or experience obtained by an applicant for licensure in a clinical laboratory located outside the United States that is not certified under CLIA meets licensure standards if the applicant can document that:

(1) The laboratory is certified to meet International Organization for Standardization (ISO) 15189 and International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards or later standards by an international accrediting organization that meets ISO/IEC 17011 standards or later standards for certifying technical facilities including clinical laboratories; and

(2) The laboratory performs tests or examinations categorized as high complexity under CLIA in the specialty or subspecialty of training; and

(3) The tests or examinations performed while obtaining the training or experience were performed on human biological specimens for diagnostic or clinical purposes, and not for academic, research, forensic, pharmaceutical, or veterinary purposes; and

(4) The training or experience is acceptable for admission to a board certification examination approved by the Department for licensure in the specialty or subspecialty of training.

(b) The applicant for licensure must provide documentation of training or experience in a laboratory not certified under CLIA with a letter signed and sent directly to the

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Department by the laboratory director or medical director of the laboratory. This documentation must include the following information:

- (1) Name and address of the laboratory and its affiliation with a university, if applicable; and
- (2) International or national accreditation held by the laboratory; and
- (3) Name and qualifications of the laboratory or medical director; and
- (4) Specialty or subspecialty of tests or examinations performed by the laboratory and number of tests or examinations performed annually; and
- (5) Dates training or experience began and ended; and
- (6) Title and responsibilities or job assignments of the applicant while in training or employed; and
- (7) Tests or examinations performed by the applicant while in training or employed; and
- (8) Signature of the laboratory director or medical director and date of signature.

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1206.5, 1208, 1209, 1210, 1260.3, and 1261, Business and Professions Code.

**ARTICLE 1.8. EXAMINATIONS FOR LICENSURE AND CERTIFICATION AND
CERTIFYING ORGANIZATIONS.**

**Section 1034. Examinations Administered by the Department for Licensure
Purposes.**

- (a) Applicants for licensure under Chapter 3 as a medical laboratory technician as specified in section 1030.6, clinical laboratory scientist as specified in sections 1030.7

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and 1030.8, clinical laboratory scientist limited to a specialty or subspecialty as specified in sections 1030.10, 1030.15, 1030.16, and 1030.17, cytotechnologist as specified in sections 1061 and 1062, or another category of license established by the Department in regulation, must achieve satisfactory performance on an examination on California clinical laboratory law provided by the Department.

(1) "Satisfactory performance" on this examination means correctly answering at least seven of the ten questions on the examination.

(2) An applicant who fails to pass the examination is allowed to retake the examination as many times as needed to achieve satisfactory performance.

(b) Applicants for licensure under Chapter 3 as bioanalysts as specified in section 1030.20, clinical chemists as specified in section 1030.21, clinical microbiologists as specified in section 1030.21, clinical toxicologists as specified in section 1030.21, clinical cytogeneticists as specified in section 1030.25, clinical genetic molecular biologists as specified in section 1030.26, oral pathology laboratory directors as specified in section 1030.27, histocompatibility laboratory directors as specified in section 1209.1 of the Business and Professions Code, or another clinical laboratory master's or doctoral degree specialist category established by the Department in regulation, must achieve satisfactory performance on an in-person examination provided by the Department.

(1) The Department must select a panel to conduct the in-person examination that includes Department staff and clinical laboratory bioanalysts or clinical laboratory master's or doctoral degree specialists not employed by the Department who are licensed under Chapter 3.

(2) "Satisfactory performance" on the in-person examination means providing correct responses for at least 70 percent of the questions on the examination, as determined by a panel selected by the Department.

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(3) An applicant who fails to pass the examination is allowed to retake the examination once.

(4) An applicant who fails to pass the examination two times is not eligible to take the examination a third time but may reapply for licensure at least one year after the date of the second examination and take the examination up to two times to satisfy the requirements for the new application.

Credits

Note: Authority cited: Section 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1208, 1209.1, 1260, 1260.3, 1261, 1261.5, 1261.6, and 1264, Business and Professions Code; and Section 120580, Health and Safety Code.

ARTICLE 2. TRAINING PROGRAMS.

