

# **GOVERNMENT GAZETTE**

## **OF THE**

# **REPUBLIC OF NAMIBIA**

N\$2.60

WINDHOEK - 16 June 2010

No. 4503

## CONTENTS

#### **GOVERNMENT NOTICES**

No. 124	Regulations relating to scope of practice of Clinical Biochemist: Medical and Dental Act, 2004	1
No. 125	Regulations relating to minimum requirements of study for registration as Clinical Biochemist: Me- dical and Dental Act, 2004	2
No. 126	Regulations relating to registration of Clinical Biochemists and Clinical Biochemist Interns, registra- tion of specialities and additional qualifications, maintaining of registers of Clinical Biochemists and Clinical Biochemist Interns, and restoration of name to register: Medical and Dental Act, 2004	4

## **Government Notices**

## MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 124

2010

## REGULATIONS RELATING TO SCOPE OF PRACTICE OF CLINICAL BIOCHEMIST: MEDICAL AND DENTAL ACT, 2004

Under section 59 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 have made the regulations set out in the Schedule.

## R.N. KAMWI MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 26 May 2010

## SCHEDULE

## Definitions

**1.** In these regulations, unless the context otherwise indicates, a word or expression defined in the Act has that meaning, and -

Page

No. 4503

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

## Scope of practice of clinical biochemist

2. For the purpose of the practising of his or her profession, a clinical biochemist may perform the following acts relating to the development and application of biochemical principles, procedures and techniques involving human tissue or body fluids, or excretion in the case of an in vitro investigation, regarding the diagnosis and treatment of diseases and the monitoring of health -

- (a) consultation with the patient or other registered persons relating to the development and application of those biochemical principles, procedures and techniques; and
- (b) the -
  - (i) interpretation, consultation and advising relating to the information obtained as a result of;
  - (ii) quality control relating to;
  - (iii) teaching, training and research relating to,

the acts so performed.

## Performing of professional acts by student or intern clinical biochemist

**3.** A student or intern in clinical biochemist may perform, as part of his or her education, tuition and training, and on the instructions, and under the direct supervision, of a clinical biochemist, any of the acts prescribed by regulation 2.

## MINISTRY OF HEALTH AND SOCIAL SERVICES

## No. 125

2010

REGULATIONS RELATING TO MINIMUM REQUIREMENTS OF STUDY FOR REGISTRATION AS CLINICAL BIOCHEMIST: MEDICAL AND DENTAL ACT, 2004

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

## R.N. KAMWI MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 26 May 2010

## SCHEDULE

## Definitions

**1.** In these regulations, unless the context otherwise indicates, a word or expression defined in the Act has that meaning, and -

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

## Minimum qualifications for registration as clinical biochemist

**2.** (1) The minimum qualification, as contemplated in section 18(1) of the Act, required for the registration by the Council of a person as a clinical biochemist under the Act, subject to the other requirements prescribed by or under the Act, is any one of the following qualifications -

<b>Educational Institution and Country</b> University of Limpopo (formerly Medical University of South Africa.	Qualification Bachelor of Science (Medicine)(Honours)
University of Limpopo (formerly University of the North) South Africa	Bachelor of Science (Medical Science)(Honours)
University of the Free State (formerly University of the Orange Free State) South Africa	Bachelor of Medical Sciences (Honours)
University of Cape Town South Africa	Bachelor of Science (Medicine) (Honours) in Medical Biochemistry
University of Pretoria South Africa	Baccalaureus Scientiae (Honours)

(2) Subject to subregulation (3) and to regulation 3, a person who is not the holder of any of the qualifications prescribed by subregulation (1), but is the holder of a Bachelors Degree in Clinical Biochemistry (Honours) obtained at an educational institution after the full time study for a period of four years, may be registered, subject to compliance with the other requirements prescribed by or under the Act, by the Council as a clinical biochemist.

(3) A qualification prescribed by subregulation (2) must include, to the satisfaction of the Council, education, tuition and training in -

- (a) Biochemistry;
- (b) Cell Biology, Genetics and Immunology;
- (c) Microbiology;
- (d) Quantitative Biology;
- (e) Chemistry;
- (f) Animal Physiology;
- (g) Plant Physiology;
- (h) Microbial Classification and Identification;
- (i) Applied and Environmental Microbiology;
- (j) Mammalian Physiology;

No. 4503

- (k) Nerve and Endocrine Physiology;
- (l) Food and Industrial Microbiology; and
- (m) Cardiovascular and Respiratory Physiology.

