



BERMUDA

BERMUDA HEALTH COUNCIL (HIGH RISK HEALTH TECHNOLOGY) REGULATIONS 2024

BR 111 / 2024

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The Minister responsible for health, after consultation with the Council, in exercise of the power conferred by section 16D of the Bermuda Health Council Act 2004, makes the following regulations:

Citation

- 1 These Regulations may be cited as the Bermuda Health Council (High Risk Health Technology) Regulations 2024.

Interpretation

- 2 In these Regulations, unless the context indicates otherwise—
 - “the Act” means the Bermuda Health Council Act 2004;
 - “day” means a calendar day;
 - “high risk health technology” or “health technology” has the meaning given in section 16E of the Act;
 - “registered owner” means the person registered with the Council as the owner of high risk health technology;
 - “website” means the website of the Council, namely, www.healthcouncil.bm;

Importing High Risk Health Technology

Applying to import health technology

- 3 (1) A person intending to import high risk health technology into Bermuda shall make application to the Council for a permit to do so in the form provided by the Council.
- (2) The application shall be accompanied with any documents requested in the application form; and the applicant shall provide such additional information or documents requested by the Council as will assist it in determining the application.
- (3) A person who, in relation to an application made under this regulation, provides false or misleading documents or information in a material respect commits an offence.

Granting application to import health technology

- 4 (1) In determining an application made under regulation 3, the Council shall make an assessment in accordance with internationally recognized and standardized processes, to determine whether there is a need for such technology in Bermuda.

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(2) Where, after completing an assessment under paragraph (1), the Council is satisfied that there is a need in Bermuda for the health technology, the Council shall grant the application and issue to the applicant a permit to import the health technology.

(3) The permit issued under paragraph (2) shall set out the conditions and restrictions attached to the permit, and may contain such other particulars as the Council considers appropriate.

(4) A permit issued under this regulation is not transferable.

(5) Where a permit issued by the Council under paragraph (2) has expired, the permit holder may make an application to the Council under regulation 3 to renew the permit.

Denying application to import health technology

5 (1) Where, following an assessment under regulation 4, the Council is of the view that an application made under regulation 3 should be denied the Council shall, before making its decision, give written notice to the applicant which shall—

- (a) state that the Council is of such a view, and give its reasons; and
- (b) inform the applicant that it may, within 21 days of the date on which the written notice is given, make written representations to, or be heard by, the Council.

(2) The Council shall take into consideration any written or oral representations made under paragraph (1)(b), and give the applicant written notice of its decision.

(3) Where the decision of the Council, after considering any written or oral representations made under paragraph (1)(b), is to deny the application, then the notice under paragraph (2) shall give reasons for the decision, and inform the applicant of its rights under regulation 20.

Registration of High Risk Health Technology

Applying to register health technology

6 (1) A person who has imported high risk health technology shall notify the Council not later than 14 days of its arrival in Bermuda.

(2) The health technology shall be registered by the Council prior to it being operated, and the owner shall make application to the Council for that purpose.

(3) The application shall be in the form provided by the Council and shall be accompanied with any documents requested in the form; and the applicant shall provide such additional information or documents requested by the Council as will assist it in determining the application.

(4) A person who, in relation to an application made under this regulation, provides false or misleading documents or information in a material respect commits an offence.

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Granting application for registration

7 (1) The Council shall grant an application made under regulation 6 where it is satisfied—

- (a) that any conditions or restrictions attached to the permit to import the high risk health technology have been complied with;
- (b) that the facility at which the health technology is to be operated is suitable for the purpose;
- (c) that the health professional employed or contracted to operate the health technology has the required qualifications, training and experience;
- (d) of any other matter which the Council considers appropriate.

(2) The Council may attach such conditions and restrictions to the registration of the health technology as it considers appropriate.

(3) Unless otherwise specified, registration of the health technology expires one year from the date of entry in the register of high risk health technology.

(4) The Council shall issue a certificate of registration to the registered owner setting out such particulars referred to in regulation 14(2) as it considers appropriate.

(5) The registered owner shall cause the certificate of registration to be prominently displayed at the facility where the health technology is operated for public inspection.

