

Introduced: 3/29/67
Referred: Health, Welfare
and Education and Finance

1 IN THE HOUSE

BY BEINE

2 HOUSE BILL NO. 327

3 IN THE LEGISLATURE OF THE STATE OF ALASKA

4 FIFTH LEGISLATURE - FIRST SESSION

5 A BILL

6 For an Act entitled: "An Act relating to the regulation of clinical labora-
7 tories, blood banks and their personnel; and providing
8 for an effective date."

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

10 * Section 1. PURPOSE. It is the purpose of this Act to secure greater
11 protection of the health, safety and welfare of the people of the state from
12 the hazards of improper performance by clinical laboratories. Clinical
13 laboratories provide essential services to the medical practitioner by
14 furnishing him vital information necessary to a determination of the nature,
15 cause and extent of the condition of his patients. The people of this state
16 are entitled to receive the highest level of competence, reliability and
17 accuracy that may be expected from clinical laboratories. Unreliable and
18 inaccurate reports may cause unnecessary anxiety, suffering, illness and
19 financial burdens, and can contribute directly to death. While legislation
20 cannot guarantee the accuracy of every laboratory report, the establishment
21 of minimum standards and qualifications assures the people of the state that
22 a certain amount of training, experience and supervision supports each report.

23 * Sec. 2. AS 08.01.010 is amended by adding a new paragraph to read:

24 (15) Clinical Laboratory Advisory Council.

25 * Sec. 3. AS 08 is amended by adding a new chapter to read:

26 CHAPTER 22. CLINICAL LABORATORIES AND BLOOD BANKS.

27 ARTICLE 1. ADMINISTRATION AND REGULATION.

28 Sec. 08.22.010. CLINICAL LABORATORY ADVISORY COUNCIL. (a) There
29 is created a Clinical Laboratory Advisory Council consisting of nine

1 members appointed by the governor for overlapping five-year terms to
2 advise and consult with the commissioner of health and welfare regarding
3 regulations and standards of operation of clinical laboratories and
4 blood banks. The council shall be composed of one physician who is not
5 a pathologist, one pathologist, one clinical laboratory director, one
6 clinical laboratory supervisor, two medical technologists, one clinical
7 laboratory assistant, one member of the Department of Health and Welfare
8 and one university faculty member. The medical technologists shall be
9 selected from different geographical locations.

10 (b) The council shall meet at least twice each year at the time
11 and place designated by the commissioner.

12 (c) Five members constitute a quorum for the transaction of
13 business.

14 (d) Members of the council are entitled to transportation expenses
15 and per diem allowance as specified in AS 39.20.180.

16 (e) Notwithstanding the provisions of AS 08.01.050(4) and (9) and
17 08.01.070(6), the council's functions shall remain advisory, and for
18 the purposes of this chapter the references in those subsections to
19 "board" shall be read "commissioner with the advice of the council."

20 Sec. 08.22.020. DUTIES OF THE COMMISSIONER. (a) The commissioner
21 shall, with the advice of the advisory council

22 (1) establish, by regulation, standards for the safe and
23 efficient operation and maintenance of clinical laboratories and blood
24 banks in the state;

25 (2) pass on qualifications of applicants and authorize the
26 issuance of licenses by the Department of Commerce under AS 08.01.050(9)
27 to those who qualify;

28 (3) provide for the preparation and grading of examinations;

29 (4) approve schools providing instruction in clinical

laboratory technique;

(5) initiate prosecution of, reprimand or discipline violators of this chapter;

(6) employ or contract with individuals or corporations to evaluate laboratory procedures and techniques and to recommend the preferred procedures and techniques to be used in a clinical laboratory;

(7) require each laboratory to establish an acceptable program for internal quality control including use of, where applicable, reference or control sera and other biological samples, concurrent calibrating standards, and control charts recording standard reading;

(8) require all laboratories to participate in performance evaluation programs including use of unknowns as prescribed by the commission, except that the commissioner may elect to accept the results of a performance evaluation program conducted by a professional group.

(b) In addition, the commissioner may employ technical or clerical assistance as needed and do whatever else is necessary to carry out the provisions of this chapter.

ARTICLE 2. LICENSING.

Sec. 08.22.050. LICENSE REQUIRED. (a) No person may operate a clinical laboratory or hold a laboratory position covered by this chapter without a license issued under this chapter.

(b) License applications shall be made to the Department of Commerce on appropriate forms supplied by that department.