**Section 1035.1. Medical Laboratory Technician Training Program Standards
Requirements for a Training School or Program for Medical Laboratory
Technicians.**

~~(a) In order to be eligible for approval by the department, a medical laboratory technician training program shall be offered by either a:~~

~~(1) California licensed clinical laboratory; or~~

~~(2) Accredited college or university in the United States of America; or~~

~~(3) United States of America military medical laboratory specialist program of at least 26 weeks duration; or~~

~~(4) Laboratory owned and operated by the United States of America.~~

~~(b) The program director of a medical laboratory technician training program shall be a physician and surgeon licensed under Chapter 5, or a doctoral scientist, clinical~~

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~~laboratory bioanalyst, clinical laboratory scientist or clinical laboratory specialist licensed under Chapter 3. The program director shall be responsible for the content, quality and conduct of the training program and shall:~~

~~(1) Employ instructors who are physicians and surgeons licensed under chapter 5; doctoral scientists, clinical laboratory bioanalysts, clinical laboratory scientists, or clinical laboratory specialists licensed under chapter 3; medical laboratory technicians with five years practical experience licensed under Chapter 3; or public health microbiologists certified pursuant to Health and Safety Code Section 101160.~~

~~(2) Assure that training includes at least 26 weeks, consisting of at least 1040 hours, of instruction and practical experience in moderate complexity testing in chemistry, including routine chemistry, urinalysis, endocrinology and toxicology; hematology; microbiology, including bacteriology, mycobacteriology, mycology, parasitology and virology; and immunology, including syphilis serology and general immunology. The training shall include at least 160 hours each in chemistry, hematology, microbiology and immunology.~~

~~(3) Provide didactic training in:~~

~~(A) Pre-analytical skills including phlebotomy, specimen processing, reagent preparation, and infection control, as specified in Section 1035.1(e) and (f); and~~

~~(B) Analytical skills required for performing tests of waived or moderate complexity, including quality control, test calibration, quality assurance, legal requirements for documentation of testing, data storage and retrieval, safety and standard precautions, troubleshooting, preventive maintenance, reagent preparation and storage; and~~

~~(C) Post-analytical skills such as knowledge of factors that influence test results and the ability to access and verify the validity of patient test results through review of quality control values prior to reporting patient test results; and~~

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~~(D) Test methods commonly used in chemistry, hematology, microbiology and immunology, including clinical significance of test results, how the tests interrelate and how the tests impact diagnosis and treatment, quality assessment of test results, information processing and regulatory compliance in state and federal law.~~

~~(4) Provide practical training in:~~

~~(A) Phlebotomy that shall include 40 hours instruction and successful completion of a minimum of 10 skin punctures and 50 venipunctures, as specified in Section 1035(f); and~~

~~(B) Instruction and practical experience in the use of instruments; and~~

~~(C) Preventive maintenance and problem solving malfunctions of instruments; and~~

~~(D) Knowledge of instrument and test parameters to assess reasonableness of results; and~~

~~(E) Validation of moderate complexity test methods and clinical correlation of test results.~~

~~(c) A medical laboratory technician training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall maintain a copy of this certificate for at least five years. This certificate shall be signed by the director of the program and shall include:~~

~~(1) Name and address of the training program; and~~

~~(2) Name of the student; and~~

~~(3) Statement of satisfactory completion of the program; and~~

~~(4) Dates that training began and ended.~~

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~~(d) A program approved to train medical laboratory technicians shall maintain records of its students for at least five years and shall make available to the department documentation of the students successfully completing their training.~~

~~(e) A medical laboratory technician training program seeking approval from the department shall provide documentation to substantiate that its program objectives meet training criteria stated in this section.~~

~~(f) A medical laboratory technician training program shall be allowed to document program compliance with the requirements of this section for a period dating up to four years prior to their initial application, after the date of implementation of these standards. The program shall document that, during the time preceding initial approval, the training program met the standards pursuant to Section 1035.1(a) and (b).~~

~~(g) A complete application for a medical laboratory technician training program shall include the following:~~

~~(1) The name and address of the primary training program, including city, state, county and zip code; telephone number, FAX number and e-mail address; and~~

~~(2) The location(s) of all sites where training will be conducted, including city, state and zip code; and~~

~~(3) The name(s) and qualifications of the person(s) directing and instructing in the program including a copy of current licensure for each person. Training programs in the United States of America but outside California shall provide evidence that the director(s) and instructor(s) substantially meet this licensure requirement by documenting inclusion, licensure or certification in a class of personnel similar to those required in Chapter 3 or requiring equivalent standards; and~~

~~(4) Dates the training program was conducted if prior approval is requested as specified in Section 1035.1(f); and~~

