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HOUSE OF REPRESENTATIVES

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SESSION

HOUSE FILE No. 1249

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The bill was read for the first time and referred to the Committee on Health Care and Human Services Policy and Oversight

1.1 A bill for an act
1.2 relating to health occupations; establishing licensure for medical laboratory
1.3 science professionals; creating the Board of Medical Laboratory Science;
1.4 establishing fees; proposing coding for new law as Minnesota Statutes, chapter
1.5 148F.

1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.7 Section 1. **[148F.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 and by the
1.14 Board of Medical Laboratory Science.

1.15 Subd. 3. **Board.** "Board" means the Board of Medical Laboratory Science
1.16 established in section 148F.03.

1.17 Subd. 4. **CLIA.** "CLIA" means Clinical Laboratory Improvement Amendments of
1.18 1988 and includes Public Law 10-578 and Code of Federal Regulations, title 42, section
1.19 493. CLIA regulations provide a minimum foundation for which personnel standards for
1.20 entry level technical personnel in this state are built. Qualifications and responsibilities
1.21 for laboratory director, technical supervisor, and technical consultant are as specified in
1.22 CLIA regulations. All clinical laboratory personnel are under the supervision, control, and
1.23 responsibility of the laboratory director.

1.24 Subd. 5. **Commissioner.** "Commissioner" means the commissioner of health or the
1.25 commissioner's designee.

2.1 Subd. 6. **Cytotechnologist.** "Cytotechnologist" means an individual who specializes
2.2 in the microscopic analysis of patient samples from all body sites, for the purpose of
2.3 evaluating, detecting, and providing diagnostic and prognostic information regarding
2.4 disease processes, including those that require the exercise of independent technical
2.5 judgment, and who:

2.6 (1) assists health care providers with the collection, detection, and interpretation
2.7 of normal and abnormal cells, infectious agents, and other noncellular material from
2.8 submitted specimens;

2.9 (2) performs a variety of ancillary tests to ascertain information to help
2.10 in classification, prognosis, or disease detection, including, but not limited to,
2.11 immunohistochemical and molecular techniques;

2.12 (3) establishes and implements protocols, quality control, method selection,
2.13 equipment selection and maintenance, and activities related to the preanalytic, analytic,
2.14 and postanalytic phases of testing; and

2.15 (4) may direct, supervise, consult, and educate and perform research functions.

2.16 Subd. 7. **Histotechnician.** "Histotechnician" means an individual who:

2.17 (1) prepares tissue specimens for microscopic examination;

2.18 (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy
2.19 and validity of laboratory testing and procedures including, but not limited to, techniques
2.20 in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining;

2.21 (3) prepares gross specimens as defined by and under the direction of a
2.22 board-certified pathologist;

2.23 (4) establishes and implements protocols, quality assurance, and quality control
2.24 related to the following procedures: histochemical, immunohistochemical, electron
2.25 microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA
2.26 hydrolysis, laser capturing, molecular techniques, and research; and

2.27 (5) participates in method selection, development, equipment selection and
2.28 maintenance, and activities related to the preanalytical and analytical phases of tissue
2.29 preparation.

2.30 Subd. 8. **Histotechnologist.** "Histotechnologist" means an individual who:

2.31 (1) prepares tissue specimens for microscopic examination;

2.32 (2) monitors, performs, selects, develops, evaluates, correlates, and ensures accuracy
2.33 and validity of laboratory testing and procedures including, but not limited to, techniques
2.34 in fixation, processing, embedding, microtomy, cryotomy, ultramicrotomy, and staining;

2.35 (3) prepares gross specimens as defined by and under the direction of a
2.36 board-certified anatomic pathologist;

3.1 (4) establishes and implements protocols, quality assurance, and quality control
3.2 related to the following procedures: histochemical, immunohistochemical, electron
3.3 microscopy, cytopreparation, in situ hybridization, enzyme histochemical, DNA
3.4 hydrolysis, laser capturing, molecular techniques, and research;

3.5 (5) establishes and implements new protocols and procedures dealing directly in
3.6 quality assessment, method development, and equipment selection and maintenance and
3.7 all activities related to preanalytical and analytical phases of tissue preparation; and

3.8 (6) may direct, supervise, consult, educate, and perform research functions.

3.9 Subd. 9. **Independent medical judgment.** In the laboratory, "independent medical
3.10 judgment" is exercised only by a pathologist or other licensed physician in the diagnosis
3.11 and treatment decisions related to clinical laboratory tests.

3.12 Subd. 10. **Independent technical judgment.** "Independent technical judgment"
3.13 means the performance or conduct of clinical laboratory tests and assumption of
3.14 responsibility for determination of the validity of clinical laboratory test results without
3.15 intervention by or under the supervision of another health care provider authorized by law
3.16 to assume responsibility for the conduct and validity of clinical laboratory tests.

3.17 Subd. 11. **Medical laboratory or laboratory.** "Medical laboratory" or "laboratory"
3.18 means any facility or office in Minnesota in which medical laboratory tests are performed.

