



[Français](#)

## Laboratory and Specimen Collection Centre Licensing Act

R.S.O. 1990, CHAPTER L.1

**Consolidation Period:** From March 30, 2011 to the [e-Laws currency date](#).

Last amendment: 2011, c. 1, Sched. 6, s. 6.

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#### Definitions

[1.](#) In this Act,

“Minister” means Minister of Health and Long-Term Care; (“ministre”)

“Ministry” means Ministry of Health and Long-Term Care. (“ministère”) R.S.O. 1990, c. L.1, s. 1; 2006, c. 19, Sched. L, s. 11 (2, 3).

[2.-4.](#) Repealed: 2006, c. 19, Sched. L, s. 6 (1).

#### HEALTH FACILITIES

#### Definitions

[5.](#) In this section and in sections 6 to 20,

“Director” means the Director of Laboratory and Specimen Collection Centre Licensing

appointed under section 6; (“directeur”)

“inspector” means an inspector appointed under section 16; (“inspecteur”)

“laboratory” means an institution, building or place in which operations and procedures for the microbiological, serological, chemical, hematological, biophysical, immunohematological, cytological, pathological, cytogenetic, molecular genetic or genetic examination, or such other examinations as are prescribed by the regulations, of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis or treatment; (“laboratoire”)

**Note: On a day to be named by proclamation of the Lieutenant Governor, the definition of “laboratory” is repealed by the Statutes of Ontario, 2007, chapter 10, Schedule P, section 18 and the following substituted:**

“laboratory” means an institution, building or place in which operations and procedures for the microbiological, serological, chemical, hematological, biophysical, immunohematological, cytological, pathological, cytogenetic, molecular genetic or genetic examination, or such other examinations as are prescribed by the regulations, of specimens taken from the human body are performed to obtain information for medical diagnosis, prophylaxis or treatment; (“laboratoire”)

**See: 2007, c. 10, Sched. P, ss. 18, 21 (2).**

“operator” means a person having charge or control of a laboratory or a specimen collection centre; (“exploitant”)

“quality management program” means a quality management program provided for in section 19; (“programme de gestion de la qualité”)

“regulations” means the regulations made under section 18; (“règlements”)

“Review Board” means the Health Services Appeal and Review Board under the *Ministry of Health and Long-Term Care Appeal and Review Boards Act, 1998*; (“Commission de révision”)

“specimen collection centre” means a place where specimens are taken or collected from the human body for examination to obtain information for diagnosis, prophylaxis or treatment, but does not include,

- (a) a place where a legally qualified medical practitioner is engaged in the practice of medicine or surgery,
- (b) a place where a registered nurse who holds an extended certificate of registration under the *Nursing Act, 1991* is engaged in the practice of nursing,
- (b.1) a place where a member of the College of Dietitians of Ontario is engaged in the practice of dietetics,
- (b.2) a place where a member of the College of Midwives of Ontario is engaged in the practice of midwifery, or
- (c) a laboratory that is established, operated or maintained under a licence under this Act; (“centre de prélèvement”)

**Note: On a day to be named by proclamation of the Lieutenant Governor, the definition of “specimen collection centre” is repealed by the Statutes of Ontario, 2007, chapter 10, Schedule P, section 18 and the following substituted:**

“specimen collection centre” means a place where specimens are taken or collected from the human body for examination to obtain information for medical diagnosis, prophylaxis or treatment, but does not include,

- (a) a place where a legally qualified medical practitioner is engaged in the practice of medicine or surgery,
- (b) a place where a registered nurse who holds an extended certificate of registration under the *Nursing Act, 1991* is engaged in the practice of nursing, or

**Note: On a day to be named by proclamation of the Lieutenant Governor, the definition of “specimen collection centre” is amended by striking out “or” at the end of clause (b) and by adding the following clauses:**

- (b.1) a place where a member of the College of Dietitians of Ontario is engaged in the practice of dietetics,
- (b.2) a place where a member of the College of Midwives of Ontario is engaged in the practice of midwifery, or

**See: 2009, c. 26, ss. 12 (2), 27 (2).**

- (c) a laboratory that is established, operated or maintained under a licence under this Act; (“centre de prélèvement”)

**See: 2007, c. 10, Sched. P, ss. 18, 21 (2).**

“test” means a procedure for carrying out an examination in a laboratory. (“test”) R.S.O. 1990, c. L.1, s. 5; 1998, c. 18, Sched. G, s. 62 (2); 2006, c. 19, Sched. L, s. 6 (2, 3); 2007, c. 10, Sched. J, s. 2; 2009, c. 26, s. 12 (1); 2009, c. 33, Sched. 18, s. 17 (2).

