The Medical Laboratory Licensing Regulations, 1995

being

Chapter M-9.2 Reg 1 (effective March 1, 1996) as amended by Saskatchewan Regulations 23/2004, 87/2007, 88/2013, 26/2019, 12/2021, 66/2021 and 57/2023.

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CHAPTER M-9.2 REG 1

The Medical Laboratory Licensing Act, 1994

Title

1 These regulations may be cited as *The Medical Laboratory Licensing Regulations, 1995*.

Interpretation

2(1) In these regulations:

(a) **"Act"** means *The Medical Laboratory Licensing Act, 1994*;

(b) **"certified combined laboratory and X-ray technician"** means a person who:

(i) has successfully completed a program for the education and training of certified combined laboratory and X-ray technicians offered by an educational institution funded by the Government of Saskatchewan or an equivalent program; and

(ii) is eligible for certified membership in The Saskatchewan Association of Combined Laboratory & X-ray Technicians, Inc.;

(c) **Repealed.** 14 Jly 2023 SR 57/2023 s3.

(d) **"medical director"** means a person who is:

(i) a duly qualified medical practitioner who has been granted certification by the Royal College of Physicians and Surgeons of Canada in:

(A) general pathology;

(B) haematological pathology;

(C) medical biochemistry;

(D) medical microbiology;

(E) anatomical pathology; or

(F) neuropathology; or

(ii) a duly qualified medical practitioner who:

(A) has been granted certification by the Royal College of Physicians and Surgeons of Canada in:

(I) haematology;

(II) infectious diseases;

(III) clinical immunology and allergy; or

(IV) medical genetics; and

(B) has at least two years' experience in the relevant laboratory specialty;

(e) **"medical laboratory technologist"** means a person who:

(i) has successfully completed a medical laboratory technology education program that is accredited by the Conjoint Committee for the Accreditation of Educational Programs in Allied Medical Disciplines; and

(ii) is eligible for certified membership in:

(A) the Canadian Society of Laboratory Technologists; and

(B) the Saskatchewan Society of Medical Laboratory Technologists Inc.;

(e.01) **"physician assistant"** means a physician assistant as defined in *The Medical Profession Act, 1981* who is practising under the supervision of a duly qualified medical practitioner as approved by the College of Physicians and Surgeons of Saskatchewan;

(e.1) **"provincial health authority"** means the provincial health authority within the meaning of *The Provincial Health Authority Act*;

(f) **"respiratory therapist"** means a person who:

(i) has successfully completed a respiratory therapy education program that is accredited by the Conjoint Committee for the Accreditation of Educational Programs in Allied Medical Disciplines; and

(ii) is eligible for certified membership in:

(A) the Canadian Society of Respiratory Therapists; and

(B) the Saskatchewan Association of Respiratory Therapists Inc.;

(g) **"scientific director"** means a person who:

(i) holds an academic doctoral degree in a relevant chemical or biological science that is approved by the director; and

(ii) has been granted certification by:

(A) The Canadian Academy of Clinical Biochemistry;

(B) The Canadian College of Medical Genetics; or

(C) The Canadian College of Microbiologists;

(h) **"technical director"** means a person who is:

(i) a medical laboratory technologist; or

(ii) a certified combined laboratory and X-ray technician.

(2) For the purposes of subclause 2(f)(iv) of the Act and in these regulations, the following types of facilities are not medical laboratories:

(a) laboratories and portions of laboratories that are used exclusively for medical or scientific research;

(b) premises in which:

(i) specimens are collected but no testing is carried out; and

(ii) the collection of specimens is carried out solely for the purposes of the business of an insurer within the meaning of *The Insurance Act*;

(c) the office of a duly qualified medical practitioner if the tests set out in Part I of the Appendix are the only tests performed in the office;

(d) premises in which point-of-care antigen testing for COVID-19 and collecting specimens for that purpose have met the following conditions:

(i) the collection of specimens is limited to the following:

(A) anterior nasal swab;

(B) nasal mid-turbinate swab;

(C) combined throat and nasal or anterior nares;

(D) saliva sampling;

(E) throat swab;

(ii) the point-of-care antigen testing or specimen collection is performed only on a non-diagnostic basis with respect to asymptomatic individuals.

12 Jan 96 c.M-9.2 Reg 1 s2; 5 Mar 2021 SR 12/2021 s2; 21 May 2021 SR 66/2021 s2; 14 Jly 2023 SR 57/2023 s3.

Accreditation program

3(1) The minister may designate the person who or association that will establish and operate the accreditation program.