3.19 Subd. 12. **Medical laboratory scientist or generalist.** "Medical laboratory
3.20 scientist" or "generalist" means an individual eligible for licensure under this chapter who:

3.21 (1) performs medical laboratory tests, including tests that require the exercise of
3.22 independent technical judgment;

3.23 (2) establishes and implements protocols, quality assessment, method development
3.24 and selection, equipment selection and maintenance, and all activities related to the
3.25 preanalytic, analytic, and postanalytic phases of laboratory testing; and

3.26 (3) may direct, supervise, consult, educate, and perform research functions.

3.27 Subd. 13. **Categorical medical laboratory scientist.** "Categorical medical
3.28 laboratory scientist" means an individual eligible for licensure under this chapter who
3.29 performs the functions of a medical laboratory scientist in one of the following areas of
3.30 the laboratory: chemistry, hematology, immunohematology, and microbiology.

3.31 Subd. 14. **Medical laboratory specialist.** "Medical laboratory specialist" means
3.32 an individual certified and eligible for licensure under this chapter to perform testing
3.33 including the tests that require the exercise of independent technical judgment needed to
3.34 establish and implement protocols, quality assessment, method development and selection,
3.35 equipment selection and maintenance, and all activities related to the preanalytic, analytic,

4.1 and postanalytic phases of laboratory testing, and who direct, supervise, consult, and
4.2 educate in a specific specialized section of the laboratory.

4.3 Subd. 15. **Medical laboratory specialist in cytogenetics.** "Medical laboratory
4.4 specialist in cytogenetics" means an individual eligible for licensure under this chapter to
4.5 perform standard cytogenetic and molecular testing procedures used to evaluate possible
4.6 genetic anomalies.

4.7 Subd. 16. **Medical laboratory specialist in molecular biology/pathology.**
4.8 "Medical laboratory specialist in molecular biology/pathology" means an individual
4.9 eligible for licensure under this chapter to perform all aspects of molecular analysis
4.10 including, but not limited to, recombinant DNA technology, polymerase chain reaction,
4.11 and hybridization techniques.

4.12 Subd. 17. **Medical laboratory specialist in histocompatibility.** "Medical
4.13 laboratory specialist in histocompatibility" means an individual eligible for licensure
4.14 under this chapter to perform histocompatibility testing procedures including, but not
4.15 limited to, molecular and serological techniques.

4.16 Subd. 18. **Medical laboratory technician.** "Medical laboratory technician" means
4.17 an individual eligible for licensure under this chapter who performs medical laboratory
4.18 tests according to established and approved protocols and requiring limited exercise of
4.19 independent judgment.

4.20 Subd. 19. **Medical laboratory test or laboratory test.** "Medical laboratory
4.21 test" or "laboratory test" means a microbiological, serological, chemical, biological,
4.22 hematological, immunological, immunohematological, radiobioassay, cytological,
4.23 histological preparation, molecular, biophysical, or any other test or procedure performed
4.24 on material derived from or existing in a human body, which provides information for
4.25 the diagnosis, prevention, or monitoring of a disease or impairment or assessment of a
4.26 medical condition. A medical laboratory test includes components of the preanalytic and
4.27 postanalytic phases of testing, as well as the analytic phase, which occurs in the laboratory.

4.28 Subd. 20. **Medical laboratory subspecialists.** "Medical laboratory subspecialists"
4.29 means an individual eligible for licensure under this chapter to perform the functions
4.30 of a medical laboratory scientist in a subspecialty or esoteric clinical laboratory that is
4.31 not one of the general categorical areas of the laboratory. The subspecialty/esoteric
4.32 laboratories may be disease or medical specialty-oriented or utilize advanced technology
4.33 not routinely used in the clinical laboratory. These subspecialty/esoteric laboratories may
4.34 be subspecialized areas within the hematology, chemistry, immunology, transfusion,
4.35 medicine, genetics, or microbiology disciplines.

5.1 Subd. 21. **Nationally recognized certification agency.** "Nationally recognized
5.2 certification agency" means an agency that provides certification exams for medical
5.3 laboratory professionals. As the agency defines new certification examinations, the
5.4 commissioner and the advisory council will recognize these examinations.

5.5 Subd. 22. **Pathologist's assistant.** "Pathologist's assistant" means an individual
5.6 specializing in prediagnostic surgical pathology and autopsy pathology who assists
5.7 pathologists.

5.8 Subd. 23. **Phlebotomist.** "Phlebotomist" means an individual who is qualified to
5.9 obtain blood samples for testing by means of venipuncture, capillary puncture, or access
5.10 of venous access devices, to perform specimen processing and preparation of samples for
5.11 testing, and to perform waived and point-of-care testing.

5.12 Subd. 24. **Point-of-care testing.** "Point-of-care testing" means analytical patient
5.13 testing activities provided within a facility, which do not require permanent dedicated
5.14 space including, but not limited to, analytic instruments that are temporarily brought to a
5.15 patient care location. Point-of-care testing must be under the direction of an individual
5.16 licensed under this chapter at the baccalaureate degree level or who qualifies as a
5.17 laboratory director under federal CLIA regulations.