## **Director**

**6.** The Minister shall appoint an officer of the Ministry to be the Director of Laboratory and Specimen Collection Centre Licensing for purposes of sections 5 to 18. R.S.O. 1990, c. L.1, s. 6.

**7.** Repealed: 1998, c. 18, Sched. G, s. 62 (3).

## **Protection from personal liability**

**8.** No action or other proceeding for damages shall be instituted against the Director or anyone acting under the authority of the Director for any act done in good faith in the execution or intended execution of his or her duty or for any alleged neglect or default in the execution in good faith of his or her duty. 1998, c. 18, Sched. G, s. 62 (4).

## **Licence required**

**9. (1)** No person shall establish, operate or maintain a laboratory except under the authority of a licence issued by the Director under this Act and the Director may issue a licence for a laboratory to perform such classes of tests or such tests within a class or classes of tests and subject to such conditions as the Director may specify in the licence. R.S.O. 1990, c. L.1, s. 9 (1).

**Issuance of licence**

(2) Subject to subsection (8), any person who applies in accordance with this Act and the regulations for a licence to establish, operate or maintain a laboratory and who meets the requirements of this Act and the regulations and who pays the prescribed fee is entitled to be issued the licence. R.S.O. 1990, c. L.1, s. 9 (2).

**Licence required for specimen collection centre**

(3) No person shall establish, operate or maintain a specimen collection centre except under the authority of a licence issued by the Director under this Act and the Director may issue a licence for a specimen collection centre to take or collect such specimens or class or classes of specimens and subject to such conditions as the Director may specify in the licence. R.S.O. 1990, c. L.1, s. 9 (3).

**Issuance of licence for specimen collection centre**

(4) Subject to subsection (8), any person who applies in accordance with this Act and the regulations for a licence to establish, operate or maintain a specimen collection centre and who meets the requirements of this Act and the regulations and who pays the prescribed fee is entitled to be issued the licence. R.S.O. 1990, c. L.1, s. 9 (4).

**Where proposal not in public interest**

(5) Except in the case of a specimen collection centre that was in operation immediately before the 10th day of June, 1974 and despite subsections (2) and (4), where an application is made for a licence and the Minister states in writing to the Director that it is not in the public interest to issue a licence to establish, operate or maintain the laboratory or specimen collection centre, as the case may be, in the area where the applicant proposes to establish, operate or maintain the laboratory or specimen collection centre, section 11 shall not apply and the Director shall not issue the licence to the applicant and shall give written notice to the applicant of the refusal and of the Minister's statement. R.S.O. 1990, c. L.1, s. 9 (5).

**Idem**

(6) Except in the case of a specimen collection centre that was in operation immediately before the 10th day of June, 1974 and despite subsections (2) and (4), where an application is made for a licence and the Minister states in writing to the Director that it is not in the public interest to issue a licence,

- (a) in the case of a laboratory, for any of such classes of tests or any of the tests within a class or classes of tests in respect of which the application is made; or
- (b) in the case of a specimen collection centre, to take or collect such specimens or class or classes of specimens in respect of which the application is made,

sections 10 and 11 shall not apply, and where the Director issues a licence to the applicant upon such application the Director shall give written notice to the applicant of the Minister's statement and the licence shall not be for such classes of tests or such tests within a class or classes of tests or for taking or collecting such specimens or class or classes of specimens as are set out in the Minister's statement. R.S.O. 1990, c. L.1, s. 9 (6).

