

AMENDED IN SENATE AUGUST 23, 1996

AMENDED IN SENATE JUNE 17, 1996

AMENDED IN ASSEMBLY MAY 29, 1996

AMENDED IN ASSEMBLY MAY 13, 1996

CALIFORNIA LEGISLATURE—1995–96 REGULAR SESSION

ASSEMBLY BILL

No. 3109

Introduced by Assembly Member Margett

February 23, 1996

An act to amend Sections 1206, 1206.5, and 1209 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 3109, as amended, Margett. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care professionals by the State Department of Health Services. *These provisions prohibit a person from performing a clinical laboratory test or examination classified as of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA; 42 U.S.C. 263a; P.L. 100-578) unless the test or examination is performed under the overall operation and administration of the laboratory director and the test is performed by specified persons, including certain health care personnel who provide direct patient care when the person meets the minimum*

clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department.

This bill would additionally require that the person performing the test or examination under this provision perform the test as an adjunct to providing direct patient care, utilize a point-of-care laboratory testing device, as defined, at a site for which the laboratory license or registration has been issued, and have demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte, as defined, to be reported. The bill would require that these persons participate in a preceptor program, as defined, prior to being authorized by the laboratory director to perform laboratory tests or examinations. The bill would add to the persons able to perform these laboratory tests or examinations under this provision a person certified as an “Emergency Medical Technician II” or paramedic while providing prehospital emergency medical care.

The bill also, among other things, would authorize testing personnel to perform and report the results of certain tests where the person has been found competent to test for a particular analyte. This bill would incorporate changes to Section 1206.5 of the Business and Professions Code made by SB 1537 (Ch. 113, Stats. 1996). ~~Under these provisions, the laboratory director of a licensed laboratory is required to, among other things, ensure that all personnel, prior to testing biological specimens, are adequately trained in compliance with regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel.~~

This bill would define “type of procedure” for purposes of this provision.

Existing law requires that the competency and performance of staff of a licensed laboratory be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA; 42 U.S.C. 263a; P.L. 100-578) depending on the type and complexity of tests being offered



~~by the laboratory. Existing law sets forth certain procedures for evaluating the competency of the staff.~~

~~This bill would provide that a person who is found to be competent to utilize a particular testing instrument pursuant to the competency and performance standards set forth in the procedures for evaluating the competency of the staff discussed above shall be authorized to perform and report all test results within the capacity of the testing instrument.~~

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1206 of the Business and
2 Professions Code is amended to read:

3 1206. (a) For the purposes of this chapter the
4 following definitions are applicable:

5 (1) "Biological specimen" means any material that is
6 derived from the human body.

7 (2) "Blood electrolyte analysis" means the
8 measurement of electrolytes in a blood specimen by
9 means of ion selective electrodes on instruments
10 specifically designed and manufactured for blood gas and
11 acid-base analysis.

12 (3) "Blood gas analysis" means a clinical laboratory
13 test or examination that deals with the uptake, transport,
14 and metabolism of oxygen and carbon dioxide in the
15 human body.

16 (4) "Clinical laboratory test or examination" means
17 the detection, identification, measurement, evaluation,
18 correlation, monitoring, and reporting of any particular
19 ~~entity~~ *analyte, entity,* or substance within a biological
20 specimen for the purpose of obtaining scientific data
21 which may be used as an aid to ascertain the presence,
22 progress, and source of a disease or physiological
23 condition in a human being, or used as an aid in the
24 prevention, prognosis, monitoring, or treatment of a
25 physiological or pathological condition in a human being,
26 or for the performance of nondiagnostic tests for assessing
27 the health of an individual.



1 (5) “Clinical laboratory science” means any of the
2 sciences or scientific disciplines used to perform a clinical
3 laboratory test or examination.

4 (6) “Clinical laboratory practice” means the
5 application of clinical laboratory sciences or the use of any
6 means that applies the clinical laboratory sciences within
7 or outside of a licensed or registered clinical laboratory.
8 Clinical laboratory practice includes consultation,
9 advisory, and other activities inherent to the profession.

10 (7) “Clinical laboratory” means any place used, or any
11 establishment or institution organized or operated, for
12 the performance of clinical laboratory tests or
13 examinations or the practical application of the clinical
14 laboratory sciences. That application may include any
15 means that applies the clinical laboratory sciences.

