DPH-20-007
Clinical Laboratory Personnel Standards:
Trainee, MLT, MLT Transition to CLS
June 7, 2023

INITIAL STATEMENT OF REASONS

SUMMARY OF PROPOSAL

The California Department of Public Health (Department) intends to adopt, amend, and repeal sections of the license and certification standards for clinical laboratory personnel regulated by the Department as specified in the Clinical Laboratory Regulations in the California Code of Regulations (CCR), title 17, sections 1029-1035.3. These changes specify requirements for education, training, experience, and examinations leading to licensure and certification and specify scope of work. The purpose of these regulations is to:

- Facilitate licensure and certification of qualified laboratory personnel for employment in California.
- Standardize licensing and certification regulations for associate-level and baccalaureate-level license categories.
- Set updated requirements for academic coursework and degrees, practical training and experience, and examinations for licensure of clinical laboratory trainees, medical laboratory technicians, and clinical laboratory scientists.
- Repeal redundant or outdated standards, replace them with more relevant standards, and create new definitions as necessary.
- Modernize existing regulations to reflect changes in technology and the needs of current industry practice.
- Clarify and adopt terms used in the industry, terms mandated through statutory language, and terms defined under federal law.
- Create new requirements for education and training of qualified persons seeking licensure or certification that reflect changes in technology and education.

This proposal consists of portions of Article 1, sections 1029 (Definitions), Article 1.5, sections 1030 through 1032.5 (Licensure of Clinical Laboratory Personnel), Article 1.8, section 1034 (Examinations for Licensure and Certification and Certifying Organizations), and Article 2, sections 1035.1 through 1035.3 (Training Programs).

POLICY STATEMENT OVERVIEW

Problem Statement:

Existing licensing and certification standards are outdated and require revision to reflect advances in laboratory science and technology and consequent changes in industry procedures, tests, techniques, and standards, and requirements for education and training. In addition, the standards need updating to account for changes to statutory law. The regulated community has also requested regulations to clarify the requirements of California laboratory law.

Objectives (Goals):
The goal of the proposed regulations is to ensure consistency and clarity in the Department regulations, specifically:

- To ensure California laboratories satisfy federal Clinical Laboratory Improvement Amendments (CLIA) standards.
- To ensure consistency and quality in clinical laboratories throughout the state.
- To address the regulatory challenges posed by new technological advances in the industry.
- To update the list of organizations whose training and examinations are accepted by the Department for licensure and certification purposes.
- To clarify the law and answer questions frequently received by the Department.
- To create a system of definitions in alphabetical order for ease of reference.
- To implement recommendations and proposals from the program's Clinical Laboratory Technology Advisory Committee (CLTAC) and stakeholders.

Benefits:
Implementation of these standards will enhance the efficiency of the licensing and certification program and help ensure compliance with related federal regulations.

Other benefits of the proposed regulations include:

- Protecting the health and safety of the public by helping ensure high quality training schools produce qualified clinical laboratory personnel.
- Increasing worker safety through ensuring proper education, training, and experience for personnel employed in laboratories.
- Promoting fairness of the licensing and certification process through objective, consistent, and equitable standards for applying and qualifying for licensure.
- Protecting the integrity and quality of test results produced by clinical laboratories.
- Implementing proper and safe use of new technologies.

Non-substantive changes in existing regulations will benefit the industry and California residents by providing clarification and ease of reference; clearer regulations will likely increase adherence to those regulations. Further, this should increase departmental efficiency, as fewer individuals will need to ask for clarification on regulations.

Authority and references
The Department is proposing to adopt, repeal, and amend portions of the regulations in the CCR, title 17, sections 1029 through 1067.15, Clinical Laboratory Regulations, under the authority provided in sections 1208, 1222.5, 1224, 1263, and 1264 of the

Business and Professions Code (BPC), sections 100275 and 131200 of the Health and Safety Code (HSC), and section 14105 of the Welfare and Institutions Code (WIC).

General Authority:

- Under HSC section 131200, the Department has authority to adopt and enforce regulations for the execution of its duties.
- Under BPC section 1224, the Department has authority to adopt, amend, or repeal any regulations necessary for the administration or enforcement of Chapter 3, Clinical Laboratory Technology.

Specific Authority:

- Under BPC section 1208, 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 BPC section 1262, 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 BPC, 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 BPC section 1222, 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)).

This proposal implements, interprets, and makes 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.

BACKGROUND

The Department (through its Laboratory Field Services branch) is charged with ensuring the qualifications of personnel working in clinical laboratories by administering a licensure and certification program. California has one of the most extensive personnel

licensure and certification programs in the nation. The Department monitors education, training, and experience of applicants, administers examinations, and oversees continuing education compliance to ensure that only qualified persons perform clinical laboratory testing. The Department also has authority to deny, suspend, and revoke licenses and certificates for failure to comply with California licensure and certification standards for quality assurance.

All clinical laboratory personnel must be qualified to perform clinical laboratory tests or examinations, pursuant to chapter 3 of the BPC. The validity of a person's qualifications is demonstrated by meeting licensing and certification standards specified in departmental regulations. These standards include requirements for education, training, experience, and examination that must be met to qualify for licensure or certification. Maintenance of current and valid licensure and certification requires completion of continuing education and payment of a renewal fee. Testing personnel must be licensed or otherwise authorized to do testing. The work scope of a licensed or certified person is limited to that defined by the person's license or certificate category. Failure to comply with personnel licensing and certification standards may result in sanctions such as revocation or suspension of licensure or certification.

The Department is responsible for administering initial issuance and renewal of licenses or certificates for 32 categories. The Department currently administers over 62,000 active clinical laboratory personnel licenses and certificates in California. Out of the estimated 62,000 total, 35 percent are licensed and the remaining 65 percent are certified. The Department also has oversight of about 202 training programs and schools as well as accrediting agencies that provide continuing education offered to clinical laboratory personnel.

In August 2009, the Department held a stakeholder meeting in Richmond, California. At this meeting, LFS discussed 14 specific clinical laboratory personnel regulation issues related to existing law and potential changes. In 2010, the Department submitted a proposal to adopt, amend, or repeal sections of the license and certification standards for clinical laboratory personnel. That regulatory proposal (DPH-08-001) was withdrawn due to the high volume of public inquiries and comments received during the 45-day comment period, and the inability of the Department to respond to the volume of comments within the time constraints of the rulemaking process.

Due to the high volume of comments received in the past regarding proposal DPH-08-001, the proposed Clinical Laboratory Personnel regulations will be submitted in separate regulatory proposals to allow time for public review, submission of comments, and departmental response within the time constraints of the rulemaking process. This package is a subpart of the package pertaining to Clinical Laboratory Personnel. The following is the list:

Proposed regulatory package DPH-11-012 was codified and effective January 1, 2021. It pertained to portions of Article 1, Definitions and Article 5.3, Blood Electrolyte Analysis by Respiratory Care Practitioners.

Proposed regulatory package DPH-16-019, Clinical Laboratory Personnel Standards: Phlebotomists.

Proposed regulatory package DPH-16-020 Clinical Laboratory Personnel Standards: Applications/Renewal & Clean-up.

Proposed regulatory package DPH-18-017, Clinical Laboratory Personnel Standards: Unlicensed Personnel.

Proposed regulatory package DPH-19-009, Clinical Laboratory Personnel Standards: Clinical Laboratory Geneticists and Clinical Reproductive Biologists.

Proposed regulatory package DPH-20-005, Clinical Laboratory Personnel Standards: Bioanalysts and Master's & Doctoral Degree Specialists.

Proposed regulatory package DPH-20-006, Clinical Laboratory Personnel Standards: Clinical Laboratory Scientists and CLS Training Programs.

Proposed regulatory package DPH-20-007, Clinical Laboratory Personnel Standards: Trainees, MLT, and CLS Who Meet Requirements for MLT Licensure.

Future packages, DPH-20-005, DPH-20-006, DPH 18-017, DPH 16-019, DPH 16-020, and DPH-19-009, which will be submitted at a later date, consist of (1) portions of Article 1, Definitions (mostly regarding licensed laboratory personnel) (2) portions of Article 1.5, Licensure of Clinical Laboratory Personnel (mainly licensure requirements and work scope of licensed laboratory personnel), (3) proposed Article 1.6, Unlicensed Laboratory Personnel, (4) portions of Article 2, Training Program Requirements, (5) Article 2.3, Clinical Laboratory Supervisors, (6) Article 2.5, Continuing Education, (7) Article 3, License, and (8) Article 7, Cytotechnology.

Stakeholder Input:
The Department has involved and considered advice from its advisory committee, the Clinical Laboratory Technology Advisory Committee (CLTAC). CLTAC is a multidisciplinary committee mandated by statute at BPC section 1228 to "assist, advise, and make recommendations for the establishment of rules and regulations necessary to ensure proper administration and enforcement of the provisions of this chapter and to assist and advise the Department in matters concerning examinations for licensees of this chapter." It is composed of 21 voting members and one non-voting member, who represent the various interest groups related to clinical laboratories.

CLTAC holds four public meetings per year and posts the agendas and minutes from those meetings on the Department LFS website. (*Clinical Laboratory Technology Advisory Committee (CLTAC)*, Laboratory Field Services, California Department of Public Health, https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/AdvisoryCommittee-CLTAC.aspx [as of June 7, 2023].) The Department also posts agendas of meetings of the CLTAC Subcommittees. Interested members of the public are welcome to attend the meetings.

The Department requested that CLTAC convene a subcommittee to consult and advise the Department about this regulatory proposal. The subcommittee has served as the conduit between the industry, interested stakeholders, and the Department in order to provide feedback to the Department on its regulation proposals.

In January 2023, written stakeholder engagement specific to this regulatory package was completed. The Department considered and incorporated stakeholder responses in the decision-making process.

CONSIDERATION OF REASONABLE ALTERNATIVES TO THE REGULATIONS AND THE DEPARTMENT'S REASONS FOR REJECTING THOSE ALTERNATIVES

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.

DETAILED DISCUSSION OF PROPOSED CHANGES

As of January 1, 2020, pursuant to BPC section 1261, subsection (b), "CLS" means a "clinical laboratory scientist" and "MLT" means a "medical laboratory technician." These abbreviations will be used throughout the detailed discussion of proposed changes in this Initial Statement of Reasons.

Article 1. Definitions

The following are amendments and adoptions of definitions in section 1029.

(1) Amend "Accredited college or university"

This Department proposes to amend this definition because the existing definition is outdated. The existing definition of "Accredited college or university" contains an outdated list of accrediting organizations or commissions that accredit colleges and universities. The outdated list consists of:

- Middle States Commission on Higher Education,
- New England Association of Schools and Colleges Commission on Institutions of Higher Education,
- North Central Association of Colleges and Schools Higher Learning Commission,
- Northwest Commission on Colleges and Universities,
- Southern Association of Colleges and Schools Commission on Colleges,
- Western Association of Schools and Colleges Accrediting Commission for Community and Junior Colleges, and
- Western Association of Schools and Colleges Senior Colleges and University Commission.

The Department proposes to repeal that list. Some of the organizations no longer exist. Some of the organizations have coalesced and some have split apart. The organization that previously pertained to colleges and universities in California has split into numerous organizations.

To avoid a regulation from becoming outdated due to a change in organizations, the proposed text does not name specific organizations, but rather, uses the accrediting associations/organizations listed on the U.S. Department of Education and California State Department of Education webpages. The proposed text is similar to the language used in the CCR, Title 17, for other health boards, including the California Board of Nursing and the California Board of Psychology. The new definition, “a post-secondary educational institution accredited by a regional association recognized by the U.S. Department of Education or the Council on Post-Secondary Accreditation (“CHEA”) or its successor organization,” refers to the list on the U.S. Department of Education and California State Department of Education webpages. Adoption of the federal standard will ensure the regulation is up-to-date and meets government standards consistent with other licensure categories. Acceptance of federally approved organizations will also be helpful for applicants who have obtained education in other states that follow the federal standard.

(2) Adopt “Approved certifying organization” as a new definition

The Department proposes adding this definition in place of an older definition, “Certifying Organization,” to clarify that the Department only accepts exam results from certain certifying organizations the Department has pre-approved. This clarifies that licensure applicants must take an examination by a certifying organization approved by the Department. The standards are in BPC, sections 1260 et seq. and CCR, title 17, sections 1029 through 1067.15. The Department has an extensive standardized process of evaluating the exams issued by the certifying organizations. This is to ensure the exams meet California and CLIA standards, and the applicant meets Department standards. The Department has had to deny applications for licensure because the applicant took an exam from a non-approved certifying organization. Adding this definition will prevent an applicant from investing their time and effort preparing for an

exam that does not satisfy the requirement for licensure. Specific certifying organizations for licensing types are detailed in relevant sections.

(3) Adopt "Approved NAACLS accredited training program" as a new definition
BCP section 1222 gives the Department the authority to approve schools accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). The Department proposes adding this definition to clarify that a laboratory training program must meet both the accreditation standards of NAACLS and the approval standards set by the Department. Many training programs may be NAACLS-accredited, but specifying "approved" in the definition clarifies that the Department maintains authority to evaluate and approve or disapprove of the training program.

NAACLS reviews and approves education programs that meet established education standards in clinical laboratory science. This includes disciplines such as medical laboratory technician and phlebotomist. The NAACLS accreditation process is recognized by the Council for Higher Education Accreditation.

The Department receives license and certification applications from many countries. It would be a burdensome and inefficient use of resources for the Department to assess each of those laboratory programs outside the United States of America. NAACLS provides the evaluation and accreditation according to standards that meet or exceed the minimum standards required by the Department. To avoid confusion about different accredited training programs, this definition will clarify that the Department accepts training obtained in programs approved by NAACLS. This will prevent license and certification applicants from obtaining training and experience that does not meet required standards. This will provide clarity to applicants, training programs, laboratories, and the regulated the community.

(4) Amend "Certified Phlebotomy Technician I"
The Department proposes this non-substantive amendment. The existing definition references section 1034, which has been renumbered to section 1030. The definition is being amended to refer to the new section number. It is necessary for the definition to refer to the accurate section number.

There is also a non-substantive minor grammatical amendment to insert a serial comma after the penultimate term in the series. A comma is added after the word "experience" to clarify that the experience required is separate from the examination. The phrase "…experience and examination…" may cause confusion; the regulated community may interpret it as one requirement, not two separate requirements.

(5) Amend "Certified Phlebotomy Technician II"
The Department proposes adding this non-substantive amendment. The existing definition references section 1034, which has been renumbered to section 1030. It is necessary for the definition to refer to the accurate section number.

There is also a non-substantive minor grammatical amendment to insert a serial comma after the penultimate term in the series. A comma is added after the word “experience” to clarify that the experience required is separate from the examination. The phrase “…experience and examination…” may cause confusion; the regulated community may interpret it as one requirement, not two separate requirements.

(6) Repeal “Certifying organization”
The Department proposes repealing this definition. The content is incorporated into a new definition, “Approved certifying organization,” which is being adopted to replace it. The necessity is explained under “Approved certifying organization” in section 1029.

(7) Adopt “Credit hour” as a new definition
The Department proposes adopting this definition because it is necessary to clarify for applicants for licensure, training schools and programs, and the regulated community how the Department calculates educational credit. Schools may use the term “hour,” “credit,” or “unit.” This definition clarifies that any of those terms are acceptable and equivalent. Most schools measure educational credit in terms of the amount of time in the classroom and the resultant amount of subject material covered/taught. Most schools will measure either two semesters (Fall and Spring) per academic year, or three quarters (Fall, Winter, and Spring) per academic year. An hour per week in a classroom lecture during one semester is about the equivalent of an hour per week in classroom (lecture) during one and a half quarters. The Department uses the standard academic calculation that equates 1 semester credit hour to 1.5 quarter credit hours. It is necessary for the regulated community to understand this method of calculation. This definition will clarify educational requirements for applicants for licensure.

(8) Adopt “Critical review of trainee laboratory test results” as a new definition
The Department proposes adopting this definition to clarify that a licensed clinical laboratory trainee may not report test results. The results of tests performed by a clinical laboratory trainee must be critically reviewed and reported by a person licensed under Chapter 3 or Chapter 5 of the Business and Professions Code. In addition to licensure, the definition requires the person evaluating the test results to have competency to perform the tests in the category for which the person will be reviewing tests.

