SF133 REVISOR BR S0133-2 2nd Engrossment

## **SENATE** STATE OF MINNESOTA **EIGHTY-EIGHTH SESSION**

A bill for an act

relating to health occupations; establishing licensure for medical laboratory

S.F. No. 133

(SENATE AUTHORS: HOFFMAN, Lourey, Marty, Sheran and Nienow)

1.1

1.2

1.23

1.24

1.25

DATE	D-PG	OFFICIAL STATUS
01/28/2013	101	Introduction and first reading
		Referred to Health, Human Services and Housing
03/10/2014	6013a	Comm report: To pass as amended and re-refer to State and Local Government
03/12/2014	6122a	Comm report: To pass as amended and re-refer to Judiciary
03/17/2014	6255	Comm report: To pass and re-referred to Health, Human Services and Housing
03/24/2014	6651a	Comm report: To pass as amended and re-refer to Finance

1.3	science professionals; creating an advisory council; providing penalties;
1.4	establishing fees; appropriating money; proposing coding for new law as
1.5	Minnesota Statutes, chapter 148G.
1.6	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
1.7	Section 1. [148G.01] DEFINITIONS.
1.8	Subdivision 1. Applicability. For purposes of this chapter, the following terms
1.9	have the meanings given them.
1.10	Subd. 2. Accredited medical laboratory educational program. "Accredited
1.11	medical laboratory educational program" means a program to provide instruction and
1.12	experience in medical laboratory science that has been accredited by an accrediting agency
1.13	recognized by the United States Department of Health and Human Services.
1.14	Subd. 3. Categorical medical laboratory scientist. "Categorical medical
1.15	laboratory scientist" means an individual eligible for licensure under this chapter who
1.16	performs the functions of a medical laboratory scientist in one or more of the following
1.17	areas of the laboratory depending upon the certification examinations passed: chemistry,
1.18	hematology, immunohematology, and microbiology.
1.19	Subd. 4. CLIA. "CLIA" means Clinical Laboratory Improvement Amendments of
1.20	1988 and includes Public Law 10-578 and Code of Federal Regulations, title 42, section
1.21	493. CLIA regulations provide a minimum foundation upon which personnel standards
1.22	for entry level technical personnel in this state are built. Qualifications and responsibilities

for laboratory director, technical supervisor, and technical consultant are as specified in

CLIA regulations. All medical laboratory personnel are under the supervision, control,

Section 1. 1

and responsibility of the laboratory director.

Subd. 5. Commissioner. "Commissioner" means the commissioner of health or the 2.1 commissioner's designee. 2.2 Subd. 6. Cytotechnologist. "Cytotechnologist" means an individual who 2.3 specializes in the cellular analysis of patient samples from all body sites, for the purpose 2.4 of evaluating, detecting, and identifying potential disease processes through the exercise 2.5 of independent technical judgment, under the supervision, control, and responsibility of 2.6 the laboratory director, and who: 2.7 (1) assists health care providers with the collection, detection, and identification 2.8 of normal and abnormal cells, infectious agents, and other noncellular material from 2.9 submitted specimens; 2.10 (2) performs a variety of medical laboratory tests that may include the use of 2.11 molecular techniques with approval and oversight of a medical director, to ascertain 2.12 information to help in classification of a specimen consistent with the scope of work 2.13 provided under the Clinical Laboratory Improvement Amendments of 1988; 2.14 2.15 (3) establishes and implements protocols, quality control, method selection, equipment selection and maintenance, and activities related to the preanalytic, analytic, 2.16 and postanalytic phases of testing; and 2.17 (4) directs, supervises, consults, educates, and performs research functions. 2.18 Subd. 7. Histotechnician. "Histotechnician" means an individual who, with the 2.19 approval, supervision, and control of a board-certified anatomic pathologist, may perform 2.20 the following functions: 2.21 (1) prepares tissue specimens for microscopic examination; 2.22 2.23 (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy and validity of laboratory testing and procedures, including, but not limited to, techniques 2.24 in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining; 2.25 2.26 (3) prepares gross specimens as defined by and under the direction of a board-certified anatomic pathologist; 2.27 (4) establishes and implements protocols, quality assurance, and quality control 2.28 related to the following procedures: histochemical, immunohistochemical, electron 2.29 microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA 2.30 hydrolysis, laser capturing, molecular techniques, and research; and 2.31 (5) participates in method selection, development, equipment selection and 2.32 maintenance, and activities related to the preanalytical and analytical phases of tissue 2.33 2.34 preparation.