#### **Recognition of qualification by Council**

**3.** The Council may recognise, for the purpose of the registration of a person as a clinical biochemist, a qualification prescribed by regulation 2(2), if -

- (a) the educational institution at which that person obtained that qualification is approved by the Council;
- (b) the registration authority responsible for the registration of a person to practise as a clinical biochemist in the country in which that person obtained the qualification, recognises that qualification for registration to practise as a clinical biochemist in that country; and
- (c) that person complies with the other requirements for registration as a clinical biochemist prescribed by or under the Act.

## MINISTRY OF HEALTH AND SOCIAL SERVICES

#### No. 126

REGULATIONS RELATING TO REGISTRATION OF CLINICAL BIOCHEMISTS AND CLINICAL BIOCHEMIST INTERNS, REGISTRATION OF SPECIALITIES AND ADDITIONAL QUALIFICATIONS, MAINTAINING OF REGISTERS OF CLINICAL BIOCHEMISTS AND CLINICAL BIOCHEMIST INTERNS, AND RESTORATION OF NAME TO REGISTER: MEDICAL AND DENTAL ACT, 2004

Under section 59 of the Medical and Dental Act, 2004 (Act No. 10 of 2004), read with sections 23, 25 and 31 of that Act, and on the recommendation of the Medical and Dental Council of Namibia, I have made the regulations set out in the Schedule.

## R.N. KAMWI MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 26 May 2010

#### SCHEDULE

## ARRANGEMENT OF REGULATIONS

## PART I PRELIMINARY

#### 1. Definitions

## PART II

## **REGISTRATION OF CLINICAL BIOCHEMISTS**

2. Application for registration as a clinical biochemist and submitting of particulars

2010

## PART III

## CLINICAL BIOCHEMIST INTERNS

- 3. Registration and training of clinical biochemist intern before registration as a clinical biochemist
- 4. Agreement of internship training
- 5. Commencement or termination of internship, or change of name
- 6. Completion of internship
- 7. Evaluation by Council

## PART IV

## REGISTRATION OF SPECIALITIES AND ADDITIONAL QUALIFICATIONS

- 8. Registrable specialities
- 9. Application for the registration of a speciality and submitting of particulars
- 10. Conditions applicable to the practising of a speciality
- 11. Cessation of speciality practice
- 12. Registrable additional qualifications
- 13. Application for the registration of an additional qualification and submitting of particulars
- 14. Registration of non-prescribed speciality or additional qualification

## PART V

## REGISTERS AND RESTORATION OF NAME TO REGISTER

- 15. Register of clinical biochemists and clinical biochemist interns
- 16. Restoration of name to register

## PART V1

## GENERAL

17. Language of forms and documents

#### ANNEXURE

Criteria pertaining to internship training programme

## PART I PRELIMINARY

## Definitions

**1.** In these regulations, unless the context otherwise indicates, a word or expression defined in the Act has that meaning, and -

"additional qualification" means an additional qualification referred to in section 31(1)(a) of the Act, awarded by an educational institution and prescribed by regulation 12;

"approved facility" means a training facility approved by the Council for the purpose of the training of an intern;

"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);

"clinical biochemist intern" means a person registered as such under these regulations, and "intern" has a corresponding meaning;

"registration authority" means the registration authority of a country responsible for the registration of a person to practice as a clinical biochemist in that country;

"speciality" means a speciality in clinical biochemistry referred to in section 31(1)(b) of the Act and prescribed by regulation 8; and

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

#### PART II

## **REGISTRATION OF CLINICAL BIOCHEMISTS**

#### Application for registration as clinical biochemist and submitting of particulars

**2.** (1) An application for the registration of a person as a clinical biochemist in accordance with section 19 of the Act must be accompanied, in addition to the documents, particulars and payments specified in subsection (2) of that section, by -

- (a) a certified copy of the identity document or of the passport of the applicant; and
- (b) subject to subregulation (2), the original certificate of registration to practise as a clinical biochemist 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.

(2) If the applicant is not registered with the registration authority referred to in paragraph (b) of subregulation (1), 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 clinical biochemist 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, that his or her name has been removed from the register and the grounds for the removal.