(2) The accreditation program is to include, but is not limited to, requirements and standards with respect to the following matters:

(a) subject to section 9, the qualifications of staff;

(b) space, facilities, equipment and supplies for the performance of laboratory work;

(c) methods and procedures to be used, including, but not limited to, methods and procedures for collection, identification, transportation and assessment of condition of specimens;

(d) safety;

(e) record keeping;

(f) an internal quality control program;

(g) an external proficiency testing program;

(h) inspections;

(i) remedial education;

(j) consultation services.

12 Jan 96 c.M-9.2 Reg 1 s3.

Assessing need for laboratory or test

4 For the purposes of subclause 6(2)(a)(i) of the Act, the following are the factors that may be considered by the director, with respect to an application for a licence, in considering whether there is a need for the medical laboratory that is the subject of the application and for the tests that are to be performed in it:

(a) whether existing medical laboratories are capable of meeting any need for additional testing or would be capable of meeting that need if they were expanded, having regard to:

(i) the types and number of tests performed in existing medical laboratories;

(ii) the number of specimens collected, transported and referred by existing medical laboratories;

(iii) the availability of facilities to transport persons and specimens to medical laboratories in the geographic area of concern;

(b) the costs of providing additional testing:

(i) in existing medical laboratories; and

(ii) in the proposed medical laboratory;

(c) whether the proposed medical laboratory or proposed additional testing would result in an unnecessary duplication of services;

(d) in the case of an application to perform a test, the medical relevance of the test;

(e) whether the proposed medical laboratory or proposed additional testing would affect the quality of patient care;

(f) whether the proposed medical laboratory or proposed additional testing would affect the reasonable access of patients to laboratory services;

(g) the mandate of the facility in which the medical laboratory is located;

(h) any other factors that the director considers relevant.

12 Jan 96 c.M-9.2 Reg 1 s4.

Categories of laboratories

5 The following categories of medical laboratories are established:

(a) Category I, comprising the medical laboratories within physicians' offices in which only the tests set out in Part II of the Appendix may be carried out;

(b) Category II, comprising the medical laboratories within physicians' offices in which only the tests set out in Part III of the Appendix may be carried out;

(c) Category III, comprising the medical laboratories in which only the tests set out in Part IV of the Appendix may be carried out;

(d) Category IV, comprising the medical laboratories in which only the tests set out in Part V of the Appendix may be carried out;

(e) Category V, comprising the medical laboratories in which only the tests set out in Part VI of the Appendix may be carried out;

(f) Category VI, comprising the medical laboratories in which only the tests set out in Part VII of the Appendix may be carried out;

(g) Category VII, comprising the medical laboratories established and operated pursuant to subsection 8(1) of *The Health Administration Act*;

(h) Category VIII, comprising the medical laboratories operated by the Canadian Red Cross Society;

(i) Category IX, comprising the medical laboratories that are not within the scope of any category described in clauses (a) to (h).

12 Jan 96 c.M-9.2 Reg 1 s5; 18 Apr 2019 SR 26/2019 s3.

Qualified professionals

6(1) For Category I and Category II medical laboratories, duly qualified medical practitioners are designated as qualified professionals.

(2) For Category III medical laboratories, the following categories of persons are designated as qualified professionals:

(a) medical directors;

(b) scientific directors;

(c) technical directors;

(d) duly qualified medical practitioners;

(e) registered nurses and registered psychiatric nurses.

(3) For Category IV medical laboratories, the following categories of persons are designated as qualified professionals:

(a) medical directors;

(b) scientific directors;

(c) technical directors.

(4) For Category V medical laboratories, the following categories of persons are designated as qualified professionals:

(a) medical directors;

(b) scientific directors;

(c) technical directors who are medical laboratory technologists.

(5) For Category VI and Category VIII medical laboratories, medical directors are designated as qualified professionals.

(6) For Category VII medical laboratories, the following categories of persons are designated as qualified professionals:

(a) medical directors;

(b) scientific directors.

(7) For Category IX medical laboratories, a person who possesses the qualifications specified in the licence is designated as the qualified professional.

(8) The qualified professional of a medical laboratory is responsible for overseeing the day-to-day operation of the medical laboratory, including, but not limited to, the supervision of test procedures, quality assurance standards and programs and the reporting of results to the persons who requested the tests.

12 Jan 96 c.M-9.2 Reg 1 s6.

Prohibition

7 No licensee shall cause or permit an individual to be the qualified professional of more than one medical laboratory without the approval of the director.