Section 1. 2

3.1	Subd. 8. Histotechnologist. "Histotechnologist" means an individual who, with
3.2	the approval, supervision, and control of a board-certified anatomic pathologist, may
3.3	perform the following functions:
3.4	(1) prepares tissue specimens for microscopic examination;
3.5	(2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy
3.6	and validity of laboratory testing and procedures including, but not limited to, techniques
3.7	in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining;
3.8	(3) prepares gross specimens as defined by and under the direction of a
3.9	board-certified anatomic pathologist;
3.10	(4) establishes and implements protocols, quality assurance, and quality control
3.11	related to the following procedures: histochemical, immunohistochemical, electron
3.12	microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA
3.13	hydrolysis, laser capturing, molecular techniques, and research;
3.14	(5) establishes and implements new protocols and procedures dealing directly in
3.15	quality assessment, method development, and equipment selection and maintenance and
3.16	all activities related to preanalytical and analytical phases of tissue preparation; and
3.17	(6) directs, supervises, consults, educates, and performs research functions.
3.18	Subd. 9. Independent medical judgment. In the laboratory, "independent medical
3.19	judgment" means medical judgment exercised only by a pathologist or other licensed
3.20	physician in the diagnosis and treatment decisions related to clinical laboratory tests.
3.21	Subd. 10. Independent technical judgment. "Independent technical judgment"
3.22	means the performance or conduct of clinical laboratory tests and assumption of
3.23	responsibility for determination of the validity of clinical laboratory tests. The authorized
3.24	exercise of independent technical judgment shall not be deemed to include or permit the
3.25	exercise of independent medical judgment in the diagnosis or treatment of, or reporting of
3.26	clinical laboratory test results or their interpretation to patients, except as authorized by a
3.27	laboratory director and according to CLIA.
3.28	Subd. 11. Medical laboratory or laboratory. "Medical laboratory" or "laboratory"
3.29	means any facility or office in Minnesota in which medical laboratory tests are performed
3.30	Subd. 12. Medical laboratory scientist or generalist. "Medical laboratory
3.31	scientist" or "generalist" means an individual eligible for licensure under this chapter who
3.32	(1) performs medical laboratory tests, including tests that require the exercise of
3.33	independent technical judgment;
3.34	(2) establishes and implements protocols, quality assessment, method development
3.35	and selection, equipment selection and maintenance, and all activities related to the
3.36	preanalytic, analytic, and postanalytic phases of laboratory testing; and

Section 1. 3

(3) directs, supervises, consults, educates, and performs research functions. 4.1 Subd. 13. **Medical laboratory specialist.** "Medical laboratory specialist" means 4.2 an individual certified in one of the categories described in subdivisions 14, 15, and 16, 4.3 to perform testing, including tests that require the exercise of independent technical 4.4 judgment needed to establish and implement protocols, quality assessment, method 4.5 development and selection, equipment selection and maintenance, and all activities related 4.6 to the preanalytic, analytic, and postanalytic phases of laboratory testing, and who direct, 4.7 supervise, consult, and educate in a specific specialized section of the laboratory. 4.8 Subd. 14. Medical laboratory specialist in cytogenetics. "Medical laboratory 4.9 specialist in cytogenetics" means an individual eligible for licensure under this chapter to 4.10 perform standard cytogenetic and molecular testing procedures used to evaluate possible 4.11 genetic anomalies. 4.12 Subd. 15. Medical laboratory specialist in molecular biology/pathology. 4.13 "Medical laboratory specialist in molecular biology/pathology" means an individual 4.14 4.15 eligible for licensure under this chapter to perform all aspects of molecular analysis, including, but not limited to, recombinant DNA technology, polymerase chain reaction, 4.16 and sequencing and hybridization techniques. 4.17 Subd. 16. Medical laboratory specialist in histocompatability. "Medical 4.18 laboratory specialist in histocompatability" means an individual eligible for licensure 4.19 4.20 under this chapter to perform histocompatibility testing procedures, including, but not limited to, molecular and serological techniques. 4.21 Subd. 17. Medical laboratory technician. "Medical laboratory technician" means 4.22 4.23 an individual eligible for licensure under this chapter who performs medical laboratory tests at all CLIA complexity levels according to established and approved protocols and 4.24 requiring limited exercise of independent judgment. 4.25 Subd. 18. Medical laboratory test or laboratory test. "Medical laboratory 4.26 test" or "laboratory test" means a microbiological, serological, chemical, biological, 4.27 hematological, immunological, immunohematological, radiobioassay, cytological, 4.28 histological preparation, molecular, biophysical, or any other test or procedure performed 4.29 on material derived from or existing in a human body, that provides information for 4.30 the diagnosis, prevention, or monitoring of a disease or impairment or assessment of a 4.31 medical condition. A medical laboratory test includes components of the preanalytic and 4.32 postanalytic phases of testing, as well as the analytic phase, that occurs in the laboratory. 4.33 Subd. 19. Medical laboratory subspecialists. "Medical laboratory subspecialists" 4.34 means an individual eligible for licensure under this chapter to perform the functions 4.35 of a medical laboratory scientist in a subspecialty or esoteric clinical laboratory that is 4.36

Section 1. 4

5.2

5.3

5.4

5.5

5.6

5.7

5.8

5.9

not one of the general categorical areas of the laboratory, and for which a certification examination does not exist. The subspecialty or esoteric laboratories may be disease or medical specialty-oriented or utilize advanced technology not routinely used in the clinical laboratory. The subspecialty or esoteric laboratories may be subspecialized areas within the hematology, chemistry, immunology, transfusion, medicine, genetics, or microbiology disciplines. Subd. 20. Nationally recognized certification agency. "Nationally recognized certification agency" means an agency that provides certification examinations for medical laboratory professionals as set forth in section 148G.07. The commissioner and the advisory council shall recognize any new certification examinations if the examination is 5.10 defined by the recognized agency. 5.11 Subd. 21. Pathologist's assistant. "Pathologist's assistant" means an individual 5.12 specializing in prediagnostic surgical pathology and autopsy pathology who assists 5.13 pathologists. 5.14 5.15 Subd. 22. **Phlebotomist.** "Phlebotomist" means an individual who is qualified to obtain blood samples for testing by means of venipuncture, capillary puncture, or access 5.16 of venous access devices, to perform specimen processing and preparation of samples for 5.17 testing, and to perform waived and point-of-care testing. 5.18 Subd. 23. **Point-of-care testing.** "Point-of-care testing" means analytical patient 5.19 testing activities provided within a facility that do not require permanent dedicated space, 5.20 including, but not limited to, analytic instruments that are temporarily brought to a patient 5.21 care location. Point-of-care testing must be under the direction of an individual licensed 5.22 5.23 under this chapter at the baccalaureate degree level or who qualifies as a laboratory 5.24 director under federal CLIA regulations. Subd. 24. Trainee/student. "Trainee/student" means an individual who has 5.25 5.26 not fulfilled the educational requirements to take an approved nationally recognized certification examination or who needs to obtain full-time comprehensive experience 5.27 under supervision. 5.28 Subd. 25. Waived test. "Waived test" means a laboratory examination or procedure 5.29 as determined by the United States Food and Drug Administration that has an insignificant 5.30 risk of an erroneous result, including those that: 5.31 (1) have been approved by the United States Food and Drug Administration for 5.32 home use; 5.33 (2) employ methodologies that are so simple and accurate as to render the likelihood 5.34

(3) pose no reasonable risk of harm to the patient if performed incorrectly.

