

1 IN THE HOUSE

BY THE STATE AFFAIRS
COMMITTEE

2 HOUSE BILL NO. 510

3 IN THE LEGISLATURE OF THE STATE OF ALASKA

4 FOURTH LEGISLATURE - SECOND SESSION

5 A BILL

6 For an Act entitled: "An Act relating to the regulation of
7 clinical laboratories and blood banks; and
8 providing for an effective date."

9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

10 * Section 1. AS 08 is amended by adding a new chapter to read:

11 CHAPTER 22. CLINICAL LABORATORIES AND BLOOD BANKS.

12 ARTICLE 1. ADMINISTRATION AND REGULATION.

13 Sec. 08.22.010. CLINICAL LABORATORY ADVISORY COUNCIL.

14 (a) There is created a Clinical Laboratory Advisory Council
15 consisting of 10 members appointed by the governor for over-
16 lapping five-year terms to advise and consult with the
17 commissioner of health and welfare regarding regulations and
18 standards of operation of clinical laboratories and blood
19 banks. The council shall be composed of one physician, one
20 director, one supervisor, four medical technologists, one
21 clinical laboratory assistant, two members of the Department
22 of Health and Welfare or one member of the Department of
23 Health and Welfare and one member of an allied health labora-
24 tory. The medical technologists shall be selected according
25 to geographical location.

26 (b) The council shall meet at least twice each year at
27 such time and place as shall be designated by the commissioner.

28 (c) Six members constitute a quorum for the transaction
29 of business.

1 Sec. 08.22.020. DUTIES OF THE COMMISSIONER. The
2 Commissioner shall, upon the advice of the advisory council,
3 (1) pass on qualifications of applicants and issue
4 licenses to those who qualify;
5 (2) prepare and grade examinations;
6 (3) approve schools providing instruction in
7 clinical laboratory technique;
8 (4) initiate prosecution of, reprimand or discipline
9 violators of this chapter;
10 (5) establish, by regulation, standards for the
11 safe and efficient operation and maintenance of clinical
12 laboratories and blood banks in the state;
13 (6) employ inspectors to evaluate laboratory
14 procedures and techniques and to recommend the preferred
15 procedures and techniques to be used in a clinical laboratory;
16 (7) require each laboratory to establish an
17 acceptable program for internal quality control including
18 use of, where applicable, reference or control sera and other
19 biological samples, concurrent calibrating standards, and
20 control charts recording standard reading;
21 (8) require all laboratories to participate in
22 performance evaluation programs including use of unknowns as
23 prescribed by the commission, except that the commissioner
24 may elect to accept the results of a performance evaluation
25 program conducted by a professional group;
26 (9) employ special examiners to administer
27 examinations;
28 (10) may employ technical or clerical assistance
29 as needed;

1 (11) do whatever else is necessary to carry out the
2 provisions of this chapter.

3 Sec. 08.22.030. COMPENSATION. Members of the advisory
4 council are entitled to transportation expenses and per diem
5 allowances specified in AS 39.20.180.

6 ARTICLE 2. LICENSING.

7 Sec. 08.22.060. QUALIFICATIONS FOR A CLINICAL LABORATORY
8 DIRECTOR LICENSE. An applicant is entitled to be licensed as

9 (1) a physician licensed to practice medicine in
10 this state;

11 (2) a pathologist certified in clinical pathology
12 and licensed to practice in this state; or

13 (3) a person with a doctoral degree who is
14 certified by the American Board of Microbiologists or the
15 American Board of Clinical Chemistry or other accredited
16 national professional societies approved by the commissioner,
17 has had four or more years of general clinical laboratory
18 training and experience, of which at least two of these years
19 were spent in acquiring proficiency in one laboratory
20 specialty in the clinical laboratory of a hospital, health
21 department, university, research institution or other labora-
22 tory acceptable to the commissioner, and passes an examination
23 given in accordance with this chapter.

24 Sec. 08.22.070. QUALIFICATIONS FOR A CLINICAL LABORA-
25 TORY SUPERVISOR LICENSE. (a) An applicant is entitled to be
26 licensed as a clinical laboratory supervisor if he has

27 (1) a B. S. degree or certification by the American
28 Society of Clinical Pathologists, National Registry of Micro-
29 biologists, Clinical Chemistry, or other national registries

1 acceptable to the commissioner;

2 (2) a minimum of four years of generalized
3 experience in a clinical laboratory employing four or more
4 medical laboratory technologists;

5 (3) passes an examination given in accordance with
6 this chapter.

7 (b) The receipt of a master's degree in a fundamental
8 medical science is the equivalent of one year of experience
9 as a clinical laboratory technologist and a doctoral degree
10 is the equivalent of three years of experience as a clinical
11 laboratory technologist.

