

The Medical Laboratory Licensing Regulations

Repealed

by Chapter M-9.2 Reg 1 (effective March 1, 1996).

Formerly

Chapter M-9.1 Reg 1 (effective April 1, 1991).

NOTE:

This consolidation is not official. Amendments have been incorporated for convenience of reference and the original statutes and regulations should be consulted for all purposes of interpretation and application of the law. In order to preserve the integrity of the original statutes and regulations, errors that may have appeared are reproduced in this consolidation.

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Appendix

CHAPTER M-9.1 REG 1
The Medical Laboratory Licensing Act

Title

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

Interpretation

- 2(1)** In these regulations:

- (a) **“Act”** means *The Medical Laboratory Licensing Act*;
- (b) **“certified combined laboratory and X-ray technician”** means a person who 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;
- (c) **“college”** means the College of Physicians and Surgeons of the Province of Saskatchewan;
- (d) **“council”** means the council of the college;
- (e) **“department”** means the department over which the minister presides;
- (f) **“differential diagnosis”** means the determination of which one of two or more diseases or conditions a patient is suffering from by systematically comparing and contrasting the clinical findings;
- (g) **“internal quality control program”** means a program in which the reliability of test results performed in a medical laboratory is continually monitored;
- (h) **“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) qualifies for certified membership in:
 - (A) the Canadian Society of Laboratory Technologists; and
 - (B) the Saskatchewan Society of Medical Laboratory Technologists;
- (i) **“proficiency testing program”** means a program in which specimens of quality control materials are sent periodically to a medical laboratory for analysis and comparison of the results of that medical laboratory with the results of other laboratories for the purpose of ensuring that the processes and activities of that medical laboratory meet acceptable standards;

(j) **“quality assurance program”** means an organized system for continuously studying the processes and activities of a medical laboratory for the purpose of ensuring that those processes and activities meet acceptable standards;

(k) **“Saskatchewan health services number”** means the number assigned by the department for the purpose of administering *The Saskatchewan Hospitalization Act* and *The Saskatchewan Medical Care Insurance Act*;

(l) **“satellite laboratory”** means a medical laboratory affiliated with a main laboratory:

(i) that is in a category established pursuant to section 6 other than Category I, II or XI; and

(ii) the manager of which is responsible for the satellite laboratory.

(2) For the purposes of subclause 2(e)(iv) of the Act and in these regulations, laboratories and portions of laboratories that are used exclusively for medical or scientific research are not medical laboratories.

15 Mar 91 cM-9.1 Reg 1 s2.

Consultation by board

3(1) The board shall consult with and consider the recommendations of the minister and the council on all matters that come before it with respect to:

- (a) the issuance of licences;
- (b) the imposition of terms and conditions of licences;
- (c) the suspension, amendment or cancellation of licences; and
- (d) the establishment and regulation of quality assurance programs.

(2) The board may consult with the council on any matter that comes before the board, and the council may refer any matter on which it is consulted to a committee of the college.

15 Mar 91 cM-9.1 Reg 1 s3.

Assessment of need

4 For the purposes of paragraph 9(1)(a)(i)(A) of the Act, the board shall, in assessing the need for a medical laboratory or a test to be performed in a medical laboratory, consider:

(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;
- (iv) the proficiency testing record of existing medical laboratories;
- (b) the costs of providing additional testing:
 - (i) in existing medical laboratories; and
 - (ii) in the proposed new medical laboratory;
- (c) whether a new medical laboratory or additional testing would result in an unnecessary duplication of services;
- (d) in the case of an application to perform a test, the medical relevancy of the test;
- (e) the quality of patient care;
- (f) the convenience of patients; and
- (g) any other criteria that the board considers relevant.