Sec. 08.22.060. QUALIFICATIONS FOR A CLINICAL LABORATORY DIRECTOR LICENSE. An applicant is entitled to be licensed as a clinical laboratory director if he is

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

(2) a pathologist certified in clinical pathology and

1 licensed to practice in this state; or

2 (3) a person with a doctoral degree who is certified by
3 the American Board of Microbiologists or the American Board of Clinical
4 Chemistry or other accredited national professional societies approved
5 by the commissioner, has had four or more years of general clinical
6 laboratory training and experience, of which at least two of these
7 years were spent in acquiring proficiency in one laboratory specialty
8 in the clinical laboratory of a hospital, health department, university,
9 research institution or other laboratory acceptable to the commissioner,
10 and passes an examination given in accordance with this chapter.

11 Sec. 08.22.070. QUALIFICATIONS FOR A CLINICAL LABORATORY SUPER-
12 VISORY LICENSE. (a) An applicant is entitled to be licensed as a
13 clinical laboratory supervisor if he has

14 (1) a B.S. degree or certification by the American Society
15 of Clinical Pathologists, National Registry of Microbiologists, Clinical
16 Chemistry, or other national registries acceptable to the commissioner;

17 (2) a minimum of four years of generalized experience in a
18 clinical laboratory employing three or more clinical laboratory tech-
19 nologists or other laboratory personnel with equivalent qualifications;

20 (3) passes an examination given in accordance with this
21 chapter.

22 (b) The receipt of a master's degree in a fundamental medical
23 science is the equivalent of one year of experience as a clinical
24 laboratory technologist and a doctoral degree is the equivalent of
25 three years of experience as a clinical laboratory technologist.

26 Sec. 08.22.080. QUALIFICATIONS FOR A CLINICAL LABORATORY TECH-
27 NOLOGIST LICENSE. (a) An applicant is entitled to be licensed as a
28 clinical laboratory technologist if he passes an examination given
29 under this chapter and if he

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

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

7 (3) has, in the opinion of the commissioner, the education
8 or experience equivalent to that specified in (a)(1) or (2) of this
9 section.

10 (b) The commissioner may, if approved by the advisory council,
11 waive the requirements of this section and issue a license to an
12 individual who, in his opinion, has equivalent education and experience
13 in one or more of the laboratory specialties. With respect to special-
14 ties not included in the license, the technologist may only be permitted
15 to act as a trainee.

16 Sec. 08.22.090. QUALIFICATIONS FOR A CLINICAL LABORATORY ASSIST-
17 ANT LICENSE. (a) A laboratory worker who does not meet the minimum
18 requirements for a clinical laboratory technologist is eligible for
19 a license as a laboratory assistant if he passes an examination given
20 under this chapter, is a high school graduate, and

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

23 (2) has been employed for a period of at least five years,
24 including at least six months of employment immediately before the
25 effective date of this chapter, as a laboratory assistant in a clinical
26 laboratory acceptable to the commissioner; or

27 (3) subsequent to graduation has served two years as a
28 trainee, or in a position with at least equivalent requirements, in a
29 clinical laboratory with a training program approved by the commissioner.

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

5 **Sec. 08.22.100. QUALIFICATIONS FOR A HISTOLOGY TECHNICIAN LICENSE.**

6 (a) A person is entitled to be licensed as a histology technician if he

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

9 (2) passes an examination given in accordance with this
10 chapter.

11 (b) The commissioner may, with the approval of the advisory council,
12 waive the requirements of this section and issue a license to an indivi-
13 dual who, in his opinion, has equivalent education and experience.

14 **Sec. 08.22.110. QUALIFICATIONS FOR A CYTOTECHNOLOGIST LICENSE.**

15 (a) A person is entitled to be licensed as a cytotechnologist if he

16 (1) is a high school graduate, has at least two years of
17 college, six months of training at a school of cytotechnology, approved
18 by the American Medical Association, and six months experience in a
19 laboratory approved by the commissioner; and

20 (2) passes an examination given in accordance with this
21 chapter.

22 (b) The commissioner may, if approved by the advisory council,
23 waive the requirements of this section and issue a license to an indi-
24 vidual who, in his opinion, has equivalent education and experience.