(3) 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.

## PART III CLINICAL BIOCHEMIST INTERNS

#### Registration and training of clinical biochemist intern before registration as clinical biochemist

**3.** (1) A person who is the holder of a minimum qualification required for registration as a clinical biochemist, after having obtained that qualification and before he or she may be registered as a clinical biochemist, must complete internship training at an approved facility for a period of one year, during which period of time the intern must successfully complete practical training, to the degree and extent that the Council may determine, and to the satisfaction of the Council, in the main domains and disciplines specified in the Annexure.

(2) An application for registration as an intern must be made in the form that the Council may determine, and the duly completed form must be submitted to the registrar.

(3) An application referred to in subregulation (2) must be accompanied by -

- (a) documentary proof, to the satisfaction of the Council, that the applicant holds a qualification referred to in subregulation (1);
- (b) a certificate of good standing, if the applicant had been registered previously in a country other than Namibia as a clinical biochemist or as an intern, or is still so registered, from the registration authority with which the applicant had been so registered or is still so registered, which certificate must have been issued not more than 120 days before the date of the submission of the application for registration to the registrar in accordance with subregulation (2);
- (c) a certified copy of the identity document or of the passport of the applicant;
- (d) the additional documents and information that the Council may determine;
- (e) a certified copy of the agreement of internship training entered into by and between the applicant and an approved facility; and
- (f) payment of the application fees, determined by the Council, relating to the registration of an intern, or proof of the payment thereof.

(4) If the applicant referred to in subregulation (1) is not registered with the registration authority referred to in subregulation (3)(b), 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 clinical biochemist 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, that his or her name has been removed from the register and the grounds for the removal.

(5) 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.

(6) If an application for registration as an intern is submitted to the registrar in accordance with this regulation, the registrar must submit the application to the Council for its decision.

- (7) The Council, after having considered the application for registration as an intern -
- (a) may grant the application, if the Council is satisfied that the applicant -
  - (i) meets the requirements relating to the registration of an intern;
  - (ii) has complied with subregulations (3) and (4); and
  - (iii) is proficient in the English language;
- (b) must refuse the application if the Council is satisfied that the applicant -
  - (i) does not meet the requirements relating to the registration of an intern; or
  - (ii) has not complied with subregulations (3) and (4); or
  - (iii) is not proficient in the English language.

- (8) The Council must -
- (a) inform the applicant in writing of the decision of the Council under subregulation (7);
- (b) issue to the applicant a certificate of registration as an intern, if the application for registration as an intern is granted, in the form that the Council may determine, and enter the name of the applicant into the register;
- (c) inform the applicant in writing, if the application for registration as an intern is refused, as soon as practicable of the grounds for the refusal.

(9) Despite subregulation (1), the Council may exempt, on the conditions that it may determine, a person from the requirements of registration and training as an intern in accordance with these regulations, or may reduce the prescribed period of training as an intern by the period of time that the Council may determine, if that person submits documentary proof to the satisfaction of the Council that he or she has -

- (a) completed, at a training facility in another country and in accordance with the laws of that country pertaining to clinical biochemists or to clinical biochemist interns, training substantially equivalent to the applicable training prescribed by subregulation (1); or
- (b) practiced in another country, in accordance with the laws of that country, as a clinical biochemist for the period of time and under the circumstances as may afford him or her experience and training substantially equivalent to the applicable training prescribed by subregulation (1).

#### **Agreement of internship training**

**4.** (1) An agreement of internship training entered into by and between an approved facility and an intern, must -

- (a) be in the form and contain the particulars that the Council may determine;
- (b) provide for training in the main domains and disciplines specified in the Annexure that, in the opinion of the Council, is adequate and satisfactory for the purposes of the internship; and
- (c) be approved by the Council.

(2) If at any time during the period of internship of an intern prescribed by these regulations, the Council considers any training approved for that purpose to be inadequate or unsatisfactory for any reason, the Council may withdraw the approval thereof by means of a written notice to both the approved facility and the clinical biochemist intern, after having afforded them both the opportunity to be heard.

(3) Unless the Council otherwise determines, on good cause shown, any period of internship completed by an intern under an agreement of internship in respect whereof the Council withdraws its approval in accordance with subregulation (2), or that is cancelled or terminated before the completion of the internship, is, for the purposes of regulation 3, null and void.

