



BERMUDA

PUBLIC HEALTH (CLINICAL LABORATORIES) REGULATIONS 2002

BR 56 / 2002

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The Minister of Health and Family Services, in exercise of the powers conferred on him by section 163 of the Public Health Act 1949, makes the following regulations:—

Citation

1 These Regulations may be cited as the Public Health (Clinical Laboratories) Regulations 2002.

Definitions

2 In these Regulations—

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“accreditation body” means a body responsible for the accreditation of clinical laboratories which has been approved by the Minister under regulation 4(2);

“Act” means the Public Health Act 1949;

“certificate” means a certificate of registration issued under regulation 5(4)(b) and includes a provisional certificate of registration issued under regulation 6(4)(b);

“clinical laboratory” means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings, but does not include-

- (a) a laboratory that only performs testing for forensic purposes;
- (b) a laboratory that only tests for drugs of abuse;
- (c) a laboratory that only provides testing for insurance companies;
- (d) research laboratories that test human specimens but do not report specific results for the diagnosis, prevention or treatment of disease, or the assessment of individual patients; and
- (e) a facility of a temporary nature, such as a health fair, that provides screening tests and procedures.

“medical practitioner” has the meaning assigned to that expression by section 2 of the Medical Practitioners Act 1950.

“register” means the register established and maintained by the Bermuda Health Council under section 163 of the Act and “registration” shall be construed accordingly.

[Regulation 2 definition "register" amended by 2018 : 66 s.2 effective 1 June 2019]

Register of clinical laboratories

3 (1) The Bermuda Health Council shall establish and maintain at its office, in an appropriate manner, a register of clinical laboratories.

(2) The register is an official record and shall consist of two lists—

- (a) one, to be called the general list, of clinical laboratories entitled to be registered pursuant to regulation 4;
- (b) one, to be called the provisional list, of clinical laboratories entitled to be registered pursuant to regulation 6.

(3) The Bermuda Health Council shall keep the register correct in accordance with the provisions of these regulations and shall make any necessary alterations in the registered particulars.

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(4) As soon as may be after 1 January in every year the Bermuda Health Council shall publish in the Gazette a notice in such form as he may determine setting forth the names of clinical laboratories and other particulars entered in the register on that date.

[Regulation 3 amended by 2018 : 66 s.2 effective 1 June 2019]

Qualifications for registration

4 (1) Subject to these regulations, an applicant is entitled to have a clinical laboratory registered if he is ordinarily resident in Bermuda and satisfies the Bermuda Health Council that—

- (a) he is the owner of a proposed clinical laboratory;
- (b) he is a fit and proper person to operate a clinical laboratory;
- (c) the building proposed to be used is fit for use as such a clinical laboratory;
- (d) he is able to provide the equipment and staff to operate such a clinical laboratory; and
- (e) the clinical laboratory has been accredited by an accreditation body.

(2) The Minister may by notice published in the Gazette approve an institution or body as an approved accreditation body for the purposes of these regulations.

[Regulation 4 amended by 2018 : 66 s.2 effective 1 June 2019]

Registration

5 (1) A person who desires to operate a clinical laboratory shall make an application to the Bermuda Health Council for the registration of the clinical laboratory.

(2) An application shall be in the form determined by the Bermuda Health Council and shall contain such additional information in relation to the operation of the clinical laboratory as the Bermuda Health Council may reasonably require including, in particular—

- (a) a description of the clinical laboratory procedures to be performed;
- (b) evidence of any tests conducted by an external agency to ensure the quality of those procedures; and
- (c) the names, qualifications and relevant experience of the staff carrying out those procedures.

(3) The Bermuda Health Council shall consider the application as soon as practicable after its receipt and may approve, refuse to approve, or approve subject to conditions, the application.

(4) Where the Bermuda Health Council approves the application to register the clinical laboratory, he shall—

- (a) enter in the register the name and address of the clinical laboratory, the name of its owner and such other particulars relating to the clinical

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laboratory as he considers necessary to identify the registered clinical laboratory; and

- (b) issue to the applicant a certificate of registration in the form determined by the Bermuda Health Council.

(5) Where the Bermuda Health Council refuses to approve an application, he shall record his decision and the reasons for it in writing and shall, not later than 7 days after making a decision on an application, inform the applicant of the decision and the reasons for it.

(6) An applicant who is aggrieved by a decision of the Bermuda Health Council may appeal against it under regulation 11.

[Regulation 5 amended by 2018 : 66 s.2 effective 1 June 2019]

Provisional registration

6 (1) Subject to paragraph (3), the Bermuda Health Council may approve an application for registration without paragraph (1)(e) of regulation 4 being complied with if he is satisfied that the applicant would not be able to take steps to comply with that paragraph otherwise.

(2) A registration approved by the Bermuda Health Council by virtue of paragraph (1) is to be known as provisional registration and may be approved for a period not exceeding two years.

(3) An applicant is entitled to have the clinical laboratory registered provisionally if he satisfies the Bermuda Health Council—

- (a) in respect of each of the requirements set out in regulation 4(1)(a) to (d); and
- (b) that the accreditation of the clinical laboratory by an approved accreditation body is being sought.

(4) Where the Bermuda Health Council approves an application to register a clinical laboratory provisionally, he shall—

- (a) enter the particulars relating to the clinical laboratory in the register; and
- (b) issue to the applicant a provisional certificate of registration in the form determined by the Bermuda Health Council.