25 **Sec. 08.22.120. QUALIFICATIONS FOR TRAINEE LICENSE.** (a) A person
26 is entitled to be licensed as a clinical laboratory technologist trainee,
27 clinical laboratory assistant trainee, histology technician trainee or
28 cytotechnologist trainee if

29 (1) he meets the educational requirements for a clinical

1 laboratory technologist, clinical laboratory assistant, histology tech-
2 nician or cytotechnologist specified in secs. 80, 90, 100 and 110,
3 respectively, of this chapter; and

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

6 (b) The training to be given an individual shall be appropriate
7 for the position for which his educational background qualified him.

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

11 (b) If a person fails an examination twice, he may not take the
12 examination again until he receives additional training specified by
13 the commissioner.

14 Sec. 08.22.140. WAIVER OF EXAMINATION AND COMITY. A person who
15 is registered by a national board of registry sponsored by a national
16 professional society acceptable to the commissioner, or who is licensed
17 by a state requiring qualifications equivalent to or higher than those
18 prescribed by this chapter, is entitled to be licensed in the category
19 for which he qualifies upon payment of the prescribed application and
20 license fees.

21 Sec. 08.22.150. TEMPORARY LICENSE. A temporary license may be
22 issued to an individual who has not failed an examination for a per-
23 manent license of the same type and who by training or experience is
24 apparently qualified. A temporary license may not be extended beyond
25 the date on which the results of the next examination are made known.

26 Sec. 08.22.160. CLINICAL LABORATORY LICENSE. (a) Application
27 for a laboratory license shall be on a form provided by the commissioner
28 and shall contain the name of the owner or owners, the name of the
29 director, the name and location of the laboratory and other information

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required by the commissioner.

(b) A separate laboratory license must be obtained for each location.

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

(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 license 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 that the application fee covers the

laboratory trainee license fee for two years.

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

(1) director	\$20
(2) supervisor	15
(3) laboratory technologist	10
(4) laboratory assistant	5
(5) histology technician	5
(6) cytotechnologist	5
(7) laboratory trainee	2

(b) The annual renewal fees for a clinical laboratory license under this chapter are

(1) for a laboratory employing five or more laboratory personnel licensed under this chapter, exclusive of the director \$30

(2) for a laboratory employing less than five laboratory personnel licensed under this chapter, exclusive of the director \$15

Sec. 08.22.190. LAPSE OF LICENSE AND REINSTATEMENT. The commissioner shall give written notice to a licensee 30 days in advance of the regular renewal date and shall give written notice by registered mail 90 days in advance of the expiration of the second year that a renewal fee has not been paid. If a renewal fee is not paid before the expiration of the second year of delinquency, the licensee may be subject to re-examination, except that no re-examination shall be required as a condition for reinstatement if the original license was issued without an examination.

Sec. 08.22.200. DISPLAY OF LICENSES. A person maintaining,

1 conducting or operating a clinical laboratory shall display in a
2 prominent place in the clinical laboratory the laboratory license and
3 the licenses of all laboratory personnel.

4 Sec. 08.22.210. REVOCATION OR SUSPENSION OF LICENSE OF LABORATORY
5 PERSONNEL. (a) A license may be revoked, suspended or annulled, or
6 the licensee may be reprimanded, censured or disciplined by the commis-
7 sioner if the licensee

8 (1) secures a license through deceit, fraud or wilful mis-
9 representation of a material fact;

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

11 (3) has a chronic or persistent inebriety or addiction to
12 habit-forming drugs which renders him incompetent to continue the
13 duties he is licensed to perform;

14 (4) violates a provision of the laws governing the practice
15 of medicine and surgery;

16 (5) advertises laboratory procedures to the public in
17 magazines, newspapers, directories, circulars, signs, or similar
18 printed matter;

19 (6) knowingly accepts an assignment for clinical
20 laboratory tests or specimens from and renders a report thereon
21 to persons not licensed by law to submit the specimens or
22 assignments;

23 (7) renders a report on clinical laboratory work actually
24 performed in another clinical laboratory without designating the
25 laboratory in which the test was performed;

26 (8) violates a provision of this chapter or a regulation
27 promulgated under it.

28 (b) The adjudication of mental illness or the voluntary
29 commitment or admission to the Alaska Psychiatric Institute or

1 other mental hospital of any licensee for a mental illness suspends
2 his right to practice under this chapter. Restoration of license
3 shall be based on competent evidence of restoration of mental
4 competence.

