

Supplemental Statement of Reasons

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations, and they are discussed below. These changes are either initiated by the Department or are in response to comments that were received during the 45-day public comment period that ended on January 19, 2024.

The Department will provide responses to all comments in the Final Statement of Reasons as is required.

DEFINITIONS

Section 1029

Subsection (a)

In response to public comment, the Department proposes to correct the definition of “Accredited college or university” by changing the phrase “Council on Post-Secondary Accreditation” to read “Council for Higher Education Accreditation.”

LICENSURE AND CERTIFICATION OF CLINICAL LABORATORY PERSONNEL

Section 1030.5

Subsection (a)(1)

The Department proposes to add a new paragraph to clarify the requirement for trainee licensure for medical laboratory technician (MLT) trainees and to specify the beginning date of this requirement as January 1, 2026. This amendment will allow trainees who are already enrolled in a training program when the regulations are adopted to complete their program without having to obtain the new license.

Subsection (a)(2)

Re-number existing subsection (a)(1) to subsection (a)(2).

Subsection (a)(2)(B)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.”

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Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours. This change is proposed throughout the regulations text.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (a)(2)(C)

In response to public comment, the Department proposes to change the requirement for coursework in physical sciences to coursework in chemical sciences to correct the text. This correction is consistent with the specification of “6 semester or equivalent quarter hours in chemistry” in this paragraph.

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (a)(2)(D)

In response to public comment, the Department proposes revised language to clarify that an applicant for a trainee license must have completed six semester or equivalent quarter credit hours in chemistry; and six semester or equivalent quarter credit hours in biology, as specified in paragraphs (a)(2)(C)1. and 2., but not all 36 credit hours of coursework specified in paragraph (C).

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each

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subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (a)(3)

Renumber existing subsection (a)(2) to subsection (a)(3).

In response to public comments, the Department proposes revisions to subsection (a)(3) and similar language in other sections regarding moderate complexity ABO/Rh type testing for clarity. In the general list of testing specialties in this section, the Department proposes to omit the reference to ABO and Rh type testing, because this testing is not a specialty, but a set of tests within the specialty of immunohematology. The Department also proposes a correction to a typographical error, to change “immunology” to “immunohematology.” More specific requirements about types of testing within the specialties are included in Section 1035.1, Requirements for a Training School for Program for Medical Laboratory Technicians and in Section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician. Those sections will specify the requirement for at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology.

Subsection (a)(4)

Renumber existing subsection (a)(3) to subsection (a)(4).

Subsection (b)(1)(B)

The Department proposes to add minor punctuation and grammatical changes to the reference to equivalent degrees for clarity.

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (b)(1)(C)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (b)(1)(C)1.

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (b)(1)(C)2.

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Subsection (c)(1)(C)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (c)(1)(D)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each

subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (c)(1)(D)1.

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (c)(1)(D)2.

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Subsection (d)(1)(B)(1.-2.)

The Department proposes to add minor punctuation and grammatical changes to the reference to equivalent degrees for clarity.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (d)(1)(C)(1.-7.)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (d)(1)(C)1.

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (d)(1)(C)2.

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Section 1030.6

Subsection (a)(2)

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (a)(3)

In response to public comment, the Department proposes to change the requirement for coursework in physical sciences to coursework in chemical sciences to correct the text. This correction is consistent with the specification of “6 semester or equivalent quarter hours in chemistry” in this paragraph.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (a)(4)

In response to public comments, the Department proposes to correct an oversight and add COLA to the list of accrediting organizations acceptable to the Department for accreditation of international laboratories.

Subsection (a)(4)(A)

The Department proposes to add language to clarify that a NAACLS-accredited training program must provide at least six months of training, for consistency with the general requirement that MLT training programs offer at least six months of training.

Subsection (a)(4)(E)

The Department proposes a minor grammatical correction for clarity, changing the phrase “experience ... that ... *performs* tests or examinations” to read “experience ... that ... *includes the performance of* tests or examinations.”

In response to public comments, the Department proposes revisions to subsection (a)(4)(E) and similar language in other sections regarding moderate complexity ABO/Rh type testing for clarity. In the general list of testing specialties in this paragraph, the Department proposes to omit the reference to ABO and Rh type testing, because this testing is not a specialty, but a set of tests within the specialty of immunohematology. More specific requirements about types of testing within the specialties are included in paragraph (a)(4)(E)2. and in Section 1035.1, Requirements for a Training School for Program for Medical Laboratory Technicians. Those sections will specify the requirement for at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology.

Subsection (a)(4)(E)2.

In response to public comments, the Department proposes revisions to language regarding the number of hours of required training in various testing specialties. The Department proposes to require a total of at least 640 hours, including at least 160 hours of testing in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of testing that includes testing in the specialties of immunology and immunohematology. This will afford programs flexibility when devising their training schedules.

The Department is proposing to clarify that training in the specialties of immunology and immunohematology must include the performance of at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology. Instruction in ABO and Rh typing is necessary because the MLT scope of practice was broadened to include such testing by AB 2281 (Irwin, Chapter 235, Statutes of 2018). This rulemaking incorporates instruction in such testing to ensure that MLTs are competent to perform blood typing of moderate complexity authorized within their scope of work.

Subsection (a)(4)(F)

The Department proposes a minor grammatical correction for clarity, changing the phrase “experience ... that ... *performs* tests or examinations” to read “experience ... that ... *includes the performance of* tests or examinations.”

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In response to public comments, the Department proposes revisions to subsection (a)(4)(F) and similar language in other sections regarding moderate complexity ABO/Rh type testing for clarity. In the general list of testing specialties in this paragraph, the Department proposes to omit the reference to ABO and Rh type testing, because this testing is not a specialty, but a set of tests within the specialty of immunohematology. More specific requirements about types of testing within the specialties are included in paragraph (a)(4)(F)2. and in Section 1035.1, Requirements for a Training School for Program for Medical Laboratory Technicians. Those sections will specify the requirement for at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology.