Section 1. 5

of erroneous results negligible; or

5.35

5.36

5.1	Sec. 2. [148G.02] EXCEPTIONS.
5.2	(a) This chapter does not apply to:
5.3	(1) the qualifications as established by federal CLIA for laboratory directors,
5.4	technical supervisors, or technical consultants;
5.5	(2) other licensed or registered professionals performing functions within the
5.6	professional's scope of practice;
5.7	(3) medical laboratory science professionals employed by the United States
5.8	government, or any bureau, division, or agency, while performing duties within the scope
5.9	of the professional's federal employment;
5.10	(4) medical laboratory science professionals engaged exclusively in basic science or
5.11	investigative research, provided that the results of any examination performed are not used
5.12	in health maintenance, diagnosis, or treatment of disease as described in federal CLIA
5.13	regulations under Code of Federal Regulations, title 42, section 493;
5.14	(5) professionals engaged exclusively in assay development or management-related
5.15	activities in the clinical laboratory, provided the results of any examination performed
6.16	are not used in health maintenance, diagnosis, or treatment of disease as described in
5.17	federal CLIA regulations;
5.18	(6) professionals engaged exclusively in the education of medical laboratory science
5.19	professionals, provided that results of any examination performed are not used in health
5.20	maintenance, diagnosis, or treatment of disease as described in federal CLIA regulations;
5.21	(7) professionals engaged exclusively in providing phlebotomy services;
5.22	(8) pathologist's assistants or individuals performing pathology assistant activities
5.23	under supervision by pathologists;
5.24	(9) students or trainees enrolled in a medical laboratory science education program
5.25	provided that:
6.26	(i) the activities performed by the student or trainee constitute a part of a planned
5.27	course in the program;
5.28	(ii) the student or trainee is clearly designated as intern, trainee, or student; and
5.29	(iii) the student or trainee is working directly under an individual licensed under
5.30	this chapter to practice medical laboratory science or under a professional who is exempt
5.31	under this section;
5.32	(10) individuals who only perform waived tests or moderately complex point-of-care
5.33	tests under the direction of a qualified CLIA laboratory director according to federal
5.34	CLIA regulations;

6 Sec. 2.

6.34

7.34

7.35

7.1	(11) individuals who prepare tissues during a Mohs procedure performed by a
7.2	dermatologist or Mohs surgeon, under the supervision of a licensed histotechnician or
7.3	histotechnologist, or a qualified CLIA laboratory director; and
7.4	(12) individuals who perform moderately complex testing as defined by federal
7.5	CLIA regulations provided that the laboratory complies with the following requirements:
7.6	(i) within the laboratory, a licensed medical laboratory scientist or individual who
7.7	qualifies as a laboratory director under federal CLIA regulations is responsible for:
7.8	(A) designing, providing, and supervising the training programs for the testing
7.9	personnel;
7.10	(B) supervising and monitoring the quality assurance and quality control activities
7.11	of the testing site;
7.12	(C) assisting in the selection of technology;
7.13	(D) reviewing the results of proficiency testing and recommending corrective
7.14	action, if necessary; and
7.15	(E) monitoring the continued laboratory testing competency of the testing personnel;
7.16	(ii) documented personnel evaluation processes are in place, which ensure and
7.17	document the continued competency of the testing personnel; and
7.18	(iii) after January 1, 2016, the licensed medical laboratory scientist or individual
7.19	who qualifies as a laboratory director under CLIA regulations must ensure that new
7.20	employees have initial certification as a certified or registered medical assistant; certified
7.21	office laboratory technician or physician office laboratory technician; or certified medical
7.22	laboratory assistant as certified by the American Medical Technologists (AMT), American
7.23	Association of Bioanalysts (AAB), the American Association of Medical Assistants
7.24	(AAMA), or other national certification agency recognized by the commissioner.
7.25	<u>Individuals</u> employed as a medical assistant or office laboratory technician on January 1,
7.26	2016, are not required to be certified. If a laboratory fails to comply with the requirements
7.27	described in this clause, these individuals will be subject to the requirements of this
7.28	chapter, and will be required to be licensed under this chapter.
7.29	(b) This chapter does not apply to a declared emergency as defined in section 12.03
7.30	that reduces laboratory capacity or increases testing demands, or other loss of critical
7.31	laboratory capacity. Practitioners who are not licensed in any state, but are certified by one
7.32	of the agencies recognized in this chapter or deemed competent by the affected laboratory
7.33	director or the director's designee, may practice as needed in the emergency situation.

# Sec. 3. [148G.03] LICENSURE REQUIRED; TITLES USED, RESTRICTED, AND ALLOWED.

7 Sec. 3.

Subdivision 1. Unlicensed practice prohibited. Effective January 1, 2016, no individual shall perform a medical laboratory test unless the individual is licensed under this chapter as a medical laboratory scientist, medical laboratory technician, or is exempt from licensure under section 148G.02.