(6) A person who contravenes a restriction imposed under this regulation commits an offence.

Denying application for registration

8 Regulation 5 applies, with the necessary modifications, where the Council is of the view that an application made under regulation 6 should be denied.

Applying to re-register health technology

9 (1) The registered owner shall apply in the form provided by the Council to re-register the high risk health technology.

(2) An application must be made not less than 30 days before the date on which the registration expires and must be accompanied with any documents requested in the application form; and the applicant shall provide such additional information or documents requested by the Council as will assist it in determining the application.

(3) In determining an application, the Council shall have regard to the matters referred to in regulation 7(1) and information contained in returns filed by the registered owner under regulation 13.

(4) Unless otherwise specified, the renewed registration expires one year from the date of entry in the register of high risk health technology.

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(5) Where the Council is of the view that an application made under paragraph (1) should be denied, regulation 5 applies with the necessary modifications.

(6) A person who, in relation to an application made under this regulation, provides false or misleading documents or information in a material respect commits an offence.

Applying to modify registration

10 (1) The registered owner of high risk health technology may apply to the Council to modify the registration of the health technology—

- (a) in respect of its ownership;
- (b) in respect of its use;
- (c) in respect of its location, including a relocation within the same building.

(2) An application shall be made in the form provided by the Council and must be accompanied with any documents requested in the form; and the registered owner shall provide such additional information or documents requested by the Council as will assist it in determining the application.

(3) A person who, in relation to an application made under this regulation, provides false or misleading documents or information in a material respect commits an offence.

Applying to vary or remove condition or restriction

11 (1) A registered owner may apply to the Council to vary or remove a condition or restriction attached to the registration of its high risk health technology.

(2) The application shall be in the form provided by the Council and be accompanied with any documents requested in the application form; and the applicant shall provide such additional information or documents requested by the Council as will assist it in determining the application.

(3) Where an application under paragraph (1) is granted, the Council shall issue a new certificate of registration to the registered owner.

(4) Where the Council is of the view that an application made under paragraph (1) should be denied, regulation 5 applies with the necessary modifications.

(5) A person who, in relation to an application made under this regulation, provides false or misleading documents or information in a material respect commits an offence.

Cancelling registration of health technology

12 Where the registered owner of high risk health technology intends to cancel registration of the technology, the owner shall notify the Council in writing at least 60 days before the date of cancellation; and the Council must satisfy itself as far as possible that matters relating to the proper removal or disposal of the technology have been administered prudently.

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Returns and record keeping

13 (1) The registered owner of high risk technology is required to file with the Council such returns requested by the Council within the time specified in the return.

(2) The registered owner is required to retain all records relating to matters set out in a return filed with the Council for a period of six years.

(3) A person who, in relation to a return filed with the Council under this regulation, provides false or misleading documents or information in a material respect commits an offence.

Powers of Council in Relation to Registration

Register of health technology

14 (1) The Council shall establish and maintain a register of high risk health technology.

(2) The register of high risk health technology shall set out the following particulars—

- (a) the name and address of the person who owns the health technology;
- (b) the address of the facility at which the health technology is operated;
- (c) the name and address of the health service provider who operates the health technology;
- (d) particulars about the health technology including type, manufacturer, and serial number;
- (e) the date on which the health technology was acquired by the registered owner;
- (f) the dates on which inspections were carried out on the health technology and the findings of such inspections;
- (g) particulars relating to any change of use of the health technology;
- (h) particulars relating to the cancellation of registration of the health technology;
- (i) the date and manner in which the health technology and its by-products are disposed of;
- (j) the date on which registration was entered in the register and the date of expiration of registration; and
- (k) such other particulars as the Council considers appropriate.