16 (8) “Direct and constant supervision” means personal
17 observation and critical evaluation of the activity of
18 unlicensed laboratory personnel by a physician and
19 surgeon, or by a person licensed under this chapter other
20 than a trainee, during the entire time that the unlicensed
21 laboratory personnel are engaged in the duties specified
22 in Section 1269.

23 (9) “Location” means either a street and city address,
24 or a site or place within a street and city address, where
25 any of the clinical laboratory sciences or scientific
26 disciplines are practiced or applied, or where any clinical
27 laboratory tests or examinations are performed.

28 (10) “Physician office laboratory” means a clinical
29 laboratory that is licensed or registered under Section
30 1265, and that is either: (A) a clinical laboratory that is
31 owned and operated by a partnership or professional
32 corporation that performs clinical laboratory tests or
33 examinations only for patients of five or fewer physicians
34 and surgeons or podiatrists who are shareholders,
35 partners, or employees of the partnership or professional
36 corporation that owns and operates the clinical
37 laboratory; or (B) a clinical laboratory that is owned and
38 operated by an individual licensed physician and surgeon
39 or a podiatrist, and that performs clinical laboratory tests
40 or examinations only for patients of the physician and



1 surgeon or podiatrist who owns and operates the clinical
2 laboratory.

3 (11) “Public health laboratory” means a laboratory
4 that is operated by a city or county in conformity with
5 Chapter 7 (commencing with Section 1000) of Part 2 of
6 Division 1 of the Health and Safety Code and the
7 regulations adopted thereunder.

8 (12) “Specialty” means histocompatibility,
9 microbiology, diagnostic immunology, chemistry,
10 hematology, immunohematology, pathology, genetics, or
11 other specialty specified by regulation adopted by the
12 department.

13 (13) “Subspecialty” for purposes of microbiology,
14 means bacteriology, mycobacteriology, mycology,
15 parasitology, virology, molecular biology, and serology
16 for diagnosis of infectious diseases, or other subspecialty
17 specified by regulation adopted by the department; for
18 purposes of diagnostic immunology, means syphilis
19 serology, general immunology, or other subspecialty
20 specified by regulation adopted by the department; for
21 purposes of chemistry, means routine chemistry, clinical
22 microscopy, endocrinology, toxicology, or other
23 subspecialty specified by regulation adopted by the
24 department; for purposes of immunohematology, means
25 ABO/Rh Type and Group, antibody detection for
26 transfusion, antibody detection nontransfusion, antibody
27 identification, compatibility, or other subspecialty
28 specified by regulation adopted by the department; for
29 pathology, means tissue pathology, oral pathology,
30 diagnostic cytology, or other subspecialty specified by
31 regulation adopted by the department; for purposes of
32 genetics, means molecular biology related to the
33 diagnosis of human genetic abnormalities, cytogenetics,
34 or other subspecialty specified by regulation adopted by
35 the department.

36 (14) “Direct and responsible supervision” means both
37 of the following:

38 (A) Personal observation and critical evaluation of the
39 activity of a trainee by a physician and surgeon, or by a
40 person licensed under this chapter other than a trainee,



1 during the entire time that the trainee is performing
2 clinical laboratory tests or examinations.

3 (B) Personal review by the physician and surgeon or
4 the licensed person of all results of clinical laboratory
5 testing or examination performed by the trainee for
6 accuracy, reliability, and validity before the results are
7 reported from the laboratory.

8 (15) “Licensed laboratory” means a clinical laboratory
9 licensed pursuant to paragraph (1) of subdivision (a) of
10 Section 1265.

11 (16) “Registered laboratory” means a clinical
12 laboratory registered pursuant to paragraph (2) of
13 subdivision (a) of Section 1265.

14 ~~(17) “Type of procedure” means a classification of~~
15 ~~procedures according to the identification of tasks~~
16 ~~required to perform a clinical laboratory test or~~
17 ~~examination in order to determine the skills necessary to~~
18 ~~competently perform those tasks.~~

19 (17) “Point-of-care laboratory testing device” means a
20 portable laboratory testing instrument to which the
21 following applies:

22 (A) It is used within the proximity of the patient for
23 whom the test or examination is being conducted.

24 (B) It is used in accordance with the patient test
25 management system, the quality control program, and
26 the comprehensive quality assurance program
27 established and maintained by the laboratory pursuant to
28 paragraph (2) of subdivision (d) of Section 1220.