15 Mar 91 cM-9.1 Reg 1 s4.

Confidentiality

5(1) Except as provided in subsection (2), a member of the board shall keep confidential any information with respect to:

- (a) the licensing or proposed licensing of any laboratory; and
 - (b) the operation of any medical laboratory;
- that comes to the attention of the member while carrying out any duties pursuant to the Act or the regulations.
- (2) A member of the board may disclose information described in subsection (1) if:
- (a) the member is authorized by the board or the minister to do so;
 - (b) the member is required by law to do so;
 - (c) the disclosure is made for the purpose, and in anticipation, of a judicial proceeding;
 - (d) the disclosure is necessary for the administration of the Act or these regulations;
 - (e) the disclosure is made on the request or with the written approval of the person to whom the information relates; or
 - (f) the disclosure is made to any official in the department.
- (3) Subject to subsection (4), the council and every member of a committee of the college mentioned in subsection 3(2) shall keep confidential any information that comes to their attention as a result of a consultation pursuant to section 3.

(4) Subsection (2) applies, with any necessary modification, to the council and to every member of a committee of the college mentioned in subsection 3(2).

15 Mar 91 cM-9.1 Reg 1 s5.

Categories of laboratories

6 The following categories of medical laboratories are established:

- (a) Category I, comprising the medical laboratories that are List 1 Laboratories in the physician payment schedule within the meaning of *The Medical Care Insurance Payment Regulations*, as amended from time to time;
- (b) Category II, comprising the medical laboratories that are List 2 Laboratories in the physician payment schedule within the meaning of *The Medical Care Insurance Payment Regulations*, as amended from time to time;
- (c) Category III, comprising the medical laboratories that are List 3 Laboratories in the physician payment schedule within the meaning of *The Medical Care Insurance Payment Regulations*, as amended from time to time;
- (d) Category IV, comprising the medical laboratories that are satellite laboratories;
- (e) Category V, comprising the medical laboratories in the hospitals that are set out in Part I of the Appendix;
- (f) Category VI, comprising the medical laboratories in the hospitals that are set out in Part II of the Appendix;
- (g) Category VII, comprising the medical laboratories in the hospitals that are set out in Part III of the Appendix;
- (h) Category VIII, comprising the medical laboratories in the hospitals that are set out in Part IV of the Appendix;
- (i) Category IX, comprising the medical laboratories established and operated pursuant to subsection 8(1) of *The Department of Health Act*;
- (j) Category X, comprising the medical laboratories operated by the Canadian Red Cross Society;
- (k) Category XI, comprising the medical laboratories:
 - (i) in which tests are performed on specimens for purposes other than the diagnosis, prophylaxis or treatment of a person by a duly qualified medical practitioner; and
 - (ii) that are not within the scope of any category of medical laboratory described in clauses (a) to (j).

15 Mar 91 cM-9.1 Reg 1 s6.

Application

7 An application for a licence pursuant to section 8 of the Act is to be in writing on a form supplied by the board.

15 Mar 91 cM-9.1 Reg 1 s7.

Manager

8 No licensee shall employ as manager of a medical laboratory a person who is not a qualified professional within the meaning of section 9.

15 Mar 91 cM-9.1 Reg 1 s8.

Qualified professional

9(1) With respect to Category I and Category II medical laboratories, a duly qualified medical practitioner is a qualified professional.

(2) With respect to Category III and Category IV medical laboratories:

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

- (i) general pathology;
- (ii) haematological pathology;
- (iii) medical biochemistry;
- (iv) medical microbiology;
- (v) anatomical pathology; or
- (vi) neuropathology; or

(b) a duly qualified medical practitioner who:

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

- (A) haematology;
- (B) infectious diseases; or
- (C) clinical immunology and allergy; and

(ii) has at least two years' experience in laboratory medicine;

is a qualified professional.

(3) With respect to Category V and Category XI medical laboratories:

- (a) duly qualified medical practitioners; and
- (b) medical laboratory technologists;

are qualified professionals.

(4) With respect to Category VI medical laboratories:

- (a) duly qualified medical practitioners; and
- (b) persons who hold academic doctorate degrees in relevant chemical, physical or biological sciences as approved in the licence;

are qualified professionals.