(4) The period of internship training prescribed by regulation 3(1) must be completed within a period of two years after the date of the first registration of the intern.

(5) If an intern fails to comply with subregulation (4), his or her registration as an intern must be regarded as cancelled, subject to subregulation (6), as from the date upon which the period of two years is exceeded.

(6) The Council may extend, on good cause shown, the two year period prescribed by subregulation (4).

(7) Before a person may commence with his or her clinical biochemist internship at an approved facility, he or she must -

- (a) enter, in accordance with subregulation (1), into a written agreement of internship with that approved facility; and
- (b) register with the Council as an intern in accordance with the Act and these regulations.

(8) An intern is subject, during his or her term of internship, to all the professional conduct regulations and rules applicable to a clinical biochemist.

(9) The Council must furnish an intern, before the commencement of his or her internship, with a copy of the professional conduct regulations and rules referred to in subregulation (8).

#### Commencement or termination of internship, or change of name

- **5.** (1) An intern must notify the Council in writing -
- (a) as soon as he or she commences internship, of the commencement and furnish the Council with the name and business address, including the telephone number and other particulars that the Council may require, of the approved facility where he or she has commenced internship;
- (b) if he or she terminates his or her internship with the approved facility referred to in paragraph (a), of the termination within a period of 30 days thereof;
- (c) if he or she intends to terminate his or her internship with the approved facility referred to in paragraph (a) and to commence internship with any other approved facility, of the intended termination of internship not less than 30 days before the date of the intended termination and apply to the Council, in the form that the Council may determine, for approval of the new agreement of internship entered into between himself or herself and the other approved facility.
- (2) If the name or surname of an intern is changed for any reason, he or she must -
- (a) give written notice to the Council of the change of name, and submit documentary proof thereof, to the satisfaction of the Council, within a period of 30 days after the occurrence thereof; and
- (b) provide the Council, in writing, with the other particulars relating to the change of name or surname that the Council may require.

#### **Completion of internship**

**6.** (1) Upon the completion of the internship training prescribed by these regulations, the intern must submit to the Council proof of the completion, by means of a certificate or certificates, to the satisfaction of the Council, by the approved facility or approved facilities where he or she completed the internship.

(2) The Council may not register a person as a clinical biochemist unless that person has submitted to the Council the certificate or certificates prescribed by subregulation (1).

## **Evaluation by Council**

7. (1) An evaluation by the Council in accordance with section 20(3) of the Act may be conducted by the Council in part, at the discretion of the Council and in the manner that it may determine, by means of the continual evaluation of the intern during the period of internship.

(2) The fees determined by the Council under section 26 of the Act relating to an evaluation referred to in this regulation must be paid to the Council before the commencement of the evaluation.

#### PART IV REGISTRATION OF SPECIALITIES AND ADDITIONAL QUALIFICATIONS

## **Registrable specialities**

**8.** (1) For the purposes of section 31(1)(b) of the Act, a Doctorate, or a Master of Science Degree, in Clinical Biochemistry is a speciality that may be registered, subject to compliance with these regulations, in the name of a clinical biochemist.

(2) The standard of the education, tuition and training provided by an educational institution in respect of a post-graduate qualification relating to a speciality prescribed by subregulation (1) must be adequate and satisfactory, in the opinion of the Council.

(3) The qualification referred to in subregulation (2) must entitle the applicant to registration, in the country where he or she obtained that qualification, as a specialist clinical biochemist in the speciality to which that qualification relates.

#### Application for the registration of a speciality and submitting of particulars

**9.** An application for the registration of a speciality in accordance with subsection (2) of section 31 of the Act, must be accompanied, in addition to the documents, information and payments specified in subsection (3) of that section, by a certified photocopy of the identity document or passport of the applicant.