The Department is frequently asked if trainees are authorized to report test results. The critical review requirement ensures that test results obtained by a trainee have been reviewed and verified for accuracy, reliability, and validity by a person with sufficient education, training, experience, and demonstrated competency to obtain full Department licensure in the personnel license category required to perform the relevant type and complexity of testing. This review process authorizes laboratory trainees to gain experience performing tests and examinations while ensuring the reliability of the trainees’ test results.

(9) Amend "Direct and constant supervision"

The Department proposes to add a non-substantive amendment. The existing definition refers to personnel licensed under "this chapter." The Department proposes to add the chapter number to clarify that personnel must be licensed under chapter 3 of the Business and Professions Code, for consistency with other references to the chapter under which laboratory personnel are licensed.

(10) Amend "Direct and responsible supervision"

The Department proposes to add a non-substantive amendment. The existing definition refers to personnel licensed under "this chapter." The Department proposes to add the chapter number to clarify that personnel must be licensed under chapter 3 of the Business and Professions Code, for consistency with other references to the chapter under which laboratory personnel are licensed.

(11) Adopt "Equivalent degree" as a new definition

The Department proposes adopting this definition because it is necessary to define "equivalent degree." Information about equivalent degrees is currently included in the definition of "Accredited college or university," which also refers to two related concepts, "equivalent degree" and "transcript evaluation or credential evaluation." Because the three concepts are included in a single definition, it is difficult for a reader seeking information about degree equivalency to locate it. Breaking the current definition into three separate definitions, one to define "accredited college or university," one to define "equivalent degree," and one to define "transcript evaluation or credential evaluation," will make it easier for the reader to locate the information.

Statute requires applicants to hold a degree from an "accredited college or university." Accreditation is normally granted by accrediting associations in the U.S. to U.S. educational institutions, but many reputable educational institutions located outside the U.S. do not hold U.S. accreditation. To enable the department to license applicants who obtained their degree from a non-accredited educational institution located outside the U.S., the department requires such applicants to demonstrate that their education is comparable to the education provided by accredited U.S. institutions.

Licensure applicants have obtained degrees or credentials from educational intuitions around the world. As the department does not have the resources to evaluate each applicant's educational credentials, the department approves professional transcript evaluation or credential evaluation services to provide such evaluations of degree comparability or equivalency. The requirement for transcript evaluation or credential evaluation and the list of approved services are referenced in the current definition of "accredited college or university." However, a person looking for a definition of "equivalent degree" or "transcript evaluation or credential evaluation" may not realize that the information about these topics is included under the definition of "accredited college or university." To provide clarity and make it easy for the reader to locate the desired information, the department is proposing to provide this information in two

separate definitions, one for “equivalent degree” and one for “transcript evaluation or credential evaluation.”

These definitions refer to the evaluation services currently approved by the department, the National Association of Credential Evaluation Services and the Association of International Credential Evaluators, Inc. The current definition adds the phrase “or another organization approved by the Department.” Approved services have historically changed names or ceased to provide the service. By specifying this third option, the Department maintains the flexibility to make necessary revisions without writing a new regulation whenever an organization makes such changes. The proposed definitions of “equivalent degree” and “transcript evaluation or credential evaluation” retain the current language to reflect the current authorized Departmental practice.

(12) Amend “Limited Phlebotomy Technician”
The Department proposes this non-substantive amendment necessary to change the section number referenced in the definition. Section 1034, Certification of Phlebotomy Technicians, has been renumbered to section 1030.

There is also a non-substantive minor grammatical amendment to insert a serial comma. A comma is added after the word “experience” to clarify that the experience required is separate from the examination. The phrase “…experience and examination…” may cause confusion; the regulated community may interpret it as one requirement, not two separate requirements.

(13) Adopt “Master’s or doctoral degree specialist” as a new definition
The Department proposes this definition to provide a standardized term for reference to a group of laboratory professionals who are licensed under sections 1203, 1207, 1209.1, 1260, and 1264 of the California Business and Professions Code to engage in clinical laboratory practice and to direct non-waived clinical laboratories and, if qualified under CLIA, to serve as a technical consultant, technical supervisor, clinical consultant, or general supervisor. Master’s or doctoral degree specialists include clinical laboratory bioanalysts, clinical chemists, clinical microbiologists, clinical toxicologists, clinical genetic molecular biologists, clinical laboratory geneticists, clinical reproductive biologists, clinical cytogeneticists, histocompatibility laboratory directors, and oral and maxillofacial pathologists, and other categories that may be added by the Department by regulations.

Section 1209.1 of the California Business and Professions Code sets the eligibility requirements and scope of work for a histocompatibility laboratory director. Sections 1203 and 1260 set requirements and scope of work for a clinical laboratory bioanalyst. Sections 1207 and 1264 of the California Business and Professions Code set licensure requirements and scope of work for a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist, clinical laboratory geneticist, clinical

reproductive biologist, clinical cytogeneticist, or oral and maxillofacial pathologist licensure.

(14) Amend "Medical Laboratory Technician"
The Department proposes this non-substantive amendment necessary to change the section number referenced in the definition. Section 1032.5, Licensure of Medical Laboratory Technicians, has been renumbered to 1030.6.

(15) Amend "On-the-job experience in phlebotomy"
The Department proposes this non-substantive amendment necessary to change the section number referenced in the definition. Section 1035.1, which regulates techniques a phlebotomist performs in a clinical laboratory in Phlebotomy Training Program Requirements, has been renumbered to section 1035.

(16) Amend "Practical experience"
The Department proposes amending existing text that states the experience must be "hands on, direct." This is vague. The proposed text uses "on-the-job" as replacement, which is clearer. "Hands on, direct" may be mistaken for work done in a classroom, not in a laboratory. "On-the-job" clarifies that work in a classroom does not count as practical experience required to gain a license.

The Department proposes to strike "and phlebotomy techniques on real patients" for clarity. The reference to phlebotomy does not pertain to the performance of moderate and high complexity clinical testing.

The Department proposes to add language specifying that work experience in clinical laboratory science must be done while licensed only "if such licensure is required." This is to clarify that the Department may count work experience obtained without licensure in laboratories located in states that do not require laboratory personnel licensure. California requires a license to perform clinical laboratory testing. Many states do not require licensure for clinical laboratory personnel. There have been highly qualified licensure applicants denied Department licensure because practical experience was gained in a laboratory located in a state not requiring personnel licensure. Adding this language will clarify to highly qualified applicants from other states that their practical experience that was gained in a state that does not require clinical laboratory personnel licensure will be accepted for licensure purposes.

The Department proposes this non-substantive change of existing text "by" to be "under." CLIA is federal law; it is not a federal agency, department, or entity. CLIA does not perform the act of certifying. The laboratory is certified by the federal Centers for Medicare & Medicaid Services under CLIA law.

This definition of practical experience specifies three options to obtain practical experience in a clinical laboratory that are accepted by the Department towards clinical laboratory personnel licensure.

These options include obtaining work experience in a clinical laboratory certified under CLIA, obtaining experience in a laboratory accredited by an international agency as specified in section 1032.5, and obtaining work experience in a clinical laboratory in any branch of the Armed Forces of the U.S. as specified in section 1261 of the BPC.

The Department proposes language specifying the tests or examinations must be for clinical purposes such as the prevention, diagnosis, or treatment of a disease or the assessment of health of a human patient, which excludes tests or examinations done in academic, research, pharmaceutical, and veterinary laboratories. This ensures experience is relevant to clinical laboratory science, not general laboratory science. This clarifies requirements to applicants, training programs, and the regulated community and ensures that applicants have the required experience in clinical testing.

(17) Adopt "Trainee" as a new definition

The Department proposes adopting "Trainee" as a new definition because the statutory definition of "Trainee" does not include MLT trainees, and these new regulations create an MLT trainee license. The Business and Professions Code, section 1263 states "The department shall license as trainees those individuals desiring to train for either a clinical laboratory scientist's license or a limited clinical laboratory scientist's license, providing those individuals meet the academic requirements." The statutory definition applies to other clinical laboratory personnel, but does not include MLT trainees because it was adopted before MLT licensure existed. This provides clarity to the reader and the regulated community.

(18) Adopt "Training school or training program" as a new definition

The Department proposes adopting this definition because there is no existing definition of "training school," "training program," or "training school or training program" in Title 17, Group 2. Clinical Laboratory Regulations. The proposed definition will provide clarification and ease of reference. There is no consistent term in the regulated community or in existing laws and regulations. Current terminology related to school or programs established to train and prepare persons for licensure or certification in clinical laboratory science used by the regulated community and in existing regulations includes "training schools," "training programs," "program," "school," and other related terms. This lack of consistency causes confusion. It is unclear to the regulated community which regulations may apply and whether programs and schools must meet the same requirements. While many training schools and training programs meet the standards and requirements set by the Department, some training programs interpret existing law as inapplicable to their program, resulting in poor quality training programs. The Department receives inquiries as to what is required of training schools and training programs, and which regulations apply. Currently, a regulation may use the term

"training school" but not "training program," or vice versa, but apply to both training schools and training programs. This definition will provide training schools and training programs clarity and ease of reference as to which regulations apply to their program or school. It will increase consistency and standardization among training schools and training programs. It will increase Department efficiency by decreasing the number of inquiries.

(19) Adopt "Transcript evaluation or credential evaluation" as a new definition
The Department proposes adopting this definition because it is necessary to define "transcript evaluation or credential evaluation." Information about transcript evaluation or credential evaluation is currently included in the definition of "Accredited college or university," which also refers to two related concepts, "equivalent degree" and "transcript evaluation or credential evaluation." Because the three concepts are included in a single definition, it is difficult for a reader seeking information about transcript evaluation or credential evaluation to locate it. Breaking the current definition into three separate definitions, one to define "accredited college or university," one to define "equivalent degree," and one to define "transcript evaluation or credential evaluation," will make it easier for the reader to locate the information.

Statute requires applicants to hold a degree from an "accredited college or university." Accreditation is normally granted by accrediting associations in the U.S. to U.S. educational institutions, but many reputable educational institutions located outside the U.S. do not hold U.S. accreditation. To enable the department to license applicants who obtained their degree from a non-accredited educational institution located outside the U.S., the department requires such applicants to demonstrate that their education is comparable to the education provided by accredited U.S. institutions.

Licensure applicants have obtained degrees or credentials from educational intuitions around the world. As the department does not have the resources to evaluate each applicant's educational credentials, the department approves professional transcript evaluation or credential evaluation services to provide such evaluations of degree comparability or equivalency. The requirement for transcript evaluation or credential evaluation and the list of approved services are referenced in the current definition of "accredited college or university." However, a person looking for a definition of "equivalent degree" or "transcript evaluation or credential evaluation" may not realize that the information about these topics is included under the definition of "accredited college or university." To provide clarity and make it easy for the reader to locate the desired information, the department is proposing to provide this information in two separate definitions, one for "equivalent degree" and one for "transcript evaluation or credential evaluation."

These definitions refer to the evaluation services currently approved by the department, the National Association of Credential Evaluation Services and the Association of International Credential Evaluators, Inc. The current definition adds the phrase "or

another organization approved by the Department." Approved services have historically changed names or ceased to provide the service. By specifying this third option, the Department maintains the flexibility to make necessary revisions without writing a new regulation whenever an organization makes such changes. The proposed definitions of "equivalent degree" and "transcript evaluation or credential evaluation" retain the current language to reflect the current authorized Departmental practice.

(20) Amend title of Article 1.5

The Department proposes to amend the existing title of Article 1.5, Licensure of Clinical Laboratory Personnel, to be Licensure and Certification of Clinical Laboratory Personnel. This amendment adds "Certification" because some of the clinical laboratory personnel positions do not require licensure but do require certification. Personnel such as phlebotomy technicians who are not authorized to perform clinical laboratory tests are certified, rather than licensed.

Amendments in Article 1.5, sections 1030 through 1034.2, amend existing regulations and current practice to provide clarity and ease of reference to the regulated community. Individual sections discuss proposed regulations, which follow a consistent format that clarifies regulatory requirements and Department procedures. The consistent format makes it easier for the public to compare the licensing requirements and work scope of each licensure in Article 1.5. These revisions are projected to lower the number of inquiries from the regulated community to the Department, thereby increasing efficiency in the Department and reducing government spending. The format of proposed regulations in Article 1.5 details the education, training, experience, and examination required for licensure or certification, and work scope authorized for each personnel category. This format aligns with the format of federal CLIA laboratory personnel qualifications and responsibilities, Title 42 Code of Federal Regulations, part 493, subpart M. This format of federal law makes it easier for the public to compare and analyze federal law and state law.

The following format is used for the new personnel standards regulations in Article 1.5 of this package and in future packages.

(a) Requirements for obtaining licensure:
    (1) Application requirements
    (2) Educational degree requirements
    (3) Coursework requirements
    (4) Training requirements
    (5) Experience requirements (some licenses require both training and experience, others allow the applicant to complete either training or experience)
    (6) Examination requirements (some licenses require both national and Department exams)
(b) Scope of work:

(1) Clinical lab practices authorized
(2) Supervisory or consultant activities, if authorized
(c) Supervision required (not required for all license categories)
(d) Maintenance of licensure
(1) Hardcopy license
(2) Posting of hardcopy license in workplace
(3) Renewal of license

(21) Amend section 1030, Certification of Phlebotomy Technicians

The Department proposes this non-substantive amendment necessary to change the section number reference. Section 1035.1 (e)(1) has been renumbered to section 1035 (e)(1).

(22) Amend section 1030.5, Trainee Requirements, to be Licensure and Work Scope of a Clinical Laboratory Trainee

The Department proposes to change the title of section 1030.5 because the new title accurately depicts the content of section 1030.5. Section 1030.5 expands the licensure and work scope of existing trainee licenses and encompasses new trainee licenses. Section 1030.5 has four trainee licenses and each one uses the (a) through (d) outline referenced above.

The Department proposes changes to the requirements and work scope for clinical laboratory scientist trainees. Existing section 1030.5, Trainee Requirements, specifies the educational requirements for licensure as a Clinical Laboratory Technologist Trainee and Limited Technologist Trainee, which are outdated. Proposed section 1030.5, Licensure and Work Scope of a Clinical Laboratory Trainee, reflects current industry standards and provides clarity and ease of reference to the regulated community. Existing section 1030.5 does not specify the work scope for trainees. Proposed section 1030.5 specifies work scope and supervision requirements for trainees.

The license titles in the current section are outdated, and the proposed section updates “clinical laboratory technologist trainee” to “clinical laboratory scientist trainee” and “limited technologist trainee” to “CLS trainee limited to a specialty or subspecialty,” respectively, to reflect current Department terminology. The updated titles reflect the fact that this training prepares trainees for licensure as CLS and CLS limited to a specialty or subspecialty. The proposed terms are currently used in existing and proposed regulations; updating titles in this section will provide clarity and consistency.

The Department is proposing two additional categories of trainee licensure in this regulations package, one for MLT trainees and one for CLS trainees who meet California requirements for MLT licensure. These new categories are needed because BPC section 1206.5 requires a person to be licensed to perform non-waived laboratory tests or examinations. Establishment of the new trainee licenses ensures applicants have met education requirements and are licensed to perform the testing they will need

to complete during training, and that they complete a standardized training program before receiving an MLT or CLS license.

Trainee licensure allows a person to perform tests or examinations under appropriate supervision while the person is training for licensure. BPC section 1205 defines a trainee as “any person licensed under this chapter for the purpose of receiving comprehensive practical experience and instruction in clinical laboratory procedures….” This statutory definition expressly applies to CLS trainees and equivalent licensee in the science or specialty or subspecialty. It does not explicitly include medical laboratory technician trainees. This proposed regulation will add trainee licensure for MLT trainees.

BPC section 1263 specifies requirements for trainee licensure for persons training to be a CLS. It does not include trainee licensure for persons training to be an MLT. For this reason, the Department proposes regulatory requirements for trainee licenses for persons in MLT consistent with CLS trainee requirements.

Requirements for this new trainee license are included in proposed section 1030.6 to place all trainee information in a single section for ease of reference. Subsections for each license follow a standard format to ensure clarity, consistency, and ease of reference.

