CHAPTER 43-48
CLINICAL LABORATORY PERSONNEL

43-48-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

1. "Board" means the North Dakota board of clinical laboratory practice.
2. "Clinical laboratory" means a site where clinical laboratory testing is done.
3. "Clinical laboratory personnel" means all clinical laboratory scientists or medical technologists or specialists, and clinical laboratory technicians or medical laboratory technicians working in a clinical laboratory, but does not include persons employed by a clinical laboratory to perform clerical duties or other duties classified as supportive functions not related to the direct performance of patient tests, such as phlebotomists, does not include clinical laboratory students, and does not include cytologists performing cytology procedures and histologists or histotechnicians performing histology procedures.
4. "Clinical laboratory student" means a person having qualified and enrolled in an approved program of structured clinical education and who is seeking training and experience required to meet minimum qualifications for a license by the board to practice as a clinical laboratory person in this state.
5. "Clinical laboratory testing" means a microbiological, serological, chemical, hematological, radiobioassay, biophysical, or immunological assay which is derived from the human body, to provide information for diagnosis, prevention, or treatment of a disease or assessment of a medical condition.
6. "Consumer" means a person who might use laboratory medicine services or the services of its practitioners, but does not derive such person's livelihood from these services.
7. "National certifying examination" means national examinations given to certify clinical laboratory personnel and recognized by the board.
8. "Screening test" means a test measuring only the approximate value of the analyte being tested and not used for diagnosis.
9. "Specimen" means any material derived from the human body for examination or other procedure for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, impairment, or assessment of the health of humans.
10. "Structured clinical education" means a program accredited by an appropriate accrediting agency to provide a predetermined amount of instruction and experience in clinical laboratory, and approved or modified by the board.

43-48-02. License required.

No person may practice as a clinical laboratory scientist or a clinical laboratory technician unless the person is the holder of a current license issued by the board, or is exempt from licensure.

43-48-03. Exemptions.

The provisions of this chapter do not apply to the following:

1. Physicians duly and currently licensed to practice medicine.
2. Nurses duly and currently licensed to practice nursing and practicing within the scope of the nursing license.
3. Persons performing clinical testing for teaching or research, provided that the results of any examination performed in such laboratories are not used in health maintenance, diagnosis, or treatment of disease.
4. Persons employed by the United States government, or any bureau, division, or agency thereof, and working in a licensed laboratory.
5. Any person in the pursuit of a supervised course of study leading to a degree at an accredited or educational program approved by the board.
6. Phlebotomy personnel performing phlebotomy procedures.

7. Persons performing testing for their own personal use and persons performing screening tests for mass screening under appropriate supervision.
8. Agents of the state or federal government performing hematological tests for anemia upon participants of the special supplemental food program for women, infants, and children.
9. An individual performing exempt tests identified by rules adopted by the board. The individual must be supervised by an individual who is licensed by the board, a physician licensed by the board of medicine, an advanced practice registered nurse licensed by the board of nursing, or other categories of individuals approved by the board by rule. The supervisor and individual shall adhere to the methods identified by rules adopted by the board.
10. Perfusionists performing clinical laboratory tests for hematology, coagulation, and chemistry during the course of a patient's perfusion procedures.
11. Personnel of the division of laboratory services of the department of health and human services or department of environmental quality who are participating in the centers for disease control and prevention's chemical terrorism toxic metals determination program.
12. A person licensed or registered under another chapter of this title and carrying out the therapy or practice for which the person is licensed or registered.
13. Personnel performing whole blood glucose waived tests as categorized by the food and drug administration based on the criteria established by the Clinical Laboratory Improvement Act of 1988 [42 U.S.C. 263a et seq.].
14. Pharmacists duly and currently licensed to practice pharmacy.

43-48-04. Powers and duties of the board.

In order to enforce and administer this chapter, the board shall:

1. Maintain an office to conduct business.
2. Conduct or approve licensing or certification examinations for entry into clinical laboratory practice as authorized under this chapter.
3. Issue and renew a license to any person who currently meets the qualifications in the category for which license is sought.
4. Establish fees and receive all moneys collected under this chapter.
5. Issue subpoenas, examine witnesses, administer oaths, and investigate allegations of practices violating the provisions of this chapter.
6. Discipline licensees as necessary, which may include reprimand of the licensee, probation, denial, suspension or revocation of license.
7. Adopt rules pursuant to chapter 28-32, necessary for the implementation of this chapter, including rules relating to professional licensure and to the establishment of standards of practice for persons holding a license to practice clinical laboratory testing in this state. The rules must specifically address the special needs of rural hospitals and clinics with regard to laboratory personnel.
8. Employ an executive director and such other professional and secretarial staff as may be necessary.
9. Authorize all expenditures necessary for conducting the business of the board. Any balance of fees and other moneys received by the board after payment of expenditures is to be used in administering the provisions of this chapter.
10. Establish or approve criteria for the continuing education of clinical laboratory personnel as it may deem reasonably appropriate as a prerequisite to the renewal of any license provided for in this chapter, so long as such requirements are uniform as to application, and are reasonably related to the measurement of qualification, performance, or competence desirable and necessary for the protection of the public health.

43-48-05. Board of clinical laboratory practice - Administration.

1. There is hereby created a North Dakota board of clinical laboratory practice which shall consist of seven persons appointed by the governor, who must be residents of

the state for at least two years prior to their appointment and who, except for the consumer members, must be currently engaged in their area of practice.

