

INITIAL STATEMENT OF REASONS

The California Department of Public Health (CDPH) proposes to amend the licensing and certification standards for clinical laboratory personnel as specified in Title 17 California Code of Regulations (CCR) Sections 1030 to 1034. Also included in this package are amendments to Section 1035 – 1035.5 which specify training requirements for licensure and certification. Definitions are proposed for Section 1029 to explain new technologies and scopes of practice. CDPH also proposes to repeal several obsolete sections and replace them with updated standards. The purpose of these amendments is to accommodate changes in technology which have driven the need for more specialty license types, to clarify avenues for training for licensure, and to improve the efficiency of the licensing program by enacting consistent standards among license types.

All clinical laboratory personnel must be qualified to perform clinical laboratory tests or examinations, pursuant to Chapter 3 of the Business and Professions (B&P) Code. Validation of a person's qualification is demonstrated by his or her meeting licensing standards set in CDPH regulations. These standards include education, training, experience and examination leading to licensure. Ongoing licensure requires completion of continuing education and maintaining a current and valid license. Sanctions for failure to comply with laboratory or personnel licensing standards include revocation and suspension of licensure.

CDPH currently licenses or certifies about 56,000 persons in California, as shown in the TABLE 1. Many of the licensing standards have not been updated for many years. Section 1030 of 17CCR which sets licensing standards for bioanalysts was first enacted in 1957, for example, and has not been significantly changed since. CDPH has been criticized for preventing licensure of qualified persons because of its archaic standards. Lack of staff resources has prevented update of these regulations. Revising these standards now has been driven by approval of certification examinations that can be used for licensure purposes in lieu of the state-administered examination. This has attracted more qualified persons from outside California seeking licensure and employment. However, the old licensing standards are creating a barrier for licensure of these persons. Therefore, it is imperative that these standards be updated to allow these persons to work in our state. There is a severe labor shortage of clinical laboratory personnel in California, partly because of the difficulty in obtaining licensure.

CDPH proposes uniform licensing standards for associate-, baccalaureate- and doctorate-degree license categories. These proposed regulations set the academic requirements, including major coursework, for each category, their practical training and experience, and their examination requirements. Implementation of these standards will add greatly to the efficiency of the licensing program which is currently administering inconsistent, outdated standards.

TABLE 1: License categories administered by
Laboratory Field Services/CDPH

License category	Status
<i>HS-diploma category</i> Certified phlebotomist	~35,000 certified
<i>Associate-degree category</i> Medical laboratory technician	New program ~ 150 licensed
<i>BS- or higher-degree categories</i> Clinical laboratory scientist Clinical chemist scientist Clinical immunologist scientist Clinical microbiologist scientist Clinical hematologist scientist Clinical toxicologist scientist Clinical histocompatibility scientist Clinical cytotechnologist Clinical cytogenetic scientist Clinical genetic molecular biologist scientist	~20,000 licensed
<i>Masters- or Doctorate-degree categories</i> Clinical bioanalyst Clinical chemist Clinical microbiologist Clinical toxicologist Clinical cytogeneticist Clinical genetic molecular biologist Histocompatibility laboratory director Oral pathology laboratory director	~300 licensed

CDPH proposes to recognize the expanding interest in genetic testing by broadening the work scope of those persons performing genetic molecular biology testing, by clarifying the “tests or examinations in molecular biology”, and by creating a doctorate-degree license category in clinical biochemical genetics.

CDPH proposes to establish licensing standards for doctorate-degree clinical embryologists and to explain the work scope of this new category. This is done to satisfy the need for the 120+ Assisted Reproduction Technology (ART) facilities in California that employ board-certified embryologists who are not allowed to perform testing on patient specimens. These standards use authority given CDPH in both B&P Code and Health and Safety (H&S) Code to set standards for personnel working in tissue banks.

Specifically, amendments are proposed for 17CCR Section 1029 to 1061 (not inclusive) as follows:

- Definitions are added to Section 1029 for “an approved NAACLS-accredited training program”, “degrees or majors in biological science, chemical science or physical science” and “official school transcript” to clarify licensure requirements.
- Definitions are added to Section 1029 for “clinical biochemical genetics”, “tests or examinations in molecular biology”, “tests or examinations in molecular pathology”, and amendments to an existing definition of “clinical genetic molecular biology” are proposed to update the workscopes for these new technology specialties.
- The definition of “clinical embryology” is added to Section 1029.210 to explain the workscope of testing in an Assisted Reproduction Technology (ART) facility.
- The definition of “critical review” in Section 1029.215 explains how laboratory test results must be evaluated before release.
- The definition of “accredited college or university” is amended at Section 1029.7 to expand the number of accrediting agencies approved by CDPH.
- Section 1030 – 1030.7 amends licensing standards for clinical bioanalysts, clinical chemists, microbiologists, toxicologists, immunologists, biochemical geneticists, clinical cytogeneticists and clinical genetic molecular biologists.
- Section 1030.1 establishes licensing standards for doctorate-degree clinical immunologists and Section 1030.3, for doctorate-degree clinical embryologists.
- Section 1031- 1031.5 amends licensing standards for baccalaureate-degree scientist candidates. Section 1031.5 adds a new license category for clinical embryologist scientists.
- Sections 1031.6 – 1031.9 amends requirements for license applications and renewals, and approval of certifying examinations
- Section 1031.11 clarifies how training gained in a laboratory that is not CLIA-certified can qualify to meet licensure requirements in California.
- Section 1031.12 clarifies how the state administers examinations on laboratory law for applicants.
- Section 1032 amends licensure requirements for clinical laboratory scientists (CLS).
- Section 1033 amends training requirements for medical laboratory technicians (MLT), CLS, clinical laboratory specialists, postgraduate fellows, and an articulation route for MLT training for CLS licensure.
- Section 1034 amends certification standards for phlebotomists.
- Section 1035 amends requirements for CLS and clinical laboratory specialist training programs.
- Section 1035.1 amends requirements for phlebotomy training programs.
- Section 1035.2 specifies requirements for postgraduate fellow training programs.
- Section 1035.5 specifies requirements for training MLT articulating to CLS licensure.

- Section 1036 and 1036.1 amend the qualification requirements for a clinical consultant and a general supervisor.
- Section 1038.1 and 1038.6 clarify continuing education requirements for laboratory personnel.
- Section 1039.2 clarifies how training obtained outside California can be used to meet licensing requirements in California.
- Sections 1060 - 1062 are repealed, the standards amended and moved to Section 1031.4.
- The California Department of Health Services was legislatively reorganized as of July 1, 2007 (SB 162, Chapter 241, Statutes of 2006) into two separate departments, the new Department of Health Care Services and the new Department of Public Health. Health and Safety Code Section 131050 transferred the duties, powers, and responsibilities of the Laboratory Field Services program to the Department of Public Health, and Health and Safety Code Section 131200 vests the Department of Public Health with rulemaking authority for the execution of its duties.

NECESSITY

CDPH is responsible for licensing clinical laboratories, clinical laboratory personnel, tissue banks and blood banks. Laboratories are dependent on a supply of qualified personnel to perform testing. If there is a shortage of qualified persons, the testing will be delayed or the laboratory work sent to laboratories outside California, resulting in loss of revenue and jobs to the state. Since 1985 the number of new persons entering the laboratory field has decreased to the point where there is a severe labor shortage in California. This has been due in part to a national reduction in available training programs and diversion of students to other fields, especially computer science and biotechnology. Graduates from other states want to work in California. CDPH enacted standards in 2005 to approve certification examinations to replace the state-administered licensing examinations, and that has greatly increased applications from board-certified persons outside our state. However, archaic requirements have continued to be impediments to licensure. The proposed standards shall streamline the licensing process, making it easier for qualified persons to be licensed in the field of laboratory science in California.

AUTHORITY

CDPH has general authority at B&P Code 1224 and H&S Code 131200 to set standards by adoption of regulations. However, it has specific authority at B&P Code 1208 and H&S Code 1639 to set standards for new categories of laboratory personnel, and authority at B&P Code 1262 and 1264 to approve board certification examinations for licensure purposes.

BACKGROUND

Laboratory Field Services (LFS) in CDPH is charged with ensuring the quality of personnel working in clinical laboratories by administering a licensure program. This program monitors education, training and experience of applicants, administers examinations and oversees continuing education compliance in an effort to assure that only qualified persons perform clinical laboratory testing. LFS also has authority to deny, suspend and revoke licenses for failure to comply with standards. Licensure of clinical laboratory personnel began in 1939 and has grown over the years to now include high school-diploma, associate-, baccalaureate-, masters- and doctorate-degree scientists. This career ladder affords qualified persons the opportunity to advance to more responsible positions in a laboratory as their education and training increase. California licensure is the model for about 14 other states which have similar, but not as extensive, licensure programs.

LFS is challenged with administering licensure of over 55,000 persons in 20 different license categories. Efforts have been made to streamline processing of applications and renewals to improve timeliness. LFS has implemented online license applications for laboratory personnel, online payment of fees and online license inquiries. This has added to the efficiency of the program, but outdated licensing regulations have hampered productivity and have been a barrier to qualified applicants. Changes are proposed to the licensing standards which shall improve the efficiency of the program.

AMENDMENTS PROPOSED

CDPH proposes to update laboratory personnel licensing standards currently enacted in Title 17 CCR, to repeal redundant or outdated standards and to clarify workscopes for persons performing genetic testing.

AMENDMENTS TO DEFINITIONS IN SECTION 1029

(1) Amend Section 1029.7. Accredited college or university.

CDPH proposes to amend the definition of an “accredited college or university” at Section 1029.7. Laboratory personnel may graduate from an accredited or non-accredited college or university. CDPH licensing standards require graduation from an accredited college or university. Most colleges or universities in the United States are accredited by one of the six accrediting organizations listed in this definition. This definition is necessary to distinguish accredited educational facilities from non-accredited.

(2) Amend Section 1029.53. Clinical Genetic Molecular Biology.

CDPH adopted the definition of “clinical genetic molecular biology” in 2001 to explain testing done on human genetic components, as DNA, RNA and nuclides, to diagnose

diseases and inherited defects. This testing incorporates molecular techniques such as polymerase chain reactions, DNA sequencing and DNA microarrays to help diagnose inherited and acquired genetic diseases. This type of testing is done by persons trained in the specialty of genetic molecular biology. CDPH established licensing standards for two new categories of licensure in 2001 and 2003 for baccalaureate- and doctorate-degree clinical genetic molecular biologist scientists, and about 700 persons have been licensed since. (See Exhibits 11, 23)

An unanticipated problem arose with the definition of clinical genetic molecular biology as adopted in 2001. The current definition limits testing to the “human genome”, preventing any testing on viruses, infectious disease pathogens or other agents originating from a biological specimen. The technology is the same whether DNA testing is performed on a human specimen or human papilloma virus, for example, yet these licensed persons are prevented from testing non-human specimens. CDPH proposes to amend the definition of clinical genetic molecular biology to expand the definition from “human” to “cell or organism” which would include both. This would broaden the work scope of these licensed persons.

(3) Adopt new Section 1029.200. An Approved NAACLS-Accredited Training Program.

CDPH proposes to add the definition of “an approved NAACLS-accredited training program.” This is needed to eliminate confusion about programs accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) which may not be comparable to training requirements established by CDPH. Training programs that are NAACLS accredited must also be approved by CDPH for training that is acceptable for licensure in California. Not all NAACLS-accredited training programs may be acceptable for approval by CDPH. (See Exhibit 34)

(4) Adopt new Section 1029.205. Clinical Biochemical Genetics.

CDPH proposes to add the definition of “clinical biochemical genetics” to Section 1029.205. This is needed to eliminate confusion about tests performed to detect inherited metabolic diseases that do not involve measurement of DNA or RNA. These tests measure complex products of metabolism as proteins, carbohydrates and lipids to aid in diagnosis of inherited metabolic dysfunction. These tests are often called proteomic (related to protein) to contrast them from genomic (related to genes). These two technologies are distinctly different and persons performing these tests for genetic purposes have different training. CDPH proposes to establish licensing standards for doctorate-degree clinical biochemical geneticists so they can be employed in California. These persons would qualify to direct laboratories performing biochemical tests used to diagnose genetic metabolic diseases. The definition of clinical biochemical genetics is necessary to distinguish this testing from other types of genetic testing. (See Exhibits 24, 25, 26, 31, 36)

(5) Adopt new Section 1029.210. Clinical Embryology.

“Clinical embryology” is the specialty of clinical laboratory tests and examinations that support fertility testing in Assisted Reproductive Technology (ART) facilities. Prior to ART treatment, the parents are subjected to testing including wellness checks, hormone assessment, antibody evaluation and sperm analysis. During the ART cycle and after conception, timely and accurate hormone tests are required. California has over 120 ART facilities which seek to employ qualified persons to perform tests or examinations in clinical embryology. This definition is necessary to explain the work scope of these persons. (See Exhibits 1 and 3)

(6) Adopt new Section 1029.215. Critical review.

CDPH regulations established at Section 1050 (h) require all clinical laboratory test results and examinations to be critically reviewed by a licensed person prior to reporting. With tests performed manually, critical review by a licensed person is required. Assembly Bill 1175 (Niello, Chapter 61, Statutes of 2007) authorized computer-assisted review of test results in certain situations in place of manual review. CDPH proposes to more clearly define critical review to include parameters for assessing accuracy and precision of the test result before release. These standards also require test results performed by persons licensed as trainees to be critically reviewed by a competent licensed person.

(7) Adopt new Section 1029.220. Degrees or Majors in Biological Science, Chemical Science or Physical Science.

Most of the license categories administered by Laboratory Field Services in CDPH require a baccalaureate, masters or doctorate degree in biology, chemistry, or clinical laboratory science. This has been a problem because some universities grant a general degree in biology and another university with the same coursework may grant the degree in botany, for example. This definition is necessary to clarify that a degree title may be general or specific as long as certain coursework requirements are met.

(8) Adopt new Section 1029.225. Official school transcript.

This definition is necessary to clarify acceptable documentation of educational credits. This is especially needed for documents received from outside the United States from universities which do not routinely issue transcripts. An official school transcript must be sent directly from the university to Laboratory Field Services, and not intercepted by the applicant. It must bear a seal and signature from an official of the university and must come in a sealed envelope. Laboratory Field Services has received transcripts found to be falsified or fabricated and has lacked a clear definition of what is an official transcript. Therefore, this definition has been added.

(9) Adopt new 1029.230. Tests or Examinations in Molecular Biology.

CDPH needs to clarify tests or examinations in molecular biology. In 2000, CDPH implemented regulations at 17CCR 1031 (b) that authorized licensed clinical chemist scientists and clinical microbiologist scientists to perform “tests and examinations in molecular biology”. However, this phrase was not defined and this has led to confusion as to what a molecular biology test is. Molecular biology is the technology that is used to analyze subcellular components to aid in diagnoses. This can involve either genetic (genomic) or protein (proteomic) analyses in many specialties of the laboratory. Persons working as licensed clinical chemist scientists and clinical microbiologist scientists would still be limited by their scopes of practice to performing molecular biology tests within their authorized specialties. (See Exhibits 29 and 30)

(10) Adopt new 1029.235. Tests or Examinations in Molecular Pathology.