12 Sec. 08.22.080. QUALIFICATIONS FOR A CLINICAL LABORA-
13 TORY TECHNOLOGIST LICENSE. (a) An applicant is entitled to
14 be licensed as a clinical technologist if he passes an
15 examination given under this chapter and if he

16 (1) has received a bachelor of arts or science
17 degree after completion of a regular four-year curriculum in
18 medical technology including one year in a qualified school
19 of medical technology;

20 (2) has received a bachelor of arts or science
21 degree with a major in one of the biological or chemical
22 sciences and has been a clinical laboratory technologist
23 trainee for at least one year;

24 (3) has, in the opinion of the commissioner, the
25 education or experience equivalent to that specified in (a)
26 (1) or (2) of this section;

27 (b) The commissioner may, if approved by the advisory
28 council, waive the requirements of this section and issue a
29 license to an individual who, in his opinion, has equivalent

1 education and experience in one or more of the laboratory
2 specialties. With respect to specialties not included in the
3 license, the technologist may only be permitted to act as a
4 trainee.

5 Sec. 08.22.090. QUALIFICATIONS FOR A CLINICAL LABORA-
6 TORY ASSISTANT LICENSE. (a) A laboratory worker, who does
7 not meet the minimum requirement for a clinical laboratory
8 technologist is eligible for a license as a laboratory
9 assistant if he passes an examination given under this
10 chapter, is a high school graduate, and

11 (1) has successfully completed 12 months of
12 training in an approved school for laboratory assistants;

13 (2) has been employed for a period of at least
14 five years, including at least six months of employment im-
15 mediately before the effective date of this chapter, as a
16 laboratory technician in a clinical laboratory acceptable
17 to the commissioner; or

18 (3) subsequent to graduation has served two years
19 as a technician or assistant trainee in a clinical laboratory
20 with a training program approved by the commissioner.

21 (b) The commissioner may, if approved by the advisory
22 council, waive the requirements of this section and issue a
23 license to an individual who, in his opinion, has equivalent
24 education and experience in one or more of the laboratory
25 specialties.

26 Sec. 08.22.100. QUALIFICATIONS FOR A CLINICAL LABORA-
27 TORY TRAINEE LICENSE. A person is entitled to be licensed
28 as a clinical laboratory trainee if

29 (1) he meets the educational requirements for a

1 clinical laboratory technologist or laboratory assistant
2 specified in secs. 80 and 90 of this chapter; and

3 (2) the laboratory at which the trainee is to
4 train is approved under this chapter.

5 Sec. 08.22.110. QUALIFICATIONS FOR A HISTOLOGY TECH-
6 NICIAN LICENSE. (a) A person is entitled to be licensed as
7 a histology technician if he

8 (1) is a high school graduate and has one year of
9 supervised training in a pathology laboratory approved by
10 the commissioner; and

11 (2) passes an examination given in accordance
12 with this chapter.

13 (b) The commissioner may, if approved by the advisory
14 council, waive the requirements of this section and issue a
15 license to an individual who, in his opinion, has equivalent
16 education and experience.

17 Sec. 08.22.120. QUALIFICATIONS FOR A CYTOTECHNOLOGIST
18 LICENSE. (a) A person is entitled to be licensed as a cyto-
19 technologist if he

20 (1) is a high school graduate, has at least two
21 years of college, six months of training at a school of
22 cytotechnology, approved by the American Medical Association,
23 and six months experience in a laboratory approved by the
24 commissioner; and

25 (2) passes an examination given in accordance with
26 this chapter.

27 (b) The commissioner may, if approved by the advisory
28 council, waive the requirements of this section and issue a
29 license to an individual who, in his opinion, has equivalent

1 education and experience.

2 Sec. 08.22.130. EXAMINATIONS. (a) Examinations for
3 licenses issued under this chapter may cover work in any one
4 basic science or proficiency in the entire field of clinical
5 laboratory work.

6 (b) If a person fails an examination twice, he may not
7 take the examination again until he receives additional train-
8 ing specified by the commissioner.

9 Sec. 08.22.140 WAIVER OF EXAMINATION AND RECIPROCITY.
10 A person who is registered by a national board of registry
11 sponsored by a national professional society acceptable to
12 the commissioner, or who is licensed by a state whose quali-
13 fications are equivalent or higher than those prescribed by
14 this chapter, is entitled to be licensed in that field for
15 which he qualifies upon payment of the prescribed applica-
16 tion and license fees.