5 **Sec. 08.22.220. REVOCATION OR SUSPENSION OF A LABORATORY LICENSE.**

6 A laboratory license may be revoked or suspended by the commissioner if

7 (1) the license was secured through deceit, fraud or wilful
8 misrepresentation of a material fact;

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

12 **ARTICLE 3. BLOOD BANKS.**

13 **Sec. 08.22.250. SUPERVISION.** All phases of the selection of
14 blood donors and of the collection, storage, processing and trans-
15 fusion of blood shall be the responsibility of a qualified, licensed
16 physician with a thorough knowledge of blood bank methods and of
17 transfusion principles and practices. No more than two blood banks
18 may be under the direction or supervision of one individual.

19 **Sec. 08.22.260. STAFF.** A blood bank shall maintain an adequate
20 staff to perform the various phases of a blood transfusion service.

21 **Sec. 08.22.270. RECORDS.** Each blood transfusion service shall
22 develop a system of record keeping which best serves its needs. The
23 record system shall make it possible to trace a unit of blood or blood
24 component from donor to recipient and to recheck the laboratory records
25 applying to the specific product.

26 **Sec. 08.22.280. STANDARDS.** A blood bank shall adhere to the
27 standards established by the commissioner under sec. 20(a)(1) of this
28 chapter. These standards shall be at least the equivalent of those
29 established by the American Association of Blood Banks or the National

1 Institute of Health.

2 **ARTICLE 4. MISCELLANEOUS.**

3 **Sec. 08.22.300. REPORT OF POSITIVE FINDINGS.** Each clinical
4 laboratory shall report positive findings of communicable disease to
5 the department in the manner and for the diseases required by the
6 commissioner.

7 **Sec. 08.22.310. CLINICAL LABORATORY DIRECTOR.** (a) A director
8 may not direct more than two laboratories nor more than one laboratory
9 and one blood bank. If a laboratory and blood bank are on the same
10 premises and are under the supervision of the same director, the
11 laboratory and blood bank are considered one laboratory for the purposes
12 of this subsection.

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

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

25 (d) A director is responsible for the employment of qualified
26 laboratory personnel.

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

1 (f) A director shall spend an adequate amount of time, commensurate with the laboratory work load, in the active direction of the
2 laboratory.
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4 Sec. 08.22.320 CLINICAL LABORATORY SUPERVISOR. A supervisor may
5 not supervise more than two laboratories nor more than one laboratory
6 and one blood bank. Where a laboratory and a blood bank are on the
7 same premises and are under the supervision of the same supervisor, the
8 laboratory and blood bank are considered one laboratory for the purposes
9 of this subsection.

10 Sec. 08.22.330. CLINICAL LABORATORY TECHNOLOGIST. A clinical
11 laboratory technologist may supervise the work of laboratory assistants
12 and trainees.

13 Sec. 08.22.340. CLINICAL LABORATORY ASSISTANT. A clinical
14 laboratory assistant may not perform procedures in a laboratory without
15 the presence of a clinical laboratory technologist. The number of
16 laboratory assistants employed in a laboratory may not exceed the
17 number of clinical laboratory technologists employed there.

18 Sec. 08.22.350. CLINICAL LABORATORY TRAINEE. A clinical labora-
19 tory trainee may work only while under direct supervision and may
20 perform only those clinical laboratory procedures which are consistent
21 with the level of competency he has acquired by virtue of his education
22 and training.

23 Sec. 08.22.360. VENIPUNCTURES. Licensed laboratory personnel may
24 perform venipunctures or skin punctures for test purposes upon the
25 authorization from a person licensed to practice the healing arts, if
26 the person may perform venipunctures or skin punctures under his license.

27 ARTICLE 5. GENERAL PROVISIONS.

28 Sec. 08.22.380. EXEMPTIONS. The provisions of this chapter do
29 not apply to clinical laboratories, or persons employed in clinical

1 laboratories, maintained by

- 2 (1) the state;
- 3 (2) the federal government;
- 4 (3) a nonprofit research institution; or
- 5 (4) a licensed physician, surgeon, osteopathic physician
- 6 and surgeon, dentist or chiropractor, who performs tests personally or
- 7 through employees, solely in connection with the treatment of his own
- 8 patients, and is not in partnership with more than one other physician.

9 Sec. 08.22.390. APPLICABILITY OF THE ADMINISTRATIVE PROCEDURE ACT.
10 The Administrative Procedure Act (AS 44.62) applies to regulations and
11 proceedings under this chapter.