CDPH proposes to clarify what constitutes tests or examinations in molecular pathology. Molecular pathology is the examination of molecules within organs, tissues or body fluids, using multidisciplinary molecular biology techniques to assess morphological changes related to disease or dysfunction. Tests or examinations in molecular pathology include, but not limited to, fluorescence in-situ hybridization and immunochemical staining of tissues. (See Exhibits 10, 28, 29, 30, 32)

(11) Repeal Section 1030. Examination for Bioanalysts’ Licenses.

The original standards for licensure of clinical bioanalysts were established in 1957 at Section 1030 and were based upon passing written, oral and practical examinations administered by CDPH. Academic courses were specified, but training and experience requirements were unclear. CDPH proposes to repeal the current standards at Section 1030 and clarify licensure standards for bioanalysts in a new Section 1030.

(12) Adopt new Section 1030. Licensure of Clinical Laboratory Bioanalysts.

The current Section 1030 for licensure of bioanalysts is unclear. Work experience is not specified and the required academic coursework is outdated. The examination requirement is no longer valid. The only avenue for bioanalyst licensure has been prior licensure as a clinical laboratory scientist and four years of practical experience. It has been difficult for CDPH to evaluate work experience received from outside the state, and it is unclear what workscope is authorized for non-doctorate bioanalysts. Also, providing licensing examinations for bioanalyst candidates have been a problem for CDPH, so a national certification examination for bioanalysts has been approved pursuant to CCR Section 1031.8. A number of amendments are being made to Section 1030 to facilitate licensure of bioanalysts. (See Exhibit 1)

The proposed new title of Section 1030, “Licensure of clinical laboratory bioanalysts” more clearly reflects the content of the new section than the previous title. This section explains the licensure requirements for a clinical laboratory bioanalyst (bioanalyst),

incorporating a national certification examination and makes it easier for qualified applicants outside California to qualify.

An applicant for bioanalyst licensure must have an earned masters or doctorate in clinical laboratory science with at least 30 hours of post-baccalaureate courses in clinical laboratory science, biological, chemical or physical science. This is consistent with requirements for other masters or doctorate-degree licenses administered by CDPH. The applicant must have at least one year of training in clinical laboratory science that would qualify him or her for licensure in California as a clinical laboratory scientist, and then at least four years of practical experience. However, the applicant would not necessarily need to have worked, or be licensed, in California. CDPH would accept equivalent licensure or certification from another state for the training and verification of work experience. This work experience must be obtained in a laboratory that has federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification, International Laboratory Accreditation Cooperation (ILAC) accreditation or is accredited by another agency acceptable to CDPH pursuant to Section 1031.11. This experience must include all the specialties listed in this section and would not allow acceptance of academic, research, veterinary, industrial or forensic experience conducted in a laboratory that lacks clinical certification or accreditation. (See Exhibits 1, 20, 21, 22)

CDPH proposes to change the examination requirement to recognize satisfactory performance on a certification examination administered for High Complexity Laboratory Directors (HCLD) or Bioanalyst Clinical Laboratory Director (BCLD) by the American Board of Bioanalysis (ABB) for licensure purposes. The applicant would still be expected to pass an oral examination on state and federal law administered by the department. (The national board would not be expected to examine an applicant on California laboratory law, so this is administered separately.) A laboratory director in California is responsible for assuring his or her laboratory complies with state and federal law. (See Exhibit 1)

Once licensed as a clinical bioanalyst, the work scope would depend on the licensee's education and date of licensure. State law authorizes licensed bioanalysts with masters degrees to direct high complexity laboratories, while federal CLIA law requires a doctorate degree and licensure. However, CLIA affords a grandfather provision to those licensed and eligible to be a director on or before February 28, 1992. Any bioanalyst licensed after that date must have a doctorate degree. State law is based on CLIA in effect on January 1, 1994 pursuant to B&P Code Section 1202.5. Since that time board certification is required for a high complexity laboratory director who is not a physician.

A licensed clinical bioanalyst is also authorized to serve as technical consultant, technical supervisor, general supervisor, clinical consultant or testing personnel in the specialties and subspecialties of a high complexity laboratory when he or she meets the experience requirements in Title 17 California Code of Regulations (CCR) Sections 1036 – 1036.4.

(13) Adoption of new Section 1030.1. Licensure of Clinical Chemists, Clinical Microbiologists, Clinical Toxicologists and Clinical Immunologists.

The licensure standards for clinical chemists, clinical microbiologists, clinical toxicologists, clinical genetic molecular biologists and clinical cytogeneticists are currently established at Section 1030.5. CDPH proposes to repeal this section entirely and replace it with new Sections 1030.1, 1030.6 and 1030.7. Section 1031.1 shall enact new licensing standards for four categories of doctorate-degree scientists: clinical chemists, clinical microbiologists, clinical toxicologists and clinical immunologists. The first three categories have been licensed in California since 1972 under authority of B&P Code 1264. The fourth category is a new license category for clinical immunologists who are currently not licensed or authorized to work in California. CDPH is authorized at B&P Code Section 1208 to establish new categories of licenses for clinical laboratory personnel, and under this authority, proposes to establish licensing standards for clinical immunologists. These standards are added to Section 1030.1.

Because of lack of clarity on licensing standards, it is difficult for qualified applicants to be licensed in California. Applicants are unsure whether their education or training will qualify them for licensure. CDPH has developed uniform licensing requirements for all doctorate-degree applicants, consistent with federal law. In addition, establishing licensure standards for clinical immunologists shall allow qualified applicants from outside the state to work in California, helping alleviate a severe labor shortage of laboratory personnel.

Authorization to direct high complexity testing

Subsection 1030.1 (a) lists those persons authorized to direct a clinical laboratory performing high complexity chemistry, microbiology, toxicology or immunology in California. These persons include a licensed bioanalyst, a licensed pathologist, or a licensed doctorate scientist when these persons also meet director requirements in federal law (CLIA) as defined in B&P Code Section 1202.5. CLIA requires doctorate candidates to have national board certification (unless previously qualified under state law without certification), state licensure (if required) and four years of experience prior to assuming a director position. These State standards do not require that a licensee maintain national board certification to be licensed as a director.

Licensure requirements

Subsection 1030.1 (b) specifies the education, training and examination requirements for licensure of clinical chemists, clinical microbiologists, clinical toxicologists or clinical immunologists. (See Exhibits 7, 8, 12, 23, 33, 37)

All candidates must have an earned masters or doctorate degree in chemistry or biology from an accredited college of university. CDPH has specified what it shall consider an acceptable degree, major and coursework for licensure at Sections 1029.220.

All candidates must complete at least four years of postgraduate practical training experience prior to licensure. If this experience is gained in a program in California, it must be in a program approved for training by CDPH and acceptable for certification by an approved certifying board. During training, the candidate must be licensed as a postgraduate fellow as specified in Section 1035.2. If the training is gained outside California, then it must be obtained in a certified or accredited laboratory that provides training equivalent to that gained in California as specified in Section 1031.11. Upon completion of the first two years of postgraduate training, the candidate may apply for a national certification examination, but still must complete a total of four years of training and experience to meet licensure requirements in California.

All candidates must successfully pass a written certification examination in their specialty, approved by CDPH for licensure purposes. The candidates need not maintain certification with the approved board for licensure purposes. They simply must pass the certification examination.

All candidates must successfully pass an oral examination on state and federal clinical laboratory law administered by CDPH. This examination is given by a panel composed of experienced licensees and Laboratory Field Services staff as specified in Section 1031.12.

Authorized workscopes of licensees

Subsection 1030.1 (c) explains the workscopes of licensed clinical chemists, clinical microbiologists, clinical toxicologists and clinical immunologists. State law (B&P Section 1264) authorizes licensure of chemists, microbiologists and toxicologists who “are a lawful holder of a master of science or doctorate degree”. CDPH can license persons in these categories with only a masters degree, but their workscope is limited by federal law. This subsection is added to defer to CLIA as defined in B&P Code Section 1202.5. A licensed doctorate scientist who is certified by an approved certifying board can direct high complexity testing. A licensed masters degree scientist would not meet requirements for certification and could not direct a high complexity laboratory. This person could direct a laboratory that performs moderate complexity testing in his or her specialty, or could serve as technical consultant, technical supervisor, general supervisor or testing person in his or her specialty. (See Exhibits 7, 8, 12)

Licensing standards for clinical immunologists.

Using authority given at B&P Code 1208 (a), CDPH has proposed to create a license category for doctorate-degree clinical immunologists in Section 1030.1. These persons are trained in complex tests and examinations related to the immune system, immunohematology, histocompatibility and cellular immunology. These tests cross over traditional specialties dealing with antigen-antibody reactions. None of the current license categories cover all these specialties. Qualified applicants in this specialty are currently not authorized to work in California. (See Exhibits 12, 33, 37)

A clinical immunologist applicant must have an earned doctorate degree in immunology or related science with at least 30 semester hours of post-baccalaureate courses in biological science. A licensed clinical immunologist with a doctorate degree is authorized to direct an immunology laboratory performing high complexity testing.

A clinical immunologist applicant must complete two years of post-doctorate training in clinical immunology in a program approved for certification by the American Board of Medical Laboratory Immunology (ABMLI), and CDPH. This board has been approved by the federal agency, CMS, for certification of clinical immunologists qualified to direct laboratories. An additional two years of practical experience performing or supervising high complexity clinical immunology testing is required for licensure in California as a postgraduate fellow as specified in Section 1033 (e). While other states may allow a board certified clinical immunologist to supervise or direct other staff after two years of training and certification, CDPH has determined that four years is necessary based on statutory requirements for similar license categories. The applicant must complete four years of postdoctoral training and meet other requirements for licensure.

An applicant for California licensure must pass an examination administered by the ABMLI. The applicant need not be certified, or maintain certification with the ABMLI, for California licensure. Certifying boards do not examine candidates on state clinical laboratory law; therefore, an applicant for licensure as a clinical immunologist must pass an oral examination administered by CDPH on state and federal clinical laboratory law. A laboratory director in California is responsible for assuring his or her laboratory complies with state and federal law.

A licensed clinical immunologist with a doctorate degree is authorized to direct a clinical laboratory performing tests and examinations in immunology, including cellular immunology, histocompatibility, immunohematology, immune systems, allergy testing and cellular toxicity. A licensed clinical immunologist may also serve as technical consultant, technical supervisor, clinical consultant or general supervisor of these specialties and subspecialties when he or she meets the experience requirements of Sections 1036 – 1036.4.

(14) Adoption of New Section 1030.2. Licensure of Clinical Biochemical Geneticists.

CDPH currently licenses two categories of personnel that perform genetic testing. The first is for baccalaureate- and doctorate-degree cytogeneticists who perform chromosomal analyses for aberrations or mutations causing human disorders (see Sections 1031.2 and 1030.6). The second is baccalaureate- and doctorate-degree genetic molecular biologists (see Sections 1031.3 and 1030.7) who analyze DNA, RNA and nuclides to diagnose human genetic disorders. The genetic community in California has urged creation of a third category of genetic scientist, the “clinical biochemical geneticist”. This category of testing personnel analyzes metabolic products to determine inborn errors of metabolism. (See Exhibits 23, 24, 25, 26, 31, 36)

Using authority given at B&P Code 1208 (a), CDPH proposes to create a new license category for doctorate-degree clinical biochemical geneticists. A baccalaureate-degree license is not needed as licensed clinical laboratory scientists and clinical chemist scientists can generally perform the metabolic tests. However, a doctorate-degree person trained in both metabolic testing and genetics is needed to serve as laboratory director, clinical consultant and technical supervisor. (See Exhibit 11)

Clinical biochemical geneticists, that are otherwise qualified, cannot be employed in California in their specialty because there is no licensure provision. Without licensure, they are considered “unlicensed personnel” with duties limited to those specified in B&P Code Section 1269. CDPH proposes to implement licensing requirements for this new license category comparable to those already enacted in state law for doctorate scientists. This shall allow qualified persons to be licensed and work in California.

Licensure requirements for clinical biochemical geneticists at Section 1030.2 are consistent with other doctorate-degree genetic license requirements given in Sections 1030.6 and 1030.7 for clinical cytogeneticists and clinical genetic molecular biologists. This license category requires both physician and doctorate-scientists to have two years of postdoctoral training and two years of practical experience, and successful passage of a national certification examination. This new license category shall be authorized to direct a laboratory performing metabolic tests for the diagnosis of inherited disorders. California law already authorizes a licensed bioanalyst or a licensed pathologist to direct such a laboratory when they meet director requirements in CLIA as defined at B&P Code Section 1202.5.

A clinical biochemical geneticist applicant must have an earned medical degree or a doctorate degree in genetics or related science with at least 30 semester hours of post-baccalaureate courses in biological or chemical science.

A clinical biochemical geneticist applicant must complete two years of post-doctorate training in clinical biochemical genetics in a certified or accredited laboratory program approved for certification by the American Board of Medical Genetics (ABMG) or the Canadian College of Medical Geneticists (CCMG), and CDPH. The ABMG has been approved by the federal agency, the Center for Medicare & Medicaid Services (CMS) for certification of clinical biochemical geneticists qualified to direct laboratories. Following the two-years of post-doctorate training, a clinical biochemical geneticist applicant must complete at least two more years of practical experience performing, supervising or directing high complexity biochemical genetics in a certified or accredited laboratory. Other states may allow a board-certified clinical biochemical geneticist to supervise or direct other staff, but this is not authorized in California without being licensed as a clinical biochemical geneticist.

An applicant for licensure as a clinical biochemical geneticist must pass a board certification examination administered by the ABMG or the CBMG for licensure purposes. The applicant need not be certified, or maintain certification by the ABMG or

the CBMG, for California licensure. An applicant is only required to pass the examination and document his or her doing so for licensure.

Finally, an applicant for licensure as a clinical biochemical geneticist must pass an oral examination administered by CDPH on state and federal clinical laboratory law. The certifying boards, as the ABMG, do not examine candidates on state clinical laboratory law, so this is administered by CDPH. A laboratory director in California is responsible for assuring his or her laboratory complies with state and federal law.

A licensed clinical biochemical geneticist with a doctorate degree is authorized to direct a clinical laboratory performing tests and examinations in biochemical genetics. A licensed clinical biochemical geneticist may also serve as technical consultant, technical supervisor, clinical consultant or general supervisor when he or she meets the experience requirements of Title 17 CCR Sections 1036 – 1036.4.

(15) Adoption of New Section 1030.3. Licensure of Clinical Embryologists.

CDPH proposes to establish licensing standards for a clinical embryologist. A clinical embryologist is a person who performs clinical tests and examinations to support human assisted reproductive technologies (ART). This is a unique blend of technologies which combines *in vitro* clinical tests on parents with *in vivo* tests on sperm, ova and embryos. These activities are performed by board-certified doctorate scientists who work in conjunction with a licensed physician who is treating patients using ART. Non-physician clinical embryologists are not authorized to treat patients directly. Typical clinical laboratory tests include semen analysis (volume, concentration, motility, morphology, presence of other cells), sperm antibody evaluation, cervical mucous examination, male and female hormone levels and evaluation of corpus luteum adequacy. ART tests and examinations include ova evaluation and selection, sperm washing and selection, and embryo storage and selection. (See Exhibits 1, 2, 3, 5, 6, 27)

ART in humans started in 1978 with the first *in vitro* fertilization pregnancy. The first baby in the United States, conceived by *in vitro* fertilization, was born in 1981, and since then, the number of ART clinics has increased dramatically. California currently has over 120 ART facilities licensed as tissue banks since they store embryos. Other ART facilities which do not store gametes or embryos are not licensed as tissue banks but may be licensed as clinical laboratories if they perform tests onsite. Many clinical embryologists are trained in the United Kingdom or Australia, and are unable to legally perform tests or examinations in California. They have asked that their board certification be recognized for licensure purposes in California. That is the purpose of these proposed licensing standards.