5.18 Subd. 25. **Trainee/student.** "Trainee/student" means an individual who has
5.19 not fulfilled the educational requirements to take an approved nationally recognized
5.20 certification examination or who needs to obtain full-time comprehensive experience
5.21 under supervision.

5.22 Subd. 26. **Waived test.** "Waived test" means a laboratory examination or procedure
5.23 as determined by the United States Food and Drug Administration which has an
5.24 insignificant risk of an erroneous result, including those which:

5.25 (1) have been approved by the United States Food and Drug Administration for
5.26 home use;

5.27 (2) employ methodologies that are so simple and accurate as to render the likelihood
5.28 of erroneous results negligible; or

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

5.30 **Sec. 2. [148F.02] EXCEPTIONS.**

5.31 This chapter does not apply to:

5.32 (1) the qualifications as established by federal CLIA for laboratory directors,
5.33 technical supervisors, or technical consultants;

5.34 (2) other licensed or registered professionals performing functions within the
5.35 professional's scope of practice;

6.1 (3) medical laboratory science professionals employed by the United States
6.2 government, or any bureau, division, or agency, while performing duties within the scope
6.3 of the professional's federal employment;

6.4 (4) medical laboratory science professionals engaged exclusively in basic science or
6.5 investigative research, provided that the results of any examination performed are not used
6.6 in health maintenance, diagnosis, or treatment of disease as described in federal CLIA
6.7 regulations under Code of Federal Regulations, title 42, section 493;

6.8 (5) professionals engaged exclusively in assay development or management-related
6.9 activities in the clinical laboratory, provided the results of any examination performed
6.10 are not used in health maintenance, diagnosis, or treatment of disease as described in
6.11 federal CLIA regulations;

6.12 (6) professionals engaged exclusively in the education of medical laboratory science
6.13 professionals, provided that results of any examination performed are not used in health
6.14 maintenance, diagnosis, or treatment of disease as described in federal CLIA regulations;

6.15 (7) professionals engaged exclusively in providing phlebotomy services;

6.16 (8) pathologist's assistants or individuals performing pathology assistant activities
6.17 under supervision by pathologists;

6.18 (9) cytotechnologists, which fall under the federally mandated CLIA personnel
6.19 certification requirements;

6.20 (10) histotechnicians and histotechnologists;

6.21 (11) students or trainees enrolled in a medical laboratory science education program
6.22 provided that:

6.23 (i) the activities performed by the student or trainee constitute a part of a planned
6.24 course in the program;

6.25 (ii) the student or trainee is clearly designated as intern, trainee, or student; and

6.26 (iii) the student or trainee is working directly under an individual licensed under
6.27 this chapter to practice medical laboratory science or by a professional who is exempt
6.28 under this section;

6.29 (12) individuals who only perform waived tests or moderately complex point-of-care
6.30 tests under the direction of a qualified CLIA laboratory director according to federal
6.31 CLIA regulations; and

6.32 (13) individuals who perform moderately complex testing as defined by federal
6.33 CLIA regulations provided that the laboratory complies with the following requirements:

6.34 (i) within the laboratory, a licensed medical laboratory scientist or individual who
6.35 qualifies as a laboratory director under federal CLIA regulations is responsible for:

- 7.1 (A) designing, providing, and supervising the training programs for the testing
 7.2 personnel;
- 7.3 (B) supervising and monitoring the quality assurance and quality control activities
 7.4 of the testing site;
- 7.5 (C) assisting in the selection of technology;
- 7.6 (D) reviewing the results of proficiency testing and recommending corrective
 7.7 action, if necessary; and
- 7.8 (E) monitoring the continued laboratory testing competency of the testing personnel;
 7.9 (ii) documented personnel evaluation processes are in place, which ensure and
 7.10 document the continued competency of the testing personnel; and
- 7.11 (iii) after the effective date of this chapter, the licensed medical laboratory scientist
 7.12 or individual who qualifies as a laboratory director under CLIA regulations must ensure
 7.13 that new employees have initial AMT or AAMS certification as a certified or registered
 7.14 medical assistant or certified office laboratory technician. Individuals employed as a
 7.15 medical assistant or office laboratory technician on the effective date of this chapter will
 7.16 be grandfathered in; and
- 7.17 (14) in a declared emergency as defined in section 12.03, that reduces laboratory
 7.18 capacity or increases testing demands, or other loss of critical laboratory capacity,
 7.19 practitioners who are not licensed in any state, but are certified by one of the agencies
 7.20 recognized in this chapter or deemed competent by the affected laboratory director may
 7.21 practice as needed in the emergency situation.
- 7.22 Failure to comply with the requirements in clause (13) subjects the unlicensed
 7.23 moderately complex testing personnel to the loss of the exemption.

7.24 **Sec. 3. [148F.03] LICENSURE REQUIRED; TITLES USED, RESTRICTED,**
 7.25 **AND ALLOWED.**

7.26 Subdivision 1. **Unlicensed practice prohibited.** Effective January 1, 2011, no
 7.27 individual shall perform a medical laboratory test unless the individual is licensed under
 7.28 this chapter as a medical laboratory scientist, categorical medical laboratory scientist,
 7.29 medical laboratory technician, medical laboratory specialist in cytogenetics, medical
 7.30 laboratory specialist in molecular biology/pathology, or medical laboratory specialist in
 7.31 histocompatibility, medical laboratory subspecialist, or is exempt from licensure under
 7.32 section 148F.02.

