

(1) Amend Section 1029.7 to read as follows:

Section 1029.7. Accredited College or University.

~~“Accredited college or university” means an educational facility which has met the standards of the United States of American Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges; or, if a non-United States college or university, one that is evaluated and found equivalent by the American Association of Collegiate Registrars and Admissions Officers.—~~

As used in these regulations, an “accredited college or university” is one that is accredited by the Western Association of Schools and Colleges, the Middle States Association of Colleges and Schools, the New England Association of Schools and Colleges, the North Central Association of Colleges and Schools, the Northwest Association of Schools and Colleges or the Southern Association of Colleges and Schools.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1213, 1222.5, 1260, 1260.3, 1261, 1261.5, 1263 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(2) Amend Section 1029.53 to read as follows:

Section 1029.53. Tests or Examinations in Clinical Genetic Molecular Biology.

“Tests or examinations in Clinical genetic molecular biology” means the determination of all the aspects of molecular organizations of the nucleic acids of the human genome with respect to genotype and phenotype evaluation of the molecular processes of replication, transcription and translation of clinically significant genetic material derived from cells and organisms to aid in the assessment of physiological conditions or diagnosis of disease or dysfunction.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~100275~~ 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, 1210, 1225, 1261.5 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(3) Adopt New Section 1029.200 to read as follows:

Section 1029.200. Approved NAACLS Accredited Training Program.

As used in these regulations, an approved NAACLS-accredited training program is one that has met accreditation standards of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) and is also approved by the department as meeting training requirements for licensure purposes in California.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1205, 1222, 1222.5, 1260.3, 1261, 1263, 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(4) Adopt New Section 1029.205 to read as follows:

Section 1029.205. Tests or Examinations in Clinical Biochemical Genetics.

“Tests or examinations in clinical biochemical genetics” are those that evaluate metabolic and enzymatic content of cells, fluids and tissues in a human biological specimen to assess physiological condition, or inherited or acquired metabolic diseases or dysfunction.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, 1210, 1225, 1261.5 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(5) Adopt New Section 1029.210 to read as follows:

Section 1029.210. Tests or Examinations in Clinical Embryology.

As used in this chapter, "tests or examinations in clinical embryology" means evaluation of patient blood, gametes and associated fluids to assess viability, morphology, and function of a human biological specimen to assist in reproductive technology. Tests and examinations include, but are not limited to, determination of hormone levels, identification of antibodies, and sperm analysis.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1208, 1225, 1261.5 and 1264, Business and Professions Code; and Sections 1639 and 131050, Health and Safety Code.

(6) Adopt New Section 1029.215 to read as follows:

Section 1029.215. Critical Review.

As used in this chapter, “critical review” of laboratory results means the evaluation of test results using established quality control parameters, assessment of analytic quality, correlation with pertinent patient data, and compliance with all requirements of state laboratory law (Division 2, Chapter 3 of Business and Professions Code) and the regulations adopted thereunder, and of CLIA (as defined at Business and Professions Code Section 1202.5) by a licensed person authorized to perform those tests and examinations and determined to be competent by a laboratory director pursuant to Business and Professions Code 1209 (e).

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1206.5, 1209, 1220, 1225, 1241, 1265, 1269, 1280, 1282, 1285, 1288, 1288.5, 1289 and 1310, Business and Professions Code; and Section 131050, Health and Safety Code.

(7) Adopt New Section 1029.220 to read as follows:

Section 1029.220. Degrees or majors in biological science, chemical science or physical science.

(a) A degree or major in “biological science” includes the fields of biochemistry, molecular biology, cellular biology, physiology, botany or ecology. As used in these regulations, a “degree or major in biological science” may include a degree or major in general biology or a more specific major in one of the biological fields as bacteriology, genetics, physiology or zoology.

(b) A “degree or major in chemical science” includes the fields of inorganic, organic or physical chemistry, or biochemistry. As used in these regulations, a “degree or major in chemical science” may include a general degree or major in chemistry or a more specific major in one of the chemical fields as pharmaceutical chemistry, chemical engineering or analytical chemistry.

(c) A “degree or major in physical science” includes the fields of chemistry, astronomy, mathematics or mechanics. As used in these regulations, a “degree or major in physical science” may include a general major in physics or a more specific major in one of the physical fields as engineering, earth science, meteorology or geology.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Section 1260, 1260.3, 1261, 1261.5, 1263 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(8) Adopt New Section 1029.225 to read as follows:

Section 1029.225. Official school transcript.

An “official school transcript” is a document issued by a school, college or university which identifies a student and attests to that student’s completion of specific courses with grades, semester or term credit hours, dates of completion, academic major(s), degree or diploma granted, and awards or honors. This transcript is received directly from the school, college or university registrar, dean or other person responsible for issuing transcripts upon the request of the student. It bears an official seal or stamp of the school and is sent in a sealed, postmarked envelope directly to the department.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Section 1260, 1260.3, 1261, 1261.5, 1263 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(9) Adopt new Section 1029.230 to read as follows:

Section 1029.230. Tests or Examinations in Molecular Biology.

“Tests or examinations in molecular biology” means the identification or evaluation of genes, DNA, mRNA, nuclides, proteins and expression products of gene components of a cell or organism.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, 1210, 1225, 1261.5 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(10) Adopt New Section 1029.235 to read as follows:

Section 1029.235. Tests or Examinations in Molecular Pathology

“Tests or examinations in molecular pathology” means the study of diseases by microscopic examination of cells within organs, tissues or body fluids to diagnose and classify human tumors or to identify dysfunction for the purpose of treatment, to monitor response and to follow disease progression.

Note: Authority cited: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1207, 1208, 1211.5, 1261, 1261.5, 1261.6, 1262, 1264, 1270, 1270.5, 1271, 1272.4, 1274, Business and Professions Code; and Section 131050, Health and Safety Code.

(11) Repeal Section 1030, as follows:

Section 1030. Examination for Bioanalysts' Licenses.

~~(a) The examination for license as a clinical laboratory bioanalyst shall consist of three sections; namely, written, oral, and practical. The subjects covered in this examination shall have to do with the technical procedures performed in clinical laboratories for the purpose of obtaining scientific data which may be used to ascertain the presence, progress, and source of disease.~~

~~(b) An official transcript of college or university training shall be furnished by each applicant. The college or university training shall include as a minimum the indicated number of semester or equivalent quarter units of standard resident courses or their subject equivalent as follows:~~

General inorganic chemistry.....	8
Quantitative analysis.....	3
Organic chemistry.....	3
Biochemistry.....	8
Bacteriology.....	8
Physics.....	3
Biology or zoology.....	4
Physiology.....	3
Parasitology.....	3
Hematology.....	2

Authority cited for Group 2: Section 208, Health and Safety Code, and Sections 1220 through 1223, Business and Professions Code. Additional authority cited: Section 102, Health and Safety Code.

(12) Adopt New Section 1030 to read as follows:

Section 1030. Licensure of Clinical Laboratory Bioanalysts.

(a) To qualify for licensure as a clinical laboratory bioanalyst, a person shall apply for a license pursuant to Section 1031.6 (a) and meet the following requirements:

(1) Hold a masters or doctorate degree in clinical laboratory science, or biological, chemical or physical science from an accredited college or university, and shall have completed at least 30 semester or equivalent quarter hours of post-baccalaureate

courses in clinical laboratory science, or biological, physical or chemical science, and

(2) Document, at the time of application, completion of one year of training in clinical laboratory science appropriate for licensure as a clinical laboratory scientist, as

approved by the department pursuant to Sections 1222.5 and 1286 of the Business and

Professions Code as specified in Section 1035 , or at least two years of documented

experience in clinical laboratory science gained outside California performing duties as specified in Section 1039.2 (c) in a clinical laboratory that is CLIA certified; and

(3) Document completion of at least four years of practical experience within the previous six years at the time of application for bioanalyst licensure either licensed as a clinical laboratory scientist pursuant to Chapter 3 or, if employed outside California,

performing the duties as specified in Section 1039.2 (c). This experience shall be

gained in a laboratory that is CLIA-certified or International Laboratory Accreditation

Cooperation (ILAC)-accredited, or both, or accredited by an international accrediting

organization approved by the department as specified in Section 1031.10. This

laboratory shall perform high complexity testing in microbiology, immunology, chemistry, hematology, immunohematology, and molecular biology; and

(4) Document satisfactory performance in a certifying examination for high complexity laboratory director (HCLD) or bioanalyst clinical laboratory director (BCLD) administered by the American Board of Bioanalysis or as approved by the department pursuant to Section 1031.10; and

(5) Demonstrate satisfactory performance in an oral examination on state and federal laboratory law administered by the department as specified at Section 1031.12.

(b) A licensed clinical laboratory bioanalyst shall be authorized to:

(1) Direct clinical laboratories performing waived, moderate or high complexity testing in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics and molecular biology techniques in these specialties, when he or she also meets the requirements of CLIA; and

(2) Serve as technical consultant, technical supervisor, general supervisor, clinical consultant or testing personnel of a laboratory performing waived, moderate or high complexity tests when he or she also meets the requirements of Sections 1036 – 1036.4 and CLIA .

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections Code 1203, 1205, 1206, 1206.5, 1208, 1209, 1213, 1260, 1261, 1262, 1263, 1264, Business and Professions; and Section 131050, Health and Safety Code.

(13) Adopt New Section 1030.1 to read as follows:

Section 1030.1. Licensure of Clinical Chemists, Clinical Microbiologists, Clinical Toxicologists and Clinical Immunologists.

(a) Except for a clinical laboratory bioanalyst licensed pursuant to Chapter 3 of the Business and Professions Code, or a pathologist or physician licensed pursuant to Chapter 5 of the Business and Professions Code, who meet the laboratory director qualifications for high complexity testing in CLIA, a laboratory director of a clinical laboratory that performs high complexity tests or examinations in the specialties of chemistry, microbiology, toxicology or immunology shall possess a valid clinical chemist, clinical microbiologist, clinical toxicologist or clinical immunologist license, respectively, issued by the department.

(b) To qualify for licensure as a clinical chemist, clinical microbiologist, clinical toxicologist or clinical immunologist, a person shall apply for a license pursuant to Section 1031.6 (a) and meet the following requirements:

(1) Hold a masters or doctorate degree in chemistry or biology from an accredited college or university, and have completed at least 30 semester or equivalent quarter hours of post baccalaureate courses in chemical or biological science related to his or her license category; and

(2) Complete two years of training in California as a postgraduate fellow as specified in Section 1033 (e) in a program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286, or two years of post graduate training in a laboratory outside California that is CLIA-certified or International Laboratory Accreditation Cooperation (ILAC)-accredited, or both, or accredited by an international

agency approved pursuant to Section 1031.11. This laboratory shall perform high complexity testing in the specialty, and the training must be approved by the department pursuant to Section 1039.2 and acceptable to a national certifying board appropriate to the license, as follows:

(A) A clinical chemist applicant shall train in a clinical chemistry program approved by the American Board of Clinical Chemistry (ABCC) or the National Registry of Clinical Chemistry (NRCC) in a program that qualifies the trainee for board certification in clinical chemistry, or

(B) A clinical microbiologist applicant shall train in a clinical microbiology program acceptable to the American College of Microbiology's Committee on Postgraduate Educational Programs, in a program that qualifies the trainee for board certification in clinical microbiology, or

(C) A clinical toxicologist applicant shall train in a clinical toxicology program acceptable to ABCC or NRCC, in a program that qualifies the trainee for board certification in clinical toxicology, or

(D) A clinical immunologist trainee shall train in a clinical immunology program acceptable to the American Board of Medical Laboratory Immunology (ABMLI), in a program that qualifies the trainee for board certification in clinical immunology, and

(3) Complete at least two years of practical experience performing or supervising clinical tests and examinations in California in his or her specialty either as a postgraduate fellow as specified in Section 1033(e) or a clinical laboratory specialist as specified in Section 1031. A person outside California shall complete at least two years of this practical experience in a laboratory that is CLIA-certified or ILAC-accredited

laboratory, or both, or accredited by an international accrediting organization approved by the department as specified in Section 1031.10. This practical experience shall be in activities specified in Section 1039.2 (c) performing high complexity testing in the specialty; and

(4) Document satisfactory performance on a certification examination, approved by the department pursuant to Business and Professions Code Section 1264 as specified at Section 1031.9, as follows:

(A) A clinical chemist applicant shall take a certifying examination in chemistry administered by the ABCC or the NRCC, or the department, or

(B) A clinical microbiologist applicant shall take a certifying examination in microbiology administered by the American Board of Medical Microbiology or the department, or

(C) A clinical toxicologist applicant shall take a certifying examination in toxicology administered by the ABCC or NRCC, or the department, or

(D) A clinical immunologist applicant shall take a certifying examination in immunology administered by the ABMLI, or the department; and

(5) Demonstrate satisfactory performance on an oral examination on state and federal laboratory law administered by the department as specified in Section 1031.12.

(c) The work scope of a licensed clinical chemist, clinical microbiologist, clinical toxicologist or clinical immunologist shall depend on their experience, as follows:

(1) A licensed clinical chemist shall be authorized to:

(A) Serve as director of a laboratory performing high complexity tests or examinations in routine chemistry, clinical microscopy, endocrinology, toxicology and immunology, as well as tests or examinations in molecular biology in these specialties and

subspecialties, when he or she meets the requirements of CLIA; and

(B) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is consulting as specified in Sections 1036 - 1036.4 and when he or she meets the requirements of CLIA.

(2) A licensed clinical microbiologist shall be authorized to:

(A) Serve as director of a laboratory performing high complexity tests or examinations in microbiology, bacteriology, mycobacteriology, mycology, parasitology, virology, and serology, as well as tests or examinations in molecular biology in these specialties and subspecialties, when he or she meets the requirements of CLIA; and

(B) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is consulting pursuant as specified in Sections 1036 – 1036.4 and when he or she meets the requirements of CLIA.

(3) A licensed clinical toxicologist shall be authorized to:

(A) Serve as director of a laboratory performing high complexity tests or examinations in toxicology, as well as tests or examinations in molecular biology in toxicology when he or she meets the requirements of CLIA; and

(B) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is consulting as specified in Sections 1036 – 1036.4 and when he or she meets the requirements of CLIA.

(4) A licensed clinical immunologist shall be authorized to:

(A) Serve as director of a laboratory performing high complexity tests or examinations in immunology, including cellular immunology, histocompatibility, immunohematology, immune systems, allergy testing and cellular toxicity, as well as tests or examinations in molecular biology in these specialties and subspecialties, when he or she meets the requirements of CLIA; and

(B) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is consulting as specified in Section 1036 – 1036.4 and when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1213, 1222.5, 1262, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(14) Adopt new Section 1030.2 to read as follows:

Section 1030.2. Licensure of Clinical Biochemical Geneticists.

(a) Except for a clinical laboratory bioanalyst who is licensed pursuant to Chapter 3 of the Business and Professions Code or a pathologist who is licensed pursuant to Chapter 5 of the Business and Professions Code, who meet the laboratory director qualifications for high complexity testing in CLIA, a laboratory director of a clinical laboratory that performs tests or examinations in the specialty of biochemical genetics shall possess a valid clinical biochemical geneticist license issued by the department.

(b) To qualify for licensure as a clinical biochemical geneticist, a person shall apply for a license pursuant to Section 1031.6 (a) and meet the following requirements:

(1) Be a physician and surgeon licensed by the State to practice medicine pursuant to Chapter 5 of the Business and Professions Code; and

(A) Complete two years of training in California as a postgraduate fellow in clinical biochemical genetics as specified in Section 1033 (e) in a program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 and acceptable to the American Board of Medical Genetics (ABMG) or the Canadian College of Medical Geneticists (CCMG) for certification, or two years of postgraduate training in a laboratory outside California that is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency approved by the department pursuant to Section 1031.10, that performs high complexity testing in biochemical genetics, which training is acceptable to ABMG or CCMG for certification, and

(B) Complete at least two years of practical experience performing or supervising high

complexity tests or examinations in clinical biochemical genetics in California as a postgraduate fellow as specified in Section 1033(3), or outside California in a laboratory that is CLIA-certified, ILAC-accredited laboratory, or accredited by an accrediting agency approved to the department pursuant to Section 1031.11, performing or supervising high complexity tests or examinations as specified in Section 1039.2 (c) in biochemical genetics, and

(C) Document satisfactory performance on an examination administered by the ABMG or the CCMG, or approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance in an oral examination on state and federal clinical laboratory law administered by the department as specified in Section 1031.12,

or

(2) Hold a doctorate degree in genetics or a field related to genetics from an accredited college or university and have completed at least 30 semester or equivalent quarter hours of post-baccalaureate courses in genetics and biological science, and

(A) Complete two years of training in California as specified in Section 1033 (e) as a postgraduate fellow in clinical biochemical genetics in a program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 and acceptable to a national certifying board appropriate to the license, or two years of post graduate training outside California performing duties as specified in Section 1039.2 (c) in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency approved by the department pursuant to Section 1031.11, performing high complexity tests or examinations in biochemical genetics, and

(B) Complete at least two years of practical experience performing and supervising

clinical biochemical genetics tests and examinations in California as a postgraduate fellow as specified in Section 1033 (e), or outside California in a CLIA-certified or ILAC-accredited laboratory, or both, or a laboratory accredited by an agency approved by the department pursuant to Section 1031.11, performing high complexity tests or examinations in biochemical genetics as specified in Section 1039.2 (c), and

(C) Document satisfactory performance on a certification examination in biochemical genetics administered by the ABMG, CCMG or approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance on an oral examination on state and federal laboratory law administered by the department as specified in Section 1031.12.