Using authority given at B&P Code 1208 (a), CDPH proposes to create new license categories for doctorate-degree clinical embryologist laboratory directors at Section 1030.3 and clinical embryologist scientists at Section 1031.5. A doctorate-degree person licensed as a clinical embryologist could serve as laboratory director, clinical

consultant and technical supervisor of licensed ART facilities performing clinical testing. A licensed clinical embryologist scientist who meets the requirements of CLIA as defined at B&P Code Section 1202.5 could serve as general supervisor, technical supervisor or testing person, but not laboratory director.

A clinical embryologist applicant must have an earned doctorate degree in biological or clinical laboratory science with at least 30 semester hours of post-baccalaureate biology and embryology courses. He or she must complete two years of post-doctorate training on human specimens in an ART facility approved by the American Association of Bioanalysts Board of Registry (AAB BOR) for board certification of embryologists, and then must complete at least two more years of practical experience in a facility performing high complexity testing related to ART. If this training and experience is obtained in California, then the applicant must obtain a postgraduate fellow license and train in a program approved pursuant to standards specified in Section 1035.2. The applicant must document that he or she passed a board certification examination either as High Complexity Laboratory Director (HCLD) in embryology or Embryology Laboratory Director (ELD) administered by the AAB BOR. The candidate also must pass an oral examination on state and federal law administered by CDPH as specified in Section 1031.12. (See Exhibits 1 and 3)

A licensed clinical embryologist shall be authorized to direct the clinical component of an ART laboratory overseeing high complexity tests related to fertility testing. He or she may serve as technical consultant, technical supervisor and general supervisor of those performing testing, and clinical consultant to physicians, when he or she meets the requirements of Sections 1036 through 1036.4.

(16) Repeal of Section 1030.5. Licensure of Clinical Chemists, Clinical Microbiologists, Clinical Toxicologists, Clinical Genetic Molecular Biologists and Clinical Cytogeneticists.

CDPH proposes to repeal Section 1030.5 and replace it with specific licensure requirements for these categories at new Sections 1030.1, 1030.6 and 1030.7.

Section 1030.5 was amended in the year 2000 when CDPH (then DHS) established licensing standards for clinical genetic molecular biologists and clinical cytogeneticists at Sections 1030.6 and 1030.7, and added those categories to the title of Section 1030.5. The standards in Section 1030.5 are inconsistent with the licensing standards for these two new categories at Sections 1030.6 and 1030.7, as well as outdated by changes in federal law. CDPH has been hampered with licensing doctorate applicants since 2000 because of lack of consistency in this section.

Section 1030.5 is unclear because it requires written and oral examinations but does not explain how or by whom these examinations are administered. It also is inconsistent with federal requirements because it requires one year training instead of two and inconsistent with other state standards since it specifies three years of experience, rather than two, for licensure.

CDPH has relied on federal standards for doctorate scientists, knowledge of standards in state law, and CDPH has 35 years of experience licensing doctorate scientists.

**(17) Amend Section 1030.6. Licensure of Clinical Cytogeneticists, and
(18) Amend Section 1030.7. Licensure of Clinical Genetic Molecular Biologists.**

Licensure standards for doctorate-degree clinical cytogeneticists and clinical genetic molecular biologists were established by CDPH regulations in 2000. Since that time about 100 of these specialists have been licensed in California. Non-substantive amendments are proposed to these sections which shall make them consistent with licensing requirements of other doctorate-degree licenses. The purpose of these changes is to make the licensing standards as clear as possible to the applicant and the public. The scopes of work specified for clinical cytogeneticists and clinical genetic molecular biologists explain that these licensees can direct a laboratory performing high complexity testing, or can serve in other technical positions when they gain the experience required in Section 1035.2 of these standards.

The licensing standards for these two categories of genetic scientists are amended to require their training in California as postgraduate fellows (as explained in Section 1033 (e)) or outside California in a similarly certified laboratory. Because some qualified applicants for licensure have trained outside the United States and not in a CLIA-certified laboratory, CDPH proposes to accept training in an International Laboratory Accreditation Cooperation (ILAC) accredited laboratory outside the United States for foreign applicants if specified training standards are met. Also, the workscope of the two license categories are clarified so that they are consistent with federal CLIA law as defined at B&P Code Section 1202.5. (See Exhibits 20, 21, 22, 23, 36)

(19) Amend Section 1031. Licensure of Clinical Laboratory Specialists.

Licensing standards for clinical laboratory specialists were first enacted in 1957 and have not been changed since 1971. The five categories of licenses impacted by this section are the baccalaureate-degree clinical chemist scientist, clinical microbiologist scientist, clinical immunohematologist scientist, clinical toxicologist scientist, and clinical hematologist scientist. CDPH proposes amendments to Section 1031 to update the licensing requirements for these categories and to make them consistent with changes already established for other specialist categories. (See Exhibits 34, 35, 38, 39, 40)

Admission to the (state-administered) examination

The current Section 1031 (a) references “admission to the (state-administered) examination”, but CDPH no longer administers licensing examinations. In 2005, CDPH enacted Section 1031.8 which specified standards by which certification examinations could be used for licensure purposes in place of state-administered examinations. Therefore, any mention of “admission to an examination” as a way to initiate the licensing process is replaced with a statement that the applicant must “apply for a license”.

Educational requirements for licensure

Several clarifications are made to the education requirements for clinical laboratory specialist licensure in Section 1031 (a). The term “equivalent major” was repealed as ambiguous and specific course requirements were specified to broaden and update acceptable classes. Although a baccalaureate degree has always been required, coursework specified in 1971 has become outdated and a barrier to licensure. The applicant is directed to Section 1031.6 for specific application requirements. Definitions of an “accredited college or university” and “official school transcript” are added to Section 1029.7 to clarify requirements for applicants.

Training requirements for licensure

The training requirements for licensure have been updated to better accommodate out-of-state applicants. A person training in California is expected to train in an approved training program as specified in Section 1035 (a). CDPH proposes to accept two years of training and/or experience outside California or outside the United States in lieu of one-year of training in California. The laboratory, however, must be CLIA-certified or if outside the United States, ILAC accredited and approved by CDPH, in order to assure equivalency. (See Exhibits 20, 21, 22)

Examination requirements for licensure

The examination requirements for licensure have been updated to specify that the applicant must successfully pass an approved certification examination in his or her specialty and a separate examination provided without charge on the internet on state laboratory law administered by CDPH. (See Exhibits 39 and 40)

Workscope of Clinical Laboratory Specialists

The workscope of licensed clinical laboratory specialists is clarified to explain that they can perform any molecular biology test or examination within their specialties. CDPH has proposed a broad definition of “tests and examinations in molecular biology” at Section 1029.230 to clarify what constitutes such testing.

(20) Amend Section 1031.1. Licensure of Clinical Histocompatibility Scientists, (21) Amend Section 1031.2. Licensure of Clinical Cytogenetic Scientists, and (22) Amend Section 1031.3. Licensure of Clinical Genetic Molecular Biologist Scientists.

CDPH proposes to amend Sections 1031.1, 1031.2 and 1031.3 that set licensing standards for baccalaureate-degree clinical histocompatibility scientists, clinical cytogenetic scientists and clinical genetic molecular biologist scientists. Standards for the first license category were enacted in 2000, and the other two in 2003 so these standards are more current than Section 1031 which set licensing standards for other specialists. However, some important changes are proposed by CDPH which require amendments to all three of these sections.

Sections 1031.1, 1031.2 and 1031.3 are amended to be consistent with other baccalaureate-degree license categories. The applicant needs to be directed to the documentation required to apply for licensure at Section 1031.6. Currently, there is no training route for persons applying from outside California or outside the United States. These sections do not specify that the applicant must pass an examination provided without charge on the internet on state laboratory law administered for all applicants. Also, Sections 1031.1, 1031.2 and 1031.3 do not mention the workscopes authorized for these license categories. CDPH proposes to expand the workscopes for clinical cytogenetic scientists and clinical genetic molecular biologist scientists to meet new technology demands.

Application for licensure

The statement that the applicant must “apply for licensure” to initiate the application process is obvious but missing from Sections 1031.1, 1031.2 and 1031.3. This statement is added with further reference to Section 1031.6 (a) for application requirements.

Training requirements for licensure

The training requirements for licensure have been updated to better explain training gained within California and outside of the State. A person training in California is expected to train in an approved training program as specified in Section 1035 (a). CDPH proposes to accept two years of training and/or experience outside California or outside of the United States in lieu of one-year of training in California. This is done to accommodate out-of-state applicants. The laboratory, however, must be CLIA-certified or if outside the United States, CLIA-certified or ILAC-accredited or accredited by another agency acceptable to CDPH as specified in Section 1031.11, in order to assure equivalency. (See Exhibits 20, 21, 22)

Examination requirements for licensure

These three license categories require certification by a national board as a condition for licensure. Examinations are provided to the applicant by approved certification organizations. Section 1031.1 (b) requires the clinical histocompatibility scientist to be certified in histocompatibility by the American Board of Histocompatibility and Immunogenetics. Section 1031.2 (b) requires the clinical cytogenetic scientist to be certified in cytogenetics by the National Credentialing Agency for Laboratory Personnel (NCA) or the American Society for Clinical Pathology Board of Certification (ASCP). Section 1031.3 (b) requires the clinical genetic molecular biology scientist to be certified in molecular biology by the NCA or the ASCP. In addition to this requirement, the examination requirements have been updated to specify that the applicant must also successfully pass a separate examination provided without charge on the internet on state laboratory law administered by CDPH. (See Exhibits 7, 35, 39, 40)

Workscopes of licensees

The workscopes of these clinical laboratory specialists are stated. A licensed clinical histocompatibility scientist is authorized to perform tests and examinations in histocompatibility. A licensed clinical cytogeneticist scientist is authorized to perform high complexity tests and examinations in clinical cytogenetics. However, CDPH proposes that a licensed cytogeneticist scientist who is certified by the ASCP in molecular biology or molecular pathology shall be authorized to also perform high complexity microscopic or morphologic tests and examinations in molecular pathology under the general supervision of a pathologist. This expansion of workscope is necessary to recognize advanced training in new technology diagnostics by qualified scientists. Finally, a licensed genetic molecular biologist scientist is authorized to perform high complexity tests and examinations in genetic molecular biology as defined at Section 1029.53. This definition expands the workscope of this license category to include genetic testing, such as infectious agents from human specimens. This has been done at the request of the laboratory community which found the workscope to be unnecessarily limiting. (See Exhibits 29, 30, 31)

(23) Adopt new Section 1031.4. Licensure of Clinical Cytotechnologists.

Concern about erroneous Pap test results in 1988 led to new federal law and regulations that set new standards for all clinical laboratories in the United States. State legislation in 1990 was enacted at B&P Code Sections 1270, 1270.5, 1271, 1271.1 1272.4, 1272.6, 1274 to set new standards for Pap testing in California. This law required CDPH (then DHS) to establish licensing standards for cytotechnologists. These standards were enacted in 1994 with the filing of emergency licensing regulations. Prior to that time, cytotechnologists verified their competency to work by achieving board certification with the American Society for Clinical Pathology (ASCP) in cytology.

B&P Code Section 1270 specifies different requirements for cytotechnologists than other license categories. CDPH proposes to amend the licensure requirements for cytotechnologists, to make them consistent with other baccalaureate-degree licenses and to move that section to Article 1.5, Licensure of Clinical Laboratory Personnel, Section 1031.4 with the other personnel licensing standards. CDPH proposes to repeal Sections 1060-1062 as outdated and unenforceable (discussed in detail at those sections).

The standards proposed for cytotechnologist licensure are consistent with other baccalaureate-degree license categories. The applicant must have an earned baccalaureate or higher degree in biology or clinical laboratory science. He or she must have at least one year of post-baccalaureate training in clinical cytology in a program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and acceptable to the American Society for Clinical Pathology (ASCP) for cytotechnologists. The applicant must successfully pass a certification examination in cytotechnology administered by the ASCP and a separate examination provided without charge on the internet on state laboratory law administered by CDPH. (See Exhibit 35)

A licensed cytotechnologist is authorized to perform high complexity tests and examinations in gynecologic and non-gynecologic cytology. However, because of new technology, the industry supports expansion of the cytotechnologist workscope to include microscopic evaluation of morphologic changes identified by molecular pathology techniques. These techniques include fluorescent and immunochemical staining and microscopic evaluation of cells under the direction of a board-certified cytopathologist. CDPH proposes to recognize expansion of the workscope of qualified cytotechnologists who achieve certification in molecular pathology or molecular biology without requiring them to gain a second license. (See Exhibits 4, 13, 14, 15, 16, 17)

Application for licensure

The applicant for cytotechnologist licensure is directed to apply for licensure providing documentation required at Section 1031.6 (a). The applicant was previously directed to Section 1061 which shall be repealed.

Education requirements for licensure

The academic requirements at Section 1061 (b) require an applicant to document “any degrees conferred” and Section 1060 (e) specifies coursework required. These standards are updated and relocated to Section 1031.4. State and federal law both require high complexity cytology testing to be performed by persons with baccalaureate degrees in science and with state licensure, where required.

Training requirements for licensure

The current training requirements for cytotechnologists at Section 1060 and 1061 are retained and relocated to Section 1031.4. Completion of twelve months training in a cytology program approved by the CAAHEP is required. Section 1060 misnames the CAAHEP as “Council” and this is corrected in Section 1031.4. Section 1061 requires CAAHEP “or its equivalent” and there is no equivalent agency. Section 1061 also accepts completion of five years of experience in lieu of one-year of training, and this is not acceptable to the ASCP for certification or to CDPH for licensure.

Examination requirements for licensure

A cytotechnologist applicant must successfully pass a certification examination administered by the ASCP in cytotechnology. Section 1061 identifies this as an ASCP “registration” certificate and this is incorrect. The proposed new Section 1031.4 shall also require the applicant to successfully pass an examination (via the internet) on state laboratory law administered by CDPH.

Workscope of licensed cytotechnologists

State law at B&P Code Section 1271 authorizes cytotechnologists to perform gynecological and non-gynecological cytology examinations, and sets their workload at 80 manually screened gynecological (Pap) tests in no less than 8 hours in a 24 hour period. "Any other duties", such as reading non-gynecologic slides, decrease this workload. CDPH proposes to expand the other duties authorized for cytotechnologists to include fluorescent and immunochemical staining techniques, and performing microscopic evaluation of cells and tissues under the direction of a pathologist.

In addition, CDPH proposes to further expand the workscope of licensed cytotechnologists who are certified by the ASCP in molecular pathology or molecular biology to use these techniques to perform high complexity microscopic tests and examinations of morphologic changes in cells and tissues under the direction of a pathologist. This expansion of workscope would be authorized with certification and without additional licensure. The licensed cytotechnologist must be found competent to perform such tests by a pathologist, pursuant to B&P Code 1209 (e). This regulation could affect approximately 1300 cytotechnologists currently licensed by CDPH.

(24) Adopt new Section 1031.5. Licensure of Clinical Embryologist Scientists.