29 (C) It meets the following criteria:

30 (i) Performs clinical laboratory tests or examinations
31 classified as waived or of moderate complexity under
32 CLIA.

33 (ii) Performs clinical laboratory tests or examinations
34 on biological specimens that require no preparation after
35 collection.

36 (iii) Provides clinical laboratory tests or examination
37 results without calculation or discretionary intervention
38 by the testing personnel.

39 (iv) Performs clinical laboratory tests or examinations
40 without the necessity for testing personnel to perform



1 calibration or maintenance, except resetting pursuant to
2 the manufacturer's instructions or basic cleaning.

3 (18) "Analyte" means the substance or constituent
4 being measured including, but not limited to, glucose,
5 sodium, or theophylline, or any substance or property
6 whose presence or absence, concentration, activity,
7 intensity, or other characteristics are to be determined.

8 (b) Nothing in this chapter shall restrict, limit, or
9 prevent any person licensed to provide health care
10 services under the laws of this state, including, but not
11 limited to, licensed physicians and surgeons, and
12 registered nurses, from practicing the profession or
13 occupation for which he or she is licensed.

14 ~~SEC. 2.—~~

15 (c) Nothing in this chapter shall authorize any person
16 to perform or order health care services, or utilize the
17 results of the clinical laboratory test or examination,
18 unless the person is otherwise authorized to provide that
19 care or utilize the results. The inclusion of a person in
20 Section 1206.5 for purposes of performing a clinical
21 laboratory test or examination shall not be interpreted to
22 authorize a person, who is not otherwise authorized, to
23 perform venipuncture, arterial puncture, or skin
24 puncture.

25 SEC. 2. Section 1206.5 of the Business and Professions
26 Code is amended to read:

27 1206.5. (a) Notwithstanding subdivision (b) of
28 Section 1206, no person shall perform a clinical laboratory
29 test or examination classified as waived under CLIA
30 unless the clinical laboratory test or examination is
31 performed under the overall operation and
32 administration of the laboratory director, as described in
33 Section 1209, including, but not limited to,
34 documentation by the laboratory director of the
35 adequacy of the qualifications and competency of the
36 personnel, and the test is performed by any of the
37 following persons:

38 (1) A licensed physician and surgeon holding a M.D. or
39 D.O. degree.



1 (2) A licensed podiatrist or a licensed dentist when the
2 results of the tests can be lawfully utilized within his or
3 her practice.

4 (3) A person licensed under this chapter to engage in
5 clinical laboratory practice or to direct a clinical
6 laboratory.

7 (4) A person authorized to perform tests pursuant to
8 a certificate issued under Chapter 7 (commencing with
9 Section 1000) of Part 2 of Division 1 of the Health and
10 Safety Code.

11 (5) A licensed physician assistant when authorized by
12 a supervising physician and surgeon in accordance with
13 Section 3502 or Section 3535.

14 (6) A person licensed under Chapter 6 (commencing
15 with Section 2700).

16 (7) A person licensed under Chapter 6.5
17 (commencing with Section 2840).

18 (8) A perfusionist when authorized by and performed
19 in compliance with Section 2590.

20 (9) A respiratory care practitioner when authorized
21 by and performed in compliance with Chapter 8.3
22 (commencing with Section 3700).

23 (10) A medical assistant, as defined in Section 2069,
24 when the waived test is performed pursuant to a specific
25 authorization meeting the requirements of Section 2069.

26 (11) A *pharmacist, when ordering drug*
27 *therapy-related laboratory tests in compliance with*
28 *subparagraph (B) of paragraph (4) of, or clause (ii) of*
29 *subparagraph (A) of paragraph (5) of, subdivision (c) of*
30 *Section 4046.*

31 (12) Other health care personnel providing direct
32 patient care.

33 (b) Notwithstanding subdivision (b) of Section 1206,
34 no person shall perform clinical laboratory tests or
35 examinations classified as of moderate complexity under
36 CLIA unless the clinical laboratory test or examination is
37 performed under the overall operation and
38 administration of the laboratory director, as described in
39 Section 1209, including, but not limited to,
40 documentation by the laboratory director of the



1 adequacy of the qualifications and competency of the
2 personnel, and the test is performed by any of the
3 following persons:

4 (1) A licensed physician and surgeon holding a M.D. or
5 D.O degree.

6 (2) A licensed podiatrist or a licensed dentist when the
7 results of the tests can be lawfully utilized within his or
8 her practice.