(c) A licensed clinical biochemical geneticist shall be authorized to:

(1) Serve as director of a laboratory performing high complexity tests or examinations in biochemical genetics as defined at Section 1029.205, when he or she meets the requirements of CLIA; and

(2) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is licensed as specified in Sections 1036 – 1036.4 and when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1213, 1222.5, 1260, 1261.5, 1262, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(15) Adopt new Section 1030.3 to read as follows:

Section 1030.3. Licensure of Clinical Embryologists.

(a) To qualify for licensure as a clinical embryologist, a person shall apply for a license pursuant to Section 1031.6 (a) and shall meet the following requirements:

(1) Hold a doctorate degree in biology, biological science or clinical laboratory science from an accredited college or a university and have completed at least 30 semester or equivalent quarter hours of post-baccalaureate courses in biological or clinical laboratory science; and

(2) Complete four years of training and experience as a postgraduate fellow in California in a program approved by the department pursuant to Section 1035.2 and acceptable to the American Board of Bioanalysis or, if outside California, complete four years of training and experience in a program acceptable to the American Board of Bioanalysis; and

(3) Document satisfactory performance on a certification examination, approved by the department as specified at Section 1031.9 and administered by the American Board of Bioanalysis either as a High Complexity Laboratory Director (HCLD) in Embryology or an Embryology Laboratory Director (ELD); and

(4) Demonstrate satisfactory performance on an oral examination on state and federal laboratory law administered by the department as specified at Section 1031.12.

(b) A licensed clinical embryologist shall be authorized to:

(1) Serve as director of a laboratory performing high complexity tests or examinations related to assisted reproduction in clinical embryology as specified at Section 1029.210, when he or she meets the requirements of CLIA; and

(2) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel appropriate to the specialties and subspecialties for which he or she is licensed as specified in Sections 1036 – 1036.4 when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1213, 1222.5, 1260, 1261.5, 1262, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(16) Repeal Section 1030.5 as follows:

~~**Section 1030.5. Licensure of Clinical Chemists, Clinical Microbiologists, Clinical Toxicologists, Clinical Genetic Molecular Biologists and Clinical Cytogeneticists.**~~

~~A written and oral examination shall be given to each applicant for licensure as a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist or clinical cytogeneticist. In addition to the requirements for licensure as specified in Section 1264 of the Business and Professions Code, an applicant shall have completed one year of training as a licensed trainee or equivalent in his or her specialty or subspecialty pursuant to Section 1207 of the Business and Professions Code. Also, each applicant shall have completed three years of experience in his or her specialty pursuant to Section 1210 of the Business and Professions Code in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in that specialty, two years of which shall have been at a supervisory level.~~

Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Section 1204, 1205, 1207, 1210, 1264, and 1265, Business and Professions Code.

(17) Amend Section 1030.6 to read as follows:

Section 1030.6. Licensure of Clinical Cytogeneticists.

(a) Except for a clinical laboratory bioanalyst who is licensed by the department pursuant to Chapter 3 of the Business and Professions Code who meets the laboratory director qualifications for high complexity testing in CLIA Section 493.1443 (b) of Title 42, Code of Federal Regulations, as published October, 1994, or a pathologist who is licensed pursuant to Chapter 5 of the Business and Professions Code who meets the laboratory director qualifications in CLIA Section 493.1443 (b) of Title 42, Code of Federal Regulations, as published October, 1994, a laboratory director of a clinical laboratory that performs tests or examinations in the subspecialty of clinical cytogenetics within the specialty of genetics shall possess a valid clinical cytogeneticist license issued by the department.

(b) To be eligible for licensure as a clinical cytogeneticist, an applicant shall apply for a license pursuant to Section 1031.6(a) and shall meet the following requirements:

(1) ~~Be a physician and surgeon licensed~~ Possess a valid physician and surgeon license issued by the State to practice medicine pursuant to Chapter 5 of the Business and Professions Code, and have:

(A) Complete ~~Two~~ two years' training as a postgraduate fellow in clinical cytogenetics as specified in Section 1033 (e) in a training program approved by acceptable to the American Board of Medical Genetics (ABMG) or the Canadian Council College of Medical Genetics Geneticists (CCMG) for certification, and approved by the department pursuant to Sections 1222.5 and 1286, Business and Professions Code, Chapter 3, or complete two years of postgraduate training outside California in a laboratory that is

CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11 that performs high complexity cytogenetics tests or examinations, which training meets the requirements for certification by the ABMG or CCMG, and

(B) Complete at least two years' practical experience performing, directing or supervising high complexity testing in the specialty of genetics cytogenetics in California as a postgraduate fellow as specified in Section 1033 (e), or outside California performing duties as specified in Section 1039.2 (c) in a clinical laboratory that possesses a certificate issued under is CLIA certified or ILAC accredited, or both, or accredited by a certifying agency approved by the department pursuant to Section 1031.11 for performing high complexity testing in cytogenetics; and

(C) Document Evidence of satisfactory performance on a written a certification examination in clinical cytogenetics administered by the ABMG, CCMG or other examination approved by the department pursuant to Section 1031.9; and

(D) Demonstrated satisfactory performance on an oral examination regarding Business and Professions Code, Chapter 3, and Title 42, CFR, Part 493, as published January 1, 1994; on state and federal clinical laboratory law administered by the department as specified by Section 1031.12, or

(2) Hold an earned doctoral ~~doctoral~~ doctorate degree in a biological science or field related to genetics from an accredited college or university with thirty semester or equivalent quarter hours of post-baccalaureate course credit in genetics or biological science posted on an official transcript from the university registrar; and

(A) Have ~~Complete~~ Complete two years' training as a postgraduate fellow in clinical cytogenetics

as specified in Section 1033 (e) in a training program approved by acceptable to the ABMG or the CCMG for certification, and approved by the department pursuant to Sections 1222.5 and 1286, Chapter 3, of Business and Professions Code, or two years of postgraduate training outside California in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity cytogenetics tests or examinations, which training is acceptable for certification by the ABMG or CCMG; and

(B) Have Complete at least two years' practical experience supervising or performing clinical laboratory tests or examinations in clinical cytogenetics in California as a postgraduate fellow as specified in Section 1033 (e), or outside California in a clinical laboratory that possesses a certificate issued under is CLIA-certified or ILAC-accredited, or both, or accredited by an agency approved by the department pursuant to Section 1031.11 for performing high complexity testing in cytogenetics; and

(C) Provide evidence of Document satisfactory performance on a written a certification examination in clinical cytogenetics administered by the ABMG, CCMG or another examination approved by the department pursuant to Section 1031.8 1031.9; and

(D) Have Ddemonstrated satisfactory performance on the an oral examination on state and federal clinical laboratory law administered by the Department, regarding Business and Professions Code, Chapter 3, and Title 42 Code of Federal Regulations, Part 493, as published January 1, 1994; as specified in Section 1031.12; or

(3) Have served as a laboratory director of a clinical laboratory performing laboratory tests limited to the subspecialty of cytogenetics on or before December 31, 1997 and either;

(A) Meet the laboratory director qualifications of CLIA Section 493.1443(b) (2) or (b) (3) of Title 42, Code of Federal Regulations, as published October 1, 1994 or

(B) Hold an earned ~~doctoral~~ doctorate degree, have four years' clinical cytogenetics training or experience in a clinical laboratory ~~certified by HCFA in~~ that is CLIA certified to perform high complexity clinical cytogenetics, and provide evidence of satisfactory performance on a written certifying examination in cytogenetics administered by the ABMG or the CCMG or another examination approved by the department pursuant to Section 1031.9, and provide evidence of satisfactory performance on an oral examination on state and federal clinical laboratory law as specified in Section 1031.12.

(c) A licensed clinical cytogeneticist shall be authorized to:

(1) Serve as director of a laboratory performing high complexity tests or examinations in cytogenetics as defined at Section 1029.32, when he or she meets the requirements of CLIA, and

(2) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel in clinical cytogenetics as specified in Sections 1036 – 1036.4 and when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 400275-131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1210, 1213, 1222.5, 1260, 1261.5, 1262, 1263, 1264, 1265, 1282, 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(18) Amend Section 1030.7 to read as follows:

Section 1030.7. Licensure of Clinical Genetic Molecular Biologists.

(a) Except for a clinical laboratory bioanalyst licensed by the department pursuant to Chapter 3 of the Business and Professions Code, Chapter 3, who meets the laboratory director qualifications for high complexity testing in CLIA Section 493.1443 (b) of Title 42, Code of Federal Regulations, as published October, 1994 and a pathologist who is licensed pursuant to Chapter 5 of the Business and Professions Code, who meets the laboratory director qualifications in CLIA Section 493.1443 (b) of Title 42, Code of Federal Regulations, as published October 1, 1994, a laboratory director of a clinical laboratory that performs tests or examinations in the subspecialty of molecular biology related to the diagnosis of abnormalities related to human genetic disorders clinical genetic molecular biology shall possess a valid clinical genetic molecular biologist license issued by the department.

(b) To be eligible for licensure as a clinical genetic molecular biologist, an applicant shall apply for a license pursuant to Section 1031.6 (a) and shall meet the following requirements:

(1) ~~Be a physician and surgeon licensed~~ Possess a valid physician and surgeon license issued by the State, pursuant to Chapter 5 of the Business and Professions Code, to practice medicine and have:

(A) Complete ~~Two~~ two years of training as a postgraduate fellow in clinical genetic molecular biology as specified in Section 1033 (e) in a training program approved by acceptable to the American Board of Medical Genetics (ABMG) or the Canadian Council College of Medical Genetics Geneticists (CCMG) for certification, and approved

by the department pursuant to Sections 1222.5 and 1286, Chapter 3 of the Business and Professions Code, or two years of postgraduate training outside California in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency approved by the department pursuant to Section 1031.11, that performs high complexity genetic molecular biology tests or examinations that meets the requirements for certification by the ABMG or CCMG; and

(B) Complete at least two years' practical experience performing directing or supervising high complexity testing in the specialty of genetics genetic molecular biology in California as a postgraduate fellow as specified in Section 1033 (e), or outside California in a clinical laboratory that possesses a certificate issued under that is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency approved by the department pursuant to Section 1031.11, that for performing performs high complexity testing tests or examinations in genetic molecular biology; and

(C) ~~Evidence of Document~~ Document satisfactory performance on a ~~written~~ certifying examination in genetic molecular biology administered by the ABMG or CCMG or an examination approved by the department pursuant to Section 1031.9 and

(D) ~~Demonstrated~~ satisfactory performance on an oral examination on state and federal clinical laboratory law administered by the department regarding ~~Chapter 3 of the Business and Professions Code and Part 493 of Title 42, Code of Federal Regulations, as published January 1, 1994;~~ as specified in Section 1031.12; or

(2) Hold an earned ~~doctoral~~ doctorate degree in a biological science or field related to genetics from an accredited university with 30 semester or equivalent quarter hours of post-baccalaureate course credit in genetics or biological sciences ~~posted on an official~~

~~transcript from the university registrar as specified at Section 1031.6 (a); and~~

- (A) ~~Have Complete two years' training as a postgraduate fellow in clinical genetic molecular biology in a training program ~~approved by~~ acceptable to the ABMG or the CCMG for certification, and approved by the department pursuant to Sections 1222.5 and 1286, Chapter 3 of Business and Professions Code, or two years of postgraduate training outside California in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency that is approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations in clinical genetic molecular biology acceptable for certification by ABMG or CCMB; and~~
- (B) ~~Have Complete at least two years' practical experience supervising or performing clinical laboratory tests or examinations in clinical genetic molecular biology in California as a postgraduate fellow as specified in Section 1033 (e), or outside California in a clinical laboratory that ~~possesses a certificate issued under~~ is CLIA-certified or ILAC-accredited, or both, or accredited by an accrediting agency approved by the department pursuant to Section 1031.11, for performing that performs high complexity testing in genetic molecular biology pursuant to Section 1029.53; and~~
- (C) ~~Provide evidence of Document satisfactory performance on a ~~written~~ certifying examination in genetic molecular biology ~~administered by~~ from the ABMG or CCMG or an examination approved by the department pursuant to Section 1031.9; and~~
- (D) ~~Have Demonstrated satisfactory performance in the oral examination on state and federal clinical laboratory law administered by the department regarding Chapter 3 of Business and Professions Code and Part 493 of Title 42 Code of Federal Regulations as published January 1, 1994; as specified in Section 1031.12; or~~

(3) Have served as a laboratory director of a clinical laboratory performing high complexity laboratory tests ~~limited to the subspecialty of~~ in genetic molecular biology related to the diagnosis of human genetic abnormalities on or before December 31, 1997, and either:

(A) Meet the qualifications of CLIA Section ~~493.1443(a), (b) (2), or (b) (3)~~ of Title 42, Code of Federal Regulations, as published October 1, 1994; or

(B) Hold an earned ~~doctoral~~ doctorate degree, have four years' clinical genetic molecular biology training or experience in a clinical laboratory that ~~possesses a certificate issued under CLIA~~ is CLIA certified for performing high complexity testing in the subspecialty of genetic molecular biology, and provide evidence of satisfactory performance on a written certifying examination in genetic molecular biology administered by the ABMG or CCMG.

(c) A licensed clinical genetic molecular biologist shall be authorized to:

(1) Serve as director of a laboratory performing high complexity tests or examinations in clinical genetic molecular biology as defined at Section 1029.33, when he or she meets the requirements at CLIA, and

(2) Serve as technical consultant, technical supervisor, clinical consultant, general supervisor, or testing personnel in clinical genetic molecular biology as specified in Sections 1036 – 1036.4 when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1213, 1222.5, 1260, 1261.5, 1262, 1263, 1264, 1265, and 1282, and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(19) Amend Section 1031 to read as follows:

Section 1031. Licensure of Clinical Laboratory Specialists.

(a) The minimum requirements for ~~admission to the limited scientist examinations~~ licensure of clinical laboratory specialists shall be as follows:

(1) An applicant ~~for admission to the examination~~ for licensure as a clinical chemist scientist ~~license~~ shall apply for a license pursuant to Section 1031.6 (a) and meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in chemistry or ~~equivalent major~~ chemical science which shall include at least 25 semester or 38 quarter units in chemistry including courses in analytical chemistry, quantitative analysis or clinical chemistry, ~~and instrumentation~~. This coursework shall be verified by an official school transcript showing ~~college or university courses, training and degree posted by an accredited college or university~~ as specified in Section 1031.6 (a); and

(B) ~~Have~~ Completed at least one year of post-baccalaureate training in all areas of the specialty of chemistry, as listed in (b)(1) ~~below, in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in the specialty of chemistry.~~ in a training program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 as specified in Section 1035, or at least two years of documented practical experience outside California performing duties as specified in Section 1039.2 (c) in all areas of the specialty of chemistry in a clinical laboratory that is CLIA certified, ILAC accredited or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity clinical chemistry tests and examinations; and

(C) Document satisfactory performance on a written examination in chemistry administered by the department or by a certifying examination approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(2) An applicant ~~for admission to the examination~~ for licensure as a clinical microbiologist scientist shall apply for a license pursuant to Section 1031.6 (a) and meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in microbiology or ~~equivalent major biological science~~ which shall include at least 25 semester or 38 quarter units in microbiology biology including courses in medical or pathogenic microbiology or bacteriology. This coursework shall be verified by an official school transcript ~~showing college or university courses, training and degree posted by an accredited college or university as specified at Section 1031.6 (a);~~ and

(B) ~~Have Ceompleted~~ at least one year of post-baccalaureate training in all areas of the specialty of microbiology, as listed in (b)(2) ~~below, in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in the specialty of chemistry.~~ in a training program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 as specified in Section 1035, or at least two years of documented experience outside California performing duties as specified in Section 1039.2 (c) in all areas of the specialty of microbiology in a clinical laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high

complexity tests or examinations in clinical microbiology; and

(C) Document satisfactory performance on a written examination in microbiology administered by the department or a by certifying examination approved by the department pursuant to Section 1031.9; and

(D) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(3) An applicant ~~for admission to the examination for licensure as~~ a clinical immunohematologist scientist ~~license~~ shall apply for a license pursuant to Section 1031.6 (a) and meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in biology, biological science or clinical laboratory science or equivalent major which shall include at least 25 semester or 38 quarter units in biology or biological science, including genetics and immunology. This coursework shall be verified by an official school transcript showing college or university courses, training and degree posted by an accredited college or university as specified in Section 1031.6 (a); and

(B) ~~Have Completed~~ at least one year of post-baccalaureate training in all areas of the specialty of immunohematology, as listed in (b)(3) ~~below, in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in the specialty of chemistry.~~ in a training program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 as specified in Section 1035, or at least two years of documented experience outside California as specified in Section 1039.2 (c) in all areas of the specialty of immunohematology in a clinical laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by an agency

approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations in immunohematology; and

(C) Document satisfactory performance on a written examination in immunohematology administered by the department or by a certifying examination approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(4) An applicant ~~for admission to the examination for licensure as a clinical toxicologist scientist license~~ shall apply for a license pursuant to Section 1031.6 (a) and meet both of the following requirements:

(A) Hold a baccalaureate or higher degree in chemistry or ~~equivalent major~~ chemical science which shall include at least 25 semester or 38 quarter units in chemistry including analytical chemistry, clinical chemistry or quantitative analysis. This coursework shall be verified by an official school transcript ~~showing college or university courses, training and degree posted by a college or university from an accredited college or university as specified in Section 1031.6 (a); and~~

(B) ~~Have C~~ompleted at least one year of post-baccalaureate training in all areas of the subspecialty of toxicology, as listed in (b)(4) below, in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in the specialty of chemistry. in a training program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 as specified in Section 1035, or at least two years of documented experience outside California performing duties as specified in Section 1039.2 (c) in all areas of the specialty of chemistry and

toxicology in a clinical laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations in clinical chemistry and toxicology;
and

(C) Document satisfactory performance on a written examination in toxicology administered by the department or a by certifying examination approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(5) An applicant ~~for admission to the examination~~ for licensure as a clinical hematologist scientist license shall apply for a license pursuant to Section 1031.6 (a) and meet both of the following requirements:

(A) Hold a baccalaureate or higher degree from an accredited college or university in biology, biological science or clinical laboratory science ~~or an equivalent major~~ which shall include at least 25 semester or 38 quarter units in biology, including hematology.