(5) With respect to Category VII, Category VIII and Category IX medical laboratories:

- (a) a duly qualified medical practitioner who has been granted certification by the Royal College of Physicians and Surgeons of Canada in:
 - (i) general pathology;
 - (ii) haematological pathology;
 - (iii) medical biochemistry;
 - (iv) medical microbiology;
 - (v) anatomical pathology; or
 - (vi) neuropathology;
- (b) a duly qualified medical practitioner who:
 - (i) has been granted certification by the Royal College of Physicians and Surgeons of Canada in:
 - (A) haematology;
 - (B) infectious diseases; or
 - (C) clinical immunology and allergy; and
 - (ii) has at least two years' experience in laboratory medicine; or
- (c) a person who holds an academic doctorate degree in a relevant chemical, physical or biological science as approved in the licence;

is a qualified professional.

(6) With respect to Category X medical laboratories, a duly qualified medical practitioner who has been granted certification by the Royal College of Physicians and Surgeons of Canada in a branch of medicine mentioned in subsection (2) is a qualified professional.

(7) With respect to a particular medical laboratory, a person who possesses the qualifications specified by the board in the licence is a qualified professional.

15 Mar 91 cM-9.1 Reg 1 s9.

Prohibition

10 No licensee shall cause or permit an individual to be the manager of more than one medical laboratory without the approval of the board.

15 Mar 91 cM-9.1 Reg 1 s10.

Staff

11(1) Subject to subsection 12(4), no licensee shall employ a person to perform tests in a medical laboratory unless that person:

- (a) possesses the qualifications set out in section 12; 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 12.

(2) For the purposes of subsection (1), a person who performs some portion of a test under the supervision of a person who:

- (a) possesses the qualifications set out in section 12; and
- (b) is responsible for the performance of the test;

is not, while performing that portion of a test, a person employed to perform tests in a medical laboratory.

15 Mar 91 cM-9.1 Reg 1 s11.

Qualifications of technical staff

12(1) A person employed to perform tests in a Category II, Category IV or Category V medical laboratory is to be:

- (a) a laboratory technologist currently eligible for certified practising membership in the Canadian Society of Laboratory Technologists; or
- (b) a certified combined laboratory and X-ray technician.

(2) A person employed to perform tests in a Category III medical laboratory is to be a laboratory technologist currently eligible for certified practising membership in the Canadian Society of Laboratory Technologists.

(3) A person employed to perform tests in a Category VI, Category VII, Category VIII, Category IX or Category X medical laboratory is to be:

- (a) a laboratory technologist currently eligible for certified practising membership in the Canadian Society of Laboratory Technologists; or
- (b) the holder of an academic bachelor's, master's or doctorate degree in a relevant chemical, physical or biological science as approved in the licence.

(4) A person employed to perform tests in a Category XI medical laboratory is to have the qualifications specified in the licence.

(5) Notwithstanding subsections (1) to (4), a medical laboratory 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 the person has:

- (a) experience in performing the tests that the person will be performing in the medical laboratory; and
- (b) the ability to perform those tests proficiently.

15 Mar 91 cM-9.1 Reg 1 s12.

Consultation services

13 A licensee of a Category I, Category II, Category V, Category VI, Category VII, Category VIII or Category IX medical laboratory that does not employ a pathologist in the medical laboratory shall obtain the services of a pathologist to:

- (a) provide education to employees in the medical laboratory;

- (b) assist the medical laboratory in maintaining an adequate level of performance; and
- (c) whenever the results of the proficiency testing program described in section 27 indicate that the medical laboratory is not performing adequately, assist the medical laboratory to become proficient.

15 Mar 91 cM-9.1 Reg 1 s13.

Adequacy

14 A licensee shall ensure that a medical laboratory has space, facilities, equipment and supplies that are adequate for the performance of the work that comes to the medical laboratory with accuracy, precision and efficiency in a manner that meets generally accepted standards.

