FINAL STATEMENT OF REASONS

As authorized by Government Code section 11346.9(d), the California Department of Public Health (Department) incorporates by reference all contents of the Initial Statement of Reasons (ISOR) into the Final Statement of Reasons. The information contained in the ISOR at the time of the initial public notice remains unchanged except for the following modifications.

Article 1. 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."

Article 1.5. Licensure and Certification of Clinical Laboratory Personnel.

General Changes

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. This change is proposed in the following subsections:

1030.5 (a)(2)(B), (a)(2)(C), (a)(2)(D), (b)(1)(B), (b)(1)(C), (c)(1)(C), (c)(1)(D), (d)(1)(B), (d)(1)(C)

1030.6 (a)(2), (a)(3)

1030.7 (b), (c)

1030.8 (a)(4)(A)

Commenters requested that the Department align the proposed regulations with recent changes to federal Clinical Laboratory Improvement Amendments (CLIA) regulations

and eliminate language stating that a degree must be in a specific science field and add language that allows the Department to accept a degree in any subject if it includes the required prerequisite coursework.

The Department agrees with these comments and is studying the Final Rule and considering how to incorporate those changes in California personnel standards in future rulemaking packages to ensure consistency across license types. We will take these comments into consideration when drafting that rulemaking package.

The Department agrees that in the interim it is important to retain the flexibility in current regulations to evaluate a college or university degree in a field not related to clinical laboratory science. In the current rulemaking package, the Department has revised the text to eliminate references to specific degree titles required for clinical laboratory personnel licensure, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, with courses pertinent to clinical laboratory science as required for the particular license.

This change is proposed in the following subsections:
1030.5 (a)(2)(B), (b)(1)(B), (c)(1)(C), (d)(1)(B)
1030.6 (a)(2)
1030.8 (a)(3)

In response to public comments, the Department proposes to clarify the requirement for coursework in analytical chemistry, to include courses in either analytical chemistry or quantitative analysis, and coursework in biological chemistry, to include courses in either clinical chemistry or biochemistry. This will accommodate variation in course titles and ensure that applicants have instruction that provides both analytical skills and clinical/biochemistry skills necessary for the performance of non-waived clinical laboratory testing.

This change is proposed in the following subsections:
1030.5 (b)(1)(C)1., (c)(1)(D)1., (d)(1)(C)1.
1030.7 (b)(1), (c)(1)
1030.8 (a)(4)(A)

In response to public comment, the Department proposes to revise the proposed text to clarify that for licensure as a clinical laboratory scientist or clinical laboratory scientist limited to a specialty, coursework in biology must include coursework in medical microbiology, clinical microbiology, or pathogenic microbiology. Commenters requested that "clinical microbiology" and “pathogenic microbiology” be included as alternatives to

"medical microbiology" since they are synonymous course names. The addition of clinical and pathogenic microbiology will accommodate variations in academic nomenclature.

This change is proposed in the following subsections:
1030.5 (b)(1)(C)2., (c)(1)(D)2., (d)(1)(C)2.
1030.7 (b)(2), (c)(2)
1030.8 (a)(4)(B)
1032 (d)

Section 1030
No comments were received and no changes were made to the initial proposal.

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)
Renumber existing subsection (a)(1) to subsection (a)(2).

Subsection (a)(2)(B)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read "semester or equivalent quarter credit hours."

In response to public comment, in this rulemaking package the Department proposes to eliminate references to specific science degree titles, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for the particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032. The listing was compiled by the Department's licensed subject matter experts in consultation with the Department's Clinical Laboratory Technology Advisory Committee. It provides general information about the courses and degrees that

the Department considers to be pertinent to clinical laboratory science for purposes of licensure. The Department includes this phrase to allow it to license applicants who hold a degree that is not related to clinical laboratory science but have completed enough courses related to clinical laboratory science to qualify for licensure. The consideration of completed coursework rather than degree title opens licensure to qualified applicants beyond those who hold traditional clinical laboratory degrees. This approach conforms with recently adopted changes to federal CLIA regulations (adopted in 2024), which have moved from requiring specific degrees to considering coursework, regardless of the title of an applicant's degree. The Department is currently studying those changes to federal law and may make additional changes in a forthcoming rulemaking package.

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 a misstatement in 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)(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 the reference to educational credit hours to read "semester or equivalent quarter credit hours."

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

In response to public comment, the Department proposes to omit the reference to moderate complexity ABO and Rh type testing under the list of testing specialties,

because this testing is not a specialty, but a set of tests within the specialty of immunohematology. Requirements for training in ABO and Rh type testing are specified in sections 1030.6 and 1035.1.

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 to clarify that baccalaureate degrees must be from an accredited college or university; equivalent degrees from educational institutions outside the US that are not accredited by a US accrediting agency must be evaluated as defined in Section 1029.

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

In response to public comment, in this rulemaking package the Department proposes to eliminate references to specific science degree titles, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for the particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032, which provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure.

Subsection (b)(1)(C)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

In response to public comments, the Department proposes to revise the coursework requirements to clarify that the biology coursework required in this subsection must

include coursework in medical microbiology, clinical microbiology, or pathogenic microbiology.

Subsection (c)(1)(C)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

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

In response to public comment, in this rulemaking package the Department proposes to eliminate references to specific science degree titles, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for the particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032, which provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure.

Subsection (c)(1)(D)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

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

Subsection (d)(1)(B)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

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

In response to public comment, in this rulemaking package the Department proposes to eliminate references to specific science degree titles and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for that particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032, which provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure.

Subsection (d)(1)(C)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

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

Section 1030.6
Subsection (a)(2)
In response to public comment, in this rulemaking package the Department proposes to eliminate references to specific science degree titles and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for that particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032, which provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure.

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

Subsection (a)(3)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

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.

Subsections (a)(4)(E) and (F)
The Department proposes a minor grammatical correction for clarity, changing the phrase “experience in a clinical laboratory… that … *performs* tests or examinations” to read “experience … that … *includes the performance of* tests or examinations.” This clarifies that the applicant must personally perform the specified testing; it is not sufficient that the laboratory performs the testing.

In response to public comments, the Department proposes revisions to subsections (a)(4)(E) and (F) to align with similar language in Section 1035.1 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. Requirements for experience in ABO and Rh type testing are specified in subsection (a)(4)(E)2. and (a)(4)(F)2.

Subsections (a)(4)(E)2. and (F)2.
In response to public comments, the Department proposes revisions to language regarding the number of hours of required experience 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.

The Department is proposing to clarify that experience 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. Experience 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 experience 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 Business and Professions Code (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.

In response to public comment, the Department proposes to add coursework 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 to clarify that these courses are acceptable for licensure purposes.

Subsection (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 the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

In response to public comment, in this section the Department proposes to eliminate references to specific science degree titles, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, that includes the courses pertinent to clinical laboratory science required for the particular license. This paragraph refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032. The listing provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure. The Department includes this phrase to allow it to license applicants who hold a degree that is not related to clinical laboratory science but have completed enough courses related to clinical laboratory science to qualify for licensure. The consideration of completed coursework rather than degree title opens licensure to qualified applicants beyond those who hold traditional clinical laboratory degrees. This approach conforms with recently adopted changes to federal CLIA regulations (adopted in 2024), which have moved from requiring specific degrees to considering coursework, regardless of the title of an applicant’s degree. The Department is currently studying those changes to federal law and may make additional changes in a forthcoming rulemaking package.

Subsection (b)(1)
In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must

include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (b)(2)
In response to public comments, the Department proposes to revise the coursework requirements to clarify that the biology coursework required in this subsection must include coursework in medical microbiology, clinical microbiology, or pathogenic microbiology.

Subsection (c)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

Subsection (c)(1)
In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

Subsection (c)(2)
In response to public comments, the Department proposes to revise the coursework requirements to clarify that the biology coursework required in this subsection must include coursework in medical microbiology, clinical microbiology, or pathogenic microbiology.

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, in this rulemaking package the Department proposes to eliminate references to specific science degree titles, and instead require that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, in any subject if it includes the courses pertinent to clinical laboratory science that are required for the particular license. This paragraph

refers readers to the listing of courses and degrees pertinent to clinical laboratory science in newly adopted Section 1032, which provides general information about the courses and degrees that the Department considers to be pertinent to clinical laboratory science for purposes of licensure.

Subsection (a)(4)
In response to public comment, the Department proposes to standardize the reference to educational credit hours to read “semester or equivalent quarter credit hours.”

In response to public comment, the Department proposes to revise the coursework requirements to clarify that the chemistry coursework required in this subsection must include coursework in either analytical chemistry or quantitative analysis, and coursework in either clinical chemistry or biochemistry.

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

Section 1030.16
No comments were received and no changes were made to the initial proposal.

Section 1030.17
No comments were received and no changes were made to the initial proposal.

Section 1031
No comments were received and no changes were made to the initial proposal.

Section 1032
Subsection (d)
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.

In response to public comments, the Department proposes to revise the course examples to add clinical microbiology and pathogenic microbiology.

Section 1032.5
No comments were received and no changes were made to the initial proposal.

Article 1.8. Examinations for Licensure and Certification and Certifying Organizations.

Section 1034
No comments were received and no changes were made to the initial proposal.

Article 2. 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 this subsection regarding moderate complexity ABO/Rh type testing for clarity. In the general list of testing specialties, 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 for training in ABO and Rh testing are specified in Subsection (h)(2)(A). That section specifies the requirement for at least 80 hours of training in 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)
Renumber 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 were made to the 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.

Statements of Determinations

Local Mandate
The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed.

Impact on Small Businesses (See ISOR, p. 61-62)

The Department has determined that the proposed regulations will have no adverse impact on small businesses. Defining terms used in the industry does not create new policies, procedures, or programs that do not already exist. Licensure requirements and scope of work standards adopted in this package do not have an impact on small businesses and do not introduce substantial changes to existing requirements that would affect small businesses.

The Department has made the initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. Most of the proposed changes to the regulations are clarifications and updates to definitions, revisions to update existing licensure regulations for clinical laboratory personnel, and repeals of outdated regulations for clarification and ease to the reader.

Alternatives Considered
The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the

Department would be more effective in carrying out the purpose for which this action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Authority Cited and References:

The Department proposes this amendment under the authority provided in Section 1224 of the Business and Professions Code (BPC) and Section 131200 of the Health and Safety Code.

Under Section 1208 of the Business and Professions Code, the Department has authority to create new categories of laboratory personnel licenses and to modify education, training, examination, and licensing standards for existing license categories.

Under Section 1262 of the Business and Professions Code, the Department has authority to approve the evaluation of national or state accrediting boards for licensure.

Under article 4, Licensing, Sections 1262, 1263, and 1264 of the Business and Professions Code, the Department has authority to issue licenses for clinical laboratory bioanalysts (Bus. & Prof. Code, § 1260), clinical laboratory scientists (Bus. & Prof. Code, § 1261), and clinical laboratory scientists limited to a specialty (Bus. & Prof. Code, § 1261.5), clinical laboratory scientist trainees and clinical laboratory scientist trainees limited to a specialty (Bus. & Prof. Code, § 1263), clinical chemists, clinical microbiologists, clinical toxicologists, clinical genetic molecular biologists, clinical cytogeneticists, and oral and maxillofacial pathologists (Bus. & Prof. Code, § 1264).

Under Section 1222 of the Business and Professions Code, the Department has authority to approve schools that are accredited by the National Accrediting Agency for Clinical Laboratory Sciences. Under BPC section 1246, the Department has authority to approve national accrediting agencies for phlebotomy (Bus. & Prof. Code, § 1246(b)(4).

The proposed regulations implement, interpret, and make specific 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, 1270, 1275, 1280, 1281, 1282, 1282.2, 1285, 1286, 1289, 1300, 1301, 1301.1, 1310, and 1320 of the BPC; sections 100275 and 120580 of the HSC; section 14123 of the WIC.

ATTACHMENTS TO THE FINAL STATEMENT OF REASONS

Addendum I
45 Day Public Notice

Summary of Comments and Responses to Comments Received

The regulation text was made available for public comment for at least 45 days, from December 1, 2023, through January 20, 2024. The Department received comments from 126 commenters during the 45-day public notice period beginning December 1, 2023, and ending January 20, 2024. Of these, 6 comments were submitted after the close of the comment period and the Department will not respond to these comments. Six comments were not directed to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or were so generalized or personalized that no meaningful response could be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The remaining 114 comments are aggregated and summarized below. If multiple comments were received about the same topic, the comments are aggregated and summarized, and a single response is provided. Individual responses are provided for unique comments. No request for a public hearing was received and no hearing was held.