Subsection (a)(4)(F)2.

In response to public comments, the Department proposes revisions to language regarding the number of hours of required training in various testing specialties. The Department proposes to require a total of at least 640 hours, including at least 160 hours of testing in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of testing that includes testing in the specialties of immunology and immunohematology. This will afford programs flexibility when devising their training schedules.

The Department is proposing to clarify that training in the specialties of immunology and immunohematology must include the performance of at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology. Instruction in ABO and Rh typing is necessary because the MLT scope of practice was broadened to include such testing by AB 2281 (Irwin, Chapter 235, Statutes of 2018). This rulemaking incorporates instruction in such testing to ensure that MLTs are competent to perform blood typing of moderate complexity authorized within their scope of work.

Subsection (b)(4)

In response to public comment, the Department proposes to amend this subsection to add language that allows a laboratory director to designate competency evaluation of licensed laboratory staff to a person who qualifies as a technical consultant or technical supervisor under CLIA for the type and complexity of testing, consistent with the authorization in BPC subsection 1209(g).

Section 1030.7

In response to public comment, the Department proposes to change the title “clinical laboratory technologist” to “clinical laboratory scientist.” This aligns with the proposed change to the title of this section.

Subsection (a)

The Department proposes to add minor punctuation and grammatical changes to the reference to equivalent degrees for clarity.

Subsection (b)

The Department proposes to add minor punctuation and grammatical changes to the reference to equivalent degrees for clarity.

Subsection (b)(1)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (b)(2)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Subsection (b)(3)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (c)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Subsection (c)(1)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (c)(2)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Subsection (c)(3)

In response to public comment, the Department proposes to standardize all references to educational credit hours to read “semester or equivalent quarter credit hours.” Consistent use of this phrase will clarify the number of credit hours required in each subsection using terminology consistent with the definition of “credit hour” added in this rulemaking and clarify that semester credit hours differ from quarter credit hours.

Section 1030.8

Subsection (a)(3)

The Department proposes to add minor punctuation and grammatical changes to the reference to equivalent degrees for clarity.

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Subsection (a)(4)(A)

In response to public comment, the Department proposes to revise this subsection to require coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (a)(4)(B)

In response to public comments, the Department proposes to revise the coursework requirements to specify that the biology coursework required in this subsection must include coursework in medical microbiology.

Section 1030.16

No changes to initial proposal

Section 1030.17

No changes to initial proposal

Section 1031

No changes to initial proposal

Section 1032

Subsection (d)(1)

In response to public comment, the Department proposes to add degrees in medical laboratory science and medical laboratory technology along with clinical laboratory science, to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations. This change will clarify that any of these degrees is acceptable for licensure purposes.

Section 1032.5

No changes to initial proposal

**EXAMINATIONS FOR LICENSURE AND CERTIFICATION AND
CERTIFYING ORGANIZATIONS**

Section 1034

No changes to initial proposal

TRAINING PROGRAMS

Section 1035.1

Subsection (a)(3)

The Department proposes to add language to clarify that a NAACLS-accredited training program must provide at least six months of training, for consistency with the general requirement that MLT training programs offer at least six months of training.

Subsection (h)(1)(D)

In response to public comments, the Department proposes revisions to subsection (h)(1)(D) and similar language in other sections regarding moderate complexity ABO/Rh type testing for clarity. In the general list of testing specialties in this section, the Department proposes to omit the reference to ABO and Rh type testing, because this testing is not a specialty, but a set of tests within the specialty of immunohematology. The Department also proposes a correction to a typographical error, to change “immunology” to “immunohematology.” More specific requirements about types of testing within the specialties are included in Subsection (h)(2) and in Section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician. Those sections will specify the requirement for at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology.

Subsection (h)(2)

In response to public comments, the Department proposes revisions to language regarding the number of hours of required training in various testing specialties. The Department proposes to require a total of at least 640 hours, including at least 160 hours of testing in each of the specialties of chemistry, microbiology, and hematology, and at least 160 hours of testing that includes testing in the specialties of immunology and immunohematology. This will afford programs flexibility when devising their training schedules.

Subsection (h)(2)(A)

The Department is proposing to add subsection (A) to clarify that practical training must include the performance of at least 80 hours of blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing within the specialty of immunohematology.

Instruction in ABO and Rh typing is necessary because the MLT scope of practice was broadened to include such testing by AB 2281 (Irwin, Chapter 235, Statutes of 2018). This rulemaking incorporates instruction in such testing to ensure that MLTs are competent to perform blood typing of moderate complexity authorized within their scope of work.

Subsection (h)(2)(B)

Re-number existing subsection (h)(2)(A) to subsection (h)(2)(B)

Subsection (h)(2)(C)

Renumber existing subsection (h)(2)(B) to subsection (h)(2)(C)

Subsection (h)(2)(D)

Renumber existing subsection (h)(2)(C) to subsection (h)(2)(D)

Subsection (h)(2)(E)

Renumber existing subsection (h)(2)(D) to subsection (h)(2)(E)

Subsection (h)(2)(F)

Renumber existing subsection (h)(2)(E) to subsection (h)(2)(F)

Subsection (h)(2)(G)

Renumber existing subsection (h)(2)(F) to subsection (h)(2)(G)

Section 1035.2

No changes to initial proposal

Section 1035.3

Subsection (h)(2)(F)

In response to public comments, the Department proposes to add the phrase “or more” to the requirement that training include “one of the following subjects,” to clarify that the program may include as many of the options as it chooses.