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~~(5) The didactic curriculum listing each class or topic with instructional objectives, the instructor(s) and the amount of time allocated for each class or topic, pursuant to Section 1035.1(b)(3); and~~

~~(6) Documentation of practical training in pre-analytical, analytical and post-analytical skills, including instructor(s) and hours spent at each activity, list of equipment, supplies and materials used pursuant to Section 1035.1(b)(4); and~~

~~(7) The signature(s) of the program director(s), telephone number(s) and date of application.~~

~~(h) A medical laboratory technician training program approval shall be valid for a four-year period. To apply for renewal, the training program shall file an application at least 120 days prior to the end of the approval period providing the following:~~

~~(1) The name and address of the primary training program, including city, state, county and zip code, telephone number, FAX number and e-mail address; and~~

~~(2) The name, address, and telephone number(s) of the director(s) and instructor(s), providing documentation of their current licensure; and~~

~~(3) Any changes in training locations, didactic and practical instruction, course objectives, equipment, supplies and materials, that shall be made to the program from that approved in the previous application; and~~

~~(4) A listing of all students who completed its program and the total number of students who enrolled in its program during the previous approval period; and~~

~~(5) The signature(s) of the program director(s) and the date of application for renewal.~~

~~(i) The training program shall notify the department in writing of any change(s) in the information and materials required by Section 1035.1(b) through (d) within 30 days after the change(s) has occurred.~~

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~~(j) Failure to meet and maintain the requirements of this section shall be good cause for denial or revocation of approval by the department.~~

(a) A person operating a school or conducting a program to train persons for medical laboratory technician (MLT) licensure under Chapter 3 must submit an application for approval of the school or program as specified in section 1035.10 and is subject to renewal of approval as specified in section 1035.10.

(b) To be approved, a program to train persons for MLT licensure must meet the requirements of this section and be offered by one of the following programs or institutions:

(1) A California-licensed clinical laboratory performing tests or examinations categorized as moderate complexity under CLIA; or

(2) An accredited college or university in the United States with affiliated clinical laboratories performing tests or examinations categorized as moderate complexity under CLIA; or

(3) A program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) with affiliated clinical laboratories that provide at least six months of instruction in the performance of tests or examinations categorized as moderate complexity under CLIA; or

(4) A United States military medical laboratory specialist program of at least 26 weeks duration; or

(5) A laboratory owned and operated by the United States government performing tests or examinations categorized as moderate complexity under CLIA.

(c) A training program must be directed by a training program director who is:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code; or

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(2) A master's or doctoral degree specialist licensed under Chapter 3; or

(3) A clinical laboratory bioanalyst licensed under Chapter 3; or

(4) A clinical laboratory scientist (CLS) or CLS limited to a specialty or subspecialty licensed under Chapter 3; or

(5) For training programs located outside California, a person with equivalent qualifications as specified in section 1039.2.

(d) A training program director must fulfill each of the following duties:

(1) Be responsible for the content, quality, and administration of the training program; and

(2) Provide for didactic instruction and clinical practical training in the analytical techniques required to perform clinical laboratory tests or examinations categorized as moderate complexity under CLIA; and

(3) Ensure that each licensed person providing direct and responsible supervision to a trainee pursuant to section 1206 of the Business and Professions Code is competent in the clinical laboratory tests or examinations the person supervises or, for training programs located outside California, ensure that each person providing supervision has licensure or qualifications equivalent to those specified in Chapter 3, pursuant to section 1039.2; and

(4) Maintain a staffing level that ensures that a licensed person provides direct and responsible supervision pursuant to section 1206 of the Business and Professions Code to no more than two trainees at one time; and

(5) Notify the Department in writing within 30 days of the date of initiation, completion, extension, or interruption of training for each trainee; and

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(6) Notify the Department in writing of any change in the information and material provided on the application and obtain approval for any change at least 30 days prior to making the change; and

(7) Notify the Department in writing of a change of director or change of instructor and obtain approval within 30 days of the change; and

(8) Ensure that all trainees in a training program are licensed as MLT trainees as specified in section 1030.5 prior to the start of training; and

(9) Require that all persons providing didactic instruction, practical training, or direct and responsible supervision meet qualifications as specified in this section; and

(10) Require through measurable criteria that all trainees master training and instruction objectives; and

(11) Maintain trainee records for at least five years; and

(12) Ensure that documentation of the students successfully completing their training is made available to the Department.