Subd. 2. Protected titles and restrictions on use. No individual shall use the following phrases: medical laboratory scientist, categorical medical laboratory scientist, medical laboratory technician, medical laboratory specialist in cytogenetics, medical laboratory specialist in molecular biology/pathology, or medical laboratory specialist in histocompatability, or medical laboratory subspecialist, cytotechnologist, histotechnician, or histotechnologist, or the initials MLS, MLT, CT, HT, or HTL, alone or in combination with any other words or initials to form an occupational title, or to indicate or imply that the individual is licensed as one of the professionals listed, unless the individual is licensed under this chapter.

Subd. 3. Persons licensed or certified in other states. An individual who is licensed or certified in another state may use the designation "licensed or certified" with a protected title only if the state of licensure or certification is clearly indicated.

#### Sec. 4. [148G.035] SCOPE OF PRACTICE.

Medical laboratory professionals licensed under this chapter shall perform laboratory tests and provide test results to physicians and patients upon request or upon physician referral according to CLIA. The practice of medical laboratory science includes:

(1) the production of test data;

8.1

8.2

8.3

8.4

8.5

8.6

8.7

8.8

8.9

8.10

8.11

8.12

8.13

8.14

8.15

8.16

8.17

8.18

8.19

8.20

8.21

8.28

8.29

8.30

8.31

8.32

8.33

8.34

- 8.22 (2) monitoring the accuracy, precision, and utility of laboratory testing;
- 8.23 (3) analytical correlation and interpretation of test data;
- 8.24 (4) designing, evaluating, and implementing new laboratory test methods; and
- 8.25 (5) documenting and reporting test results.

8.26 The services provided by medical laboratory professionals must be consistent with good practice and sound professional ethics.

### Sec. 5. [148G.04] DUTIES OF THE COMMISSIONER.

The commissioner shall:

(1) administer the procedures for this chapter, including, but not limited to, verifying the qualifications and standards for education, experience, examinations, and continuing education, as established by the certification agencies recognized in this chapter, and other methods for determining whether an applicant or licensee is qualified, as specified under this chapter;

Sec. 5. 8

9.1	(2) issue licenses to qualified individuals;
9.2	(3) collect and deposit fees as established under section 148G.16;
9.3	(4) on the recommendation of the advisory council, approve future nationally
9.4	recognized, validated, competency-based written, oral, or practical examinations
9.5	developed by the American Society for Clinical Pathology Board of Certification,
9.6	American Medical Technologists, American Association of Bioanalysts, and American
9.7	Society for Histocompatibility and Immunogenetics, or their successor organizations,
9.8	for purposes of licensure requirements for medical laboratory science professionals as
9.9	provided for in this chapter; and
9.10	(5) maintain a roster of the names and addresses of individuals currently licensed
9.11	under this chapter and of all licensees who have been disciplined under this chapter.
9.12	Sec. 6. [148G.05] MEDICAL LABORATORY SCIENCE PROFESSIONAL
9.13	LICENSING ADVISORY COUNCIL.
9.14	Subdivision 1. Membership and qualifications of advisory council. (a) The
9.15	commissioner shall appoint a nine-member advisory council that may include applicants
9.16	recommended by laboratory professional associations. Members must be actively
9.17	employed for at least two years in their specific area of practice.
9.18	(b) Six members must be medical laboratory science professionals who are licensed
9.19	under this chapter and include:
9.20	(1) one nonphysician laboratory director;
9.21	(2) one medical laboratory scientist;
9.22	(3) two medical laboratory technicians;
9.23	(4) one specialist in cytogenetics, histocompatibility, molecular biology, or a
9.24	cytotechnologist; and
9.25	(5) one histotechnician or histotechnologist.
9.26	(c) Two members must be physicians certified by the American Board of Pathology or
9.27	the American Board of Osteopathic Pathology. One must be certified in clinical pathology
9.28	(d) One member must be a public member as defined in section 214.02.
9.29	Subd. 2. Duties. The advisory council shall:
9.30	(1) advise and make recommendations to the commissioner regarding the medical
9.31	laboratory science practitioner licensure standards;
9.32	(2) advise the commissioner on enforcement of this chapter;
9.33	(3) provide for distribution of information regarding medical laboratory science

BR

S0133-2

2nd Engrossment

REVISOR

SF133

Sec. 6. 9

practitioners licensure standards;

9.34

10.1	(4) review applications upon the request of the commissioner and make
10.2	recommendations on granting or denying licensure or licensure renewal;
10.3	(5) advise the commissioner on issues related to receiving and investigating
10.4	complaints, conducting objective hearings, and imposing disciplinary action in relation to
10.5	complaints received against medical laboratory science practitioners; and
10.6	(6) perform other duties requested by the commissioner.
10.7	Subd. 3. Organization. The advisory council shall be organized and administered
10.8	under section 15.059.
10.9	Subd. 4. Chair. The council must elect a chair from among its members. The chair
10.10	serves a two-year term.
10.11	Subd. 5. Support. The commissioner shall provide the necessary staff support
10.12	and meeting space for the advisory council.
10.13	Subd. 6. Sunset. This section expires January 1, 2022.
10.14	Sec. 7. [148G.06] LICENSURE REQUIREMENTS FOR MEDICAL
10.15	LABORATORY SCIENCE PROFESSIONALS EMPLOYED ON JULY 1, 2014.
10.16	(a) The commissioner shall issue a license to an individual who does not meet the
10.17	education, training, and experience qualifications for any license described in this chapter
10.18	provided the individual:
10.19	(1) submits an application to the commissioner, on forms prescribed by the
10.20	commissioner, by January 1, 2016;
10.21	(2) is employed as a medical laboratory science professional on July 1, 2014, or has
10.22	six months of acceptable experience of at least half time, 1,040 hours per year, in the three
10.23	years immediately prior to July 1, 2014; and
10.24	(3) submits as part of the application, job, title, description of the position, period
10.25	of employment, and confirmation of competent practice, as attested by the applicant's
10.26	employer, who shall submit to the commissioner a signed statement stating that the
10.27	applicant is not the subject of a disciplinary action or past disciplinary action in their
10.28	employment, professional association membership, or under any credentialing authority in
10.29	this or another jurisdiction, and is not disqualified on the basis of section 148G.14.
10.30	(b) The commissioner and advisory council shall determine which type of license
10.31	the applicant is eligible for and issue the license if the requirements of this section are met.
10.32	(c) An initial license issued under this section may be renewed following the
10.33	procedures required under section 148G.11, provided the license is maintained without
10.34	interruption. If the initial license issued under this section is not renewed and is allowed to