Proposed subsection 1030.5(a), licensure requirements and work scope for an MLT trainee, specifies the minimum qualifications of education and training required for licensure as an MLT trainee and defines the work scope of these trainees. This is a new trainee license category.

The Department is proposing to create this category of trainee licensure for compliance with the requirement in BPC section 1206.5 for licensure as a prerequisite for performing non-waived clinical laboratory tests or examinations. MLT trainee licensure will allow people enrolled in MLT training programs to perform moderate-complexity testing under supervision. This will ensure the accuracy and reliability of their testing, and at the same time ensure that candidates for MLT licensure receive appropriate training.

Proposed subsection 1030.5(a)(1) specifies education requirements for MLT trainee licensure, which are for the most part the requirements for MLT licensure. The only difference is in subsection (C), to allow trainees to complete non-science coursework concurrently with completing practical training if the person has completed the requisite science courses before training.

Proposed subsection 1030.5(a)(1)(A) clarifies the requirement for submitting an application, as specified in existing section 1031.

Proposed subsection 1030.5(a)(1)(B) specifies education requirements for trainee licensure. An MLT trainee must have completed at least 60 credit hours from an accredited college or university, and those 60 credit hours must include at least 36 credit hours in physical and biological sciences with an emphasis on applied clinical laboratory science, 6 credit hours in chemistry, and 6 credit hours in biology.

Proposed subsection 1030.5(a)(1)(C) allows trainees to complete coursework concurrently with practical training, if they have completed at least 36 semester hours of coursework in physical and biological sciences, including at least 6 hours of chemistry and 6 hours of biology. This ensures that trainees have sufficient education to perform testing and obtain accurate and reliable results, and at the same time allows students greater flexibility in completing their education and training.

A number of community colleges in California offer academic coursework for MLTs with practical training done off site at a licensed clinical laboratory approved for training. Faculty members of these programs have told the Department that a requirement that all 60 hours of coursework be completed prior to training would be a hardship for their students and programs and could result in fewer community college programs for MLTs.

The proposed requirement allows students to begin practical training as soon as they have completed the required science coursework, and complete the non-science coursework required for their degree concurrently with their practical training. This may expedite their completion of their education and training, and their entry into the laboratory workforce. This also gives training programs flexibility when assigning students to practical training slots.

Proposed subsection 1030.5(a)(2) requires a licensed MLT trainee to train in an approved program in specialties specified for the MLT scope of work at BPC section 1260.3.

The proposed section authorizes a licensed trainee to perform tests or examinations categorized as waived or moderate-complexity under CLIA in the specialties of chemistry, microbiology, diagnostic immunology, and hematology, as well as moderate-complexity ABO and Rh type immunology. These are the testing categories specified in BPC section 1260.3 for the MLT license for which the person is training.

Proposed subsection 1030.5(a)(3) requires an MLT trainee to perform tests or examinations under the supervision of a person licensed under Chapter 3 of the BPC or a physician and surgeon licensed under Chapter 5 of the BPC. The requirement that a trainee work under adequate supervision and that supervisors are responsible for the trainee’s work ensures the integrity of test samples and the accuracy and reliability of test results.

Proposed subsection 1030.5(b), "Licensure requirements and work scope for a CLS" specifies the minimum qualifications of education and training required for licensure as a clinical laboratory scientist (CLS) trainee and defines the work scope of these trainees.

Proposed subsection 1030.5(b)(1) adopts and amends requirements from current section 1030.5 that specify education requirements for CLS trainee licensure, which are for the most part the requirements for CLS licensure in section 1030.7.

Proposed subsection 1030.5(b)(1)(A) clarifies the requirement for submitting an application, as specified in section 1031.

Proposed subsection 1030.5(b)(1)(B) adopts and amends requirements in current section 1030.5, which requires a baccalaureate degree with a major in clinical laboratory science or courses pertinent to the clinical laboratory field as may be determined by the Department. The proposed subsection requires a baccalaureate or equivalent degree, to give the Department flexibility to accept degrees obtained at educational institutions outside the United States. The meaning of "equivalent degree" and the process for determination of equivalency is clarified in new definitions in section 1029 proposed in this package.

The proposed requirements broaden the field of study acceptable for licensure to include biological, chemical, and physical science. This change ensures that trainees have adequate education in subjects pertinent to the testing they will perform as CLSs. It also clarifies which fields of study are acceptable, and standardizes the application process.

Current regulations require a CLS trainee to hold a degree from a college or university maintaining standards equivalent to those institutions accredited by the Western Association of Schools and Colleges. The proposed section omits this reference because it is out of date. Instead, it refers to an accredited college or university. A new definition of "accredited college or university" in section 1029 replaces references to that association with updated information. Under the proposed regulation, the Department will accept accreditations from a regional accrediting association that is recognized by the U.S. Department of Education, the Council on Higher Education Accreditation (CHEA) or its successor organization, or another agency approved by the Department. These associations are recognized by the U.S. Department of Education as the reliable authorities on educational quality and the effectiveness of the higher education institutions and programs they accredit.

The new definition will clarify what constitutes an accredited college or university and update the list of accreditation associations accepted by the Department.

This subdivision retains a provision in current section 1030.5 that allows trainees to complete coursework concurrently with practical training, if the training is part of a program that will lead to a baccalaureate degree upon completion of training. Before obtaining a trainee license, the applicant must complete 90 credit hours of coursework, including the core science requirements for CLS licensure specified in subsection (C). This ensures that trainees have sufficient education to perform testing and obtain accurate and reliable results, and at the same time allows students greater flexibility in completing their education and training.

Proposed subsection 1030.5(b)(1)(C) specifies minimum coursework in various fields. Current section 1030.5 requires 16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry, 18 semester or equivalent quarter hours of biological science, including instruction in immunology, hematology, and medical microbiology, which may include bacteriology, mycology, virology, and parasitology; and 3 semester or equivalent quarter hours of physics including instruction in principles of light and electricity.

The regulated community has requested changes to the current course requirements, which require outdated courses, many of which are no longer routinely available at colleges and universities. The Department proposes to modify and broaden the courses required of an applicant with a baccalaureate degree that is not in clinical laboratory science.

The proposed subsection retains the requirement of 16 credit hours of chemistry, but updates the fields of study to reflect current academic practice and nomenclature, and to accept classes in clinical chemistry. The proposed section also provides more options for completing chemistry coursework. Current chemistry requirements are more intensive than is necessary for CLSs, because much of routine chemistry testing is now automated. These chemistry course requirements have been an impediment for otherwise qualified applicants.

The proposed subsection reduces the number of credit hours of biological science from 18 to 16. Because most undergraduate science classes are four credits, the requirement of 18 credit hours requires applicants to complete additional coursework. The new requirement conforms to current academic practice and is consistent with the chemistry requirement of 16 credit hours of chemistry. The proposed subsection retains the requirements for coursework in hematology and immunology, but changes the microbiology requirement from medical microbiology to microbiology to reflect current academic nomenclature. It also eliminates microbiology requirements for coursework in bacteriology, mycology, virology, and parasitology, as these topics are covered during practical training and are not routinely available in most colleges and universities.

The proposed subsection changes the current requirement for three credit hours of physics to eliminate instruction in principles of light and electricity, and broadens this

requirement to accept coursework in mathematics and statistics. The requirement of light and electricity is outdated, and many applicants and licensed CLSs have questioned its applicability and usefulness to the current CLS scope of work. Such classes are difficult to obtain because academic practice no longer includes this instruction in basic physics classes. Many otherwise qualified applicants, including applicants who have trained in the US armed forces, have not received instruction in light and electricity and must take additional coursework to satisfy this requirement.

CLTAC recommended that the Department update this requirement to include more pertinent fields of study, and the Department agrees that coursework in mathematics and statistics is more important for CLS work than principles of light and electricity, and will better prepare people for licensure.

Proposed subsection 1030.5(b)(2) specifies that a licensed CLS trainee is authorized to perform tests or examinations classified under CLIA as waived, moderate-, or high-complexity and lists the specialties and subspecialties in which they are allowed to test: chemistry, microbiology, diagnostic immunology, immunohematology, hematology, histocompatibility, and genetic testing, as specified in proposed section 1035.2. This clarifies the work scope of CLS trainees.

Proposed subsection 1030.5(b)(3) specifies the level of supervision of a required for CLS trainee. This level of “direct and responsible supervision” is defined in section 1029 and in section 1206 of the Business and Professions Code. It requires personal observation and critical evaluation of the activity of a trainee the entire time the trainee is performing clinical laboratory tests or examinations by a person licensed under Chapter 3 of the BPC or Chapter 5 of the BPC. It also requires personal review by the supervisor of the results of clinical laboratory testing or examination to ensure accuracy, reliability, and validity before the results are reported from the laboratory.

Proposed subsection 1030.5(c) specifies the minimum qualifications of education and training required for CLS trainee licensure of an applicant who meets requirements for licensure as a medical laboratory technician (MLT) under Chapter 3. This is a new CLS licensure pathway. The Department is proposing licensure requirements for this pathway in this regulatory package under section 1030.8, “Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure.”

The trainee licensure proposed in subsection 1030(c) is necessary because licensed MLTs are authorized to perform tests or examinations classified under CLIA as waived or moderate-complexity but will require licensure that allows them to perform high-complexity testing while training.

Currently, applicants who qualify for California MLT licensure must complete a full CLS training program that duplicates some of the training they have already completed to qualify for MLT licensure.

To qualify for MLT licensure under the requirements proposed in these regulations under section 1030.6, applicants must complete 60 hours of coursework, including 36 credit hours in physical and biological sciences. They must train for 26 weeks in a limited number of clinical laboratory specialties, performing clinical tests and examinations classified under CLIA as waived or moderate complexity.

Applicants for CLS licensure must complete a baccalaureate or equivalent degree, including 35 credit hours in chemistry, biology, and physics, math, or statistics. They must train for one year in all specialties, performing tests and examinations classified under CLIA as waived, moderate, or high complexity.

Many stakeholders, including some California community colleges, have urged the Department to develop a pathway for graduates of MLT programs to progress to the higher CLS license category without having to complete a full CLS training program, which would repeat some of the training the graduates completed to qualify for MLT licensure. In 2019, California law was amended to require the Department to implement such an “MLT to CLS” pathway program. (BPC § 1261(b), SB 334, Chapter 144, Statutes of 2019)

The Department is proposing a new licensure pathway for these MLTs that will focus on advanced coursework and training in the high complexity testing required for CLS licensure, without repeating training in waived and moderate-complexity testing. This will allow qualified MLTs to transition efficiently and quickly to CLS licensure, reducing their expenditure of time and money to repeat coursework and training.

This proposed licensure pathway will be available only to applicants who meet California MLT licensure requirements. To qualify for trainee licensure, they will have to meet coursework requirements for CLS licensure before they begin CLS training, and complete six months of training that focusses on high-complexity testing in all specialties, which is not covered in MLT training.

The Department sets standards for MLT licensure and training programs and is confident that candidates who hold California MLT licensure have education and training that meets the Department’s requirements and prepares them for a streamlined training pathway. MLTs who have trained outside California are allowed to follow this pathway if they have completed coursework and training that meet the Department’s MLT licensure requirements. If they do not have equivalent coursework and training, they have the option of completing a full twelve-month CLS training program as specified in section 1030.7 or obtaining a California MLT license as specified in section 1030.6 and then completing an MLT-to CLS program.

This MLT-to-CLS pathway will create a career path that encourages MLTs to pursue CLS licensure. It will save MLTs time and money when completing CLS requirements by eliminating duplication of coursework and training. It will free up limited space in CLS training programs. By encouraging qualified people to pursue CLS licensure and enabling MLTs to make this transition more easily, it will help alleviate the severe, long-standing shortage of qualified CLSs in California laboratories.

A more complete discussion of this proposed CLS licensure pathway is provided below under section 1030.8, Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure. Corresponding requirements for training programs for these applicants are discussed under section 1035.3, Requirements for a Training School or Program for Clinical Laboratory Scientists Who Meet Requirements for Medical Laboratory Technician Licensure.

Proposed subsection 1030.5(c) adopts and amends requirements from current section 1030.5 that specify education requirements for CLS trainee licensure, which are mostly the requirements for CLS licensure in proposed section 1030.8.

Proposed subsection 1030.5(c)(1)(A) clarifies the requirement for submitting an application, as specified in section 1031. (See BPC § 1263.)

Proposed subsection 1030.5(c)(1)(B) adopts a requirement for the proposed MLT articulation pathway for CLS licensure to make it available only to applicants who hold current California MLT licensure or meet California MLT licensure requirements. To qualify for trainee licensure, applicants will have to meet science coursework requirements for CLS licensure before they begin training, and complete six months of training that focusses on high-complexity testing in all specialties not covered in MLT training.

The Department sets standards for MLT licensure and training programs and is confident that candidates who hold California MLT licensure have education and training that meets the Department's requirements and prepares them for a streamlined training pathway. MLTs who have trained outside California are allowed to follow this pathway if they have completed coursework and training that meet the Department's MLT licensure requirements. If they do not have equivalent coursework and training, they have the option of completing a full twelve-month CLS training program as specified in section 1030.7 or obtaining a California MLT license as specified in section 1030.6 and then completing an MLT-to CLS program.

Proposed subsection 1030.5(c)(1)(C) adopts and amends requirements in current section 1030.6, which requires a baccalaureate degree with a major in clinical laboratory science or courses pertinent to the clinical laboratory field as may be determined by the Department. The proposed subsection requires a baccalaureate or

equivalent degree. Including the option of equivalent degree gives the Department flexibility to accept degrees obtained at educational institutions outside the United States. The meaning of “equivalent degree” and the process for determination of equivalency is clarified in a new definition in section 1029 proposed in this package.

The proposed requirements broaden the field of study acceptable for licensure to include biological, chemical, and physical science. This change ensures that trainees have adequate education in subjects pertinent to the testing they will perform as CLSs. It also clarifies which fields of study are acceptable, and standardizes the application process.

The proposed subsection adopts a provision that allows trainees to complete coursework concurrently with practical training, if the training is part of a program that will lead to a baccalaureate degree upon completion of training. Before obtaining a trainee license, the applicant must complete 90 credit hours of coursework, including the core science requirements for CLS licensure specified in subsection (C). This ensures that trainees have sufficient education to perform testing and obtain accurate and reliable results, and at the same time allows students greater flexibility in completing their education and training.

Proposed subsection 1030.5(c)(1)(D) specifies minimum coursework an applicant must complete in various fields.

Current section 1030.5 requires CLS trainees to complete 16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry, 18 semester or equivalent quarter hours of biological science, including instruction in immunology, hematology and medical microbiology which may include bacteriology, mycology, virology, and parasitology; and 3 semester or equivalent quarter hours of physics including instruction in principles of light and electricity.

The regulated community has requested changes to the current course requirements, which require outdated courses, many of which are no longer routinely available at colleges and universities. The Department proposes to modify and broaden the courses required of an applicant with a baccalaureate degree that is not in clinical laboratory science.

The proposed subsection retains the requirement of 16 credit hours of chemistry, but updates the fields of study to reflect current academic practice and nomenclature, and to accept classes in clinical chemistry. The proposed section also provides more options for completing chemistry coursework. Current chemistry requirements are more intensive than is necessary for CLSs, because much of routine chemistry testing is now automated. These chemistry course requirements have been an impediment for otherwise qualified applicants.

The proposed subsection reduces the number of credit hours of biological science from 18 to 16. Because most undergraduate science classes are four credits, the requirement of 18 credit hours requires applicants to complete additional coursework. The new requirement conforms to current academic practice and is consistent with the chemistry requirement of 16 credit hours of chemistry. The proposed subsection retains the requirements for coursework in hematology and immunology, but changes the microbiology requirement from medical microbiology to microbiology to reflect current academic nomenclature. It also eliminates microbiology requirements for coursework in bacteriology, mycology, virology, and parasitology, as these topics are covered during practical training and are not routinely available in most colleges and universities.