This coursework shall be verified by an official school transcript ~~showing college or university courses, training and degree posted by an accredited college or university~~ as specified in Section 1031.6 (a); and

(B) ~~Have~~ Completed at least one year of post-baccalaureate training in all areas of the specialty of hematology as listed in (b)(5) ~~below, in a clinical laboratory that possesses a certificate issued under CLIA for performing high complexity testing in the specialty of hematology.~~ in a training program approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 as specified in Section 1035, or at

least two years of documented practical experience as specified in Section 1039.2 (c) outside California in all areas of the specialty of hematology in a clinical laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11 to perform high complexity tests or examination in hematology; and

(C) Document satisfactory performance on a written examination in hematology administered by the department or a by certifying examination approved by the department pursuant to Section 1031.9, and

(D) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(b) Any current and valid license issued under this section shall ~~specify the particular specialty or subspecialty in which the licentiate may perform tests under such license.~~

A license issued for: authorize the licensee to perform waived, moderate or high complexity tests in the following:

(1) A clinical chemist scientist ~~shall specify that the licentiate is authorized to perform clinical laboratory tests or examinations classified as high complexity under CLIA in the specialty or subspecialties of chemistry, including routine chemistry, clinical microscopy, endocrinology and toxicology; immunology, including diagnostic immunology and syphilis serology; and molecular biology~~ tests or examinations in these specialties.

(2) A clinical microbiologist scientist ~~shall specify that the licentiate is authorized to perform clinical laboratory tests or examinations classified as high complexity under CLIA in the specialty or subspecialties of microbiology including bacteriology, mycobacteriology, mycology, parasitology, and virology; immunology, including~~

diagnostic immunology and syphilis serology; and molecular biology tests or examinations in these specialties.

(3) A clinical immunohematologist scientist ~~shall specify that the licensee~~ is authorized to perform clinical laboratory tests or examinations classified as high complexity under CLIA limited to the specialty of immunohematology including ABO/Rh Type or Group, unexpected antibody detection, compatibility testing and antibody identification and molecular biology tests or examinations in this specialty.

(4) A clinical toxicologist scientist ~~shall specify that the licensee~~ is authorized to perform clinical laboratory tests or examinations ~~classified as high complexity under CLIA~~ limited to the subspecialty of toxicology and molecular biology tests or examinations in toxicology.

(5) A clinical hematologist scientist ~~shall specify that the licensee~~ is authorized to perform clinical laboratory tests or examinations ~~classified as high complexity under CLIA~~ limited to the specialty of hematology including routine hematology and coagulation and molecular biology tests or examinations in hematology.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1202.5, 1204, 1205, 1206, 1206.5, 1208, 1209, 1209.1, 1210, 1213, 1222.5, 1261, 1261.5, 1262, 1263 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(20) Amend Section 1031.1 to read as follows:

Section 1031.1. Licensure of Clinical Histocompatibility Scientists.

(a) Each person performing high complexity laboratory tests or examinations in the subspecialty of histocompatibility in a licensed clinical laboratory shall possess a valid clinical histocompatibility scientist license except for the following persons:

(1) A physician and surgeon licensed by the State to practice medicine pursuant to Chapter 5 of the Business and Professions Code; or

(2) A histocompatibility laboratory director licensed pursuant to Chapter 3 of the Business and Professions Code; or

(3) A clinical laboratory bioanalyst licensed pursuant to Chapter 3 of the Business and Professions Code; or

(4) A clinical laboratory scientist licensed pursuant to Chapter 3 of the Business and Professions Code.

(b) To be eligible for licensure as a clinical histocompatibility scientist an applicant shall apply for licensure pursuant to Section 1031.6 (a) and shall have been certified as a Clinical Histocompatibility Technologist by the American Board of Histocompatibility and Immunogenetics (ABHI), either:

(1) Prior to January 1, 1997 and have had at least ~~6~~ six years' experience in all areas of clinical histocompatibility testing in a clinical laboratory, or

(2) After January 1, 1997 and have a baccalaureate degree in biological or clinical science and one year of clinical laboratory ~~experience~~ training in all areas of clinical histocompatibility testing in a clinical laboratory in California that is approved by the department pursuant to Business and Professions Code Sections 1222.5 and 1286 and

acceptable to ABHI for certification, or two years of documented experience outside California performing duties as specified in Section 1039.2 (c) in all areas of histocompatibility in a clinical laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations in histocompatibility; and

(3) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(c) A licensed clinical histocompatibility scientist shall be authorized to perform high complexity tests or examinations in histocompatibility and immunology.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1213, 1222.5, 1260, 1261, 1261.5, 1262, 1263, 1264, 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(21) Amend Section 1031.2 to read as follows:

Section 1031.2. Licensure of Clinical Cytogeneticist Scientists.

(a) Each person performing high complexity tests or examinations in the specialty of cytogenetics in a licensed clinical laboratory shall possess a valid clinical cytogeneticist scientist license except for the following persons:

(1) A physician and surgeon licensed by the State to practice medicine pursuant to ~~€~~Chapter 5 of division 2 of the Business and Professions Code; or

(2) A clinical cytogeneticist licensed to direct a cytogenetics laboratory pursuant to ~~€~~Chapter 3; or

(3) A clinical laboratory bioanalyst licensed pursuant to ~~€~~Chapter 3; or

(4) A clinical laboratory scientist licensed pursuant to ~~€~~Chapter 3.

(b) To be eligible for licensure as a clinical cytogeneticist scientist, an applicant shall apply for licensure pursuant to Section 1031.6 (a) and shall:

(1) Hold a baccalaureate ~~or an equivalent~~ or higher degree in biological or clinical science, which shall include at least 25 semester or 38 quarter hours in biology, chemistry or clinical laboratory science from an accredited college or university, and

(2) Provide evidence of satisfactory performance on ~~a written~~ an examination in the specialty of cytogenetics ~~administered by~~ from the National Credentialing Agency for Laboratory Personnel (NCA) or the American Society for Clinical Pathology (ASCP) and either:

(A) On or after March 14, 2003, have completed at least one year of training ~~and/or experience~~ in clinical cytogenetics in a clinical laboratory that is approved by the department pursuant to Business and Professions Code Section 1222.5 and 1286 and

is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations by the Centers for Medicare and Medicaid Services (CMS) in clinical cytogenetics, or two years of documented practical experience outside California performing duties as specified in Section 1039.2 (c) in high complexity clinical cytogenetics in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity tests or examinations in clinical cytogenetics. This training or experience shall be approved by the department pursuant to Section 1035 and acceptable for admission to an examination by the NCA or ASCP in the specialty of cytogenetics; or

(B) Prior to March 14, 2003, have completed training and/or experience in clinical cytogenetics, which is acceptable for admission to an examination by the NCA in the specialty of cytogenetics, in a CLIA-certified clinical laboratory ~~certified by CMS in that~~ performs high complexity tests or examinations in clinical cytogenetics or in histopathology (cytogenetics); and

(C) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(c) A licensed clinical cytogeneticist scientist shall be authorized to perform high complexity tests and examinations in clinical cytogenetics.

(d) A licensed clinical cytogeneticist scientist who is certified by the ASCP in Molecular Pathology or Molecular Biology shall also be authorized to perform high complexity microscopic or morphologic tests and examinations in molecular pathology under the

general supervision of a board-certified or board eligible anatomical pathologist who is licensed under Chapter 5 of the Business and Professions Code and who has documented the cytogenetic scientist's competency to do so pursuant to Business and Professions Code 1209 (e).

Note: Authority cited: Sections 1224, 1261 and 1261.5, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1205, 1206, 1206.5, 1207, 1208, 1209, 1210, 1213, 1222.5, 1260, 1261, 1261.5, 1262, 1263, 1264, 1282 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(22) Amend Section 1031.3 to read as follows:

Section 1031.3. Licensure of Clinical Genetic Molecular Biologist Scientists.

(a) Each person performing high complexity tests or examinations in the subspecialty of genetic molecular biology in a licensed clinical laboratory shall possess a valid clinical genetic molecular biologist license except for the following persons:

(1) A physician and surgeon licensed by the State to practice medicine pursuant to Chapter 5 of division 2 of the Business and Professions Code; or

(2) A clinical genetic molecular biologist licensed to direct a genetics laboratory pursuant to Chapter 3; or

(3) A clinical laboratory bioanalyst licensed pursuant to Chapter 3; or

(4) A clinical laboratory scientist licensed pursuant to Chapter 3.

(b) To be eligible for licensure as a clinical genetic molecular biologist scientist, an applicant shall apply for licensure pursuant to Section 1031.6 (a) and shall hold a baccalaureate ~~or an equivalent~~ or higher degree in a biological science or clinical laboratory science, ~~or field related to genetics~~ from an accredited college or university; and

(1) ~~Have~~ Completed at least one year of training ~~and/or experience~~ in clinical genetic molecular biology in a clinical laboratory ~~certified by the Center for Medicare & Medicaid Services (CMS)~~ that is approved by the department pursuant to Business and Professions Code Section 1222.5 and 1286 and is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11, performing that performs high complexity testing in clinical genetic molecular biology, or two years of documented experience outside California performing high

complexity tests or examinations in clinical genetic molecular biology as specified in Section 1039.2 (c) in a laboratory that is CLIA-certified or ILAC-accredited, or both, or accredited by another agency approved by the department pursuant to Section 1031.11.

This training and/or experience shall be acceptable for admission to an examination by the National Credentialing Agency for Laboratory Personnel (NCA) or the American Society for Clinical Pathology (ASCP) in the specialty of molecular biology. On or after March 14, 2003, this training shall be approved by the department pursuant to Section 1035; and

(2) Provide evidence of satisfactory performance on ~~a written~~ an examination in molecular biology ~~administered by~~ from the NCA, the ASCP, or other organization approved by the department pursuant to Section 1031.9; and

(3) Demonstrate satisfactory performance on a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(c) A licensed clinical genetic molecular biologist scientist shall be authorized to perform high complexity genetic molecular biology tests or examinations as defined at Section 1029.53.

Note: Authority cited: Sections 1224, 1261 and 1261.5, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1205, 1206, 1206.5, 1207, 1208, 1209, 1210, 1213, 1222.5, 1260, 1261, 1261.5, 1262, 1263, 1264, 1282 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(23) Adopt New Section 1031.4 to read as follows:

Section 1031.4. Licensure of Clinical Cytotechnologists.

(a) To qualify for licensure as a clinical cytotechnologist, a person shall apply for a license pursuant to Section 1031.6 (a) and meet the following requirements:

(1) Hold a baccalaureate or higher degree in biological or clinical laboratory science from an accredited college or university; and

(2) Complete at least one year of training in clinical cytotechnology in a program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or the Canadian Society for Medical Laboratory Science (CSMLS) and acceptable for certification by the American Society for Clinical Pathology (ASCP) for cytotechnologists, and

(3) Demonstrate successful passage of a certification examination in cytotechnology administered by the ASCP, from the ASCP; and

(4) Demonstrate successful passage of a separate self-administered examination on clinical laboratory law provided by the department as specified in Section 1031.12.

(b) A licensed cytotechnologist shall be authorized to perform high complexity tests and examinations in gynecologic and non-gynecologic cytology, fluorescent and immunochemical staining, and microscopic and morphologic evaluation of cells and tissue under the direction of a board-certified or board-eligible anatomical pathologist licensed pursuant to Chapter 5 of the Business and Professions Code, who has documented the cytotechnologist's competency to do so pursuant to Business and Professions Code Section 1209 (e).

(c) A licensed cytotechnologist who is certified by the ASCP in Molecular Pathology or

Molecular Biology shall also be authorized to perform high complexity microscopic and morphologic tests and examinations in molecular pathology under the general supervision of a board-certified or board-eligible anatomical pathologist who is licensed under Chapter 5 of the Business and Professions Code who has documented the cytotechnologist's competency to do so pursuant to Business and Professions Code Section 1209 (e).

Note: Authority cited: Sections 1224 and 1270, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1205, 1206, 1206.5, 1209, 1211.5, 1222.5, 1263, 1270, 1270.5, 1271, 1271.1, 1272.4, 1272.6, 1274 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(24) Adopt new Section 1031.5 to read as follows:

Section 1031.5. Licensure of Clinical Embryologist Scientists.

(a) To qualify for licensure as a clinical embryologist scientist, a person shall apply for a license pursuant to Section 1031.6 (a) and shall meet the following requirements:

(1) Hold a baccalaureate, masters or doctorate degree in biology, biological science or clinical laboratory science from an accredited college of university that shall include at least 25 semester or equivalent quarter hours in biological or clinical laboratory science;

and

(2) Complete training and experience in an assisted reproduction technology (ART) facility program approved by the department pursuant to Section 1035 and acceptable to the American Society for Reproductive Medicine (ASRM) for certification. If the applicant has a baccalaureate degree, he or she must complete four years of training and experience. If the applicant has a masters degree, he or she must complete two years, and if the applicant has a doctorate degree, he or she must complete one year of training and experience; and

(3) Document satisfactory performance on a certification examination approved by the department as specified in Section 1031.9 and administered by the American Board of Bioanalysis as Technical Supervisor of Embryology; and

(4) Demonstrate satisfactory performance on an examination on state and federal laboratory law administered by the department as specified at Section 1031.12.

(b) A licensed clinical embryologist scientist shall be authorized to serve as technical consultant, technical supervisor, general supervisor or testing personnel in clinical embryology as defined at Section 1029.210 in an ART facility as specified in Sections

1036 – 1036.4 when he or she meets the requirements of CLIA.

Note: Authority cited: Sections 1208 and 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1207, 1208, 1209, 1213, 1222.5, 1260, 1261.5, 1262, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(25) Renumber Section 1031.4 to 1031.6 and amend to read as follows:

Section ~~1031.4~~ 1031.6. Requirements and Timeframes for Applications for Licensure and Certification.

~~(a) Applications for admission to a state-administered licensing examination shall be complete when the information specified in Section 1031.4 (b) has been received by the department. For an applicant to be eligible for a scheduled examination, the completed application must be postmarked at least 120 days prior to the examination date as published by the Department of Health Services. When applying for admission to the examination, the applicant shall state whether he or she has previously applied to the department for admission to an examination.~~

~~(b)~~ (a) An application for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations under Chapter 3 shall be considered complete when the following is provided to the department:

- (1) Name and address of the applicant, including city, state and zip code; and
- (2) Social security number of the applicant (pursuant to the authority found in Section 1224 of the Business and Professions Code and in Section 131200 of the Health and Safety Code, and as required by Section 17520 of the Family Code, it is mandatory to provide the social security number. The social security number will be used for purposes of identification.); and
- (3) Gender and birthdate; and
- (4) License for which the applicant is applying; and
- (5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and

(6) Documentation of the applicant's education including:

(A) Name, address, major course of study, dates of attendance, number of credits, and degree/completion date for all colleges and universities attended by the applicant; and

(B) Official school transcripts ~~as specified in Section 1029.225 from the registrar~~ of all accredited colleges or universities attended by the applicant ~~showing all courses, course credits, degrees conferred and date of conference~~; and

(C) Official school transcripts from all non-accredited colleges or universities shall be evaluated for equivalent education at the applicant's expense by the American Association of Collegiate Registrars and Admissions Officers (ACCRAO); and

(~~E~~) (D) Official school transcripts from non-United States colleges or universities which are not in English shall be ~~returned to the applicant to obtain translation from~~ translated into English at the applicant's expense by a translation service approved in the United States for legal or government documents.

(7) Documentation of the applicant's training including:

(A) Name and address of training program, dates of training, specialty and subspecialty areas of training, length of time in each specialty and subspecialty area of training, and name and title of the training program director or responsible person; and

(B) Signed documentation from the training program director or responsible person that this training has been successfully completed; and

(8) Documentation of the applicant's practical experience, appropriate to the specific license for which the applicant is applying, including the following:

(A) ~~Facility~~ Laboratory name, laboratory certification, address, dates of employment, number of hours per week employed, the specialties and subspecialties in which clinical

laboratory tests or examinations were performed and a description of clinical laboratory tests or examinations performed; and

(B) Signed documentation of such experience from the director of the laboratory or other responsible person; and

(9) Evidence of satisfactory performance as specified in Section 1029.81 on a licensing examination pursuant to Section 1029.81; administered by the department or approved pursuant to Section 1031.9; and

(10) Demonstration of satisfactory performance on a self-administered examination on state and federal law administered by the department as specified in Section 1031.12;
and

~~(10)~~ (11) Signature of the applicant, telephone number and date of application; and

~~(11)~~ (12) Payment of license application fee pursuant to Business and Professions Code Section 1300. Masters and doctorate applicants shall pay fees pursuant to Section 1300 (a), associate and baccalaureate applicants shall pay fees pursuant to Section 1300 (c), cytotechnologist applicants shall pay fees pursuant to Section 1300 (d), and trainee applicants shall pay fees pursuant to Section 1300 (l).

~~(c)~~ (b) An application for certification in phlebotomy shall be considered complete when the following is provided to the department:

(1) Name and address of the applicant, including city, state and zip code; and

(2) Social security number of the applicant (pursuant to the authority found in Section 1224 of the Business and Professions Code and in Section 131200 of the Health and Safety Code, and as required by Section 17520 of the Family Code, it is mandatory to provide the social security number. The social security number will be used for

purposes of identification.); and

(3) Gender and birthdate; and

(4) Category of phlebotomy certification for which the applicant is applying; and

(5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and

(6) Documentation of the applicant's education including:

(A) Name, address, dates of attendance, coursework completed and graduation as verified by official school transcripts; or

(B) Documentation of a passing score on the general educational development (GED) test or equivalent education as evaluated at the applicant's expense by the American Association of Collegiate Registrars and Admissions Officers for secondary education; or

(C) For official school transcripts which are not in English, documentation of equivalent education as obtained through translation at the applicant's expense into English from a translation service approved in the United States for legal or government document.