12 Jan 96 c.M-9.2 Reg 1 s7.

Employment of staff

8(1) Subject to clause 9(4)(a), no licensee shall employ a person to perform tests in a medical laboratory unless that person:

(a) possesses the qualifications set out in section 9; or

(b) is a student and is employed for the purpose of acquiring training that leads to the acquisition of the qualifications set out in section 9.

(2) For the purposes of subsection (1), a person who performs under supervision some portion of a test in accordance with the accreditation program is not, while performing that portion of a test, a person employed to perform tests in a medical laboratory.

12 Jan 96 c.M-9.2 Reg 1 s8.

Qualifications of staff

9(1) Subject to subsection (2), a person employed to perform tests in a Category II, Category III, Category IV, Category V, Category VI, Category VII or Category VIII medical laboratory must be:

(a) a registered nurse, a registered psychiatric nurse, a licensed practical nurse, a physician assistant or a duly qualified medical practitioner;

(b) a certified combined laboratory and X-ray technician;

(c) a medical laboratory technologist;

(d) the holder of an academic bachelor's, master's or doctoral degree in a relevant chemical or biological science as approved in the licence; or

(e) a medical director.

(2) The categories of persons mentioned in subsection (1) are subject to the following restrictions:

(a) a duly qualified medical practitioner or a physician assistant shall perform only the tests set out in Parts I and IV of the Appendix;

(b) a registered nurse, a registered psychiatric nurse or a licensed practical nurse shall perform only the tests set out in Part IV of the Appendix;

(c) a certified combined laboratory and X-ray technician shall perform only the tests set out in Part V of the Appendix;

(d) the holder of an academic bachelor's, master's or doctoral degree in a relevant chemical or biological science as approved in the licence shall perform only the tests specified in the licence.

(3) A person employed to perform tests in a Category I or Category IX medical laboratory must have the qualifications specified in the licence.

(4) Notwithstanding subsections (1) to (3):

(a) a licensee may continue to employ a person who was employed in the medical laboratory on March 31, 1991 and who does not possess the required qualifications if:

(i) on or before March 31, 1991, the person was regularly performing the tests that the person will be performing in the medical laboratory;

(ii) on April 1, 1991, the medical laboratory was licensed to perform the tests that the person will be performing in the medical laboratory; and

(iii) the person is under the supervision of the qualified professional in accordance with the accreditation program; and

(b) a licensee may employ a respiratory therapist who is trained to perform blood gas analyses to perform blood gas analyses in a Category V or Category VI medical laboratory.

12 Jan 96 c.M-9.2 Reg 1 s9; 14 Jly 2023 SR 57/2023 s4.

Tests to be requested

10(1) A licensee shall ensure that no tests, examinations or procedures are performed unless:

(a) they are requested by:

(i) a physician who is entitled to practise medicine pursuant to *The Medical Profession Act, 1981*;

(i.1) a physician assistant who is entitled to practise as a physician assistant pursuant to *The Medical Profession Act, 1981* when it is within the physician assistant's authorized scope of practice to request the test, examination or procedure;

(ii) a dentist who is entitled to practise dentistry pursuant to *The Dental Disciplines Act*;

(iii) a midwife who is entitled to practise midwifery pursuant to *The Midwifery Act*;

(iv) a registered nurse who is entitled pursuant to *The Registered Nurses Act, 1988* to practise in the nurse practitioner category or in the general category with additional authorized practice; or

(v) a podiatrist who is entitled to practise podiatry pursuant to *The Podiatry Act;*

(b) the qualified professional requires further tests to reach a diagnosis.

(2) Subsection (1) does not apply:

(a) to a Category IX medical laboratory where the licence contains a statement that subsection (1) does not apply to that medical laboratory; or

(b) where the tests are performed as part of an anonymous testing program for sexually transmitted diseases.

12 Jan 96 c.M-9.2 Reg 1 s10; 7 May 2004 SR 23/2004 s2; 21 Sep 2007 SR 87/2007 s2; 25 Oct 2013 SR 88/2013 s2; 18 Apr 2019 SR 26/2019 s4; 14 Jly 2023 SR 57/2023 s5.

Duty of licensee re transfusions

11 Where a licensee becomes aware of the occurrence of a significant adverse transfusion effect as a result of a transfusion of blood or blood products, the licensee shall immediately notify the Canadian Red Cross Society of the occurrence.

12 Jan 96 c.M-9.2 Reg 1 s11.

R.R.S. c.M-9.1 Reg 1 repealed

12 *The Medical Laboratory Licensing Regulations* are repealed.