The proposed subsection changes the current requirement for three credit hours of physics to eliminate instruction in principles of light and electricity, and broadens this requirement to accept coursework in mathematics and statistics. The requirement of light and electricity is outdated, and many applicants and licensed CLSs have questioned its applicability and usefulness to the current CLS scope of work. Such classes are difficult to obtain because academic practice no longer includes this instruction in basic physics classes. Many otherwise qualified applicants, including applicants who have trained in the US armed forces, have not received instruction in light and electricity and must take additional coursework to satisfy this requirement.

CLTAC recommended that the Department update this requirement to include fields of study more pertinent to the work scope of CLSs, and the Department agrees that coursework in mathematics and statistics is more important for CLS work than principles of light and electricity, and will better prepare people for licensure.

Proposed subsection 1030.5(c)(2) adopts a requirement that a licensed CLS trainee must train in a program approved by the Department.

This proposed section authorizes a licensed CLS trainee to perform tests or examinations classified under CLIA as waived, moderate, or high complexity in the specialties and subspecialties of chemistry, microbiology, diagnostic immunology, immunohematology, hematology, histocompatibility, and genetic testing, as specified in proposed section 1035.2. This clarifies the work scope of CLS trainees, which reflects the work scope specified in BPC section 1204 for the CLS license for which the person is training.

Proposed subsection 1030.5(c)(3) requires a CLS trainee to perform tests or examinations under the supervision of a person licensed under Chapter 3 of the BPC or Chapter 5 of the BPC. The requirement that trainees work under adequate supervision and that supervisors are responsible for their work ensures the integrity of test samples and the accuracy and reliability of test results.

Proposed subsection 1030.5(d) specifies the minimum qualifications of education and training required for licensure as a CLS trainee limited to a specialty or subspecialty and defines the work scope of these trainees.

Proposed subsection 1030.5(d)(1) adopts and amends requirements from current section 1030.5 that specify education requirements for licensure of CLS trainees limited to a specialty or subspecialty, which are for the most part the requirements for CLS licensure limited to a specialty or subspecialty in sections 1030.10 through 1030.17.

Proposed subsection 1030.5(d)(1)(A) clarifies the requirement for submitting an application, as specified in section 1031. (See BPC 1263.)

Proposed subsection 1030.5(d)(1)(B) adopts and amends requirements in current section 1030.5, which requires a baccalaureate degree with a major in clinical laboratory science or courses pertinent to the clinical laboratory field as may be determined by the Department. The proposed subsection requires a baccalaureate or equivalent degree, to give the Department flexibility to accept degrees obtained at educational institutions outside the United States. The meaning of “equivalent degree” and the process for determination of equivalency is clarified in a new definition in section 1029 proposed in this package.

Current regulations require a CLS trainee to hold a degree from a college or university maintaining standards equivalent to those institutions accredited by the Western Association of Schools and Colleges. The proposed section omits this reference because it is out of date. Instead, it refers to an accredited college or university. A new definition of “accredited college or university” in section 1029 replaces references to that association with updated information. Under the proposed regulation, the Department will accept accreditations from a regional accrediting association that is recognized by the U.S. Department of Education, the Council on Higher Education Accreditation (CHEA) or its successor organization, or another agency approved by the Department. These associations are recognized by the U.S. Department of Education as the reliable authorities on educational quality, and the effectiveness of the higher education institutions and programs they accredit.

The proposed requirements broaden the field of study acceptable for licensure to include biological, chemical, and physical science. This change ensures that trainees have adequate education in subjects pertinent to the testing they will perform as CLSs. It also clarifies which fields of study are acceptable, and standardizes the application process.

The proposed section also specifies the acceptable fields of study rather than retaining current language that leaves decisions about acceptability in individual cases to the Department, which may result in inconsistency. The proposed section will introduce greater clarity and consistency.

Proposed subsection 1030.5(d)(1)(C) specifies minimum coursework for licensure in each of the various specialties and subspecialties. The course requirements specified here are consistent with course requirements specified in sections 1030.10 through 1030.17; the information is listed here for ease of reference and clarity.

Proposed subsection 1030.5(d)(2) specifies that a licensed CLS trainee limited to a specialty or subspecialty is authorized to perform tests or examinations classified under CLIA as waived, moderate-, or high- complexity in the specialty or subspecialty authorized for the limited license for which the trainee is training. Existing regulations do not specify the work scope of CLS trainees. The inclusion of this information provides clarity to trainees, laboratory staff, and directors about the work scope of trainees.

Proposed subsection 1030.5(d)(3) requires a CLS trainee limited to a specialty or subspecialty to perform tests or examinations under the supervision of a person licensed under Chapter 3 of the BPC or Chapter 5 of the BPC. The requirement that trainees work under adequate supervision and that supervisors are responsible for their work ensures the integrity of test samples and the accuracy and reliability of test results.

Proposed subsection 1030.5(e) clarifies that a clinical laboratory trainee may perform tests but may not report the results. It also clarifies that all trainees' test results must be critically reviewed as defined in Section 1029 and reported by the person providing supervision, who must be licensed under Chapter 3 or Chapter 5. This critical review requirement ensures that test results obtained by a trainee have been reviewed and verified for accuracy, reliability, and validity by a person with sufficient education, training, experience, and demonstrated competency to obtain full licensure required to perform the relevant type and complexity of testing. This provision will safeguard public health by ensuring the reliability of trainees' test results.

Proposed subsection 1030.5(f) adopts a requirement that a clinical laboratory trainee must be licensed during the entire time the trainee performs tests in a California clinical laboratory. Most other states do not license trainees or require trainee licensure, so it is important to clarify that trainees are required to have licensure to perform testing in laboratories located in California.

This requirement is consistent with statute at BPC section 1282, which states that it is unlawful to engage in clinical laboratory practice unless one is a physician or surgeon or is duly authorized to do so under Chapter 3.

Proposed subsection 1030.5(f)(1) specifies that licensed trainees must have in their possession the trainee license issued by the Department. This allows the laboratory director and Department inspectors to verify that the trainee has the required licensure.

Proposed subsection 1030.5(f)(2) specifies that the trainee's license must be posted in the laboratory where the trainee performs testing, as specified in BPC section 1266. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so.

Proposed subsection 1030.5(f)(2)(A) In response to many requests for clarification from laboratory owners and personnel, this section clarifies that if a trainee performs testing in more than one location of a laboratory under a single clinical lab license, it is sufficient that the license be posted in the trainee's primary work location. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so. However, it could be onerous to post the license at each testing location if a trainee is working at multiple locations within the same laboratory, for example, during rotations to train in many different types of testing. Posting at the trainee's main location is sufficient to allow interested persons to verify the trainee's licensure.

Proposed subsection 1030.5(f)(2)(B) In response to many requests for clarification from laboratory owners and personnel, this section clarifies that if a trainee performs testing for more than one employer or in a number of different laboratories that are not covered under a single clinical laboratory license, the trainee's license must be posted in the trainee's primary work location at each address where the trainee performs testing. This ensures that interested persons can easily verify the trainee's licensure at the address at which testing is performed.

Proposed subsection 1030.5(f)(3) specifies that a trainee license is valid for one year. It also clarifies that a trainee license may be renewed. The Department has received many requests for renewal from trainees who were unable to complete their training before the expiration of their licenses, usually because of delays in obtaining a trainee placement. The proposed subsection will allow these trainees to renew their trainee licenses in order to complete their training.

(23) Amend section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician

Existing section 1030.6 is outdated; proposed section 1030.6 updates the licensure requirements and work scope of a medical laboratory technician (MLT) to reflect current industry standards and provide clarity and ease of reference to the regulated community.

Existing section 1030.6, Licensure of Medical Laboratory Technicians, contains education, training, experience requirements for medical laboratory technician licensure. It also specifies a portion of the scope of work MLT's are authorized to perform, license fees and renewal, and continuing education requirements.

Proposed section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician, is more comprehensive than current regulations and reflects current industry standards. It specifies the minimum qualifications of education and training required for licensure as an MLT and defines the work scope of an MLT.

The structure of proposed section 1030.6 is like that of proposed section 1030, Licensure and Work Scope of Clinical Laboratory Trainee, which includes MLT trainee licenses and CLS trainee licenses. Proposed license and work scope regulations for other clinical laboratory positions will use a similar structure. This ensures that similar sections of the code for laboratory personnel licensure address the same topics in a standardized order, providing clarity and ease of reference when determining the licensure and work scope of each license category and comparing the licensure and work scope of closely related laboratory licenses.

Proposed subsection 1030.6(a) specifies the minimum qualifications of education and training required for licensure as an MLT and defines the work scope of an MLT.

This provides clarity to licensure applicants, licensed MLT trainees, licensed MLTs, training schools and programs, and the regulated community.

Business and Professions Code, section 1260.3 provides specific authority and statutory law upon which these regulations are based. Business and Professions Code, subsection 1260.3(a)(1) establishes basic education, training, and application requirements for MLT licensure. Business and Professions Code, subsection 1260.3(b) establishes the basic work scope an MLT may perform and the level of supervision required.

Portions of the regulations proposed in section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician, are found in existing regulations in section 1030.6, Licensure of Medical Laboratory Technicians. Section 1030.6 contains current education, training, and experience licensure requirements for a medical laboratory technician. It also specifies the scope of work MLT's are authorized to perform, license fees and renewal, and continuing education requirements. Existing section 1030.6 is outdated, and the proposed section 1030.6 updates licensure and work scope of a medical laboratory technician to reflect current industry standards and provide clarity and ease of reference to the regulated community.

Portions of the regulations proposed in section 1030.6 refer to existing section 1031, Requirements and Timeframes for Application for Licensure and Certification. Section 1031 specifies the information required for licensure application. It pertains to documentation of the applicant's education, training, experience, and satisfactory performance.

Existing section 1030.6 is outdated and not thorough; the proposed section 1030.6 provides extensive information about licensure and work scope of an MLT to reflect current statute and industry standards and provide clarity and ease of reference to the regulated community.

The structure of proposed section 1030.6 is like that of proposed section 1030, Licensure and Work Scope of Clinical Laboratory Trainee, which includes MLT trainee licenses and CLS trainee licenses. Proposed license and work scope regulations for other clinical laboratory positions will use a similar structure. This ensures that similar sections of the code for laboratory personnel licensure address the same topics in a standardized order, providing clarity and ease of reference when determining the licensure and work scope of each license category and comparing the licensure and work scope of closely related laboratory licenses.

Proposed subsection 1030.6(a) provides education, training, and experience requirements for obtaining an MLT license.

Existing subsection 1030.6(a) uses semester units and quarter units of measurement when calculating educational credit. Proposed subsection 1030.6 will use credit hours as the unit of measurement. The term “credit hour” is defined in this rulemaking package. This definition is necessary to applicants for licensure, training schools and programs, and the regulated community, to clarify to how the Department calculates educational credit. Schools may use the term “hour,” “credit,” or “unit.” This definition clarifies that any of those terms are acceptable and equivalent. Most schools measure educational credit in terms of the amount of time in the classroom and the resultant amount of subject material covered/taught. Most schools will measure either two semesters (Fall and Spring) per academic year, or three quarters (Fall, Winter, and Spring) per academic year. An hour per week in a classroom lecture during one semester is about the equivalent of an hour per week in classroom (lecture) during one and a half quarters. The Department calculates 1 semester credit hour to 1.5 quarter credit hours. It is necessary for the regulated community to understand this method of calculation. This definition will clarify educational requirements for applicants for licensure.

Proposed subsection 1030.6(a)(1) specifies that an applicant for licensure must apply as specified in section 1031 and meet requirements. The application procedure is clarified in section 1031 to ensure that all applicants meet the statutory and regulatory requirements and submit applications using a standardized procedure to enable the Department to process applications as efficiently as possible and to ensure fairness in the application review process.

Proposed subsection 1030.6(a)(2) specifies the education requirements for MLT licensure. It specifies and clarifies the minimal education requirements for applying for MLT licensure.

Existing law does not include a reference to degrees in chemical science or medical laboratory technology courses, which are now offered in many institutions of higher learning. This adds these fields to the listing of acceptable coursework to clarify that applicants with coursework in these fields may qualify, updates the requirements to reflect new academic developments, and provides specificity and clarity to license applicants, training schools, associations, accrediting organizations, and the regulated community.

Current law requires an MLT licensure applicant to have completed at least 60 semester (90 quarter) units from an accredited college or university, which must include at least 36 semester units of physical or biological sciences with an emphasis on applied clinical science. The proposed section requires an associate degree, or equivalent education of at least 60 credit hours of coursework, in a chemical, physical, or biological science or medical laboratory technology, or equivalent education of at least 60 credit hours from an accredited college or university. This clarifies that the Department may accept education equivalent to an associate degree even if the applicant does not hold that specific degree. This provides the Department flexibility to license individuals who have completed the necessary academic coursework, but may not hold a degree. The proposed section uses credit hours as the unit of measurement instead of semester units or quarter units cited in existing regulations. Evidence of need for this change is discussed in the analysis of proposed amendments in subsection in 1030.5(a). The credit hours proposed in this section are equivalent to the educational requirements in existing regulations.

Proposed subsection 1030.6(a)(3) specifies the required academic coursework, which must include at least 36 credit hours in physical and biological sciences with an emphasis on applied clinical laboratory science, including at least 6 credit hours in chemistry and 6 credit hours in biology. The coursework and credit hours proposed in this section are the same as the requirements in existing regulations. Stating this requirement provides clarity to licensure applicants, training schools and programs, and the regulated community. This will guide licensure applicants to complete the proper courses and encourage training schools and programs to provide the necessary coursework to ensure that applicants have sufficient education to perform testing and obtain accurate and reliable results.

Proposed subsection 1030.6(a)(4) specifies the training or experience requirement for MLT licensure. This specifies that the training or experience must be obtained in a clinical laboratory either certified under CLIA or 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 or later standards by an international accrediting organization that meets ISO/IEC 17011 standards or later standards at the time an applicant obtained the

training or experience. Section 1032.5 is being added to this rulemaking package to clarify that the Department also accepts training or experience obtained in a laboratory located outside the US that is not certified under CLIA but that meets international standards set forth in ISO 15189 and ISO/IEC 17025. Requiring the training or experience be performed in a CLIA certified, CAP or JCI accredited, or ISO certified laboratory assures that the trainee will obtain quality education and training, resulting in accurate, reliable testing and safety.

CLIA, regulations set federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease of human beings. The federal Centers for Medicare & Medicare Services (CMS) administers certification under CLIA regulations. CLIA standards ensure that laboratory personnel have sufficient education, training, and experience to perform accurate testing. California personnel licensure requirements meet and often exceed CLIA standards to ensure accuracy and reliability of test results.

CAP and JCI accredited laboratories are up to date with the latest standards and accreditation changes. They are required to meet standards from CLIA, FDA, and OSHA. JCI is the author of rigorous international standards on quality and patient safety. Laboratory accreditation by CAP maintains accuracy of test results and ensures accurate patient diagnosis. This ensures the training or experience obtained is sufficient to meet federal CLIA quality standards.

CAP and JCI are both US-based organizations. Some licensure applicants obtain their training and experience in other countries. There is currently a nation-wide shortage of qualified licensed clinical laboratory personnel and a need to increase the pool of licensed testing personnel. One way to increase this number, while maintaining the high quality of training and experience required, is to accept training and experience obtained at a clinical laboratory certified to meet ISO and ISO/IEC current and later standards. These standards meet the minimum qualifications required by the State. This would ensure that the licensure applicant received the necessary training and experience in a clinical laboratory that meets the standards of federal CLIA but is not necessarily certified by CAP or by JCI.

A significant number of regulations in proposed in section 1030.6(a)(4) are similar to those found in existing section 1030.6. Existing section 1030.6, Licensure of Medical Laboratory Technicians, provides six options to complete the training and experience required to obtain an MLT license:

- A NAACLS accredited MLT training program,
- An MLT training program approved by the Department,
- Meeting admission requirements for a CLS licensing examination,
- Three years of on-the-job practical experience in a laboratory outside of California as an MLT,

- Three years of on-the-job practical experience in a laboratory outside of California as a CLS,
- Three years on-the-job practical experience as an MLT or CLS in a California physician office laboratory or laboratory owned and operated by the United States of America.