List of 45-Day Commenters

Unique Comments

1. Danielle Sabine

2. Victor La Fond

3. Sherry Etoch, Hoag Memorial Hospital Presbyterian

4. Kathy Nucifora, COLA

5. Jason Pedro, Folsom Lake College, with an attachment with 47 co-signers; 54 duplicate copies of the attachment were forwarded in separate emails

6. Marisa James, National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)

7. Erica Padilla, Sutter Health, Valley Area

8. Dora Goto, California Association for Medical Laboratory Technology (CAMLT)

9. Traci Hundley, California Clinical Laboratory Association (CCLA)

10. Kristi Foy, California Clinical Laboratory Association (CCLA)

11. Rowena Carino, Scripps Health

12. Sharon McGoldrick, UC Davis Health Pathology & Laboratory Medicine

13. Matthew Schulze, American Society for Clinical Pathology (ASCP and ASCP BOP)

14. Sharlene Washington, San José State University

15. Menaka Rosechandran

16. Sarah Turkel, California State University Dominguez Hills

Co-signers of the letter attached to comment 5

(47 people co-signed the letter attached to comment 5 but did not send individual emails)

17. Natalie Cherok-Fenner

18. Erika Cobar

19. Kim Zwerenz

20. Alex Febo

21. Debbie Wagner

22. Patricia Buchner

23. Deanna Reinacher

24. Timothy Tomaso

25. Sharon Arase

26. Victoria Cusick

27. Joshua Segur

28. Danielle Layola

29. Vanessa Robles
30. Isabel Nevarez Paniagua
31. Thomas Loarie
32. Karla Theis
33. Hannah Mirrashed
34. Laura Laakso
35. Erin Bose
36. Chris Ha
37. Alisha Ram
38. Arezoo Ardalan
39. Sasha Pavlitsky
11. Rowena Carino also sent an email with individual comments
40. Keau Wong
41. Saba Tafkikialamdari
42. Giovanna Centeno
43. Kathryn Ma
44. Elizabeth Buck
45. Jennifer Le
46. Enosh Chu
47. Diana Martinez
48. Jaskaran Sandhu
49. Michelle MacLaren
50. Kami Hamor
51. Naomi Almanzor
52. Tatyana Bratan
53. Harpreet Singh

54. Lebn Leippe-Yudell

55. Gagandeep Saini

56. Danielle Magadia

57. Shirley Chau

58. Angie Jablonski

59. Larysa Sledz

60. Jessica Georguson

61. Amber Miller

62. Payal Patel also sent an email with a copy of the letter without additional comments

Duplicate Comments

(54 people sent copies of the letter attached to comment 5 without commenting or signing the letter)

62. Payal Patel co-signed the letter and sent an email with a copy of the letter without additional comments

63. Son Nguyen

64. Shireen Khadivi

65. Laleh Dashti

66. Minh Huong Pham

67. Mei Tu

68. Melissa Jupp

69. Lily Wu

70. Yi Qing Chen

71. Quyen Tran

72. Sophia Abarra

73. Rinku Ranka

74. Jason Pedro

75. Vali Javaherchian
76. Joan Licudo
77. Trina Nahm
78. Angie Pettenato
79. Lorie Liwanag
80. Kathryn Ma
81. Andrea Jaramillo
82. Rosa Duncan
83. Archana Sawhney
84. Jonathan Glover
85. Ngoc Lam
86. Maninder Kaur
87. Hoai-Thu Ho
88. Ryan Favre
89. Suganthi Sriram
90. M. Patel
91. Phuc Huynh
92. Vanessa Robles
93. Margaret Yamada Kuruma
94. Yijin Nikki Sun
95. Daisy Estrada
96. Thuy Quach
97. Dipika Ghandi
98. Kajal Shah
99. Camille Custodio
100. Sandra Lamar

101. Kim Chau

102. Mandeep Bains

103. Rosa Melgar-Takahashi

104. Peter Nguyen

105. Uyen Quach

106. Christine Luu

107. Samson Ku

108. Chau Le

109. Sudha Gundavajhala

110. Kristina Stueck

111. Guillermo Bernardino

112. Doan-Trang Nguyen

113. Dhifaf Yaqoob

114. Unsigned fax with no identification of sender’s name

Comments Not Related to the Proposed Rulemaking Text or Requests for Assistance

115. Aeli Saif

116. Caroline Satyadi

117. Jamie Wood

118. Joshua Davis

119. Steven Springer, American Association of Pathologists' Assistants

120. Chevanne Scordinsky, American Association of Pathologists' Assistants

Untimely Comments

121. Stephanie Stenshoel, Vitalant

122. Michael Bowling, San José State University

123. Angele Chen (duplicate copy of the attachment to comment 5)

124. Megan Vinson (duplicate copy of the attachment to comment 5)

125. Dao Tram (duplicate copy of the attachment to comment 5)

126. Hang Quach (duplicate copy of the attachment to comment 5)

The Department's responses to comments received during the initial comment period are provided below.

General Comments

Multiple Sections

Comment Topic: Omit physical science as a qualifying degree

Comment: In the December 28, 2023, Federal Register, the Centers for Medicare & Medicaid Services (CMS) published the long-awaited final rules, including revisions to CLIA personnel requirements. As expected, CLIA is removing "physical science" as a qualifying degree for various laboratory personnel. COLA respectfully suggests that CDPH also remove physical science as an acceptable degree for clinical laboratory personnel throughout DPH-20-007.

Commenter: 4

Comment: In numerous provisions of the proposed rule, the Department outlines the academic degrees it will accept for licensure. In subsection 1030.5(1)(B), the Department proposes to recognize degrees in a "chemical, physical, or biological science or medical laboratory technology." In a recently released Final Rule, the Centers for Medicare & Medicaid Services (CMS) finalized a proposal to eliminate physical science as an acceptable degree (the effective date for the personnel provisions of the rule is December 28, 2024). … Grandfathering provisions in CLIA allow these degree holders who are currently performing high complexity testing to continue doing so. Moreover, CMS stated that these individuals may still qualify to perform such testing by satisfying one of CLIA's coursework requirements, such as the one identified for high complexity testing personnel at (future citation) 42 CFR 493.1489(b)(3)(ii) [currently 42 CFR 493.1489(b)(2)(ii)].

ASCP and ASCP BOP recommend that the Department parallel CMS's new policy.

Commenter: 12

Department Response: The Department agrees with commenters on the need to align California regulations with the changes made in the CMS Final Rule. The Department is studying the Final Rule with the intention of making changes to conform California law to CLIA.

However, due to the timing of release of the Final Rule, which came after the proposed rulemaking had already been released for public comment, the Department needs time to study the changes to CLIA regulations and adapt them, and consequently we will make those changes in a future package of personnel standard regulations to ensure consistency across license types. We will take these comments into consideration when drafting that rulemaking package.

Comment Topic: Medical Laboratory Science
Comment: In multiple sections of the proposed rule, such as paragraph 1030.5(1)(B), "medical laboratory technology" or "clinical laboratory science" is listed. Increased consistency along with accurate, unified nomenclature is needed here such that medical laboratory technology, clinical laboratory science and medical laboratory science should all be listed as applicable for licensure, just as they are recognized in the new CLIA Final Rule.

Commenter: 12

Department Response: The Department agrees that accurate, unified nomenclature is needed to clarify that medical laboratory technology, clinical laboratory science and medical laboratory science are all acceptable degrees for California licensure, as they are recognized in the new CMS Final Rule. The Department has added "medical laboratory science and medical laboratory technology" along with "clinical laboratory science" throughout the proposal to accommodate changes in academic nomenclature and mirror recent changes to federal CLIA regulations.

Comment Topic: Credit hours
Comment: Regarding inconsistencies in terminology for number of hours/units of completed course work, to avoid confusion, terminology should be consistent and standardized, in both verbiage and list of included courses. We recommend doing away with the use of "hours" and instead use "semester or quarter units."

Commenter: 10

Department Response: The Department agrees and has standardized 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.

Article 1. Definitions.

Section 1029

Subsection (a)

Comment Topic: “Accredited college or university”

Comment: The acronym for CHEA needs correction. CHEA stands for the Council for Higher Education Accreditation, and we recommend correcting the acronym accordingly.

Commenter: 6

Department Response: The Department thanks the commenter for pointing out this error and has made the requested change to correct the reference.

Comment Topic: “Approved certifying organization”

Comment: There is a reference to an “approved certifying organization”, which is also termed a national accreditation or accrediting board or agency. We believe the italicized phrasing may lead to confusion. We propose revising the sentence as follows:

“An ‘Approved certifying organization’ refers to 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.”

Commenter: 6

Department Response: The Department declines to make the requested change. Different organizations use different nomenclature. and the Department will retain the proposed language to clarify that it intends to include all such organizations.

Comment Topic: “Practical experience” - Accept academic, research, forensic, pharmaceutical, and veterinary lab experience

Comment: The proposed rule would maintain the current restriction that practical experience working in academic, research, forensic, pharmaceutical, or veterinary laboratories does not count towards required experience for clinical laboratory personnel. CCLA believes that the experience from these industries can easily be

complementary to or compatible with experience in clinical environments. If the goal of the experience is to gain knowledge about test methodologies, handling requirements, or other factors that can impact test results, this sort of experience can often be just as useful as experience derived from a clinical environment. Some meaningful and appropriate degree of credit should be allowed for such practical experience.

Commenters: 9, 10

Department Response: The Department disagrees with the suggestion to allow a degree of credit for practical experience obtained in academic, research, forensic, pharmaceutical, or veterinary laboratories. Federal CLIA regulations specify that personnel performing clinical laboratory testing must obtain training or experience in a facility that meets the definition of a laboratory subject to CLIA under § 493.2 and is not excepted from CLIA under § 493.3(b). (See the Final Rule by Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) [https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and] for specific comments on the definition of laboratory training and experience that states training or experience must be obtained in a clinical laboratory.)

California law likewise requires that qualifying experience be obtained in a clinical laboratory. (See, for example, BPC § 1260 specifies that “The applicant also shall have a minimum of four years’ experience as a clinical laboratory scientist performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory certified under CLIA.” See also BPC §§ 1261 and 1261.5.)

The Department will retain the requirement that clinical laboratory personnel have training or experience examining and performing tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring an individual's condition.

Article 1.5. Licensure and Certification of Clinical Laboratory Personnel.

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

Multiple Subsections

Comment Topic: Change coursework requirements for MLT trainee

Comment: Section 1030.5 of the Licensure and Work Scope of a Clinical Laboratory Trainee requires clarification, particularly in Sections (a)(1)(C and D). The language used in these sections is confusing and raises questions about whether students

applying for an MLT Trainee License must have already completed an A.S. Degree. Most MLT programs are associated with an AS degree, but this degree is typically awarded after the program concludes.

Moreover, Sections C and D seem to imply the issuance of an MLT training license after 36 credit hours. This credit hour requirement appears high if it only pertains to basic Chemistry and Biology courses. It is assumed that this encompasses the didactic portion of the MLT program.

Recommendation: Remove the MLT Trainee License altogether. If that is not possible, refine the credit hour requirements to only include core science prerequisite courses (i.e. 12 credit hours) such that it accounts for students just initiating their sole A.S. degree in MLT.

Commenter: 5, co-signers, and duplicates

Comment: We are concerned about the timing of students receiving the MLT trainee license, as its important that students are ready for externship immediately after finishing didactic coursework. This section is unclear, will you be requiring 36 credit hours before issuing MLT trainee license? Recommend this be changed to minimally require the 6 chemistry and 6 biology to issue the trainee license, with remaining credits, including AA degree, to be verified prior to issuing MLT license.

Commenter: 7

Comment: Concern about timeline for the MLT trainee license. MLT AA degree programs currently include the applied/hands on training practicum hours to meet degree requirements. The requirements as listed would cause restructuring of current MLT programs if the MLT training license requires an associate degree and 36 credit hours. Consider aligning the MLT training license with the current MLT AA program structure. Suggest MLT licensing include the 6 chemistry and 6 biology credit hours and enrollment in an approved MLT training program.

Commenter: 11

Department Response: The Department declines to make the requested change to remove the MLT trainee license and will retain the requirement of licensure for MLT trainees. Trainee licensure is necessary to ensure compliance with California law, which requires licensure for personnel performing non-waived testing (BPC § 1282). This trainee license was not added when MLT licensure and training programs were introduced, and the proposed rulemaking corrects this oversight.

However, to provide flexibility for trainees already enrolled in an approved training program when the proposed regulations are adopted, the Department has added

language to clarify the beginning date of the requirement for licensure and provide a grandfather clause for persons already enrolled in a training program when the regulations are adopted.

The Department agrees that it is not reasonable to require students to complete all required science coursework before beginning training. The Department is retaining the requirement that applicants for MLT licensure complete 36 credit hours of coursework in laboratory science but has accepted commenters' suggestions and has revised the text as requested to clarify that an applicant for an MLT trainee license must complete the only the coursework in subsections (C) 1. and 2., that is, 12 hours of basic science coursework including 6 chemistry and 6 biology credit hours, to obtain a trainee license.

This will allow an applicant to obtain a trainee license after completing minimal science coursework and complete the remaining coursework during the training period. This requirement ensures that trainees have the requisite academic coursework to perform accurate and reliable testing during the practical training.

Comment Topic: Add chemical science to the list of acceptable degrees for MLT licensure
Comment: ASCP and ASCP BOP note in several sections of the rule, such as paragraph 1030.5(a)(1)(C), chemistry is not listed as an acceptable degree. With the possible exception of some specialist licenses, chemistry should be recognized in all areas where the Department is specifying approved degrees.

Commenter: 12

Department Response: The Department thanks the commenter for pointing out this problem with sections1030.5 and 1030.6. These subsections specify coursework that must be completed by applicants who hold one of the degrees listed in these subsections, which include chemical science degrees.

The Department agrees that these subsections should require coursework in chemical and biological sciences, and not physical sciences, as the following subsection specifies chemistry and biology coursework, but not physical science coursework. The Department has omitted the term "physical" and replace it with "chemical" here and in the parallel subsection, 1030.6(a)(3).

Comment Topic: Revise the MLT scope of training
Comment: MLT trainee authorization is too narrow, recommend changing "moderate complexity ABO an Rh type immunology" to "immunohematology". This will allow

flexibility to provide instruction in any moderate complexity blood bank testing and provide adequate understanding of this specialty.