(7) Certification of the applicant's instruction in phlebotomy as specified in Section 1035.1(h); and

(8) Certification of the applicant's on-the-job experience in phlebotomy, if applicable, including:

(A) Name and address of the laboratory where employed, dates of employment, number of hours of experience in techniques specified in Section 1035.1(f) and an estimate of the number of skin punctures, venipunctures or arterial punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfills all the

sampling requirements of all clinical laboratory tests or examinations; and

(B) Signed documentation from the director of the laboratory that the above information accurately represents the applicant's experience in phlebotomy; and

(9) Evidence of satisfactory performance on a certification examination in phlebotomy administered by a certifying organization that was approved by the department pursuant to Section 1031.7 at the time the examination was administered; and

(10) Signature of the applicant, telephone number and date of application; and

(11) Payment of a two-year certification fee. ~~of \$50.~~ pursuant to Business and Professions Code Section 1246.

(c) An application for a training license for a person in a clinical laboratory science shall be considered complete when the following is provided to the department:

(1) Name and address of the applicant, including city, state and zip code; and

(2) Social security number of the applicant (pursuant to the authority found in Section 1224 of the Business and Professions Code and Section 100275 of the Health and Safety Code, and as required by Section 17520 of the Family Code, it is mandatory to provide the social security number. The social security number will be used for purposes of identification); and

(3) Gender and birth date;

(4) Category of training license for which the applicant is applying; and

(5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and

(6) Documentation of the applicant's education including:

(A) Name, address, major course(s) of study, dates of attendance, coursework

completed and dates of completion of degrees for all colleges or universities attended by the applications; and

(B) Official school transcripts as specified in Section 1029.225 of all accredited colleges or universities attended by the applicant; and

(C) Official school transcripts from all non-accredited colleges or universities shall be evaluated for equivalent education at the applicant's expense by the American Association of Collegiate Registrars and Admissions Officers (ACCRAO) and the department; and

(D) Official school transcripts from non-United States colleges or universities which are not in English shall be translated to into English at the applicant's expense by a translation service approved in the United States for legal or government documents.

(7) Payment of license application fee pursuant to Business and Professions Code 1300 (k).

(d) Timeframes for processing applications for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations or for certification to perform phlebotomy pursuant to Chapter 3 shall be as follows:

(1) The department shall notify the applicant in writing, within 90 days of receipt of an application, of one of the following:

(A) The application is complete and will be processed by the department; or

(B) The application is incomplete and not accepted for processing. The department's written notification shall include the specific information, documentation or fee in which the application is deficient; or

(C) The application has been reviewed and does not meet the requirements and that

approval is denied. The department shall give written notification of the basis for the denial.

(2) The department shall notify the applicant within 90 days of postmark date of resubmission of application requirements pursuant to Section ~~4031.4(d)(1)(B)~~ 1031.6 (d) (1) (B) whether the application has been approved or denied.

(3) Written notification by the department to applicants shall be deemed to occur on the date of the postmark from the department.

(4) The department shall deem an application abandoned by an applicant who fails to respond or to supply all information, documents, verifications or payment of applicable fees within 30 days of notification by the department.

(5) The department's time periods for processing an application for licensure or certification from the date the application is complete to the date the final decision is made regarding an approval are as follows:

(A) The median time for processing an application is 90 days;

(B) The minimum time for processing an application is 30 days; and

(C) The maximum time for processing an application is 150 days.

~~(e) Certification shall be valid for a period of 2 years unless revoked.~~

(f) ~~(e)~~ Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.

~~(g)~~ ~~(f)~~ All applicants, licensees and certificants pursuant subject to Section ~~4031.4~~ 1031.6 shall notify the department in writing of any change(s) of name and /or address within 30 calendar days after the change(s) has occurred.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code; and Section 17520, Family Code.
Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1220, 1241, 1242, 1242.5, 1246, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301, 1301.1 and 1320 Business and Professions Code and Sections 120580 and 131050, Health and Safety Code; . and Section 15376, Government Code.

(26) Renumber Section 1031.5 to 1031.7 and amend to read as follows:

Section ~~1031.5~~ 1031.7. Requirements and Timeframes for Renewal of Licenses and Certificates.

(a) In order to maintain a license in active status, licenses shall be renewed by filing a renewal application within 60 days prior to the end of the license period.

(b) A complete license renewal application shall include name and address of the licensee, license number, current work location(s), documentation of continuing education credits, an attestation stating whether the licensee has or has not been convicted of any felonies or misdemeanors other than minor traffic violations in the previous two years, license renewal fee, signature and date of application for renewal.

The license renewal fee for masters and doctorate licensees is given at Business and Professions Code Section 1300 (b), for associate and baccalaureate licensees, at Section 1300 (e), for cytotechnologist licensees, at Section 1300 (d), and for trainee licensees, at Section 1300 (l).

(c) In order to maintain a phlebotomy certificate in active status, certificates once approved shall be renewed at biennial intervals by filing a renewal application within 60 days prior to the end of the certificate period. A phlebotomy certificate shall become invalid if not renewed within 60 days after expiration date. A certified phlebotomist cannot perform phlebotomy as specified in Section 1029.133 with an invalid certificate. He or she must complete the renewal application specified in 1031.6 (d) and be in possession of a valid phlebotomy certificate or a temporary authorization available on the Laboratory Field Services website for no more than 90 days after the issue date of the renewal of the certificate.

(d) A complete phlebotomy certificate renewal application shall include name and address of the certificant, certificate number, current work location(s), documentation of continuing education performed during the previous 24 months, an attestation stating whether the certificant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations in the previous two years, certification renewal fee of ~~\$50~~, signature and date of application for renewal.

Note: Authority cited: Sections 1224, Business and Professions Code; Section ~~400275~~ 131200, Health and Safety Code; and Section 17520, Family Code.
Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1226, 1241, 1242, 1242.5, 1246, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301, and 1301.1, Business and Professions Code; and Sections 120580 and 131050, Health and Safety Code.

(27) Renumber Section 1031.7 to 1031.8 to read as follows:

Section ~~1031.7~~ 1031.8. Conditions for Approval of Certifying Organizations to Administer Phlebotomy Certification Examinations.

(a) In order for a certifying organization to be eligible for approval by the department to administer a phlebotomy certification examination for state certification purposes, the certifying organization shall meet the following conditions:

- (1) The certifying organization shall be a national, independent, not-for-profit, professional certifying organization; and
 - (2) The certifying organization shall offer examinations in phlebotomy; and
 - (3) The certifying organization shall provide the following to the department:
 - (A) The organization's name and address; and
 - (B) Names of the organization's officers and board of directors; and
 - (C) A description of the organization's structure; and
 - (D) The identity of the person designated by the organization to be responsible for overseeing the administration and coordination of all examination activities; and
 - (E) A schedule of dates and times that the examination will be conducted within the state; and
 - (F) Listing of procedures for monitoring the content, quality, validity and relevance of the phlebotomy examinations pursuant to Section 1031.7 (b); and
 - (G) The philosophy of the organization, demonstrating a commitment to accurate assessment of a candidate's preparation for phlebotomy certification.
- (b) In order for a certifying organization's examination to be approved for certification

purposes, the organization shall document the following standards to support a request for approval:

- (1) Evaluation of relevant standards in phlebotomy and how the organization's examinations address knowledge and skills that would assure competence of the candidate; and
- (2) Explanation of how the examinations are developed by the organization and the qualifications of person(s) who develop the examination questions; and
- (3) Documentation that the organization's examinations are subject to annual review for current relevance; and
- (4) Demonstration of the ability of the organization to evaluate its examinations, subjecting the examinations to validity and reliability assessments using psychometric performance standards, and the capability of the organization to provide this information at least once yearly or upon request to the department.

(c) An organization approved to administer a phlebotomy examination shall:

- (1) Agree to make the content of its examinations available to the department for confidential review; and
- (2) Demonstrate how it will maintain security during administration of the examination, ensure the identity of the examinee, and maintain the confidentiality of the examination; and
- (3) Document how it will make its records accessible to the department regarding those persons participating in the examination and their scores; and
- (4) Provide verification of those persons successfully passing the certification examination to the department and shall maintain these records for five years; and

(5) Issue a certificate to those passing the examination with the examinee's name, name of the certifying organization, type of certificate, effective date and official signature.

(d) Timeframes for processing applications for approval of a certifying organization's certification examination shall be as follows:

(1) Within 90 calendar days of receipt of an application, the department shall inform the organization in writing that the application is either complete and accepted for review or that it is deficient and what specific information or documentation is required to complete the application.

(2) Within 180 calendar days from the date of filing a completed application, the department shall inform the applicant certifying organization in writing whether the organization has been approved or denied as a certifying organization for the administration of the certification examination.

(3) The department shall deem an application abandoned by an applicant certifying organization that fails to respond or to supply all information, documents, or verifications within 30 days of notification pursuant to Section 1031.7(d)(1).

(4) The department's time periods for processing an application for approval as a certifying organization, from the receipt of the initial application to the final decision regarding the approval, are as follows:

(A) The median time for processing is 180 calendar days.

(B) The minimum time for processing is 90 calendar days.

(C) The maximum time for processing is 360 calendar days.

- (e) Approval shall be valid for a period of four years unless revoked.
- (f) To apply for renewal, a certifying organization shall file a renewal application at least 120 days prior to the end of the approval period providing the following:
 - (1) The name and address of the certifying organization; and
 - (2) Names of the organization's officers and board of directors; and
 - (3) Name of the person designated by the organization to be responsible for overseeing the administration and coordination of all examination activities; and
 - (4) A schedule of dates and times that the examination will be conducted within the state for the next 12 months; and
 - (5) A copy of the current examination; and
 - (6) Signature of the program director and date of application for renewal.
- (g) Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.
- (h) A certifying organization shall notify the department in writing of any change(s) in the information and material required by Subsections (a) through (c) within 30 days after the change(s) has occurred.

Note: Authority cited: Sections 1224 and 1320, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.
Reference: Section 1242, 1242.5, 1246 and 1269, Business and Professions Code; and Sections 120580 and 131050, Health and Safety Code.

(28) Renumber Section 1031.8 to 1031.9 and amend to read as follows:

Section ~~1031.8~~ 1031.9. Conditions for Approval of a Certifying Organization to Administer a Certifying Examination for Licensure Purposes.

(a) In order for a certifying organization to be eligible for approval by the department to administer a category of certifying examination, the organization shall file a complete application that consists of the following:

- (1) Documentation that the certifying organization is a national, independent, not-for-profit, professional certifying organization; and
- (2) The organization's name and address; and
- (3) Names of the organization's officer(s) and board of directors; and
- (4) Description of the organization's structure and organizational chart; and
- (5) The identity of the person designated by the organization to be responsible for overseeing the administration and coordination of examination activities; and
- (6) A mission statement that demonstrates the philosophy of the certifying organization commits to an accurate assessment of a candidate's preparation in the clinical laboratory science category in which the candidate is examined; and
- (7) Schedule of dates that the examination will be available to California licensure applicants during the next four years; and
- (8) Listing of procedures for monitoring the content, quality, validity, reliability and relevance of the examination in the specialty being tested, and

- (9) Demonstration of how the organization's examination addresses the relevant standards in the clinical laboratory science category being examined, and how it evaluates the knowledge and skills that would assure competence of the candidate; and
- (10) Explanation of how the examination structure is developed by the organization, and the qualifications of person(s) who develop the examination questions; and
- (11) Documentation that the organization's examination is subject to annual review for current relevance; and
- (12) Demonstration of the ability of the organization to evaluate its examination, subjecting it to validity and reliability assessments using psychometric performance standards, and the capability of the organization to provide this information at least annually or upon request to the department; and
- (13) Explanation of how the examination is developed and weighted using a job task survey to determine knowledge and skills required to be competent in the examination category; and
- (14) Explanation of how examination questions are established, evaluated and updated to match current practice for the category; and
- (15) Explanation of how the cutoff score for those successfully passing the examination is determined; and
- (16) Documentation of performance statistics for the examination during the previous five years, including pass/fail rate, number of applicants and number accepted to the examination for each time that the examination has been administered by the certifying organization during the five years immediately prior to the date of application, or, for

specialties that have been established for less than five years, during the period dating from the establishment of the specialty to the date of the application; and

(17) Submission of printed copies of examinations given each year for the previous four years, if the examinations were offered. These examination shall be subject to confidential review by the department, shall not be copied, and shall be returned to the organization; and

(18) Submission of an agreement to provide the examination to candidates who have been approved for admission to the examination by the department; and

(19) Submission of an agreement to provide verification of those persons successfully passing the examination to the department and to maintain these records for five years; and

(20) Submission of an agreement to give evidence of satisfactory performance as official notification to those passing the examination with the examinee's name, name of the certifying organization, examination category, effective date and official signature; and

(21) Demonstration of how the organization will maintain security during development and administration of the examination, ensure the identity of the examinee, and maintain the confidentiality of the examination; and

(22) Listing of procedures in use and required of the organization's personnel to ensure security and confidentiality of the examination, and steps to be taken if a breach is discovered; and

(23) An agreement that a breach of security shall be reported to the department and that the department is authorized to investigate and withdraw approval of the examination category; and

(24) Documentation of how the organization will make its records accessible to the department regarding those persons participating in the examination and their scores; and

(25) The name, title, and signature of the person who is responsible for overseeing the administration and coordination of all examination activities, and the date the application was signed.

(b) Initial approval of an organization's examination category shall include confidential review of an examination given each year up to four years immediately preceding the date of approval, so that examinations taken during this time shall be acceptable for licensure purposes.

(c) Timeframes for processing applications for approval of a certifying organization's examination in a clinical laboratory science category for licensure purposes shall be as follows:

(1) The department shall notify the applicant organization within 90 days of submission of an application of one of the following:

(A) That the application is complete and acceptable for processing by the department;
or

(B) That the application is incomplete and not accepted for processing. This notification shall include the specific information or documentation that the applicant shall submit within 30 days in order for the department to consider the application acceptable; or

(C) That the application has been reviewed and does not meet the requirements of this section and that approval is denied.

(2) The department shall consider an application to have been abandoned by any applicant who fails to respond to the department's request to submit specific information or documentation within 30 days of notification pursuant to Section ~~4031.8(c)(1)(B)~~.
1031.9 (c)(1)(B).

(d) Written notification by the department to the applicant organization shall be considered to occur on the date the documents are postmarked.

(e) A certifying organization shall notify the department in writing of any change in the information and materials required by this section within 30 calendar days after the change has occurred.

(f) Failure to meet and maintain the requirements of this section shall be good cause for denial or revocation of approval by the department.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1208, 1228, 1261, 1261.5, 1262, 1263 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(29) Renumber Section 1031.9 to 1031.10 and amend to read as follows:

Section ~~1031.9~~ 1031.10. Conditions for Renewal of a Certifying Organization's Approval to Administer Examinations Acceptable for Licensure Purposes.

(a) Approval of a certifying organization shall be valid for a period of four years unless revoked. At least 120 days prior to the end of the approval period, the certifying organization that wants to continue approval of its examination shall apply for reapproval. Failure to reapply 120 days in advance shall cause a lapse in approval after which time the examination would not be acceptable for licensure purposes until the certifying organization regains approval. A certifying organization that fails to reapply at least 120 days in advance and subsequently elects to seek approval shall make application pursuant to Section ~~1031.8~~ 1031.9.

(b) To apply for renewal of a certifying organization's approval to administer examinations, the organization shall provide the following:

- (1) The name and address of the certifying organization; and
- (2) Names of the organization's officer(s) and board of directors; and
- (3) Name of the person designated by the organization to be responsible for overseeing the administration and coordination of all examination activities; and
- (4) A schedule of dates that the examination will be available to California applicants during the next four years; and
- (5) A summary of the performance statistics of the examination during the previous approval period, including the number of California applicants applying for, and successfully passing, the certifying examination, the applicant scores, what efforts have been made to evaluate the examination and update the examination questions to match current practice for the category; and

(6) The name, title and signature of the person responsible for overseeing the administration and coordination of all examination activities and date of application for renewal.

(c) The timeframes for processing an application of a certifying organization seeking renewal of its examination approval shall be as follows:

(1) The certifying organization shall submit an application for renewal of approval of its examination at least 120 days prior to the end of the approval period.

(2) Within 30 days of receipt of a renewal application, the department shall inform the organization in writing that the renewal application is complete and accepted for review, or deficient and what specific information or documentation is required to complete the application.

(3) Within 30 days of receiving a completed renewal application, the department shall inform the applicant organization in writing whether the examination has been reapproved or denied.

(d) Failure to meet and maintain the requirements of this section shall be good cause for denial of reapproval by the department.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1208, 1228, 1261, 1261.5, 1262, 1263 and 1264, Business and Professions Code; and Section 131050, Health and Safety Code.

(30) Adopt new Section 1031.11 to read as follows:

Section 1031.11. Conditions for Approval of Training Performed at a Laboratory Outside the United States that is not certified by CLIA.