(e) A person providing didactic instruction to program trainees must be:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code, if the training program is located in California, or a physician and surgeon with equivalent qualifications as specified in section 1039.2, if the training program is located in the United States outside California; or

(2) A master's or doctoral degree specialist, clinical laboratory bioanalyst, CLS, CLS limited to a specialty or subspecialty, or MLT licensed under Chapter 3, if the training program is located in California, or a person with equivalent qualifications as specified in section 1039.2, if the training program is located in the United States outside California, who is limited to the work scope of the person's license category; or

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(3) A certified phlebotomy technician certified under Chapter 3 with at least three years of experience in the previous five years, if the training program is located in California, or a person with equivalent qualifications as specified in section 1039.2, if the training program is located in the United States outside California, who is limited to providing instruction in phlebotomy; or

(4) A public health microbiologist certified pursuant to section 101160 of the Health and Safety Code, who is limited to providing instruction in microbiology or immunology; or

(5) Additional instructors designated by the program director, whose total instruction time may not exceed 10 percent of total training time; or

(6) A person with an earned baccalaureate, master's, or doctoral degree appropriate to the specialty or subspecialty of instruction.

(f) A person providing instruction to program trainees during practical training must be any of the persons listed in subdivisions (e) (1) through (5).

(g) A person providing direct and responsible supervision pursuant to section 1206 of the Business and Professions Code to program trainees during practical training must be competent in the clinical laboratory tests or examinations the person supervises and must be:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code, if the training program is located in California, or a physician and surgeon with equivalent qualifications as specified in section 1039.2, if the training program is located in the United States outside California; or

(2) A master's or doctoral degree specialist, clinical laboratory bioanalyst, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3, if the training program is located in California, or a person with equivalent qualifications as specified in section 1039.2, if the training program is located in the United States outside California, who is limited to the work scope of the person's license category.

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(3) A person providing direct and responsible supervision to program trainees during practical training may provide direct and responsible supervision to no more than two trainees at one time.

(h) A training program must establish and provide to the Department a training schedule for at least six months of activities that include didactic instruction and practical training. The program must address pre-analytical, analytical, and post-analytical components of clinical laboratory science.

(1) Didactic instruction must include instruction and testing in each of the following subjects:

(A) Pre-analytical skills including phlebotomy, specimen processing, reagent preparation, and infection control, as specified in section 1035; and

(B) Analytical skills required for performing tests of moderate complexity, including quality control, test calibration, test validation, quality assurance, legal requirements for documentation of testing, data storage and retrieval, safety, and standard precautions, troubleshooting, preventive maintenance, reagent preparation and storage; and

(C) Post-analytical skills, including knowledge of factors that influence test results and the ability to access and verify the validity of patient test results through review of quality control values prior to reporting patient test results; and

(D) Test methods commonly used in the specialties of chemistry, microbiology, diagnostic immunology, hematology, and immunohematology, including clinical significance of test results, how clinical tests interrelate, the impact of tests on diagnosis and treatment, quality assessment of test results, information processing, and regulatory compliance with state and federal law; and

(E) Didactic instruction may also be given in performance of tests categorized as waived under CLIA; and

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(F) Compliance with laws affecting clinical laboratories including California clinical laboratory law, CLIA, the federal Health Insurance Portability and Accountability Act, regulations of the California Division of the Occupational Safety and Health Administration of the Department of Industrial Relations, and local ordinances; and

(G) Test reporting, data handling, and patient confidentiality requirements; and

(H) Professional standards and ethics.

(2) Practical training must be obtained in a clinical laboratory certified under CLIA and must consist of at least 160 hours of practical training in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of practical training in immunology and immunohematology, for a total of at least 640 hours. Practical training must include each of the following subjects:

(A) At least 80 hours of training in blood typing of moderate complexity, such as automated ABO/Rh testing and antibody screen testing; and

(B) Practical training in phlebotomy that must include 40 hours instruction and successful completion of at least 10 skin punctures and 50 venipunctures, as specified in section 1035; and

(C) Instruction and practical training in the use of instruments; and

(D) Preventive maintenance and problem-solving malfunctions of instruments; and

(E) Knowledge of instrument and test parameters to assess test results; and

(F) Validation of moderate complexity test methods and clinical correlation of test results.