Commenter: 7

Department Response: The Department agrees on the need for revisions to clarify the requirements in sections 1030.5 (a), 1030.6, and 1035.1 and has changed the list of specialties in which MLT trainees are authorized to train to include testing in the specialties of chemistry, microbiology, diagnostic immunology, hematology, and immunohematology. The Department has omitted the reference to ABO and Rh type testing because this testing is not a specialty, but a subset of tests within the specialty of immunohematology.

In sections 1030.6 and 1035.1, the Department clarifies 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

Comment Topic: Allow MLTs as trainers

Comment: 1030.5, subsection D (3) states: 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. The absence of specific mention regarding Medical Laboratory Technicians as designated trainees in this section is noteworthy. Given that Phlebotomist can train Phlebotomy trainees and Clinical Lab Scientists can train Clinical Lab Scientist trainees, it is reasonable to ask that licensed MLTs have the authority to train MLT trainees.

Recommendation: Ensure language in section 1030.5 includes licensed MLTs as authorized trainers.

Commenter: 5, co-signers, and duplicates

Comment: Does the phrase "licensed under chapter 3 as specified in section 1035.1" include MLTs? An experienced MLT trainer should be able to supervise a trainee in moderate complexity tests.

Commenter: 7

Department Response: The Department declines to make the requested revisions, as they are unnecessary. Proposed regulations in subsections 1035.1(e and f) explicitly allow MLTs to provide both didactic instruction and practical training.

However, MLTs are not listed in subsection 1035.1(g), which refers not to instructors or trainers, but to persons authorized to provide direct and responsible supervision to MLT trainees during their practical training. The proposed licensure requirements for a person providing direct and responsible supervision of MLT trainees are the same as those required for persons providing supervision of licensed MLTs as stated in Business and Professions Code subsection 1260.3(b): “The medical laboratory technician shall work under the supervision of a licensed physician and surgeon or a baccalaureate, masters, or doctoral level person licensed pursuant to this chapter.”

It would not make sense for an MLT trainee to be under the supervision of a person who is less qualified than the person providing supervision to a licensed MLT.

The Department will retain the proposed requirements for persons providing supervision in subsection 1030.5(a), 1030.6(c), and 1035.1(g).

Comment Topic: Accept coursework rather than requiring specific degrees for Clinical Laboratory Scientist (CLS) licensure

Comment: Throughout the document, the proposed regulation aims to narrow the acceptable baccalaureate degrees for Clinical Laboratory Scientists {CLS} to majors in biological, chemical, physical, or clinical laboratory science. While many students will fit into these specified categories, there are individuals with baccalaureate degrees seeking a career change or may have initially majored in a non-science. Despite meeting all other CLS criteria, having taken all required science coursework, these individuals would not qualify for CLS licensure under the proposed regulations. Mandating these students to undertake additional courses beyond the requirements for their license appears, in order to receive a second baccalaureate degree in a science, is impractical given the current CLS shortage.

Recommendation: Remove the requirement that a baccalaureate degree must major in biology, chemical, physical, or clinical laboratory science. Simply require the appropriate course work.

Commenter: 5, co-signers, and duplicates

Comment: CLS trainee must have degree in science: This is too restrictive and will eliminate a strong student who didn't discover CLS during undergrad and has taken all the needed courses but their degree happens to be in something else. Nursing,

nutrition, kinesiology are examples we've seen in the past. This section says it is defined in section 1029, but it appears to be better defined in section 1032 on page 38. Recommend revising wording allowing other degrees as long as course work specifics are met (C), or referencing section 1032.

Commenter: 7

Comment: CCLA views the statement in section 1030.7 as also overly limiting when discussing qualifications to sit for the CLS exam. The section states that the applicant must have graduated from an approved school with "a baccalaureate and a major in a biological, chemical, physical, or clinical laboratory science, the last year of which course shall have been primarily clinical laboratory procedures in a clinical laboratory training school acceptable to the department" (emphasis added). The availability of such specific curricula among approved schools may not be sufficient to ensure the necessary supply of exam applicants.

Commenters: 9 and 10

Comment: ASCP and the ASCP BOC recommended that CMS develop a coursework requirement to qualify individuals who may not possess a degree in a CLIA-recognized science but have enough academic coursework in the applicable sciences to be equivalent to an approved degree. We believe state licensure programs would benefit from creating a similar coursework requirement/licensure pathway. Consequently, we recommend that the Department parallel CMS's new policy.

Commenter: 12

Comment: While the proposed text appears to broaden the degree requirements by removing the major of CLS as a requirement to train, by also removing the language "or a baccalaureate and courses pertinent to the clinical laboratory field as may be determined by the department" it does the opposite. The original regulatory text allows for students to meet academic requirements for a CLS trainee license with a bachelor's degree in any field if the specified course requirements are met. The proposed text drastically limits who can become a CLS (as well as a limited or specialized CLS). … Limiting the kinds of bachelor degrees permitted to train as a CLS, if the student has completed the specified academic course requirements in the proposed regulatory text, is entirely unreasonable and restrictive. … The proposed text, as written, will be counterproductive to California's goal of increasing the number of CLSs in the state. It will require training programs to turn away smart, qualified, and capable students, which will be a detriment to the state and profession.

Recommendation: Remove the requirement that a baccalaureate degree must be obtained in biology, chemical, physical, or clinical laboratory science. Simply require the appropriate course work.

Commenter: 14

Department Response: The Department agrees with these comments and is studying the CMS Final Rule and considering how to incorporate the recent changes to federal requirements into California personnel standards in future rulemaking packages to ensure consistency across license types. We will take these comments into consideration when drafting that rulemaking package.

The Department agrees that in the interim it is important to retain the flexibility in current regulations to evaluate a college or university degree in a field not related to clinical laboratory science. In the current rulemaking package, the Department has eliminated references to specific degree titles required for clinical laboratory personnel licensure, and instead requires that an applicant document completion of a degree from an accredited college or university, or an equivalent degree, with courses pertinent to clinical laboratory science as required for the particular license.

Comment Topic: Omit coursework for applicants with approved science degrees
Comment: ASCP and ASCP BOP presume that the coursework requirement found in section 1030.5(b)(1)(C) serves to ensure that licensed CLS trainees meet the CLIA high complexity personnel requirements for individuals who have less than baccalaureate degree [See new citation 42 CFR 493.1489(b)(3)(ii)]. The construction of paragraph 1030.5(b)(1)(B), however, indicates that the coursework requirement applies to both individuals who have a bachelor’s degree in biology, chemistry, etc. as well as those who do not.

In our policy statement on the licensure of laboratory personnel, we outline our support for the licensure of individuals who have earned a baccalaureate degree in an approved academic science, successfully completed work experience or accredited training, passed a nationally-recognized certification examination, and satisfied continuing education requirements. We do not believe additional coursework is necessary for those who have an approved baccalaureate degree and graduated from an accredited training program.

As a result, we recommend that the Department eliminate the coursework requirement for individuals who possess an approved bachelor's degree. We suggest the Department reconfigure the coursework requirement for those individuals who do not have a qualifying bachelor’s degree or who have yet to obtain one.

Commenter: 12

Department Response: The Department declines to change the CLS licensure requirements to omit coursework. The Department must ensure that applicants for licensure have completed all the coursework necessary to prepare them to provide reliable and accurate clinical testing. A person may complete a degree in biology, for example, without completing courses that ensure competence in medical microbiology.

Comment Topic: Reinstate the requirement for medical microbiology
Comment: There has been substantial resistance to the exclusion of Medical Microbiology from CLS license requirements. Considering the intricate nature of Microbiology training, the decision to omit it raises legitimate concerns. It's worth noting that a majority of CLS programs in the state will persist in mandating Medical Microbiology at the program level.

Recommendation: Reinstate the medical microbiology requirement for CLS licensure.

Commenter: 5, co-signers, and duplicates

Comment: Microbiology course must be a medical microbiology course. There are tens of thousands of microorganisms that can be included in a non-medical microbiology course that are not relevant to human pathological disease. A medical microbiology course will include instruction on clinical pathogen identification and antibiotic sensitivity whereas a non-medical microbiology course will not include such essential instruction. Only a medical microbiology course will adequately prepare a CLS trainee to meet the academic and clinical training standards needed for satisfactory performance on the licensing exams and clinical bench rotations.

Recommendation: Reinstate the medical microbiology course requirement for CLS licensure.

Commenter: 8

Comment: The course ‘Microbiology’ is no longer prefaced with 'medical' in the course name. This does not therefore assume an applicant will complete a course focusing on human pathogens and disease, and does not stipulate education in subchapters of bacteriology, mycology, virology and parasitology. With the removal of ‘medical’ from the course name, many applicants will substitute a general, lower division course that is too basic in rigor and content. Applicants who are proactive in best preparing themselves for the clinical lab field may unknowingly misuse time on this less applicable course. We feel strongly that a ‘clinical or medical’ microbiology course remain as the standard prerequisite, and not allow acceptance of a general micro course.

Commenter: 10

Strongly suggest that medical microbiology/ pathogenic bacteriology remains a CLS generalist training license requirement. Request CDPH review course requirements for the CLS training license and continue to require medical microbiology.

Commenter: 11

Comment: The removal of Medical Microbiology as an academic requirement to train will leave CLS trainees ill-equipped and unprepared for the clinical microbiology rotation in the clinical laboratory and the national board exam. Basic microbiology courses do not cover the necessary didactic material. Most basic microbiology courses cover only introductory microbiology concepts, as in 'what is a bacteria/virus/parasite', and do not prepare students how to think clinically, understand the characteristics and differences between specific pathogens and normal flora, or begin to identify organisms on the bench.

Recommendation: Reinstate the medical microbiology requirement for CLS licensure.

Commenter: 14

Department Response: The Department accepts these comments and has revised this section and parallel sections to clarify that, for licensure as a clinical laboratory scientist or clinical laboratory scientist limited to a specialty, coursework in biology must include coursework in medical microbiology.

Comment Topic: Reinstate the requirement for analytical chemistry and biochemistry or clinical chemistry
Comment: Throughout Sections 1030.5 and 1030.7, "16 credit hours in chemistry, including either a) Quantitative analysis and biochemistry; or b) Clinical chemistry; and" has replaced "16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry;" as a requirement to obtain a CLS trainee, CLS generalist, CLS limited license in chemistry or CLS limited license in toxicology.

A separate course in quantitative analysis should remain an essential course. With the exception of qualitative tests, all chemistry tests quantitatively measure an analyte. A complete and thorough understanding of quantitative analysis can only be obtained by successfully completing a separate course in analytical chemistry.

Recommendation: Reinstate the analytical chemistry course requirement for CLS licensure.

Commenter: 8

Comment: A course named Quantitative Analysis has been replaced fairly universally by a course named 'Analytical Chemistry' at a majority of academic institutions. Historically either Quantitative Analysis or Analytical Chemistry was acceptable by CDPH. It would be helpful to applicants to list both course names in the regulations, as we field many question from potential applicants about this.

Commenter: 10

Comment: University of California Davis Health (UCDH) interprets clinical chemistry to be equivalent to biochemistry as lab math and laboratory extractions are not sufficiently covered in clinical chemistry. UCDH CLS training includes extensive training in validation studies and lab math- not having a quantitative analysis or analytical chemistry course is detrimental to the success of the UCDH enrolled CLS trainee.

Currently, UCDH program specific requirements include either a Quantitative analysis or analytical chemistry course. This is no longer in alignment with the CDPH CLS Trainee license requirements, suggest reviewing the current CDPH practice of accepting clinical chemistry as meeting analytical chemistry.

Commenter: 11

Department Response: The Department agrees with these comments and has revised this section and parallel sections to clarify the requirement for coursework in analytical chemistry, which may include courses in either analytical chemistry or quantitative analysis, and coursework in biological chemistry, which may include courses in either clinical chemistry or biochemistry. This will accommodate changes in course titles and ensure that applicants have instruction that provides both analytical skills and clinical/biochemistry skills necessary for the performance of non-waived clinical laboratory testing.

Comment Topic: Require coursework in human immunology
Comment: Immunology courses focusing primarily on techniques and methodology have been increasing, and students who take these courses seem not to receive education on any relevant human diseases and processes. We are not sure how to resolve this dilemma, perhaps enhanced wording can be added to the regulations defining acceptability of a course.

Commenter: 10

Department Response: The Department appreciates the suggestion but will retain the current broad term “immunology” because we have not been able to identify generally recognized terminology or academic coursework that specifies immunology of human diseases.

Comment Topic: Require coursework in molecular biology
Comment: With the advent of molecular biology technologies in the clinical lab profession, a course in molecular biology, molecular techniques, or a related course should be required.

Commenter: 10

Department Response: The Department agrees that knowledge of and competency in molecular techniques is increasingly important for clinical laboratory personnel. The Department plans to address this issue in a future rulemaking package when it revises CLS licensure requirements, adding these techniques to the requirements for both MLTs and CLSs to ensure consistency across license types, including trainee requirements. In the interim, the Department is proposing optional instruction in molecular techniques in the training recommendations in sections 1035.1 and 1035.3.