Proposed section 1030.6(a)(4) provides six options to complete the training and experience required to obtain an MLT license:

- An approved NAACLS accredited MLT training program,
- A six-month MLT training program approved by the Department,
- Two years of training and experience in the military as a military laboratory specialist,
- Meeting educational and training requirements for CLS licensure,
- Three years of on-the-job practical experience as an MLT or CLS outside of California, or
- Three years of on-the-job practical experience as an MLT or CLS in a California physician office laboratory or laboratory owned and operated by the United States of America.

Proposed subsection 1030.6(a)(4) establishes six ways to complete the training and experience required to obtain an MLT license.

Proposed subsection 1030.6(a)(4)(A) specifies that completion of an MLT training program accredited by the National Accreditation Agency for Clinical Laboratory Sciences (NAACLS) and approved by the Department will satisfy the training and experience requirement. For ease of reference and clarity, the subsection refers to the definition of “approved NAACLS accredited training program” proposed in section 1029.

NAACLS reviews and approves education programs that meet established education standards in clinical laboratory science. This includes disciplines such as Medical Laboratory Technician and Phlebotomist. The NAACLS accreditation process is recognized by the Council for Higher Education Accreditation.

The Department receives license and certification applications from many states. It would be a burdensome and inefficient use of resources for the Department to assess each of those laboratory programs outside California. Therefore, the Department accepts NAACLS evaluation and accreditation, because NAACLS standards meet the minimum standards required by the Department. To prevent license and certification applicants from obtaining training and experience that does not meet Department standards, this section specifies that an applicant must complete a program accredited by NAACLS and approved by the Department. This will provide clarity to applicants, training programs, laboratories, and the regulated the community.

Proposed subsection 1030.6(a)(4)(B) specifies that completion of six months of MLT training as a licensed MLT trainee approved by the Department will satisfy the training and experience requirement.

The MLT trainee license issued by the Department means the training program completed by the MLT trainee was previously reviewed and met Department standards. This subsection clarifies that for licensure purposes a training must be approved by the Department to ensure that trainees will enroll in training programs that will meet Department requirements.

Proposed subsection 1030.6(a)(4)(C) specifies that completion of two years of training and experience as a military laboratory specialist, including one or more years of basic (Phase 1) and one of more years of advanced (Phase 2) training as a clinical laboratory technician or medical laboratory technician will satisfy the training and experience requirement.

Some applicants receive training and experience as a military laboratory specialist during their military service. The Department has reviewed US military training programs and has determined that they meet the Department's standards. To avoid requiring service members to repeat the training and experience they already obtained, the Department accepts their military training and experience in Subsection (c) to satisfy the training and experience licensure requirement. This expands the pool of applicants in the current industry shortage, benefits military veterans by crediting them for training and experience they completed during military service, allowing them to transition quickly into the civilian workforce, and benefits the public who receive health care in California.

Proposed subsection 1030.6(a)(4)(D) is similar to existing subsection 1030.6(2)(C), meeting admission requirements for a clinical laboratory scientist licensing examination. The education and training experience required for a clinical laboratory scientist licensure pursuant to section 1032 is more extensive than the training and experience required to obtain an MLT license. CLS training and experience includes training and experience in the tests and examinations authorized for an MLT. Therefore, the Department has determined that satisfying the training and experience required to obtain a CLS license satisfies the training and experience required to obtain an MLT license. Current regulations were adopted at a time when the Department administered the examination required for CLS licensure, and they required an applicant to meet the requirements to sit for the Department's examination. The Department no longer administers CLS examinations, but instead accepts national board examination results. The proposed language is revised to reflect that change, requiring CLS applicants to meet the education and training requirements in California law rather than Department-administered examination requirements.

Proposed subsection 1030.6(a)(4)(E) specifies that three years of on-the-job practical experience as an MLT or CLS in a clinical laboratory located outside California, with certain specifications as to the tests and examinations performed during that time, satisfies the training and experience requirement.

The proposed changes to existing law and policy reflect the Department's aim to increase the pool of qualified MLT applicants by expanding opportunities for people trained in other states to obtain a California MLT license. Existing law requires the experience be obtained in the previous five years. Proposed law requires the experience to be obtained in the last ten years to expand the opportunity for qualified applicants. Existing law also states the experience must be as a medical laboratory technician. Proposed law will also accept practical experience as a CLS because not all MLT licensure applicants have experience as an MLT. Many have experience performing the same tests and examinations as a CLS.

Proposed subsection 1030.6(a)(4)(E)(2) specifies the specialties in which an applicant must train and clarifies the hours of training required in each specialty.

Existing regulations require completion of 480 hours in each of the specialties of chemistry, hematology, microbiology, and immunology. This requirement was confusing to the public, as the intention and policy of the Department was to require a total of 480 hours of testing, which included training in each of four specialties, that is, 120 hours in each specialty. Proposed regulations require a total of 640 hours of practical experience, and clarify that training must include at least 128 hours of testing in each of the specialties of chemistry, microbiology, diagnostic immunology, hematology, and moderate complexity ABO and Rh type immunohematology. The increase in training hours was adopted at the request of the Department's advisory committee, the Clinical Laboratory Technology Advisory Committee. The addition of testing in moderate complexity ABO and Rh type immunohematology incorporates statutory changes made in 2018 that expanded the MLT scope of practice to include moderate complexity blood smear reviews other than manual leukocyte differentials, microscopic urinalysis, and blood typing of moderate complexity such as automated ABO/Rh testing and antibody screen testing. The additional hours of training, including training in newly authorized areas of testing, will increase the knowledge, skills, and abilities of MLTs and ensure the integrity of test samples, the accuracy and reliability of laboratory test results.

Proposed subsection 1030.6(a)(4)(E)(3) incorporates an existing requirement into this section. Existing regulations, section 1031, require providing documentation of the applicant's education, training, and experience. The requirement was added to the section on licensure requirements to provide clarity to the regulated community and ease of reference in determining requirements by listing all the requirements in one section.

Proposed subsection 1030.6(a)(4)(F) specifies that three years of on-the-job practical experience as an MLT or CLS in a clinical laboratory located in a licensed physician office laboratory in California or in a laboratory owned and operated by the government of the United States, with certain specifications as to the tests and examinations, satisfies the training and experience requirement.

The proposed changes to existing law and policy reflect the Department's aim to increase the pool of qualified MLT applicants by expanding opportunities for people to obtain an MLT license. Existing law requires the experience be obtained in the previous five years. Proposed law requires the experience to be obtained in the last ten years to expand the opportunity for qualified applicants. Existing law also states the experience must be as a medical laboratory technician. Proposed law will also accept practical experience as a CLS because not all MLT licensure applicants have experience as an MLT. Many have experience performing the same tests and examinations as a CLS.

Proposed subsection 1030.6(b) specifies the authorized scope of work of a licensed MLT. This subsection provides clarity to licensure applicants, licensed MLTs, training schools and programs for the regulated community about the work scope of MLT licensees.

Proposed subsection 1030.6(c) specifies types and levels of supervision required for a licensed MLT to perform clinical laboratory tests and examinations classified as moderate complexity under CLIA. Existing regulations specify the personnel who are authorized to provide supervision and require on-site supervision during the entire time the MLT is performing tests or examination. Proposed regulations retain these supervision requirements, including the requirement that the supervisor cannot supervise remotely, but must be available at the location where the MLT is performing testing. Existing requirements specify a ratio of one supervisor for no more than four MLTs. Proposed regulations change the ratio to require one supervisor for no more than eight MLTs. This change was made on the advice of the Department's advisory committee, CLTAC. The Department has reviewed inspection and complaint records and has determined that the ratio of supervisors to MLTs can safely be expanded to allow a licensed supervisor to oversee the work of up to eight MLTs. The Department further determined that the existing ratio of one supervisor for four MLTs has restricted the employment of MLTs in California.

Proposed subsection 1030.6(d) specifies requirements of an MLT to maintain licensure, complete continuing education, and post the license. It adopts a requirement that an MLT must be licensed during the entire time the MLT performs tests in a California clinical laboratory. Most other states do not require laboratory personnel licensure, so it is important to clarify that MLTs are required to have licensure to perform testing in laboratories located in California.

This requirement is consistent with statute at BPC section 1282, which states that it is unlawful to engage in clinical laboratory practice unless one is a physician or surgeon or is duly authorized to do so under Chapter 3.

Proposed subsection 1030.6(d)(1) specifies that licensed MLTs must have in their possession the MLT license issued by the Department. This allows the laboratory director and Department inspectors to verify that the MLT has the required licensure.

Proposed subsection 1030.6(d)(2) specifies that the MLT's license must be posted in the laboratory where the MLT performs testing, as specified in BPC section 1266. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so.

Proposed subsection 1030.6(d)(2)(A), in response to many requests for clarification from laboratory owners and personnel, clarifies that if an MLT performs testing in more than one location of a laboratory under a single clinical lab license, it is sufficient that the license be posted in the MLT's primary work location. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so. However, it could be onerous to post the license at each testing location if an MLT is working at multiple locations within the same laboratory. Posting at the MLT's main location is sufficient to allow interested persons to verify the MLT's licensure.

Proposed subsection 1030.6(d)(2)(B), in response to many requests for clarification from laboratory owners and personnel, clarifies that if an MLT performs testing for more than one employer or in a number of different laboratories that are not covered under a single clinical laboratory license, the MLT's license must be posted in the MLT's primary work location at each address where the MLT performs testing. This ensures that interested persons can easily verify the MLT's licensure at the address at which testing is performed.

Proposed subsection 1030.6(d)(3) retains existing requirements about renewal and continuing education requirements, specifying that an MLT license is valid for two years. It also clarifies that an MLT license must be renewed every two years. To renew licensure, an MLT must complete at least 24 hours of continuing education in clinical laboratory related courses from an approved provider of continuing education.

Proposed subsection 1030.6(e) retains the information in current section 1030.6(c) specifying that the application and renewal fee for an MLT license will be the same as that for a clinical laboratory scientist license specified in Business and Professions Code section 1300. That statute provides the amount of application, registration, and license fees for many clinical laboratory personnel positions. However, it does not specify a fee amount for an application or renewal fee for an MLT license, but requires the Department to establish the amount in regulations. Business and Professions Code

section 1300 (c) states “The application fee for a clinical laboratory scientist’s or limited clinical laboratory scientist’s license is thirty-eight dollars ($38) commencing on July 1, 1983.” Section 1300 (e) states “The annual renewal fee for a clinical laboratory scientist’s or limited clinical laboratory scientist’s license is twenty-five dollars ($25) commencing on July 1, 1983.” This proposed regulation is necessary to provide clarity to the regulated community as to the amount of the application and renewal fees for an MLT license. This will benefit the licensure applicants, renewal applicants, and training schools.

In addition, the proposed subsection indicates that the application and renewal fees are non-refundable. This clarifies for applicants that the Department will not refund fees, for example, in case the application is rejected or abandoned for lack of timely completion of the application.

(24) Amend title of section 1030.7, Examination for Clinical Laboratory Technologist’s License to be Examination for Clinical Laboratory Scientist’s License

The amended title of section 1030.7 provides consistency in Article 1, Article 1.5, and Article 2. Some existing regulations use the word “Clinical Laboratory Technologist” and others use “Clinical Laboratory Scientist” referring to the same position. This has caused confusion as to which regulations apply to CLS licensure requirements. The latter term is the one commonly used by the regulated community and used consistently in the proposed text. This consistency of terminology in these regulations will provide clarity as to which regulations apply. This clarification will reduce the number of inquiries from the public and allow the Department to make more efficient use of time and public funding.

(25) Amend section 1030.7, Examination for Clinical Laboratory Technologist’s License to be Examination for Clinical Laboratory Scientist’s License

The Department proposes to amend section 1030.7 to update academic coursework requirements for CLS licensure to reflect changes in science, laboratory technology, and current academic programs. These changes modernize course requirements to reflect changes in the field and facilitate licensure by broadening the accepted coursework.

Proposed subsection 1030.7(a) broadens the baccalaureate majors acceptable for CLS licensure. Current regulations accept a major in clinical laboratory science. The proposed regulations broaden this to add a baccalaureate in a biological, chemical, or physical science. This change was recommended to the Department by the regulated community and the Department’s advisory committee, CLTAC, and the Department has determined that this change will facilitate licensure for qualified applicants.

Proposed subsection 1030.7(b)(1) specifies minimum coursework in various fields. Current section 1030.7 requires 16 semester or equivalent quarter hours of chemistry,

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

The regulated community has requested changes to the current course requirements, which require outdated courses, many of which are no longer routinely available at colleges and universities. The Department proposes to modify and broaden the courses required of an applicant with a baccalaureate degree that is not in clinical laboratory science.

The proposed subsection retains the requirement of 16 credit hours of chemistry, but updates the fields of study to reflect current academic practice and nomenclature, and to accept classes in clinical chemistry. The proposed section also provides more options for completing chemistry coursework. Current chemistry requirements are more intensive than is necessary for CLSs, because much of routine chemistry testing is now automated. These chemistry course requirements have been an impediment for otherwise qualified applicants.

Proposed subsection 1030.7(b)(2) reduces the number of credit hours of biological science from 18 to 16. Because most undergraduate science classes are four credits, the requirement of 18 credit hours requires applicants to complete additional coursework. The new requirement conforms to current academic practice and is consistent with the chemistry requirement of 16 credit hours of chemistry. The proposed subsection retains the requirements for coursework in hematology and immunology, but changes the microbiology requirement from medical microbiology to microbiology to reflect current academic nomenclature. It also eliminates microbiology requirements for coursework in bacteriology, mycology, virology, and parasitology, as these topics are covered during practical training and are not routinely available in most colleges and universities.

Proposed subsection 1030.7(b)(3) changes the current requirement for three credit hours of physics to eliminate instruction in principles of light and electricity, and broadens this requirement to accept coursework in mathematics and statistics. The requirement of light and electricity is outdated, and many applicants and licensed CLSs have questioned its applicability and usefulness to the current CLS scope of work. Such classes are difficult to obtain because academic practice no longer includes this instruction in basic physics classes. Many otherwise qualified applicants, including applicants who have trained in the US armed forces, have not received instruction in light and electricity and must take additional coursework to satisfy this requirement.

CLTAC recommended that the Department update this requirement to include more pertinent fields of study, and the Department agrees that coursework in mathematics

and statistics is more important for CLS work than principles of light and electricity, and will better prepare people for licensure. The changes to requirements have been made in consultation with stakeholders.

Other changes to CLS licensure requirements and scope of work will be made in a subsequent package that will revise the entire section, but these changes are needed now to align requirements with new requirements adopted in this package for CLS trainees and MLTs transitioning to CLS licensure.

(26) Amend section 1030.8, Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure

The Department proposes to change the title of section 1030.8 from Licensure of Oral Pathology Laboratory Directors to Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure. This is because existing section 1030.8 contains no text, as the text pertaining to oral pathology directors was renumbered to section 1030.27 in 2022 to make this section available for regulations on licensure and work scope for the newly established MLT to CLS pathway. The reason for moving the MLT to CLS pathway license to this section was to align it with the new order of sections 1030 et seq. The licensure and certification of clinical laboratory personnel sections 1030 et seq. now start with positions with the most basic requirements and work scope and proceed to those with more advanced requirements and work scope. Oral pathology director is one of the most advanced laboratory personnel positions, and the regulations for that license have been relocated to Section 1030.27, along with sections regulating licensure of other laboratory directors. The sections regulating licensure of all director positions follow sections regulating licensure of phlebotomy technicians, clinical laboratory trainees, clinical cytotechnologists, medical laboratory technicians, and clinical laboratory scientists. This will provide clarity and ease of reference to the reader seeking information about specific licensure requirements and work scope.

(27) Adopt section 1030.8, Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure

The Department proposes to adopt section 1030.8, Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure as the new “MLT-to-CLS” pathway established in accordance with Senate Bill 334 (Pan, Chapter 144, Statutes of 2019) that amended section 1261 of the Business and Professions Code to require the Department to establish a pathway allowing an MLT to apply work experience and training from a Department-approved MLT training program towards the completion of a CLS training program.

Proposed subsection 1030.8(a) specifies the minimum qualifications of education and training required for licensure as a clinical laboratory scientist and defines the work scope of a CLS.