Council may attach or vary a condition or restriction of registration

15 (1) The Council may at any time—

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- (a) attach or vary a condition of registration of high risk health technology;
or
 - (b) impose a restriction on the registration of high risk health technology.
- (2) Where the Council proposes to act in accordance with paragraph (1), it shall give the registered owner a written warning notice which shall—
 - (a) state the Council's proposal to attach or vary a condition or impose a restriction;
 - (b) give reasons for the proposed action;
 - (c) specify the condition or restriction proposed to be attached, varied or imposed;
 - (d) state the date on which the proposed attachment, variation or imposition is to take effect; and
 - (e) state that the owner may, within 21 days of the date on which the warning notice is given, make written representations to, or be heard by, the Council.
- (3) The Council shall take into consideration any written or oral representations made under paragraph (2)(e), and give the registered owner a written decision notice.
- (4) Where the decision of the Council, after considering any representations made under paragraph (2)(e), is to act in accordance with paragraph (1), then the decision notice under paragraph (3) shall specify the condition to be attached or varied or the restriction to be imposed, give reasons for the decision, state the date on which the attachment, variation or imposition is to take effect, and inform the registered owner of its rights under regulation 20.
- (5) Where the Council decides to impose a restriction, the decision notice given under paragraph (3) shall notify the owner that where a restriction imposed under this regulation is contravened, the registration of the high risk technology is liable to be cancelled under regulation 17.
- (6) A person who contravenes a restriction imposed under this regulation commits an offence.

Council may suspend registration

- 16
- (1) The Council may suspend the registration of high risk health technology where a condition attached to the registration of the health technology has not been complied with (except a condition relating to the disposal of the health technology or its by-products).
 - (2) Where the Council intends to act in accordance with paragraph (1), it shall give a written warning notice to the registered owner which shall—
 - (a) state that it proposes to suspend the registration of the health technology;

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- (b) specify the matter to which the proposed suspension relates;
- (c) specify the action it proposes that the registered owner take in order to remedy the matter; and
- (d) inform the registered owner that it may, within 14 days of the date on which the warning notice is given, make written representation to, or be heard by, the Council.

(3) Where the decision of the Council, after considering any representations made under paragraph (2)(d), is to suspend the registration, then the Council shall give a written decision notice which shall—

- (a) give reasons for the suspension;
- (b) give such directions to the registered owner which shall—
 - (i) state the manner in which the matter is to be remedied;
 - (ii) specify the period within which the direction is to be complied with;and
- (c) inform the registered owner of its rights under regulation 20.

Council may cancel registration of health technology

17 (1) The Council may cancel the registration of high risk health technology where the registered owner has contravened a restriction imposed on the registration under regulation 7 or regulation 15.

(2) Where the Council intends to cancel the registration, it shall give the registered owner written warning notice which shall—

- (a) state that the Council proposes to cancel the registration;
- (b) give reasons for the proposed cancellation; and
- (c) inform the registered owner that it may, within 14 days of the date on which the warning notice is given, make written representations to, or be heard by, the Council.

(3) The Council shall take into consideration any written or oral representations made under paragraph (2)(c), and give the registered owner a written decision notice.

(4) Where the decision of the Council, after considering any representations made under paragraph 2(c), is to cancel the registration, then the decision notice under paragraph (3) shall give reasons for the decision, and inform the registered owner of its rights under regulation 20.

(5) For the avoidance of doubt, a person who operates high risk health technology while the registration is cancelled commits an offence under section 16B(2) of the Act.

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Decision notices

18 (1) Where the Council gives a written warning notice under regulation 15, 16, 17 or 19, it shall give a written decision notice within 90 days beginning with the day on which the warning was given.

(2) If the Council decides not to take the action proposed in the warning notice, it must give a written notice of discontinuance to the person to whom the warning notice was given.

(3) The notice of discontinuance must identify the action which is being discontinued.

(4) Notwithstanding paragraphs (2) and (3), if no written decision notice is given within the period of 90 days, then the Council shall be treated as having at the end of that period decided not to take the action proposed in the warning notice.

Civil Penalties, Judicial Review, Penalties for Offences

Civil penalties

19 (1) Where a registered owner has failed to comply with a requirement under regulation 13(1) or (2), or has failed to comply with a condition attached to its registration and the Council is of the view that a civil penalty should be imposed, then the Council shall, before making its decision, give a written warning notice to the owner which shall—

- (a) state that the Council is of such a view, and give its reasons; and
- (b) inform the registered owner that it may, within 21 days of the date on which the notice is given, make written representations to, or be heard by, the Council.