(a) The department shall accept training or experience gained by an applicant in a clinical laboratory outside of the United States that is not certified by CLIA when the laboratory:

(1) Is certified by an international accrediting organization that meets ISO/IEC (International Organization for Standardization /International Electrotechnical Commission) 17011 standards for certifying technical facilities including clinical laboratories, and ensures peer review by a Conformity Assessment Body for ongoing compliance prior to initiation of training; and

(2) Performs high complexity clinical laboratory tests and examinations on human biological specimens in the specialty or subspecialty for which the applicant is working; and

(3) Has a laboratory director or responsible person delegated by the laboratory director who can serve as training program director who is qualified to perform the duties as specified in Section 1039.2 (c) of technical supervisor as specified in Section 1036.4; and

(4) Provides an attestation of completion of a training plan, pursuant to Section 1035.2 signed by the training program director, that lists dates training was initiated and completed, rotation schedule and training objectives at each rotation site, and measures taken to assess adequacy of training.

(b) This training or experience must be acceptable to a national certifying board for

admission to a certification examination approved by the department pursuant to
Section 1031.9.

Note: Authority cited: Section 1224, Business and Professions Code; and Section
131200, Health and Safety Code.

Reference: Section 1202.5, 1205, 1206, 1206.5, 1207, 1208, 1209, 1210, 1213, 1222I,
1222.5, 1262, 1263, 1264, 1286, Business and Professions Code; and Section 131050,
Health and Safety Code.

(31) Adopt new Section 1031.12 to read as follows:

Section 1031.12. State Administration of Examinations on Laboratory Law.

(a) Applicants for masters or doctorate scientist licenses issued pursuant to Section 1030.0 – 1030.8 shall demonstrate satisfactory performance on an oral examination on state and federal laboratory law administered by the department. The fee for the oral examination shall be \$200 pursuant to Business and Professions Code Section 1300

(o). Satisfactory performance shall be correct answers on at least 70% of the questions as determined by a panel selected by the department. This panel shall include four persons licensed as masters or doctorate scientists under Chapter 3 and department staff. If an applicant fails the oral examination, he or she must reapply, pay another \$200 and retake the examination.

(b) Applicants for baccalaureate scientist or specialist licenses issued pursuant to Sections 1031.0 – 1031.4 or an associate license issued pursuant to Section 1032.5 must provide evidence of satisfactory performance on an online, self-administered examination provided by the department. Satisfactory performance shall be correct answers on at least 7 of the 10 questions asked. The applicant may re-take the online examination as many times as necessary to pass the examination.

(c) Applicants for certification pursuant to Section 1034 shall not be required to take an examination on laboratory law.

Note: Authority: Section 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1203, 1204, 1206.5, 1207, 1210, 1228, 1260, 1260.3, 1261, 1261.5, 1262, 1264, and 1300, Business and Professions Code; and Section 131050, Health and Safety Code.

(32) Repeal Section 1032 as follows:

~~Section 1032. Examination for Clinical Laboratory Technologist's License.~~

~~With the exception as provided in Section 1262 of the Business and Professions Code, written, oral, or practical examinations shall be conducted by the department to aid it in judging the qualifications of applicants for licensure as clinical laboratory technologists.~~

~~In addition to the requirements for licensure as specified in Section 1261 of the Business and Professions Code, the prerequisites for entrance into the licensing examination shall be one of the following:~~

~~(a) Graduation from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges, or an essentially equivalent accrediting agency, with a baccalaureate and a major in clinical laboratory science, the last year of which course shall have been primarily clinical laboratory procedures in a clinical laboratory training school acceptable to the department; or~~

~~(b) Graduation from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Eastern Association of Schools and Colleges, or an essentially equivalent accrediting agency, with a baccalaureate and courses pertinent to the clinical laboratory field as may be determined by the department plus one year as a clinical laboratory technologist trainee or the equivalent as determined by the department in a clinical laboratory acceptable to the department; provided, however, that a baccalaureate obtained after July 1, 1973, must include at least:~~

~~(1) 16 semester or equivalent quarter hours of chemistry, including instruction in~~

~~analytical and biological chemistry;~~

~~(2) 18 semester or equivalent quarter hours of biological science, including instruction in immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology;~~

~~(3) 3 semester or equivalent quarter hours of physics, including instruction in principles of light and electricity; or~~

~~(c) A minimum of two years of experience as a licensed trainee or the equivalent as determined by the department doing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory acceptable to the department and 90 semester hours or equivalent quarter hours of university or college work in which are included the following courses, or essential equivalent as may be determined by the department: general inorganic chemistry -8; quantitative analysis -3; basic biological sciences -8; bacteriology -4; provided, however, that university or college work completed after July 1, 1973, must include at least:~~

~~(1) 16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry;~~

~~(2) 18 semester or equivalent quarter hours of biological science including instruction in immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology;~~

~~(3) 3 semester or equivalent quarter hours of physics, including instruction in principles of light and electricity.~~

Note: Authority Cited: Sections 102 and 208, Health and Safety Code.
Reference: Sections 1246, 1261, 1263, 1264, and 1301, Business and Professions Code.

(33) Adopt New Section 1032 to read as follows:

Section 1032. Licensure of Clinical Laboratory Scientists.

To qualify for licensure as a clinical laboratory scientist, a person shall apply for a license pursuant to Section 1031.6 (a) and meet the following requirements:

(a) Hold a baccalaureate degree from an accredited college or university, or complete a medical specialist program offered by the armed forces of the United States, that includes one of the following:

(1) A major in clinical laboratory science or medical technology, or

(2) A major in chemical, biological or physical science that includes the following coursework:

(A) 16 semester hours or equivalent quarter hours of chemistry that includes one course in analytical chemistry, instrumental analysis or quantitative analysis and one course in clinical chemistry, biochemistry or organic chemistry, and

(B) 18 semester hours or equivalent quarter hours of biology that includes one course in microbiology or pathogenic bacteriology and one course in immunology or serology, and

(C) 3 semester hours or equivalent quarter hours of physics, mathematics or statistics related to clinical laboratory science; and

(b) Complete at least one year of training which includes all specialties of the clinical laboratory as specified in Section 1035 (a) – (c). Training completed outside California

shall be completed at a training program that meets the requirements of Section 1035

(c), as approved by the department. Two years of training and experience in a military

specialist program that includes basic (Phase 1) and advanced (Phase 2) training as a clinical laboratory technician or medical laboratory technician shall be considered

equivalent to one year of training in an approved program. Medical laboratory technicians who meet education requirements of this section may articulate their training for clinical laboratory scientist licensure by completing at least six months training in high complexity testing specialties in a program as specified in Section 1035.5. A person employed as a medical laboratory technician outside California performing duties as specified in Section 1039.2 (c) must meet the education requirements of this section before he or she can articulate their training for clinical laboratory scientist licensure; and

(c) Document satisfactory performance on a clinical laboratory scientist examination administered by a certifying organization approved by the department pursuant to Section 1031.9, and

(d) Demonstrate satisfactory performance on a separate self-administered examination (via the internet) on clinical laboratory law provided by the department as specified in Section 1031.12.

Note: Authority cited: Sections 1224, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1204, 1205, 1206, 1206.5, 1213, 1222, 1222.5, 1242, 1261, 1261.5, 1262, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(34) Amend Section 1033 to read as follows:

Section 1033. Licensure of Trainees Requirements.

~~In addition to the requirements for licensure as specified in Section 1263 of the Business and Professions Code, the prerequisites for licensure as a trainee shall be as follows:-~~

~~(a) Clinical Laboratory Technologist Trainee. Applicants shall have graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent agency with a baccalaureate and a major in clinical laboratory science, or a baccalaureate and courses pertinent to the clinical laboratory field as may be determined by the department. An individual who is not a graduate but possesses at least 90 semester hours or equivalent quarter hours of university or college work may be licensed as a clinical laboratory technologist trainee, provided he will be granted a baccalaureate at the conclusion of 12 months of training, and have completed at least 90 semester hours or equivalent quarter hours, must have included in the college work the following courses or essential equivalent as may be determined by the department: general inorganic chemistry -8; quantitative analysis -3; basic biological sciences -8; bacteriology -4; provided, however, that university or college work completed after July 1, 1973, must include at least:~~

~~(1) 16 semester or equivalent quarter hours of chemistry, including instruction in analytical and biological chemistry;~~

~~(2) 18 semester or equivalent quarter hours of biological science, including instruction in~~

~~immunology, hematology and medical microbiology which may include bacteriology, mycology, virology and parasitology;~~

~~(3) 3 semester or equivalent quarter hours of physics including instruction in principles of light and electricity.~~

~~(b) Limited Technologist Trainee. Applicants shall have graduated from a college or university maintaining standards equivalent, as determined by the department, to those institutions accredited by the Western Association of Schools and Colleges or an essentially equivalent accrediting agency with a baccalaureate and a major in the specialty for which licensure is sought. If the major is not designated by the college or university as one of those required under this chapter for limited technologist licenses in clinical chemistry, clinical microbiology, immunohematology, or toxicology, the department may determine the essentially equivalent major.~~

(a) Medical Laboratory Technician Trainee Requirements. To qualify for a medical laboratory technician trainee license, a person shall apply for a license pursuant to Section 1031.6 (c) and shall document completion of education requirements specified in Section 1032.5 (a) (1). A licensed medical laboratory technician trainee shall be authorized to train in an approved program as specified in Section 1035.3 in waived or moderate complexity tests or examinations in the specialties of chemistry, hematology, immunology and microbiology under the supervision of a person licensed under Chapter 3. All test results performed by a licensed trainee shall be critically reviewed by a licensed person who is authorized and shown competent to perform the tests and examinations. The program director shall notify the department within 30 calendar days when a licensed trainee fails to complete training or needs to extend his or her

training for remedial needs.

(b) Clinical Laboratory Scientist Trainee Requirements. To qualify for a clinical laboratory scientist trainee license, a person shall apply for a license pursuant to Section 1031.6 (c) and shall document completion of at least a baccalaureate degree in clinical laboratory science or related degree from an accredited college or university with successful completion of the coursework specified in Section 1032 (a). A licensed clinical laboratory science trainee shall be authorized to train in waived, moderate and high complexity tests or examinations in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, and genetics under the supervision of baccalaureate- or doctorate-level persons licensed under Chapter 3. All test results performed by a licensed trainee shall be critically reviewed by a licensed person who is authorized and shown competent to perform the tests and examinations. The program director shall notify the department within 30 calendar days when a licensed trainee fails to complete training or needs to extend his or her training for remedial needs.

(c) Requirements for Medical Laboratory Technicians to train for Clinical Laboratory Scientist Licensure. To qualify for a clinical laboratory scientist trainee license, a person shall apply for a license pursuant to Section 1031.6 (c) and shall document employment for at least three of the previous five years as a medical laboratory technician licensed under Chapter 3 or equivalent licensure or certification as a medical laboratory technician outside California performing duties as specified in Section 1039.2(c). The clinical laboratory scientist trainee shall be authorized to train in high complexity tests in a modified program approved by the department as specified in

Section 1035.5 that shall recognize the completion of six months training for medical laboratory technician licensure. A medical laboratory technician who is licensed as a clinical laboratory scientist trainee shall train for at least six months in high complexity tests and examinations. All test results performed by a licensed trainee shall be critically reviewed by a licensed person who is authorized and shown competent to perform the tests and examinations. The program director shall notify the department within 30 calendar days when a licensed trainee fails to complete training or needs to extend his or her training for remedial needs.

(d) Clinical Laboratory Specialist Trainee Requirements. To qualify for a clinical laboratory specialist trainee license in the specialty of histocompatibility, microbiology, chemistry, toxicology, hematology, immunohematology, cytogenetics, genetic molecular biology, embryology or cytology, a person shall apply for a license pursuant to Section 1031.6 (c) and shall document completion of at least a baccalaureate degree in biology or chemistry from an accredited college or university. Trainees in histocompatibility, hematology, immunohematology, microbiology, cytogenetics, genetic molecular biology, embryology and cytology shall have at least a baccalaureate degree in biological science. Trainees in chemistry and toxicology shall have at least a baccalaureate degree in chemical science. A licensed clinical laboratory specialist trainee shall be authorized to train in waived, moderate and high complexity tests in their specialty and waived and moderate in the other specialties under the supervision of baccalaureate- or doctorate-level persons licensed under Chapter 3. All test results performed by a licensed trainee shall be critically reviewed by a licensed person who is authorized and shown competent to perform the tests and examinations. The program director shall

notify the department within 30 calendar days when a licensed trainee fails to complete training or needs to extend his or her training for remedial needs.

(e) Postgraduate Fellow Requirements. To qualify for a postgraduate fellow license to train in histocompatibility, microbiology, immunology, chemistry, toxicology, cytogenetics, embryology, biochemical genetics or genetic molecular biology, a person shall apply for a license pursuant to Section 1031.6 (c) and shall document completion of a masters or doctorate degree in a clinical, chemical, physical or biological science from an accredited university with at least 30 semester or equivalent quarter hours of post-baccalaureate course credit in the major field of study. A licensed postgraduate fellow shall complete two years of postdoctoral training in high complexity tests in his or her specialty in a program approved by the department as specified in Section 1035.2 and acceptable to a national certifying board for board certification. During these two years, all test results performed by the licensed trainee shall be critically reviewed by the program director or a licensed person who is authorized and shown competent to perform the tests and examinations. Upon completion of the two years of training and successful passage of an approved certification examination as specified in Sections 1030.1 – 1030.7, a licensed postgraduate fellow shall be authorized to perform tests and supervise performance of tests in his or her specialty as a testing person, technical supervisor, technical consultant, general supervisor or clinical consultant pursuant to CLIA , under the general supervision of the program director or designated licensed baccalaureate- or doctorate-level scientist. Upon completion of four years of postgraduate training and experience, a masters-level or doctorate-level candidate shall be deemed to have met training and experience

requirements for licensure as a clinical chemist, clinical microbiologist, clinical toxicologist, clinical molecular biologist or clinical cytogeneticist. Upon completion of four years of postgraduate training and experience, a doctorate-level candidate shall be deemed to have met training and experience requirements for licensure as a histocompatibility laboratory director, clinical immunologist, clinical biochemical geneticist or clinical genetic molecular biologist. Six months prior to completion of the fourth year of postgraduate training and experience, the postgraduate fellow may apply for licensure in his or her specialty and is authorized to take the state-administered oral examination during the last three months of training, completing licensure requirements when the training is completed.

Note: Authority cited: Sections 1224 and 1263, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1213, 1222, 1222.5, 1262, 1263, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(35) Amend Section 1034 to read as follows:

Section 1034. Certification of phlebotomy technicians.

(a) The education, training and experience required for certification in phlebotomy shall be as follows:

(1) For a person to be eligible for certification as a Limited Phlebotomy Technician, he or she shall:

(A) Be a high school graduate or have achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 20 hours basic didactic instruction pursuant to Section 1035.1(e)(1) from a phlebotomy training program approved by the department; and

(C) Have completed a minimum of 25 skin punctures, performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations, in a clinical setting on patients, under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, or licensed clinical laboratory scientist, who will certify in writing with a signed certificate that this training has been completed; and

(D) Apply to the department for certification as a Limited Phlebotomy Technician pursuant to Section 1031.4(c).

(2) For a person with no on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

(A) Be a high school graduate, or have achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section 1035.1(e) from a phlebotomy training program approved by the department; and

(C) Have completed a minimum of 40 hours practical instruction from a phlebotomy training program approved by the department pursuant to Section 1035.1(f), which instruction shall include completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

(D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department pursuant to Section 1031.7; and

(E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4(c).

(3) For a person who has less than 1040 hours on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

(A) Be a high school graduate or have achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section

- 1035.1(e) from a phlebotomy training program approved by the department; and
- (C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting to his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years, which shall include the activities listed in Section 1035.1(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and
- (D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department pursuant to Section 1031.7; and
- (E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4(c).
- (4) For a person who has 1040 hours or more of on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:
- (A) Be a high school graduate or have achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and
- (B) Have completed a minimum of 20 hours advanced didactic instruction pursuant to Section 1035.1(e)(2) from a phlebotomy training program approved by the department; and

(C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting to his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years which shall include the activities listed in Section 1035.1(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

(D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department pursuant to Section 1031.7; and

(E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4(c).

(5) For a person to be eligible for certification as a Certified Phlebotomy Technician II, he or she shall:

(A) Be a Certified Phlebotomy Technician I who holds a current, valid certificate from the department or who meets certification requirements as a Certified Phlebotomy Technician I pursuant to Section 1034(a)(4)(A)-(D) and who has at least 1040 hours on-the-job experience in phlebotomy in the previous 5 years as certified in writing by the director(s) of the laboratory(ies) employing the person; and

(B) Have completed a minimum of 20 arterial punctures within the previous five years performed pursuant to the Business and Professions Code Section 1220(d)(1) or

(d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and performed under the general overall responsibility of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, respiratory care practitioner or a licensed clinical laboratory scientist, who will certify in writing that this person has completed this practical instruction; and

(C) Apply to the department for certification as a Certified Phlebotomy Technician II pursuant to Section 1031.4(c).

(b) Performance of phlebotomy by a person certified by the department shall be limited as follows:

(1) A Limited Phlebotomy Technician shall perform skin punctures only when he or she:

(A) Maintains a current, valid certification with the department as a Limited Phlebotomy Technician; and

(B) Performs skin punctures under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a designee. A designee shall be licensed or certified under Chapter 3 and shall be accountable to the laboratory director for skin punctures and other duties related to blood collection performed by the Limited Phlebotomy Technician. The supervisor shall review the work of the technician at least once a month and be accessible to the location where the technician is working to provide on-site, telephone, or electronic consultation when blood is being collected; and

(C) Is shown to be competent to perform skin punctures after employment without direct and constant supervision before being allowed to perform skin puncture on

patients. Documentation of competency shall be done at least annually; and

(D) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(E) Has posted at the work location in the laboratory employing the person, a current, valid state certificate as a Limited Phlebotomy Technician. When performing skin punctures at multiple sites for the same clinical laboratory employer, the original certificate shall be posted at the main location. At each of the multiple sites, a copy shall be posted which is dated, clearly labeled as "COPY," and includes the address where the original certificate is posted. A Limited Phlebotomy Technician with more than one clinical laboratory employer shall obtain duplicate original certificates from the department for posting at each employer's primary location with copies at alternative sites. When performing skin punctures at non-fixed locations away from the posted location, the Limited Phlebotomy Technician shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Limited Phlebotomy Technician..