Sec. 7. 10

2nd Engrossment

lapse for any period of time, the licensee must meet the applicable standards for licensure 11.1 11.2 described in section 148G.07 before the lapsed license may be renewed. Sec. 8. [148G.07] STANDARDS FOR LICENSURE. 11.3 Subdivision 1. Medical laboratory scientist (MLS). (a) The commissioner shall 11.4 issue a medical laboratory scientist's license to an individual who meets the following 11.5 requirements: 11.6 (1) has met the medical laboratory experience and training required by the 11.7 appropriate nationally recognized certification agency; and 11.8 (2) passes a nationally recognized certification examination administered 11.9 by the American Society for Clinical Pathology Board of Certification, American 11.10 11.11 Medical Technologists, American Association of Bioanalysts, the American Board of Histocompatibility and Immunogenetics, or successor organizations in one of the 11.12 following areas: 11.13 11.14 (i) medical laboratory scientist or medical technologist generalist; 11.15 (ii) medical laboratory scientist, categorical; (iii) medical laboratory specialist in molecular biology; 11.16 11.17 (iv) medical laboratory specialist in cytogenetics; (v) histocompatibility technologist; 11.18 11.19 (vi) cytotechnologist; or (vii) histotechnologist. 11.20 (b) As an alternative to paragraph (a), a medical laboratory subspecialist may meet 11.21 11.22 the following requirements in order to be eligible for a license under this subdivision: 11.23 (1) possess a baccalaureate degree from a regionally accredited college or university that has been verified by one of the nationally recognized certification agencies; 11.24 11.25 (2) has met the medical laboratory experience and training required by the nationally recognized certification agency through one year of on-the-job training; and 11.26 (3) either is deemed competent through written confirmation by the respective 11.27 laboratory director or passes a nationally recognized certification examination 11.28

(c) The commissioner shall issue a medical laboratory scientist's license to an individual who has completed an official military training program of at least 50 weeks that was approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the commissioner, and held

administered by the American Society for Clinical Pathology Board of Certification, or

Sec. 8.

11.29

11.30

11.31

11.32

11.33

11.34

successor organizations.

the military enlisted occupational specialty of medical laboratory specialist and possesses a baccalaureate degree.

- Subd. 2. Medical laboratory technician (MLT). (a) The commissioner shall issue a medical laboratory technician's license to an individual who meets the following requirements:
- (1) possesses an associate degree from a regionally accredited college or university that has been verified by the appropriate nationally recognized certification agency;
- (2) has met the medical laboratory experience and training required by the nationally recognized certification agency; and
- (3) passes a nationally recognized certification examination administered by the American Society for Clinical Pathology Board of Certification, American Medical Technologists, American Association of Bioanalysts, or successor organizations in one of the following areas:
  - (i) medical laboratory technician; or
- 12.15 (ii) histotechnician.

12.1

12.2

12.3

12.4

12.5

12.6

12.7

12.8

12.9

12.10

12.11

12.12

12.13

12.14

12.16

12.17

12.18

12.19

12.20

12.21

12.22

12.23

12.24

12.25

12.26

12.27

12.28

12.29

12.30

12.31

12.32

12.33

12.34

(b) The commissioner shall issue a medical laboratory technician's license to an individual who has completed an official military training program of at least 50 weeks that was approved by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the commissioner, and held the military enlisted occupational specialty of medical laboratory specialist, and possesses an associate degree from a regionally accredited college or university.

#### Sec. 9. [148G.08] RECIPROCITY.

Subdivision 1. Licensure. The commissioner may waive the licensure requirements for an applicant who holds a valid license or its equivalent issued by another state provided that the requirements under which that license or its equivalent was issued are equivalent to or exceed the standards required by this chapter. Once the license is up for renewal, the applicant shall be issued a Minnesota license upon meeting the license renewal requirements in section 148G.11.

Subd. 2. Current credentials required. An applicant applying for licensure by reciprocity must provide all necessary evidence to the commissioner that the applicant holds a current and unrestricted license for the practice of medical laboratory science in another jurisdiction that has requirements equivalent to or higher than the standards required to be licensed as a medical laboratory professional in one of the categories defined in this chapter.

Sec. 9. 12

Subd. 3. Verification of credentials required. An applicant for licensure under this section must have maintained the appropriate and unrestricted credentials in each jurisdiction during the last five years as demonstrated by submitting letters of verification to the commissioner. Each letter must state the applicant's name, date of birth, credential number, date of issuance, a statement regarding disciplinary actions, if any, taken against the applicant, and the terms under which the credential was issued.