[Regulation 6 amended by 2018 : 66 s.2 effective 1 June 2019]

Conditions

7 (1) The Bermuda Health Council may attach such conditions as he considers appropriate to the registration of a clinical laboratory and such conditions, if any, shall be specified in the certificate.

(2) The conditions imposed by the Bermuda Health Council under paragraph (1) may include,—

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- (a) restrictions on the type of procedures to be provided at the clinical laboratory;
- (b) requirements for repairs or alterations to the building proposed to be used as the clinical laboratory;
- (c) requirements for the maintenance of equipment to be used at the clinical laboratory;
- (d) requirements for qualifications, certification and training of staff and connected matters;
- (e) hours of operation.

[Regulation 7 amended by 2018 : 66 s.2 effective 1 June 2019]

Duration and fees

8 (1) Subject to these regulations, a certificate shall be issued for a period of two years and may be renewed.

(2) An applicant shall pay such fee as may be prescribed under the Government Fees Act 1965.

Cancellation of registration or variation of conditions

9 (1) Subject to paragraphs (2), (3) and (4), the Bermuda Health Council may—

- (a) cancel the registration of a clinical laboratory;
- (b) suspend the registration of a clinical laboratory;
- (c) vary any conditions attached to the registration of a clinical laboratory.

(2) Where the Bermuda Health Council proposes to exercise a power under paragraph (1) he shall—

- (a) not less than 14 days before the date on which he proposes to exercise the power, in writing, inform the owner of the clinical laboratory of the proposal and the reasons for it;
- (b) give the owner an opportunity to make representations, orally or in writing; and
- (c) take into account any representations made under sub-paragraph (b) before a decision is made.

(3) Where the Bermuda Health Council decides to exercise the power, he shall—

- (a) set out the decision in writing and state the reasons for the decision;
- (b) serve a copy of the decision on the owner;
- (c) inform the owner that he may appeal against that decision.

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(4) The cancellation or suspension of registration or the variation of conditions attached thereto has effect on the expiration of 2 months beginning on the date of service of the decision on the owner.

[Regulation 9 amended by 2018 : 66 s.2 effective 1 June 2019]

Surrender of certificate

10 Where the Bermuda Health Council cancels or suspends the registration of a clinical laboratory under regulation 9, the owner of the clinical laboratory shall surrender his certificate to the Bermuda Health Council immediately on the expiration of the two-month period referred to in regulation 9(4) or until the time when any appeal has been determined.

[Regulation 10 amended by 2018 : 66 s.2 effective 1 June 2019]

Appeals to Minister

11 (1) A person aggrieved by a decision of the Bermuda Health Council may, within 21 days after the date on which notice of the decision is given or within such longer period as the Minister may allow, appeal to the Minister against that decision.

(2) On an appeal under this regulation the Minister may give such direction as he considers appropriate and the Bermuda Health Council shall comply with any such direction.

[Regulation 11 amended by 2018 : 66 s.2 effective 1 June 2019]

Appeals to court

12 (1) A person aggrieved by a decision of the Minister may, in accordance with section 163(4) of the principal Act, appeal to the court against that decision.

(2) On an appeal pursuant to this regulation, the court may make such order as it considers appropriate and the Minister shall comply with any such order.

Administration and reporting of test results

13 (1) As soon as practicable after every test conducted in a clinical laboratory, an owner shall ensure—

- (a) that a written report in respect of the results is prepared and signed by a qualified person on the staff of the clinical laboratory;
- (b) that the written report is sent to the patient's medical practitioner;
- (c) if the patient is tested for a communicable disease of the first or second category (other than COVID-19), that the Chief Medical Officer is forthwith notified of any positive test result for the communicable disease; and
- (d) if the patient is tested for COVID-19, that the Chief Medical Officer is forthwith notified of the patient's test result, whether positive or negative.

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(2) An owner shall keep proper records relating to the operation of his clinical laboratory for a period of 7 years from the date on which a report is signed pursuant to subsection (1).

[Regulation 13 heading amended and paragraphs (1)(c) and (1)(d) inserted by BR 100 / 2020 reg. 2 effective 9 September 2020]

Confidentiality of records

14 (1) The owner and the staff of a clinical laboratory shall maintain the confidentiality of all reports and records relating to any person and the results of tests except for the purpose of disclosure to a medical practitioner, the Chief Medical Officer or other person lawfully entitled to the information .

(2) Any person who contravenes paragraph (1) is guilty of an offence and liable on summary conviction to the penalty set out in section 171 of the Act.

[Regulation 14 amended by BR 100 / 2020 reg. 3 effective 9 September 2020]

Transitional

15 (1) Subject to paragraph (2), any permission by whatever name called, which in relation to any clinical laboratory is in force immediately before the date of coming into operation of these regulations ("commencement date") has effect from the commencement date as if granted pursuant to these regulations.

(2) A person who, immediately before the commencement date, was operating a clinical laboratory or other such establishment to which these regulations applies may continue to operate that clinical laboratory or establishment under these regulations—

- (a) during the period of 6 months beginning next after the commencement date; and
- (b) if within that period application is made in accordance with these regulations for registration of that clinical laboratory, until that application is finally disposed of or withdrawn.

Made this 14th day of November 2002

Minister of Health and Family Services

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[Amended by:

2018 : 66

BR 100 / 2020]