Comment Topic: Delete the requirement for quantitative coursework
Comment: While ASCP and ASCP BOP certification and qualification examinations do include exam items with mathematical equations pertinent to laboratory testing, the ASCP BOC no longer requires individuals to complete an algebra course in their eligibility requirements. Our decision to eliminate the algebra course is based on scope of practice and alignment with removing potential barriers for laboratory professional applicants. While some laboratory professionals may engage in work that requires more advanced skills in mathematics, most do not. As a result, we believe that the math, statistics, and qualitative analysis course requirement is no longer necessary. Accordingly, we recommend that this be deleted. If there is evidence to support these courses as inclusion criteria, this not well vetted or publicized.

These changes need to be made to numerous sections of the proposed rule, including Sections 1030.5, 103.7, and 103.8, as well as other provisions of LFS's personnel rules not addressed here.

Commenter: 12

Comment Topic: Remove specific course requirements and align with CLIA
Comment: CCLA is opposed to the new requirement which is listed in multiple places in the proposed rule which requires that a bachelor's degree must include specific courses within the subset of Chemistry, to include quantitative analysis, biochemistry, or clinical chemistry. We believe this is unnecessarily restrictive, and many colleges or universities may not have those specific courses. Similarly, the requirement that credit hours in biology must include microbiology, hematology, and immunology is unnecessarily restrictive. We propose that the educational requirements of this section align with the corresponding educational requirements under CLIA.

Commenters: 9 and 10

Department Response: The Department disagrees that the specification of chemistry and biology coursework is unnecessary. This is also the position of several commenters who specifically requested the inclusion of analytical chemistry and medical microbiology, to ensure that training equips CLS with the skills necessary to perform clinical testing. The Department's regulations aim to ensure minimal competency in specific areas of laboratory testing because a generalist CLS license authorizes licensees to perform testing in all areas of the laboratory.

Comment Topic: Make trainee licenses valid for two years
Comment: Several MLT programs in the state extend beyond a duration of 12 months. Additionally, there are instances where students may need to defer their training due to unforeseen circumstances. We kindly request that you take these factors into account when determining the validity period for the training license.

Recommendation: Make training licenses valid for at least two years to account for most MLT programs extending beyond 12 months.

Commenter: 5, co-signers, and duplicates

Comment: Consider making trainee licenses good for 2 years. This is consistent with licenses, and would allow many trainees to not have to renew the trainee license during their one-year training period.

Commenter: 7

Comment: Consider modifying training licenses to cover a 2-year period. UCDH encourages applicants to not apply for a CLS Training license until they are accepted into training. A 2-year training license would prevent the need for renewal.

Commenter: 11

Department Response: The Department declines to make the requested revisions. To accommodate students whose training course extends beyond the expiration of their trainee license, the Department is proposing a renewable one-year trainee license. This allows trainees to renew their license annually but does not require all trainees to pay for a second year of licensure they may not need. To ensure this flexibility and in fairness to trainees who complete their training within one year, the Department will retain the proposed language.

Subsection (a)(4)

Comment Topic: Add COLA to the list of international accrediting organizations

Comment: Under section 1030.6, “Licensure and Work Scope of a Medical Laboratory Technician,” it states:

a) “(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) 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…”

COLA accredits laboratories in all 50 states, as well as laboratories in several foreign countries and non-USA territories. We respectfully request that COLA be added to this section of the proposed rules, along with the CAP and JCI.

Commenter: 4

Department Response: The Department accepts this suggestion and has corrected the oversight by adding COLA to the list of accrediting organizations acceptable to the Department for accreditation of international laboratories.

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

Introductory paragraph

Comment Topic: Change "clinical laboratory technologist" to "clinical laboratory scientist"

Comment: Correct text of section 1030.7 as follows:

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.

Commenter: 8

Department Response: The Department accepts this suggestion and has changed the title "clinical laboratory technologist" to "clinical laboratory scientist" to align with the proposed change to the title of this section.

Article 2. Training Programs.

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

Multiple Subsections

Comment Topic: Change the ratio of trainees to trainers

Comment: While it is assumed that the provision in 1035.1(d)(4) refers exclusively to clinical practicums and does not encompass didactic courses or student labs, clarity on this distinction is needed. Assuming its applicability solely to clinical practicums, the limitation of two students per trainer will lead to certain training sites accommodating fewer students, ultimately resulting in a decrease in the overall number of MLT and CLS graduates going forward.

Recommendation: Increase the number of maximum trainees to five, and ensure the language applies solely to clinical practicums.

Commenter: 5, co-signers, and duplicates

Comment: Two trainees max is insufficient for some training situations, request change to a maximum of 5 trainees to allow for uncommon but effective group training experiences at the training program's discretion.

Commenter: 7

Department Response: Department declines to make the suggested change, as it is unnecessary. This provision regulates the number of trainees for which a supervisor can provide direct and responsible supervision, which is defined in BPC 1206 (a)(10) and specified for trainees in BPC 1205. It does not limit the number of trainees for which an instructor or trainer can provide instruction. Therefore, the requested change is not needed to allow persons providing practical training to instruct more than two trainees at one time, and consequently the Department will not make the requested change.

Regarding the request to add clarifying language to state that the ratio of trainees to supervisors applies solely to the supervision of trainees during practical training, the Department declines to make the suggested change, as it is unnecessary. The definition of "direct and responsible supervision," in BPC § 1206 (a)(10) and 17 CCR § 1029 refers specifically to supervision “of all results of clinical laboratory testing or examination performed by the trainee” “during the entire time that the trainee is performing clinical laboratory tests or examinations.”

When drafting the proposed section limiting the number of trainees a person may supervise, the Department consulted stakeholders, and the consensus was that a maximum of two trainees per supervisor was necessary to ensure direct and responsible supervision of trainees. Internal subject matter experts agreed. The Department will not change this requirement and will retain the current ratio of trainees to supervisors.

Comment Topic: Revise requirements for MLT training hours per specialty
Comment: To streamline practicum scheduling and ensure simplicity, it is recommended to consider a more rounded figure than 128 hours in 1035.1(h)(2). 128 hours does provide a convenient framework for clinical practicum scheduling purposes.

Assigning 128 hours exclusively to ABO and RH training is overly specific and neglects various other essential areas where a Medical Laboratory Technician (MLT) could contribute, such as screening testing and unit typing. A more comprehensive approach is proposed, rephrasing the requirement as "*128 hours of Moderate Complexity testing, including ABO and RH*,” allowing for a broader scope of training that better reflects the diverse functions of an MLT. This also aligns better with the MLT work scope defined in 1030.6.

Furthermore, designating 128 hours solely to Diagnostic Immunology, and referring to it as a specialty is problematic considering that immunology testing is ubiquitous and integrated throughout the entire laboratory.

Recommendation: Remove diagnostic immunology as a separate practicum and integrate it within other departments to align with current clinical practice. Set the total hours for other core departments to 160 to account for this change. Include other moderate-complexity tests, such as screening, in the Immunohematology practicum hours.

Rewrite example:
Practical training must be obtained in a clinical laboratory certified under CLIA and must consist of at least 640 hours of practical training in the specialties of chemistry, microbiology, diagnostic immunology, hematology, and moderate complexity Immunohematology including, ABO and Rh.

Commenter: 5, co-signers, and duplicates

Comment: MLT trainee authorization is too narrow, recommend changing "moderate complexity ABO an Rh type immunology" to “immunohematology". This will allow flexibility to provide instruction in any moderate complexity blood bank testing and provide adequate understanding of this specialty.

Consider adjusting the required hours per specialty - this change to 128 hours of immunology is too many hours given the limited amount of testing in this section. We have spent years developing and executing a comprehensive training program aligned with the current specialty sections and hours required. The program is highly successful both in student exam pass rate and in high-quality, prepared graduates. Requiring these changes in hours and rearranging specialties would require extensive rework of our program materials, time we do not have. And we have no evidence the student outcomes would improve.

Recommend changing to prior standards of 160 hours each for "chemistry, microbiology, hematology, and immunohematology/immunology".

Commenter: 7

Department Response: The Department appreciates these comments and has made revisions to the number of hours of required training in various testing specialties. The Department has changed the requirement to 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 to include testing in the specialties of immunology and immunohematology. This will afford programs flexibility when devising their training schedules.

However, the Department does not accept the proposed amendment, which omits the specification of 160 hours in each specialty. The Department will retain this specification to ensure standard training in each area of testing.

The Department has omitted the reference to ABO and Rh type testing from the list of specialties, because this testing is not a specialty, but a set of tests within the specialty of immunohematology. Instead, the revision will 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.

Comment Topic: Allow classroom skin punctures
Comment: The shift in 1035.1(h)(1)(A) to mandating skin punctures in a clinical setting is impractical and places an undue burden on clinical sites. Currently, the majority clinical laboratory personnel seldom perform skin punctures on patients. Consequently, this regulations alteration introduces an extra layer to training, and will discourage clinical sites from participating altogether. To address this concern, it is recommended that skin punctures be permitted in a classroom setting under the supervision of a qualified instructor.

Recommendation: Regarding Skin Punctures, revert to the previous language to allow classroom-based skin punctures:
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.l(f).

Commenter: 5, co-signers, and duplicates

Comment: Can the skin punctures be done in the classroom setting? In CPT-1 programs students can do that during classroom and we focus the patient phlebotomy time on venipunctures. Skin punctures during clinical time would be very challenging to accommodate as laboratory staff do not do any skin punctures, we would have to coordinate this with nursing staff trainers.

Commenter: 7

Department Response: The Department declines to make the requested change. The proposed language retains the current requirement in 17 CCR 1035.1(b) that an MLT training program provide both didactic instruction and practical training in phlebotomy as

specified in 17 CCR subsections 1035 (e-f) (formerly 17 CCR 1035.1 §§ (e-f)): 40 hours of didactic instruction in phlebotomy, which may take place in a classroom setting, and 40 hours of practical training in phlebotomy, including instruction and successful completion of punctures, which must take place in a clinical setting according to requirements specified in section 1035(f).

These requirements remain the same in the proposed regulations. Section 1035 requires completion of skin punctures and venipunctures in a clinical setting to provide trainees with access to patients of varying ages, including pediatric and geriatric, and of varying health and obesity status. An MLT training classroom does not provide access to the full range of patients; consequently, the Department will retain the current requirement in Sections 1035.1, consistent with the requirement in Section 1035.

Comment Topic: Change “6 months" to "17 weeks"
Comment: 1030.6 (a)(4)(B): change “6 months" to "17 weeks" to be consistent with experience details of 640 hours of lab testing plus 40 hours of phlebotomy.

1030.8(a)(5): change “6 months” to “17 weeks: to be consistent with later training details.

Commenter: 7

Department Response: The Department declines to make this change. This section and parallel language in section 1035.1 require a training program to provide at least six months of training, which must include at least 640 hours of training in specific areas of testing. For that reason, we will not make the requested change to “17 weeks,” which would be only four months.

The Department prefers to use the term “six months” rather than specifying the number of weeks to allow training programs maximum flexibility in devising programs, including flexibility around holidays. The section specifies “at least six months” to allow programs the flexibility to extend training time as they see fit, while ensuring that trainees receive at least the minimum amount of instruction.

Comment Topic: Allow designees to perform competency assessment
Comment: Why is it specified in 1030.6(b)(4) that competency assessment for testing and phlebotomy of MLTs is done by the lab director? This is covered elsewhere. It is more than what is required for other lab licenses, and introduces confusion when for others the competency assessments can be delegated. Consider removing this line.

Commenter: 7

Comment: Concern that competency assessment for testing and phlebotomy of MLTs is done by the lab director. This is unnecessary and would create challenges. Modify language to align with other license competency assessment practice.

Commenter: 11

Department Response: The Department agrees with these comments and has amended 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 for delegation of competency assessment in BPC subsection 1209(g).

Section 1035.2. Training Schools for Clinical Laboratory Scientists.

Subsection (e)

Comment Topic: Change specialty hour requirements for CLS

Comment: In addition to the proposed changes to section 1035.2, an update to the amount of practical training required by each laboratory is warranted, to compensate for the changes in workflow and scope by today's clinical laboratories.

We find that 3 weeks of Parasitology, 4 weeks of Urinalysis and 12 weeks of Biochemistry are excessive, and recommend a minimum of 1 week, 2 weeks and 10 weeks respectively.

Additionally we find that more than 8 weeks of Hematology and 4 weeks of Transfusion Medicine are necessary to train a fully competent CLS trainee. We recommend a minimum of 9 weeks and 8 weeks respectively.

A minimum of 1 week in Molecular techniques and methodologies must also be incorporated as an additional requirement.

Commenter: 10

Department Response: The Department plans to make extensive revisions to the requirements for CLS licensure in Section 1030.7 and requirements for CLS training programs in Section 1035.2 in a future rulemaking package. The revisions will be made in the same rulemaking to ensure alignment of licensure requirements and training program requirements. The Department will consider these recommendations when making those revisions.

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

Multiple Subsections

Comment Topic: Concerns about the alignment of the proposed bridge program with SB 334

Comment: Why does the summary of proposal differ from what is stated in the bill [SB 334 (Pan, Chapter 144, Statutes of 2018)]: 'Pathway program that would authorize a licensed MLT to apply their work experience and training from an approved MLT training program towards the completion of a CLS training program.'

The proposed summary does nothing with what is stated in the bill and instead requires a training program.

…

Laboratory persons have been pushing for this pathway since 2009. CDPH had issues handling the issues in 2010 due to the volume of comments; obviously we want change. This is something that your constituents have been calling for you to change for over 15 years. I feel that the 6-month training, if implemented, would only give access to a handful of MLTs who can afford to work for free, again. You are diminishing the opportunity for hard working MLTs who have been waiting patiently for an improvement to the system.