Clinical embryologist scientists are laboratory specialists that support the treatment of infertility and the performance of specific clinical laboratory testing related to fertility in Assisted Reproduction Technology (ART) facilities. While licensed clinical laboratory scientists are authorized to perform much of the testing, they are not necessarily trained in the specialized testing involved at ART clinics. Similarly, many specialists coming from outside California or outside the United States do not meet specific licensure requirements as clinical laboratory scientists. Therefore the ART community has urged creation of licensure standards which shall recognize doctorate and non-doctorate scientists and allow them to be employed in California. CDPH has proposed licensing standards for doctorate candidates at Section 1030.3. Section 1031.5 shall set licensing standards for persons with at least a baccalaureate degree. Their workscopes shall be determined by their education, training, certification and licensure.

Persons employed in ART facilities support the treatment of infertility under the direction of physician specialists. Some of the work performed in an ART facility is not subject to clinical laboratory law. Patient treatment is considered the practice of medicine and clinical testing on zygotes, blastulas or embryos does not meet the definition of a clinical laboratory test or examination at B&P Code Section 1206 (a)(6). However, any clinical testing performed on biological specimens derived from a man or woman participating in ART is subject to clinical laboratory law. The problem arises since persons trained in ART procedures are often trained in graduate programs using animal models followed with on-the-job training in an ART clinic. The training includes clinical laboratory testing of semen (morphology, antibodies, white blood cells, viability, chemical tests as fructose, sperm chromatin structure, acrosome reaction, hyaluron binding, sperm penetration and de-condensation assays), hormone testing (testosterone, HCG, FSH,

LH, estradiol) and genetic test interpretation. Persons with this specialized training are not currently authorized to perform clinical laboratory testing and require licensure to perform testing in ART facilities in California. (See Exhibits 2, 5, 6, 27)

Section 1031.5 sets licensure standards for persons with at least a baccalaureate degree and specialized training acceptable for certification, to be licensed as embryologist scientists in California. These persons could serve as a testing person, technical supervisor, technical consultant or general supervisor in an ART facility under the direction of a qualified licensed physician or licensed clinical embryologist who also meets the requirements of CLIA as defined at B&P Code Section 1202.5. CDPH believes that the certification standards enacted by the American Board of Bioanalysts for Technical Supervisors in Embryology are sufficient to ensure competency in this area. The ABB tests for expertise both in clinical laboratory testing and embryology procedures. (See Exhibits 3, 5, 6, 8)

Application for licensure

A candidate for licensure is directed to Section 1031.6 (a) for application requirements.

Educational requirements for licensure

A clinical embryologist scientist must have at least a baccalaureate degree, but may have a masters or doctorate degree in biological science. CDPH is specifying that the candidate must have at least 25 semester or equivalent quarter hours in biological or clinical laboratory science. A clinical embryologist scientist with a masters or doctorate degree would have more semester hours, but this is not necessary for this license.

Experience requirements for licensure

If ART training in embryology is obtained in California, then the training program must meet requirements specified in Section 1035 and be approved by CDPH. The amount of training required for licensure depends on the education of the applicant. A clinical embryologist scientist candidate with a baccalaureate degree must have four years of documented experience in an ART facility, a candidate with a masters degree must have two years of documented experience, and a doctorate candidate must have at least one year of documented experience. All training shall be approved by CDPH and acceptable to the ABB for admission to an examination for Technical Supervisor of Embryology.

Examination requirements for licensure

Candidates for licensure as a clinical embryologist scientist must successfully pass a certification examination approved by CDPH pursuant to Section 1031.9 for licensure as a clinical embryologist scientist. This examination is administered by the ABB for Technical Supervisor of Embryology. The candidate must also pass an examination provided without charge on the internet on state laboratory law administered by CDPH.

Workscope of licensed clinical embryologist scientists

A licensed clinical embryologist scientist is authorized to serve as technical consultant, technical supervisor, general supervisor or testing personnel in clinical embryology as defined in Section 1029.210, in an ART facility when he or she also meets the requirements of CLIA as defined at B&P Code 1202.5. He or she is not authorized to serve as laboratory director of an ART facility unless licensed as a clinical embryologist as specified in Section 1030.3.

(25) Section 1031.6: Amend Section 1031.4. Requirements and Timeframes for Applications for Licensure and Certification.

Amendments are proposed to Section 1031.4, renumbering it to Section 1031.6. Important updates are needed since it was originally enacted in 2000. This section specifies requirements and timeframes for licensure to direct a clinical laboratory and perform clinical laboratory tests, or certification in phlebotomy. CDPH shall also add requirements for licensure as a trainee. CDPH no longer administers written licensing examinations so information in Subsection (a) on how to apply for such an examination is unnecessary. CDPH receives non-United States academic transcripts in support of license applications. CDPH is not able to assure the validity of a foreign transcript and therefore specifies an approved agency for evaluating these documents for all license categories. Application requirements for trainee licenses need to be specified to facilitate training in California. These and other non-substantive changes are made in this section.

Change in section number

The number of this section is amended from Section 1031.4 to 1031.6.

Repeal of subsection (a)

Subsection (a) explains timeframes for applicants who apply for admission to a state-administered examination. However, CDPH no longer administers state written examinations, so this subsection is obsolete and shall be repealed. License applicants now apply to approved certification organizations for admission to their examinations which are usually scheduled throughout the year.

Documentation of license applicant's education

Section 1031.4 (b) (6) is amended to make clarifications on how an applicant's education should be documented. CDPH has defined "official school transcript" and "accredited college or university" at Section 1029.225 and 1029.7 to avoid any misunderstanding of requirements. This section is also amended to explain how CDPH shall evaluate transcripts from non-accredited colleges or universities and how non-English transcripts shall be translated and evaluated. These changes are made to facilitate licensure of qualified non-United States applicants.

Evaluation of foreign transcripts

CDPH proposes to specify that non-United States college transcripts be evaluated by the American Association of Collegiate Registrars and Admissions Officers (AACRAO) or the department. Evaluation of foreign transcripts is sometimes a problem as they are often not in English and the courses are hard to translate into United States equivalents. CDPH has relied on AACRAO over the years for their expertise in the evaluation of non-United States transcripts and believes it is in the best interest of the public to maintain this requirement.

Documentation of license applicant's training

Amendments are made to Section 1031.4 (b)(7) and (8) to require a training program director or other responsible person to attest to the accuracy of training completed, to require "practical" experience as defined at Section 1029.134, and to clearly identify the laboratory where training occurred.

Examination requirements for license applicant

Amendments are made to Section 1031.4 (b)(9) to add national certification examinations approved for licensure purposes as a condition for licensure and satisfactory performance on an examination provided without charge on the internet on state laboratory law. Both these options have been adopted since 2000 and need to be referenced in this section. CDPH shall continue to administer oral and online examinations for licensure, but not written, technical examinations.

Changes made to phlebotomy certification application requirements

Section 1031.4 (c) gives application requirements for phlebotomy certification. Two amendments are made to this section. CDPH shall specify that if a transcript is not in English, then the applicant is expected to pay for the translation into English and evaluation for equivalency. Also, the fee of \$50 is repealed and is referenced to B&P Code Section 1246. Senate Bill 744 (Strickland, Chapter 201, Statutes of 2009) increased the fee to \$100 and it is not necessary to specify a fee here.

Clarification of trainee license requirements

CDPH has added a new Subsection 1031.5 (c) which specifies requirements for licensure as a trainee as authorized in B&P Code Section 1263. This requirement shall apply to all trainee categories: medical laboratory technicians, clinical laboratory scientists and postgraduate fellows. Only persons training in phlebotomy are not required to have trainee licenses.

Persons training in California are required to have a trainee license in order to perform laboratory tests or examinations. B&P Code Section 1206.5 lists those persons licensed or authorized to perform tests including licensed trainees.

The demographic information required of trainee applicants is generally the same as that required of other license applicants: name, address, social security number, category of training anticipated, and whether the applicant has any felony convictions. The requirement for a social security number may limit training by foreign applicants in the United States who lack a social security number. Identification of felony convictions by an applicant helps prevent training of persons who may be a risk to patients. CDPH does evaluate appeals from applicants with convictions who can document changes in behavior with letters of support or extenuating circumstances that led to the conviction.

Applicants for a trainee license must document that they have met all educational requirements for licensure prior to application for a trainee license. Generally a person is not licensed as a trainee until they have completed their educational requirements.

Phlebotomy certification period

Subsection 1031.5 (f) which states that “certification shall be valid for a period of 2 years unless revoked”, is repealed for lack of clarity and specificity. Although this subsection presumably relates to certification of phlebotomists, it is not clear. CDPH shall repeal this statement here and add it to Section 1034 (c) under “Certification of phlebotomy technicians”.

(26) Section 1031.7: Requirements and Timeframes for Renewal of Licenses and Certificates.

Change in section number

The number of the section shall be changed from Section 1031.5 to Section 1031.7.

Clarification of a grace period for certified phlebotomists

B&P Code Section 1301 (b)(3) authorizes a grace period of 60 days after the expiration date of a license during which time the license is still considered active and valid. If the licensee renews his or her license and pays the renewal fee during that 60 day grace period, he or she can continue working and will not have to pay the delinquency fee authorized in B&P Code 1300. However, if the licensee fails to renew his or her license within 60 days of its expiration date, then the license is forfeited and the licensee must reapply for a license and pay a delinquency fee. During this time the licensee is not authorized to work. Such a grace period for certified phlebotomists is not specified in Section 1301 (b)(3) or in CDPH regulations, and this has been a hardship for phlebotomists and their employers. It has also created a workload problem for LFS. Even though phlebotomists are sent renewal notices 60 to 90 days prior to expiration, many delay sending in their renewal documents before their certificate expires. They expect LFS to provide special services so they can continue working. In fairness to phlebotomists certified under Chapter 3 of B&P Code, LFS shall extend the same grace period for certified phlebotomists that it affords other license categories.

Phlebotomy certificate fee

The reference to a \$50 fee for phlebotomy certification is repealed. The fee specified at B&P Code 1246 was changed to \$100 in Senate Bill 744 (Chapter 201, Statutes of 2009) and need not be specified here.

(27) Amend Section 1031.7. Conditions for Approval of Certifying Organizations to Administer Phlebotomy Certification Examinations.

Change in section number

The number of the section shall be changed from Section 1031.7 to Section 1031.8. No other changes are proposed.

(28) Amend Section 1031.8. Conditions for Approval of a Certifying Organization to Administer a Certifying Examination for Licensure Purposes.

Change in section number

The number of the section shall be changed from Section 1031.8 to Section 1031.9, and one reference to Section 1031.8 within the current section shall be changed to 1031.9. No other changes are proposed.

(29) Amend Section 1031.9. Conditions for Renewal of a Certifying Organization's Approval to Administer Examinations Acceptable for Licensure Purposes.

Change in section number

The number of the section shall be changed from Section 1031.9 to Section 1031.10. No other changes are proposed.

(30) Adopt new Section 1031.11. Conditions for Approval of Training Performed in a non-CLIA-certified Laboratory.

Federal certification of clinical laboratories has been required since enactment of CLIA in 1992. All personnel licensing standards adopted by CDPH since that time have required practical training or experience be gained in a laboratory that was CLIA-certified in high complexity testing in the specialty(ies) in which the person was working. However, this has been a barrier for qualified persons training or gaining experience outside the United States. These persons were obligated to repeat their training in a CLIA-certified laboratory in the United States before they could meet the training requirements for licensure in California.

CDPH has determined that an international agency called the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) that sets standards labeled "17011" for accrediting technical facilities. The ISO/IEC gives deeming authority to other accrediting agencies that accredit facilities that meet these standards. Many laboratories in Europe and Asia are accredited by the International Laboratory Accrediting Cooperation (ILAC). This is an international agency of laboratory and inspection accreditation bodies formed 30 years ago to set standards for clinical laboratories. Some United States laboratories are also accredited by ILAC. (See Exhibits 20, 21, 22)

CDPH has proposed that training performed in a non CLIA-certified laboratory outside the United States, especially for doctorate scientists, shall be considered acceptable for licensure purposes in California when the laboratory where the training was conducted is accredited by ILAC or another agency given deeming accreditation by the ISO/IEC. However, certain other requirements shall also be imposed. The applicant must document that the laboratory performs high complexity tests or examinations in his or her specialty and that the testing was done on human patients for diagnostic purposes. There must be a qualified director of the training program who will attest to extent and completion of training. Finally, the training must be acceptable to a United States national certifying board for admission to a certification examination approved by CDPH. Therefore, essentially all training requirements are the same whether the applicant trains or gains experience in a CLIA-certified or ILAC-accredited laboratory, or one that is accredited by another agency approved by the ISO/IEC.

The purpose of enacting these standards is to facilitate licensure of qualified scientists who train or gain experience outside the United States.

(31) Adopt new Section 1031.12. Administration of Examinations on State and Federal Clinical Laboratory Law.

CDPH is authorized to administer examinations for licensure at B&P Code Sections 1260, 1261, 1261.5, 1262 and 1264, and has been doing so for over fifty years. The department historically tested applicants on their knowledge of state and federal clinical laboratory law. Masters and doctorate-degree candidates are required to successfully pass written examinations in their specialty of license and an oral examination on state and federal law. Candidates for baccalaureate-degree licenses were tested on their knowledge of laboratory law in a written examination provided by LFS and developed with subject matter experts. In 2005, LFS began approving certification examinations for licensure in California.

Emergency regulations were enacted at Section 1031.8 in 2005 that set standards for approval of certifying examinations administered by national certifying organizations for licensure purposes. Since then, LFS has approved at least one certifying examination in each license category. LFS no longer administers written technical examinations for licensure purposes, but instead, authorizes accreditation organizations to administer approved certification examinations for licensure.

When the Section 1031.8 regulations, “Conditions for Approval of a Certifying Organization to Administer a Certifying Examination for Licensure Purposes”, were released for public comment in 2005, CDPH proposed that an approved certifying examination should test the applicant on their knowledge of state and federal law. Several certifying organizations responded to the proposed regulations that they could not develop a test to include questions on California state law. Therefore, CDPH removed this from Section 1031.8 and the standards were implemented without this requirement. Since 2005, however, LFS has retained the authority to test applicants on laboratory law by providing an examination without charge on the internet that all non-doctorate license applicants must pass. This ten-question examination has multiple choice, randomly selected questions on ten key topics of laboratory law.

The purpose of adding Section 1031.12 is to clarify examination requirements for licensure.

Administration of an oral examination.

Subsection (a) explains the conditions under which an applicant must pass an oral examination on state and federal law. A panel of licensed subject matter experts and LFS managers provides questions with acceptable responses scored, and the applicant must achieve at least 70% to pass. The charge for the oral examination is \$200 as authorized in B&P Code Section 1300 (o).

Administration of an online examination.

Subsection (b) specifies how baccalaureate-degree applicants are tested on laboratory law. Since the certifying organizations do not test on California regulatory issues, LFS requires the applicant to take an online examination and obtain a minimum score of 70%. The applicant can retake the examination as many times as necessary to obtain a passing score. LFS is notified online when an applicant has passed the examination. The purpose of this examination is to make the applicant aware of basic laboratory law issues.

Examination exempted for phlebotomist applicants.

Subsection (c) explains that applicants for phlebotomy certification are not required to take either an oral or online examination on state law. That category is the only one that is not examined separately on laboratory law.

(32) Repeal Section 1032. Examination for Clinical Laboratory Technologist’s License.