## Conditions applicable to the practising of a speciality

- 10. A specialist clinical biochemist -
- (a) must confine his or her practice to the speciality registered in his or her name;
- (b) may not take over a patient from another clinical biochemist, whether practising as a specialist or as a clinical biochemist, without the consent of that clinical biochemist, unless consent to that taking over is unreasonably withheld;
- (c) may examine, and conduct tests on, a patient referred to him or her by medical practitioner, as requested by that medical practitioner in the referral;
- (d) must report to the medical practitioner who referred the patient to him or her as prescribed by paragraph (c), the result of the tests conducted by him or her on that patient; and

- (e) may charge fees for examinations or procedures which usually pertain to another speciality only if the examination or procedures are also recognised in his or her speciality as generally accepted practice, but -
  - (i) those fees may not exceed the fees charged by a clinical biochemist for the same examinations or procedures; and
  - (ii) the examinations or procedures must be carried out only relating to his or her *bona fide* patients.

#### **Cessation of speciality practice**

**11.** A specialist who discontinues practising his or her speciality must notify the registrar in writing thereof within a period of 30 days after the date upon which he or she so ceases to practise that speciality.

#### **Registrable additional qualifications**

12. For the purposes of section 31(1)(a) of the Act, the additional qualifications that may be registered by the Council in respect of a person registered as a clinical biochemist is a Masters Degree in any of the main domains prescribed by paragraph (a) of the Annexure, obtained at an educational institution approved by the Council and acknowledged for registration as an additional qualification by the registration authority of the Country in which the clinical biochemist obtained that masters degree.

#### Application for the registration of an additional qualification and submitting of particulars

**13.** An application for the registration of an additional qualification in accordance with subsection (2) of section 31 of the Act, must be accompanied, in addition to the documents, information and payments specified in subsection (3) of that section, by a certified photocopy of the identity document or passport of the applicant.

## Registration of non-prescribed speciality or additional qualification

- **14.** (1) In this regulation -
- (a) "non-prescribed additional qualification" means an additional qualification not prescribed by regulation 12 as a registrable additional qualification; and
- (b) "non-prescribed speciality" means a speciality not prescribed by regulation 8 as a registrable speciality,

but that complies with subsection (5) of section 31 of the Act.

(2) If an application for the registration of a non-prescribed speciality or non-prescribed additional qualification is submitted to the Council in accordance with section 31(2) of the Act, the application must be accompanied, in addition to the documents and particulars specified in subsection (3) of that section and regulation 9, or regulation 13, by a transcript, issued by the educational institution or examining body where that speciality or additional qualification, has been obtained, specifying particulars, to the satisfaction of the Council, of that speciality or additional qualification, including the curriculum applicable thereto.

#### PART V

## REGISTERS AND RESTORATION OF NAME TO REGISTER

#### Register of clinical biochemists and clinical biochemist interns

**15.** The register established and kept in accordance with subsection (2) of section 23 of the Act, for -

- (a) clinical biochemists must contain, in addition to the particulars specified by subsection (3) of that section, particulars of -
  - (i) the specialities and additional qualifications registered under the Act in the name of that clinical biochemist; and
  - (ii) any change in any of the particulars recorded in the register; and
- (b) clinical biochemist interns, must contain, in addition to the particulars specified by subsection (3) of that section, particulars of -
  - (i) particulars of the approved facility or facilities where the intern is completing his or her internship; and
  - (ii) any change in any of the particulars recorded in the register.

## **Restoration of name to register**

16. An application in accordance with section 25 of the Act for the restoration of the name of a person to a register, in addition to the documentation referred to in subsection (2) of that section, must be accompanied by -

- (a) the original registration certificate issued under section 20(4)(b) of the Act in the name of the applicant, or if for any reason the original certificate cannot be submitted, proof to the satisfaction of the Council that the applicant had been so registered; and
- (b) a photocopy of the identity document or the passport of the applicant, duly certified.

## PART VI GENERAL

#### Language of forms and documents

**17.** (1) Any form or document required to be submitted to the Council or to the registrar in terms of these regulations must be, subject to subregulation (2), 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 translation thereof into that language, acceptable to the Council.

## ANNEXURE CRITERIA PERTAINING TO INTERNSHIP TRAINING PROGRAMME (Regulation 3)

The approved facility with which the clinical biochemist intern has entered into an agreement of internship in accordance with regulation 4, must provide the intern, to the degree and extent that the Council may determine, and to the satisfaction of the Council, with practical training in -

- (a) the main domains of, or relating to -
  - (i) Frontier Technologies in Biosciences; and
  - (ii) Biostatistics and Bioinformatics; and
- (b) Computer and Laboratory Courses; and
- (c) Project Work; and
- (d) Ethics and Jurisprudence.