**Matters to be considered by Minister**

(7) In considering,

- (a) under subsection (5), whether it is in the public interest to issue a licence,

- (i) to establish, operate or maintain a laboratory in an area, or
  - (ii) to establish, operate or maintain a specimen collection centre in an area; or
- (b) under subsection (6), whether it is in the public interest,
- (i) in the case of a laboratory, to limit the classes of tests or the tests within a class or classes of tests, or
  - (ii) in the case of a specimen collection centre, to limit the specimens or class or classes of specimens,
- in respect of which the Director may issue a licence to the applicant,

the Minister shall take into account,

- (c) the number of laboratories or specimen collection centres, as the case requires, that operate under the authority of licences issued under this Act,
  - (i) in the area, or
  - (ii) in the area and any other area;
- (d) the number of laboratories or specimen collection centres, as the case requires, operated by a Ministry or Ministries of the Crown,
  - (i) in the area, or
  - (ii) in the area and any other area;
- (e) the tests and classes of tests performed in the laboratories or the specimens or class or classes of specimens taken or collected in the specimen collection centres, as the case requires,
  - (i) in the area, or
  - (ii) in the area and any other area;
- (f) the utilization of existing laboratories or specimen collection centres, as the case requires, and their capacity to handle increased volume;
- (g) the availability of facilities for the transportation of persons and specimens to laboratories or for the transportation of persons to specimen collection centres, as the case requires,
  - (i) in the area, or
  - (ii) in the area and any other area; or
- (h) the funds available to provide payment for laboratory tests that are insured services under the *Health Insurance Act*. R.S.O. 1990, c. L.1, s. 9 (7).

### **Grounds for refusal**

(8) Subject to section 11, the Director may refuse to issue a licence where in his or her opinion,

- (a) the past conduct of the applicant or, where the applicant is a corporation, of its officers or directors affords reasonable grounds for belief that the laboratory or specimen collection centre will not be operated in accordance with the law and with honesty and

integrity;

- (b) the proposed laboratory or specimen collection centre or its operation would contravene this Act or the regulations or any other Act or regulation or any municipal by-law respecting its establishment or location;
- (c) the applicant is not competent to operate a laboratory or specimen collection centre, as the case requires, in accordance with this Act and the regulations;
- (d) the equipment and premises are not suitable for the performance of the tests or the taking or collecting of the specimens for which the licence is sought. R.S.O. 1990, c. L.1, s. 9 (8).

### **Provisional licence**

[\(9\)](#) Where the applicant for a licence does not meet all the requirements for issuance of the licence and requires time to meet such requirements, the Director may issue a provisional licence for the laboratory or specimen collection centre. R.S.O. 1990, c. L.1, s. 9 (9).

### **Expiration and renewal of provisional licence**

[\(10\)](#) A provisional licence expires six months after the date of its issue but may be renewed by the Director for two further six-month periods where in the opinion of the Director sufficient progress in complying with the requirements for issuance of a licence has been made. R.S.O. 1990, c. L.1, s. 9 (10).

### **Expiration and renewal of licence**

[\(11\)](#) A licence that is not a provisional licence expires twelve months from the date of its issue or renewal and a renewal shall be issued where the applicant is not disqualified under subsection (17). R.S.O. 1990, c. L.1, s. 9 (11).

### **Stay of refusal to renew**

[\(12\)](#) Where the Director refuses to renew a licence, the laboratory or specimen collection centre shall be deemed to continue to be licensed until an order is made by the Review Board or until the time for requiring a hearing by the Review Board expires, whichever occurs first. R.S.O. 1990, c. L.1, s. 9 (12); 1998, c. 18, Sched. G, s. 62 (1).

### **Operator to be named in licence**

[\(13\)](#) It is a condition of a licence that the operation of the laboratory or specimen collection centre be under the charge and control of the operator named in the licence as operator and that the ownership of the laboratory or specimen collection centre be only in the persons named in the licence as owners. R.S.O. 1990, c. L.1, s. 9 (13).

### **Conditions to laboratory licence**

- [\(14\)](#) It is a condition of a licence for a laboratory that,
- (a) the operation of the laboratory meet the requirements of a quality management program;
  - (b) the owner and the operator of the laboratory permit an agency designated in the regulations to carry out a quality management program;
  - (c) the owner of the laboratory pay the fees prescribed by the regulations for an assessment under a quality management program. 2006, c. 19, Sched. L, s. 6 (4).

### **Same**

**(15)** Where an agency designated in the regulations to carry out a quality management program reports to the Director that the operation of a laboratory does not meet the requirements of the program, the Director may impose any conditions upon the laboratory's licence that the Director considers necessary or advisable in order that the health of the public be protected. 2006, c. 19, Sched. L, s. 6 (4).