9 (3) A person licensed under this chapter to engage in
10 clinical laboratory practice or to direct a clinical
11 laboratory.

12 (4) A person authorized to perform tests pursuant to
13 a certificate issued under Chapter 7 (commencing with
14 Section 1000) of Part 2 of Division 1 of the Health and
15 Safety Code.

16 (5) A licensed physician assistant when authorized by
17 a supervising physician and surgeon in accordance with
18 Section 3502 or Section 3535.

19 (6) A person licensed under Chapter 6 (commencing
20 with Section 2700).

21 (7) A perfusionist when authorized by and performed
22 in compliance with Section 2590.

23 (8) A respiratory care practitioner when authorized
24 by and performed in compliance with Chapter 8.3
25 (commencing with Section 3700).

26 (9) A person performing nuclear medicine technology
27 when authorized by and performed in compliance with
28 Chapter 7.2 (commencing with Section 25625) of
29 Division 20 of the Health and Safety Code.

30 (10) Any person when performing blood gas analysis
31 in compliance with Section 1245.

32 (11) (A) *A person certified as an "Emergency*
33 *Medical Technician II" or paramedic pursuant to*
34 *Division 2.5 (commencing with Section 1797) of the*
35 *Health and Safety Code while providing prehospital*
36 *medical care, a person licensed as a psychiatric technician*
37 *under Chapter 10 (commencing with Section 4500) of*
38 *Division 2, as a vocational nurse pursuant to Chapter 6.5*
39 *(commencing with Section 2840) of Division 2, or as a*
40 *midwife licensed pursuant to Article 24 (commencing*



1 with Section 2505) of Chapter 5 of Division 2, or certified
2 by the department pursuant to Division 5 (commencing
3 with Section 70001) of Title 22 of the California Code of
4 Regulations as a nurse assistant or a home health aide,
5 who provides direct patient care ~~when the person~~, so long
6 as the person is performing the test as an adjunct to the
7 provision of direct patient care by the person, is utilizing
8 a point-of-care laboratory testing device at a site for
9 which a laboratory license or registration has been issued,
10 meets the minimum clinical laboratory education,
11 training, and experience requirements set forth in
12 regulations adopted by the department, and has
13 demonstrated to the satisfaction of the laboratory
14 director that he or she is competent in the operation of
15 the point-of-care laboratory testing device for each
16 analyte to be reported.

17 (B) Prior to being authorized by the laboratory
18 director to perform laboratory tests or examinations,
19 testing personnel identified in subparagraph (A) shall
20 participate in a preceptor program until they are able to
21 perform the clinical laboratory tests or examinations
22 authorized in this section with results that are deemed
23 accurate and skills that are deemed competent by the
24 preceptor. For the purposes of this section, a “preceptor
25 program” means an organized system that meets
26 regulatory requirements in which a preceptor provides
27 and documents personal observation and critical
28 evaluation, including review of accuracy, reliability, and
29 validity, of laboratory testing performed.

30 (12) Any other person within a physician office
31 laboratory when the test is performed under the
32 supervision of the patient’s physician and surgeon or
33 podiatrist who shall be accessible to the laboratory to
34 provide onsite, telephone, or electronic consultation as
35 needed, and shall: (A) ensure that the person is
36 performing test methods as required for accurate and
37 reliable tests; and (B) have personal knowledge of the
38 results of the clinical laboratory testing or examination
39 performed by that person before the test results are
40 reported from the laboratory.



1 (13) A pharmacist, when ordering drug
2 therapy-related laboratory tests in compliance with
3 subparagraph (B) of paragraph (4) of, or clause (ii) of
4 subparagraph (A) of paragraph (5) of, subdivision (c) of
5 Section 4046.

6 (c) Notwithstanding subdivision (b) of Section 1206,
7 no person shall perform clinical laboratory tests or
8 examinations classified as of high complexity under CLIA
9 unless the clinical laboratory test or examination is
10 performed under the overall operation and
11 administration of the laboratory director, as described in
12 Section 1209, including, but not limited to,
13 documentation by the laboratory director of the
14 adequacy of the qualifications and competency of the
15 personnel, and the test is performed by any of the
16 following persons:

17 (1) A licensed physician and surgeon holding a M.D. or
18 D.O. degree.

19 (2) A licensed podiatrist or a licensed dentist when the
20 results of the tests can be lawfully utilized within his or
21 her practice.