7.33 Subd. 2. **Protected titles and restrictions on use.** No individual shall use the phrase
 7.34 medical laboratory scientist, categorical medical laboratory scientist, medical laboratory
 7.35 technician, medical laboratory specialist in cytogenetics, medical laboratory specialist

8.1 in molecular biology/pathology, or medical laboratory specialist in histocompatibility,
8.2 or medical laboratory subspecialist, or the initials MLS, MLT, alone or in combination
8.3 with any other words or initials to form an occupational title, or to indicate or imply that
8.4 the person is licensed as one of the professionals listed in this subdivision unless the
8.5 individual is licensed under this chapter.

8.6 Subd. 3. **Persons licensed or certified in other states.** An individual who
8.7 is licensed under this chapter and licensed or certified in another state may use the
8.8 designation licensed or certified with a protected title only if the state of licensure or
8.9 certification is clearly indicated.

8.10 **Sec. 4. [148F.035] SCOPE OF PRACTICE.**

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

- 8.14 (1) the production of test data;
8.15 (2) monitoring the accuracy, precision, and utility of laboratory testing;
8.16 (3) analytical correlation and interpretation of test data; and
8.17 (4) designing, evaluating, and implementing new laboratory test methods.

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

8.20 **Sec. 5. [148F.04] DUTIES OF THE COMMISSIONER.**

8.21 The commissioner, with the advice of the advisory council, shall:

- 8.22 (1) administer the procedures for this chapter, including, but not limited to, verifying
8.23 the qualifications and standards for education, experience, examinations, and continuing
8.24 education, as established by the certification agencies recognized in this chapter, and
8.25 other methods for determining whether an applicant or licensee is qualified, as specified
8.26 under this chapter;
8.27 (2) enforce standards for professional conduct found in the Code of Professional
8.28 Ethics;
8.29 (3) issue licenses to qualified individuals;
8.30 (4) collect and deposit fees as established under section 148F.16;
8.31 (5) on the recommendation of the advisory council, approve future nationally
8.32 recognized, validated, competency-based written, oral, or practical examinations
8.33 developed by the National Credentialing Agency, American Society for Clinical
8.34 Pathology Board of Registry, American Medical Technologists, and American Society

9.1 for Histocompatibility and Immunogenetics, or successor organizations, for purposes of
 9.2 licensure of medical laboratory science professionals as provided for in this chapter; and
 9.3 (6) maintain a roster of the names and addresses of individuals currently licensed
 9.4 under this chapter and of all individuals whose licenses have been disciplined under
 9.5 this chapter.

9.6 **Sec. 6. [148F.05] MEDICAL LABORATORY SCIENCE PROFESSIONAL**
 9.7 **LICENSING ADVISORY COUNCIL.**

9.8 Subdivision 1. **Membership and qualifications of advisory council.** (a) The
 9.9 commissioner shall appoint a nine-member advisory council that may include applicants
 9.10 recommended by laboratory professional associations. Members must be actively
 9.11 employed for at least two years in their specific area of practice.

9.12 (b) Four members must be medical laboratory science professionals who are licensed
 9.13 under this chapter and include:

9.14 (1) one nonphysician laboratory director;

9.15 (2) one medical laboratory scientist;

9.16 (3) one medical laboratory technician; and

9.17 (4) one specialist in cytogenetics, histocompatibility, or molecular biology.

9.18 (c) Three members must be physicians certified by the American Board of Pathology
 9.19 or the American Board of Osteopathic Pathology. All three must be certified in clinical
 9.20 pathology.

9.21 (d) One of the members must be a physician who is not a laboratory director and
 9.22 is not a pathologist.

9.23 (e) One member must be a public member as defined in section 214.02.

9.24 Subd. 2. **Duties.** The advisory council shall:

9.25 (1) advise and make recommendations to the commissioner regarding the medical
 9.26 laboratory science practitioner licensure standards;

9.27 (2) advise the commissioner on enforcement of this chapter;

9.28 (3) provide for distribution of information regarding medical laboratory science
 9.29 practitioners licensure standards;

9.30 (4) review applications upon the request of the commissioner and make
 9.31 recommendations on granting or denying licensure or licensure renewal;

9.32 (5) advise the commissioner on issues related to receiving and investigating
 9.33 complaints, conducting objective hearings, and imposing disciplinary action in relation to
 9.34 complaints received against medical laboratory science practitioners; and

9.35 (6) perform other duties requested by the commissioner.

10.1 Subd. 3. **Organization.** The advisory council shall be organized and administered
10.2 under section 15.059. The advisory council shall select a chair from its membership at
10.3 the first meeting of the advisory council.

