



BERMUDA

PUBLIC HEALTH (DIAGNOSTIC FACILITIES) (MAMMOGRAPHY)
REGULATIONS 2000

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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 (Diagnostic Facilities) (Mammography) Regulations 2000.

Interpretation

2 In these Regulations, unless the context otherwise requires—

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“accreditation body” means a body responsible for the accreditation of diagnostic facilities which has been approved for that purpose under regulation 4(2);

“application” means an application for registration under regulation 5(1) and “applicant” shall be construed accordingly;

“Bermuda Health Council” means the Bermuda Health Council established under section 3 of the Bermuda Health Council Act 2004;

“certificate” means a registration certificate issued by the Chief Medical Officer under regulation 5(4)(b);

“Chief Medical Officer” *[deleted by 2018 : 66 s. 2]*

“diagnostic imaging technologist” and “specialist diagnostic imaging technologist” have the meanings assigned respectively to those expressions by the Schedule to the Professions Supplementary to Medicine Act 1973;

“facility” means a hospital, an out-patient department, a clinic, a radiology practice, a mobile unit, a medical practitioner’s office or any other establishment within which mammograms are produced;

“Minister” means the Minister responsible for health;

“mammogram” means a radiographic image produced through mammography;

“mammography” means radiology of the breast;

“mammography services” includes the production of mammograms and their interpretation;

“medical physicist” means a medical physicist recognised by an accreditation body as qualified to certify facilities seeking accreditation as diagnostic radiological facilities;

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

“owner” includes—

- (a) a person to whom a certificate has been issued under these regulations; and
- (b) the manager, administrator or other person responsible for the operation of a facility;

“principal Act” means the Public Health Act 1949;

“register” means the register established and maintained by the Chief Medical Officer under section 163 of the principal Act and “registration” shall be construed accordingly.

[Regulation 2 definition “Chief Medical Officer” deleted, and “definition “Bermuda Health Council” inserted by 2018 : 66 s. 2 effective 1 June 2019]

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Register of facilities

3 (1) The Bermuda Health Council shall establish and maintain at his office in such manner as he considers appropriate a register of facilities.

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

(a) one, to be called the general list, of facilities entitled to be registered pursuant to regulation 4;

(b) one, to be called the provisional list, of facilities 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 from time to time make any necessary alterations in the registered particulars.

(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 facilities 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 facility registered if he is Bermudian or is ordinarily resident in Bermuda and satisfies the Bermuda Health Council that—

(a) he is the owner of a proposed facility;

(b) he is a fit and proper person to operate a facility;

(c) the building proposed to be used is fit for use as such a facility;

(d) he is able to provide the equipment and personnel to operate such a facility;

(e) the facility has been accredited by an accreditation body; and

(f) he possesses a certificate of inspection issued by a medical physicist.

(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 facility shall make an application to the Bermuda Health Council for the registration of the facility.

(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 facility as the Bermuda Health Council may reasonably require including, in particular—

(a) a description of the mammography procedures to be performed;

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- (b) particulars relating to the manufacturer of each x-ray machine, image receptor and processor and the model and type thereof;
 - (c) the names, qualifications and relevant experience of—
 - (i) the diagnostic imaging technologists or specialist diagnostic imaging technologists to be responsible for the production of mammograms;
 - (ii) the medical practitioners to be responsible for the interpretation of the results of mammograms.
- (3) The Bermuda Health Council shall consider the application as soon as practicable after its receipt and may approve, refuse to approve the application.
- (4) Where the Bermuda Health Council approves the application to register the facility, he shall—
- (a) enter in the register the name and address of the facility, the name of its owner and such other particulars relating to the facility as he considers necessary to identify the registered facility; 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 one year.
- (3) An applicant is entitled to have the facility 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 (f); and
 - (b) that the accreditation of the facility by an approved accreditation body is being sought.

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

- (a) enter the particulars relating to the facility 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 facility 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, in particular—

- (a) restrictions on the type of procedures to be provided at the facility;
- (b) requirements for repairs or alterations to the building proposed to be used as the facility;
- (c) requirements for the maintenance of equipment to be used at the facility;
- (d) requirements for qualifications, certification, training of personnel 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 one year and may be renewed.

(2) An applicant shall, for the period beginning on the day on which his certificate is issued or renewed and ending on 31 March next following, pay such fee as may from time to time 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 facility;
- (b) suspend the registration of a facility;
- (c) vary any conditions attached to the registration of a facility.

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

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- (a) not less than 14 days before the date on which he proposes to exercise the power, in writing, inform the owner of the facility 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.

(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 facility under regulation 9, the owner of the facility 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

13 (1) As soon as practicable after every mammography, an owner shall ensure—

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- (a) that a written report in respect of the results is prepared and signed by the medical practitioner who interpreted the mammogram;
- (b) that—
 - (i) the written report is sent to the patient's medical practitioner; or
 - (ii) in a case where there is no such practitioner, the report accompanied by a summary of it in words likely to be understood by the patient is sent to the patient.
- (2) An owner shall keep proper records relating to the operation of his facility for a period of 10 years from the date on which a report is signed by the medical practitioner.
- (3) Records to be kept pursuant to subsection (2) include, in particular—
 - (a) original mammograms produced at the facility (except where a mammogram has been sent to the patient's medical practitioner); and
 - (b) copies of reports prepared under paragraph(1).

Transitional

14 (1) Subject to paragraph (2), any permission by whatever name called, which in relation to any facility 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 facility or other such establishment to which these regulations applies may continue to operate that facility 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 facility, until that application is finally disposed of or withdrawn.

Made this 26th day of July, 2000

Minister of Health and Family Services

[Amended by:

2018 : 66]