Section 1032 was enacted by CDPH (then DHS) in 1970, amended in 1972 and has not been amended since. This section is outdated and has become a hindrance to licensure of clinical laboratory scientists (CLS). The name of this license category was

changed in 1996 in Senate Bill 113 (Chapter 510, statutes of 1996) from clinical laboratory technologist to CLS. This category of laboratory personnel is the highly-regarded generalist in California who is authorized at B&P Code Section 1204 to perform all high complexity clinical laboratory tests or examinations except cytology and pathology. Currently there are about 17,000 persons licensed as CLS by CDPH.

The regulations have not kept pace with technological and academic program advances. The department has received many requests from the regulated community that these standards be updated. Also, qualified applicants from outside the state cannot be licensed unless they complete coursework that is no longer considered necessary. This has added to the shortage of laboratory personnel in California.

The Clinical Laboratory Technology Advisory Committee (CLTAC) has advised CDPH to amend the licensure requirements for CLSs and has submitted several position papers to assist. CDPH has relied on this input and input from other stakeholders to update these standards. CDPH proposes to repeal the entire Section 1032 for reasons that follow. (See Exhibits 39 and 40)

Repeal of the title

The title, “Examination for Clinical Laboratory Technologist’s License”, is repealed because CDPH no longer administers examinations for licensure purposes and the name of this category of license was changed to CLS in 1996 as explained above.

Repeal of examination requirements

The reference to the department administering “written, oral or practical” examinations is repealed because CDPH no longer administers such examinations for CLS candidates, and only gives oral examinations for doctorate-degree candidates as specified in new Section 1031.12.

Repeal of education requirements

In subsections (a) and (b), the graduation requirements are repealed because there is no alternative given to a required major in clinical laboratory science. Also, subsection (a) specifies that the education requirement may be met if the last year is spent in a clinical laboratory training school, but this would negate completion of the required academic courses.

The specified coursework requirements in subsection (b) are repealed and re-stated in the new Section 1032. The current coursework includes outdated classes, as “instruction in principles of light and electricity” and non-specific classes, as “instruction in immunology”. It shall be replaced with relevant classes offered for CLS students in the new Section 1032.

An alternative to the education requirements that are specified in (a) and (b) is given in subsection (c). This shall also be repealed. This alternative would recognize a minimum of two years of experience as a licensed trainee and 90 semester hours of specified coursework for licensure. The baccalaureate degree is not required if the coursework was completed "after July 1, 1973". This is not acceptable as a baccalaureate degree in science is required in state law for persons performing high complexity testing as a CLS.

(33) Adopt new Section 1032. Licensure of Clinical Laboratory Scientists.

There are currently about 17,000 licensed clinical laboratory scientists (CLS) in California, down from about 27,000 in 1994. In 1994, compulsory continuing education for licensed laboratory personnel was implemented pursuant to B&P Code 1275 and as specified in CDPH regulations at Section 1038.1. This had an impact on the number of licensed CLS. Many CLS had retired, moved out of state or left the laboratory field while retaining licensure. Many of these persons let their licenses lapse rather than complete continuing education. The total number of licensed CLS' started to decline then, and has continued each year since then with about 400 new licenses being issued each year with about 1000 persons not renewing. In addition, there is a national shortage of qualified clinical laboratory scientists. The number of persons licensed now is inadequate for laboratory needs and has led to a severe labor shortage of laboratory personnel in California. The purpose of updating these standards for CLS licensure is to improve access to licensure for qualified, certified persons from outside California, as well as for recent graduates in California.

The purpose of the proposed amendments is to update the requirements, and make them more reasonable and understandable in order to facilitate licensure of qualified applicants.

New section title.

The title of Section 1032 is changed to "Licensure of Clinical Laboratory Scientists." The category of license was named clinical laboratory scientist in 1996 with enactment of Senate Bill 113 (Chapter 510, Statutes of 1996, Maddy).

Application requirements.

The CLS applicant is directed to Section 1031.6 (a) for requirements that must be documented in the application.

Education requirements.

Subsection (a) specifies the education requirements for CLS licensure. A baccalaureate degree or required coursework earned by a military specialist is specified. The college degree must be from an accredited college or university. A graduate of a non-United States college or university which is not accredited by a

United States agency must have his or her education transcripts evaluated as specified at Section 1031.5 (a).

If the baccalaureate degree is in a major in clinical laboratory science or medical technology, no further course requirements are specified. If the degree is a major in chemical, biological or physical science, or coursework credits from the United States military, then specified coursework must be completed, for any major. The coursework specified has been updated. The requirement for “instruction in principles of light and electricity” in the previous Section 1032 is replaced with “physics, mathematics or statistics related to clinical laboratory science”, for example. The chemistry requirement gives the student the option of 16 hours coursework that should include one course of analytical chemistry, instrumental analysis or quantitative analysis and one course of clinical chemistry, biochemistry or organic chemistry. CDPH has specified these courses upon the advice of California colleges and universities which teach students to prepare them for CLS licensure. These courses are available routinely to students and should prepare them well for post-baccalaureate training in clinical laboratory science and licensure, or graduate school.

Training requirements

Training requirements are specified in 1032 (b). At least one year of post-baccalaureate training is required for licensure. Persons training outside California must essentially meet the minimum training requirements specified at Section 1035 (c) and as approved by CDPH. CDPH proposes to repeal the current section 1035 in its entirety and adopt a new section 1035.

Recognition of training by military specialists is specified in Subsection (b). Medical specialists complete basic and advanced training in clinical chemistry, urinalysis, hematology, immunology, immunohematology, and microbiology in conjunction with accredited colleges and universities. Upon completion of coursework and training, they serve in the armed forces as clinical laboratory technicians or medical laboratory specialists. CDPH shall accept two years of training and experience as a military specialist as meeting the training requirement for CLS licensure. (Exhibit 38)

An articulation route for licensed medical laboratory technicians (MLT) to train for CLS licensure is also given in Subsection (b). These persons must have a baccalaureate degree and meet the CLS coursework requirements before admission to this program. An experienced, licensed MLT in California must complete at least six months training in a program approved to train MLTs for CLS licensure by CDPH as specified in Section 1035.5. A person employed as an MLT outside California must meet education and experience requirements before they can articulate their training for CLS licensure in California.

Examination requirements

Subsection (c) states that the CLS applicant for licensure must document satisfactory performance on a certifying examination approved by CDPH for CLS licensure as specified in Section 1031.9. Several CDPH approved examinations are available and the applicant is expected to apply for admission and take the examination at his or her own expense. Ongoing certification by the certifying organization is not required, only satisfactory performance on the examination. Approved certifying organizations electronically notify LFS of those California applicants passing their examinations.

Subsection (d) requires the applicant to take an examination on state and federal clinical laboratory law provided by CDPH. This ten-question examination is provided and graded online at the LFS website as explained in Section 1031.12.

(34) Amend Section 1033. Licensure of Trainees.

The current Section 1033 was enacted by Department of Health Services regulations in 1972 to explain the prerequisites for CLS and clinical laboratory specialist training. Subsection (a) is a reiteration of the old Section 1032. As stated above, this section must be amended to clarify and update the educational requirements. Subsection (b) specifies educational requirements for specialist categories. Additionally, CDPH has proposed new trainee requirements for these categories at the new Sections 1033 (b) and (d).

The current version of Section 1033 is a reiteration of academic requirements given in Section 1032. Both sections are outdated and shall be amended by CDPH. These sections do not explain the workscope, supervision or restricted activities of CLS or clinical laboratory specialist trainees. There is no explanation about how post graduate fellows in California can be licensed to perform clinical laboratory tests or examinations. This impacts post doctoral persons who want to train in California. The sections lack any information on how MLT or postgraduate fellows can train. There is no explanation of how a licensed MLT can articulate to CLS licensure. The lack of clear standards has led to difficulty in evaluating applicants who want to train in California. The purpose of the proposed amendments is to update the requirements, and make them more reasonable and understandable.

CDPH makes these changes based on Laboratory Field Services' 50 years of experience approving training programs for clinical laboratory trainees, input from boards that certify doctorate candidates, input from training programs in California and information from colleges and universities that educate students for clinical laboratory careers. (See Exhibits 3, 9, 10, 11, 12, 13, 14, 16, 24, 25, 28, 29, 30, 33, 34, 35, 37, 38, 39, 40)

Amended section title

The title of Section 1033 is changed from “Trainee Requirements” to “Licensure of Trainees” to more clearly reflect the content of the section.

Amend clinical laboratory technologists (scientists) and limited technologists (scientists) trainee licensure requirements

Subsections (a) and (b) are amended as explained below.

Requirements for medical laboratory technician training licensure

Subsection (a) now is subtitled, “Medical Laboratory Technician Trainee Requirements”. Senate Bill 1809 (Chapter 356, Statutes of 2002) established the medical laboratory technician (MLT) license category in California at B&P Code Section 1260.3 by urgency legislation. CDPH regulations enacted in 2005 implemented licensing standards at Section 1032.5. One oversight in the regulations was the omission of standards for licensure of MLT trainees in California. This has made it difficult for unlicensed persons to train as MLT in licensed clinical laboratories in California because only persons listed in B&P Code Section 1206.5 (b), including licensed trainees, are authorized to perform moderate complexity tests.

Subsection (a) directs the applicant to Section 1031.5 (c) for trainee application requirements, Section 1032.5 for education requirements, and Section 1035.3 for training standards. This section also specifies the type and complexity of tests an MLT trainee is authorized to perform and the supervision required. The proposed 1033 (a) states that all tests performed by a licensed MLT trainee during his or her training must be critically reviewed by a licensed person who is responsible for the accuracy of the results.

Requirements for clinical laboratory scientists training licensure

Subsection (b) of Section 1033 is now subtitled, “Clinical Laboratory Scientist Trainee Requirements.” This section clarifies the licensing requirements for CLS trainees. These persons are directed to Section 1031.6 (c) for application requirements, Section 1031 (a) for educational requirements, and Section 1035 for training standards. The specialties and complexities that a licensed CLS trainee is authorized to perform is listed, as well as their supervision required during training. This training includes all levels of complexity testing in histocompatibility, microbiology, immunology, chemistry, hematology, immunohematology and genetics. This section also states that all test results performed by a licensed CLS trainee during his or her training must be critically reviewed by a licensed person who is responsible for the accuracy of the results obtained during training.

Requirements for MLTs training for CLS licensure

Subsection (c) of Section 1033 is subtitled, "Requirements for Clinical Laboratory Scientist Training by Medical Laboratory Technicians." This section explains an articulation route for experienced, licensed MLT to train for CLS licensure. Such an option has been requested by persons employed as MLTs outside California who have baccalaureate degrees and want to be licensed in California as CLSs. For MLT training, Section 1035.3 (b) requires at least 26 weeks of instruction and practical experience in moderate complexity testing in chemistry, hematology, microbiology and immunology. An MLT is not authorized to train or perform testing in other specialties authorized for a CLS, or high complexity testing in any specialty. Therefore, an articulation route for CLS licensure by an MLT would have to include training in all the tests not included in MLT training.

CDPH proposes to make such an articulation route possible in California for experienced, licensed MLTs. An experienced MLT is one who has at least three years of employment as an MLT within the past five years, either in California or in an equivalent class outside the state. A training program would have to structure a modified CLS program which would focus on training that was lacking in an MLT training program. This modified program would have to be reviewed for compliance with standards at Section 1035.5 and approved by CDPH. The minimum length of training for the articulation route would be six months, but additional time may be needed. The licensee would be authorized to train in all the types and complexity of specialties authorized for a CLS trainee. However, he or she would not have to repeat the training received for MLT licensure. Section 1033 (c) also states that all test results performed by a licensed CLS trainee during his or her training must be critically reviewed by a licensed person who is responsible for the accuracy of the results obtained during training.

Requirements for clinical laboratory specialist training licensure

Subsection (d) of Section 1033 is subtitled "Clinical Laboratory Specialist Trainee Requirements". These licensed trainees are authorized to train for 12 months in high complexity testing in one of these specialties: histocompatibility, microbiology, chemistry, toxicology, hematology, immunohematology, cytogenetics, genetic molecular biology or cytology. CDPH currently licenses baccalaureate-degree persons in these specialties and they are designated clinical histocompatibility scientists or clinical microbiologist scientists and so on. These trainees are also authorized to train in waived and moderate complexity testing in other specialties. Applicants are directed to Section 1031.6 (c) for application requirements and Section 1035 for education requirements. During training, all test results performed by a licensed trainee during his or her training must be critically reviewed by a licensed person who is responsible for the accuracy of the results obtained during training.

Requirements for postgraduate fellow training licensure

Subsection (e) of Section 1033 is subtitled, "Postgraduate Fellow Training Requirements". This section specifies a new license category, the postgraduate fellow. It has been difficult or impossible for postgraduates to train in California as they lacked licensure and are not authorized in B&P Code Section 1206.5 (c) to perform high complexity testing. Creation of this new license category shall recognize postgraduate scientists and authorize them to perform tests and examinations during training.

An applicant for postgraduate fellow license must have completed a masters or doctorate degree in science related to his or her specialty as specified in Section 1030.1 – 1030.7 prior to training. Section 1033 (e) directs the candidate to application requirements at Section 1031.5 and postgraduate training program requirements at Section 1035.2.

A licensed postgraduate fellow is authorized to train for four years in his or her specialty in California in order to meet licensure requirements. The first two years of training must be in a program approved by CDPH and acceptable to an approved national certification board in the specialty. During this time all test results performed by the postgraduate fellow must be critically reviewed by the program director as designated by the laboratory director before release. After completion of two years of training and successful passing of the certification examination, the postgraduate fellow shall be authorized to continue testing and start supervising tests in his or her specialty to gain two more years of experience, under the general supervision of the program director as designated by the laboratory director. During this time the licensed postgraduate fellow may release test results when he or she has demonstrated competency to do so by the program director. Upon completion of four years of training and experience, the postgraduate fellow shall have met training and experience requirements for licensure as a doctorate scientist.

In order to facilitate licensure of masters- or doctorate-degree candidates for licensure, CDPH shall accept applications for licensure within six months of completion of the fourth year of training and experience. A state-administered oral examination on state and federal laboratory law shall be scheduled during the last three months, allowing the candidate to complete all license requirements when training is completed. This is proposed to eliminate a delay in licensure upon completion of four years of training.

(35) Amend Section 1034. Certification of phlebotomy technicians.

The Migden legislation (AB 1557, Chapter 695, Statutes of 1999) required Department of Health Services at B&P Code Section 1246 to enact certification standards for phlebotomists. These standards were implemented in April 2003. The program has continued to expand and as of March 2010 about 39,000 persons have been certified in phlebotomy by these standards.

CDPH proposes to make three amendments to Section 1034 because of unanticipated problems and a need for clarification of the current standards. One problem deals with the requirement that phlebotomists post their certificates at their workplace. The second amendment is necessary at Section 1034 (a) (5) to specify that the Certified Phlebotomy Technician II (Two) have recent experience in arterial punctures. The third amendment shall move the explanation about the length of certification for phlebotomists from Section 1031.5 (e) to its more logical location at Section 1034 (c).

Posting of phlebotomist certificates

Certified phlebotomists are often assigned to multiple patient service centers by an employer, or to home blood collections at various sites. Subsections (b)(1)(E), (b)(2)(E) and (b)(3)(E) of Section 1034 require phlebotomists to post their certificates at their worksite; however, many have multiple worksites. This has required phlebotomists to pay for duplicate certificates so they can post them at each additional work site. CDPH had thought issuance of cards would authenticate certification, but posting of certificates is expected similar to that of licensed personnel.