(G) No more than 20 percent of training may be performance of clinical laboratory tests or examinations categorized as waived under CLIA and/or training in phlebotomy.

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(i) A training program must provide a certificate of completion to its trainees upon successful completion of the program.

(1) The certificate must be signed by the program director and must include:

(A) Name and address of the training program; and

(B) Name and trainee license number of the trainee; and

(C) A statement documenting that the trainee completed and met all requirements of the training program; and

(D) Dates training began and ended; and

(2) The program must maintain a copy of the certificate for at least five years.

(j) A training program must maintain records of its trainees for at least five years and must make available to the Department documentation of the students successfully completing their training.

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; and ~~Section Sections~~ 100275 and 131200, Health and Safety Code. Reference: Sections ~~1206.5, 1208, 1209, 1222, 1222.5, 1242, 1246, 1260.3, 1269, and 1286 and 1300~~, Business and Professions Code.

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...

(d) The ratio of licensed clinical laboratory personnel to trainees shall be no less than 2:1. A person providing direct and responsible supervision to program trainees during practical training pursuant to section 1206 of the Business and Professions Code:

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(1) Must be competent in the clinical laboratory tests or examinations the person supervises; and

(2) May provide direct and responsible supervision to no more than two trainees at one time.

...

Credits

Note: Authority cited: Sections 1222.5 and 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: ~~Sections 1208 and Section 1222.5~~, Business and Professions Code.

Section 1035.3. Requirements for a Training School or Program for Clinical Laboratory Scientists Who Meet Requirements for Medical Laboratory Technician Licensure.

(a) A person operating a school or conducting a program to train persons who are licensed as a medical laboratory technician (MLT) or who meet requirements for licensure as an MLT, pursuant to Chapter 3, for clinical laboratory scientist (CLS) licensure pursuant to Chapter 3 must submit an application for approval of the school or program as specified in section 1035.10 and is subject to renewal of approval as specified in section 1035.10.

(b) To be approved, a program to train persons who are licensed as an MLT or who meet requirements for licensure as an MLT, pursuant to Chapter 3, for CLS licensure must meet the requirements of this section and be offered by one of the following programs or institutions:

(1) A California-licensed clinical laboratory performing tests or examinations categorized as moderate and high complexity under CLIA; or

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(2) An accredited college or university in the United States with affiliated clinical laboratories performing tests or examinations categorized as moderate and high complexity under CLIA.

(c) A training program must be directed by a training program director who is:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code; or

(2) A master's or doctoral degree specialist licensed under Chapter 3; or

(3) A clinical laboratory bioanalyst licensed under Chapter 3; or

(4) A CLS or CLS limited to a specialty or subspecialty licensed under Chapter 3.

(d) A training program director must fulfill each of the following duties:

(1) Be responsible for the content, quality, and administration of the training program; and

(2) Provide for didactic instruction and clinical practical training in the analytical techniques required to perform clinical laboratory tests or examinations categorized as moderate and high complexity under CLIA; and

(3) Ensure that each licensed person providing direct and responsible supervision to a trainee pursuant to section 1206 of the Business and Professions Code is competent in the clinical laboratory tests or examinations the person supervises; and

(4) Maintain a staffing level that ensures that a licensed person provides direct and responsible supervision pursuant to section 1206 of the Business and Professions Code to no more than two trainees at one time; and

(5) Notify the Department in writing within 30 days of the date of initiation, completion, extension, or interruption of training for each trainee; and

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(6) Notify the Department in writing of any change in the information and material provided on the application and obtain approval for any change at least 30 days prior to making the change; and

(7) Notify the Department in writing of a change of director or change of instructor and obtain approval within 30 days of the change; and

(8) Ensure that all trainees in a training program are licensed as CLS trainees as specified in section 1030.5 prior to the start of training; and

(9) Require that all persons providing didactic instruction, practical training, or direct and responsible supervision meet qualifications as specified in this section; and

(10) Require through measurable criteria that all trainees master training and instruction objectives; and

(11) Maintain trainee records for at least five years; and

(12) Ensure that documentation of the students successfully completing their training is made available to the Department.