Commenter: 1

Comment: The proposed model of MLT to CLS Bridge Education raises significant challenges in identifying an ideal provider of bridge training.

…

SB-334 states: " ... the department shall establish an "MLT-to-CLS" pathway program by January 1, 2022, that would authorize a licensed MLT to apply their work experience and training from a department-approved MLT training program towards the completion of a CLS training program." Yet, there appears to be no provisions in the proposed regulations that allow MLTs to apply any work experience to their bridge training programs.

Considering the language outlined in SB-334 and the emphasis on training contributing to the completion of a CLS Program, it becomes apparent why the proposed language concentrated on the development of standalone bridge programs. A potential need for a revision to SB-334 may be required to establish a more authentic employee-based bridge. If such is the case and we are forced to work within these limitations, then the

proposed bridge education programs should be tailored towards hospital-based laboratories rather than academic-based institutions.

Commenter: 5, co-signers, and duplicates

Department Response: The Department declines to make the requested changes. The Department has responsibility to oversee the licensure of clinical laboratory personnel, including oversight of training programs, which must have Departmental approval to operate. The Department sets training program standards that ensure that programs are operated by qualified personnel and that they employ qualified personnel to provide instruction, training, and supervision. CLS training program curriculum standards ensure that programs provide trainees with the theoretical knowledge (didactic instruction) and hands on experience (practical training) required for California licensure, and that all trainees who complete California training programs have one year of training that prepares them to independently perform accurate and reliable non-waived testing in all areas of the laboratory.

SB 334 (Pan, Chapter 144, Statutes of 2018) directed the Department to create a program to enable MLTs to transition to CLS licensure. According to the Fact Sheet for SB 334, the intent of this legislation was that “The Pathway would create an expedited process for an MLT to obtain licensure as a CLS by allowing an MLT’s training to satisfy some components of the CLS training program that are redundant under existing law. This career pathway would not impact the education requirements needed to obtain a CLS license…. By creating a pathway for MLTs to CLS’, MLTs will be able to apply their 6-month clinical training program to satisfy a portion of the training requirements needed to obtain a CLS license. … As a result, the creation of an MLT-to-CLS pathway could potentially cut a one-year CLS training program by months for eligible candidates. For many MLTs the time commitment needed to complete a training program serves as an extra impediment to obtaining a CLS license.”

The proposed bridge program implements the mandate and intent of SB 334 for a program that allows California MLTs to fulfill all the education and training requirements for to qualify for CLS licensure, and ensures that trainees in the bridge program will have the education and training required of CLSs who completed a regular CLS training program, including instruction that prepares them to perform all levels of testing in all areas of the laboratory.

MLT licensure requires an associate degree or equivalent coursework in science and six months of training in the performance of waived and moderate complexity testing. CLS licensure requires a baccalaureate degree with specific coursework in clinical laboratory sciences and one year of training in moderate and high complexity testing in all areas of the laboratory.

The proposed bridge program is half the length of traditional CLS training programs but is structured to ensure that MLTs who complete that program will have the same qualifications as CLSs who complete a regular CLS program, including one year of training. It credits MLTs with the training and experience completed for MLT licensure, not requiring further training in moderate-complexity testing. It specifies requirements to ensure the program provides trainees with theoretical instruction and hands-on experience doing high complexity testing in all areas of the laboratory under the supervision of licensed personnel with competency in the testing they are supervising.

The Department lacks authority to make changes to the proposed program that exceed the mandate of the statute, make statutory changes, or change statutory requirements for CLS licensure through regulations, or exempt programs from meeting general standards.

Comment Topic: Requests for an employer-based program
Comment: The proposed model of MLT to CLS Bridge Education raises significant challenges in identifying an ideal provider of bridge training. Most hospitals are disinclined to establish their own program due to the associated logistical and resource burdens, including the need for a designated program director, the didactic training requirements, and the application process to become a CLS program.

…

A more efficient bridge solution would revolve around employee-based training, where approved employers deliver necessary training by fulfilling hour requirements, mirroring models used for CLS/MLT licensure in military or out-of-state labs. The supplementary clinical training will specifically target high-complexity testing within each department, aligning with the discrepancy in training duration between MLT and CLS programs. Laboratory supervisors would possess the authority to assess competence in each specific area and attest to the completion of training for individuals.

This approach would permit hospitals to provide training on their time line without grappling with the intricacies of CDPH CLS program approval. It would allow employers to confirm their employees' compliance with specific hour requirements. This not only provides flexibility for hospitals but also bolsters the motivation to hire and train MLTs, and ultimately contributes to an increased number of qualified Clinical Laboratory Scientists (CLSs).

Commenter: 5, co-signers, and duplicates

Comment: We are an approved hospital based CLS Training program currently training 6 CLS students per year, and thus have many facets of the proposed infrastructure in

place to educate trainees via the MLT-to-CLS pathway. However a few items on the list of requirements in the proposed training model for us would be quite challenging, time-consuming and likely deter us from seriously considering incorporating this training into our hospital system.

Preferably, we find incorporation of an “Employee based bridge program” more efficient and compatible, and most likely to be accommodated in our hospital-based environment. We agree with the proposed comments to be submitted by the MLT Bridge focus group (Jason Pedro, et al), and have added our name (Winnie Carino; Scripps Health CLS Training Program) to the group list of supporters.

Commenter: 10

Department Response: The Department appreciates these comments but declines to make changes as requested because the suggestions for employer-based training are beyond the scope of the current statute, which directs the Department to establish a program that allows MLTs to apply their work experience and training from a Department-approved MLT program towards the completion of a CLS training program. SB 334 did not change the requirements for CLS licensure, which are a baccalaureate degree with specific science coursework, plus one year of training from a Department approved training program.

The Department proposes an MLT to CLS transition program consistent with requirements for regular CLS training programs but does not have authority to create individualized employer-based training exempt from the general requirements for CLS licensure and approval of CLS training programs.

Comment Topic: Remove “didactic” language
Comment: Removal of didactic language. Given the comprehensive didactic education MLT students typically receive and their inherent motivation to study for and pass a CLS exam, there is no necessity for additional didactic education stipulations in the regulations. Instead, insist on "instruction" in the various topics listed to offer hospital-based bridge programs to use a variety of learning modalities and practicum education.

Commenter: 5, co-signers, and duplicates

Comment: What constitutes didactic training? This term is confusing and requiring formal lecture style didactic training would be a burden that would eliminate many hospital based programs from participating. Consider changing to "training must include instruction in each of the following subjects" to allow programs to use a variety of learning tools as appropriate.

Commenter: 7

Comment Topic: Credit MLT work experience, remove specific training hours, and allow programs to waive areas for individual students
Comment: In accordance with SB-334, acknowledge and credit the work experience of MLTs by affording programs the flexibility to tailor training to individual students, addressing specific areas where further training is needed. Keep the same program total week requirement but allow bridge programs to waive areas where students demonstrate competency from their work experience as an MLT. Recognize that most testing conducted in the clinical laboratory is classified as "moderate complexity" and prescriptive department week requirements create gross repetition in some areas, as well as deficiencies in others.

Commenter: 5, co-signers, and duplicates

Comment: The required weeks, especially for chemistry and diagnostic immunology, are too much. For example, it is common that 100% of Chemistry tests in a large acute lab setting are moderate complexity, and as such an experienced MLT completing the CLS bridge portion of training would have no new tests they could learn in Chemistry. With flexibility allowed, we could distribute the 24 weeks on subjects needing more time to gain CLS level training experiences, such as advanced hematology and immunohematology.

Recommend keeping the same 24 week total but allowing program to customize schedule creation for students based on their previous work experience. This would provide the most effective and efficient use of valuable training time.

Commenter: 7

Comment: Section 1035.3.(h) requires a training program to 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.

Rather than a stringent requirement of defining the exact number of weeks (four) for each discipline subject, define instead a minimum number of weeks for each. The program can then have a small amount of flexibility in creating a curriculum and schedule that adheres to the requirements, but allows some creativity in adjusting training based on current system workflows and resources, and enhance applicability. Justification may include consideration of the MLT's of work history in certain disciplines (e.g. four weeks may be unnecessarily too long in routine chemistry or urinalysis if the MLT has prior work experience in these areas).

Commenter: 10

Comment: Recommend adjusting the required hours, to simply total applied education hours needed for bridge training. Removing specific testing section requirements for established CA approved CLS training programs will allow flexibility to create meaning bridge training as needed for each student.

Allowing programs with established training success to review competency in areas the MLT has been working- and shift training hours to testing they are unfamiliar- focusing on CLS generalist training would be incredibly beneficial and ensure training is educational and not utilizing training hours in work duties the MLT is currently performing.

Consider removing required weeks in specific testing areas, allowing established programs to structure the 24 weeks in a manner to utilize training time most effectively.

Commenter: 11

Department Response: The Department declines to make the requested changes to remove the requirements that specify a minimum number of hours of training in various laboratory specialties and create individualized programs for trainees based on their past work experience, allowing bridge programs to waive areas where students demonstrate competency from their work experience as an MLT, or having approved employers deliver necessary training by fulfilling hour requirements, with supplementary clinical training specifically targeting high-complexity testing within each department.

The proposed curriculum standards, which are those of regular CLS programs, ensure training that prepares trainees to independently perform accurate and reliable high complexity testing in all areas of the laboratory.

Removing specificity would fail to ensure minimal training in each specialty. The Department understands the desire for flexibility but must balance that with a concern

that trainees for a generalist CLS license are competent in all areas of testing. Regulations for the bridge program did not eliminate or alter the requirements for CLS licensure, and consequently the requirements for training programs cannot differ significantly in scope from the requirements for CLS licensure. This ensures that all CLS applicants have the standard education and training required to perform the testing authorized by their license.

The proposed bridge program gives MLTs credit for their education, training, and experience performing moderate complexity testing, and creates a program focused on completing training in high-complexity testing. Because MLTs are not allowed to perform high complexity testing under California law, the Department cannot credit MLT work experience in California as a fulfillment of all the requirements for CLS licensure.

Regarding the suggestion to omit requirements defining the exact number of weeks for each discipline subject and define instead a minimum number of weeks for each, the Department declines to make that change because it is unnecessary. The proposed text does not limit training to four weeks, but rather sets a minimum (“at least 4 weeks”), so a program can tailor instruction to the needs of its trainees.

Regarding the comment that the required weeks, especially for chemistry and diagnostic immunology, are too much because chemistry tests in a large acute laboratory setting are moderate complexity, even if a CLS doesn't do high-complexity chemistry in a specific job, their CLS license authorizes them to do it (if the need should emerge in the future or if they change jobs), so training must equip them to do it accurately, reliably, and consistently. For this reason, the Department will retain the requirement for training in high complexity testing in all specialties.

The proposed regulations ensure that trainees in the bridge program, like trainees in a regular CLS training program, will have the education and training required of CLSs who completed a regular CLS training program, including instruction that prepares them to perform all levels of testing in all areas of the laboratory.

Comment Topic: Add more training hours
Comment: The scope of MLTs in California is limited to the extent that MLTs cannot keep any skill level in areas such as Blood Banking, Microbiology and manual microscopic testing and interpretation. Only four weeks in Blood Banking, Microbiology and Hematology & Urinalysis is very concerning especially if MLTs have been out of school and their MLT training for many years. It would not be possible to attain competency in these areas with just four weeks of training in each area. Eight weeks in Hematology & Urinalysis, ten weeks in Blood Banking and twelve weeks in Microbiology

would be required to properly expose, train and obtain minimum level of competency for MLTs to bridge to CLS licensure.

Commenter: 3

Department Response: The Department declines to make the suggested changes. The six months of training in the proposed rulemaking, added to six months of training for MLT licensure, meets the statutory requirement for one year of training for CLS licensure. The commenter's suggestion to add 18 weeks of training to the proposed six-month MLT to CLS bridge program, in addition to the 26 weeks training required for MLT licensure, would ultimately require MLTs transitioning to CLS licensure to have more training than is required for traditional CLS training programs.

This would defeat the intent of the legislation that created the MLT to CLS bridge program, which was to credit MLTs for the coursework and training they already completed to obtain MLT licensure and provide a shortened program to expedite CLS licensure. Therefore, the Department will not make the suggested changes.

Comment Topic: Allow non-consecutive training
Comment: Training may be completed in non-consecutive months, i.e. over the course of 6-18 months, as long as full training is completed within 6-18 months of the start of training.

Commenter: 10

Department Response: The Department declines to make the requested change because it is unnecessary. The proposed regulations do not require training to occur in consecutive months, so non-consecutive training is already available as an option.

Comment Topic: Amend "one of the following" to "one, or a combination, of the following"
Comment: Section 1035.3(h)(2)(F) states "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:

(F) One of the following subjects:

Change "One of the following subjects…" to "One, or a combination, of the following subjects…"

Commenter: 10

Department Response: The Department agrees with this suggestion and has added the phrase “or more” to the requirement that training include “one of the following subjects,” to clarify that the program has the option of including as many of the options, in any combination, as it chooses.

Comment Topic: Streamline administrative processes
Comment: Streamline administrative processes, including minimizing clerical work and simplifying the application process, to facilitate the establishment of a hospital-based bridge program.

Recognize that these administrative barriers pose a significant obstacle for prospective hospital-based programs due to their limited resources. Furthermore, streamline the administrative process for existing CLS programs that wish to train their own MLT staff.