It has been difficult for CDPH to ameliorate this situation as photocopying of licensing certificates is prohibited at B&P Code Section 119. LFS has informed laboratories that phlebotomy certificates must be posted at the main location. However, patients want to make sure their phlebotomist is certified and often want to see the certificate posted at the blood collection site. Therefore, CDPH is proposing that phlebotomists may photocopy an official certificate if the copies are clearly marked as “copy” in such a manner that it could not be mistaken for a valid certificate. The official certificate must be posted at the primary location of the same employer. If a phlebotomist has two employers, then he or she must purchase duplicate certificates for posting for each employer. LFS discussed this issue with its advisory committee who strongly urged CDPH to issue cards that could be carried with the phlebotomist to multiple sites. This may be possible, but still CDPH is adhering to the requirement that a phlebotomist's certificate be posted where it is visible to persons having their blood drawn. Posting a copy labeled with the location of the official certification will reassure patients.

It should also be noted that many laboratories issue identification cards to their employees, including phlebotomists, to identify them while they work.

Experience in arterial punctures

Arterial punctures may cause harm to a patient if performed incorrectly. The second change to Section 1034 shall add the requirement that experience in arterial punctures be completed within the previous five years to ensure competency. This section requires that the phlebotomist be personally observed by a physician or other qualified person to ensure current competency before drawing arterial blood from patients.

Two-year certification of phlebotomists

The third change to Section 1034 shall add Subsection (c), "Certification of phlebotomists shall be valid for 2 years unless revoked." This statement shall be moved from Section 1031.5 (e) where it was incorrectly placed. Laboratory Field Services has had to take revocation action on several phlebotomy certificants, and has denied dozens of applicants with criminal convictions.

(36) Amend Section 1035. Training Schools.

Section 1035, entitled "Training Schools", shall be amended to clarify training school requirements. Section 1035 enacted in 1957 is outdated and has been updated to recognize technological advancement in the laboratory.

Lack of clarity about requirements for training

Subsection (a) requires "such information as may be required" for approval of a training program. Subsection (b) asks that training "fully qualify individuals" to meet requirements, but does not specify the requirements. Subsection (c) mentions "appropriate laboratory specialty" without explanation. Subsection (e) requires "adequate space" as defined by the department, but this is not defined.

Outdated training and education requirements

Trainees are required in Subsection (e) to train in established techniques such as tests for sedimentation rates, for protozoa and serological tests, but newer technologies are not mentioned. Training timelines are inappropriate as 4 weeks training is required in both urinalysis and serology, and only 4 weeks in immunohematology (blood typing and compatibility testing). Updated education and training requirements in the new Section 1035 has incorporated input from California universities and the CDPH advisory committee, the Clinical Laboratory Technology Advisory Committee (CLTAC).

Retention of some current standards

Certain current standards shall be retained, upon the advice of the CLTAC. The ratio of licensed laboratory persons to licensed trainee of 2 to 1 in the current standards shall be retained. Minimum training weeks in each specialty shall be amended. CDPH shall continue to require names and addresses of persons training and shall retain authority to rescind approval of training for failure to meet training requirements.

(37) Adopt new Section 1035. Clinical Laboratory Scientist and Specialist Training Programs.

CDPH proposes to adopt a new Section 1035 to clarify the requirements a program must meet to be approved to train baccalaureate-degree CLS or clinical laboratory specialists (CL Specialists). Many activities in a laboratory are the same for all licensed

persons, such as quality control and quality assurance, proficiency testing, test calibrations, test validations and safety. Other activities are unique to the specialty, such as high complexity testing using specialized equipment and techniques. These differences are reflected in the didactic curriculum and practical training that is submitted for approval by CDPH.

Types of acceptable training programs

In order to be approved to train CLS or CL Specialists, the training program must be one of four types: (1) A program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) which also meets California requirements; (2) A clinical laboratory that is CLIA-certified in the appropriate specialties; (3) An accredited college or university program that has affiliated clinical laboratories; (4) A full year military specialist program. It is required that the practical training undertaken by students shall be obtained in a clinical laboratory with appropriate equipment and reagents performing diagnostic testing on actual patients.

Training program requirements

The director of the training program must be a licensed physician, licensed doctorate scientist, licensed bioanalyst, licensed CLS or licensed CL specialist. The program director is responsible for the quality and content of the program as specified in Section 1035 (b). The director must hire qualified instructors, assure adequacy of the training period, and maintain a staffing ratio of two licensed personnel for every one trainee. The students must be trained in phlebotomy and other pre- and post-analytical activities. Their training in waived, moderate and high complexity testing must include training in instrumentation and information technology; as well as experience in problem solving and trouble shooting. The director must assure that student records are maintained for at least 5 years.

Training timelines

Subsection (c) gives the minimum weeks of practical and didactic instruction required in each specialty and subspecialty for CLSs. It is required that a full year of training will include a minimum of 48 weeks. The training program can specify the time spent in either practical or didactic, but a minimum of 4 weeks of practical experience in microbiology, chemistry, immunohematology and hematology each is required. Other disciplines, as phlebotomy, histocompatibility, cytogenetics, and genetic molecular biology shall require a minimum of 8 weeks practical experience or observation. Approval to train requires documentation of didactic curriculum that supports the training, and includes, but is not limited to, time spent in each specialty, techniques taught, instructor qualifications and learning objectives.

Subsection (d) similarly requires a minimum of 48 weeks training for CL specialists. This practical and didactic training shall be in specialties and subspecialties related to the license category. This section lists all the specialty areas that a trainee would be

expected to experience in those 48 weeks. Any training program approved to train specialists shall make comprehensive training in the specialty available to the trainee. In addition, the training program shall provide the opportunity for the trainee either to perform or observe waived and moderate complexity testing in other specialties pursuant to Business and Professions Code Section 1210.

Termination of training

Subsection (e) specifies that the training program director is required to notify CDPH within 30 calendar days if a trainee terminates the program prior to completion or if the trainee needs to extend his or her training for remedial or health reasons.

Application requirements

Application requirements are listed in Subsection (f). These documents are required to show compliance with training standards including qualifications of the program director and instructors, time spent in each specialty, practical training objectives, instrumentation and training resources available, and time spent on didactic instruction.

Approval timeframe and renewal of approval

Subsection (g) states that an approved training program is approved for five years. The approval period of an approved NAACLS program, as specified at Section 1029.200, shall be consistent with its NAACLS accreditation, but shall not exceed seven years. Subsection (h) requires a training program applying for renewal of its approval to apply at least 60 calendar days prior to the end of its approval period. The program must provide information about the number of students who have successfully completed the program and any changes anticipated in the program curriculum.

Revocation of program approval

Subsection (i) states that once a training program is approved, it may be subject to onsite verification that it complies with stated standards when approved. Failure to comply may result in suspension or revocation of approval.

Certificate of completion

An approved training program is required in Subsection (j) to provide a certificate of completion, signed by the program director, attesting to satisfactory completion of the training program. This shall be used by the candidate for licensure to document completion of required training.

Maintenance of training records

Subsection (k) requires an approved training program to maintain records of its students for at least five years and to make these records available to CDPH as needed to verify training.

(38) Amend Section 1035.1. Phlebotomy Training Program Requirements.

Standards to approve phlebotomy training programs were enacted at Section 1035.1 in 2003 by emergency filing. Using these standards, about 120 phlebotomy training programs have been approved in California to date and over 34,000 persons have been certified, most of whom have attended one of these training programs. The training specified in this section is comprised of didactic and practical instruction. Training taken at unapproved programs inside or outside California cannot be used to meet certification requirements for phlebotomists in California. Phlebotomists from outside California must repeat at least the minimal didactic instruction in order to be certified.

Two unanticipated problems have arisen with these standards, and CDPH proposes to make amendments to correct these.

Section 1035.1 (c) specifies who can provide instruction in an approved program. These include a licensed physician, physician assistant, registered nurse, person licensed under B&P Code Chapter 3 (as a CLS or bioanalyst), a respiratory care practitioner or an experienced certified phlebotomy technician (CPT). In specifying what experience the phlebotomy training instructor must have, CDPH requires 3 years of experience in the last 5 years. When the standards were implemented in 2003 instructors were required to be California certified CPTs. The requirement for California certification prevents experienced nationally certified phlebotomists within and outside of the state from qualifying as an instructor in California. Existing law requires that they obtain additional training and become certified as a California CPT. Therefore CDPH proposes to broaden the instructor pool by authorizing phlebotomists who are certified by an national certifying organization, whose examination is approved by CDPH, to qualify as instructors. In addition they must have at least 3 years experience in the previous 5 years. This experience may be practical experience performing phlebotomy or teaching experience in phlebotomy, or both.

CDPH shall also amend the allowance at Section 1035.1 (c) for a person without phlebotomy certification to be an instructor if he or she was employed as an instructor on or before December 31, 2003. This grandfather provision was enacted by Department of Health Services in 2003 to allow instructors to work until they had the opportunity to be certified. This provision was subject to sunset in 2003 and shall be removed.

Also, Section 1035.1(d), implemented in 2003, requires all instructors to pass a written certifying examination in phlebotomy before they could instruct other phlebotomists. While this is reasonable for phlebotomists teaching phlebotomy, it is unreasonable for

physicians who may be teaching anatomy of the circulatory system or clinical laboratory scientists lecturing on safety precautions. CDPH proposes to repeal this subsection (d).

(39) Adopt new Section 1035.2. Postgraduate Fellow Training Program Requirements.

Standards enacted at Section 1035 in 1971 specified training required for licensure of clinical laboratory technologists (now, clinical laboratory scientists). Section 1030.5, also enacted in 1971, specified training of “three years of experience in his or her specialty” for masters or doctorate-degree scientists. The details of this training or experience were not explained, and it has been very difficult for doctorate candidates to train in California. No trainee licenses are available for doctorate-degree trainees, only baccalaureate-degree. Doctorate scientists seeking to train in California are obligated to obtain a lower baccalaureate-degree scientist license in order to work and gain four years of experience in California.

Federal CLIA standards enacted in 1994 required a laboratory director to have an MD or PhD degree, four years of training and experience, and board certification. (Note that federal law also allowed some grandfather provisions, not relevant here.) This made the three-year requirement at Section 1030.5 inconsistent with federal standards. Doctorate-degree persons completing three years of experience would not meet federal requirements to direct a laboratory. CDPH enacted regulations later in 2000 that specified the four year training requirement for doctorate-degree cytogeneticists and genetic molecular biologists at Sections 1030.6 and 1030.7. However, without the postgraduate fellow license, these persons also lacked a route to train in California.

CDPH currently lacks standards to allow doctorate degree license candidates to train in California. Such candidates have been obligated to obtain a lower level, baccalaureate degree license in order to be employed and gain necessary experience for doctorate licensure. This has made it easier for doctorate applicants to train outside the state and country rather than in California. Academic centers in California have trained postdoctoral students who achieve board certification but are ineligible for licensure here because they did not train in an approved training program as required at B&P Code 1286. It is imperative that clear standards be enacted for approval of training programs for postgraduate fellows so they can train and gain experience in California in order to qualify for licensure.

CDPH is enacting important new standards to facilitate licensure of doctorate scientists. Section 1033 (e) specifies requirements for a person to train as a licensed postgraduate fellow. Qualified postgraduate fellows would be licensed and able to train and gain experience while working as testing personnel, technical supervisors and clinical consultants.

Section 1035.2 is a companion to Section 1033 (e) in that it sets standards for approval of training programs that train postgraduate fellows for licensure in California. The training program requirements are similar to those for baccalaureate-degree training.

However, standards are specified that would better accommodate training not only in California, but also outside California in the United States or outside the United States. Many qualified doctorate scientists are currently training outside California, but seek employment in our State. The purpose of these standards in Section 1035.2 is to set certain basic requirements for approval of postgraduate training programs while giving them flexibility to set up their own training plan within a specialty.

Section 1035.2 shall broaden training to include that obtained outside California or outside the United States in a non CLIA-certified laboratory. Current requirements specify training in a CLIA-certified laboratory which generally excludes foreign applicants. This section also allows the training program flexibility to design a training plan that is consistent with board certification requirements and program specialties. Most importantly, Section 1035.2 changes the workscope and supervision requirements for postgraduate fellows after they complete two years of training and pass an approved national certification examination. Although still considered a postgraduate fellow, these board-certified persons do not require direct and responsible supervision and can assume expanded responsibilities in the laboratory until fully licensed.

Training program requirements

Subsection 1035.2 (a)(1) requires an approved training program to perform high complexity tests and examinations appropriate to the specialty or subspecialty of testing for training. To assure the quality of testing at the laboratory, it must be state licensed if in California, CLIA-certified if in the United States, or have other accreditation if located outside the United States. Laboratories in the United States are required by federal law to be CLIA-certified, while laboratories outside the United States are not unless they test specimens originating from the United States. An alternate accreditation chosen by many laboratories in Europe, Asia and South America is that issued by the International Laboratory Accreditation Cooperation (ILAC). The ILAC itself meets high accreditation standards as explained at Section 1031.10 and CDPH would also approve a laboratory accredited outside the United States by these standards. The purpose of approving ILAC or other accreditations is to afford an opportunity for qualified candidates who train outside the United States to gain licensure in California. (See Exhibits 20, 21, 22)

The laboratory at which the postgraduate fellow trains would be expected to have available resources for practical training. It should have equipment, reagents, developed tests, and reference materials in the specialty of testing. The postgraduate fellow should be able to perform diagnostic tests, review results, review quality control data, carry out quality assurance procedures, participate in problem solving, supervise other testing personnel and interact with ordering physicians. It is expected that the laboratory experience should allow the fellow to gain practical experience that would enable him or her to take full responsibility as technical supervisor or director of a laboratory when licensed as a doctorate scientist.

Training program director

An approved training program for postgraduate fellows must have a responsible training program director who is either a licensed physician and surgeon or licensed doctorate scientist. Programs outside the United States would be required to have similarly qualified directors. The program director is responsible for the content, quality and conduct of training.

Training plan

In order to afford flexibility of training, Section 1035.2 allows the training director to devise a training plan at his or her laboratory for postgraduate fellows. This should be prepared for each postgraduate fellow within 30 days of initiation of training in California. The training plan should include all the details of the two or four year training, including dates initiated and completed, rotation schedule, training objectives and measures used to assess adequacy of training. The plan should include instrumentation, technology, staffing and instruction. If a postgraduate fellow trains at more than one location, then a training plan is required for each location. If a postgraduate fellow were to change training locations to another program, then another training plan must be submitted to LFS within 30 days of transfer if the training is performed in California. If the training is done outside California, then a training plan for work conducted for four years must be submitted by the program director on behalf of the applicant.

Alteration of training plan

If a postgraduate fellow were to terminate his or her program before completion, or require a longer time to complete his or her training, Section 1035.2 requires the program director to notify LFS within 30 days. A person who has not completed the full four years of training or experience would not meet licensure requirements. A person who has completed four years of training could not continue employment as a licensed trainee and would be expected to complete licensure requirements.