### **Notice of changes**

**(16)** Where the operator or the owner named in the licence is a corporation, the corporation shall notify the Director in writing within fifteen days of any change in the officers or directors of the corporation. R.S.O. 1990, c. L.1, s. 9 (16).

### **Revocation or suspension of licence**

**(17)** The Director may revoke or refuse to renew a licence where,

- (a) any person has made a false statement in the application for the licence or a renewal thereof or in any report, document or other information required to be furnished by this Act or the regulations or any other Act or regulation that applies to the laboratory or specimen collection centre;
- (b) any test authorized by the licence is incompetently performed;
- (c) any specimen taking or collecting authorized by the licence is incompetently carried out;
- (d) there is a breach of a condition of the licence;
- (e) the owner or the operator does not comply with this Act or the regulations;
- (f) the services that can be provided by the laboratory or specimen collection centre are misrepresented; or
- (g) a change in the officers or directors of any corporation which is an operator or owner of a laboratory or specimen collection centre named in the licence would afford grounds for refusing to issue a licence under clause (8) (a). R.S.O. 1990, c. L.1, s. 9 (17).

### **Hearing re terms of licence**

**10. (1)** Where the Director issues a licence under this Act and any party to the proceeding is dissatisfied with the terms and conditions thereof prescribed by the Director, the party may by written notice given to the Director and the Review Board require a hearing by the Review Board, and the Review Board shall appoint a time for and hold a hearing. R.S.O. 1990, c. L.1, s. 10 (1); 1998, c. 18, Sched. G, s. 62 (1).

### **Decision of Review Board**

**(2)** Pursuant to a hearing under subsection (1), the Review Board may affirm the terms and conditions prescribed for the licence by the Director or may cancel such terms and conditions or may prescribe such other terms and conditions for the licence in the place of those prescribed by the Director as it considers proper and such terms and conditions shall be terms and conditions of the licence. R.S.O. 1990, c. L.1, s. 10 (2); 1998, c. 18, Sched. G, s. 62 (1).

### **Proposal to refuse to issue, revoke or impose condition**

**11. (1)** Where the Director proposes to revoke or to refuse to issue or renew a licence or to impose a condition on an existing licence under this Act, the Director shall serve notice of his or her proposal, together with written reasons therefor, on the applicant in the case of a proposal to refuse to issue or renew the licence and on the owner and operator in the case of a proposal to

revoke or to impose a condition on the licence. R.S.O. 1990, c. L.1, s. 11 (1).

### **Notice**

(2) A notice under subsection (1) shall inform the applicant or the owner and operator that they are entitled to a hearing by the Review Board if they mail or deliver, within fifteen days after the notice under subsection (1) is served on them, notice in writing requiring a hearing by the Review Board and each of them may so require such a hearing. R.S.O. 1990, c. L.1, s. 11 (2); 1998, c. 18, Sched. G, s. 62 (1).

### **Powers of Director where no hearing**

(3) Where the applicant or the owner or operator do not require a hearing by the Review Board in accordance with subsection (2), the Director may carry out the proposal stated in the notice under subsection (1). R.S.O. 1990, c. L.1, s. 11 (3); 1998, c. 18, Sched. G, s. 62 (1).

### **Power of Review Board where hearing**

(4) Where an applicant or an owner or operator requires a hearing by the Review Board in accordance with subsection (2), the Review Board shall appoint a time for and shall hold the hearing and, on the application of the Director at the hearing, may by order direct the Director to carry out his or her proposal or refrain from carrying out the proposal and to take such action as the Review Board considers the Director ought to take in accordance with this Act and the regulations, and for such purposes the Review Board may substitute its opinion for that of the Director. R.S.O. 1990, c. L.1, s. 11 (4); 1998, c. 18, Sched. G, s. 62 (1).

### **Extension of time for requiring hearing**

(5) The Review Board may extend the time for the giving of notice requiring a hearing by an applicant or an owner or operator under this section either before or after the expiration of such time where it is satisfied that there are apparent grounds for granting relief to the applicant or the owner or operator pursuant to a hearing and that there are reasonable grounds for applying for the extension, and the Review Board may give such directions as it considers proper consequent upon the extension. R.S.O. 1990, c. L.1, s. 11 (5); 1998, c. 18, Sched. G, s. 62 (1).