Commenter: 5, co-signers, and duplicates

Department Response: This request is outside the scope of the proposed regulations, which do not amend administrative processes such as applications. The Department plans to revise application and approval processes in a future rulemaking package and will consider the constituent’s comments when making revisions to the approval application process.

Comment Topic: Make the bridge program an addendum to approved CLS program
Comment: Section 1035.3.(a) requires that 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.

A more effective method for approving a program interested in committing to training MLT’s via the new pathway would be to allow a current CLS program in good standing to provide an ‘addendum’ to their current approval status’d CLS program that would delineate items in section 1035.(h), without having to resubmit the entire package of items required when initially approved for CLS training.

Commenter: 10

Department Response: This request is outside the scope of the proposed regulations. However, the Department plans to revise standards for general CLS training programs in a future rulemaking package and will consider the constituent's comments when making those revisions.

Comment Topic: Exams for students in the bridge programs
Comment: There are concerns regarding the eligibility of bridge students for the ASCP examination. Graduates may not qualify for any of the existing ASCP certification routes. Route 1 mandates NAACLS accreditation, an onerous endeavor that will deter most hospitals from participating in the bridge program. The alternative routes necessitate several years of full-time work or military experience. It may be necessary for CDPH to collaborate with ASCP to establish a new route or implement a California-specific exam for bridge graduates.

Commenter: 5, co-signers, and duplicates

Comment: What CLS licensing exams will be allowed for MLT bridge candidates? Currently ASCP doesn't list any route that would fit for applicants completing this new path per section 1030.8.

Commenter: 7

Department Response: The Department chooses not to specify examinations by indicating the titles of specific licensing exams in regulations. Organizations whose licensure examinations are approved by the Department for licensure purposes are specified on the Department website when the examinations are approved. Because the examinations may change, the Department posts approved examinations on the website for efficiency and timeliness. The Department is working with examination providers to ensure that applicants who complete the MLT to CLS bridge program will qualify for a CLS examination.

Comment Topic: Change "6 months" to "24 weeks"
Comment: 1035.3(h) and 1030.8(a)(5): Change 6 months to 24 weeks for consistency.

Commenter: 11

Department Response: The Department declines to make this change. These sections require at least six months of training, which must include at least 640 hours of training in specific areas of testing. The Department prefers to use the term six months rather than specifying the number of weeks to allow training programs maximum flexibility in

devising programs, including flexibility around holidays. The section specifies “at least six months” to allow programs the flexibility to extend training time as they see fit, while ensuring that trainees receive at least the minimum amount of instruction in each specialty of testing. For that reason, we will not make the change to “24 weeks” as requested.

Comment Topic: Definition of “weeks”
Comment: The term “weeks” used in the text: is that a period of 5 days, 8 hours per day? Is there a specific number of hours?

Commenter: 2

Department Response: The Department prefers the generally used term “week” rather than specifying the number of days or hours, to afford programs flexibility.

Comment Topic: Program isn’t less burdensome
Comment: The department’s reason for rejecting alternatives (on page 6 of the Initial Statement of Reasons). That the proposed would be “less burdensome” to affected private persons. How is requiring 6-month training determined to be less burdensome and more cost effective? It would be the complete opposite; like it is stated in the cost impacts (page 60) which states that non-paid training would cost an MLT in California $31,000 in wages. It doesn’t matter that the cost can be made back once working as a CLS.

Commenter: 1

Department Response: This statement from the Initial Statement of Reasons says that the Department considered the proposed regulations and determined that the adoption of these regulations is the most effective, least burdensome, and most cost-effective way to achieve the implementation of the statutory policies they implement. The statute for the MLT-to-CLS requires the Department to create a training program that allows MLTs to meet the requirements for CLS licensure in a shorter time than the completion of a regular CLS training program. The Department has determined that adoption of these regulations is the best way to implement such a training program, as the proposed regulations offer a six-month program in place of the one-year program currently required for CLS licensure, while ensuring that trainees acquire the minimum competencies needed to perform accurate and reliable clinical testing, including high-complexity testing, in all areas of the laboratory.

Comment Topic: Concerns about the burdensome nature of the proposed program
Comment: It is waste of my time and money if i have re-do all the course works because it is 5+ years in order to eligible to re-apply for the CLS program. (Do they ask to re-do the whole bachelors program again....?) I really not getting the login.

I rotated in all departments. I wish to get a chance to take the CLS exam to check my knowledge, which I earned from my work experience and studies, instead of making me re-do all the classes which I did under the MLT program.

I saw lots of my co-workers going out of state to become a CLS with a national license and coming back to California to take the exam for a CLS license in California. I do not understand the logic of restrictions,

1. MLT & CLS are doing the same job in the chemistry department but getting different pay.

2. With the long work experience even training new CLS's and CLS trainees.

Commenter: 15

Department Response: The comments appear to misinterpret some aspects of the proposed training program. The bridge program is designed to avoid duplication of training. An MLT is required to complete six months of training in moderate complexity testing, and trainees in the bridge program are credited with this work and are only required to complete six months of training in high-complexity testing. This allows them to meet the requirement for one year of training for CLS licensure. All CLS applicants must have the equivalent of a baccalaureate with specified coursework, but an applicant who already has a baccalaureate degree with such coursework is not required to obtain a second baccalaureate or to repeat coursework already completed.

The Department disagrees with the argument that MLTs do the same work as CLSs and should receive credit for that work. MLT licensure authorizes a person to perform only waived or moderate complexity testing. An MLT who is performing any high-complexity testing is working beyond the authorization of the MLT license. The proposed bridge program gives MLTs credit for their education, training, and experience performing moderate complexity testing, and creates a program focused on completing training in high-complexity testing, but the Department cannot credit MLTs for work performing high-complexity testing that is beyond their authorized scope of work.

Unrelated or Irrelevant comments

General Topics

Comment Topic: Hybrid programs

Comment: Will Lab Field Services or Licensing accept programs from out of state that are online hybrids such as the LSU MLT to MLS degree?

Will accredited programs outside the state still have to apply for a training certificate or approval with Lab Field Services and notify the state upon starting, pausing, and ending program time for each student of trainee? When changing Directors, etc? Where and how do they do that?

Commenter: 2

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

Training programs located outside California that apply for CDPH approval must meet the requirements of California law, but the Department cannot respond to questions about the qualifications of specific programs in this rulemaking package. Please contact the Department at LFSCLSTrainingProgram@cdph.ca.gov for more information.

Comment: Is there sufficient demand to warrant the start-up costs for administering a program? From our analysis, we don't believe so. The didactic portion of the proposed bridge could not be integrated into our three-semester/52-week long CLS program. It would require its own courses and instructors and would require a minimum number of students in cohort to be sustainable (~12). There would need to be a sufficient size student population that would be stable and continue over many years to justify ramping up a program.

Our data does not support this. In each applicant cohort of now well over 200 candidates we only receive applications from 3-6 MLTs in each cohort. From our perspective, we do not see a sufficient volume of MLTs wishing to pursue CLS training.

Commenter: 13

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful

response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

While the Department appreciates the commenter's input, we disagree that there is not a demand for this program. The Department has received many requests over a period of many years requesting a bridge program to facilitate the CLS licensure of individuals licensed as MLTs.

Comment Topic: Provide more training programs
Comment: There is no shortage of highly qualified applicants for our [CLS] program. We generally receive applications from well over 200 candidates in each of our application cohorts (Fall/Spring). Our last cohort for Fall 2024 was 241 applicants, most of them highly qualified. Of that number, we are able to train only 25-30 students because training depends on there being a training facility to provide the practical training.

In the last few years, we started compiling information for an outreach program to try and secure more training affiliates. We have compiled a spreadsheet that contains ~500 hospitals. We assume most of them have laboratories and require CLSs and MLTs to operate BUT they do not train students. Many of them, as well as Biotech companies, hire our graduates away from the hospitals that invested in their training, leaving our training affiliates frustrated and discouraged about continuing to train.

What we in our program would like to see the State of California do to address the shortage of licensed CLSs is:

- Streamline the process for training affiliates to get approvals from LFS to provide that training.
- Help facilitate relationships between the hospitals (and biotech companies) and the schools that provide the didactic portion of training.
- Provide more CLS training opportunities for the students who live in California and earned their degrees from California colleges and universities.

There is no shortage of qualified applicants for the training programs. The shortage is in suppliers of the practical training—hospitals (and biotech companies) willing to invest in training the lab personnel they need. Help BRIDGE that gap.

Commenter: 13

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The current rulemaking does not amend administrative processes such as applications. The Department plans to revise application and approval processes in a future rulemaking package and will consider the constituent's comments when making revisions to the approval application process.

The Department does not provide training programs. It is authorized to oversee training programs, including review and approval of applications to operate programs, but it lacks the authority to require institutions to offer such programs.

The Department lacks authority to facilitate relationships between the hospitals (and biotech companies) and the schools that provide the didactic portion of training. Experience or training must be obtained in a clinical laboratory. Experience in a research laboratory such as a biotech company is not acceptable for purposes of clinical laboratory licensure under both State and federal law.

Comment Topic: Request for Assistance
Comment: I just received the update for clinical lab bridge. I am having a hard time understanding it. Can I schedule a phone call tomorrow to discuss?

Commenter: 115

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

Comment Topic: Opposition to AB 1741
Comment: I strongly OPPOSE this effort to amend CA - BPC 1269 regulations in clinical lab personnel standards and in alignment to the CLIA 88 Standards.

Commenter: 116

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

This comment appears to address AB 1741 (2023, vetoed by the Governor). The proposed regulations in DPH 20-007 do not affect BPC section 1269, which regulates unlicensed laboratory personnel.

Comment Topic: Personal Qualifications
Comment: 1. Current I am a licensed MLT in CA and have a CLS generalist trainee license. Do I need to apply for another trainee license if I apply for the MLT to CLS program?

2. Am I eligible to take a national exam such as ASCP if after finishing pathway program?

3. Can I ask my current employer to train me on high complexity tasks for 6 months? If so, do they need to create an own training director or I have to apply this program to the CLS training schools such as SFSU or SJSU?

4.Do I need to take CLS advanced courses during 6 months training?

Commenter: 67

Comment: Based on my degree, licenses, experience, etc, am I someone who would fit into the "exception" category.

Personally, I went to the NACCLS approved MLT program at Southwestern College in National City, CA. The program had me do training in all departments just like the CLS program does. I have been working as an MLT since 2017; therefor I have 6 years of experience in a busy hospital laboratory. I also have a bachelor's in biology, and I challenged the ASCP CLS requirements and was granted the opportunity to take the exam and I passed. I have experience in all departments including Blood bank as MLTs can work in the department at Rady's Children Hospital in San Diego, CA.

Commenter: 1

Department Response: These comments are not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

The Department cannot evaluate or comment on an individual's qualifications in the Statement of Reasons. The constituents are encouraged to contact the Department at LFSScientist@cdph.ca.gov for more information.

Comment Topic: Request for copy of proposed changes
Comment: I am interested in finding out what personnel changes are proposed for laboratories in the state of California. May I receive a copy of the proposed changes?

Commenter: 117

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The Department provided the commenter with a link to the proposed rulemaking.

Comment Topic: Request for other rulemaking packages
Comment: I cannot find the link and would appreciate your guidance so that I can read:

1. DPH-16-019

2. DPH-16-020

3. DPH-18-017

4. DPH-20-006

Commenter: 118

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The requested rulemaking packages are in progress and have not yet been published for public comment.

Comment Topic: Licensure of Pathologists' Assistants
Comment: In light of the revisions proposed to the Clinical Laboratory Regulations within the California Code of Regulations (CCR), specifically title 17, sections 1029-1035.3, which aim to delineate the educational, training, and experiential prerequisites, as well as the examination standards requisite for licensure and certification of laboratory professionals, and to clarify the scope of responsibilities for such professionals; the American Association of Pathologists' Assistants (AAPA) proposes the establishment of a licensure pathway for Pathologists' Assistants in California.

…

If the time is not right for an update to legislation at this time, we would like to formally request to arrange a call or in-person meeting between you and members of our Legislative Subcommittee to discuss this legislation in hopes of reaching an agreement that will be beneficial to our profession and to your state. Thank you for your time and consideration.

Commenters: 119 and 120

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

Comment Topic: California laboratory standards
Comment: I would like for the council to address specifically why California standards are more difficult than nation standards (ASCP and other states licensure)? California is not promoting fairness.

Commenter: 1

Department Response: This comment is not specifically directed at the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

California standards for clinical laboratory personnel are established in statute. The Department cannot comment on the intent of the legislature in establishing those standards and lacks authority to make statutory changes through the rulemaking process.

Expressions of Support
Comment: We support the Department's proposals to improve its flexibility with regard to accepting work experience and military service towards MLT licensure. We also

support the Department's proposal to recognize "MLT training from an approved NAACLS-accredited training program."

Commenter: 12

Comment: I greatly appreciate all the work you have done to make the MLT to CLS bridge a reality.

Commenter: 11

Department Response: The Department appreciates these comments of support.

Expressions of Support and Opposition

Comment: Thank you for your dedicated work on the recent regulation changes for MLT, CLS, and the Bridge programs, and for your thorough review of the public comments. As MLT & CLS program directors and faculty, clinical sites, former and current students, we wish to highlight a several areas of concern, outlined below. We are open to further discussion, and you are welcome to reach out to us at your convenience.