(2) A Certified Phlebotomy Technician I shall perform skin punctures and venipunctures only when he or she:

(A) Maintains a current, valid certification with the department as a Certified Phlebotomy Technician I; and

(B) Performs skin punctures and venipunctures under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a designee. A

designee shall be a person licensed or certified under Chapter 3 and shall be accountable to the laboratory director for skin punctures, venipunctures and other duties related to blood collection performed by the Certified Phlebotomy Technician I. The supervisor shall review the work of the technician at least once a month and be accessible to the location where the technician is working to provide on-site, telephone, or electronic consultation as needed; and

(C) Is shown to be competent to perform skin puncture and venipuncture after employment without direct and constant supervision before being allowed to perform skin punctures or venipunctures on patients. Documentation of competency shall be done at least annually; and

(D) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(E) Has posted at the work location of the laboratory employing the person, a current, valid state certificate as a Certified Phlebotomy Technician I. When performing skin punctures or venipunctures at multiple sites for the same clinical laboratory employer, the original certificate shall be posted at the main location. At each of the multiple sites, a copy shall be posted which is dated, clearly labeled as "COPY," and includes the address where the original certificate is posted. A Certified Phlebotomy Technician I with more than one clinical laboratory employer shall obtain duplicate original certificates from the department for posting at each employer's primary location with copies at alternative sites. When performing skin punctures or venipunctures at non-fixed locations away from the posted location, the Certified Phlebotomy Technician I

shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Certified Phlebotomy Technician I.

(3) A Certified Phlebotomy Technician II shall perform skin punctures and venipunctures only under conditions pursuant to Section 1034(b)(2), and shall be limited to performing arterial punctures only when a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a respiratory care practitioner is present at the location during performance of an arterial puncture, and when he or she:

(A) Maintains a current, valid certification with the department as a Certified Phlebotomy Technician II; and

(B) Is shown to be competent to perform arterial punctures after employment by direct, personal observation and documentation of his or her expertise in arterial punctures by a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a respiratory care practitioner. Documentation of competency shall be done at least annually; and

(C) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(D) Has posted at the work location in the laboratory employing the person, a current, valid state certificate as a Certified Phlebotomy Technician II. When performing arterial punctures, skin punctures, or venipunctures at multiple sites for the same clinical

laboratory employer, the original certificate shall be posted at the main location. At each of the multiple sites, a copy shall be posted which is dated, clearly labeled as "COPY," and includes the address where the original certificate is posted. A Certified Phlebotomy Technician II with more than one clinical laboratory employer shall obtain duplicate original certificates from the department for posting at each employer's primary location with copies at alternative sites. When performing skin punctures or venipunctures at non-fixed locations away from the posted location, the Certified Phlebotomy Technician II shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Certified Phlebotomy Technician II.

(c) Certification of phlebotomists shall be valid for two years unless revoked.

Authority cited: Sections 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246, 1260, Business and Professions Code; and Sections 120580 and 131050, Health and Safety Code.

(36) Repeal Section 1035 as follows:

~~Section 1035. Training Schools.~~

~~(a) Any person operating a school or conducting any course for the purpose of training or preparing individuals for a license under the provisions of Chapter 3, Division 2 of the Business and Professions Code shall submit, on forms provided by the department and subject to periodic renewal, such information as may be required by the department to satisfactorily evaluate the personnel, equipment, quality of instruction, and scope of activities of said schools.~~

~~(b) Persons providing instruction in general or specialized technic shall provide training which when successfully completed will fully qualify individuals to meet the minimum requirements for licensure under the provisions of Article 4, Chapter 3, Division 2 of the Business and Professions Code.~~

~~(c) A training school shall accept a person licensed for training in clinical laboratory procedures only if there are on active duty in the laboratory a minimum of two full-time actively employed persons who possess any of the following licenses: clinical laboratory technologist, clinical laboratory bioanalyst, physician and surgeon, or appropriate laboratory specialty.~~

~~(d) The ratio of licensed clinical laboratory personnel to trainees shall be no less than 2:1.~~

~~(e) The following shall be minimum requirements for approval of laboratories to employ clinical laboratory technologist trainees as provided for in Article 2 of Chapter 3, Division 2 of the Business and Professions Code:~~

~~(1) There shall be adequate space and necessary equipment as defined by the~~

department to carry out the procedures of the laboratory and to provide training for the clinical laboratory technologist trainees.

(2) The workload of the laboratory training clinical laboratory technologist trainees shall meet minimum standards set by the department and shall include at least the following: routine chemical determinations commonly required on blood, spinal fluid, and other body fluids; morphological, cultural, chemical and immunological tests for microbial pathogens; tests for helminths and protozoa; examinations for normal and abnormal blood cells; sedimentation rates, bleeding and coagulation time determinations and other commonly employed tests in hematology; precipitation, flocculation, agglutination or complement fixation tests; blood typing, Rh factor determinations and pretransfusion procedures; commonly employed serological tests; routine and microscopic urinalyses and such other techniques as may be required to properly instruct clinical laboratory technologist trainees in current clinical laboratory procedures.

(3) The amount of practical training required by each clinical laboratory technologist trainee in order to fulfill the minimum requirements for admission to the licensing examinations shall be in accordance with the provisions of Article 4, Chapter 3, Division 2 of the Business and Professions Code. When one year of practical training in all subjects is necessary, the minimum time devoted to each shall be as follows:

Biochemistry.....	2 Weeks
Hematology.....	8 Weeks
Pretransfusion Procedures.....	4 Weeks
Urinalysis.....	4 Weeks
Bacteriology.....	9 Weeks

~~Serology..... 4 Weeks~~

~~Parasitology..... 3 Weeks~~

~~Miscellaneous and review..... 8 Weeks~~

~~(4) When less than one or more than one year of practical training is required toward admission to the clinical laboratory technologists' examination, the above time devoted to the various subjects shall be decreased or increased proportionately after the laboratory director has secured approval from the department for the modification.~~

~~(5) However, when one or more years of practical training in any one basic science or specialty is necessary, the laboratory director shall modify this schedule, subject to prior approval by the department, so that the area of concentration is in one or more subjects.~~

~~(6) Unless a trainee is a college graduate, he must receive during the course of his training program a minimum of 40 clock hours of recitation or instruction in the subjects covered in clinical laboratory work other than that received as practical training in the laboratory. Any laboratory school approved for specialist or limited technologist training must provide the department with adequately documented workload and program information and must comply with the minimum requirements heretofore stated in that special field of training.~~

~~(7) The requirements for the members of the teaching staff must be those considered minimum for licensure, and in addition, persons with an advanced degree in one or more of the fields covered in the curriculum may be included on the teaching staff.~~

~~(8) The director of any school shall supply sufficient information to the department to~~

~~satisfy the department that adequate specimen material will be made available for training purposes.~~

~~(9) There shall be available to persons receiving training a technical library adequate in the number of copies of each text book.~~

~~(10) The names and addresses of persons receiving training are to be reported to the department at the time of entrance to course and again at completion of course.~~

~~(11) The department may require such other information as may be necessary to satisfactorily evaluate the application for approval including periodic on-site reviews.~~

~~(12) Approval for training granted by the department pursuant to requirements of this section may be denied or withdrawn if the school is unable to meet or maintain these requirements.~~

~~(f) Colleges or universities accredited by the Western College Association or the Northwest Association of Secondary and Higher Schools or an essentially equivalent accrediting agency, as determined by the department, conducting courses for the purpose of training or preparing persons for a license under the provisions of Chapter 3, Division 2 of the Business and Professions Code, shall be considered approved by the department. Provided, however, that when such training is carried out in cooperation with other laboratories than those of said institutions, specific approval shall be obtained.~~

(37) Adopt New Section 1035 to read as follows:

Section 1035. Clinical Laboratory Scientist and Specialist Training Programs.

(a) To qualify for approval by the department, a clinical laboratory scientist or clinical laboratory specialist training program shall be offered by either:

(1) A program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or

(2) A CLIA certified clinical laboratory performing moderate and high complexity tests and examinations; or

(3) An accredited college or university with affiliated clinical laboratories performing high complexity tests and examinations; or

(4) A one-year military specialist program that includes basic and advanced training in clinical laboratory science.

(b) The program director of a training program shall be a physician and surgeon licensed under Chapter 5, or a doctorate scientist, clinical laboratory bioanalyst, clinical laboratory scientist or clinical laboratory specialist licensed under Chapter 3. The program director shall be responsible for the content, quality and conduct of the training program and shall:

(1) Employ instructors for practical training who are a physician and surgeon licensed under Chapter 5, a doctorate scientist, clinical laboratory bioanalyst, clinical laboratory scientist, clinical laboratory specialist, or phlebotomist licensed or certified under Chapter 3; public health microbiologist certified pursuant to Health and Safety Code Section 101160, or other persons as designated by the program director not to exceed 10 percent of total training time; and

- (2) Assure a staffing level ratio of at least two licensed laboratory personnel for every licensed trainee; and
- (3) Assure that the program provides didactic instruction in pre-analytical skills, such as specimen collection and storage, reagent preparation, preventive maintenance of equipment, universal precautions and safety; and
- (4) Assure that the program provides instruction in analytical techniques required for performing waived, moderate and high complexity tests or examinations. The didactic training shall include quality control, quality assurance, performance improvement, troubleshooting, documentation and legal requirements, calibrator material stability and specimen handling and storage; and
- (5) Assure that the program provides didactic training in post-analytical skills as knowledge of factors that influence test results and the ability to verify the validity of patient test results, and
- (6) Assure that the program provides practical training in the use of laboratory instruments and information technology systems; and
- (7) Assure the program provides practical training so the student can assess instrument and test parameters to assess reasonableness and clinical correlation of test results; and
- (8) Assure that the program notifies the department within 30 calendar days of the dates training was initiated, completed or interrupted for each trainee; and
- (9) Assure that the program maintains student records for a minimum of five years.
- (c) A training program for clinical laboratory scientists shall include a minimum of 48 weeks of didactic and practical instruction and observation of clinical laboratory science

specialties, as follows:

(1) Microbiology, including bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, serology and molecular biology techniques related to microbiology and infectious disease testing, a minimum of four weeks practical experience.

(2) Chemistry, including routine chemistry, clinical microscopy, endocrinology, toxicology and molecular biology techniques related to chemistry, a minimum of four weeks practical experience.

(3) Immunohematology , including ABO/Rh Type or Group, unexpected antibody detection, compatibility testing and antibody identification and molecular biology techniques related to immunohematology, a minimum of four weeks practical experience.

(4) Hematology, including routine hematology and coagulation and molecular biology techniques related to hematology, a minimum of four weeks practical experience.

(5) Phlebotomy, histocompatibility, cytogenetics, genetic molecular biology, and other relevant topics and review, as determined by the program director, for a minimum of eight weeks.

(d) A training program for clinical laboratory specialists shall include a minimum of 48 weeks of didactic and practical training and observation, as follows:

(1) Clinical chemist scientist, waived, moderate and high complexity tests in routine chemistry, clinical microscopy, urinalysis, endocrinology, toxicology, immunology including diagnostic immunology and syphilis serology, and molecular biology techniques related to clinical chemistry tests or examinations, as well as waived and

moderate complexity tests in other specialties and subspecialties.

(2) Clinical microbiology scientist, waived, moderate and high complexity tests in bacteriology, mycobacteriology, mycology, parasitology, virology, immunology including diagnostic immunology and syphilis serology, and molecular biology techniques related to microbiology and infectious disease testing, as well as waived and moderate complexity tests in other specialties and subspecialties pursuant to Section 1206(a)(12)(13) of the Business and Professions Code.

(3) Clinical immunohematologist scientist, waived, moderate and high complexity tests in ABO/Rh Type or Group, expected antibody detection, histocompatibility and blood compatibility testing, antibody identification and molecular biology techniques related to immunohematology, as well as waived and moderate complexity tests in other specialties and subspecialties pursuant to Section 1206(a)(12)(13) of the Business and Professions Code.

(4) Clinical toxicology scientist, waived, moderate and high complexity toxicology and molecular biology techniques related to toxicology, and waived and moderate complexity tests in other specialties and subspecialties.

(5) Clinical hematologist scientist, waived, moderate and high complexity tests in routine hematology of blood, body fluids and bone marrow, flow cytometry, coagulation and molecular biology techniques related to hematology, as well as waived and moderate complexity tests in other specialties and subspecialties.

(6) Clinical histocompatibility scientist, waived, moderate and high complexity tests of histocompatibility of blood and tissues, transplantation immunity, major and minor antigens and isoantigens, and molecular biology techniques related to

histocompatibility, as well as waived and moderate complexity tests in other specialties and subspecialties pursuant to Section 1206(a)(12)(13) of the Business and Professions Code.

(7) Clinical cytogeneticist scientist, waived, moderate and high complexity tests in clinical cytogenetics, chromosomal analyses for evaluation of genetic abnormalities causing disease or dysfunction, as well as waived and moderate complexity tests in other specialties and subspecialties pursuant to Section 1206(a)(12)(13) of the Business and Professions Code.

(8) Clinical genetic molecular biologist scientist, waived, moderate and high complexity tests in genetic molecular biology, the analysis of cellular components, DNA, RNA and nucleotides for genetic abnormalities leading to disease or dysfunction, as well as waived and moderate complexity tests in other specialties and subspecialties pursuant to Section 1206(a)(12)(13) of the Business and Professions Code.

(e) The program director shall notify the department within 30 calendar days of any trainee who terminates the program prior to completion or who requires a time extension for any reason to complete training.

(f) The application for approval of a program to train clinical laboratory scientists or clinical laboratory specialists shall include the following:

(1) Name and address of the training program;

(2) Location(s) at which training shall be conducted;

(3) Name(s) and qualifications of the person(s) directing the program;

(4) Name(s) and qualifications of the person(s) instructing in the program;

(5) Didactic curriculum showing classes, objectives, topics, instructor and time spent;

(6) Practical training showing objectives, techniques taught, instructor and time spent;

(7) Phlebotomy training, showing objectives, techniques taught, instructor and time spent;

(8) Lists of equipment, supplies and materials used for instruction; and

(9) Signature(s) of the program director(s) and date of application.

(g) A training program shall be approved by the department for a period of five years. A NAACLS-accredited program approval shall be consistent with their accreditation cycle, but shall not exceed seven years.

(h) To apply for renewal by the department, the training program shall file an application at least 60 days prior to the end of the approval period by providing the following:

(1) Name and address of the training program;

(2) Any changes in directors, instructors, didactic, practical or phlebotomy instruction, equipment, supplies and materials that were made to the program since the previous application;

(3) A list of students who completed its program since the previous approval was granted; and

(4) Signature(s) of the program director(s) and date of application for renewal.

(i) Once approved, a training program may be subject to onsite verification of compliance with approval standards. Approval for training may be denied, suspended or revoked if the program fails to meet or maintain approved standards.

(j) A clinical laboratory scientist or specialist training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall maintain a copy of the certificate for at least five years. This certificate shall be

signed by the director of the program and shall include:

(1) Name and address of the training program; and

(2) Name of the student; and

(3) Statement of satisfactory completion of the program; and

(4) Dates that training began and ended.

(k) A program approved to train clinical laboratory scientists shall maintain records of its students for at least five years and shall make available to the department documentation of the students successfully completing their training.

Note: Authority cited: Sections 1224 and 1263, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1202.5, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1213, 1222, 1222.5, 1262, 1263, 1263, 1264 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(38) Amend Section 1035.1 to read as follows:

Section 1035.1. Phlebotomy Training Program Requirements.

(a) In order to be eligible for approval by the department to provide didactic and/or practical phlebotomy instruction leading to certification of phlebotomists, a phlebotomy training program shall meet the requirements of this section and be offered by either a:

- (1) National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) approved program for training phlebotomists; or
- (2) Accredited college or university; or
- (3) Private, post-secondary program or occupational program registered or approved by the Bureau for Private Postsecondary and Vocational Education; or
- (4) California Adult Education or Regional Occupational Program (ROP); or
- (5) United States of America military medical laboratory specialist program; or
- (6) California licensed clinical laboratory.

(b) A phlebotomy training program shall be directed by a licensed physician and surgeon, licensed physician assistant, registered nurse, or person licensed under Chapter 3, who shall be responsible for:

- (1) Overall operation and administration of the phlebotomy training program; and
- (2) Ensuring the quality of the technical, scientific and clinical instruction; and
- (3) Ensuring that the person(s) providing instruction meets the qualifications of this section; and
- (4) Ensuring that the person(s) providing instruction is competent and that his or her work performance is periodically evaluated, monitored and documented.

(c) The person(s) providing instruction shall be a:

- (1) Licensed physician and surgeon; or
 - (2) Licensed physician assistant; or
 - (3) Registered nurse; or
 - (4) Person licensed under Chapter 3; or
 - (5) Respiratory care practitioner with a minimum of 2 years of experience in the previous 5 years; or
 - (6) Certified phlebotomy technician with a minimum of 3 years of experience in the previous 5 years. ~~or a phlebotomist with 3 years of experience in the previous 5 years and employed as a phlebotomy instructor, who shall meet certification requirements pursuant to Section 1034(a)(4) on or before December 31, 2003.; or~~
- ~~(d) Person(s) specified in Subsection (c) (1) through (5) shall pass a written examination in phlebotomy, administered by a certifying organization approved by the department pursuant to Section 1031.7 either:~~
- ~~(1) Prior to employment by a phlebotomy training program approved by the department pursuant to this section; or~~
 - ~~(2) No later than December 31, 2003, if employed as a phlebotomy instructor on or before April 9, 2003.~~
- (e) (d) An approved phlebotomy training program shall provide the following didactic instruction to its students:
- (1) A basic phlebotomy curriculum consisting of a minimum of 20 hours lecture and testing for knowledge of:
 - (A) Basic infection control, universal precautions and safety; and
 - (B) Basic anatomy and physiology of body systems with emphasis on the circulatory

system, the appropriate medical terminology; and

(C) Proper identification of patient and specimens, the importance of accuracy in overall patient care; and

(D) Proper selection and preparation of skin puncture site, including selection of antiseptic; and

(E) Blood collection equipment, types of tubes and additives, proper order of draw when additives are required, special precautions; and

(F) Post-puncture care; and

(G) Appropriate disposal of sharps, needles and waste.