12 Sec. 08.22.400. PROHIBITED ACTS. (a) It is unlawful for a person

13 (1) to act as a director, supervisor, clinical laboratory
14 technologist, laboratory assistant, histology technician, cytotech-
15 nologist, or laboratory trainee unless he is licensed in that capacity
16 under this chapter;

17 (2) to own, operate, maintain, direct or engage in the
18 business of operating a clinical laboratory unless he possesses a
19 valid laboratory license;

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

22 (A) a licensed laboratory person in the subject or
23 subjects to which the test or examination relates; or

24 (B) a physician licensed to practice medicine in this
25 state;

26 (4) to send clinical laboratory specimens to laboratories
27 outside the state for testing and reporting unless the out-of-state
28 laboratory is certified by the department as meeting standards at
29 least equivalent to those in this state.

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

3 (1) employ a person to perform clinical laboratory procedures
4 who is not a licensed supervisor, technologist, assistant, histology
5 technician, cytotechnologist, trainee or physician;

6 (2) permit a laboratory trainee to work in the laboratory
7 unless one or more licensed supervisors, technologists or physicians
8 are on active duty in the laboratory.

9 Sec. 08.22.410. PENALTY. A person who violates a provision of
10 this chapter is guilty of a misdemeanor.

11 Sec. 08.22.420. DEFINITIONS. In this chapter

12 (1) "commissioner" means the commissioner of health and
13 welfare;

14 (2) "clinical laboratory" means a facility for the micro-
15 biological, serological, chemical, hematological, biophysical, cyto-
16 logical or pathological examination of materials derived from the human
17 body, for the purpose of obtaining information for the diagnosis, pre-
18 vention, or treatment of disease or the assessment of medical condition.

19 (3) "blood bank" means a facility for blood grouping or
20 typing, cross matching, collection, storage, or processing of human
21 blood or blood derivatives, or from which or by means of which human
22 blood or blood derivatives are distributed or made available;

23 (4) "clinical laboratory director" or "director" means a
24 person who administers the technical and scientific operation of a
25 clinical laboratory including the reporting of the findings of clinical
26 laboratory tests;

27 (5) "clinical laboratory supervisor" or "supervisor" means
28 a person who, under the general direction of a clinical laboratory
29 director, supervises technical personnel, performs tests requiring

1 special scientific skills and reports the findings of clinical labora-
2 tory tests;

3 (6) "clinical laboratory technologist" means a person who,
4 under general supervision, performs clinical laboratory tests which
5 require the exercise of independent judgment, and reports findings of
6 clinical laboratory tests to authorized personnel; the term is equiva-
7 lent to "medical technologist";

8 (7) "clinical laboratory assistant" means a person who
9 carries out laboratory procedures which require limited technical skill
10 and responsibility and who performs clinical laboratory procedures
11 under direct supervision of a clinical laboratory technologist;

12 (8) "clinical laboratory trainee" means a person who
13 receives instruction in a clinical laboratory in the performance of
14 clinical laboratory procedures for the purpose of qualifying as a
15 technologist or laboratory assistant;

16 (9) "cytotechnologist" means a person who, under the direc-
17 tion of a pathologist, prepares and screens slides for cell abnormalities.

18 (10) "histology technician" means a person who prepares
19 tissues dissected and selected from a human body by a pathologist or
20 prepares materials containing cells from the human body for their
21 examination by a pathologist.

22 * Sec. 4. Until January 1, 1970, a person is entitled to be licensed as
23 a clinical laboratory technologist if he passes an examination given under
24 this Act and he has completed 60 semester hours or equivalent quarter hours
25 of university or college work of which at least 18 semester hours or their
26 equivalent are courses in the biological or chemical sciences and has at
27 least three years of experience as a clinical laboratory technologist trainee.

28 * Sec. 5. A resident of Alaska who has regularly served in the capacity
29 of a director, supervisor, laboratory technologist, laboratory assistant,

1 histology technician, cytotechnologist or laboratory trainee in an established
2 and properly equipped laboratory in this state for a period of at least one
3 year before the effective date of this Act shall, upon application to the
4 commissioner, together with evidence which the commissioner may require, be
5 issued a license in the category for which he qualifies without examination.
6 Application under this section must be made within three months after the
7 effective date of this Act and shall be accompanied by the required license
8 fees.

9 * Sec. 6. This Act takes effect January 1, 1969.

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