17 Sec. 08.22.150. TEMPORARY LICENSE. A temporary license
18 may be issued to an individual who has not failed an examina-
19 tion for a permanent license of the same type and who by
20 training or experience is apparently qualified. A temporary
21 license may not be extended beyond the date on which the
22 next examination is given.

23 Sec. 08.22.160. CLINICAL LABORATORY PERMIT. (a)
24 Application for a laboratory permit shall be on a form
25 provided by the commissioner and shall contain the name of
26 the owner or owners, the name of the director, the name and
27 location of the laboratory and other information required
28 by the commissioner.

29 (b) A separate laboratory permit must be obtained for

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each location.

(c) A laboratory permit is automatically revoked if there is a change of address, director, or ownership of the laboratory and the commissioner is not advised of the change within seven days.

(d) A laboratory permit is valid for the remainder of the calendar year for which it is issued unless revoked.

Sec. 08.22.170. APPLICATION FEES. (a) The fee for license applications made under this chapter are

- (1) supervisor \$25
- (2) laboratory technologist 15
- (3) laboratory assistant 10
- (4) laboratory trainee 2
- (5) histology technician 10
- (6) cytotechnologist 10
- (7) director 30

(b) A physician or pathologist licensed in this state is exempt from payments of the director application fee.

(c) The application fee for a clinical laboratory permit is

(1) for a laboratory employing five or more laboratory personnel licensed under this chapter, exclusive of the director \$50

(2) for a laboratory employing less than five laboratory personnel licensed under this chapter, exclusive of the director 25

(d) Payment of the application fee entitles the applicant to take an examination if required and covers the license fee for the remainder of the calendar year, except

1 that the application fee covers the laboratory trainee
2 license fee for two years.

3 Sec. 08.22.180. RENEWAL FEES. (a) Licenses shall be
4 renewed annually on or before January 1 of each calendar year.
5 The annual renewal fees for laboratory personnel licenses
6 under this chapter are

- 7 (1) supervisor \$15
8 (2) laboratory technologist 10
9 (3) laboratory assistant 5
10 (4) laboratory trainee 2
11 (5) histology technician 5
12 (6) cytotechnologist 5
13 (7) director 20

14 (b) The annual renewal fees for a clinical laboratory
15 permit under this chapter are

- 16 (1) for a laboratory employing five or more
17 laboratory personnel licensed under this chapter,
18 exclusive of the director \$30
19 (2) for a laboratory employing less than
20 five laboratory personnel licensed under this chapter,
21 exclusive of the director 15

22 Sec. 08.22.190. LAPSE OF LICENSE AND REINSTATEMENT.
23 The commissioner shall give written notice to a licensee 30
24 days in advance of the regular renewal date and shall give
25 written notice by registered mail 90 days in advance of the
26 expiration of the second year that a renewal fee has not been
27 paid. If a renewal fee is not paid before the expiration of
28 the second year of delinquency, the licensee may be subject
29 to reexamination, except that no reexamination shall be

1 required as a condition for reinstatement if the original
2 license was issued without an examination.

3 Sec. 08.22.200. DISPLAY OF LICENSES. A person main-
4 taining, conducting or operating a clinical laboratory shall
5 display in a prominent place in the clinical laboratory the
6 laboratory permit and the licenses of all laboratory person-
7 nel.

8 ARTICLE 3. UNLAWFUL ACTS.

9 Sec. 08.22.230. GROUNDS FOR REVOCATION OF A LABORATORY
10 PERMIT. A laboratory permit may be revoked or suspended by
11 the commissioner if

12 (1) the permit was secured through deceit, fraud
13 or wilful misrepresentation of a material fact;

14 (2) the laboratory is being conducted, maintained
15 or operated in violation of a provision of this chapter or
16 a regulation promulgated under it.

17 Sec. 08.22.240. GROUNDS FOR REVOCATION OF LICENSE. (a)
18 A license may be revoked, suspended or annulled, or the
19 licensee may be reprimanded, censured or disciplined by the
20 commissioner after a hearing under AS 44.62 if the licensee

21 (1) secures a license through deceit, fraud or
22 wilful misrepresentation of a material fact;

23 (2) is convicted of a crime involving moral
24 turpitude;

25 (3) has a chronic or persistent inebriety or
26 addiction to habit-forming drugs which renders him incompe-
27 tent to continue the duties he is licensed to perform;

28 (4) violate a provision of the laws governing the
29 practice of medicine and surgery;

1 (5) advertises laboratory procedures to the public
2 in magazines, newspapers, directories, circulars, signs, or
3 similar printed matter;

4 (6) knowingly accepts an assignment for clinical
5 laboratory tests or specimens from and renders a report
6 thereon to persons not licensed by law to submit the speci-
7 mens or assignments;

8 (7) renders a report on clinical laboratory work
9 actually performed in another clinical laboratory without
10 designating the laboratory in which the test was performed;

11 (8) violates a provision of this chapter or a
12 regulation promulgated under it.