12 Jan 96 c.M-9.2 Reg 1 s12.

Appendix

PART I

Tests Performed by Duly Qualified Medical Practitioner or Physician Assistant

[*Clauses 2(2)(c) and 9(2)(a)*]

Microscopic slide examination:

- fungi
- scales
- secretions
- trichomonas
- yeast.

12 Jan 96 c.M-9.2 Reg 1 Part I; 14 Jly 2023 SR 57/2023 s6.

PART II

Tests that may be Performed in Category I Medical Laboratories

[*Clause 5(a)*]

Glucose
Haematocrit
Haemoglobin
Occult blood
Pregnancy test
Urinalysis dipstick
Urinalysis - complete - dipstick and microscopic examination.

12 Jan 96 c.M-9.2 Reg 1 Part II.

PART III

Tests that may be Performed in Category II Medical Laboratories

[*Clause 5(b)*]

Automated haematology profiles including one or more of the following: haemoglobin, white blood cell count, red blood cell count, haematocrit or red blood cell indices
Erythrocyte sedimentation rate
Glucose
Glucose tolerance
Haematocrit
Haemoglobin
Indices (mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration)
Infectious mononucleosis screening test
Occult blood
Pregnancy test
Prothrombin time
Semen analysis
Urea
Urinalysis dipstick
Urinalysis - complete - dipstick and microscopic examination
White blood cell count
White blood cell differential and morphology.

12 Jan 96 c.M-9.2 Reg 1 Part III.

PART IV

Tests that may be Performed in Category III Medical Laboratories

[*Clauses 5(c) and 9(2)(a)*]

Glucose diagnostic stick
Haemoglobin
Occult blood
Pregnancy test
Urinalysis dipstick.

12 Jan 96 c.M-9.2 Reg 1 Part IV.

PART V

Tests that may be Performed in Category IV Medical Laboratories

[*Clauses 5(d) and 9(2)(b)*]

Activated partial thromboplastin time
Amylase
Aspartate aminotransferase
Automated haematology profiles
Calcium
Carbon dioxide
Cell count - body fluids including cerebrospinal fluid
Cell differential - body fluids including cerebrospinal fluid
Chloride
Creatine kinase
Creatinine
Erythrocyte sedimentation rate
Glucose
Glucose tolerance
Haematocrit
Haemoglobin
Indices (mean cell volume, mean cell haemoglobin, mean cell haemoglobin concentration)
Infectious mononucleosis screening test
Microscopic slide examination - wet preparation
Occult blood
Platelet count
Potassium
Pregnancy test
Prothrombin time
Reducing substances
Semen analysis
Sodium
Total bilirubin
Urea
Urinalysis dipstick
Urinalysis - complete - dipstick and microscopic examination
White blood cell count
White blood cell differential and morphology.

PART VI

Tests that may be Performed in Category V Medical Laboratories

[*Clause 5(e)*]

All tests within the disciplines of:

Haematology
Immunohaematology

All tests listed in Part V

In addition to the tests listed in Part V, the following tests within the discipline of clinical chemistry:

Acetominophen
Acid Phosphatase
Alanine transaminase
Albumin
Alkaline phosphatase
Barbiturates
Blood gases
Carbamazepine
Cholesterol
C-reactive protein
Creatine kinase isoenzymes
Creatinine clearance
Digoxin
Dilantin
Direct bilirubin
Drug screen (qualitative)
Ethanol
Gamma glutamyl transferase
Gentamicin
HDL/LDL cholesterol
Ionized calcium
Iron
Iron binding/transferrin
Ketones - serum (qualitative)
Lactate dehydrogenase
Lactic acid
Lithium
Magnesium
Phenobarbital
Phosphate
Rheumatoid factor

Salicylate
Theophylline
Tobramycin
Total protein - cerebrospinal fluid
Total protein - serum
Total protein - urine
Triglycerides
Uric acid
Valproic acid

In addition to the tests listed in Part V, the following tests within the discipline of microbiology:

Antibiotic sensitivity testing
Antistreptolysin O serology
Bacterial culture testing
Gram stain
Group A streptococcus throat screening test
India ink/potassium hydroxide preparation
Stool - ova and parasites.

12 Jan 96 c.M-9.2 Reg 1 Part VI.

PART VII
Tests that may be Performed in Category VI Medical Laboratories
[*Clause 5(f)*]

All tests within the disciplines of:

Anatomical pathology
Clinical chemistry
Cytogenetics
Cytology
Haematology
Immunohaematology
Microbiology.

12 Jan 96 c.M-9.2 Reg 1 Part VII.

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