

The Medical Laboratory Licensing Act, 1994

being

Chapter M-9.2* of the *Statutes of Saskatchewan, 1994* (effective March 1, 1996) as amended by the *Statutes of Saskatchewan, 2002, c.R-8.2; 2013, c.S-15.1; 2015, c.F-15.11; and 2017, c.P-30.3.*

***NOTE:** Pursuant to subsection 33(1) of *The Interpretation Act, 1995*, the Consequential Amendment sections, schedules and/or tables within this Act have been removed. Upon coming into force, the consequential amendments contained in those sections became part of the enactment(s) that they amend, and have thereby been incorporated into the corresponding Acts. Please refer to the Separate Chapter to obtain consequential amendment details and specifics.

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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CHAPTER M-9.2

An Act respecting the Licensing and Operation of Medical Laboratories

SHORT TITLE AND INTERPRETATION

Short title

1 This Act may be cited as *The Medical Laboratory Licensing Act, 1994*.

Interpretation

2 In this Act:

- (a) **“accreditation program”** means a program to determine whether a medical laboratory meets standards of quality assurance that are acceptable to the minister or the person who or association that operates the accreditation program;
- (b) **“applicant”** means an applicant for a licence;
- (c) **“director”** means the director of the medical laboratory licensing program appointed pursuant to section 3 and includes any deputy director appointed pursuant to that section;
- (d) **“licence”** means a valid licence granted pursuant to section 6;
- (e) **“licensee”** means a person to whom a licence has been granted;
- (f) **“medical laboratory”** means a place where a test is performed or where a specimen is taken or collected for the purpose of transporting it to another medical laboratory where it is to be tested, but does not include:
 - (i) the office of a duly qualified medical practitioner where:
 - (A) every specimen is taken or collected by that practitioner, or by a person who is employed in the office under the direct supervision of that practitioner, for a purpose that is directly related to the provision of medical services by that practitioner to the person from whom the specimen is taken or collected; and
 - (B) specimens are not tested;
 - (ii) a place of residence where:
 - (A) specimens are not taken or collected from any person other than a resident of that place; and
 - (B) specimens are not examined or analyzed by a person other than the person from whom the specimens are taken or collected;

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- (iii) with respect to a facility designated as a hospital pursuant to *The Provincial Health Authority Act*, a part of the hospital where specimens are not examined or analyzed; or
- (iv) a place or category of places that is exempted in the regulations;
- (g) **“minister”** means the member of the Executive Council to whom for the time being the administration of this Act is assigned;
- (h) **“qualified professional”** means an individual who:
 - (i) is a member of a category of persons designated in the regulations as qualified professionals; or
 - (ii) is designated in a licence as a qualified professional;
- (i) **“test”** means the examination or analysis of a specimen taken or collected from a human body to obtain information for:
 - (i) screening;
 - (ii) diagnosis;
 - (iii) prophylaxis;
 - (iv) treatment; or
 - (v) any other health-related purpose.

1994, c.M-9.2, s.2; 2002, c.R-8.2, s.106; 2017,
cP-30.3, s.11-1.

DIRECTOR

Director

3 The minister may appoint an employee of the Department of Health as the director of the medical laboratory licensing program and may appoint one or more other employees of the Department of Health as deputy directors for the purposes of this Act.

1994, c.M-9.2, s.3.

LICENCE

Licence required

4 No person shall operate a medical laboratory unless that person holds a licence that authorizes that person to do so.

1994, c.M-9.2, s.4.

Application

5 An applicant for a licence shall:

- (a) submit to the director:
 - (i) an application in writing on a form supplied by the director; and
 - (ii) the application fee in the amount prescribed in the regulations; and
- (b) provide any information or material that the director requests and considers relevant to the application.

1994, c.M-9.2, s.5.

Granting of licence

6(1) The director shall:

- (a) consider each application received pursuant to section 5, including any information or materials requested by the director; and
- (b) consider the standards of the accreditation program for the medical laboratory that is the subject of the application.

(2) The director shall:

- (a) grant the licence if the director is satisfied that:
 - (i) there is a need, based on factors set out in the regulations, for the medical laboratory that is the subject of the application and for the tests that are to be performed in that laboratory;
 - (ii) the medical laboratory that is the subject of the application will be operated in compliance with this Act, the regulations and any terms and conditions contained in the licence; and
 - (iii) granting a licence to the applicant would not be contrary to the public interest; or
- (b) refuse to grant a licence.

(3) The director shall notify the applicant in writing of his or her decision.

(4) The director may include as provisions of a licence any terms or conditions that the director considers appropriate, including, without limiting the generality of the foregoing, any terms or conditions that constitute standards of the accreditation program.

1994, c.M-9.2, s.6.

Qualified professional

7(1) Subject to the regulations, a licensee must employ or engage the services of a qualified professional for the medical laboratory for which the licence is granted.