#### Sec. 10. [148G.09] TEMPORARY LICENSE REQUIREMENTS.

13.1

13.2

13.3

13.4

13.5

13.6

13.7

13.8

13.9

13.10

13.11

13.12

13.13

13.14

13.15

13.16

13.17

13.18

13.19

13.20

13.21

13.22

13.23

13.24

13.25

13.26

13.27

13.28

13.29

13.30

13.31

13.32

13.33

13.34

- (a) The commissioner may issue a temporary license to an applicant who:
- (1) is eligible to sit for and registered to take a certification examination or has taken the examination and is awaiting results;
- (2) meets the educational requirements of the nationally recognized certification agency and is seeking to qualify for the certification examination by completing the required supervised medical laboratory experience; or
- (3) meets the educational requirements for the position and is undergoing the required on-the-job training necessary for a specialized clinical laboratory.
- (b) A temporary license shall be issued for a 12-month period and may be renewed for two additional 12-month periods at the discretion of the commissioner, in order to allow the applicant to complete the required supervised medical laboratory experience or retake a certification examination, or be deemed competent by the laboratory director.
- (c) A temporary license expires 12 months after it is issued or on the date the commissioner issues or denies a permanent license to the holder.
- (d) A temporary license authorizes the holder to perform medical laboratory tests only in the area of practice for which the individual seeks to be permanently licensed.

#### Sec. 11. [148G.10] LICENSURE APPLICATION PROCEDURES.

- (a) Applicants must submit an application for licensure to the commissioner upon the forms prescribed and furnished by the commissioner, and must submit with the application the designated application fee as specified in section 148G.16.
- (b) Upon receipt of the application and the application fee, the commissioner shall determine if the applicant meets the requirements for licensure. The commissioner, or the advisory council at the commissioner's request, may investigate information provided by an applicant to determine whether the information is accurate and complete.
- (c) The commissioner shall issue a license for a medical laboratory scientist or a medical laboratory technician to an individual who meets the qualifications and requirements specified in this chapter. The commissioner may issue a license with

Sec. 11. 13

CE100	DELUCOD	D.D.	00100	0.15
SF133	REVISOR	BR	S0133-2	2nd Engrossment

conditions, or refuse to grant the license if the qualifications and requirements of this chapter have not been met.

- (d) The commissioner shall notify an applicant of action taken on the application, and if licensure is denied or issued with conditions, the grounds for the commissioner's determination.
- (e) An applicant denied licensure or granted licensure with conditions may make a written request to the commissioner, within 30 days of the date of the commissioner's determination, for reconsideration of the commissioner's determination. Individuals requesting reconsideration may submit information that the applicant wants considered in the reconsideration. After reconsideration of the commissioner's determination to deny licensure or grant licensure with conditions, the commissioner shall determine whether the original determination should be affirmed or modified. An applicant is allowed no more than one request in any one biennial licensure period for reconsideration of the commissioner's determination to deny licensure or approve licensure with conditions.

#### Sec. 12. [148G.11] LICENSURE RENEWAL.

14.1

14.2

14.3

14.4

14.5

14.6

14.7

14.8

14.9

14.10

14.11

14.12

14.13

14.14

14.15

14.16

14.17

14.18

14.19

14.22

14.26

14.27

14.28

14.29

14.30

14.31

14.32

14.33

14.34

Subdivision 1. Renewal term. Licenses issued under this chapter must be renewed every two years. The renewal term is the effective date of the initial license or renewed license to the date of expiration of the license.

- Subd. 2. Renewal applications. In order to renew a license, a licensee must submit:
- 14.20 (1) a completed and signed application for renewal on a form prescribed by the commissioner;
  - (2) the applicable renewal fee as specified in section 148G.16; and
- (3) documentation that the licensee has completed continuing education
  requirements as prescribed by the nationally recognized certification agencies or 24 hours
  of documented continuing education.

# Sec. 13. [148G.12] LICENSURE FOLLOWING LAPSE OF LICENSURE STATUS.

For an applicant whose licensure status has lapsed, the applicant must:

- (1) apply for licensure renewal according to section 148G.11 and document compliance with the continuing education requirements as prescribed by the nationally recognized certification agency since the applicant's license lapsed; and
- (2) fulfill the requirements of section 148G.07 and provide evidence of compliance with the continuing education requirements as prescribed by one of the nationally recognized certification agencies.

Sec. 13. 14

15.1	Sec. 14. [148G.13] CONTINUING EDUCATION REQUIREMENTS.
15.2	Continuing education requirements shall be as described by the applicable
15.3	certification agencies or their successors as recognized under this chapter.
15.4	Sec. 15. [148G.14] INVESTIGATION PROCESS; GROUNDS FOR
15.5	DISCIPLINARY ACTION.
15.6	(a) The commissioner may impose disciplinary action as described in paragraph
15.7	(b) against an applicant or licensee whom the commissioner, by a preponderance of the
15.8	evidence, determines has:
15.9	(1) violated a statute, rule, or order that the commissioner issued or is empowered
15.10	to enforce;
15.11	(2) been convicted of or pled guilty to a felony, gross misdemeanor, misdemeanor,
15.12	an essential element of which is dishonesty, or of any crime that is directly related to the
15.13	practice of the profession;
15.14	(3) made a misrepresentation for the purpose of obtaining licensure, either on an
15.15	application provided by the commissioner or in response to oral or written questions
15.16	from the commissioner;
15.17	(4) violated the code of professional conduct in subdivisions 2 to 4;
15.18	(5) engaged in dishonorable, unethical, or unprofessional conduct of a character
15.19	likely to deceive, defraud, or harm the public;
15.20	(6) failed to perform services with reasonable judgment, skill, or safety due to the
15.21	use of alcohol, drugs, or other physical or mental impairment;
15.22	(7) aided, abetted, or assisted another person in violating any provision of this
15.23	chapter or any applicable rules;
15.24	(8) made any misrepresentation with regard to the existence or category of license or
15.25	other certification or professional qualification held in connection with any employment
15.26	application;
15.27	(9) intentionally submitted false or misleading information in response to a written
15.28	request by the commissioner or advisory council;
15.29	(10) failed, within 30 days, to provide information in response to a written request by
15.30	the commissioner or advisory council or otherwise failed to cooperate in an investigation
15.31	conducted under this section;
15.32	(11) performed services for which the license is issued in an incompetent manner or
15.33	in a manner that falls below community standards;