### **Continuation of licence pending renewal**

(6) Where, within the time prescribed therefor or, if no time is prescribed, before the expiry of the licence, the owner or operator has applied for renewal of the licence and paid the prescribed fee, the licence shall be deemed to continue,

- (a) until the renewal is granted; or
- (b) where the owner or operator is served with notice that the Director proposes to refuse to grant the renewal, until the time for giving notice requiring a hearing by the Review Board has expired and, where a hearing is required, until the Review Board has made its decision. R.S.O. 1990, c. L.1, s. 11 (6); 1998, c. 18, Sched. G, s. 62 (1).

### **Parties**

12. (1) The Director, the applicant or the owner or operator who has required the hearing and such other persons as the Review Board may specify are parties to proceedings before the Review Board under this Act. R.S.O. 1990, c. L.1, s. 12 (1); 1998, c. 18, Sched. G, s. 62 (1).

### **Notice of hearing**

(2) Notice of a hearing under section 11 shall afford the applicant or the owner or operator a reasonable opportunity to show or to achieve compliance before the hearing with all lawful



requirements for the issue or retention of the licence. R.S.O. 1990, c. L.1, s. 12 (2).

### **Examination of documentary evidence**

(3) Any party to proceedings under section 11 shall be afforded an opportunity to examine before the hearing any written or documentary evidence that will be produced or any report the contents of which will be given in evidence at the hearing. R.S.O. 1990, c. L.1, s. 12 (3).

### **Members holding hearing not to have taken part in investigation, etc.**

(4) Members of the Review Board holding a hearing shall not have taken part before the hearing in any investigation or consideration of the subject-matter of the hearing and shall not communicate directly or indirectly in relation to the subject-matter of the hearing with any person or with any party or the representative of the party except upon notice to and opportunity for all parties to participate, but the Review Board may seek legal advice from an adviser independent from the parties and in such case the nature of the advice should be made known to the parties in order that they may make submissions as to the law. R.S.O. 1990, c. L.1, s. 12 (4); 1998, c. 18, Sched. G, s. 62 (1).

### **Recording of evidence**

(5) The oral evidence taken before the Review Board at a hearing shall be recorded and, if so required, copies of a transcript thereof shall be furnished upon the same terms as in the Superior Court of Justice. R.S.O. 1990, c. L.1, s. 12 (5); 1998, c. 18, Sched. G, s. 62 (1); 2006, c. 19, Sched. C, s. 1 (1).

### **Findings of fact**

(6) The findings of fact of the Review Board pursuant to a hearing shall be based exclusively on evidence admissible or matters that may be noticed under sections 15 and 16 of the *Statutory Powers Procedure Act*. R.S.O. 1990, c. L.1, s. 12 (6); 1998, c. 18, Sched. G, s. 62 (1).

(7) Repealed: 1998, c. 18, Sched. G, s. 62 (5).

### **Release of documentary evidence**

(8) Documents and things put in evidence at a hearing shall, upon the request of the person who produced them, be released to the person by the Review Board within a reasonable time after the matter in issue has been finally determined. R.S.O. 1990, c. L.1, s. 12 (8).

### **Appeal to court**

**13. (1)** Any party to the proceedings before the Review Board under this Act may appeal from its decision or order to the Divisional Court in accordance with the rules of court. R.S.O. 1990, c. L.1, s. 13 (1); 1998, c. 18, Sched. G, s. 62 (1, 6).

### **Record to be filed in court**

(2) Where any party appeals from a decision or order of the Review Board, the Review Board shall forthwith file in the Superior Court of Justice the record of the proceedings before it in which the decision was made, which, together with the transcript of evidence if it is not part of the Review Board's record, shall constitute the record in the appeal. R.S.O. 1990, c. L.1, s. 13 (2); 1998, c. 18, Sched. G, s. 62 (1); 2006, c. 19, Sched. C, s. 1 (1).

### **Minister entitled to be heard**

(3) The Minister is entitled to be heard, by counsel or otherwise, upon the argument of an appeal under this section. R.S.O. 1990, c. L.1, s. 13 (3).