15 Mar 91 cM-9.1 Reg 1 s14.

Proper condition

15 A licensee shall ensure that:

- (a) all equipment and instruments are maintained so that they operate within the manufacturer's specifications at all times;
- (b) a preventive maintenance schedule is developed and maintained for all equipment and instruments in use in the laboratory; and
- (c) all supplies are suitable and acceptable for the purposes for which they are used.

15 Mar 91 cM-9.1 Reg 1 s15.

Methods and procedures

16(1) A licensee shall ensure that:

- (a) subject to subsection (2), only standard methods and procedures that are generally accepted by the medical profession are used in the medical laboratory; and
- (b) a written manual setting out all procedures performed in the medical laboratory is developed and maintained.

(2) Where a licensee uses a method or procedure other than one described in clause (1)(a), the licensee shall, on the request of the board or a designate of the board, furnish proof that the method or procedure is accurate.

15 Mar 91 cM-9.1 Reg 1 s16.

Tests to be requested

17 A licensee shall ensure that, except in the case of Category XI medical laboratories, no tests, examinations or procedures are performed unless:

- (a) they are requested by a duly qualified medical practitioner or a dentist or dental surgeon who holds a valid and subsisting licence pursuant to *The Dental Profession Act*;

- (b) the manager requires further tests to reach a differential diagnosis; or
- (c) the licensee has been authorized by the board in the licence to accept tests from a person other than a person mentioned in clause (a).

15 Mar 91 cM-9.1 Reg 1 s17.

Collection of specimens

18 A licensee of a medical laboratory where specimens are to be collected shall ensure that the medical laboratory is equipped to provide for:

- (a) the comfort, safety and privacy of patients; and
- (b) the identification of specimens taken from patients.

15 Mar 91 cM-9.1 Reg 1 s18.

Identification of specimens

19(1) A licensee shall ensure that every test result can be correctly attributed to the person from whom the specimen was taken.

(2) A licensee shall ensure that every unit of blood, blood component or blood product that is cross-matched or administered to a patient is traceable to the patient and that patient's physician.

15 Mar 91 cM-9.1 Reg 1 s19.

Transportation of specimens

20 A licensee shall use methods for transporting specimens to the licensee's medical laboratory or to any other medical laboratory that will ensure that the physical integrity and composition of the specimens remain intact.

15 Mar 91 cM-9.1 Reg 1 s20.

Condition of specimens

21(1) Subject to subsection (2), a licensee shall ensure that no specimen is tested if the specimen is unsuitable for testing for any reason that may be sufficient to render the test results of doubtful validity.

(2) A licensee may permit the testing of a specimen that is unsuitable for testing for the reason set out in subsection (1) if the licensee ensures that the deficiencies in the specimen are identified in the records kept with respect to that specimen.

15 Mar 91 cM-9.1 Reg 1 s21.

Ill effects from transfusions

22 Whenever a licensee becomes aware of the occurrence of any significant serological transfusion effect or notifiable infectious disease suffered by a patient as a result of a transfusion of blood or blood products, the licensee shall immediately notify the Canadian Red Cross Society of the occurrence.

15 Mar 91 cM-9.1 Reg 1 s22.

Records required

23(1) A licensee shall ensure that a system of clear, concise records is established and maintained and that this system includes records of the continuity of specimens.

(2) A licensee shall ensure that each specimen that it refers to another laboratory is accompanied by the name, month and year of birth, sex and Saskatchewan health services number of the patient from whom the specimen was collected.

(3) A licensee shall ensure that all records, including worksheets, are kept for a period of not less than 25 months.

15 Mar 91 cM-9.1 Reg 1 s23.

Supervision

24 A licensee shall ensure that accurate and reliable test results are produced in the medical laboratory under the supervision of the manager.

5 Mar 91 cM-9.1 Reg 1 s24.

Quality assurance program

25 A licensee shall establish a quality assurance program that:

- (a) meets generally accepted standards; and
- (b) includes the programs required by sections 26 and 27.