13 (b) The adjudication of mental illness or the voluntary
14 commitment or admission to the Alaska Psychiatric Institute
15 or other mental hospital of any licensee for a mental illness
16 suspends his right to practice under this chapter. Restora-
17 tion of license shall be based on competent evidence of
18 restoration of mental competence.

19 Sec. 08.22.250. PROHIBITED ACTS. (a) It is unlawful
20 for a person

21 (1) to act as a director, supervisor, clinical
22 laboratory technologist, laboratory assistant, histology
23 technician, cytotechnologist, or laboratory trainee unless
24 he is licensed in that capacity under this chapter;

25 (2) to own, operate, maintain, direct or engage
26 in the business of operating a clinical laboratory unless
27 he possesses a valid laboratory permit;

28 (3) to make a test or examination in a clinical
29 laboratory unless the person is

1 (A) a licensed laboratory person in the sub-
2 ject or subjects to which the test or examination relates;
3 or

4 (B) a physician licensed to practice medicine
5 in this state.

6 (b) It is unlawful for a person who conducts, maintains
7 or operates a clinical laboratory to

8 (1) employ a person to perform clinical laboratory
9 procedures who is not a licensed supervisor, technologist,
10 assistant, trainee or physician;

11 (2) permit a laboratory trainee to work in the
12 laboratory unless one or more licensed supervisors, technolo-
13 gists or physicians are on active duty in the laboratory.

14 Sec. 08.22.260. PENALTY. A person who violates a
15 provision of this chapter is guilty of a misdemeanor.

16 ARTICLE 4. BLOOD BANKS.

17 Sec. 08.22.290. SUPERVISION. All phases of the selec-
18 tion of blood donors and of the collection, storage, pro-
19 cessing and transfusion of blood shall be the responsibility
20 of a qualified, licensed physician with a thorough knowledge
21 of blood bank methods and of transfusion principles and
22 practices.

23 Sec. 08.22.300. STAFF. A blood bank shall maintain an
24 adequate staff to perform the various phases of a blood
25 transfusion service.

26 Sec. 08.22.310. REGULATIONS. The commissioner shall
27 promulgate regulations specifying standards of safety for
28 the operation of a blood bank.

29 Sec. 08.22.320. RECORDS. Each blood transfusion service

1 shall develop a system of record keeping which best services
2 its needs. The record system shall make it possible to trace
3 a unit of blood or blood component from donor to recipient
4 and to recheck the laboratory records applying to the specific
5 product.

6 ARTICLE 5. MISCELLANEOUS.

7 Sec. 08.22.350. CLINICAL LABORATORY DIRECTOR. (a) A
8 director may not direct more than two laboratories, or more
9 than one laboratory and one blood bank. If a laboratory and
10 blood bank are on the same premises and are under the super-
11 vision of the same director, the laboratory and blood bank
12 are considered one laboratory for the purposes of this sub-
13 section.

14 (b) A person directing only one laboratory engaged in
15 a limited scope of medical laboratory work may direct the
16 laboratory on a part-time basis, but shall be present in the
17 laboratory during each day of operation, shall have working
18 knowledge of the work performed in the laboratory, and shall
19 be responsible for all of its operations.

20 (c) In small hospital laboratories where limited
21 laboratory work is performed and only one technologist is
22 employed, the director shall be available for consultation
23 during the hours the laboratory is in operation, have a
24 working knowledge of the procedures employed, have current
25 knowledge of the work being performed in the laboratory and
26 be responsible for all of its operations, including the
27 issuance of reports.

28 (d) A director is responsible for the employment of
29 qualified laboratory personnel.

1 (e) If a director is to be absent for more than 30
2 consecutive days, a person acceptable to the commissioner
3 shall be designated as the interim director.

4 (f) A director shall spend an adequate amount of time,
5 commensurate with the laboratory work load, in the active
6 direction of the laboratory.

7 Sec. 08.22.360. CLINICAL LABORATORY SUPERVISOR. A
8 supervisor may not supervise more than two laboratories or
9 more than one laboratory and one blood bank. Where a labora-
10 tory and a blood bank are on the same premises and are under
11 the supervision of the same supervisor, the laboratory and
12 blood bank are considered one laboratory for the purposes of
13 this subsection.

14 Sec. 08.22.370. CLINICAL LABORATORY TECHNOLOGIST. A
15 clinical laboratory technologist may supervise the work of
16 laboratory assistants and trainees.