10.4 **Sec. 7. [148F.06] TEMPORARY REQUIREMENTS FOR LICENSURE;**
10.5 **TRANSITION PERIOD.**

10.6 Subdivision 1. **License required.** After the effective date of rules adopted by the
10.7 commissioner, no individual may perform medical laboratory tests unless that individual
10.8 holds a valid license under this chapter or is exempt from licensure under section 148F.02.

10.9 Subd. 2. **Experienced medical laboratory science professionals transition.**

10.10 (a) Notwithstanding section 148F.03, an individual who is certified by or eligible to be
10.11 certified by a certification agency recognized by the commissioner to perform medical
10.12 laboratory testing, or meets the subspecialty requirements in section 148F.07, subdivision
10.13 7, may perform medical laboratory tests without the appropriate license provided the
10.14 individual has applied to the commissioner for licensure and:

10.15 (1) the application has not been denied by the commissioner; or

10.16 (2) the application has not been withdrawn.

10.17 (b) This subdivision expires January 1, 2011.

10.18 Subd. 3. **Employed medical laboratory science professional transition.** (a) An
10.19 individual who does not meet the education, training, and experience qualifications for
10.20 any license described in this chapter on July 1, 2009, has until January 1, 2011, to apply
10.21 for a license under this subdivision.

10.22 (b) The commissioner shall issue a license under this subdivision if the applicant:

10.23 (1) is practicing in the field on July 1, 2009, or has six months of acceptable
10.24 experience of at least half time, 1040 hours per year, in the three years immediately prior
10.25 to July 1, 2009; and

10.26 (2) on a form provided by the commissioner submits the job, title, description of the
10.27 position, and period of employment as attested to by the applicant's employer.

10.28 (c) The commissioner and advisory council shall determine which type of license the
10.29 applicant is eligible for and issue the license if the requirements of this subdivision are met.

10.30 (d) An initial license issued under this subdivision must be reviewed following the
10.31 procedures required under section 148F.10, provided the license is maintained without
10.32 interruption.

10.33 (e) This subdivision expires January 1, 2011.

10.34 **Sec. 8. [148F.07] STANDARDS FOR LICENSURE.**

11.1 Subdivision 1. **Medical laboratory scientist (MLS).** The commissioner shall issue
11.2 a medical laboratory scientist's license to an individual who:

11.3 (1) possesses a baccalaureate degree from a regionally accredited college or
11.4 university and verified by the nationally recognized certification agencies;

11.5 (2) has met the medical laboratory experience and training required by the
11.6 recognized certification agencies; and

11.7 (3) passes a nationally recognized certification examination administered by the
11.8 American Society for Clinical Pathology Board of Registry, the National Credentialing
11.9 Agency, American Medical Technologists, or successor organizations.

11.10 Subd. 2. **Medical laboratory scientist, categorical.** The board shall issue a
11.11 categorical medical laboratory scientist's license to an individual who:

11.12 (1) possesses a baccalaureate degree from a regionally accredited college or
11.13 university and verified by the nationally recognized certification agencies;

11.14 (2) has met the medical laboratory experience and training required by the
11.15 recognized certification agencies; and

11.16 (3) passes a nationally recognized certification examination administered by the
11.17 American Society for Clinical Pathology Board of Registry, the National Credentialing
11.18 Agency, or American Medical Technologists, or successor organizations.

11.19 Subd. 3. **Medical laboratory technician (MLT).** The commissioner shall issue a
11.20 medical laboratory technician's license to an individual who:

11.21 (1) possesses an associate degree from a regionally accredited college or university
11.22 verified by the nationally recognized certification agencies;

11.23 (2) has met the medical laboratory experience and training required by the
11.24 recognized certification agencies; and

11.25 (3) passes a nationally recognized certification examination administered by the
11.26 American Society for Clinical Pathology Board of Registry, the National Credentialing
11.27 Agency, or the American Medical Technologists, or successor organizations.

11.28 Subd. 4. **Medical laboratory specialist in molecular biology.** The commissioner
11.29 shall issue a medical laboratory specialist in molecular biology license to an individual
11.30 who:

11.31 (1) possesses a baccalaureate degree from a regionally accredited college or
11.32 university verified by the recognized certification agencies;

11.33 (2) meets the medical laboratory experience and training required by the nationally
11.34 recognized certification agencies, or alternatively one year of on-the-job training; and

11.35 (3) either passes a nationally recognized certification examination administered by
11.36 the American Society for Clinical Pathology Board of Registry, the National Credentialing

12.1 Agency, or successor organizations or is deemed competent via written confirmation by
12.2 the respective laboratory director.

12.3 Subd. 5. **Medical laboratory specialist in cytogenetics.** The commissioner shall
12.4 issue a medical laboratory specialist in cytogenetics license to an individual who:

12.5 (1) possesses a baccalaureate degree from a regionally accredited college or
12.6 university verified by the nationally recognized certification agencies;

12.7 (2) has met the medical laboratory experience and training required by the nationally
12.8 recognized certification agencies or alternatively one year of on-the-job training; and

12.9 (3) passes a nationally recognized certification examination administered by the
12.10 National Credentialing Agency or successor organizations or is deemed competent via
12.11 written confirmation by the respective laboratory director.