Commenter: 3

Comment: Thank you for your dedicated work on the recent regulation changes for MLT, CLS, and the Bridge programs, and for your thorough review of the public comments. As MLT & CLS program directors and faculty, clinical sites, former and current students, we wish to highlight several areas of concern, outlined below. We are open to further discussion, and you are welcome to reach out to us at your convenience.

Commenter: 5, co-signers, and duplicates

Department Response: The Department appreciates these comments of support and has also considered and responded to the opposition in its responses to specific comments.

Expressions of Opposition

Comment: Unfortunately, given some of the very specific and restrictive language currently in the draft guidance, we are concerned about growing, and even continuing, our training programs given the many changes needed to be compliant with the new regulation details.

Commenter: 7

Comment: Some of the proposed regulatory changes being considered would ignore or worsen this problem rather than help to resolve it, as detailed further below. … If these issues remain unresolved, we are concerned that they could worsen the laboratory workforce shortage unnecessarily, and an opportunity to provide relief will have been missed. We urge CDPH to amend the proposed rule accordingly to address these issues and help ensure that an adequate supply of qualified clinical laboratory personnel is available to serve the medical needs of California's residents.

Commenter: 9, 10

Department Response: The Department appreciates these comments and has considered and responded to the opposition in its responses to specific comments.

Addendum II
15 Day Public Notice

Summary of Comments and responses to Comments Received

The regulation text was revised in response to comments and made available for public comment for at least 15 days, from May 28, 2024, through June 17, 2024. The Department received comments from 58 commenters during the 15-day public notice period beginning May 28, 2024, and ending June 17, 2024. If multiple comments were received about the same topic, the comments are aggregated and summarized, and a single response is provided. Individual responses are provided for unique comments.

One comment attached a letter with extensive comments co-signed by 47 individuals that was submitted during the initial 45-day comment period. The comments in that letter were not directed to the revisions made by the Department to the proposed text or to the procedures followed by the Department in making those revisions. The responses to that letter are provided in Addendum I above. The Department has no additional responses.

No request for a public hearing was received and no hearing was held.

List of 15-Day Commenters

Unique Comments

1. Jamie Stypinski, School of Medical Laboratory Science, Eisenhower Health
2. Ralph Miranda
3. Dora Goto, California Association for Medical Laboratory Technology (CAMLT)
4. Erica Padilla, Sutter Health, Valley Area
5. Jason Pedro, Folsom Lake College, with an attachment with 46 co-signers
6. Ellena Peterson, University of California, Irvine
7. Patricia Buchner, De Anza College
8. Debbie Wagner, De Anza College
9. Melissa Jupp
10. Huy Le, San Francisco State University
11. Sarah Turkel, California State University Dominguez Hills

Co-signers of the letter attached to comment 5

(47 people co-signed the letter attached to comment 5 but did not send individual emails)

12. Natalie Cherok-Fenner

13. Erika Cobar

14. Kim Zwerenz

15. Alex Febo

8. Debbie Wagner also sent an email with individual comment

7. Patricia Buchner also sent an email with individual comments

18. Deanna Reinacher

19. Timothy Tomaso

20. Sharon Arase

21. Victoria Cusick

22. Joshua Segur

23. Danielle Layola

24. Vanessa Robles

25. Isabel Nevarez Paniagua

26. Thomas Loarie

27. Karla Theis

28. Hannah Mirrashed

29. Laura Laakso

30. Erin Bose

31. Chris Ha

32. Alisha Ram

33. Arezoo Ardalan

34. Sasha Pavlitsky
35. Rowena Carino
36. Keau Wong
37. Saba Tafkikialamdari
38. Giovanna Centeno
39. Kathryn Ma
40. Elizabeth Buck
41. Jennifer Le
42. Enosh Chu
43. Diana Martinez
44. Jaskaran Sandhu
45. Michelle MacLaren
46. Kami Hamor
47. Naomi Almanzor
48. Tatyana Bratan
49. Harpreet Singh
50. Lebn Leippe-Yudell
51. Gagandeep Saini
52. Danielle Magadia
53. Shirley Chau
54. Angie Jablonski
55. Larysa Sledz
56. Jessica Georguson
57. Amber Miller
58. Payal Patel

The Department's responses to comments received during the second comment period are provided below.

Comment Topic: Accept coursework rather than requiring specific degrees for CLS licensure

Comment: I would like to eliminate the type of degree and simplify it by simply stating a baccalaureate degree that must include the required CLS prerequisite coursework. I firmly disagree with the decision by CDPH/LFS to exclusively accept B.S. degrees and disregard B.A. degrees with the necessary CLS prerequisite coursework. This places an unjustifiable burden on potential CLS applicants to get a second bachelor's degree and does not align with the proficiency demonstrated by many B.A. CLS students. Such a change at this time is particularly concerning given the current shortage of CLS professionals. Additionally, the proposed changes exceed the requirements laid out by CLIA.

Recommendation: Eliminate the type of degree and simplify it by simply stating a baccalaureate degree that must include the required CLS prerequisite coursework.

Commenter: 1

Comment: CLS trainee must have degree in science, This is too restrictive and will eliminate a strong student who didn't discover CLS during undergrad and has taken all the needed courses, but their degree happens to be in something else. Nursing, nutrition, kinesiology are examples we've seen in the past. Please revise wording either here or in section 1032 allowing any bachelor's degree at LFS discretion as long as sufficient credits in science was obtained.

Please revise wording either here or in section 1032 allowing any bachelor's degree at LFS discretion as long as sufficient credits in science was obtained.

Commenter: 4

Comment: We firmly disagree with the decision by CDPH/LFS to exclusively accept B.S. degrees and disregard B.A. degrees with the necessary CLS prerequisite coursework. This places an unjustifiable burden on potential CLS applicants to get a second bachelor's degree and does not align with the proficiency demonstrated by many B.A. CLS students. Such a change at this time is particularly concerning given the current shortage of CLS professionals.

Recommendation: Revisit the decision. If nothing else, add Nutrition, Kinesiology, and Nursing to the list of acceptable degrees to avoid future ambiguity for evaluators.

Commenter: 5 and co-signers

Comment: Limiting the bachelor's degree to a BS degree in the sciences indicated disregards individuals who may have obtained a BA degree who later wanted to change career directions. They could obtain all the science prerequisites without obtaining a second bachelor's (in this case a BS) without the expense required of another "4-year" degree. Most can obtain all the science prerequisites within two years.

Having applicants with a broad liberal arts education in addition to having a solid foundation in science is a bonus that will only add to the CLS profession. Having CLS that can use their BA education in management, writing, teaching, etc. to be our next generation of CLS educators and leaders in the field is a bonus, not a reason to reject.

With the constant changing of the names of majors deciding which "BS" degrees qualify for licensing although all may have the prerequisite science classes is also problematic for those having to make this decision as to whether the particular BS qualifies.

We already have the required science courses stated that are needed for a California CLS training license and eventual CLS license so why add they type of college/university degree? What is the rationale?

Commenter: 6

Comment: Consider expanding the list of acceptable degrees for CLS trainee licenses. Many successful candidates possess degrees in fields such as Nutrition, Kinesiology, and Nursing. Broadening the range of accepted degrees could provide a more diverse pool of qualified applicants and enrich the profession with individuals from varied educational backgrounds.

Commenter: 10

Comment: One glaring issue remains unresolved: the requirement that prospective clinical laboratory scientists must have a baccalaureate degree in a biological, chemical, physical, or clinical laboratory science.

The requirement to limit this profession to those with a baccalaureate degree in only a science is redundant, unreasonable, and unnecessarily restrictive. If there is required coursework, this limitation should not exist. Other professional programs do not require a baccalaureate degree in a specific field. For example, medical schools welcome students with baccalaureate degrees in any discipline – as long as the student has completed the necessary course requirements. We should continue to award a CLS Trainee License to any person with a baccalaureate degree in any subject who is willing to complete the required coursework. And then they can earn their license when they

finish their training and pass the appropriate certification exam - just like other clinical professions - and how it has been for decades.

The proposed text, as written, will be counterproductive to California's goal of increasing the number of CLSs in the state. It will require training programs to turn away smart, qualified, and capable students. It will disproportionately impact those who discover the field of clinical laboratory science after obtaining their bachelor's degree – which is a very common scenario in our profession.…This restriction does not align with CLIA Standard 493.1489, Testing personnel qualifications. These proposed Standards are more restrictive and does not mirror CLIA.

Do not arbitrarily limit our profession to those holding a baccalaureate degree in a scientific discipline – completing the prerequisite coursework with any baccalaureate degree should suffice. This requirement serves no purpose. It is needless and cruel and will damage our profession.

Commenter: 14

Department Response: The Department agrees that it is important to retain the flexibility in current regulations to evaluate a college or university degree in a field not related to clinical laboratory science and accept it for licensure if it documents the applicant's successful completion of coursework in science required for a particular license.

In response to requests that the Department eliminate language stating that a degree must be in a specific science field and add language that allows the Department to accept a degree in any subject if it includes the required prerequisite coursework, the Department has revised the licensure requirements in Sections 1030.5, 1030.6, 1030.7, and 1030.8, omitting references to specific degree titles required for clinical laboratory personnel licensure, eliminating the listing of acceptable degrees, and instead requiring that an applicant document successful completion of a degree from an accredited college or university, or an equivalent degree, with courses pertinent to clinical laboratory science as required for the particular license.

The Department also agrees that recent changes to CLIA regulations may require changes to California regulations. The Department is studying the revised CLIA regulations and plans to revisit this issue in a future regulations package that revises CLS requirements, to ensure that changes can be made across license types. In the interim, the Department will retain current language that allows it to evaluate degrees in fields other than chemical, physical, biological, and laboratory science and accept applicants who complete a baccalaureate or equivalent degree with the required science coursework.

Comment Topic: Medical microbiology
Comment: Colleges and Universities often have different names for courses. For example, medical microbiology is known as pathogenic bacteriology and clinical microbiology. Therefore, I would like to propose adding these names but also allowing for courses to be evaluated by LFS should the course name not match.

Commenter: 1

Comment: The document has several references to “Medical Microbiology”. To limit ambiguity among evaluators, we request that "Clinical Microbiology" and “Pathogenic Microbiology” be included as well since they are synonymous course names.

Commenter: 5 and co-signers

Department Response: The Department agrees with these comments and has revised Sections 1030.5, 1030.6, 1030.7, 1030.8, and 1032 to clarify that for licensure as a clinical laboratory scientist or clinical laboratory scientist limited to a specialty, coursework in biology must include coursework in medical microbiology, clinical microbiology, or pathogenic microbiology. The addition of clinical and pathogenic microbiology will clarify the requirement and accommodate variations in academic nomenclature.

Comment Topic: Quantitative analysis and biochemistry
Comment: Why are quantitative analysis/analytical chemistry and clinical chemistry or biochemistry are now both being required instead of either/or to become a CLS? Would general chemistry courses that include quantitative analysis techniques suffice? If so, it should be noted on the revised proposal as CLS training programs usually just mirror state requirements for required courses. How will this affect licensed MLTs who already have the CLS Trainee license? Training programs will be changing their course requirements and some of those MLTs are now going to be missing another course by requiring both instead of either/or like how it currently is.

Commenter: 2

Department Response: The revision to coursework requirements for CLS licensure corrects an error in the initial proposal that divided the requirements for quantitative analysis and biochemistry or clinical chemistry incorrectly. The initial proposal required “1. quantitative analysis and biochemistry OR 2. clinical chemistry.” The Department has revised that sentence to read “1. Quantitative analysis or analytical chemistry; and 2. Clinical chemistry or biochemistry.” The revised version retains current requirements for

"16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry," but adds alternate course titles to accommodate changes to academic terminology and clarify that "analytical chemistry" could include coursework in "quantitative analysis" or "analytical chemistry," and "biological chemistry" could include coursework in "biochemistry" or "clinical chemistry." The proposed revision will accommodate changes in course titles and ensure that applicants have instruction that provides both analytical and clinical/biological chemistry, both of which are necessary for the performance of non-waived clinical laboratory testing.

Because the proposed regulations clarify, but do not change, the current requirements for licensure, trainees who entered training programs under the current requirement for "chemistry, including instruction in analytical and biological chemistry," will not be affected if the new regulations are adopted during their training.

Unrelated or Irrelevant comments

General Topics

Comment Topic: Supervision of trainees and MLTs as trainers

Comment: In 1030.5(a)(4), 1030.5(b)(3), and 1030.5(c)(3) is "work under" referring to general oversight and supervision? If so, that is fine, but we are concerned this reads as if only CLS and above can be trainers. We feel strongly that an experienced MLT trainer should be able to supervise a trainee in moderate complexity tests (with CLS staff also present in lab of course).

Commenter: 4

Comment: The exclusion of explicit reference to Medical Laboratory Technicians as designated trainers in this section fails to accurately represent their integral role and participation in training future MLTs. Moreover, it contradicts NAACLS standards, which allow MLTs to serve as formal preceptors. An experienced MLT, working within their scope, should be permitted to train others within said scope. This rationale is supported by the fact that both CLSs and MLTs receive training in phlebotomy from Certified Phlebotomy Technicians (CPT-1s), as phlebotomy falls within the scope of practice for a CPT-1. Therefore, there is no valid justification for restricting the participation of experienced MLTs in training activities.

Furthermore, the exclusion of MLTs as trainers suggests that hospitals may need to adjust their existing training protocols to ensure that MLTs are exclusively trained by CLSs. Given the shortage of CLSs, this adjustment could potentially result in a complete halt to training activities.