17 Sec. 08.22.380. CLINICAL LABORATORY ASSISTANT. A
18 clinical laboratory assistant may not perform procedures in
19 a laboratory without the presence of a clinical laboratory
20 technologist. The number of laboratory assistants employed
21 in a laboratory may not exceed the number of clinical labora-
22 tory technologists employed there.

23 Sec. 08.22.390. CLINICAL LABORATORY TRAINEE. A
24 clinical laboratory trainee may work only while under direct
25 supervision and may perform only those clinical laboratory
26 procedures which are consistent with the level of competency
27 he has acquired by virtue of his education and training.

28 Sec. 08.22.400. VENIPUNCTURES. Licensed laboratory
29 personnel may perform venipunctures or skin punctures for

1 test purposes upon the authorization from a person licensed
2 to practice the healing arts, if the person may perform
3 venipunctures or skin punctures under his license.

4 ARTICLE 6. GENERAL PROVISIONS.

5 Sec. 08.22.430. EXEMPTIONS. The provisions of this
6 chapter do not apply to clinical laboratories, or persons
7 employed in clinical laboratories, maintained by

- 8 (1) the state;
9 (2) the federal government;
10 (3) a nonprofit research institution; or
11 (4) a licensed physician, surgeon, osteopathic
12 physician and surgeon, dentist or chiropractor, who performs
13 tests personally, or through employees, solely in connection
14 with the treatment of his own patients, and is not in partner-
15 ship with more than one other physician.

16 Sec. 08.22.440. DEFINITIONS. In this chapter

- 17 (1) "commissioner" means the commissioner of
18 health and welfare;
19 (2) "clinical laboratory" means a facility for the
20 microbiological, serological, chemical, hematological, bio-
21 physical, cytological, or pathological examination of
22 materials derived from the human body, for the purpose of
23 obtaining information for the diagnosis, prevention, or treat-
24 ment of disease or the assessment of medical condition;
25 (3) "blood bank" means a facility for blood
26 grouping or typing, cross matching, collection, storage, or
27 processing of human blood or blood derivatives, or from
28 which or by means of which human blood or blood derivatives
29 are distributed or made available;

1 (4) "clinical laboratory director" or "director"
2 means a person who administers the technical and scientific
3 operation of a clinical laboratory including the reporting
4 of the findings of clinical laboratory tests;

5 (5) "clinical laboratory supervisor" or "super-
6 visor" means a person who, under the general direction of a
7 clinical laboratory director, supervises technical personnel,
8 performs tests requiring special scientific skills and
9 reports the findings of clinical laboratory tests;

10 (6) "clinical laboratory technologist" means a
11 person, who, under general supervision, performs clinical
12 laboratory tests which require the exercise of independent
13 judgment, and reports findings of clinical laboratory tests
14 to authorized personnel;

15 (7) "clinical laboratory assistant" means a person
16 who carries out laboratory procedures which require limited
17 technical skill and responsibility and who performs clinical
18 laboratory procedures under direct supervision of a clinical
19 laboratory technologist;

20 (8) "clinical laboratory trainee" means a person
21 who receives instruction in a clinical laboratory in the
22 performance of clinical laboratory procedures for the purpose
23 of qualifying as a technologist or laboratory assistant;

24 (9) "histology technician" means a person who
25 prepares tissues dissected and selected from a human body
26 by a pathologist or prepares materials containing cells from
27 the human body for their examination by a pathologist;

28 (10) "cytotechnologist" means a person who, under
29 the direction of a pathologist, prepares and screens slides

1 for cell abnormalities.

2 * Sec. 2. Until January 1, 1969, a person is entitled to be
3 licensed as a clinical laboratory technologist if he passes an
4 examination given under this Act and he has completed 60 semester
5 hours or equivalent quarter hours of university or college work
6 of which at least 18 semester hours or their equivalent are
7 courses in the biological or chemical sciences and has at least
8 three years of experience as a clinical laboratory technologist
9 trainee.

10 * Sec. 3. A resident of Alaska who was regularly engaged in
11 the capacity of a director, a supervisor, laboratory technologist,
12 laboratory assistant, histology technician, cytotechnologist or
13 laboratory trainee in an established and properly equipped labora-
14 tory in this state for a period of at least one year before the
15 effective date of this Act shall, upon application to the com-
16 missioner, together with evidence which the commissioner may
17 require, be issued a license in the category for which he qualifies
18 without examination. Application under this section must be made
19 within three months after the effective date of this Act and shall
20 be accompanied by the required license fees.

21 * Sec. 4. This Act takes effect January 1, 1967.
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