Training acceptable to certification board

Section 1035.2 requires postgraduate training, obtained in California or outside, to be acceptable for admission to a national certification board in the United States. The program would be expected to design their program to comply with certification standards. (See Exhibits 1, 3, 7, 12, 33, 37)

First two years of postgraduate training

State law incorporated federal CLIA law in effect on January 1, 1994 with implementation of SB 113 (Chapter 510, Statutes of 1996) in 1996. This federal law requires a doctorate scientist to be licensed, if required by a state, before he or she can serve as laboratory director or technical supervisor in that state. State law at B&P Code

Section 1264 requires doctorate scientists to have four years of training and experience, two years at the supervisory degree, prior to licensure. Many national certification boards only require two years of postdoctoral training before a candidate may sit for, and pass, a national certification examination. Persons with a doctorate degree and board certification are allowed to serve as technical supervisor in other states, and CDPH shall provide such an option for licensed postgraduate fellows in California.

During the first two years of postgraduate training, Section 1035.2 (b) specifies that the laboratory director or program director must provide direct and responsible supervision to the fellow. Direct and responsible supervision is defined at B&P Code Section 1206 (a)(14) as, in part, "personal observation and critical evaluation of the activity of a trainee", and "personal review....of all results of clinical laboratory testing...for accuracy, reliability and validity before the results are reported from the laboratory." Critical review is further defined at Section 1029.215. All test results performed by licensed trainees must be critically reviewed before release as specified in B&P 1209 and these regulations.

During the first two years a postgraduate fellow trains in California, the laboratory director or qualified designee is responsible for verifying the accuracy and reliability of test results performed by the postgraduate fellow. At the end of the first two years, the postgraduate fellow may opt to take a national certification examination approved by CDPH in his or her specialty.

Second two years of postgraduate experience

A postgraduate fellow who completes two years of training in an approved training program in California and who passes a national certification examination in his or her specialty may continue gaining experience as a postgraduate fellow for two more years. However, during the second two year period, the postgraduate fellow who passes a national certification examination approved by CDPH may perform and report tests and examinations. He or she may serve as technical supervisor, technical consultant, general supervisor or clinical consultant under the direction of the laboratory director. At the completion of four years of training and experience, the postgraduate fellow would meet education, training, experience and written examination requirements for licensure. He or she would be required to sit for an oral examination on state clinical laboratory law as specified in Section 1031.12, to complete licensure requirements.

If a postgraduate fellow who completes two years of training in an approved training program does not pass a national certification examination in his or her specialty, the fellow would still be subject to direct and responsible supervision by the laboratory director or training program director. After the licensed postgraduate fellow successfully passes a national certification examination approved by CDPH, he or she may perform other duties such as General Supervisor, Technical Consultant, Technical Supervisor, Clinical Consultant and testing personnel for the remainder of the four years in California.

LFS shall not specify specific training requirements for postgraduate fellows, but shall allow programs flexibility to submit a training plan for approval as specified in Section 1035.2. This plan must be prepared for each fellow and submitted within 30 days after initiation of training. Also, since LFS receives many applications for licensure from persons who have trained outside California or outside the United States, CDPH is proposing these standards to facilitate documentation from doctorate scientists seeking licensure and employment in California.

(40) Amend Section 1035.3. Medical Laboratory Technician Training Programs.

Licensure of MLTs in California was implemented in 2005 with CDPH regulations following public demand for licensure of a category that did not require a baccalaureate degree. Section 1035.3 sets standards for training medical laboratory technicians (MLTs). CDPH is proposing amendments to clarify these regulations.

Approval of NAACLS-accredited MLT training programs

The CDPH advisory committee, the Clinical Laboratory Technology Advisory Committee (CLTAC), and the regulated community have urged acceptance of MLT training obtained at a program approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). Many MLT training programs outside California are NAACLS accredited, and approval of such programs would facilitate licensure of candidates from outside California. CDPH has added an NAACLS-accredited MLT training program to those acceptable for licensure. These programs, however, must meet other requirements for approval, such as director, instructors and content and length of training. Section 1029.200 is added to define a CDPH approved NAACLS approved training program, to clarify this issue. (See Exhibit 34)

Practical experience during training

Practical experience is defined at Section 1029.134. It is important that an MLT gain practical experience during training, so CDPH is specifying that instructors assure this is provided at Section 1035.3 (b)(1).

Ratio of MLT trainees to baccalaureate-degree licensed persons

Programs that train CLS and CL specialists are required to maintain a ratio of two baccalaureate-degree licensed persons for every one trainee (Section 1035). Such a ratio was not originally specified in Section 1035.3. CDPH is amending this section to specify a ratio of no more than four MLT trainees to one baccalaureate-degree licensed person during training.

(41) Adopt new Section 1035.5. Training Programs for Medical Laboratory Technicians Articulating to Clinical Laboratory Scientist Licensure.

Part of the justification for licensure of Medical Laboratory Technicians (MLTs) in 2002 (Senate Bill 1809, Machado, Chapter 356, Statutes of 2002) was creation of a career ladder in the clinical laboratory for MLTs. As MLTs gain more education and job experience, they would be encouraged to seek licensure as Clinical Laboratory Scientists (CLS). However, CLS licensure requires 12 months training. CDPH, at the urging of its advisory committee, was asked to develop standards for a training program that would recognize the six months training already completed. A training program would be able to “fill in the gaps” for training needed for CLS licensure.

These standards reflect the requirements for approval of a program to train a CLS, but make important differences. A training program for MLTs articulating to CLS licensure would be specially designed to allow training in those areas not experienced by MLTs, such as high complexity tests in all specialties, including immunohematology and genetics. Without these standards, an experienced MLT wishing to articulate to CLS licensure would have to complete an entire 12 months training program, repeating much of the training already received.

MLT licensure requires the equivalent of an associate degree in science and 6 months approved training in clinical laboratory science. CLS licensure, on the other hand, requires a baccalaureate degree in science and one year of approved training. The workscope of an MLT is limited to waived and moderate complexity testing and no microscopic tests or tests in immunohematology. A CLS is authorized to perform waived, moderate and high complexity in all specialties except cytology and pathology. Therefore, a licensed CLS has many more employment opportunities than a licensed MLT.

Many persons working in clinical laboratories as unlicensed persons possess a baccalaureate degree or higher. Similarly, persons employed as MLTs outside California have the appropriate education, but lack clinical training needed for licensure. At the request of the department's advisory committee, LFS has developed standards that would allow an experienced MLT to articulate to licensure as a CLS by completing the training not included in their MLT training.

The training standards for CLS licensure are stated at Section 1035 and for MLT licensure, at Section 1035.3. An MLT would not be expected to repeat training already completed as an MLT trainee, that is, waived and moderate complexity testing in chemistry, hematology, microbiology and immunology. He or she would need to train in high complexity tests in these specialties, plus waived, moderate and high complexity tests in the other specialties, immunohematology, histocompatibility and genetics. A training program would have to design a curriculum that would allow an MLT to complete the missing training components for CLS licensure. Although this would require planning and coordination by a training program, the advantage would be shorter time to train MLTs for CLS licensure.

Section 1033 (c) specifies that in order to qualify for CLS training, an MLT applicant must document at least three years of experience in the previous five years as a licensed MLT in California or if employed outside California, that same experience as an MLT with equivalent licensure or certification outside the state. This shall ensure that only experienced MLTs are authorized to expand their training for CLS licensure.

Section 1035.5 specifies the requirements for approval of a training program that would allow MLTs to articulate to CLS licensure. Many of the requirements are similar to those that train CLS students, as described in Training Program Requirements.

Training program requirements

An approved training program must either be a clinical laboratory that possesses a state license and CLIA certificate for performing moderate and high complexity tests and examinations in all specialties, or an accredited college or university affiliated with such a laboratory.

An approved training program must have a program director who is responsible for the content, quality and conduct of the training and must employ qualified instructors.

The minimum length of the training program is 26 weeks, half a year, which includes at least 1040 hours of instruction, practical training and observation of tests in all specialties, especially those not learned during MLT training. This training should emphasize high complexity tests in all specialties, including practical experience in analytical techniques, quality control, quality assurance, test verifications, safety, universal precautions, information technology, and regulatory requirements. Upon successful completion of this abbreviated program, the student shall be considered to have met all training requirements for CLS licensure. He or she would be issued a certificate of completion showing name of program, training dates and a statement of satisfactory completion. This would be used to document completion of training for licensure.

Approval to train MLTs articulating to CLS licensure shall be granted for five years. Renewal of approval is due at least 60 days prior to end of the approval date.

(42) Amend Section 1036. Clinical consultant.

Section 1036 was enacted by emergency filing in 2000. This section, along with Sections 1036.1 to 1036.4, incorporated federal supervisor categories into state law, explaining their qualifications and work scopes.

Federal law, at Title 42 Code of Federal Regulations 493.1455 states, in part, "The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care." Section 1036 (c) states in California a clinical consultant provides consultation,

assists in test ordering, ensures test results have an interpretation and communicates test interpretations relative to patient conditions.

Section 1036 explains the qualifications of a clinical consultant in a laboratory performing high complexity tests and examinations. A clinical consultant must possess a valid license issued under Business and Professions Code Chapter 3 to direct a clinical laboratory or possess a valid license issued under Business and Professions Code Chapter 5 to practice medicine, osteopathy or podiatry. To serve as a clinical consultant, a person must also comply with federal law which requires postdoctoral training and board certification (42CFR 493.1443 (b)). CDPH shall amend Section 1036 to specify that a licensed postgraduate fellow who has completed at least two years of postgraduate training and who has successfully passed an approved national certification examination can serve as a clinical consultant in his or her specialty in a licensed clinical laboratory under the operation and administration of a qualified laboratory director.

Section 1036 is amended to authorize a person who possesses a current, valid license as a postgraduate fellow and who has successfully passed an approved national certification examination to serve as clinical consultant during his or her third and fourth year of experience in California. Similarly, a person who has completed two years of postgraduate training in an approved program outside California and who has passed his or her board certification can be licensed as a postgraduate fellow and serve as clinical consultant for two years while the four year training requirement is completed.

Currently postgraduate trainees must work in California for four years before they are authorized to participate in laboratory operations. This amendment shall authorize board certified doctorate scientists who have completed two years of postdoctoral training to serve as clinical consultants during their third and fourth years of working in California.

(43) Amend Section 1036.1. General Supervisor.

Section 1036.1 was enacted with emergency filing in 2000 to incorporate the federal general supervisor requirements into state law. Title 42 Code of Federal Regulations Section 493.1463 states, "The general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results." Section 1036.1 requires a general supervisor to have a current, valid license issued pursuant to Business and Professions Code Chapter 3 or Chapter 5, and two years of experience.

An unexpected problem has arisen since Section 1036.1 was enacted in 2000. Subsections (b)(1) and (2) require that the person be licensed in the specialty which they are supervising and have testing experience in that specialty. This is unnecessarily restrictive since the laboratory is required to have a technical consultant or technical supervisor who provides expertise in the specialties. CDPH shall amend

this section to remove the requirement that general supervisors be licensed and experienced in all specialties that they supervise.

(44) Amend Section 1038.1. Continuing Education Requirements.

Section 1038.1 was enacted in 1994 when CDPH (then DHS) implemented continuing education requirements for all persons licensed under Business and Professions Code Chapter 3 as mandated in B&P Code Section 1275. At that time all licenses were issued annually and 12 hours of continuing education credits were required each year. However, in 2007, CDPH implemented a transition to biennial licenses issued on a person's birthday. A person issued a two-year license is required to provide evidence of completing 24 hours of continuing education. Implementation of staggered, biennial personnel licenses has made Section 1038.1 outdated, and CDPH has made appropriate amendments.

Licensing timeframes

References to calendar year are changed to a "12-month period" and 24-month period is added.

Continuing education requirements

During the transition, some licensees have been issued a 12-month license, so these persons are required to show completion of 12 hours of continuing education. Others who have a 24-month license (after 2009 only biennial licenses shall be issued) are required to document completion of 24 hours of continuing education.

Section 1038.1 has been updated to remove the reference to licensure by calendar year, and add the requirement for 24 hours of continuing education for a biennial license renewal.

(45) Amend Section 1038.6. Inactive Status.

Section 1038.1 specifies that the license of a person who does not complete his or her continuing education requirement shall be put on inactive status. A person is allowed to maintain an inactive license for five years during which time he or she cannot work as a licensed person. At the end of five years, an inactive license becomes forfeited pursuant to Business and Professions Code Section 1301, and the person must reapply for licensure.

Administration Section 1038.1 has been difficult for LFS since implementation of biennial licenses. Persons are confused as to how many continuing education hours are required for reinstatement of their license. Amendments are made to specify that 24 hours of continuing education are required during the 24 month period prior to reinstatement or before the end of the fifth year of inactive status. Persons who do not complete continuing education prior to that time cannot reinstate their licenses.

Amendments are made to Section 1038.1 to specify that the inactive licensee must complete 24 hours of continuing education during the 24 months prior to reinstatement of his or her license.

(46) Amend Section 1039.2. Clinical Laboratory Personnel Requirements.

Section 1039.2 was enacted by emergency filing in 1996 by CDPH (then DHS). Senate Bill 113 (Chapter 510, Statutes of 1996, Maddy) was enacted that year which required laboratories outside California testing specimens originating from California to meet California licensure requirements. In order to be licensed then, all persons directing, supervising and performing tests would also have to be state licensed, and this would have been impossible. Department regulations at Section 1039.2 enacted in 1996 have been used to qualify persons outside California. Such persons must “substantially meet” California licensure requirements by documenting their inclusion, licensure or certification “in a class of personnel similar to those required in Chapter 3 or requiring equivalent standards.”

“Substantially meet” means the person meets education, training and examination requirements for licensure in California even if they are not licensed in California and work in a state that does not require licensure. Many states rely on board certification and national certifying boards to set their own education and training requirements. Most national boards require a person performing high complexity testing to have a baccalaureate degree and one year of approved training for admission to their certification examination. Similarly, physicians and doctorate scientists must meet education and training requirements, and have board certification in order to meet federal requirements. The term “substantially meet” shall continue in this section.

Additionally, Laboratory Field Services receives many requests for licensure of persons who train outside California or outside the United States. These persons often seek to use work experience gained outside California to meet experience requirements for licensure as a doctorate scientist or laboratory director. CDPH wants to facilitate the ability of qualified applicants to document that, while they were performing these duties outside California, they met qualifications in a class similar to which they are seeking licensure. This provision has been added to Section 1039.2.

Amendments are proposed to Section 1039.2 which shall clarify how experience gained outside California can be used to meet state licensure requirements, particularly for doctorate scientists. The experience must be gained performing duties that a licensed person would do in California. Approval would not be given for research, new product development, forensic or non-diagnostic testing, for example. The work experience must include the duties that a class of personnel for which they are seeking licensure would be expected to perform.

(47) Repeal Section 1060. Definitions: Cytotechnologist Licensure.

Assembly Bill 32 (Chapter 927, Statutes of 1989, Tanner) required licensure of cytotechnologists, limited their workload and required competency testing. This added language to B&P Code Sections 1270, 1270.5 and 1271. In response to this legislation, CDPH (then DHS) enacted emergency regulations at Sections 1060-1062 in 1993 to explain how the legislation would be carried out. Laboratory Field Services started licensing cytotechnologists at that time and currently licenses about 1300 persons in and outside California.

The standards set for cytotechnologists at Sections 1060-1062 include requirements in addition to those specified for other license categories. Some of the standards were found to be difficult or impossible to implement. CDPH shall repeal these sections. The amended cytotechnologist licensing standards shall be specified in a new Section 1031.4.