Mar 91 cM-9.1 Reg 1 s25.

Internal quality control program

26(1) A licensee shall establish and operate an internal quality control program that includes:

- (a) the selection of appropriate test methods;
- (b) the prescribing of acceptable levels of variation of test results;
- (c) the prescribing of appropriate actions that are to be taken before acceptance or rejection of batches or analytical runs;
- (d) the development and maintenance of current procedure manuals; and
- (e) the making of records of all quality control test results at the time when the test results are obtained.

(2) A licensee shall ensure that the records mentioned in clause (1)(e) are retained for a period of not less than one year.

Mar 91 cM-9.1 Reg 1 s26.

Proficiency testing

27(1) A licensee shall ensure that the medical laboratory participates, in accordance with this section, in a proficiency testing program conducted by the board.

- (2) The board may submit specimens to a medical laboratory for the purposes of proficiency testing.
- (3) The licensee of a medical laboratory that receives specimens pursuant to subsection (2) shall:
- (a) ensure that, during normal working hours:
 - (i) the specimens are accepted;
 - (ii) the required tests are performed on the specimens in the medical laboratory;
 - (iii) the persons who, in the ordinary course of their work, perform tests in the medical laboratory participate equally in the testing of the specimens; and
 - (iv) the specimens are tested using the same methods used in testing ordinary clinical specimens;
 - (b) report the results of the tests promptly to the board on their completion; and
 - (c) ensure that the name of the person who performs each test appears legibly on the report.

Mar 91 cM-9.1 Reg 1 s27.

Lack of proficiency

28(1) Where the results of proficiency testing of a medical laboratory are, in the opinion of the board, unsatisfactory, the board shall notify the licensee in writing of those unsatisfactory results and specify the nature of the problem.

- (2) A licensee who has received a notice pursuant to subsection (1) shall:
- (a) take all practicable steps to rectify the problem; and
 - (b) co-operate with the board in rectifying the problem.
- (3) A licensee shall, within 14 days after receiving the notice mentioned in subsection (1), provide the board with a written statement setting out all the measures that the licensee has employed or intends to employ in the medical laboratory to rectify the problem.
- (4) If:
- (a) the board is not satisfied that the measures set out in the statement mentioned in subsection (3) will be sufficient to rectify the problem; or
 - (b) the licensee fails to furnish a statement in accordance with subsection (3);
- the board may direct the licensee to take any measures that the board considers necessary to rectify the problem.
- (5) A licensee shall comply promptly with any direction of the board pursuant to subsection (4).

Mar 91 cM-9.1 Reg 1 s28.

Forms

29 A licensee shall ensure that all test requisition forms and report forms used in the medical laboratory are forms that are approved by the board.

Mar 91 cM-9.1 Reg 1 s29.

Appendix**PART I**

[*clause 6(e)*]

Category V Laboratories (Rural Hospitals)

Arborfield Union Hospital
Assiniboia Union Hospital
Balcarres Union Hospital
Beechy Union Hospital
Bengough Union Hospital
Bienfait Coalfields Union Hospital
Big River Union Hospital
Biggar Union Hospital
Birch Hills Memorial Union Hospital
Borden Union Hospital
Border Union Hospital, Climax
Broadview Union Hospital
Brock Union Hospital, Arcola
Cabri Union Hospital
Canora Union Hospital
Carrot River Union Hospital
Central Butte Union Hospital
Coronach Union Hospital
Craig and District Health Centre
Cupar Union Hospital
Cut Knife Union Hospital
Davidson Union Hospital
Dinsmore Union Hospital/Prairie Manor Health Care Centre
Doddsland Union Hospital
The Eastend Union Hospital
Eatonia Union Hospital
Elrose Union Hospital
Eston Union Hospital
Evergreen Health Centre, Leoville
Fillmore Union Health Centre Integrated Facility
Foam Lake Union Hospital
Fort Qu'Appelle Indian Hospital
Gainsborough and Area Union Hospital
L. Gervais Memorial Health Centre, Goodsoil
Grenfell Union Hospital
Gull Lake Union Hospital
Hafford Union Hospital