Sec. 15. 15

15.34

(12) violated any provision of this chapter;

16.1	(13) been convicted of violating any state or federal law, rule, or regulation which
16.2	directly relates to the practice related to the discipline for which the individual is licensed;
16.3	(14) violated a federal or state court order, including a conciliation court judgment,
16.4	or a disciplinary order issued by the commissioner, related to the individual's practice for
16.5	which the individual is licensed under this chapter;
16.6	(15) been disciplined for conduct in the practice of an occupation by the state of
16.7	Minnesota, another jurisdiction, or a national professional association, if any of the
16.8	grounds are the same or substantially equivalent to those in this chapter;
16.9	(16) engaged in conduct with a patient that is sexual or may reasonably be interpreted
16.10	by the patient as sexual, or in any verbal behavior that is or may be reasonably interpreted
16.11	as seductive or sexually demeaning to a patient; or
16.12	(17) engaged in any other behavior that gives rise to just cause for discipline related
16.13	to the practice for which they are licensed under this chapter.
16.14	(b) If grounds for disciplinary action exist under paragraph (a), the commissioner
16.15	may take one or more of the following actions:
16.16	(1) refuse to grant or renew a license;
16.17	(2) revoke a license;
16.18	(3) suspend a license;
16.19	(4) impose limitations or conditions on a license, including, but not limited to,
16.20	practice under supervision, continued practice on the demonstration of knowledge or skill
16.21	by appropriate examination or other review of knowledge, skill, and competence;
16.22	(5) censure or reprimand the licensee;
16.23	(6) impose a civil penalty not exceeding \$10,000 for each separate violation,
16.24	the amount of the civil penalty to be fixed so as to deprive the applicant or licensee
16.25	of any economic advantage gained by reason of the violation charged, to discourage
16.26	similar violations, or to reimburse the commissioner for the cost of the investigation and
16.27	proceeding including, but not limited to, fees paid for services provided by the Office of
16.28	Administrative Hearings, legal and investigative services provided by the Office of the
16.29	Attorney General, court reporters, witnesses, reproduction of records, advisory council
16.30	members' per diem compensation, staff time, and travel costs and expenses incurred
16.31	by staff and advisory council members; or
16.32	(7) any reasonable lesser action, including, but not limited to, censure, reprimand, or
16.33	restriction on licensure, or any action authorized by statute.
16.34	(c) Upon notice from the commissioner denying licensure renewal or upon notice
16.35	that disciplinary actions have been imposed and the person is no longer entitled to provide
16.36	the services for which the person was previously licensed under this chapter, the person

Sec. 15. 16

17.2

17.3

17.4

17.5

17.6

17.7

17.8

17.9

17.10

17.11

17.12

17.13

17.14

17.15

17.16

17.17

17.18

17.19

17.20

17.21

17.22

17.23

17.24

17.25

17.26

17.27

17.28

17.29

17.30

17.31

17.32

17.33

17.34

shall cease to provide the services under this chapter, to use the protected titles pursuant to this chapter, and to represent to the public that the person is licensed by the commissioner.

S0133-2

- (d) A person who has had licensure suspended may request and provide justification for reinstatement following the period of suspension specified by the commissioner. The requirement of this chapter for renewing licensure and any other conditions imposed with the suspension must be met before licensure may be reinstated.
- (e) The commissioner shall contract with the health professional services program as authorized by sections 214.31 to 214.37 to provide these services to practitioners under this chapter. The health professional services program does not affect the commissioner's authority to discipline violations of this chapter.

#### Sec. 16. [148G.15] REPORTING OBLIGATIONS.

Subdivision 1. **Permission to report.** A person who has knowledge of any conduct constituting grounds for disciplinary action under this chapter may report the violation to the commissioner.

Subd. 2. **Institutions.** A state agency, political subdivision, agency of a local unit of government, private agency, hospital, clinic, prepaid medical plan, or other health care institution or organization located in this state shall report to the commissioner any action taken by the agency, institution, or organization or any of its administrators or medical or other committees to revoke, suspend, restrict, or condition a medical laboratory professional's privilege to practice in the institution, or as part of the organization, any denial of privileges, or any other disciplinary action for conduct that might constitute grounds for disciplinary action by the commissioner under this chapter. The institution, organization, or governmental entity shall also report the resignation of any medical laboratory science professional before the conclusion of any disciplinary action proceeding for conduct that might constitute grounds for disciplinary action under this chapter, or before the commencement of formal charges but after the practitioner had knowledge that formal charges were contemplated or were being prepared.

Subd. 3. **Professional societies.** A state or local professional society for medical laboratory science professionals shall report to the commissioner any termination, revocation, or suspension of membership or any other disciplinary action taken against a medical laboratory science professional. If the society has received a complaint that might be grounds for discipline under this chapter against a member on which it has not taken any disciplinary action, the society shall report the complaint and the reason why it has not taken action on it or shall direct the complainant to the commissioner.

