

Clinical Laboratory Personnel Standards: Trainee, Medical Laboratory Technician, Medical Laboratory Technician Transition to Clinical Laboratory Scientist
CDPH-20-007
June 8, 2023
15-day Availability

**Methodology to Indicate Changes to:
DPH-20-007**

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The proposed changes for comment that are the subject of this second 15-day public comment period are indicated as follows:

- Deleted text is indicated by single strike-through (~~strike-through~~) and highlighted in grey.
- Additions to the regulations text are indicated by single underline (underline) and highlighted in grey.

**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**

Adopt Article 1 to read as follows:

Adopt Section 1029 to read as follows:

Section 1029. General Definitions.

No change to text.

Adopt Article 1.5 to read as follows:

Adopt Section 1030 to read as follows:

Section 1030. Certification of Phlebotomy Technicians.

No change to text.

Adopt Section 1030.5 to read as follows:

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

(a) through (a)(2)(A)

No change to text.

(a)(2)(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 accredited college or university with courses pertinent to clinical laboratory science as determined by the department ~~in a biological, chemical, or physical science, or~~

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~~clinical laboratory science, medical laboratory science, or medical laboratory technology~~; and

(a)(2)(C) through (b)(1)(A)

No change to text.

(b)(1)(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 determined by the department ~~in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology~~; 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.

(b)(2) through (c)(1)(B)

No change to text.

(c)(1)(C) Document successful completion of a baccalaureate, or an equivalent degree as defined in section 1029, from an accredited college or university with courses

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~~pertinent to clinical laboratory science as determined by the department in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology;~~ 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.

(c)(2) through (d)(1)(A)

No change to text.

(d)(1)(B) Document successful completion of a baccalaureate, or an 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, immunochemistry, 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 determined by the department in a biological, chemical, or

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~~physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology; 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 determined by the department ~~in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology, or a field related to genetics; and~~

(d)(1)(C) and (d)(1)(C)1.

No change to text.

(d)(1)(C)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;

(d)(1)(C)3 through (f)(3)

No change to text.

Credits

Note: Authority cited: Sections 100275 and 131200, Health and Safety Code; and Sections 1208 and 1224, Business and Professions Code. Reference: Sections 1205, 1261, 1263, and 1301, Business and Professions Code.

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Adopt Section 1030.6 to read as follows:

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

(a) through (a)(1)

No change to text.

(a)(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 determined by the department ~~in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology;~~ and

(a)(3) through (e)

No change to text.

Credits

NOTE: Authority cited: Section 1224, Business and Professions Code; and Sections 100275 and 131200, Health and Safety Code. Reference: Sections 1206.5, 1242, 1260.3, 1275, and 1300, Business and Professions Code.

Adopt Section 1030.7 to read as follows:

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

Introduction and (a)

No change to text.

(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 clinical laboratory science as determined by the department ~~in a biological,~~

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~~chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology,~~ plus one year as a clinical laboratory technologist trainee or the equivalent as 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

(A) Quantitative analysis or analytical chemistry; and

(B) Clinical chemistry or biochemistry; and

(2) 16 semester or equivalent quarter credit hours of biological science, including medical, clinical, or pathogenic microbiology, hematology, and immunology; and

(3) 3 semester or equivalent quarter credit hours of physics, math, or statistics; or

(c) and (c)(1)

No change to text.

(c)(2) 16 semester or equivalent quarter credit hours of biological science including medical, clinical, or pathogenic microbiology, hematology, and immunology; and

(c)(3)

No change to text.

Credits

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

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Adopt Section 1030.8 to read as follows:

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

(a) through (a)(2)

No change to text.

(a)(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 determined by the department in a biological, chemical, or physical science, or clinical laboratory science, medical laboratory science, or medical laboratory technology; and

(4) Complete at least

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

1. Quantitative analysis or analytical chemistry; and

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.

(a)(5) through (c)(3)(b)

No change to text.

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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.

Adopt Section 1030.16 to read as follows:

Section 1030.16. Licensure and Work Scope of Clinical Cytogeneticist Scientists.

No change to text.

Adopt Section 1030.17 to read as follows:

Section 1030.17. Licensure and Work Scope of Clinical Genetic Molecular Biologist Scientists.

No change to text.

Adopt Section 10301 to read as follows:

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

No change to text.

Adopt Section 1032 to read as follows:

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

Section (a) through (d)(1)

No change to text.

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(d)(2) Courses may include: Cytology, Hematology, Immunology, Clinical Chemistry, Immunoematology, 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.

Adopt Section 1032.5 to read as follows:

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

No change to text.

Adopt Article 1.8 to read as follows:

Adopt Section 1034 to read as follows:

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

No change to text.

Adopt Article 2 to read as follows:

Adopt Section 1035.1 to read as follows:

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

No change to text.

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Adopt Section 1035.2 to read as follows:

Section 1035.1 Requirements for a Training School or Program for Clinical Laboratory Scientists.

No change to text.

Adopt Section 1035.3 to read as follows:

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

No change to text.