Herbert Morse Union Hospital
Hudson Bay Union Hospital
Indian Head Union Hospital
Invermay Canora Union Hospital
Ituna Union Hospital
Kamsack Union Hospital
Kelvington Union Hospital
Kerrobert Union Hospital
Kincaid Union Hospital
Kindersley Union Hospital
Kinistino Union Hospital
Kipling Memorial Union Hospital
Kyle and District Health Centre
Lady Minto Union Hospital, Edam
Lafleche Union Hospital
Lampman Union Hospital
Langenburg Union Hospital
Lanigan Union Hospital
La Ronge Hospital
Leader Union Hospital
Long Lake Valley Integrated Facility, Imperial
Loon Lake Union Hospital and Special Care Home
Lucky Lake Health Centre
Maidstone Union Hospital
Maple Creek Union Hospital
Meadow Lake Union Hospital
Midale Union Hospital
Milden Union Hospital
Montmartre Union Hospital
Moosomin Union Hospital
Neilburg and District Hospital
Nokomis Health Centre
Norquay Canora Union Hospital
Outlook Union Hospital
Oxbow Union Hospital
Pangman Union Hospital
Paradise Hill Union Hospital
Ponteix Union Hospital
Porcupine Carragana Union Hospital
Prairie View Health Centre, Mankota
Preeceville Union Hospital
Rabbit Lake Integrated Facility
Radville Community Hospital
Redvers Union Hospital
Riverside Memorial Union Hospital, Turtleford
Rockglen Union Hospital
Rose Valley Integrated Care Facility

Rosetown Union Hospital
 Rosthern Union Hospital
 St. Anthony's Hospital, Esterhazy
 St. Joseph's Hospital, Gravelbourg
 St. Joseph's Hospital, Ile a la Crosse
 St. Joseph's Hospital, Macklin
 St. Joseph's Union Hospital, Lestock
 St Martin's Hospital, La Loche
 St. Michael's Hospital, Cudworth
 St. Walburg Union Hospital
 Shaunavon Union Hospital
 Shellbrook Union Hospital
 Smeaton Union Hospital
 Spalding Union Hospital
 Spiritwood Union Hospital
 Theodore Union Hospital/Heritage Special Care Home Inc.
 Tisdale Union Hospital
 Unity Union Hospital
 Uranium City Hospital
 Vanguard Union Hospital
 Wadena Union Hospital
 Wakaw Union Hospital
 Watrous Union Hospital
 Watson Union Hospital
 Wawota Memorial Union Hospital
 Whitewood Moosomin Union Hospital
 Wilkie Union Hospital
 Wolseley Memorial Union Hospital
 Wynyard Union Hospital

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PART II
 [clause 6(f)]

Category VI Laboratories (Large Community Hospitals)

Lloydminster Hospital
 Melfort Union Hospital
 Nipawin Union Hospital
 St. Elizabeth's Hospital, Humboldt
 St. Joseph's General Hospital, Estevan
 St. Peter's Hospital, Melville
 Weyburn Union Hospital

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PART III
[*clause 6(g)*]

Category VII Laboratories (Regional Hospitals)

Battlefords Union Hospital, North Battleford
Holy Family Hospital, Prince Albert
Moose Jaw Union Hospital
Providence Hospital, Moose Jaw
Swift Current Union Hospital
Victoria Union Hospital, Prince Albert
Yorkton Union Hospital
Wascana Rehabilitation Centre, Regina

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PART IV
[*clause 6(h)*]

Category VIII Laboratories (Urban Hospitals)

Pasqua Hospital, Regina
Plains Health Centre, Regina
Regina General Hospital
Royal University Hospital, Saskatoon
St. Paul's Hospital, Saskatoon
Saskatoon City Hospital

15 Mar 91 cM-9.1 Reg 1.