(2) An advanced phlebotomy curriculum consisting of a minimum of 20 hours of lecture and testing for knowledge of:

(A) Advanced infectious disease control and biohazards; and

(B) Anti-coagulation theory; and

(C) Knowledge of pre-analytical sources of error in specimen collection, transport, processing and storage; and

(D) Anatomical site selection and patient preparation; and

(E) Risk factors and appropriate responses to complications which may arise from phlebotomy; and

(F) Recognition of, and corrective actions to take, with problems in test requisitions, specimen transport and processing; and

(G) Applications of basic concepts of communication, interpersonal relations, stress management, professional behavior, ethics and legal implications of phlebotomy; and

(H) Quality assurance in phlebotomy necessary to provide accurate and reliable

laboratory test results; and

(l) Legal issues related to blood collection.

(f) (e) An approved phlebotomy training program shall provide a clinical setting for a minimum of 40 hours of practical instruction in phlebotomy. This setting shall provide access to patients whose blood is being tested by a clinical laboratory. In order for a program to be eligible for approval by the department, it shall provide documentation of a training curriculum that includes:

(1) Selection of blood collection equipment appropriate to test requisitions; and

(2) Preparation of the patient and infection control; and

(3) Skin punctures for testing purposes from patients of varying ages, including pediatric and geriatric, and of varying health and obesity status; and

(4) Venipunctures from patients of varying ages, health and obesity status; and

(5) Post-puncture care; and

(6) Processing of blood containers after collection, including centrifugation; and

(7) Proper disposal of needles, sharps and medical waste; and

(8) Observation of arterial punctures; and

(9) A practical examination showing evidence of successful completion of Subsections

(f)(1) through (7).

(g) (f) A phlebotomy training program shall be responsible for assuring that a student completes a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical

laboratory tests or examinations during or after his or her practical instruction.

(h) (g) A phlebotomy training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall maintain a copy of this certificate for five years. This certificate shall be signed by the director of the program and shall include:

- (1) Name and address of the training program; and
- (2) Name of the student; and
- (3) Statement of satisfactory completion of the program; and
- (4) Dates that training began and ended.

(i) (h) A phlebotomy training program seeking approval from the department shall provide documentation to substantiate that its program objectives meet training criteria stated in this section. Verification may include an on-site inspection of the program.

(j) (i) A complete application for phlebotomy training program approval shall include the following:

- (1) Name and address of the training program; and
- (2) Location(s) of all sites where didactic and practical instruction occur; and
- (3) Name(s) and license number(s) of the physician and surgeon, physician assistant, registered nurse, or person licensed under Chapter 3 who is directing the program; and
- (4) Name(s), license number(s) or certificate number(s) and experience in phlebotomy, ~~and evidence of satisfactory performance on a phlebotomy certification examination administered by a certifying organization with departmental approval in effect at the time the examination was administered,~~ of every physician and surgeon, physician assistant, registered nurse, person licensed under Chapter 3, respiratory care practitioner,

certified phlebotomy technician, or phlebotomist pursuant to Subsection (c)(6) who is supervising or providing instruction; and

(5) List of equipment, supplies and educational materials used for instruction; and

(6) Curriculum and instructional objectives, including hours spent at each activity.

(k) (j) Timeframes for approval of training programs shall be as follows:

(1) Submission of an application for approval shall be deemed to occur on the date the complete application is received by the department.

(2) Written notification by the department to the applicant shall be considered to occur on the date the documents are postmarked.

(3) The department shall notify the applicant within 60 days of submission of an application for training program approval, of one of the following:

(A) That the application is complete and acceptable for processing by the department;
or

(B) That the application is incomplete and not accepted for processing. This notification shall include the specific information or documentation that the applicant shall submit within 30 days in order for the department to consider the application acceptable; or

(C) That the application has been reviewed and does not meet the requirements of this section and that approval is denied.

(4) The department shall consider an application to have been abandoned by any applicant who fails to respond to the department's request to submit specific information or documentation within 30 days of notification pursuant to Section 1035.1(k)(j)(3)(B).

(5) The department's time periods for processing an application, from the date the initial application is received to the date the final decision is made regarding approval, are as

follows:

- (A) The median time for processing an application is 90 days.
- (B) The minimum time for processing is 30 days.
- (C) The maximum time for processing is 150 days.
- (~~f~~) (k) Approval shall be valid for a two-year period.
- (~~m~~) (l) To apply for renewal, a training program shall file a renewal application at least 60 days prior to the end of the approval period and provide the following:
 - (1) The name and address of the training program; and
 - (2) The name and license number of all directors; and
 - (3) The name, license or certificate number of all instructors; and
 - (4) The name(s) and location(s) of all didactic and practical instruction; and
 - (5) The curriculum and instructional objectives, including hours spent at each activity;
and
 - (6) The schedule of didactic and practical instruction for the next 24 months; and
 - (7) The listing of students who completed its program and the total number of students who enrolled in its program in the previous approval period; and
 - (8) The signature of the director(s) and date of the application for renewal.
- (~~n~~) (m) Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.
- (~~o~~) (n) The training program shall notify the department in writing of any change(s) in the information and material required by Subsections (a) through (h) within 30 calendar days after the change(s) has occurred.

Note: Authority cited: Sections 1224 and 1320 Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.
Reference: 1208, 1220, 1222, 1222.5, 1242, 1242.5, 1246, 1269, 1300, Business and Professions Code; and Sections 120580 and 131050, Health and Safety Code.

(39) Adopt new Section 1035.2 to read as follows:

Section 1035.2 Postgraduate Fellow Training Program Requirements.

(a) To qualify for approval by the department, a program that provides training and/or experience for a postgraduate fellow that shall be deemed acceptable for licensure shall meet the following requirements:

(1) The clinical laboratory in which the training occurs shall be CLIA certified, ILAC accredited or accredited by another agency approved by the department pursuant to Section 1031.11, that performs high complexity clinical laboratory tests or examinations in the specialty and subspecialties appropriate for the training; and

(2) The program director of the training program shall be a physician and surgeon licensed under Chapter 5 or a doctorate scientist licensed under Chapter 3 in the specialty of training. The program director shall be responsible for the content, quality and conduct of the training provided the postgraduate fellow; and

(3) The program director of the training program shall submit a training plan to the department for each postgraduate fellow within 30 days of initiation of training. The plan shall include the dates training is initiated and shall be completed, rotation schedule and training objectives at each rotation site, and measures used to assess adequacy of training. An acceptable training plan shall include equipment, technology, staffing and instruction. If the postgraduate fellow transfers to another training program, completion of training at the first location must be documented by that program director and another training plan must be submitted by the new program director to the department within 30 calendar days; and

(4) The postgraduate training program must have equipment, developed tests and

examinations, and reference materials in all areas of the specialty, allowing the trainee to perform diagnostic tests, evaluate results, review quality control parameters, conduct quality assurance procedures, participate in problem solving, and interact with ordering physicians and testing personnel; and

(5) The postgraduate training program must meet requirements for a candidate to be admitted to a national certification board examination approved by the department as specified in Sections 1030.1 – 1030.7; and

(6) The program director shall notify the department within 30 calendar days of any postgraduate fellow that terminates his or her program prior to completion date or who requires a time extension to complete training.

(b) The program director of the training program shall provide “direct and responsible supervision” to the postgraduate fellow. The laboratory director shall be responsible for assuring that the tests and examinations performed by the postgraduate fellow during the first two years of training are subject to critical review for accuracy and reliability as specified in Section 1033 (e). When the postgraduate fellow completes his or her first two years of training and successfully passes an approved national certification examination as specified in Section 1030.1 – 1030.7, the program director shall maintain direct supervision of the postdoctoral fellow as he or she completes two years of practical experience prior to full licensure as a doctorate scientist.

Note: Authority cited: Sections 1224 and 1264, Business and Professions Code; and Section 131200, Health and Safety Code.
Reference: Sections 1205, 1206, 1207, 1213, 1222.5, 1263, 1264, 1286 and 1300, Business and Professions Code; and Section 131050, Health and Safety Code.

(40) Amend Section 1035.3 to read as follows:

Section 1035.3 Medical laboratory technician training standards.

(a) In order to be eligible for approval by the department, a medical laboratory technician training program shall be offered by: ~~either a:~~

(1) A California licensed clinical laboratory; or

(2) An ~~a~~Accredited college of university in the United States of America; or

(3) A United States of America military medical laboratory specialist program of at least 26 weeks duration; or

(4) A ~~L~~laboratory owned and operated by the United States of America; or

(5) A program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) for training medical laboratory technicians.

(b) The program director of a medical laboratory technician training program shall be a physician and surgeon licensed under Chapter 5, or a doctorate scientist, clinical laboratory bioanalyst, clinical laboratory scientist or clinical laboratory specialist licensed under Chapter 3. The program director shall be responsible for the content, quality and conduct of the training program and shall:

(1) Employ instructors for practical experience who are physicians and surgeons licensed under Chapter 5; ~~doctoral-~~ doctorate scientists, clinical laboratory bioanalysts, clinical laboratory scientists, or clinical laboratory specialists licensed under Chapter 3; medical laboratory technicians with five years of practical experience licensed under Chapter 3; ~~or~~ public health microbiologists certified pursuant to Health and Safety Code Section 101160; and

(2) Assure that training includes at least 26 weeks, consisting of at least 1040 hours, of

instruction and practical experience in moderate complexity testing in chemistry, including routine chemistry, urinalysis, endocrinology and toxicology; hematology; microbiology, including bacteriology, mycobacteriology, mycology, parasitology and virology; and immunology, including syphilis serology and general immunology. The training shall include at least 160 hours each in chemistry, hematology, microbiology and immunology.

(3) Assure that the ratio of medical laboratory technician trainee to baccalaureate-level person licensed under Chapter 3 is no greater than four to one during practical training.

~~(3)~~ (4) Provide didactic training in:

- (A) Pre-analytical skills including phlebotomy, specimen processing, reagent preparation, and infection control, as specified in Section 1035.1(e) and (f); and
- (B) Analytical skills required for performing tests of waived or moderate complexity, including quality control, test calibration, quality assurance, legal requirements for documentation of testing, data storage and retrieval, safety and standard precautions, troubleshooting, preventive maintenance, reagent preparation and storage; and
- (C) Post-analytical skills such as knowledge of factors that influence test results and the ability to access and verify the validity of patient test results through review of quality control values prior to reporting patient test results; and
- (D) Test methods commonly used in chemistry, hematology, microbiology and immunology, including clinical significance of test results, how the tests interrelate and how the tests impact diagnosis and treatment, quality assessment of test results, information processing and regulatory compliance in state and federal law.

~~(4)~~ (5) Provide practical training in:

(A) Phlebotomy that shall include 40 hours instruction and successful completion of a minimum of 10 skin punctures and 50 venipunctures, as specified in Section 1035.1(f);

and

(B) Instruction and practical experience in the use of instruments; and

(C) Preventive maintenance and problem solving malfunctions of instruments; and

(D) Knowledge of instrument and test parameters to assess reasonableness of results;

and

(E) Validation of moderate complexity test methods and clinical correlation of test results.

(c) A medical laboratory technician training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall maintain a copy of this certificate for at least five years. This certificate shall be signed by the director of the program and shall include:

(1) Name and address of the training program; and

(2) Name of the student; and

(3) Statement of satisfactory completion of the program; and

(4) Dates that training began and ended.

(d) A program approved to train medical laboratory technicians shall maintain records of its students for at least five years and shall make available to the department documentation of the students successfully completing their training.

(e) A medical laboratory technician training program seeking approval from the department shall provide documentation to substantiate that its program objectives meet training criteria stated in this section.

(f) A medical laboratory technician training program shall be allowed to document program compliance with the requirements of this section for a period dating up to four years prior to their initial application, after the date of implementation of these standards. The program shall document that, during the time preceding initial approval, the training program met the standards pursuant to Section 1035.3(a) and (b).

(g) A complete application for a medical laboratory technician training program shall include the following:

(1) The name and address of the primary training program, including city, state, county and zip code; telephone number, FAX number and e-mail address; and

(2) The location(s) of all sites where training will be conducted, including city, state and zip code; and

(3) The name(s) and qualifications of the person(s) directing and instructing in the program including a copy of current licensure for each person. Training programs in the United States of America but outside California shall provide evidence that the director(s) and instructor(s) substantially meet this licensure requirement by documenting inclusion, licensure or certification in a class of personnel similar to those required in Chapter 3 or requiring equivalent standards; and

(4) Dates the training program was conducted if prior approval is requested as specified in Section 1035.3(f); and

(5) The didactic curriculum listing each class or topic with instructional objectives, the instructor(s) and the amount of time allocated for each class or topic, pursuant to Section 1035.3(b)(3); and

(6) Documentation of practical training in pre-analytical, analytical and post-analytical

skills, including instructor(s) and hours spent at each activity, list of equipment, supplies and materials used pursuant to Section 1035.3(b)(4); and

(7) The signature(s) of the program director(s), telephone number(s) and date of application.

(h) A medical laboratory technician training program approval shall be valid for a four-year period. To apply for renewal, the training program shall file an application at least 120 days prior to the end of the approval period providing the following:

(1) The name and address of the primary training program, including city, state, county and zip code, telephone number, FAX number and e-mail address; and

(2) The name, address, and telephone number(s) of the director(s) and instructor(s), providing documentation of their current licensure; and

(3) Any changes in training locations, didactic and practical instruction, course objectives, equipment, supplies and materials, that shall be made to the program from that approved in the previous application; and

(4) A listing of all students who completed its program and the total number of students who enrolled in its program during the previous approval period; and

(5) The signature(s) of the program director(s) and the date of application for renewal.

(i) The training program shall notify the department in writing of any change(s) in the information and materials required by Section 1035.3(b) through (d) within 30 calendar days after the change(s) has occurred.

(ii) Failure to meet and maintain the requirements of this section shall be good cause for denial or revocation of approval by the department.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Sections 1206.5, 1208, 1209, 1222, 1222.5, 1242, 1246, 1260.3, 1269, 1286 and 1300, Business and Professions Code; and Section 131050, Health and Safety Code.

(41) Adopt new Section 1035.5 to read as follows:

Section 1035.5 Training Programs for Medical Laboratory Technicians

Articulating to Clinical Laboratory Scientist Licensure.

(a) To qualify for approval by the department, a training program that trains medical laboratory technicians for clinical laboratory scientist licensure shall be offered by either:

(1) A (Clinical laboratory certified by CLIA for performing moderate and high complexity tests and examinations, or

(2) An accredited college or university with affiliated clinical laboratories that are CLIA-certified to perform high complexity tests and examinations.

(b) The program director of the training program shall be a physician and surgeon licensed under Chapter 5, or a doctorate scientist licensed under Chapter 3. The program director shall be responsible for the content, quality and conduct of the training program and shall:

(1) Employ instructors for practical experience who are physicians and surgeons licensed under Chapter 5, doctorate scientists, clinical laboratory bioanalysts, clinical laboratory scientists or clinical laboratory specialists licensed under Chapter 3, public health microbiologists certified pursuant to Health and Safety Code 101160; and

(2) Assure that the didactic and practical experience includes at least 26 weeks consisting of at least 1040 hours of instruction, practical experience and observation of high complexity testing in histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology and genetics, including tests and examinations in molecular biology; and

- (3) Assure that the program provides practical experience in analytical techniques required for performing high complexity testing, including quality control, quality assurance, performance improvement, safety, universal precautions, and reagent control and storage; and
- (4) Assure that the program provides practical experience in the use of laboratory instruments and information technology systems; and
- (5) Assure that the program provides practical experience so the student can assess instrument and test parameters to assess reasonableness and clinical correlation of test results; and
- (6) Assure that the program provides instruction in clinical laboratory laws and regulations, laboratory administration and management.
- (7) The program shall issue a certificate of completion, signed by the program director, to its students upon completion of training. The certificate shall include the name of the student, name of the training program, dates training began and ended, and a statement of satisfactory completion. The program shall maintain student records for a minimum of five years.
- (c) The application for approval of a program to train medical laboratory technicians for articulation to clinical laboratory scientist licensure shall include the following:
- (1) Name and address of the training program; and
- (2) Location(s) at which training shall be conducted; and
- (3) Name(s) and qualification(s) of the person(s) directing the program; and
- (4) Name(s) and qualification(s) of the person(s) instructing in the program; and
- (5) Didactic curriculum showing classes, objectives, topics, instructor(s) and time

spent; and

(6) Practical training showing objectives, techniques taught, instructor(s) and time

spent; and

(7) Lists of equipment used for instruction; and

(8) Signature(s) of program director(s) and date of application.

(d) A training program shall be approved by the department for a period of five years.

(e) To apply for renewal by the department, the training program shall file an application at least 60 days prior to the end of the approval period by providing the following:

(1) Name and address of training program; and

(2) Any changes in directors, instructors, didactic or practical instruction, and equipment, and locations of training made to the program since the previous application; and

(3) A list of students who completed the program since its last approval; and

(4) Signature(s) of program director(s) and date of application for renewal.

