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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 277

2018

REGULATIONS RELATING TO MINIMUM REQUIREMENTS OF STUDY, REGISTRATION AND SCOPE OF PRACTICE OF BIOMEDICAL ENGINEER: MEDICAL AND DENTAL ACT, 2004

Under section 59 read with section 18(1) of the Medical and Dental Act, 2004 (Act No. 10 of 2004), and on the recommendation of the Medical and Dental Council of Namibia, I make the regulations set out in the Schedule.

DR. B. HAUFIKU

MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 11 October 2018

SCHEDULE

1. Definitions
2. Minimum qualifications for registration as biomedical engineer
3. Application for registration as biomedical engineer
4. Registrable additional qualifications
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Annexure A

Definitions

1. In these regulations, a word or an expression to which a meaning has been assigned in the Act has that meaning and, unless the context otherwise indicates -

“additional qualification” means an additional qualification referred to in section 31(1)(a) of the Act and prescribed by these regulations;

“certified” means certified as a true copy of the original by a commissioner of oaths appointed under section 5, or designated under section 6, of the Justices of the Peace and Commissioners of Oaths Act, 1963 (Act No. 16 of 1963); and

“the Act” means the Medical and Dental Act, 2004 (Act No. 10 of 2004).

Minimum qualifications for registration as biomedical engineer

2. (1) The Council may register a person as a biomedical engineer if that person holds any of the following qualifications in biomedical engineering -

- (a) Bachelors of Engineering in Biomedical Engineering, successfully completed after full-time study for a period of three years; or
- (b) Master of Science in Biomedical Engineering, successfully completed after full-time study for a period of four years,

granted by an educational institution, subject to compliance with all the other requirements specified in the Act.

(2) The qualification referred to in subregulation (1)(a) must include, to the satisfactions of the Council, the following subjects:

- (a) chemistry;
- (b) electric circuits;
- (c) physics;
- (d) mathematics;
- (e) introductory life science;
- (f) mechanics;
- (g) electronics;
- (h) microprocessors;
- (i) molecular and cell biology;
- (j) biomedical statistics and numerical methods;

- (k) biomedical signals, systems and control;
- (l) physiology and medical biochemistry;
- (m) biomedical transport phenomena;
- (n) software development;
- (o) electric and magnetic systems;
- (p) signals and systems;
- (q) biomedical measurement, instrumentation and imaging; and
- (r) anatomy.

(3) In addition to the subjects referred to in subregulation (2), the qualification set out in subregulation (1)(b) must include, to the satisfaction of the Council, the following subjects -

- (a) molecular biology;
- (b) cellular biology;
- (c) tissue engineering;
- (d) pathology informatics; and
- (e) biomaterials.

Application for registration as biomedical engineer

3. (1) An application for the registration of a person as a biomedical engineer in terms of section 19 of the Act must be -

- (a) submitted to the registrar, in the form determined by the Council, and
- (b) accompanied by -
 - (i) a certified copy of the identity document or passport of the applicant;
 - (ii) payment of the application fees as determined by the Council; and
 - (iii) any additional documents that Council may require.

(2) An application for the registration of a person as a biomedical engineer in accordance with section 19 of the Act must be accompanied by -

- (a) the documents, particulars and payments specified in subsection (2) of that section; and
- (b) the original certificate of registration to practice as a biomedical engineer in the country where the applicant obtained the qualification referred to in section 19(2)(a) of the Act, issued by the registration authority of that country, subject to subregulation (3).

(3) If the applicant is not registered with the registration authority referred to in paragraph (b) of subregulation (2), he or she must submit to the registrar, together with his or her application for registration -

- (a) a certificate, issued by that registration authority, certifying that the qualification or qualifications of which the applicant is the holder, entitles him or her to registration as a biomedical engineer in that country; or
- (b) if he or she had been so registered previously, a certificate issued by that registration authority, specifying that the applicant had been so registered previously, and that his or her name has been removed from the register and the grounds for the removal.

(4) The Council may require the applicant to furnish proof, in the manner that the Council may determine, of the applicant's proficiency in the English language.

(5) A person currently registered under the Act as a biomedical engineer, at the commencement of these regulations is deemed to have been registered under these regulations.

Registrable additional qualifications

4. The additional qualifications specified in Annexure A may be registered as additional qualifications under section 31(1)(a) of the Act.

Register of biomedical engineers

5. The register of biomedical engineers, established and kept in terms of section 23 of the Act, must contain particulars of the additional qualifications registered against the name of the biomedical engineer and any change of the particulars recorded in the register, in addition to the particulars specified by subsection (3) of that section.

Restoration of name to register

6. An application in terms of subsection (1) of section 25 of the Act for the restoration of a name to the register must, in addition to the documents specified by subsection (2) of that section, be accompanied by -

- (a) a certified copy of the applicant's identity document or passport; and
- (b) the original registration certificate issued to the applicant under section 20(4)(b) of the Act or a certified copy thereof.

Language of forms and documents

7. (1) Subject to subregulation (2) any form or document required to be submitted to the Council or the registrar in terms of these regulations must be in the English language.

(2) Any form or document referred to in subregulation (1) that is not in the English language must be accompanied by a sworn translation of it in the English language.

Scope of practice of biomedical engineer

8. (1) A biomedical engineer applies knowledge of engineering, biology, and biomechanical principles to the design, development, and evaluation of biological health systems and products.

- (2) The following acts are regarded to be acts which fall within the scope of practice of a biomedical engineer:
- (a) conducting research, along with life scientists, chemists, and medical scientists, on the engineering aspects of the biological systems of humans;
 - (b) designing and developing medical diagnostic and clinical instrumentation, equipment, and procedures, utilizing the principles of engineering and bio-behavioral sciences;
 - (c) developing models or computer simulations of human bio-behavioral systems in order to obtain data for measuring or controlling life processes;
 - (d) evaluating the safety, efficiency and effectiveness of biomedical equipment;
 - (e) installing, adjusting, maintaining and repairing biomedical equipment;
 - (f) researching new materials to be used for products such as implanted artificial organs;
 - (g) adapting or designing computer hardware or software for medical science uses;
 - (h) advising hospital administrators on the planning, acquisition and use of medical equipment;
 - (i) analysing new medical procedures in order to forecast likely outcomes;
 - (j) designing and delivering technology to assist people with disabilities;
 - (k) developing new applications for energy sources, such as using nuclear power for biomedical implants; and
 - (l) diagnosing and interpreting bio-electric data, using signal processing techniques.

ANNEXURE A

Registrable Additional Qualifications

(Regulation 4)

The following qualifications may be registered as additional qualifications:

- (a) specialised biomedical engineering training in the field of medical diagnostics;
 - (b) electrical engineering specialising in clinical or hospital engineering; or
 - (c) Masters degree in biomedical science, imaging biomechanics, neuro engineering and regenerative engineering.
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