This provides clarity to licensure applicants, licensed MLTs, licensed CLS Trainees, licensed CLSs, training schools and programs, and the regulated community.

Business and Professions Code section 1261, Clinical laboratory scientist's licenses or limited licenses; qualifications, provides specific authority and statutory law upon which these regulations are based. Business and Professions Code, section 1261, establishes some basic education and training requirements for CLS licensure. It requires the Department to develop regulations to implement the statute.

Portions of the regulations related to educational requirements proposed in section 1030.8, Licensure and Work Scope of a Clinical Laboratory Scientist Who Meets Requirements for Medical Laboratory Technician Licensure, are found in existing regulations section 1030.7, Examination for Clinical Laboratory Technologist License. Existing section 1030.7 contains current educational requirements of CLS Licensure.

Portions of the regulations proposed in section 1030.8 are found in existing section 1031, Requirements and Timeframes for Application for Licensure and Certification. Section 1031 specifies the information required for licensure application. It pertains to documentation of the applicant's education, training, experience, and satisfactory performance.

Existing section 1030.7 is outdated and not thorough; the proposed section 1030.8 provides extensive information about licensure and work scope of a CLS to reflect current industry standards and provide clarity and ease of reference to the regulated community. It provides a roadmap for licensed MLTs to become licensed CLSs, as codified on July 30, 2019, in Section 1261 of the Business and Professions Code.

The proposed section 1030.8 uses the same structure as proposed section 1030, Licensure and Work Scope of Clinical Laboratory Trainee, which includes MLT trainee licenses and CLS trainee licenses, and proposed section 1030.6, Licensure and Work Scope of a Medical Laboratory Technician. The consistent structure will make it easier to compare the minimum qualifications required for licensure of an MLT Trainee and licensure of a CLS Trainee in section 1030, licensure of an MLT in section 1030.6, and licensure of an MLT transitioning to CLS licensure in this section. This will provide clarity as to the education and training required for advancement from MLT to CLS licensure. It will also make it easier to compare the minimum qualifications required for licensure of CLS trainees who meet the requirements for MLT licensure and the traditional pathway of licensure of CLSs. This will provide clarity as to the education and training required for a person who meets requirements for MLT licensure to advance to CLS licensure. Proposed license and work scope requirements for other clinical laboratory license categories will use a similar structure. This provides clarity and ease of reference when comparing the licensure and work scope of closely related laboratory licenses.

Proposed subsection 1030.8(a)(1) specifies applicants must apply and meet the application requirements in existing section 1031. Applicants must also meet the proposed requirements in subsection 1030.8(a).

Proposed subsection 1030.8(a)(2) specifies the applicant must hold a current MLT license or meet the requirements for an MLT license. The legislative intent in creating the MLT to CLS pathway was to create an expedited process for an MLT to obtain licensure as a CLS by allowing MLT training to satisfy some components of the CLS training program that are redundant, without impacting the education requirements needed to obtain a CLS license. This would address a shortage of CLSs in California by enabling MLTs to qualify for CLS licensure more quickly than they could in traditional CLS training program.

Proposed subsections 1030.8(a)(3) and (4) contain educational requirements consistent with proposed CLS licensure educational requirements. Current statute in Business and Professions Code section 1261 and current regulations in section 1030.7 require a CLS applicant to have a baccalaureate degree or equivalent.

Existing MLT regulations require an applicant to have completed at least 60 semester units from an accredited college or university, with at least 36 semester units of physical and biological sciences with an emphasis on applied clinical science, including 6 semester units of chemistry and 6 semester units of biology appropriate for transfer to a baccalaureate program in science. Proposed MLT regulations are similar, requiring an associate degree from an accredited college or university in a chemical, physical, or biological science or medical laboratory technology, or equivalent education of at least 60 credit hours of coursework, including at least 36 credit hours in physical and biological sciences with an emphasis on applied clinical laboratory science, including at least 6 credit hours in chemistry and 6 credit hours in biology.

Proposed CLS regulations require an applicant to have a baccalaureate in a biological, chemical, physical, or clinical laboratory science, with coursework that includes at least 16 credit hours in chemistry, including either quantitative analysis and biochemistry or clinical chemistry; 16 credit hours in biology, including microbiology, hematology, and immunology; and 3 credit hours of physics, math, or statistics.

Proposed MLT to CLS licensure educational requirements in section 1030.8 require documentation that the applicant has successfully completed a baccalaureate in a biological, chemical, physical, or clinical laboratory science, with coursework that includes at least 16 credit hours in chemistry, including either quantitative analysis and biochemistry or clinical chemistry, 16 credit hours in biology, including microbiology, hematology, and immunology, and 3 credit hours of physics, math, or statistics.

Proposed subsection 1030.8(a)(5) requires a person licensed as an MLT or who meets MLT requirements to complete a training program of at least 6 months duration. The

contents of such programs are specified in proposed section 1035.3 of this rulemaking package. The training program must provide instruction and practice in high-complexity tests and examinations, which are not covered in MLT training programs because MLTs are restricted to performing only waived or moderate-complexity testing. The program will require less time than a traditional CLS program because it will cover only material that is unique to the CLS work scope, while avoiding training that duplicates training an applicant already completed for MLT licensure. This will shorten the training time while ensuring that applicants in the MLT to CLS program have received education and training equivalent to the education and training required for applicants who complete a traditional CLS training program.

Proposed subsection 1030.8(a)(6) requires an applicant licensed as an MLT or who meets MLT requirements to pass the same examinations required of other CLS applicants, including a national board examination and a Department-administered examination on California clinical laboratory law. These examinations ensure that applicants meet national standards and also have sufficient knowledge of State laws that regulate their daily work in the laboratory.

Proposed subsection 1030.8(b) specifies the scope of work for a CLS. The work scope authorized for a CLS who is licensed as an MLT or meets the requirements for MLT licensure are the same as the work scope for a CLS who obtained licensure in a traditional program. These requirements are not specified in current section 1030.7, but are specified in this section to clarify that a licensed CLS may perform waived, moderate-complexity, and high-complexity tests in the specialties of chemistry, microbiology, diagnostic immunology, immunohematology, hematology, histocompatibility, and genetics.

In addition to performing clinical testing, a licensed CLS may also serve as a general supervisor, moderate complexity laboratory technical consultant, waived laboratory supervisor, or technical supervisor if the CLS meets requirements specified in sections 1036.1 – 1036.4 relevant to the position as well as requirements specified in federal CLIA regulations.

Proposed subsection 1030.8(c) specifies that a CLS must be licensed during the entire time the CLS performs tests in a California clinical laboratory. Most other states do not require laboratory personnel licensure, so it is important to clarify that CLSs are required to have licensure to perform testing in laboratories located in California.

This requirement is consistent with statute at BPC section 1282, which states that it is unlawful to engage in clinical laboratory practice unless one is a physician or surgeon or is duly authorized to do so under Chapter 3.

Proposed subsection 1030.8(c)(1) specifies that licensed CLSs must have in their possession the CLS license issued by the Department. This allows the laboratory director and Department inspectors to verify that the CLS has the required licensure.

Proposed subsection 1030.8(c)(2) specifies that the CLS's license must be posted in the laboratory where the CLS performs testing, as specified in BPC section 1266. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so.

Proposed subsection 1030.8(c)(2)(A) In response to many requests for clarification from laboratory owners and personnel, this section clarifies that if an CLS performs testing in more than one location of a laboratory under a single clinical lab license, it is sufficient that the license be posted in the CLS's primary work location. Licensure posting allows the general public and Department inspectors to ascertain easily that a person performing testing is licensed to do so. However, it could be onerous to post the license at each testing location if an CLS is working at multiple locations within the same laboratory. Posting at the CLS's main location is sufficient to allow interested persons to verify the CLS's licensure.

Proposed subsection 1030.8(c)(2)(B) In response to many requests for clarification from laboratory owners and personnel, this section clarifies that if an CLS performs testing for more than one employer or in a number of different laboratories that are not covered under a single clinical laboratory license, the CLS's license must be posted in the CLS's primary work location at each address where the CLS performs testing. This ensures that interested persons can easily verify the CLS's licensure at the address at which testing is performed.

Proposed subsection 1030.8(c)(3) retains existing requirements about renewal and continuing education requirements, specifying that an CLS license is valid for two years. It also clarifies that an CLS license must be renewed every two years. In order to renew licensure, an CLS must complete at least 24 hours of continuing education in clinical laboratory related courses from an approved provider of continuing education.

(28) Amend section 1030.16, Licensure of Clinical Cytogeneticist Scientists
This is a non-substantive amendment necessary to change the section number reference. Section 1035 has been renumbered to section 1035.2.

(29) Amend section 1030.17, Licensure of Clinical Genetic Molecular Biologist Scientists
This is a non-substantive amendment necessary to change the section number reference. Section 1035 has been renumbered to section 1035.2.

(30) Amend section 1031, Requirements and Timeframes for Applications for Licensure and Certification.

This is a non-substantive amendment necessary to change the section number reference. Section 1035.1 (h) has been renumbered to section 1035 (h).

(31) Amend title of section 1032, Examples of Degrees or Courses in a Biological Science, Chemical Science, Physical Science, or Clinical Laboratory Science.
The Department proposes to change the title of section 1032, Examination for Clinical Laboratory Technologist's License, to be Examples of Degrees or Courses in a Biological Science, Chemical Science, Physical Science, or Clinical Laboratory Science because existing section 1032 contains no text; the text pertaining to Examination for Clinical Laboratory Technologist's License was renumbered to section 1030.7 in 2022. The reason for moving the section was to be in line with the new order of sections 1030 et seq.

(32) Adopt section 1032, Examples of Degrees or Courses in a Biological Science, Chemical Science, Physical Science, or Clinical Laboratory Science.
Due to scientific advancement, many new areas of studies have emerged in the field of laboratory sciences resulting in new names of degrees and courses. The Department receives many inquiries as to which degrees and courses are acceptable towards licensure. Providing this extensive, but not exhaustive, list of examples would provide answers to frequent questions. This would provide ease of reference and clarity as to which degrees and courses are acceptable to the Department, reducing the amount of time required to respond to inquiries.

(33) Amend title of section 1032.5, Licensure of Medical Laboratory Technicians
The Department proposes to change the title of section 1032.5, Licensure of Medical Laboratory Technicians to be Acceptance of Training or Experience Obtained in a Laboratory Outside the United States because existing section 1032.5 contains no text; the text pertaining to Licensure of Medical Laboratory Technicians was renumbered to section 1030.6 in 2022. The reason for moving the section was to be in line with the new order of sections 1030 et seq.

(34) Adopt section 1032.5, Acceptance of Training or Experience Obtained in a Laboratory Outside the United States
There is a shortage of laboratory personnel to staff clinical and public health laboratories in California. Proposed section 1032.5 is being adopted because there are many highly qualified applicants who obtained their training and experience in a laboratory outside the United States that is not CLIA certified. The Department is proposing to create a way to verify the adequacy of training and experience obtained in non-U.S. labs so such training or experience can be accepted without compromising the accuracy and reliability of testing. The Department estimates this will increase the number of license applicants and Department income from license application fees. It also estimates the proposal will increase the number of licensed personnel and help alleviate the shortage of laboratory personnel. This may improve access to laboratory tests and timeliness of results. Requirements in proposed section 1032.5 are similar to

the requirements for acceptance of training and experience obtained in a laboratory inside the U.S. This separate section provides ease of reference for applicants from other countries.

This section specifies that acceptable training and experience obtained outside the U.S. must be obtained in a clinical laboratory certified to meet International Organization for Standardization (ISO) and International Standards by an Organization for Standardization/International Organization Electrotechnical Commission (ISO/IEC) current and later standards. These standards meet the minimum qualifications required by the State. This would ensure that the licensure applicant received required training and experience equivalent to training and experience obtained in a clinical laboratory certified by CLIA, CAP, or JCI.

Proposed subsection 1032.5(a)(1) requires the training or experience be obtained in a laboratory that is certified to meet the ISO 15189 and ISO/IEC 17025. This is to ensure the laboratory training and experience meets minimum quality standards. It also requires that the international accrediting organization that certifies the laboratory meet ISO/IEC 17011 standards. This is to ensure the accrediting organization that evaluates the laboratory meets standards for certifying technical facilities including clinical laboratories.

Proposed subsection 1032.5(a)(2) specifies that the laboratory performs tests or examinations categorized as high complexity under CLIA to ensure the applicant's training and experience align with federal and California law.

Proposed subsection 1032.5(a)(3) requires the training and experience to be performed on human specimens for the purpose of clinical or diagnostic testing, matching requirements for training and experience obtained in the U.S. The Department is frequently asked if training or experience in an academic or research laboratory is acceptable for clinical laboratory licensure. This will clarify that applicants must have experience with clinical diagnostic testing on human specimens.

Proposed subsection 1032.5(a)(4) requires the foreign training or experience to be acceptable for admission to board certification examinations the Department has approved. This is a current requirement for training and experience obtained in the U.S. This ensures that an applicant's training or experience will qualify the applicant to take a board certification examination that is one of the requirements for licensure.

Proposed subsection 1032.5(b) requires the documentation of training or experience in a laboratory be sent directly to the Department by the laboratory director or medical director of the laboratory and clarifies the information that must be included in the documentation. This is a current requirement pursuant to section 1031. The required documentation in 1032.5(b)(1-8) is currently required for documentation of training and experience obtained in a laboratory inside the U.S. The required information enables

the Department to verify that the laboratory or institution meets federal and State standards, and that the applicant has experience in the required areas and complexity of testing. The requirement that documentation be sent directly to the Department from the laboratory or educational institution ensures that documents are genuine documents from a laboratory and have not been altered by the applicant. It is being added to this section for ease of reference for applicants from other countries.

(35) Adopt Article 1.8, Examinations for Licensure and Certification

Proposed article 1.8 is created to group regulatory sections regarding examinations for personnel licensure and certification for ease of reference. Examinations are either provided by the Department or by certifying organizations the Department has approved. Proposed section 1034, Examinations Administered by the Department for Licensure Purposes, is adopted under this article. In future packages, additional regulations about examinations will be added to Article 1.8.

(36) Amend title of section 1034, Certification of Phlebotomy Technicians to be Examinations Administered to the Department for Licensure Purposes

The Department proposes to change the title of section 1034, Certification of Phlebotomy, to be Examinations Administered to the Department for Licensure Purposes because existing section 1034 contains no text; the text pertaining to Certification of Phlebotomy was renumbered to be section 1030 in 2022. The reason for moving Certification of Phlebotomy to section 1030 and using this section for examinations was to align with the new order of sections 1030 et seq. The licensure and certification of clinical laboratory personnel sections 1030 et seq. now start with positions with the most basic requirements and work scope and proceed to those with more advanced requirements and work scope. Regulations about examinations administered by the Department for licensure purposes are located after regulations about the licensure and certification of all clinical laboratory personnel. This provides clarity and ease of reference to the reader.

(37) Adopt section 1034, Examinations Administered by the Department for Licensure Purposes

Proposed subsection 1034(a) requires satisfactory performance on an examination on California clinical laboratory law provided by the Department. Satisfactory performance, which is defined in existing section 1029, is required in existing regulations for licensure of MLTs, CLSs, and CLSs limited to a specialty or subspecialty. There are ten questions on the examination for licensure. This examination is required to ensure that people who work in a California clinical laboratory know necessary applicable laws. This information is being specified in the proposed section for ease of reference because the Department has been asked by the regulated community to clarify. Proposed subsection 1034(a)(2) allows the applicant to retake the examination as many times as necessary to achieve a passing score. The examination is part of the online application process. If an application is abandoned, the applicant will need to reapply, and will be required to take the examination as part of the new application process.

Proposed subsection 1034(b) requires an applicant for licensure as a bioanalyst or master's or doctoral degree specialist to achieve satisfactory performance on an in-person examination conducted by a panel selected by the Department. This applies to applicants for licensure under Chapter 3 that authorizes a person to direct a non-waived laboratory, including bioanalysts, clinical chemists, clinical microbiologists, clinical toxicologists, clinical cytogeneticists, clinical genetic molecular biologists, clinical laboratory geneticist, clinical reproductive biologists, oral pathology laboratory directors, histocompatibility laboratory directors, or other clinical laboratory master's or doctoral degree specialist categories. Satisfactory performance on this examination requires successful correct completion of seventy percent of the questions. The in-person exam includes written questions and an oral exam by a panel of licensed laboratory specialists. This subsection specifies that the panel will include Department staff and clinical laboratory specialists who are not employed by the Department. This increases objectivity and transparency and ensures that the panel includes specialists from various fields.