Section 1060 shall be repealed in its entirety. Section 1060 gives definitions used in Sections 1061 and 1062. These three sections shall be repealed.

“Competency testing service or program” is defined as an organization approved by CDPH for administering cytotechnology competency examinations. CDPH submitted Request for Proposals for a contracted competency testing service or program, but no viable proposals were received. Currently three competency testing programs are approved by the Center for Medicare & Medicaid Services (CMS) for testing competency of cytotechnologists and cytopathologists. (See Exhibits 18 and 19)

“Cytotechnologist competency examination” is defined in great detail, and includes testing in both gynecological (Pap tests) and non-gynecological cytology. Competency examinations measure the ability of a person to obtain an accurate result.

“Entry level skills” explains the skills a cytotechnologist is expected to have when applying for licensure. These skills include experience in technical, administrative, instructional and supervisory activities.

“Examinee” is defined as an applicant who has a baccalaureate degree with specified coursework and either 12 months training in an accredited program or five years of fulltime experience performing the duties of a cytotechnologist. CDPH shall retain the requirement that an applicant for cytotechnologist licensure must have a baccalaureate degree and 12 months approved training in the new Section 1031.4.

“Evidence of satisfactory performance” is a document that either attests to a cytotechnologist’s passing a competency examination or a certification examination administered by the American Society for Clinical Pathologists.

“Satisfactory performance” and “passing score” are defined as indicators of performance as determined by competency or certifying organizations approved by the department.

“Owner” is defined to explain the responsible entity that would be approved as a cytotechnologist competency testing service.

(48) Repeal Section 1061. Cytotechnology Licensure.

Section 1061 was enacted as CDPH (then DHS) emergency regulations in 1993 to implement Assembly Bill 32 in 1990, as discussed in Section 47. This bill required licensure of cytotechnologists at B&P Code Sections 1270, 1270.5 and 1271.

The title of Section 1061 is misleading since it is entitled “Cytotechnology Licensure” rather than “Cytotechnologist Licensure”. This section was isolated from other licensing standards in 1993. It was positioned in Title 17 California Code of Regulations, Group 2, Clinical Laboratory Regulations, Article 7, “Cytotechnology” instead of with the other personnel licensing standards at Article 1.5, “Licensure of Clinical Laboratory Personnel”. This has set this license category apart from the rest of the licenses. CDPH shall update this section and relocate it with the other clinical laboratory personnel licenses at Section 1031.4 in Article 1.5.

Cytotechnologist licensure requirements

Section 1061 shall be repealed in its entirety.

Section 1061 (a) specifies an application fee pursuant to Section 1300, but this is unnecessary as cytotechnologists are included in the fee requirement with clinical scientists at Section 1300 (c).

Section 1061 (b) requires an applicant for cytotechnologist licensure to document his or her education, but does not specify what that education should be. The new Section 1031.4 specifies the educational requirements for licensure.

Section 1061 (b) states that an applicant has the option of providing his or her social security number. This needs to be repealed because a social security number is now required by Family Code Section 17520. This updated requirement is added to the new Section 1031.4.

Section 1061 (b) currently requires cytotechnologist applicants to provide documentation of their education, training and experience in gynecologic and non-gynecologic cytology testing. This section specifies that the applicant may either complete formal 12 month training in an approved program or complete five years of fulltime experience in cytology. The option for acceptance of on-the-job experience is removed in the updated Section 1031.4.

Section 1061 (b) requires the applicant to document his certification by the American Society for Clinical Pathology (ASCP). This shall be repealed because certification by the ASCP is not necessary for maintenance of a license. The new Section 1031.4 specifies that an applicant must successfully pass a certification examination administered by the ASCP for California licensure purposes, but is not required to maintain certification.

Section 1061 (b) requires the applicant to supply his or her current laboratory employer(s), number of hours employed by each and volumes of types of specimens examined at each location. This shall be repealed because a person applying for licensure would not be authorized to work as a cytotechnologist prior to licensure, so this requirement is meaningless.

Section 1061 (c), (d) and (e) specifies timeframes for the department to process an application and renewal. This is repealed and not included in the new Section 1031.4 because timeframes are already specified in Section 1031.6 and 1031.7.

Section 1061 (f) requires a licensed cytotechnologist to notify the department within 30 days of any and all changes of employment, hours employed by each, and change in certification status. B&P Code Section 1227 requires a licensed person to notify the department within 30 days of a change of home address. Other information is not needed or retained, so this is repealed.

(49) Repeal Section 1062. Cytotechnologist Competency Testing Services or Programs.

Section 1062 specifies how the department would administer a competency testing program for its licensed cytotechnologists as mandated in Business and Professions Code Section 1270 (b). This section of the law states that “the issuance of a cytotechnologist license shall be contingent upon the applicant’s satisfactory performance....in a competency testing program for cytotechnologists.” While this requirement may have been justified in 1993 because of public fear about erroneous Pap tests, it has been difficult to implement. This law would require competency testing prior to licensure.

All specialties in a clinical laboratory are subject to proficiency testing, but not competency examinations. Proficiency testing measures the ability of a laboratory to obtain accurate test results compared with peers performing the same test on the same instrument. Competency examinations measure the ability of a person, not a laboratory, to obtain an accurate result. Business and Professions Code Section 1270 (b) requires a person to be competency tested by the department or a competency testing service prior to licensure. Applicants for licensure are subjected to a certification examination administered by the ASCP, but not a “competency” examination, as such.

The department does not have the resources to administer a competency examination for applicants, and was unable to find a contractor to perform these duties. It developed

a request for proposal in 1994, giving the competency service requirements, listed it on the State Contracts Index and had one respondent. Upon further discussion, this professional organization withdrew its interest and no other agency expressed any interest. Regrettably, the department has been unable to offer or oversee an administrator for competency testing of licensing cytotechnologists as required by law.

The Center for Medicare & Medicaid Services (CMS) started administering cytology proficiency testing in 2006. Title 42 Code of Federal Regulations 493.855 (a) states, "The laboratory must ensure that each individual engaged in the examination of gynecological preparations is enrolled in a proficiency testing (PT) program approved by the Centers for Medicare & Medicaid Services." Effective in 2005, all CLIA-certified laboratories that performed gynecological cytology testing had to enroll their cytotechnologists and cytopathologists in a CMS-approved program. Three programs were approved by CMS, the College of American Pathologists, the State of Maryland Cytology PT program and the American Society for Clinical Pathology program. This proficiency testing program has been controversial since its inception since it cited persons rather than laboratories, including pathologists, for failure in proficiency testing. However, all cytotechnologists in California have been subjected to routine cytology proficiency testing by CMS since that date. (See Exhibits 18 and 19)

The standards specified in Section 1062 shall be repealed as unnecessary since a competency examination is administered by the federal government, CMS.

A list of documents used to develop these regulations is attached and titled Addendum A: Documents Relied Upon.

STATEMENT OF DETERMINATIONS

(a) Alternative Considered

CDPH has determined that no alternative considered by CDPH would be more effective in carrying out the purpose for which the action was taken or would be as effective and less burdensome to affected private persons than the proposed action.

(b) Local Mandate Determinations

CDPH has determined that the regulations do not impose any mandate on local agencies or school districts.

(c) Economic Impact Statement

CDPH has determined that the regulations would not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with business in other states. The proposed action will make it easier for qualified persons to gain employment in California, alleviating a severe labor shortage in clinical laboratories.

(d) Effect on Small Business

CDPH has determined that the regulations may have a positive impact on small businesses such as assisted reproduction technology clinics. Licensing embryologists shall relieve a labor shortage for these facilities.

ADDENDUM A

DOCUMENTS RELIED UPON—LISTED BY EXHIBIT NUMBER

The following documents were relied upon for formulating the reasoning behind the proposed amendments to CCR, Title 17 Section 1029 to 1062, not inclusive.

Exhibit Number	Exhibit Content
1	About the American Board of Bioanalysis (ABB), “ABB Certifications”, “Certification Standards for Bioanalyst Clinical Laboratory Director (BCLD)” and “Certification Standards for Embryology Laboratory Director (ELD)”, www.abb.org , as of March 15, 2010.
2	“The Laboratory’s Role in Assisted Reproduction”, Linda C Rogers, MLO, January 2005, pages 12-23 not inclusive.
3	About the American Board of Bioanalysis (ABB), “Examinations” and “Content Outline for Embryology”, adopted June 25, 2008, www.aab.org , as of March 15, 2010.
4	“Specific Applications of Molecular Diagnostics for Cytopathology”, Part II, E. Blair Holladay, American Society of Cytopathology, 2004, Volume 41, Number 7, pages 29-33.
5	“Practices contributing to quality performance in the embryo laboratory and the status of laboratory regulation in the US”, Thomas B. Pool, Human Reprod., 1997, Volume 12, pages 2591-2593.
6	“The Assisted Reproductive Technology Laboratories and Regulatory Agencies”, Brooks A. Keel, Infertility and Reproductive Medicine Clinics of North America, April 1998, Volume 9, Number 2, pages 311-329.
7	“Certifying Excellence: How Board Exams Position Laboratorians on the Cutting Edge”, Bill Malone, Clinical Laboratory News, March 2009, Volume 35, Number 3, www.aacc.org/publications/cln/2009/March/Pages/CovStory2March09.aspx
8	About the American Board of Bioanalysis (ABB), “ABB Certifications, Director Certifications, Three Levels; Consultant, One Level; Supervisor, Two Levels”, pages 1-2; “Certification Standards for High Complexity Clinical Laboratory Director (HCLD)” and “Certification Standards for

	Technical Supervisors”, American Board of Bioanalysis, “Certifications”, February 3, 2010, www.aab.org .
9	“Assessment of Credentials, General Information”, Canadian College of Medical Geneticists, 2009, pages 1-2; www.ccmg-ccgm.org/cred , as of February 10, 2010.
10	“Certification in Molecular Pathology in the United States (Training and Education Committee, the Association for Molecular Pathology)”, Anthony A. Killeen, et al, Journal of Molecular Diagnostics, November 2002, Volume 4, Number 4, pages 181-184.
11	“Specialties of Genetics”, American Board of Medical Genetics, Revised July 16, 2008, as of February 9, 2010.
12	“Postdoctoral Training Programs in Medical Microbiology and Immunology Accredited by the Committee on Postgraduate Education Programs”, American Society for Microbiology, www.asm.org/Academy/index.asp , as of January 17, 2008.
13	“Embracing a Brave New World: Molecular Diagnostics for Cytotechnologists”, Part I, E. Blair Holladay, American Society of Cytopathology 2004, Volume 41, Number 5, pages 25-28.
14	“Fluorescence <i>in situ</i> Hybridization: A Morphology-Based Molecular Technique”, Amy J. Wendel, American Society of Cytopathology, September 2008, Volume 45(XLV), Number 5, pages 100-105.
15	“Plotting the Future of Cytotechnology”, Summary, American Society of Cytopathology, www.cytopathology.org/website/article.asp?id=1202 , as of June 4, 2009.
16	“For cytotechnologists, molecular training a must”, Barbara Benstein et al, CAP Today, August 2008.
17	“Cytotechnology: A profession on the move--Then and Now”, Kalyani Naik and M. Sue Zaleski, Lab Medicine April 2008, Volume 39, Number 4, pages, 201-206.
18	“Cytology Proficiency Testing”, US Department of Health and Human Services, Centers for Medicare & Medicaid Services,

	www.cms.hhs.gov/CLIA/o2_CytologyProficiencyTesting , as of January 26, 2006.
19	“State Survey Agency Responsibilities for 2007 Regarding Gynecologic Cytology Proficiency Testing (PT) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Additional Program Information—Update, Centers for Medicare & Medicaid Services, Attachment: Survey Protocols for Compliance with Cytology Proficiency Testing-2007”, December 7, 2006.
20	“ISO Accreditation Comes to America, Are Labs Ready to Embrace an International Quality Management System?”, Bill Malone, Clinical Laboratory News, January 2009, Volume 35, Number 1, pages 1-7.
21	“Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies”, ISO/IEC 17011:2004(E).
22	“About ILAC (International Laboratory Accreditation Cooperation) and ILAC’s Role”, www.ilac/aboutilac , as of February 9, 2010.
23	“Standards and Guidelines for Clinical Genetics Laboratories--Clinical Biochemical Genetics”, American College of Medical Genetics, 2006 Edition, pages 1-9, www.acmg.net , as of February 10, 2010.
24	“Standards and Guidelines for Clinical Genetics Laboratories--Personnel Policies”, American College of Medical Genetics, 2006 Edition, pages 1-3, www.acmg.net , as of February 10, 2010.
25	“Personnel Standards and Quality Assurance Practices of Biochemical Genetic Testing Laboratories in the United States”, Margaret M. McGovern et al, Arch Pathol Lab Med, Volume 127, January 2003, Number 1, pages 71-76.
26	CDC Genetic Testing Activities/Introduction to Genetics Workgroup/ CLIAC Genetics Workgroup Report/CLIAC Discussion Regarding Genetic Testing, Addenda P-R, pages 23-27, February 7-8, 2001.
27	Assisted Reproduction Technology, “Introduction and Cause of Infertility”, pages 1-3, “Diagnostic Tests”, pages 3-6, John C. Petrozza, eMedicine Obstetrics and Gynecology, Sept 29, 2008. www.emedicine.medscape.com/article/263907-overview
28	“Technologist in Molecular Pathology, MP(ASCP), Examination Content Guideline”, American Society for Clinical Pathology, August 2008.

29	"The Development of a Post-Baccalaureate Certificate Program in Molecular Diagnostics", Gail S. Williams, et al, The Journal of Molecular Diagnostics, 2000, Volume 2, Number 4, pages 1-6.
30	"Molecular Techniques Take Center Stage", Shannon Rose, Clinical Laboratory Products, June 2009, pages 9-11.
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32	"Accreditation Requirements in Molecular Pathology", Helen Fernandes, May 20, 2009, LAP Audioconference Series, College of American Pathologists, www.cap.org
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34	Guide to Approval, "About NAACLS", National Accrediting Agency for Clinical Laboratory Sciences, pages i-v, April 2008, www.naacls.org/accreditation/newguide_accreditation .
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39	Position paper of the Clinical Laboratory Technology Advisory Committee, Subcommittee on Examination and Certification, December 1999. www.cdph.ca.gov/programs/lfs/pages/advisorycommittee(CLTAC) .
40	Position paper of the Clinical Laboratory Technology Advisory Committee, Subcommittee on Education and Training, August 2001. www.cdph.ca.gov/programs/lfs/pages/advisorycommittee(CLTAC)

DOCUMENTS RELIED UPON---LISTED BY SUBJECT

The documents relied upon for formulating the reasoning behind the proposed amendments to CCR Title 17 Section 1029 to 1062, not inclusive, arranged by subject are shown below.

Subject	Exhibit Numbers
Assisted Reproduction Technology (ART)	2, 5, 6, 27
Baccalaureate- or masters-level certification or licensure	34, 35, 38, 39, 40
Biochemical genetics certification	9,11, 23, 24, 25, 26, 31, 36
Cytotechnologist workscope	4,13,14,15,16,17
Cytology proficiency (competency) testing	18,19
Doctorate-level certification or licensure	1, 3, 7, 8,12, 33, 37
Embryologist certification	1, 3
Immunologist certification	12, 33, 37
International clinical laboratory accreditation	20, 21, 22
Molecular pathology	10, 28, 29, 30, 32, 36