### **Powers of court on appeal**

**(4)** An appeal under this section may be made on questions of law or fact or both and the court may affirm or may rescind the decision of the Review Board and may exercise all powers of the Review Board to direct the Director to take any action which the Review Board may direct him or her to take and as the court considers proper and for such purposes the court may substitute its opinion for that of the Director or of the Review Board, or the court may refer the matter back to the Review Board for rehearing, in whole or in part, in accordance with such directions as the court considers proper. R.S.O. 1990, c. L.1, s. 13 (4); 1998, c. 18, Sched. G, s. 62 (1).

### **Tests permitted**

**14. (1)** Every owner and operator of a laboratory shall ensure that no tests are performed in the laboratory other than tests authorized by the licence, and no person employed in the laboratory shall knowingly participate in such tests. R.S.O. 1990, c. L.1, s. 14 (1).

### **Specimen taking or collecting permitted**

**(2)** Every owner and operator of a specimen collection centre shall ensure that no specimen taking or collecting is carried out in the specimen collection centre other than specimen taking or collecting authorized by the licence, and no person employed in the specimen collection centre shall knowingly participate in such specimen taking or collecting. R.S.O. 1990, c. L.1, s. 14 (2).

### **Advertising**

**15. (1)** No person shall advertise or cause to be advertised the services of the laboratory, but any person may notify such classes of persons as are specified by the regulations respecting,

- (a) the name and address of the laboratory;
- (b) laboratory employees and the tests that are authorized to be performed under the laboratory licence;
- (c) the laboratory equipment and premises and list of procedures and tariff;
- (d) information as to new tests provided. R.S.O. 1990, c. L.1, s. 15 (1).

### **Idem**

**(2)** No person shall advertise or cause to be advertised the services of a specimen collection centre, but any person may notify such classes of persons as are specified by the regulations respecting,

- (a) the name and address of the specimen collection centre;
- (b) employees of the specimen collection centre and the specimens or class or classes of specimens that are authorized to be taken or collected under the specimen collection centre licence;
- (c) the equipment, premises, procedures and tariff of the specimen collection centre;
- (d) information as to new specimen taking or collecting provided. R.S.O. 1990, c. L.1, s. 15 (2).

### **Appointment of inspectors**

**16. (1)** The Minister may appoint one or more persons as inspectors for the purposes of sections 5 to 18 and the regulations and such appointments shall be in writing. R.S.O. 1990, c. L.1, s. 16 (1).

## **Certificate of appointment**

(2) The Minister shall issue every inspector appointed under subsection (1) a certificate of appointment and every inspector, in the execution of his or her duties under this section and the regulations, shall produce the certificate of appointment upon request. R.S.O. 1990, c. L.1, s. 16 (2).

## **Powers of inspectors**

(3) An inspector may at all reasonable times inspect the premises, operations, all records and test samples of all laboratories and specimen collection centres to ensure that the provisions of sections 5 to 18 and the regulations are complied with. R.S.O. 1990, c. L.1, s. 16 (3).

## **Idem**

(4) Where the Director has reasonable and probable grounds to believe that any institution, building or place other than a private dwelling is being used as a laboratory or specimen collection centre without being licensed under this Act, the Director may direct an inspector to make an inspection and the inspector at any reasonable time may enter the institution, building or place other than a private dwelling to make an inspection for the purpose of determining whether or not any person is in contravention of subsection 9 (1) or (3). R.S.O. 1990, c. L.1, s. 16 (4).

## **Idem**

(5) Upon an inspection under this section, the inspector may upon giving a receipt therefor remove any material referred to in subsection (3) that relates to the purpose of the inspection for the purpose of making a copy thereof, provided that such copying is carried out with reasonable dispatch and the material in question is promptly thereafter returned to the person being inspected. R.S.O. 1990, c. L.1, s. 16 (5).

## **Admissibility of copies**

(6) Any copy made as provided in subsection (5) and purporting to be certified by an inspector is admissible in evidence in any action, proceeding or prosecution as proof, in the absence of evidence to the contrary, of the original. R.S.O. 1990, c. L.1, s. 16 (6).

## **Obstruction**

(7) No person shall obstruct the inspector or withhold or destroy, conceal or refuse to furnish any information or thing required by the inspector for the purposes of the inspection. R.S.O. 1990, c. L.1, s. 16 (7).