(2) The Council shall take into consideration any written or oral representations made under paragraph (1)(b), and give the registered owner a written decision notice.

(3) Where the decision of the Council, after considering any representations made under paragraph (1)(b), is to impose a civil penalty, then the notice under paragraph (2) shall give reasons for the decision, state the amount of the penalty and the date of payment, and inform the registered owner of its rights under regulation 20.

(4) Where registration of high risk health technology has been suspended under regulation 16, the Council shall not also impose a civil penalty in relation to the same matter in respect of which registration was suspended.

Judicial review

20 (1) A registered owner aggrieved by a decision of the Council to—

- (a) deny its application made under—
 - (i) regulation 3 for a permit to import high risk health technology;
 - (ii) regulation 6 to register high risk health technology;
 - (iii) regulation 9 to re-register high risk health technology;

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- (iv) regulation 10 to modify the registration of high risk health technology;
- (v) regulation 11 to vary or remove a condition or restriction attached to the registration of high risk health technology;
- (b) suspend its registration under regulation 16;
- (c) cancel its registration under regulation 17,
- (d) impose a civil penalty under regulation 19,

may, within 28 days after the date on which the written notice of decision was given, apply to the Supreme Court for the decision to be reviewed.

(2) Subject to paragraph (3), the registered owner may at the time of making an application under paragraph (1), apply to the Court for suspension of the operation of the Council's decision pending the Court's determination of its application under paragraph (1).

(3) Paragraph (2) does not apply to a decision of the Council to deny an application made under regulation 3, regulation 6, or regulation 11.

(4) The matter for determination by the Court in respect of an application made under paragraph (1) is whether, for the reasons adduced by the applicant, the decision of the Council was unlawful or not justified by the evidence on which it was based.

[Regulation 20(1)(a)(iv) and 20(4) in force by Notice in Gazette. See BR 109 / 2024]

Penalties for offences

21 (1) A person who commits an offence under—

- (a) regulation 3(3);
- (b) regulation 6(4);
- (c) regulation 9(6);
- (d) regulation 10(3);
- (e) regulation 11(5);
- (f) regulation 13(3);

is liable on summary conviction to a fine of \$20,000.00.

(2) A person who commits an offence under regulation 7(6) or 15(6) is liable on summary conviction to a fine of \$40,000.00 and on conviction on indictment to a fine of \$50,000.00.

(3) Where an offence under these regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other officer of the body corporate, he, as well as the body corporate, shall be deemed to have committed an offence and is liable to be proceeded against and punished accordingly.

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(4) Where the affairs of a body corporate are managed by its members, paragraph (3) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(5) Where a partnership commits an offence under these regulations, every partner, other than a partner who is proved to have been ignorant or to have attempted to prevent the commission of the offence, is also deemed to have committed the offence and is liable to be proceeded against and punished accordingly.

(6) Where any other association, incorporated or not, commits an offence under these regulations—

- (a) every officer of the association who is bound to fulfil any duty of which the breach is the offence; or
- (b) if there is no such officer, every member of the governing body other than a member who is proved to have been ignorant of or to have attempted to prevent the commission of the offence,

is also deemed to have committed the offence and is liable to be proceeded against and punished accordingly.

Transitional and Final Provisions

Transitional

22 Where, immediately before the coming into operation of these Regulation, any person, group of person or organization which—

- (a) is in the process of importing high risk health technology, or owns high risk health technology; and
- (b) applies to the Council—
 - (i) in accordance with regulation 3 for a permit; or
 - (ii) in accordance with regulation 9 to register the technology,within 60 days from the day these Regulations come into operation,

may, notwithstanding sections 16A(1) and 16B(1) of the Act, continue with the importation or operation of such technology until its application is determined by the Council.

Commencement

23 These Regulations come into operation on such day as the Minister appoints by notice published in the Gazette.

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Made this 16th day of October 2024

Minister of Health

[Operative Date: 16 October 2024]