Proposed section 1034(b)(2) specifies the applicant may retake the examination with limitations. If an applicant takes the exam two times unsuccessfully, the applicant must wait a year until taking it a third time. If the applicant is unsuccessful taking the examination a third time, the applicant must wait two years until taking it a fourth time. If unsuccessful the fourth time, the applicant may retake the examination no more than once every two years. Requiring the applicant to wait (one year before taking the examination a third time or two years before taking the examination a fourth time) provides the applicant time to gain the necessary knowledge and skills and ensures efficient use of Department resources.

(38) Amend title of Article 2. Training Program Requirements

The Department proposes to amend the title of Article 2, "Training," to "Training Program Requirements" because it clarifies that Article 2 deals only with requirements for training programs, not requirements of the trainee. It provides clarity that Article 2 is narrowly construed and does not apply to trainee licenses, training of unlicensed persons, or acceptability of training outside the U.S. Those topics will be covered in other sections of this package and future packages.

Article 2. Training Program Requirements

This a general summary of Article 2, sections 1035 et seq. There are general changes to the requirements of training programs in Clinical Laboratory Regulations. The title of existing Article 2, Training Programs, is vague. The article provides regulations for three existing program categories: (1) Section 1035, Phlebotomy Training Program Requirements, (2) Section 1035.1, Medical Laboratory Technician Training Program Standards, and (3) Section 1035.2, Training Schools (which covers only CLS Training Program Standards). Existing law lacks the necessary training program regulations for CLS limited to subspecialties or specialties and MLTs transitioning to CLS licensure.

The scope of existing Section 1035.2, Training Schools, is vague; the title does not clearly specify that it applies to training programs for licensure of generalist Clinical Laboratory Scientists exclusively, not of other licensed or certified laboratory personnel. The format proposed will allow sections 1035-1035.5 to be divided in Article 2, Training Program Requirements, to address five program categories: (1) generalist clinical laboratory scientists, (2) clinical laboratory scientists limited to subspecialties or specialties, (3) phlebotomists, (4) medical laboratory technicians, and (5) medical laboratory technicians transitioning to clinical laboratory scientist licensure. This will allow for more clarity and specificity for the training programs and the community. Two of the training programs will be addressed in this package. Other training programs will be addressed in future packages.

The format of the existing titles and text of the sections in Article 2 are not consistent. The various titles of these Sections are inconsistent and broad; the titles involve "Training Schools," "[Position] Training Programs," and "[Position] Program Standards." For clarity and ease of reference the proposed section titles will be more narrowly defined and consistent with the titles of other training program sections: "Requirements of a Training School or Program for [Position Title]". The text within each proposed section is also structured consistently with the other sections in Article 2, which allows for easier comparison of the different program requirements. The term "school" is added to the titles to clarify that the regulations also apply to programs that use the term "school" in addition to those that use the word "program."

(39) Amend title of section 1035.1, Medical Laboratory Technician Training Program Standards to Requirements of a Training School or Program for Medical Laboratory Technicians

Proposed section 1035.1, Requirements of a Training School of Program for Medical Laboratory Technicians is being amended to replace existing regulations. Differences between existing section 1035.1 and proposed section 1035.1 are significant and necessitate striking all text in existing 1035.1 and proposing all new text in section 1035.1 instead of amending this section in parts throughout.

The format of the content in sections 1035.1 and 1035.3 in Article 2., Training Programs, will be standardized to follow the format of categories of clinical laboratory personnel certification and licensure and work scope for consistency, clarity, and ease of reference.

(40) Amend section 1035.1, Requirements of a Training School or Program for Medical Laboratory Technicians

The Department proposes to amend all existing text in section 1035.1, Medical Laboratory Technician Training Program Standards and propose entirely new text under the new title, Requirements of a Training School or Program for Medical Laboratory Technicians, to address components of regulations in current section 1035.1. Existing

training school regulations in Article 2., Training Programs, have different formats, which has resulted in confusion in the regulated community. The changes in this proposed section are significant and necessary; the scope of proposed section 1035.1 is broader and more detailed than that of the current section. The proposed changes reflect changes in laboratory technology, changes in the MLT work scope, and changes in educational requirements. For consistency and ease of reference to the reader, the proposed text is organized in the same format as requirements of training schools and programs for the MLT transition to CLS training schools and programs, and for other clinical laboratory programs in future packages. That is as follows:

(a) Requirement to submit an application to the Department to operate a training program
(b) List of programs or institutions authorized to offer a training program
(c) List of people allowed to serve as program director:
(d) Required duties of a training program director
(e) List of people allowed to provide didactic training
    a. Qualifications and limits on scope of instruction
(f) List of people allowed to provide practical training
(g) List of people authorized to provide direct and responsible supervision of trainees
(h) Required training program contents
    a. Didactic instruction
    b. Practical training

Proposed subsection 1035.1(a) specifies a person must apply for Department approval to operate a school or training program for MLTs.

Proposed subsection 1035.1(b) adopts requirements a program must meet for approval of licensure of the MLT school or program and specifies the entities that may offer these programs

Existing law, section 1035.1(a) specifies four entities that may offer a program: (1) a California clinical laboratory, (2) accredited college or university in the U.S., (3) U.S. military medical laboratory specialist program with at least 26 weeks duration, and (4) laboratory owned and operated by the United States government. The existing regulations do not specify the classification of testing complexity that the training program must offer trainees. The categorization of test complexity is governed by federal Clinical Laboratory Improvement Amendments (CLIA). Specifying CLIA test categorization in section 1035.1(b) (1), (2), (3), and (5), ensures that the program provides instruction in the performance of testing categorized as moderate complexity under CLIA. MLTs are authorized to perform waived and moderate-complexity tests. It is important that they train in a laboratory that offers the full range of testing they will perform in the course of their daily work, to ensure the training school provides the state with properly and adequately trained graduates.

In addition to existing law that provides the four types of entities that may offer MLT training programs, the proposed section provides a fifth option, which provides an opportunity for qualified out-of-state applicants. The fifth option is through a program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) that meets specified requirements. Those requirements are that the program be affiliated with clinical laboratories that provide instruction in the performance tests classified as moderate complexity under CLIA. This increases the number of programs acceptable towards California licensure and enables MLTs who completed a program outside California to obtain California licensure. This expands training opportunities for potential MLT trainees and increases the number of MLTs in the job market. There is a great need for more licensed MLTs in the California laboratory workforce.

Proposed subsection 1035.1(c)
Existing regulations in section 1035.1 provide a list of licensures, one or more of which the program director must hold: (1) physician and surgeon licensed under Chapter 5, or a (2) master's or doctoral degree specialist, (3) clinical laboratory bioanalyst, (4) clinical laboratory scientist or limited clinical laboratory specialist licensed under Chapter 3. Proposed section 1035.1(c) adopts new terminology for the master's or doctoral degree specialist, and clinical laboratory scientist limited to a specialty, but retains existing terminology for clinical laboratory bioanalyst and clinical laboratory scientist licensed under Chapter 3 and physician and surgeon licensed under chapter 5.

Proposed section 1035.1(c)(5) specifies that training programs located outside California must be directed by a person with qualifications equivalent to the California licensure requirements. This is necessary because some states do not require licensure so the training director would not meet the 1035.1(c)(1-4) requirement to be licensed under Chapter 3 or Chapter 5. This is current practice of the Department. It is being specified in this section for ease of reference and clarity because the Department receives inquiries. It also allows the Department to approve training programs in states outside California if they choose to apply for California approval. This allows the Department to license applicants from a broader range of programs, which increases the pool of applicants for California licensure and may help address a shortage of personnel in California laboratories.

Proposed subsection 1035.1(d) provides clarity regarding the duties and responsibilities of the director of training program. Current regulations are vague and, in some cases, assign responsibilities to the training program, but do not specify the director of the training program is responsible. This has resulted in confusion as to who is responsible, and the regulated community has used terms such as training administrator to avoid responsibility. This new regulation is much more specific and will avoid confusion about the director's responsibility.

Proposed subsection 1035.1(d)(2) Requires the director to ensure that the program provides instruction and training in moderate complexity testing, which is the complexity

of testing allowed under the MLT scope of work. This ensures that trainees are trained in the testing they will be authorized to perform in their daily work.

Proposed subsection 1035.1(d)(3) adopts a requirement that laboratory personnel who provide supervision to trainees are competent in the tests they supervise. It is being added for specificity and clarity to the regulated community.

Proposed subsection 1035.1(d)(4) requires the director to ensure that staffing is adequate and sets a ratio for the number of trainees and supervisors. A supervisor may provide direct and responsible supervision to no more than two trainees at one time to ensure that trainees receive direct attention from a supervisor. This clarifies how many trainees can be supervised by a single supervisor at one time, based on feedback from program directors, trainees, and licensed laboratory personnel.

Proposed subsection 1035.1(d)(5) requires the director to notify the Department in writing within 30 days of the date of initiation, completion, extension, or interruption of training for each trainee. Current regulations require a program to notify the Department of all students who completed the program. This subsection adds information that will enable the Department to track the progress of licensed trainees and to assess the effectiveness of training programs under its oversight.

Proposed subsections 1035.1(d)(6) and (7) are similar to current regulations. There are two proposed changes.

Existing regulations require the director to notify the Department of change of directors, or a change of information and materials, which includes instructors. In addition, the proposed regulations will clarify that the director must notify the Department of “change of instructor.” This clarifies and specifies the scope of notification and ensures that the director will provide the Department with adequate and current information to ensure quality training by qualified, approved instructors.

Proposed subsection 1035.1(d)(6) clarifies that the director must notify the department of any change in the information and material provided on the application and obtain approval for any change at least 30 days prior to making the change. This timeline allows the Department to review proposed changes to the content or policies of the program before those changes are made, and notify the program if a change is unacceptable and will jeopardize the program’s approval.

Proposed subsection 1035.1(d)(7) adopts a 30-day time limit to notify the Department of a change in director or instructor. Current regulations require the director to notify the Department of any changes in the information and materials required by Section 1035.1(b) through (d) within 30 days after the change has occurred. Thirty days is an adequate and reasonable amount of time for the school to notify the Department and for the Department to decide whether to approve the change. It limits the amount of time a

training school may spend waiting for the determination. The proposed change clarifies and specifies that the program must notify the Department of changes of directors or instructors, which is included in current requirements but not specifically stated. This will reduce confusion about the requirement. The Department allows notification after the change has been made because personnel may become unable to perform their duties due to an emergency that cannot be foreseen 30 days in advance.

Proposed subsection 1035.1(d)(8) requires the director to ensure that all trainees are licensed before they begin training. This ensures that trainees are licensed as required by California law before they begin to perform clinical tests and holds the program director responsible for ensuring compliance.

Proposed subsection 1035.1(d)(9) makes the director responsible for ensuring that all personnel who provide instruction, training, and supervision meet regulatory requirements. This ensures that trainees receive training from qualified personnel.

Proposed subsection 1035.1(d)(10) requires the training program use measurable criteria to ensure all trainees master training and instruction to avoid inequality, bias, or vagueness. Measurable criteria can be evaluated objectively and can be compared to other training programs. It provides objective data that the Department can use to track and evaluate the quality of training.

Proposed subsections 1035.1(d)(11) and (12) specify the director's responsibilities regarding maintenance of trainee records and providing documentation to the Department. Current regulations require the program to do this. The proposed subsections clarify that the director is responsible for ensuring compliance regarding trainee records.

Proposed subsection 1035.1(e) specifies requirements for a person providing didactic instruction to trainees. This includes persons who qualify to be a director under 1035.1(c) or equivalent if the training program is in the United States outside California. It also includes phlebotomy technicians with specific qualifications, limited to providing instruction in phlebotomy, public microbiologists with specific scope, an instructor designated by the director, a person with a baccalaureate, master's, or doctoral degree appropriate to the specialty or subspecialty because these other categories have specialized experience in the subject matter they teach. The proposed subsection clarifies that these specialists are limited to providing instruction only in the area of their specialized knowledge and experience.

Proposed subsection 1035.1(f) specifies that the person providing instruction during practical training must also meet the same requirements as those providing didactive instruction. Existing regulations already require that, but the Department receives inquiries as to whether it applies to both. This new format separates didactic instruction

and practical training for clarify. “Practical training” is a new definition proposed in section 1029 for clarify and ease of reference.

Proposed subsection 1035.1(g) specifies that the person providing direct and responsible supervision during practical training must be competent in the tests or examinations the person is supervising. Direct and responsible supervision is defined in Section 1029. Requirements for trainee supervisors are being adopted for clarity for training programs and training laboratories because the program receives inquiries about this topic.

Proposed subsection 1035.1(g)(3) specifies that a person providing direct and responsible supervision may supervise no more than two trainees at one time. This ensures that trainees receive sufficient attention and guidance during practical training, and training supervisors are able to provide guidance in new skills, observe their trainees’ performance, and document competency.

Proposed subsection 1035.1(h) establishes requirements specifying the content of didactic instruction and practical training. The requirement of six months is already in existing regulations, which are being repealed.

Proposed subsection 1035.1(h)(1) specifies subject matter requirements for didactic instruction and testing. This already exists in regulations section 1035.1(b)(3), which is being repealed. Proposed subsection 1035.1(h)(1)(D) lists test methods to be taught during didactic training. The words “moderate complexity ABO and Rh type immunohematology” are being added because this is a new technique MLTs are authorized to perform by statutory changes in 2018 (AB 2281, Irwin, Chapter 235, Statutes of 2018). Since MLTs are authorized to perform moderate complexity ABO and Rh type immunohematology in laboratories, didactic instruction must include such test methods. The words “test validation” are added to the list of analytical skills because such validation is necessary to perform analytical testing and examination. It is a skill currently included in didactic instruction curriculum added for clarity to trainees, didactic trainers, and program directors.

Proposed subsection 1035.1(h)(2) specifies requirements for practical training. Existing regulations section 1035.1(b)(4) require the training listed in this proposed subsection. The only proposed change is the addition of section 1035.1(h)(2)(F), which limits the percentage of training in the performance of tests or examinations of waved complexity. This limit is necessary to insure most of the training is devoted to moderate complexity tests and examinations. This ensures that people who have completed the training are able to successfully perform moderate complexity tests and examinations that will be required of them as a licensed MLT.

The existing regulations require a total of 1040 hours (40 hours per week for 26 weeks), which includes at least 640 hours devoted to training in specialty areas, with 160 hours

in each of the specialties of chemistry, hematology, microbiology, and immunology. The proposed regulations specify at least 128 hours of each specialty because the proposed regulations add a fifth specialty, moderate complexity ABO and Rh type immunohematology, to provide training in this newly authorized area. There are now five required specialties and to divide them equally would calculate to 128 hours for each, for a total of 640 hours of specialty training.

Proposed sections 1035.1(h)(1)(A-E) retain subjects listed in existing regulations.

Proposed section 1035.1(h)(2)(F) adopts a limit on the amount of training that may be waived testing. The Department does not want more than 20 percent of the training to be waived testing because MLT training should prepare trainees to perform moderate complexity. Most of the tests and examinations MLTs must perform on the job are of moderate complexity.

Proposed subsection 1035.1(i) lists the information the medical laboratory technician training program is required to provide in the certificate of completion provided to the students. This list currently exists under section 1035.1(c), except for the addition of “trainee license number of the trainee” with the student’s name. This is not in existing regulations because there are currently no MLT trainee licenses. This proposed package is creating the MLT trainee license. The certificate of completion needs to include the trainee license number in addition to the name of the student. This is to show that the trainee met the qualifications required of the trainee license and was qualified to complete MLT training.

Proposed subsection 1035.1(j) retains the current requirement that a training program must retain student records for at least five years and make them available to the Department.

(41) Amend section 1035.2

The Department proposes to amend the title of section 1035.2 from “Training Schools” to "Training Schools for Clinical Laboratory Scientists.”