Sec. 16. 17

18.2

18.3

18.4

18.5

18.6

18.7

18.8

18.9

18.10

18.11

18.12

18.13

18.14

18.15

18.16

18.17

18.18

18.19

18.20

18.21

18.22

18.23

18.24

18.25

18.26

18.27

18.28

18.29

18.30

18.31

18.32

18.33

18.34

18.35

Subd. 4. Licensed professionals. A licensed health professional shall report to the commissioner personal knowledge of any conduct that the licensed health professional reasonably believes constitutes grounds for disciplinary action under this chapter by a medical laboratory science professional, including conduct indicating that the individual may be medically incompetent, or may be medically or physically unable to engage safely in the provision of services. If the information was obtained in the course of a client relationship, the client is a medical laboratory science professional, and the treating individual successfully counsels the medical laboratory science professional to limit or withdraw from practice to the extent required by the impairment, the commissioner may deem this limitation of or withdrawal from practice to be sufficient disciplinary action.

Subd. 5. Self-reporting. A medical laboratory science professional shall report to the commissioner any personal action that would require that a report be filed with the commissioner by any person, health care facility, business, or organization under subdivisions 2 to 4. The medical laboratory science professional shall also report the revocation, suspension, restriction, limitation, or other disciplinary action in this state and report the filing of charges regarding the practitioner's license or right of practice in another state or jurisdiction.

Subd. 6. **Deadlines**; forms. Reports required by subdivisions 2 to 5 must be submitted no later than 30 days after the reporter learns of the occurrence of the reportable event or transaction. The commissioner may provide forms for the submission of required reports, may require that reports be submitted on the forms provided, and may adopt rules necessary to ensure prompt and accurate reporting.

Subd. 7. Immunity for reporting. A person, health care facility, business, or organization is immune from civil liability or criminal prosecution for reporting to the commissioner violations or alleged violations of this chapter. All such reports are classified under section 13.41.

Subd. 8. **Immunity for investigation.** The commissioner, employees of the Minnesota Department of Health, consultants to the department, and advisory council members are immune from civil liability and criminal prosecution for any actions, transactions, or publications in the execution of, or relating to, their duties under this chapter.

#### Sec. 17. [148G.16] FEES.

Subdivision 1. **Initial licensure fee.** The initial licensure fee for a medical laboratory scientist and a medical laboratory technician is \$155. The commissioner shall prorate fees based on the number of quarters remaining in the biennial licensure period.

Sec. 17. 18

19.1	Subd. 2. Licensure renewal fee. The biennial licensure renewal fee for a medical
19.2	laboratory scientist and a medical laboratory technician is \$115.
19.3	Subd. 3. Late fee. The fee for late submission of a renewal application is \$45.
19.4	Subd. 4. Temporary licensure fee. The fee for temporary licensure is \$50.
19.5	Subd. 5. Verification to other states. The fee for verification of licensure to other
19.6	states is \$25.
19.7	Subd. 6. Verification to institutions. The fee for verification of licensure to
19.8	institutions is \$10.
19.9	Subd. 7. Nonrefundable fees. All fees are nonrefundable.
19.10	Subd. 8. Penalty fees. (a) The penalty fee for practicing medical laboratory science
19.11	without a current license after the credential has expired and before it is renewed is the
19.12	amount of the license renewal fee for any part of the first month, plus the license renewal
19.13	fee for any part of any subsequent month up to 36 months.
19.14	(b) The penalty fee for applicants who engage in the unauthorized practice of medical
19.15	laboratory science before being issued a license is the amount of the license application fee
19.16	for any part of the first month, plus the license application fee for any part of any subsequent
19.17	month up to 36 months. This paragraph does not apply to applicants not qualifying for a
19.18	license who engage in the unauthorized practice of medical laboratory science.
19.19	(c) The penalty fee for failing to submit a continuing education report by the due date
19.20	with the correct number or type of hours in the correct time period is \$50. The licensee must
19.21	obtain the missing number of continuing education hours by the next reporting due date.
19.22	(d) Civil penalties and discipline incurred by licensees prior to January 1, 2016, for
19.23	conduct described in paragraph (a), (b), or (c), shall be recorded as nondisciplinary penalty
19.24	fees. For conduct described in paragraph (a) or (b) occurring on or after January 1, 2016,
19.25	and exceeding six months, payment of a penalty fee does not preclude any disciplinary
19.26	action reasonably justified by the individual case.
19.27	Sec. 18. MEDICAL LABORATORY SCIENCE PROFESSIONAL LICENSING
19.28	ADVISORY COUNCIL; DEADLINES.
19.29	The commissioner of health shall complete the first appointments required by
19.30	Minnesota Statutes, section 148G.05, no later than January 1, 2015. When making
19.31	initial appointments, the commissioner shall designate four appointees to have terms
19.32	coterminous with the governor. The initial appointees who serve a term that is coterminous
19.33	with the governor shall serve until the start of the governor's term that begins in 2019. The
19.34	remainder of the initial appointees shall serve until 2020. Terms after the initial terms will
19.35	be as described in Minnesota Statutes, section 15.059, subdivision 3. The commissioner's

Sec. 18. 19

20.1	designee shall convene the first meeting of the council no later than February 1, 2015. The		
20.2	council must select a chair from its membership at the first meeting of the council.		
20.3	Sec. 19. APPROPRIATION.		
20.4	\$284,000 in fiscal year 2015 is appropriated from the state government special		
20.5	revenue fund to the commissioner of health to implement this act. Base funding is		
20.6	\$488,000 in fiscal year 2016 and \$376,000 in fiscal year 2017.		
20.7	Sec. 20. EFFECTIVE DATE.		
20.8	Sections 1 to 19 are effective July 1, 2014.		

BR

S0133-2

2nd Engrossment

REVISOR

SF133

Sec. 20. 20