12.12 Subd. 6. **Histocompatibility technologist.** The commissioner shall issue a medical
12.13 laboratory specialist in histocompatibility license to an individual who:

12.14 (1) possesses a baccalaureate degree from a regionally accredited college or
12.15 university verified by the nationally recognized certification agencies;

12.16 (2) has met the medical laboratory experience and training required by the nationally
12.17 recognized certification agencies or alternatively one year of on-the-job training; and

12.18 (3) passes a nationally recognized certification examination administered by the
12.19 American Board of Histocompatibility and Immunogenetics or is deemed competent via
12.20 written confirmation by the respective laboratory director.

12.21 Subd. 7. **Medical laboratory subspecialist.** The commissioner shall issue a
12.22 medical laboratory subspecialist license to an individual who:

12.23 (1) possesses a baccalaureate from a regionally accredited college or university
12.24 verified by the recognized certification agencies;

12.25 (2) has met the required medical laboratory experience and training through one
12.26 year of on-the-job training; and

12.27 (3) either is deemed competent via written confirmation by the respective laboratory
12.28 director or passes a nationally recognized certification examination administered by the
12.29 National Credentialing Agency, Board of Registry, or successor organizations

12.30 **Sec. 9. [148F.08] RECIPROCALITY.**

12.31 Subdivision 1. **Licensure.** The commissioner may waive the licensure requirements
12.32 for an applicant who holds a valid license or its equivalent issued by another state
12.33 provided that the requirements under which that license or its equivalent was issued are
12.34 equivalent to or exceed the standards required by this chapter. Once the license is up

13.1 for renewal, the applicant shall be issued a Minnesota license upon meeting the license
 13.2 renewal requirements in section 148F.11.

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

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

13.15 **Sec. 10. [148F.09] TEMPORARY LICENSE REQUIREMENTS.**

13.16 (a) The commissioner may issue a temporary license to an applicant who:

13.17 (1) is eligible to sit for and registered to take a certification examination or has taken
 13.18 the examination and is awaiting results;

13.19 (2) meets the educational requirements of the recognized certification agency and is
 13.20 seeking to qualify for the certification examination by completing the required supervised
 13.21 medical laboratory experience; or

13.22 (3) meets the educational requirements for the position and is undergoing the
 13.23 required on-the-job training necessary for a specialized clinical laboratory.

13.24 (b) A temporary license shall be issued for a 12-month period and may be renewed
 13.25 for two additional 12-month periods at the discretion of the commissioner, in order to
 13.26 allow the applicant to complete the required supervised medical laboratory experience or
 13.27 retake a certification examination, or be deemed competent by the laboratory director.

13.28 (c) A temporary license expires 12 months after it is issued or on the date the
 13.29 commissioner issues or denies a permanent license to the holder.

13.30 (d) A temporary license authorizes the holder to perform medical laboratory tests
 13.31 only in the area of practice for which the individual seeks to be permanently licensed.

13.32 **Sec. 11. [148F.10] LICENSURE APPLICATION PROCEDURES.**

14.1 (a) Applicants must submit an application for licensure to the commissioner upon
 14.2 the forms prescribed and furnished by the commissioner, and must submit with the
 14.3 application the designated application fee as specified in section 148F.16.

14.4 (b) Upon receipt of the application and the application fee, the commissioner shall
 14.5 issue a license for a medical laboratory scientist, a medical laboratory technician, or
 14.6 an appropriate specialty license to an individual who meets the qualifications specified
 14.7 in this chapter.

14.8 **Sec. 12. [148F.11] LICENSURE RENEWAL.**

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

14.12 Subd. 2. **Renewal applications.** In order to renew a license, a licensee must submit:

14.13 (1) a completed and signed application for renewal on a form prescribed by the board;

14.14 (2) the applicable renewal fee as specified in section 148F.16; and

14.15 (3) documentation that the licensee has completed continuing education
 14.16 requirements as prescribed by the recognized certification agencies or 12 hours of
 14.17 documented continuing education.

14.18 **Sec. 13. [148F.12] LICENSURE FOLLOWING LAPSE OF LICENSURE**
 14.19 **STATUS.**

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

14.21 (1) apply for licensure renewal according to section 148F.11 and document
 14.22 compliance with the continuing education requirements as prescribed by the recognized
 14.23 certification agency since the applicant's license lapsed; and

14.24 (2) fulfill the requirements of section 148F.07 and provide evidence of compliance
 14.25 with the continuing education requirements as prescribed by one of the recognized
 14.26 certification agencies.

14.27 **Sec. 14. [148F.13] CONTINUING EDUCATION REQUIREMENTS.**

14.28 Continuing education requirements shall be as described by the applicable
 14.29 certification agencies recognized under this chapter.