(2) Every licence must contain the name of the qualified professional of the medical laboratory for which the licence is granted.

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(3) Where the qualified professional named in the licence granted for a medical laboratory ceases to be the qualified professional, the licensee shall immediately provide the director with the name of another qualified professional who is to replace that qualified professional.

1994, c.M-9.2, s.7.

Duties of licensee

8 No licensee shall fail to:

- (a) comply with any term or condition contained in the licence or any standard prescribed in the regulations; or
- (b) take part in the accreditation program.

1994, c.M-9.2, s.8.

Duration of licence

9(1) Subject to subsection (2) and section 11, a licence is valid for:

- (a) the period specified in the licence; or
- (b) where no period is specified in the licence, a period of one year after the day on which the licence is granted.

(2) No licence is to be granted for a period greater than three years.

1994, c.M-9.2, s.9.

Licence not transferable

10 A licence is not transferable.

1994, c.M-9.2, s.10.

Suspension or cancellation

11(1) The director may amend, suspend or cancel a licence where, in the opinion of the director, the licensee:

- (a) has failed to comply with:
 - (i) a provision of this Act or the regulations; or
 - (ii) a term or condition contained in the licence;
- (b) has failed to take part in the accreditation program; or
- (c) is operating the medical laboratory in a manner that is contrary to the public interest.

(2) For the purposes of section 4, a licence that is suspended pursuant to this section is, for the period of the suspension, deemed to have not been granted.

1994, c.M-9.2, s.11.

Appeal

12(1) In this section, “**aggrieved person**” means a person who is aggrieved by a decision of the director to:

- (a) refuse to grant a licence;
- (b) place a term or condition in a licence; or
- (c) amend, suspend or cancel a licence.

(2) An aggrieved person may appeal a decision of the director to the minister within 30 days after the decision is made by:

- (a) serving the minister with a written notice setting out the grounds of appeal; and
- (b) providing the minister with any information and materials that may be prescribed in the regulations.

(3) On hearing an appeal, the minister may:

- (a) dismiss the appeal;
- (b) vary the decision of the director; or
- (c) substitute the minister’s own decision for that of the director.

(4) The director shall take all necessary steps to comply with the minister’s decision.

(5) The minister may appoint any person to perform the duties and exercise the powers of the minister respecting appeals pursuant to this section.

1994, c.M-9.2, s.12.

GENERAL**Request for information**

13(1) The director may:

- (a) request from a licensee any information that the director requires for the purposes of this Act and the regulations; and
- (b) specify the manner in which, and reasonable time limits within which, the licensee shall provide the information mentioned in clause (a).

(2) No licensee shall fail to provide the director, in the manner and within the reasonable time limits specified by the director, with any information that the director requests pursuant to subsection (1).

1994, c.M-9.2, s.13.

Inspection

14(1) For the purposes of administering this Act and the regulations, the director or any person designated by the director for the purpose may make any inspection, investigation or inquiry that the director or that person considers necessary.

(2) Every licensee shall:

(a) cause the medical laboratory for which the licence is granted to be open for inspection by the director or a person designated pursuant to subsection (1) at all reasonable times during the hours of operation of the medical laboratory; and

(b) cause all books, documents, records, specimens and equipment pertaining to the operation of the medical laboratory to be available for inspection by the director or a person designated pursuant to subsection (1) during the times described in clause (a).

(3) The director or a person appointed pursuant to subsection (1) shall not enter a private dwelling without a warrant issued pursuant to section 15 unless the occupant of the dwelling consents to the entry.

1994, c.M-9.2, s.14.

Warrant

15(1) A justice of the peace or a judge of the Provincial Court of Saskatchewan may issue a warrant authorizing the director or a person designated pursuant to subsection 14(1) to enter and search any place or premises named in the warrant where the director or person believes, on reasonable and probable grounds, that:

(a) an offence against this Act has been committed; and

(b) there is evidence of the offence to be found at the place or premises proposed to be searched.

(2) With a warrant issued pursuant to subsection (1), the director or a person designated pursuant to subsection 14(1) may:

(a) enter and search any place or premises named in the warrant;

(b) use any machinery, equipment, appliance or thing located at the place or premises for the purposes of the search;

(c) require the production of and examine any books, records, papers or documents that the director or person believes, on reasonable and probable grounds, may contain information related to an offence against this Act;

(d) subject to section 16, remove any books, records, papers or documents examined pursuant to this section for the purpose of making copies, if a receipt is given; and

(e) seize and remove from any place or premises searched anything that may be evidence of an offence against this Act.

(3) No person shall obstruct any person who is authorized to conduct a search pursuant to this section.

1994, c.M-9.2, s.15.