**17.** Repealed: 2011, c. 1, Sched. 6, s. 6 (1).

## **Regulations**

- 18.** The Lieutenant Governor in Council may make regulations,
- (a) providing for the issuance and renewal of licences and provisional licences and prescribing terms and conditions thereof;
  - (b) prescribing examinations for the purpose of the definition of “laboratory” in section 5;
  - (c) prescribing classes of tests for the purposes of this Act and the regulations;
  - (d) respecting the officers and employees of laboratories and prescribing their duties, responsibilities and qualifications;
  - (e) respecting the employees of specimen collection centres and respecting the duties, responsibilities and qualifications of the employees of specimen collection centres;

- (f) prescribing the classes of persons who may perform tests in a laboratory;
- (g) prescribing the classes of persons who may take or collect specimens in a specimen collection centre;
- (h) prescribing classes of persons who shall not be owners of laboratories or specimen collection centres or of any interest therein;
- (i) respecting the management and operation of laboratories and specimen collection centres and requiring laboratories and specimen collection centres to keep such records and make such reports as are prescribed;
- (j) specifying classes of persons whom laboratories and specimen collection centres may notify respecting their services;
- (k) Repealed: 2006, c. 19, Sched. L, s. 6 (5).
- (l) prescribing fees for licences, provisional licences and renewals and for laboratory services performed by the Ministry;
- (m) exempting laboratories or specimen collection centres or any class of either of them or any class of persons from any provisions of this Act or the regulations;
- (n) prescribing tests to which this Act does not apply;
- (o) prescribing other duties and powers of the Director and the Review Board, including the approval of educational qualifications of officers and employees of laboratories and specimen collection centres;
- (p) instituting a system for the payment by the Province of all or any part of the annual expenditures of laboratories in lieu of amounts payable under the *Health Insurance Act*;
- (q) prescribing fees for assessments under a quality management program;
- (r) designating an agency or agencies to carry out a quality management program. R.S.O. 1990, c. L.1, s. 18; 1998, c. 18, Sched. G, s. 62 (1); 2006, c. 19, Sched. L, s. 6 (5, 6); 2011, c. 1, Sched. 6, s. 6 (2).

### **Agreement**

**19.** The Minister may enter into an agreement with an agency or agencies designated in the regulations to provide for the carrying out of a quality management program acceptable to the Director. 2006, c. 19, Sched. L, s. 6 (7).

### **Committee**

**20.** The Minister may establish a committee of not fewer than five persons for the purpose of recommending to the Minister standards and procedures for assessments under a quality management program. 2006, c. 19, Sched. L, s. 6 (7).

### **Money**

**21.** The money required for the administration of the quality management program shall be paid out of the money appropriated by the Legislature for the purpose. 2011, c. 1, Sched. 6, s. 6 (3).

### **FINES AND THE RECOVERY THEREOF**

### **Offences**

**22. (1)** Subject to subsection (2), a person who contravenes any provision of this Act or of the regulations is guilty of an offence and on conviction is liable,

- (a) for a first offence, to a fine of not more than \$25,000 or to imprisonment for a term of not more than 12 months, or to both;
- (b) for a subsequent offence, to a fine of not more than \$50,000 or to imprisonment for a term of not more than 12 months, or to both. 2006, c. 19, Sched. L, s. 6 (8); 2011, c. 1, Sched. 6, s. 6 (4).

**Same, corporation**

**(2)** A corporation that is convicted of an offence under subsection (1) is liable to a fine of not more than \$50,000 for a first offence and to a fine of not more than \$200,000 for a subsequent offence. 2002, c. 18, Sched. I, s. 13 (2).

**Directors and officers**

**(3)** Where a corporation has been convicted of an offence under subsection (1),

- (a) each director of the corporation; and
- (b) each officer, servant or agent of the corporation who was in whole or in part responsible for the conduct of that part of the business of the corporation that gave rise to the offence,

is a party to and guilty of the offence, and on conviction is liable to the punishment provided for under subsection (1), unless he or she satisfies the court that he or she had no knowledge of any of the acts constituting the offence, and could not reasonably be expected to have had such knowledge and that reasonable diligence to prevent the commission of the offence was exercised. R.S.O. 1990, c. L.1, s. 22 (3); 2011, c. 1, Sched. 6, s. 6 (5).

**No limitation**

**(4)** Section 76 of the *Provincial Offences Act* does not apply to a prosecution under this section. 2002, c. 18, Sched. I, s. 13 (3).

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