The current title of Section 1035.2, Training Schools, is vague and does not clearly specify that it applies to training programs for licensure of generalist Clinical Laboratory Scientists exclusively, not of other licensed or certified laboratory personnel. The amendment will clarify the scope of the section.

The Department proposes to amend section 1035.2(d), the ratio of trainees to supervisors, to align with a ratio adopted in sections 1035.1 and 1035.3. This will clarify the requirements and ensure consistency across training programs, and was made in consultation with and at the request of the regulated community. The Department will introduce further revisions to this section, in a future package revising CLS regulations; this change is needed now to ensure consistency across training programs.

(42) Adopt section 1035.3, Requirements of a Training School or Program for Clinical Laboratory Scientists Who Meet Requirements for Medical Laboratory Technician Licensure

The Department is proposing this section because in 2018, Assembly Bill 2281 (Irwin, Chapter 2365, Statutes of 2018) mandated the establishment of a new MLT-to-CLS pathway. The purpose of proposed regulations in section 1035.3 is to carry out the intent of the legislature. It will cover all the areas of training that are not already covered in MLT training but are required for CLS licensure. It is a six-month program rather than a one-year program because people who are MLTs will already have completed the training a CLS would receive for moderate complexity testing. People in this program will only need to cover the training a CLS would receive for high complexity testing. The applicants will still need to meet all the CLS generalist requirements, including a bachelor's degree and one year of training in all categories of testing in all specialties of the lab.

Proposed section 1030.8 specifies the licensure and work scope requirements for CLS licensure through the MLT-to-CLS pathway. This section pertains to the requirements for training schools and programs to provide training required for CLS licensure through the pathway. The proposed changes reflect changes in laboratory technology, changes in the MLT and CLS work scope, and changes in educational requirements. For consistency and ease of reference to the reader, the proposed text is organized in the same format as requirements of training schools and programs for licensure of MLTs in this package and of other type of licensures in future packages.

The regulations in section 1035.1, Requirements of a Training School or Program for Medical Laboratory Technicians, are similar to this section. To reduce duplication and for ease of comparison, only differences between the two sections will be discussed below. For details about sections that are the same, see the analysis of section 1035.1 in this ISOR.

Proposed subsection 1035.3(a) specifies a person must apply for Department approval and licensure of a school or training program for CLSs who have obtained or meet requirements for MLT licensure.

Proposed subsection 1035.3(b) adopts requirements a program must meet for approval of licensure of the MLT to CLS training school or program.

This section provides two ways a program may be offered: (1) a California clinical laboratory, just as in section 1035.1, and (2) an accredited college or university in the United States with affiliated clinical laboratories that performs tests or examinations categorized as moderate and high complexity under CLIA. Section 1035.1 requires the college or university to perform tests of moderate complexity, not high complexity, whereas this section requires performance of moderate and high complexity because it

is for a CLS license and CLSs perform high complexity tests or examinations on the job. Specifying CLIA complexity categories in section 1035.3 ensures that the program provides instruction in the performance of testing categorized as moderate and high complexity under CLIA and requires the students to perform at the proper level of complexity, not waived tests. This ensures the training school provide the state with properly and adequately trained graduates.

Proposed subsection 1035.3(c)
Existing law for MLT training programs provides a list of licensures, one or more of which the program director must hold: (1) physician and surgeon under Chapter 5, or a (2) doctoral scientist, (3) clinical laboratory bioanalyst, (4) clinical laboratory scientist or clinical laboratory specialist licensed under Chapter 3. Similar to proposed section 1035.1(c), proposed section 1035.3(c) clarifies that the list of persons authorized to direct a program must all be licensed under Chapter 3 or Chapter 5.

Since this MLT-to-CLS pathway is only applicable to training programs located in California, the training program director located outside California would not be qualified to direct the MLT-to-CLS training program.

Proposed subsection 1035.3(d) does not contain the subsection in MLT training schools about training programs located outside California for reasons previously stated. The level of complexity of techniques performed in this subsection 1035.3(d) for CLS licensure differs from subsection 1035.1(d) for MLT licensure. The level of complexity of techniques learned in CLS training schools must include testing categorized as moderate and high complexity under CLIA, but MLT training schools require only moderate complexity. This is because licensed CLSs perform moderate and high complexity on the job; MLTs are only authorized to perform moderate complexity. Proposed subsection 1035.3(d) requires the training program to ensure all trainees are licensed CLS trainees. Proposed subsection 1035.1(d) requires them to be licensed MLT trainees.

Proposed subsection 1035.3(e) specifies requirements for a person providing didactic instruction to trainees. The list of qualified persons in 1035.3(e)(1-6) includes persons who qualify to be a director under 1035.1(c), phlebotomy technicians with specific qualifications and scope, public microbiologists with specific scope, an instructor designated by the director, a person with a baccalaureate, master's, or doctoral degree appropriate to the specialty or subspecialty.

It is the same list as 1035.1(e)(1-6) except 1035.1, MLT training, allows a person with equivalent qualifications if the training program is located in the U.S. outside of California to provide didactic instruction. Subsection 1035.3(e) does not, since training programs outside of California are not approved by the Department to provide training under the provisions of the MLT-to-CLS pathway as previously explained.

Proposed subsection 1035.3(f) lists requirements also in proposed subsection 1035.1(f); this subsection specifies that the person providing instruction during practical training must also meet the same requirements as those providing didactic instruction.

Proposed subsection 1035.3(g) contains two categories of who may supervise trainees during practical training.

Proposed subsection 1035.3(h) establishes different requirements for didactic instruction than those listed in section 1035.1 because requirements for didactic instruction of CLS programs are broader than those for MLT programs, specific to the broader work scope of CLSs.

The didactic instruction components listed as required in 1035.3(h)(1) are currently provided in CLS didactic instruction. Including them in this section provides clarity to the trainees, didactic trainers, and program directors.

Proposed subsection 1035.3(h)(1) contains an extensive list of subject matter the CLS trainee must learn. This list specifies the subjects that must be included in a CLS training curriculum. Each subject listed in this section is currently covered in the education and training in a standard CLS program in existing regulations. This conforms to existing requirements for the CLS program and provides ease of reference and clarity.

Proposed subsection 1035.3(h)(2) specifies requirements for practical training. The proposed subsection requires trainees in the MLT to CLS program to complete practical training in areas not covered during MLT practical training to ensure that they meet the requirements for CLS licensure, specifically, it sets requirements in areas of high-complexity testing that are required in the routine work of a CLS but are not in the MLT scope of work.

Proposed subsection 1035.3(h)(2)(G) limits the percentage of training in tests or examinations of waived complexity. This limit is necessary to ensure most of the training is in moderate and high complexity tests and examinations. This ensures that people who have completed the training are able to successfully perform moderate and high complexity tests and examinations that will be required of them as a licensed CLS.

Proposed subsection 1035.1(i) lists the information the MLT-to-CLS training program is required to provide in the certificate of completion to the students. This list is identical to proposed section 1035.1 for MLT training programs. This list is in existing regulations, section 1035.1(c), except the proposed addition of “trainee license number of the trainee” with the student’s name. The certificate of completion needs to include the trainee license number in addition to the name of the student. This is to show that the trainee met the qualifications required of the trainee license and was qualified to complete the MLT-to-CLS training.

[End of Detailed Discussion of Proposed Changes]

Cost Impacts on Representative Private Persons or Businesses (Significant Statewide Adverse Economic Impact Directly Affecting Private Persons, or Businesses, Including Ability to Compete)

The Department has determined that the proposed regulatory action would have no significant direct economic impact on California business enterprises, including the ability of California businesses to compete with businesses in other states. The proposed regulatory action could alleviate a shortage of qualified laboratory personnel in California by making it easier for applicants with training or experience in non-U.S. laboratories to obtain California licensure. This is unlikely to create new jobs, but it will make it easier for California labs to fill CLS positions that currently are unfilled because of extreme market shortages and increase the productivity of those labs.

To the extent it alleviates the staffing shortage, this regulatory action may reduce costs for labs that must currently hire travelling lab technicians, who are typically paid more than regular employees. California CLSs are among the highest paid clinical laboratory professionals in the U.S. workforce, and this proposed action may make California labs more attractive by enhancing career accessibility for potential candidates. However, the proposed action is unlikely to significantly increase the competitiveness of California labs because the lab workforce shortage is nationwide, and this proposal alone is unlikely to result in a significant increase in available lab staff.

The Department estimates that the proposed regulatory action will benefit individuals seeking licensure as clinical laboratory scientists (CLS) by providing a pathway that allows individuals who meet requirements for licensure as medical laboratory technicians (MLT) to count their MLT training towards CLS licensure. This will allow them to move to the higher-paid position of CLS in a shorter time than would be required for a traditional CLS training. On average, CLS salaries are approximately 20 percent to 30 percent higher than MLT salaries. Completion of a CLS training program requires one year beyond the baccalaureate degree, while the new pathway will allow a person who meets MLT licensure requirements to complete training in six months beyond the baccalaureate degree. Trainee positions are generally not paid positions. Thus, an individual who meets MLT licensure requirements will lose only six months' salary during the unpaid training period, rather than a full years' salary, and will be able to enter the workforce at the higher-paid CLS level six months sooner.

The federal Bureau of Labor Statistics and the California Employment Development Department (EDD) Occupational Guides conflate MLT and CLS into a single category for purposes of wage reporting, with the EDD Occupational Wages data reporting a mean annual salary for this category as $70,914. A polling of stakeholders and a survey of salary websites indicates that MLTs in California earn an average of $61,000 per year and CLSs earn an average of $91,000 per year.

During a one-year training in a traditional unpaid CLS training program, an MLT would lose approximately $61,000 in wages. An MLT in the transitional pathway would lose

only $30,500 in wages during the six-month training period, but would be able to enter the workforce as a CLS after six months, and could potentially earn up to $45,500, resulting in a gain of as much as $15,000.

For trainees who complete either training program and work as CLSs, the economic benefit of going from full-time employment as an MLT to full-time CLS employment would be between $20,000 and $40,000 each year for the remainder of their career. If the person worked as a CLS for 35 years, this could increase the individual's earnings by as much as $1,400,000.

Other regulatory actions in this rulemaking package could result in increased employment opportunities for qualified applicants with training or experience in non-U.S. laboratories, but it is difficult to quantify the impact, due to the wide variation in individual circumstances and the wide range of laboratory positions for which these individuals might qualify.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations

The Department evaluated this proposal and determined that it, if adopted, it will not be inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to personnel in clinical laboratory science. An internet search of other state agency regulations was also performed. It was determined that no other state regulations address the same subject matter.

Mandated Use of Specific Technologies, Equipment, Actions, or Procedures

The Department has determined that the proposed regulations do not mandate new prescriptive standards mandating the use of specific technologies, equipment, actions, or procedures rather than performance standards.

Statements of Determination

(a) Local Mandate:

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, and not impose any costs for which reimbursement is required by part 7 (commencing with section 17500) of division 4 of the Government Code.

(b) Effect on Small Business:

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.

(c) Housing Costs Determination:
The Department has determined that the proposed regulations will have no impact on housing costs. The regulations affect standards only for clinical laboratory personnel in licensed, certified, or registered clinical laboratories, accredited schools and training programs, military specialist programs, and U.S. government laboratories.

Economic Impact Analysis

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.

Creation or elimination of jobs within California:
There would likely be no significant creation or elimination of jobs within the state. There may be a slight possible increase in the creation of jobs in California. More applicants who obtained training or experience in a foreign country may qualify for licensure as a result of regulations broadening the acceptance of experience and training in labs located outside the U.S. California laboratories have been unable to fill vacant positions because of the shortage of qualified personnel. The proposed regulations may enable them to fill the vacant positions or create new positions if more individuals apply for and receive California licensure, expanding the number of employees in their businesses in California. Since applicants with non-U.S. training and experience are a small percentage of license applicants in clinical laboratory jobs in general, this expansion of possible licensure is not likely to have a significant effect.

Creation or elimination of new businesses within California:
There would likely be no significant creation or elimination of businesses within the state.

The revision of current requirements for licensure in the categories of clinical lab trainee, medical lab technician, and clinical lab scientist is not likely to eliminate existing laboratories or create new laboratories. Instead, it is likely to make it easier for existing clinical laboratories to hire qualified personnel. The regulatory action will affect the state as a whole.

Colleges and universities that provide education and training to clinical laboratory personnel will not be significantly impacted by expanding acceptance of personnel with training and experience at labs outside the U.S. There is currently a severe shortage of qualified clinical lab personnel in labs across the U.S., so licensure of additional personnel trained outside the U.S. who meet California standards will not detract from enrollment in United States education and training programs, nor will licensure of these personnel displace U.S.-trained lab personnel, but will allow labs to fill positions that are currently vacant due to a lack of qualified applicants.

As California labs are experiencing a workforce shortage, the creation of a new program to facilitate the move of MLTs to a higher licensure category as CLSs is unlikely to result in the expansion of lab businesses in California, but it may help alleviate the shortage and allow labs to fill positions that are currently vacant.

Impact on California Businesses to compete with businesses in other states:
There is no foreseeable negative impact on the ability of California businesses to compete with businesses in other states. The potential positive impact is not significant. The regulations may create a slight increase in the number of out-of-state laboratory personnel who apply for and are granted a license because their experience and training outside the U.S. may be acceptable for California licensure under the proposed regulatory action.

Additionally, the creation of a pathway facilitating the transition from licensure as an MLT to higher licensure as a CLS may attract additional lab personnel to work in California labs. This may slightly increase the pool of qualified job candidates, which may increase the ability of California businesses to hire qualified clinical laboratory personnel and will likely help to alleviate the current industry shortage of licensed clinical personnel in California. This may lead to a slight increase in the number of jobs created. However, the Department does not anticipate a significant economic or fiscal impact on businesses in California.

Expansion of businesses currently doing business within the state:
There is not likely to be significant expansion of businesses currently doing business within the state. (See the discussion under Creation or elimination of new businesses within California.)

The proposed regulations will allow applicants who obtained training or experience in non-U.S. labs to qualify for California licensure if the lab in which they trained meets California standards. This may increase the number of clinical laboratory personnel, which may help alleviate the shortage of qualified clinical laboratory staff and allow for a small expansion of clinical laboratory businesses in the state. More staff may allow clinical laboratories to be more efficient, perform more tests or examinations, and possibly expand the number of laboratories in California. However, due to the current

shortage of qualified laboratory personnel in the State and across the nation, while the increase in qualified job applicants may allow labs to fill exiting vacancies, it is unlikely to result in a significant expansion of current businesses. (See the discussion under Impact on California Businesses to compete with businesses in other states.)

Benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment:
There are several broad and specific benefits to the proposed regulations. Implementation of these standards will enhance the efficiency of the licensing and certification process. Acceptance of training and experience obtained in non-U.S. labs that meet California standards may result in an increase in the number of qualified testing personnel in California labs, which may ease the workforce shortage currently affecting California labs and thus increase the availability and timeliness of lab test results. Facilitating the transition from MLT licensure to full CLS licensure will provide upward mobility to laboratory personnel and increase the number of fully qualified testing personnel available to staff California labs.

These regulations are proposed to protect the health and safety of California residents by ensuring high quality training schools and programs that produce qualified clinical laboratory personnel. Finally, other benefits of these proposed regulations include:

- Increasing worker safety by ensuring proper education, training, and experience of clinical laboratory personnel.
- Promoting fairness of the licensing and certification process by establishing more objective and equitable standards for applying and qualifying for licensure.
- Implementing proper and safe use of new technologies.
- Protecting the integrity and quality of test results produced by clinical laboratories.
- Increasing the efficiency and accuracy of laboratory test result on which healthcare professionals rely for the diagnosis, treatment, and monitoring of disease.

Fiscal Impact Analysis

The proposed regulations have no foreseeable fiscal impact. The proposed regulations make only technical and clarifying changes to current law regulations. The proposed regulations do not affect any local entity or program, any State agency or program, or any federal funding for any State agency or program.

Business Reporting Requirements

The proposed regulations do not impose new reporting requirements on businesses.

Forms Incorporated by Reference

No forms are incorporated in the proposed regulations by reference.

Mandated by Federal Law/Regulations

The proposed regulations are not mandated by federal law or regulations.