Copies of documents

- 16(1)** Where any books, records, papers or documents are inspected pursuant to section 14 or seized, examined or produced pursuant to section 15, the director or any person designated pursuant to subsection 14(1) may make copies of those books, records, papers or documents.
- (2) Any person authorized to make copies pursuant to subsection (1) shall:
- (a) make those copies as soon as is reasonably possible; and
 - (b) promptly return the books, records, papers or documents from which the copies were made to:
 - (i) the place from which they were removed; or
 - (ii) any other place that may be agreed to by the person authorized to make copies and the person who furnished them or from whom they were seized.
- (3) A document certified by the minister to be a copy made pursuant to this section:
- (a) is admissible in evidence without proof of the office or signature of that person appearing to have certified the document; and
 - (b) has the same probative force as the original document.

1994, c.M-9.2, s.16.

Regulations

- 17(1)** For the purpose of carrying out this Act according to its intent, the Lieutenant Governor in Council may make regulations:
- (a) defining, enlarging or restricting the meaning of any word or expression used in this Act but not defined in this Act;
 - (b) establishing categories of applicants, licensees, qualified professionals, other persons, medical laboratories, licences or tests;
 - (c) exempting any person or category of persons from all or any of the provisions of this Act;
 - (d) exempting any place or category of places from the definition of medical laboratory for the purposes of subclause 2(f)(iv);
 - (e) designating categories of persons as qualified professionals for the purposes of clause 2(h);
 - (f) prescribing the amount of the application fee for the purposes of subclause 5(a)(ii);
 - (g) establishing factors for determining the need for a medical laboratory or a test for the purposes of subclause 6(2)(a)(i);
 - (h) governing appeals pursuant to section 12;
 - (i) governing the operation of medical laboratories;

- (j) without limiting the generality of clause (i):
 - (i) respecting the performance of tests in medical laboratories;
 - (ii) prescribing the qualifications and duties of licensees and persons who work in medical laboratories;
 - (iii) establishing standards for facilities in which medical laboratories are located;
 - (iv) establishing standards for the operation of medical laboratories;
 - (v) requiring and governing the making, maintaining and retaining of records by licensees;
 - (k) governing the accreditation program with respect to the operation of medical laboratories and authorizing the minister to designate the person who or association that will establish and operate the accreditation program;
 - (l) respecting confidentiality and access to information with respect to:
 - (i) the administration of this Act and the regulations; or
 - (ii) the operation of a medical laboratory;
 - (m) prescribing any matter or thing required or authorized by this Act to be prescribed in the regulations;
 - (n) respecting any other matter or thing that the Lieutenant Governor in Council considers necessary to carry out the intent of this Act.
- (2) If a provision of a regulation made pursuant to subsection (1) conflicts with:
- (a) a bylaw made pursuant to *The Medical Profession Act, 1981*;
 - (b) a provision of:
 - (i) *The Dangerous Goods Transportation Act*;
 - (ii) *The Environmental Management and Protection Act*;
 - (iii) *The Fire Safety Act*;
 - (iv) Part III of *The Saskatchewan Employment Act*;
 - (v) Part III of *The Saskatchewan Employment Act*; or
 - (vi) *The Uniform Building and Accessibility Standards Act*; or
 - (c) a regulation made pursuant to any of the Acts mentioned in clause (b);
- the bylaw or the provision of that Act or the regulation made pursuant to one of those Acts prevails.

Offence

18 Every person who contravenes any provision of this Act or the regulations is guilty of an offence and liable on summary conviction:

- (a) in the case of an individual, to a fine of not more than \$1,000 and, in the case of a continuing offence, to a further fine of not more than \$100 for each day during which the offence continues;
- (b) in the case of a corporation, to a fine of not more than \$5,000 and, in the case of a continuing offence, to a further fine of not more than \$500 for each day during which the offence continues.

1994, c.M-9.2, s.18.

Limitation on prosecution

19 No prosecution with respect to an alleged offence pursuant to this Act or the regulations is to be commenced after two years from the day of the commission of the alleged offence.

1994, c.M-9.2, s.19.

No action against minister, etc.

20 No action lies or shall be instituted against the minister, the director or any person or association designated by the minister pursuant to clause 17(1)(k) where the minister, director or designated person or association is acting pursuant to the authority of this Act or the regulations, for any loss or damage suffered by a person by reason of anything in good faith done, caused, permitted or authorized to be done, attempted to be done or omitted to be done, by any of them, pursuant to or in the exercise or supposed exercise of any power conferred by this Act or the regulations or in the carrying out or supposed carrying out of any duty imposed by this Act or the regulations.

1994, c.M-9.2, s.20.

REPEAL, TRANSITIONAL AND COMING INTO FORCE

21 **Dispensed.** This section makes consequential amendments to another Act. The amendments have been incorporated into the corresponding Act.

Transitional

22 Every valid licence granted pursuant to *The Medical Laboratory Licensing Act* that is in force on the day on which section 6 comes into force is continued pursuant to this Act and may be dealt with as if it were granted pursuant to this Act.

1994, c.M-9.2, s.22.