Recommendation: Ensure language in section 1030.5 D(3) includes licensed MLTs as authorized trainers.

Commenter: 5 and co-signers

Comment: 1030.5, subsection D (3) states: 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.

This excludes a Medical Laboratory Technician trainee participating in the clinical training portion of the MLT Program from being trained by a CA licensed Medical Technician who is employed in the clinical laboratory. There is no rationale for this decision. Phlebotomy students are trained by CA certified CPT-1s, Clinical Laboratory Science students are trained by CA licensed CLS, it seems only reasonable that MLT students can be trained by CA licensed MLTs.

Recommendation: Ensure language in section 1030.5 D(3) includes licensed MLTs as authorized trainers.

Commenter: 8

Comment: Allow experienced licensed MLTs with three or more years of experience to participate in the training of MLT trainees. Most hospitals rely on both MLTs and CLSs to provide a comprehensive learning experience for MLT students. The proposed regulation may limit the flexibility hospitals need to train MLTs effectively. By allowing seasoned MLTs to contribute to the practicum training process, we can ensure a robust learning environment for future MLTs.

Commenter: 10

Department Response: These comments are not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

The proposed regulations specifically allow MLTs to serve as trainers in subsections 1035.1(e) and (f). Nothing in this subsection or elsewhere in the proposed regulations prohibits or restricts qualified MLTs from providing instruction or training or participating in training activities, or requires trainers to be licensed CLSs.

Subsections 1030.5(a)(4) and parallel 1035.1(g) refer specifically to the requirements for supervisors providing direct and responsible supervision, who must have qualifications that differ from the qualifications for trainers. The qualifications listed in this section are the qualifications set in statute for supervision of licensed MLTs, which restrict supervision to "a licensed physician and surgeon or a baccalaureate, masters, or doctoral level person licensed pursuant to this chapter." (BPC § 1260.3(b)) It would not make sense to allow MLT trainees to work under supervision of persons with lower qualifications than those required for the supervision of licensed MLTs.

Comment Topic: Make trainee licenses valid for two years
Comment: Consider making trainee licenses good for 2 years. This is consistent with licenses and would allow many trainees to not have to renew the trainee license during their one-year training period.

Commenter: 4

Comment: As previously noted, given that most MLT programs span at least 18 months, all prospective students would need to renew their licenses at least once during their education. Therefore, it would be beneficial if the MLT training licenses were valid for two years to better correspond with the actual duration of the training programs.

Recommendation: Make training licenses valid for at least (2) years to account for most MLT programs extending beyond one year. Increase the licensure fee if cost is a limiting factor.

Commenter: 5 and co-signers

Comment: California approved MLT programs offer a variety of scheduling options for students. Some operate in a cohort, while others offer students a more flexible part-time option. In both cases, the length of California MLT Programs expand more than a year. It would be beneficial to students if the MLT training license were valid for two years.

It is my opinion that MLT training programs will require students to obtain an MLT training license before being admitted to the program in order to avoid any evaluation issues that may arise before clinical training.

Recommendation: Make training licenses valid for at least (2) years to account for most MLT programs extending beyond one year.

Commenter: 8

Department Response: These comments are not specifically directed at changes made to the Department’s proposed regulations or to the procedures followed by the

Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

This section refers to all trainee licenses, both MLT and CLS trainee licenses. Some trainees are able to complete their training in one year. In fairness to these trainees, the Department will retain a one-year trainee license with the option of renewal.

Comment Topic: Requirements for Clinical Toxicology Scientist licensure
Comment: A separate course in quantitative analysis or analytical chemistry should remain an essential course. With the exception of qualitative tests, all toxicology tests quantitatively measure an analyte. A complete and thorough understanding of quantitative analysis can only be obtained by successfully completing a separate course in analytical chemistry.

Recommendation: Reinstate the analytical chemistry course requirement for CLS limited licensure in toxicology.

Commenter: 3

Department Response: This comment is not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The Department agrees that the requirements for limited license clinical laboratory scientist (CLS) trainees require changes. However, it will defer consideration of this issue to the future package that will revise requirements for limited licenses in toxicology and make coordinated changes to the trainee requirements, to ensure consistency.

Comment Topic: Assessment of trainer competency
Comment: Requiring training program directors to verify competency on all trainers is excessive and onerous for both site and program. Remove this statement, this is more appropriately covered in program-site contracts or confirmation by program that lab is accredited by regulatory agency.

Commenter: 4

Department Response: This comment is not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department

in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The Department declines to make the suggested change, and will retain the language in its initial proposal, to clarify that the program director is ultimately the responsible for ensuring that a person providing direct and responsible supervision is competent in the tests the person supervises. This section requires the program director to ensure competency of all persons providing direct and responsible supervision but does not mention trainers. Further, this section does not require the director to personally assess or verify the competency of supervisors. Competency assessment is normally performed by the laboratory director or the director's designee (BPC § 1209(g)), but the Department requires the director of a training program to ensure that persons providing direct and responsible supervision of trainees are competent to perform the testing they supervise and holds the program director responsible for deficiencies.

Comment Topic: Supervision during training
Comment: Two trainees max is insufficient for some training situations, request change to a maximum of 5 trainees to allow for uncommon but effective group training experiences at the training program's discretion.:

Commenter: 4

Comment: Section 1035.1, subsection 4 states: "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" However, on Pg. 52 it states: "(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."

For consistency and clarity regarding the relevance of the trainer: trainee ratio, please make the following amendments:

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 <u>during practicum training</u>.

Commenter: 5 and co-signers and 8

Comment: Please remove the limitation of "no more than two trainees at one time" as this severely limits the numbers of trainees per year, especially in areas such as microbiology where there are limited sites that meet the requirements to train in the first

place. For consistency and clarity regarding the relevance of the trainer: trainee ratio, please make the following amendments: 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 during practicum training.

Commenter: 7

Department Response: These comments are not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

Subsections 1035.1(d)(4) and 1035.3(d)(4) refer not to trainers, but to persons providing direct and responsible supervision to trainees. They regulate the number of trainees for which a supervisor can provide direct and responsible supervision, which is defined in BPC 1206 (a)(10) and specified for trainees in BPC 1205. These subsections do not limit a trainer from providing training to no more than two trainees at one time.

The Department declines to make the suggested change to increase the ratio of trainees to supervisors. When drafting the proposed section limiting the number of trainees a person may supervise, the Department consulted stakeholders, and the consensus was that a maximum of two trainees per supervisor was necessary to ensure direct and responsible supervision of trainees. Internal subject matter experts agreed. The Department will not change this requirement but will retain the current ratio of trainees to supervisors.

The Department declines to make the suggested change to add the phrase "during practicum training," as it is unnecessary. The definition of "direct and responsible supervision," in BPC 1206 (a)(10) and 17 CCR 1029 states that direct and responsible supervision is "personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations."

Comment Topic: Allow classroom skin punctures
Comment: Remove specific mention of skin punctures during practical training. In CPT-1 programs students can do that during classroom and we focus the patient phlebotomy time on venipunctures. Skin punctures during clinical time would be very challenging to

accommodate as laboratory staff do not do any skin punctures, we would have to coordinate this with nursing staff trainers.

Commenter: 4

Comment: “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”

The term "practical" presents an issue as it inherently suggests that skin punctures must occur solely within a practicum setting and are prohibited in a classroom environment. However, skin punctures are seldom conducted in hospitals today, except for newborn babies, a practice which hospital affiliates are often reluctant to permit for training purposes. Consequently, this regulation alteration introduces an extra layer to training, and may discourage clinical sites from participating altogether. To address this concern, it is recommended that skin punctures be permitted in a classroom setting under the supervision of a qualified instructor.:

Commenter: 5 and co-signers

Department Response: These comments are not specifically directed at changes made to the Department’s proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

The proposed language retains the requirements of current language in 17 CCR 1035.1(b), which requires an MLT training program to provide both didactic instruction and practical training in phlebotomy as specified in 17 CCR 1035 (e) and (f). Under current regulations, an MLT program must provide 40 hours of didactic instruction in phlebotomy (which may take place in a classroom setting) and 40 hours of practical training in phlebotomy, including instruction and successful completion of punctures, which must take place in a clinical setting according to requirements specified in section 1035(f). These requirements remain the same in the proposed regulations. Section 1035 requires completion of skin punctures and venipunctures in a clinical setting to provide trainees with access to patients of varying ages, including pediatric and geriatric, and of varying health and obesity status. An MLT training classroom does not provide access to the full range of patients.

Comment Topic: Concerns about the proposed bridge program and the intent of SB 334

Comment: We would like to take this opportunity to once again emphasize our initial concerns regarding the feasibility of the proposed bridge pathway. As outlined in our original letter (in Appendix), there are multiple barriers that are likely to hinder the participation of most institutions. Ultimately, the public anticipates that CDPH/LFS will establish regulations that facilitate the development of robust and effective MLT to CLS bridge programs, consistent with the intentions of SB-334. However, it is anticipated that very few bridge programs will come to fruition under this regulation, leaving many anxiously awaiting MLTs, without a viable bridge option.

One serious issue with the proposed MLT bridge is that there are no provisions allowing an MLT to apply any of their work experience to the bridge training program. This seems to be in direct violation of SB-334.

They requested the Department to continue to work to improve the bridge program, incorporating MLT work experience into the bridge as SB-334 requires, review other MLT to CLS bridge programs throughout the country to adopt some of their criteria, and collaborate with ASCP to ensure bridge students may qualify for the ASCP CLS examination.

Re-review the original letter in appendix, and continue to work to improve the bridge program, which may require changes to SB-334 itself. Work with lobbyists and other stakeholders to ensure a robust and effective MLT to CLS bridge programs become a reality, and not simply a theoretical pathway.

Commenters: 5 and co-signers and 8

Comment: SB-334 states: "…the department shall establish an "MLT-to-CLS" pathway program by January 1, 2022, that would authorize a licensed MLT to apply their work experience and training from a department-approved MLT training program towards the completion of a CLS training program." Yet, there appears to be no provisions in the proposed regulations that allow MLTs to apply any work experience to their bridge training programs.

Restating the importance of recognizing clinical work experience as stated in our original submittal of public comments. "A more efficient bridge solution would revolve around employee-based training, where approved employers deliver necessary training by fulfilling hour requirements, mirroring models used for CLS/MLT licensure in military or out-of-state labs. The supplementary clinical training will specifically target high-complexity testing within each department, aligning with the discrepancy in training duration between MLT and CLS programs. Laboratory supervisors would possess the authority to assess competence in each specific area and attest to the completion of

training for individuals." Competency assessment would adhere to the same system and standards as the clinical site currently maintains. (a) In accordance with SB-334, acknowledge and credit the work experience of MLTs by affording programs the flexibility to tailor training to individual students, addressing specific areas where further training is needed. Keep the same program total week requirement but allow bridge programs to waive areas where students demonstrate competency from their work experience as an MLT.

Commenter: 7

Department Response: These comments are not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or are too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comments. (See Gov. Code Section 11346.9(a)(3).)

The concerns expressed in the letter appended to comment 5 address the original draft text, but do not address changes made to that original proposal. The concerns in that letter were addressed in the responses to the 45-Day Comment period.

The existing statute as amended by SB 334 (BPC 1261(b)) does not change the requirements for CLS licensure, so the regulations must remain consistent with those requirements.

Comment Topic: MLT transition to limited license CLS
Comment: I do not see any regulations regarding licensed MLTs who want to be trained in a limited CLS specialty only. For example, if I just want to be a CLS in microbiology, how long should the training be? Can existing limited specialty training programs shorten training for MLTs?

Commenter: 2

Department Response: This comment is not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The proposed regulations implement section 1261 of the BPC, which requires the Department to create a pathway program to authorize a licensed MLT to apply their work experience and training from a Department-approved MLT training program

towards the completion of a CLS training program. The statute does not include a provision to allow MLTs to transition to limited CLS licensure.

Comment Topic: Bridge program requirements for a person who holds MLT and Ltd License CLS

Comment: My comment is just that if you have both an MLT and a limited license that this should count for training in that section. For example if you are a licensed CLS-Microbiologist you would only have to do rotations in the other sections of the lab during your bridge program. That way you can get more time in the other sections.

Commenter: 9

Department Response: This comment is not specifically directed at changes made to the Department's proposed regulations or to the procedures followed by the Department in proposing or adopting these regulations or is too generalized or personalized so that no meaningful response can be formulated to refute or accommodate the comment. (See Gov. Code Section 11346.9(a)(3).)

The situation described in this comment concerns a trainee who holds both an MLT and a limited CLS license and is now training for a CLS generalist license. The proposed regulations do not attempt to cover every unusual situation that may arise but set general requirements that all applicants must meet.

Expressions of Support and Opposition

Comment: I am writing to express my gratitude for the grace period extended by the Laboratory Field Services, which allows MLT students to obtain the necessary prerequisite courses for their MLT trainee license. However, I would like to raise a few concerns and suggestions regarding the proposed regulations.

Commenter: 10

Department Response: The Department appreciates this comment of support and has also considered and responded to the opposition in its responses to specific comments.

Addendum III
Second 15 Day Public Notice

Summary of Comments and responses to Comments Received

The regulation text was revised in response to the comments received during the second comment period and made available for public comment for at least 15 days, from July 8, 2024, through July 28, 2024. The Department received no comments during the 15-day public notice period beginning July 8, 2024, and ending July 28, 2024. No request for a public hearing was received and no hearing was held. No changes were made following the second 15-day public comment period.