(e) A person providing didactic instruction to program trainees must be:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code; or

(2) A master's or doctoral degree specialist, clinical laboratory bioanalyst, CLS, CLS limited to a specialty or subspecialty, or MLT licensed under Chapter 3, who is limited to the work scope of the person's license category; or

(3) A certified phlebotomy technician certified under Chapter 3 with at least three years of experience in the previous five years, who is limited to providing instruction in phlebotomy; or

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(4) A public health microbiologist certified pursuant to section 101160 of the Health and Safety Code, who is limited to providing instruction in microbiology or immunology; or

(5) Additional instructors designated by the program director, whose total instruction time may not exceed 10 percent of total training time; or

(6) A person with an earned baccalaureate, master's, or doctoral degree appropriate to the specialty or subspecialty of instruction.

(f) A person providing instruction to program trainees during practical training must be any of the persons listed in subdivisions (e) (1) through (5).

(g) A person providing direct and responsible supervision pursuant to section 1206 of the Business and Professions Code to program trainees during practical training must be competent in the clinical laboratory tests or examinations the person supervises and must be:

(1) A physician and surgeon licensed under chapter 5 of the Business and Professions Code; or

(2) A master's or doctoral degree specialist, clinical laboratory bioanalyst, CLS, or CLS limited to a specialty or subspecialty licensed under Chapter 3, who is limited to the work scope of the person's license category; and

(3) A person providing direct and responsible supervision to program trainees during practical training may provide direct and responsible supervision to no more than two trainees at one time.

(h) A training program must establish and provide to the Department a training schedule for at least six months of activities that include didactic instruction and practical training. The program must address pre-analytical, analytical, and post-analytical components of clinical laboratory science.

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(1) Didactic instruction must include instruction and testing in each of the following subjects:

(A) Principles and theory underlying clinical laboratory tests or examinations performed during practical training in clinical laboratory practice; and

(B) Clinical significance and application of clinical laboratory tests or examinations; and

(C) An understanding of laboratory test results or examinations and the factors that influence their accuracy, precision, and clinical correlation with other test results; and

(D) Principles and practices of quality assurance, quality control, and laboratory statistics that ensure test accuracy; and

(E) Problem solving of pre-analytical, analytical, and post-analytical procedures, taking corrective action for test failure, avoiding adverse events, and assuring continuous test improvement; and

(F) Laboratory safety and hygiene, infection control, standard precautions, and waste disposal; and

(G) Principles of laboratory management; and

(H) Compliance with laws affecting clinical laboratories including California clinical laboratory law, CLIA, the federal Health Insurance Portability and Accountability Act, regulations of the California Division of the Occupational Safety and Health Administration of the Department of Industrial Relations, and local ordinances; and

(I) Test reporting, data handling, and patient confidentiality requirements; and

(J) Laboratory computer applications and information security; and

(K) Professional standards and ethics.

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(2) Practical training must be obtained in a clinical laboratory certified under CLIA and must consist of at least four weeks of practical training in each of the following subjects, for a total of at least 24 weeks:

(A) Chemistry, including routine chemistry, urinalysis, clinical microscopy, endocrinology, and toxicology; and

(B) Microbiology, including bacteriology, mycobacteriology, mycology, parasitology, virology, and infectious disease testing; and

(C) Diagnostic immunology, including syphilis serology and general immunology; and

(D) Immunohematology, including ABO group and Rh type, unexpected antibody detection, compatibility testing, and antibody identification; and

(E) Hematology, including routine hematology and coagulation; and

(F) One or more of the following subjects:

1. One or more other areas, such as histocompatibility, cytogenetics, genetic molecular biology; or

2. Phlebotomy and clinical laboratory practice; or

3. Laboratory administration including practical training in quality control, quality assurance, performance improvement, safety, standard precautions, and reagent control and storage, the use of laboratory instruments and information technology systems; and the assessment of instruments and test parameters for clinical correlation of test results; or

4. Review, as determined by the program director.

(G) No more than 20 percent of training may be performance of clinical laboratory tests or examinations categorized as waived under CLIA and/or training in phlebotomy.

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(i) A training program must provide a certificate of completion to its trainees upon successful completion of the program.

(1) The certificate must be signed by the program director and must include:

(A) Name and address of the training program; and

(B) Name and trainee license number of the trainee; and

(C) A statement documenting that the trainee completed and met all requirements of the training program; and

(D) Dates training began and ended; and

(2) The program must maintain a copy of the certificate for at least five years.

(i) A training program must maintain records of its trainees for at least five years and must make available to the Department documentation of the students successfully completing their training.

Credits

Note: Authority cited: Section 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections-1222, 1222.5, 1242, 1261, and 1286, Business and Professions Code.