14.30 **Sec. 15. [148F.14] INVESTIGATION PROCESS; GROUNDS FOR**
 14.31 **DISCIPLINARY ACTION.**

15.1 Subdivision 1. **Disciplinary action.** (a) The commissioner may impose disciplinary
15.2 action as described in paragraph (b) against an applicant or licensee whom the
15.3 commissioner, by a preponderance of the evidence, determines:

15.4 (1) has violated a statute, rule, or order that the commissioner issued or is empowered
15.5 to enforce;

15.6 (2) has been convicted of or pled guilty to a felony, gross misdemeanor,
15.7 misdemeanor, or petty misdemeanor, an essential element of which is dishonesty, or of
15.8 any crime which is directly related to the practice of the profession;

15.9 (3) has made a misrepresentation for the purpose of obtaining licensure, either on
15.10 an application provided by the commissioner or in response to oral or written questions
15.11 from the commissioner;

15.12 (4) violated the code of professional conduct in subdivisions 2 to 4;

15.13 (5) engaged in dishonorable, unethical, or unprofessional conduct of a character
15.14 likely to deceive, defraud, or harm the public;

15.15 (6) failed to perform services with reasonable judgment, skill, or safety due to the
15.16 use of alcohol, drugs, or other physical or mental impairment;

15.17 (7) aided or assisted another person in violating any provision of this chapter or any
15.18 rule adopted hereunder;

15.19 (8) made any misrepresentation with regard to the existence or category of license or
15.20 other certification or professional qualification held in connection with any employment
15.21 application;

15.22 (9) intentionally submitted false or misleading information in response to a written
15.23 request by the commissioner or advisory council;

15.24 (10) failed, within 30 days, to provide information in response to a written request
15.25 by the commissioner or advisory council;

15.26 (11) performed services for which the license is issued in an incompetent manner or
15.27 in a manner that falls below community standards;

15.28 (12) violated any provision of this chapter;

15.29 (13) been convicted of violating any state or federal law, rule, or regulation which
15.30 directly relates to the practice related to the discipline for which the individual is licensed;

15.31 (14) violated a federal or state court order, including a conciliation court judgment,
15.32 or a disciplinary order issued by the commissioner, related to the individual's practice for
15.33 which they are licensed under this chapter;

15.34 (15) aided or abetted another person in violating any provision of this chapter;

16.1 (16) been disciplined for conduct in the practice of an occupation by the state of
16.2 Minnesota, another jurisdiction, or a national professional association, if any of the
16.3 grounds are the same or substantially equivalent to those in this chapter;

16.4 (17) not cooperated with the commissioner or the advisory council in an investigation
16.5 conducted according to this paragraph;

16.6 (18) engaged in conduct with a patient that is sexual or may reasonably be
16.7 interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually
16.8 demeaning to a patient; or

16.9 (19) any other just cause related to the practice for which they are licensed under
16.10 this chapter.

16.11 (b) If grounds for disciplinary action exist under paragraph (a), the commissioner
16.12 may take one or more of the following actions:

16.13 (1) refuse to grant or renew a license;

16.14 (2) revoke a license;

16.15 (3) suspend a license;

16.16 (4) impose limitations or conditions on a license, including, but not limited to,
16.17 practice under supervision, continued practice on the demonstration of knowledge or skill
16.18 by appropriate examination or other review of knowledge, skill, and competence;

16.19 (5) censure or reprimand the licensee;

16.20 (6) impose a civil penalty not exceeding \$10,000 for each separate violation,
16.21 the amount of the civil penalty to be fixed so as to deprive the applicant or licensee
16.22 of any economic advantage gained by reason of the violation charged, to discourage
16.23 similar violations, or to reimburse the commissioner for the cost of the investigation and
16.24 proceeding including, but not limited to, fees paid for services provided by the Office of
16.25 Administrative Hearings, legal and investigative services provided by the Office of the
16.26 Attorney General, court reporters, witnesses, reproduction of records, advisory council
16.27 members per diem compensation, staff time, and travel costs and expenses incurred by
16.28 staff and advisory council members; or

16.29 (7) any reasonable lesser action including, but not limited to, censure, reprimand, or
16.30 restriction on licensure, or any action authorized by statute.

16.31 (c) Upon notice from the commissioner denying licensure renewal or upon notice
16.32 that disciplinary actions have been imposed and the person is no longer entitled to provide
16.33 the services for which the person was previously licensed under this chapter, the person
16.34 shall cease to provide the services under this chapter, to use the protected titles pursuant to
16.35 this chapter, and to represent to the public that the person is licensed by the commissioner.

17.1 (d) A person who has had licensure suspended may request and provide justification
17.2 for reinstatement following the period of suspension specified by the commissioner. The
17.3 requirement of this chapter for renewing licensure and any other conditions imposed with
17.4 the suspension must be met before licensure may be reinstated.

17.5 (e) The commissioner shall contract with the health professional services program as
17.6 authorized by sections 214.31 to 214.37 to provide these services to practitioners under
17.7 this chapter. The health professional services program does not affect the commissioner's
17.8 authority to discipline violations of this chapter.

17.9 Subd. 2. **Duty to patient.** Medical laboratory professionals are accountable for the
17.10 quality and integrity of the laboratory services they provide. This obligation includes
17.11 maintaining individual competence in judgment and performance and striving to safeguard
17.12 the patient from incompetent or illegal practice by others.

17.13 Medical laboratory professionals maintain high standards of practice. They exercise
17.14 sound judgment in establishing, performing, and evaluating laboratory testing.