22 (3) A person licensed under this chapter to engage in
23 clinical laboratory practice or to direct a clinical
24 laboratory when the test or examination is within a
25 specialty or subspecialty authorized by the person's
26 licensure.

27 (4) A person authorized to perform tests pursuant to
28 a certificate issued under Chapter 7 (commencing with
29 Section 1000) of Part 2 of Division 1 of the Health and
30 Safety Code when the test or examination is within a
31 specialty or subspecialty authorized by the person's
32 certification.

33 (5) A licensed physician assistant when authorized by
34 a supervising physician and surgeon in accordance with
35 Section 3502 or Section 3535.

36 (6) A perfusionist when authorized by and performed
37 in compliance with Section 2590.

38 (7) A respiratory care practitioner when authorized
39 by and performed in compliance with Chapter 8.3
40 (commencing with Section 3700).



1 (8) A person performing nuclear medicine technology
2 when authorized by and performed in compliance with
3 Chapter 7.2 (commencing with Section 25625) of
4 Division 20 of the Health and Safety Code.

5 (9) Any person when performing blood gas analysis in
6 compliance with Section 1245.

7 (10) Any other person within a physician office
8 laboratory when the test is performed under the onsite
9 supervision of the patient's physician and surgeon or
10 podiatrist who shall: (A) ensure that the person is
11 performing test methods as required for accurate and
12 reliable tests; and (B) have personal knowledge of the
13 results of clinical laboratory testing or examination
14 performed by that person before the test results are
15 reported from the laboratory.

16 (d) Clinical laboratory examinations classified as
17 physician-performed microscopy under CLIA may be
18 performed by a licensed physician and surgeon holding
19 a M.D. or D.O. degree.

20 *SEC. 3.* Section 1209 of the Business and Professions
21 Code is amended to read:

22 1209. (a) As used in this chapter, "laboratory
23 director" means any person who is a duly licensed
24 physician and surgeon, or is licensed to direct a clinical
25 laboratory under this chapter and who substantially
26 meets the laboratory director qualifications under CLIA
27 for the type and complexity of tests being offered by the
28 laboratory. The laboratory director, if qualified under
29 CLIA, may perform the duties of the technical
30 consultant, technical supervisor, clinical consultant,
31 general supervisor, and testing personnel, or delegate
32 these responsibilities to persons qualified under CLIA. If
33 the laboratory director reapportions performance of
34 those responsibilities or duties, he or she shall remain
35 responsible for ensuring that all those duties and
36 responsibilities are properly performed.

37 (b) (1) The laboratory director is responsible for the
38 overall operation and administration of the clinical
39 laboratory, including administering the technical and
40 scientific operation of a clinical laboratory, the selection



1 and supervision of procedures, the reporting of results,
2 and active participation in its operations to the extent
3 necessary to assure compliance with this act and CLIA.
4 He or she shall be responsible for the proper performance
5 of all laboratory work of all subordinates and shall employ
6 a sufficient number of laboratory personnel with the
7 appropriate education and either experience or training
8 to provide appropriate consultation, properly supervise
9 and accurately perform tests, and report test results in
10 accordance with the personnel qualifications, duties, and
11 responsibilities described in CLIA and this chapter.

12 *(2) Where a point-of-care laboratory testing device is*
13 *utilized and provides results for more than one analyte,*
14 *the testing personnel may perform and report the results*
15 *of all tests ordered for each analyte for which he or she has*
16 *been found by the laboratory director to be competent to*
17 *perform and report.*

18 (c) As part of the overall operation and administration,
19 the laboratory director of a registered laboratory shall
20 document the adequacy of the qualifications
21 (educational background, training, and experience) of
22 the personnel directing and supervising the laboratory
23 and performing the laboratory test procedures and
24 examinations. In determining the adequacy of
25 qualifications, the laboratory director shall comply with
26 any regulations adopted by the department that specify
27 the minimum qualifications for personnel, in addition to
28 any CLIA requirements relative to the education or
29 training of personnel.