2. The board must be composed of:
   a. One physician licensed to practice medicine in the state and qualified to practice as a pathologist.
   b. The following laboratory persons, whose names may be included on a list of such persons qualified to serve submitted to the governor by the North Dakota society for medical technology or other interested persons, such list to contain at least three names for each vacancy:
      (1) One administrative nonphysician clinical laboratory director;
      (2) One clinical laboratory scientist; and
      (3) One clinical laboratory technician.
   c. Two consumer members, each of whom must be a citizen of the United States, a resident of North Dakota for at least two years before the date of appointment, and a current resident of North Dakota.
   d. The state health officer or such officer's designee, ex officio.
3. The members of the board shall serve for terms of three years.
4. Each member of the board shall qualify by taking the oath required by civil officers and shall hold office until the successor is duly appointed and qualified.
5. The governor may remove any board member for good cause after giving that member a written statement of the reason for removal and after the member has had an opportunity for hearing.
6. Whenever any board vacancy shall occur, the appointment authority shall in the same manner as the prior appointment, appoint a successor of like qualifications for the remainder of the unexpired term.
7. The board must be authorized to appoint subcommittees which must be representative of the various disciplines licensed under this chapter to assist, advise, and make recommendations to the board.
8. The board shall meet at least once during the first three months of each calendar year and at least one additional meeting must be held before the end of each calendar year. Other meetings may be convened at the call of the board chairperson or the written request of any three board members.
9. In addition to the expenses incurred while engaged in the performance of their duties, each board member shall receive a per diem fee set by the board, not to exceed the fee established by law for the legislative assembly.

43-48-06. Fees.

The board shall set by rule the applicable licensure fee for those persons subject to this chapter, including the initial fee, license fee, late renewal fees, and limited permit fees. These fees must be set in such reasonable amount as to reimburse the board for the cost of its services.

43-48-07. Duties and qualifications of clinical laboratory personnel - Requirements for licensure.

An applicant applying for license as a clinical laboratory scientist or clinical laboratory technician shall file a written application provided by the board, along with the appropriate fee, showing to the satisfaction of the board that the applicant is qualified for the said position.

43-48-08. Clinical laboratory scientist or medical technologist or clinical laboratory specialist - Licensure qualifications.

1. A clinical laboratory scientist or medical technologist has graduated with a bachelor of science or a bachelor of arts degree in a science-related discipline and has passed a national certifying examination approved by the board. Upon receipt of documentation that all necessary educational and experience qualifications for a clinical laboratory scientist or medical technologist have been met, or upon successful completion of an

examination approved by the board, the board shall issue a clinical laboratory scientist or medical technologist license to any person meeting the above qualifications.

2. A clinical laboratory scientist or specialist is educated in chemical, physical, or biological science and performs in a clinical laboratory only functions directly related to such person's particular specialty. Upon successful completion of an examination covering only those fields in which an applicant is eligible to be examined, and documentation of competency by a nationally recognized certifying agency, the board shall issue a clinical laboratory specialist license to any person meeting the following minimum qualifications:
   a. A baccalaureate or higher degree with a major in one of the chemical, physical, or biological sciences.
   b. Has passed a national certifying examination in a specialty area.

   A license issued must be issued as a clinical laboratory specialist followed by designation of area of specialty.

43-48-09. Clinical laboratory technician or medical laboratory technician - Licensure qualifications.

A clinical laboratory technician or medical laboratory technician has successfully completed the academic requirements of an educational program recognized by the board and has passed a national certifying examination approved by the board.

Upon receipt of documentation that all necessary educational and experience qualifications for clinical laboratory technician have been met, or upon successful completion of an examination approved by the board, the board shall issue a clinical laboratory technician license to any person meeting the above qualifications.

43-48-10. Student work authorization.

A clinical laboratory student may perform tests under the supervision of licensed clinical laboratory personnel without being licensed therefor by the board.

43-48-11. Provisional permits.

The board may, under criteria established by the board, grant a limited permit to a person who has completed the education and experience requirements of this chapter. Such permit allows the person to practice medical technology in association with licensed clinical laboratory personnel. The permit is valid for no longer than a period of three years or until the person holding the permit is duly issued a license or the permit is revoked by the board.

43-48-12. Grandfather provisions.

Repealed by S.L. 2013, ch. 334, § 3.

43-48-13. Issuance of license.

The board shall issue a license to any person who meets the requirements of this chapter upon application therefor and payment of the license fee established by the board.

43-48-14. Renewal of license.

A license issued under this chapter is subject to biennial renewal and expires unless renewed in the manner prescribed by the board and upon the payment of a renewal fee. The board may provide for the late renewal of a license upon the payment of a late fee in accordance with its rules.

43-48-15. Supervision and revocation of license - Refusal to renew.

1. The board may deny, refuse to renew, suspend, or revoke a license or permit, or may impose probationary conditions if the licensee or permittee or applicant for a license or permit has been found to have committed unprofessional conduct which has endangered or is likely to endanger the health, welfare, or safety of the public. Unprofessional conduct includes:

a. Obtaining or attempting to obtain a license by means of fraud, deceit, misrepresentation, or concealment of facts.
b. Being convicted of an offense, as defined by section 12.1-01-04, and which the board determines has a direct bearing upon a person's ability to serve the public as a licensed clinical laboratory personnel or, following the conviction of any offense, if the board determines that the person is not sufficiently rehabilitated.
c. Violating any lawful order or rule rendered or adopted by the board.
d. Violating any provision of this chapter.

2. A denial, refusal to renew, suspension, revocation, or imposition of probationary conditions upon a licensee or permittee may be ordered by the board after a hearing in the manner provided by rules adopted by the board and in conformance with chapter 28-32. An application for reinstatement may be made to the board one year from the date of the revocation of a license. The board may accept an application for reinstatement, and may hold a hearing to consider such reinstatement.

43-48-16. Penalty.

Any person who violates section 43-48-02 is guilty of a class B misdemeanor.