17.15 Medical laboratory professionals maintain strict confidentiality of patient
17.16 information and test results. They safeguard the dignity and privacy of patients and provide
17.17 accurate information to other health care professionals about the services they provide.

17.18 Subd. 3. **Duty to colleagues and profession.** Medical laboratory professionals
17.19 uphold and maintain the dignity and respect of the profession and strive to maintain a
17.20 reputation of honesty, integrity, and reliability. They contribute to the advancement of
17.21 the profession by improving the body of knowledge, adopting scientific advances that
17.22 benefit the patient, maintaining high standards of practice and education, and seeking fair
17.23 socioeconomic working conditions for members of the profession.

17.24 Medical laboratory professionals actively strive to establish cooperative and
17.25 respectful working relationships with other health care professionals with the primary
17.26 objective of ensuring a high standard of care for the patients they serve.

17.27 Subd. 4. **Duty to society.** As practitioners of an autonomous profession, medical
17.28 laboratory professionals have the responsibility to contribute from their sphere of
17.29 professional competence to the general well being of the community.

17.30 Medical laboratory professionals comply with relevant laws and regulations
17.31 pertaining to the practice of medical laboratory science and actively seek, within the
17.32 dictates of their consciences, to change those which do not meet the high standards of care
17.33 and practice to which the profession is committed.

17.34 Sec. 16. **[148F.15] REPORTING OBLIGATIONS.**

18.1 Subdivision 1. **Permission to report.** A person who has knowledge of any conduct
18.2 constituting grounds for disciplinary action relating to the practice of alcohol and drug
18.3 counseling under this chapter may report the violation to the commissioner.

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

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

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

18.34 Subd. 5.. **Self-reporting.** A medical laboratory science professional shall report
18.35 to the commissioner any personal action that would require that a report be filed with
18.36 the commissioner by any person, health care facility, business, or organization under

19.1 subdivisions 2 to 4. The medical laboratory science professional shall also report the
 19.2 revocation, suspension, restriction, limitation, or other disciplinary action in this state
 19.3 and report the filing of charges regarding the practitioner's license or right of practice
 19.4 in another state or jurisdiction.

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

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

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

19.19 **Sec. 17. [148F.16] FEES.**

19.20 Subdivision 1. **Initial licensure fee.** The initial licensure fee for medical laboratory
 19.21 scientist, categorical medical laboratory scientist, medical laboratory specialist in
 19.22 molecular biology, medical laboratory specialist in cytogenetics, histocompatibility
 19.23 technologist, other specialists and categoricals, and medical laboratory technicians is
 19.24 \$..... The commissioner shall prorate fees based on the number of quarters remaining
 19.25 in the triennial licensure period.

19.26 Subd. 2. **Licensure renewal fee.** The triennial licensure renewal fee for medical
 19.27 laboratory scientist, categorical medical laboratory scientist, medical laboratory specialist
 19.28 in molecular biology, medical laboratory specialist in cytogenetics, histocompatibility
 19.29 technologist, other specialists and categoricals, and medical laboratory technicians is \$.....

19.30 Subd. 3. **Late fee** The fee for late submission of a renewal application is \$45.

19.31 Subd. 4. **Temporary licensure fee.** The fee for temporary licensure is \$50.

19.32 Subd. 5. **Verification to other states.** The fee for verification of licensure to other
 19.33 states is \$25.

19.34 Subd. 6. **Verification to institutions.** The fee for verification of licensure to
 19.35 institutions is \$10.

20.1 Subd. 7. **Nonrefundable fees.** All fees are nonrefundable.

20.2 Subd. 8. **Penalty fees.** (a) The penalty fee for practicing medical laboratory science
20.3 without a current license after the credential has expired and before it is renewed is the
20.4 amount of the license renewal fee for any part of the first month, plus the license renewal
20.5 fee for any part of any subsequent month up to 36 months.

20.6 (b) The penalty fee for applicants who engage in the unauthorized practice of
20.7 medical laboratory science before being issued a license is the amount of the license
20.8 application fee for any part of the first month, plus the license application fee for any part
20.9 of any subsequent month up to 36 months. This paragraph does not apply to applicants not
20.10 qualifying for a license who engage in the unauthorized practice of medical laboratory
20.11 science.

20.12 (c) The penalty fee for failing to submit a continuing education report by the due
20.13 date with the correct number or type of hours in the correct time period is \$50. The
20.14 licensee must obtain the missing number of continuing education hours by the next
20.15 reporting due date.

20.16 (d) Civil penalties and discipline incurred by licensees prior to January 1, 2011, for
20.17 conduct described in paragraph (a), (b), or (c), shall be recorded as nondisciplinary penalty
20.18 fees. For conduct described in paragraph (a) or (b) occurring after January 1, 2011, and
20.19 exceeding six months, payment of a penalty fee does not preclude any disciplinary action
20.20 reasonably justified by the individual case.

20.21 **Sec. 18. EFFECTIVE DATE.**

20.22 Setup of licensing functions and creation of the advisory council shall be effective
20.23 July 1, 2009. Licensure shall be effective January 1, 2011.