30 (d) As part of the overall operation and
31 administration, the laboratory director of a licensed
32 laboratory shall do all of the following:

33 (1) Ensure that all personnel, prior to testing
34 biological specimens, have the appropriate education and
35 experience, receive the appropriate training for the type
36 and complexity of the services offered, and have
37 demonstrated that they can perform all testing
38 operations reliably to provide and report accurate results.
39 In determining the adequacy of qualifications, the
40 laboratory director shall comply with any regulations



1 adopted by the department that specify the minimum
2 qualifications for, and the type of procedures that may be
3 performed by, personnel in addition to any CLIA
4 requirements relative to the education or training of
5 ~~personnel. The laboratory director shall not determine~~
6 ~~that the qualifications of a person described in paragraph~~
7 ~~(11) of subdivision (b) of Section 1206.5 are adequate~~
8 ~~unless that person meets the minimum clinical laboratory~~
9 ~~education, training, and experience requirements set~~
10 ~~forth in regulations which shall be adopted by the~~
11 ~~department.~~ *personnel. Any regulations adopted*
12 *pursuant to this section that specify the type of procedure*
13 *that may be performed by testing personnel shall be*
14 *based on the skills, knowledge, and tasks required to*
15 *perform the type of procedure in question.*

16 (2) Ensure that policies and procedures are
17 established for monitoring individuals who conduct
18 preanalytical, analytical, and postanalytical phases of
19 testing to assure that they are competent and maintain
20 their competency to process biological specimens,
21 perform test procedures, and report test results promptly
22 and proficiently, and, whenever necessary, identify needs
23 for remedial training or continuing education to improve
24 skills.

25 (3) Specify in writing the responsibilities and duties of
26 each individual engaged in the performance of the
27 preanalytic, analytic, and postanalytic phases of clinical
28 laboratory tests or examinations, including which clinical
29 laboratory tests or examinations the individual is
30 authorized to perform, whether supervision is required
31 for the individual to perform specimen processing, test
32 performance, or results reporting, and whether
33 consultant, supervisor, or director review is required
34 prior to the individual reporting patient test results.

35 (e) The competency and performance of staff of a
36 licensed laboratory shall be evaluated and documented
37 by the laboratory director, or by a person who qualifies as
38 a technical consultant or a technical supervisor under
39 CLIA depending on the type and complexity of tests
40 being offered by the laboratory. ~~A person who is found~~



1 ~~to be competent to utilize a particular testing instrument~~
2 ~~pursuant to the competency and performance standards~~
3 ~~set forth below shall be authorized to perform and report~~
4 ~~all test results within the capacity of the testing~~
5 ~~instrument.~~

6 (1) The procedures for evaluating the competency of
7 the staff shall include, but are not limited to, all of the
8 following:

9 (A) Direct observations of routine patient test
10 performance, including patient preparation, if
11 applicable, and specimen handling, processing, and
12 testing.

13 (B) Monitoring the recording and reporting of test
14 results.

15 (C) Review of intermediate test results or worksheets,
16 quality control records, proficiency testing results, and
17 preventive maintenance records.

18 (D) Direct observation of performance of instrument
19 maintenance and function checks.

20 (E) Assessment of test performance through testing
21 previously analyzed specimens, internal blind testing
22 samples, or external proficiency testing samples.

23 (F) Assessment of problem solving skills.

24 (2) Evaluation and documentation of staff
25 competency and performance shall occur at least
26 semiannually during the first year an individual tests
27 biological specimens. Thereafter, evaluations shall be
28 performed at least annually unless test methodology or
29 instrumentation changes, in which case, prior to
30 reporting patient test results, the individual's
31 performance shall be reevaluated to include the use of
32 the new test methodology or instrumentation.

33 (f) The laboratory director of each clinical laboratory
34 of an acute care hospital shall be a physician and surgeon
35 who is a qualified pathologist, except as follows:

36 (1) If a qualified pathologist is not available, a
37 physician and surgeon or a clinical laboratory bioanalyst
38 qualified as a laboratory director under subdivision (a)
39 may direct the laboratory. However, a qualified



1 pathologist shall be available for consultation at suitable
2 intervals to ensure high quality service.

3 (2) If there are two or more clinical laboratories of an
4 acute care hospital, those additional clinical laboratories
5 that are limited to the performance of blood gas analysis,
6 blood electrolyte analysis, or both may be directed by a
7 physician and surgeon qualified as a laboratory director
8 under subdivision (a), irrespective of whether a
9 pathologist is available.

10 As used in this subdivision, a qualified pathologist is a
11 physician and surgeon certified or eligible for
12 certification in clinical or anatomical pathology by the
13 American Board of Pathology or the American
14 Osteopathic Board of Pathology.

15 (g) Subdivision (f) does not apply to any director of a
16 clinical laboratory of an acute care hospital acting in that
17 capacity on or before January 1, 1988.