(f) The training program shall be subject to unannounced onsite verification of compliance with approval standards. Approval for training may be denied, suspended or revoked if the program fails to meet or maintain approved standards.

Note: Authority cited: Sections 1224 and 1263, Business and Professions Code; and Section 131200, Health and Safety Code.

Reference: Sections 1205, 1206, 1213, 1222.5, 1260.3, 1261, 1262, 1263 and 1286, Business and Professions Code; and Section 131050, Health and Safety Code.

(42) Amend Section 1036 to read as follows:

Section 1036. Clinical consultant.

(a) Every clinical laboratory director, under whom moderate or high complexity tests or examinations are performed, shall either perform the duties of a clinical consultant or employ a clinical consultant who can provide consultation about the appropriateness of testing ordered and interpretation of test results, as specified in Section 1209, Chapter 3 of the Business and Professions Code.

(b) The clinical consultant shall possess a current, valid license issued by the State to direct a clinical laboratory pursuant to Chapter 3, Business and Professions Code, or to practice medicine, osteopathy or podiatry pursuant to Chapter 5, Business and Professions Code, or possess a current, valid license as a postgraduate fellow who has successfully passed an approved national certification examination as specified in Section 1033 (e) appropriate to the specialties or subspecialties for which he or she is consulting.

(c) The clinical consultant shall:

- (1) Provide clinical consultation to the clients of the laboratory; and
- (2) Assist in ordering tests appropriate to meet clinical expectations; and
- (3) Ensure that test results include pertinent information required for interpretation in relation to specific patient conditions; and
- (4) Communicate matters about quality of test results reported and interpretation in relation to specific patient conditions.

Note: Authority cited: Section 1224, Business and Professions Code and Section ~~400275~~ 131200, Health and Safety Code;
Reference: Sections 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code; and Section 131050, Health and Safety Code.

(43) Amend Section 1036.1 to read as follows:

Section 1036.1 General Supervisor

(a) Every clinical laboratory director, under whom high complexity tests or examinations are performed, shall either perform the duties of a general supervisor or employ a general supervisor who shall be responsible for the day-to-day supervision of laboratory operation and personnel performing and reporting high complexity tests, pursuant to Section 1209, ~~Chapter~~ Chapter 3 of Business and Professions Code.

(a) A general supervisor shall:

(1) Possess an active, valid license issued by the State to perform high complexity testing pursuant to ~~Chapter~~ Chapter 3 of Business and Professions Code or to practice medicine, osteopathy or podiatry pursuant to ~~Chapter~~ Chapter 5 of Business and Professions Code ~~appropriate to the specialty or specialties they are supervising~~; and

(2) Have a minimum of two years' experience in high complexity testing in the specialty of specialties they are supervising.

(c) The general supervisor shall be accessible to testing personnel at all times testing is performed by providing on-site, telephone or electronic consultation to resolve technical problems.

(d) The general supervisor shall be responsible for ensuring that tests and examinations are performed in compliance with ~~Chapter~~ Chapter 3 of the Business and Professions Code and Title 42, Code of Federal Regulations, Part 493 standards as published January 1, 1994.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference: Section 1206, 1207, 1208, 1209, 1209.1 and 1210, Business and Professions Code; and Section 131050, Health and Safety Code.

(44) Amend Section 1038.1 to read as follows:

Section 1038.1. Continuing Education Requirements.

- (a) All persons licensed under Division 2, Chapter 3 of the Business and Professions Code, commencing with Section 1200, whose license is in active status shall complete 12 contact hours of continuing education ~~each calendar year~~ within a 12-month period or 24 contact hours of continuing education within a 24-month period. All persons licensed with more than one active license type pursuant to Division 2, Chapter 3 of the Business and Professions Code shall be able to renew all license types after completion of a total of 12 contact hours of continuing education ~~each calendar year~~ within a 12-month period or 24 contact hours of continuing education within a 24-month period.
- (b) At the time of renewal, each licensee shall provide the Department with the date, accrediting agency number, name and number of contact hours received for each continuing education program successfully completed by the licensee in the previous ~~calendar year~~ licensing period.
- (c) The licensee shall retain continuing education documents received from approved providers under Section 1038.4 for a minimum of four years.
- (d) A random sample of licensees shall be audited by the Department to determine compliance with the continuing education requirement. Those licensees selected for audit shall submit to the Department, within 30 calendar days of notification of selection, a copy of each document provided the licensee under section 1038.4(c) since the date of last license renewal.
- (e) Any licensee who is found to have not successfully completed the continuing education requirement of this article will be placed in inactive status. The licensee shall have the right to appeal such findings to the Department. An appeal shall be conducted in compliance with Chapter 5 (commencing with section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

Note: Authority cited: Sections 1224 and 1275, Business and Professions Code; and Section ~~208, 131200~~, Health and Safety Code. Reference: Section 1275 and 1301.1, Business and Professions Code; and Section 131050, Health and Safety Code.

(45) Amend Section 1038.6 to read as follows:

Section 1038.6. Inactive Status

A licensee whose license issued pursuant to Division 2, Chapter 3 of the Business and Professions Code is in inactive status shall document completion of 12 24 contact hours of continuing education ~~for the year~~ during the 24 months prior to reinstatement or before the end of the fifth year of inactive status. ~~or pass the examination for licensure prior to reinstatement to active status.~~

Note: Authority cited: Sections 1224 and 1275, Business and Professions Code; and Section ~~208~~ 131200, Health and Safety Code.

Reference: Section 1275, Business and Professions Code; and Section 131050, Health and Safety Code.

(46) Amend Section 1039.2 to read as follows:

Section 1039.2 Clinical Laboratory Personnel Requirements.

(a) All persons performing, supervising, consulting on, or directing clinical laboratory tests or examinations in California shall meet the requirements for performing, supervising, consulting on, or directing laboratory tests or examinations as set forth in Chapter 3 of the Business and Professions Code for the type and complexity of tests performed and irrespective of whether the clinical laboratory is operated under a CLIA certificate or under a state license or registration.

(b) All persons performing, supervising, consulting on, or directing clinical laboratory tests or examinations outside California on biological specimens originating in California, and irrespective of whether the clinical laboratory where the tests or examinations are performed is operated under a CLIA certificate or under a state license or registration, shall meet all personnel requirements set forth in Chapter 3 for the type and complexity of testing performed, or shall provide evidence to the department that they substantially meet those requirements by documenting inclusion, licensure or certification in a class of personnel similar to those required in Chapter 3 or requiring equivalent standards.

(c) All persons applying for licensure in California utilizing experience obtained outside California to meet training or experience requirements for licensure in California, must provide evidence that their experience was obtained while they met requirements in Chapter 3 or CLIA for performing these duties by documenting inclusion, licensure or certification in a category of personnel equivalent to that for which they are seeking licensure.

Note: Authority cited: Section 1224, Business and Professions Code; and Section ~~400275~~ 131200, Health and Safety Code.

Reference; Sections 1206, 1206.5, 1209, 1241, 1244, 1265, 1281 and 1288.5, Business and Professions Code; and Section 131050, Health and Safety Code.

(47) Repeal Section 1060 as follows:

~~Section 1060. Definitions: Cytotechnologist License.~~

~~(a) The definitions in subsections (b) through (i) shall govern the interpretation of this article.~~

~~(b) "Competency testing service or program" means an organization that has been approved by the Department pursuant to section 1270 of the California Business and Professions Code to administer a cytotechnology competency examination.~~

~~(c) "Cytotechnologist competency examination" means an examination which evaluates a person's entry level skills and abilities in cytotechnology, including his or her understanding of: (1) the underlying scientific principles, technical and procedural aspects of cytotechnology; (2) the identification of cellular changes in gynecological and non-gynecological specimens through both a written and visual component; (3) cytopreparatory techniques; and (4) cytology laboratory operations; and which include the following subject areas in the following ratios: 48% to 52% female reproductive system (to include both the genital system and breast); 13% to 17% respiratory system; 9% to 12% male and female genitourinary systems; 6% to 10% alimentary system; and 13% to 17% body cavity fluids and other body sites.~~

~~(d) "Entry Level Skills" means the following skills and abilities expected at career entry:~~

~~(1) Knowledge and understanding of:~~

~~(A) the underlying scientific principles as well as the technical and procedural aspects of the examination of cytology specimens~~

~~(B) the physiological, biochemical, microbiological, and genetic factors which affect cell health and disease, and the importance of cytology laboratory examinations to medical~~

care;

~~(C) quality assurance sufficient to monitor and to implement quality control programs;~~

~~(D) the introduction and implementation of new procedures and the evaluation of new instruments;~~

~~(E) basic management theory and functions.~~

~~(2) Technical skills so that the examinee is capable of:~~

~~(A) performing examinations on cytology specimens;~~

~~(B) exercising initiative and independent judgment in dealing with the broad scope of procedural and technical problems;~~

~~(C) participating in, or being delegated, the responsibility for decisions involving quality control programs, or reagent purchases;~~

~~(D) communicating technical or general information to medical, paramedical, or lay individuals;~~

~~(E) participating in and developing responsibility for the establishment of technical and administrative procedures;~~

~~(F) supervising technicians, aides, and clerical personnel, as directed; and~~

~~(G) providing instruction in the basic theory, technical skills, and application of cytology laboratory procedures.~~

~~(e) "Examinee" means an individual who meets the following requirements:~~

~~(1) Has a baccalaureate degree from a college or university accredited by the Western Association of Schools and Colleges or its equivalent with 20 semester hours (30 quarter hours) of biological science, 8 semester hours (12 quarter hours) of chemistry and 3 semester hours (4 quarter hours) of mathematics; and~~

~~(2) Has completed:~~

~~(A) A 12-month cytotechnology program accredited by the Council on Accreditation of Allied Health Educational Program (CAAHEP) or its equivalent; or~~

~~B) Five years, of at least 40 hours a week, clinical laboratory experience in cytopreparatory techniques, microscopic analysis and evaluation of the body systems within the last ten years. At least two of these years must be subsequent to the completion of the academic component and at least two years must be under the supervision of a licensed physician who is a pathologist certified or eligible for certification by the American Board of Pathology in Anatomic Pathology or has other qualifications acceptable to the competency testing service or program.~~

~~(f) "Evidence of Satisfactory Performance" means (1) a copy of a document issued to an examinee after January 1, 1993 by a cytotechnology competency testing service or program indicating satisfactory performance by the examinee on a cytotechnologist competency examination; or (2) a copy of a document issued to an individual by the American Society of Clinical Pathologists (ASCP) Board of Registry (BOR) indicating satisfactory performance by the individual on an ASCP Cytotechnology Examination taken prior to the approval of a competency testing service or program under the provisions of this article.~~

~~g) "Satisfactory performance" means (1) receipt of a passing score on a cytotechnologist competency examination given after January 1, 1993; or (2) passage of an ASCP Cytotechnology Examination prior to the approval of a competency testing service or program under the provisions of this article.~~

~~(h) "Passing score" means a score determined by a cytotechnologist competency~~

~~testing service or program utilizing the criteria approved by the Department pursuant to section 1062.~~

~~(i) "Owner(s)" means any person who is a sole proprietor, or holds a partnership interest in, or who is an officer, director, or 5% (five percent) or more shareholder in a corporation which owns an organization that is applying for approval as a cytotechnologist testing service or program.~~

Note: Authority cited: Sections 1224 and 1270, Business and Professions Code.
Reference: Section 1270, Business and Professions Code.

(48) Repeal Section 1061 as follows:

~~Section 1061.— Cytotechnology Licensure.~~

~~(a) A cytotechnologist license shall be issued to an individual who submits the following to the Department:~~

~~(1) A verified and complete application as described in subsection (b);~~

~~(2) Evidence of satisfactory performance;~~

~~(3) The application fee required under Business and Professions Code Section 1300 and Health and Safety Code Section 116.~~

~~(b) A complete application for a cytotechnologist license shall include the following verified information on a form, Application for Cytotechnologist License (LAB 124, Rev. 11/93), provided by the Department:~~

~~(1) Name, address, social security number (optional), and ASCP registration number, if any, of the applicant; and~~

~~(2) The applicant's education, training and experience in gynecological and non-gynecological cytology including:~~

~~(A) An official copy of any and all college credits including a statement of any degrees conferred; and~~

~~(B) Documentation of each of the following, if completed or obtained by the applicant:~~

~~1. The completion of a 12 month training program approved by CAAHEP or its equivalent, or~~

~~2. The completion of five years of full-time, of at least 40 hours a week, clinical laboratory experience in cytology;~~

~~3. ASCP registration certificate;~~

~~4. Licensure by the Department under Business and Professions Code section 1270-
subsection (c) or subsection (d); and~~

~~(3) The name and address of the applicant's current laboratory employer(s), and the
number of hours employed (by each) and the time devoted, and volume of types of
specimens examined at each location.~~

~~(c) Within 30 calendar days of receipt of an application for a cytotechnologist license,
the Department shall inform the applicant in writing that the application is either
complete and accepted for filing or that it is incomplete and what specific information is
required before the application may be accepted for filing.~~

~~(d) Within 90 calendar days from the date the Department receives the information and
documentation required in subdivision (a), it shall inform the applicant in writing whether
a cytotechnologist license shall be issued or denied. If a license is denied, the
Department shall indicate the reasons therefore.~~

~~(e) The Department's time periods for processing an application for cytotechnologist
license, from receipt of the initial application to the final decision regarding the license,
are as follows~~

~~(1) The median time for processing is 240 calendar days.~~

~~(2) The minimum time for processing is 120 calendar days.~~

~~(3) The maximum time for processing is 360 calendar days.~~

~~(f) Each licensed cytotechnologist shall notify the Department within 30 calendar days of
any and all changes in his or her employment, including any changes in the name and
address of his or her employer(s), the hours employed by each, and the information
specified in subsection (b)(3) above.~~

Note: Authority: Sections 1224, 1270, 1270(f), Business and Professions Code;
Reference: 1270, 1271, 1300, Business and Professions Code; Section 15376,
Government Code; and Section 116, Health and Safety Code.

(49) Repeal Section 1062 as follows:

~~Section 1062. Cytotechnologist Competency Testing Services Or Programs.~~

~~(a) Any organization seeking approval by the Department as a cytotechnologist competency testing service or program shall submit an application to the Department which shall include documentation of the following:~~

~~(1) The organization's name, address, and owner(s);~~

~~(2) The organization's mechanism for assuring that each individual for whom a cytotechnologist competency testing examination is administered meets the criteria as an examinee;~~

~~(3) The organization's mechanism for assuring that each cytotechnologist competency examination administered by the organization shall test each examinee on his or her entry level skills and understanding of:~~

~~(A) The underlying scientific principles and the technical and procedural aspects of cytology;~~

~~(B) The identification of cellular changes in gynecologic and non-gynecologic specimens through both a written and visual component;~~

~~(C) Cytopreparatory techniques; and~~

~~(D) Cytology laboratory operations, and that each test shall include the following subject areas in the following ratios: 48% to 52% female reproductive system (to include both genital system and breast); 13%-17% respiratory system; 9%-12% male and/or female genitourinary system; 6%-10% alimentary system; and 13%-17% body cavity fluids and other body sites;~~

~~(4) The organization's mechanism for determining the validity and passing score for each cytotechnologist competency examination administered by the organization in order that there is a consistency between and among all testing events as to entry level skills that must be demonstrated in order for an examinee to pass the examination; and,~~
~~(5) The organization's mechanism for assuring the security of each cytotechnologist competency examination administered by it.~~

~~(b) Upon receipt of the above, and the determination by the Department that the documentation provides assurances of the following, the Department shall approve the organization as a cytotechnologist competency testing service or program and shall issue an approval document indicating the terms of the organization's approval:~~

~~(1) The organization shall only administer cytotechnologist competency examinations to persons who qualify as an examinee;~~

~~(2) Each cytotechnologist competency examination administered by the organization shall challenge each examinee on his or her entry level skills and understanding of the subjects, and shall contain the subject matter in the ratios identified in subsection (a)-~~

~~(3), above;~~

~~(3) Each cytotechnologist competency examination administered by the organization shall be validly constructed and have a passing score that fosters a consistency between and among all testing events as to entry level skills that must be demonstrated in order for an examinee to pass the examination; and,~~

~~(4) Each cytotechnologist competency examination shall be administered in a secure fashion.~~

~~(c) Within 15 days of receipt of an application by an organization for approval as a~~

~~cytotechnologist competency testing service, the Department shall inform the organization in writing that the application is complete and accepted for review or deficient and what specific information or documentation is required to complete the application.~~

~~(d) Within 30 calendar days from the date of filing of a completed application, the Department shall inform the applicant organization in writing whether the organization has been approved as a cytotechnologist competency testing service or program.~~

~~(e) The Department's time periods for processing an application for approval as a cytotechnologist competency testing service or program, from the receipt of the initial application to the final decision regarding the approval, are as follows:~~

~~(1) The median time for processing is 90 calendar days.~~

~~(2) The minimum time for processing is 45 calendar days.~~

~~(3) The maximum time for processing is 135 calendar days.~~

~~(f) Cytotechnologist competency testing services or programs shall issue a document to each examinee who obtains a passing score on each cytotechnologist competency examination administered by the service or program.~~

~~(g) Cytotechnologist competency testing services or programs shall maintain, for a minimum of five years, and shall make available to the Department, records showing the validation, content, passing score, date and place of each competency testing examination administered by it, and a record of each examinee tested.~~

~~(h) A cytotechnologist competency testing service or program shall be subject to review by the Department to determine adherence to the requirements of this article and its approval. Failure of a cytotechnologist competency testing service or program to meet~~

~~the requirements of this article or its terms of approval shall constitute good cause for
revocation of approval by the Department.~~

Note: Authority cited: Sections 1224 and 1270, Business and Professions Code.
Reference: Section 1270, Business and Professions Code; and Section 15376,
Government Code.