



VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION

on the education, rights and obligations of biomedical scientists and criteria for granting of licences and specialist licences, No. 1132/2012.

SECTION I

General provisions.

Article 1

Scope.

This Regulation applies to biomedical scientists holding licences and specialist licences from the Medical Director of Health under Articles 2 and 5.

SECTION II

Licences.

Article 2

Professional title.

The right to use the professional title of biomedical scientist and to practise as such in Iceland is confined to those who have been granted a licence by the Medical Director of Health.

Article 3

Criteria for granting of a licence.

A licence under Article 2 may be granted to those who have completed a BS degree in biomedical science followed by one year's study leading to a diploma in biomedical science from the biomedical science programme of the Faculty of Medicine in the University of Iceland's School of Health Sciences.

A licence may also be granted on the basis of education from a state within the European Economic Area (EEA) and Switzerland. Recognition of professional qualifications and competence of a biomedical scientist who meets the criteria of Directive 2005/36/EC, on the recognition of professional qualifications, with subsequent amendments, is subject to Regulation on recognition of professional qualifications and competence of healthcare practitioners from other EEA states, No. 461/2011, or to Nordic Convention on a common Nordic labour market for certain health professionals and veterinarians, No. 36/1993 (*cf.* Amendment No. 6/2001).

A licence may also be granted to those who have completed a comparable qualification from an educational institution in a state outside the EEA or Switzerland, which is recognised as such by Icelandic health authorities, and by health authorities in the state where the education took place.

Other criteria for the issue of a licence are subject to Article 12.

Article 4

Opinions.

Before a licence is granted under Article 2 on the basis of education outside Iceland under the third paragraph of Article 3, the Medical Director of Health shall elicit the opinion of the biomedical science programme of the Faculty of Medicine in the University of Iceland's School of Health Sciences, with regard to whether the applicant fulfils the criteria for education under the first paragraph of Article 3, for granting of a licence.

The Medical Director of Health may elicit opinions from other bodies, as deemed necessary.

SECTION III

Specialist licences in biomedical science.

Article 5

Specialist licences.

The right to use the title of specialist in a specialty or specialised field of biomedical science and to practise as such in Iceland is confined to those granted a licence by the Medical Director of Health.

Article 6

Criteria for specialist licences.

Specialist licences may be granted in clinical specialist field or specialised fields of biomedical science. This is subject to the criterion that the specialist training of the applicant is defined as being within the specialist field or specialised field for which he/she applies for a specialist licence.

The relevant specialist field or specialised field shall have a solid theoretical basis, and an equivalent shall exist in a recognised international forum.

A specialised clinical field or specialist field refers to research in biological sciences.

In order to be entitled to receive a specialist licence under Article 5 a biomedical scientist shall fulfil the following standards:

1. he/she shall be licensed as a biomedical scientist in Iceland under Article 2; and
2. he/she shall have completed a master's or doctoral degree in biomedical science from a recognised university, or hold an equivalent education; and
3. he/she shall have worked as a biomedical scientist after graduation under indent 2 for the equivalent of at least two years full-time in the specialty or field for which the application for a specialist licence is made. If he/she has worked less than full-time, the duration shall be proportionately longer.

Up to twelve months full-time may be subtracted if the person has been employed in the relevant specialised clinical field alongside doctoral studies.

Further criteria for the granting of a specialist licence are subject to Article 12.

Article 7

Application and opinions.

An application for a specialist licence in biomedical science, together with documents confirming education and professional experience, and other necessary documents, shall be submitted to the Medical Director of Health.

Before a specialist licence is granted under Article 5 on the basis of education outside Iceland, the Medical Director of Health shall elicit the opinion of the biomedical science programme of the Faculty of Medicine in the University of Iceland's School of Health Sciences, with regard to whether the applicant fulfils the criteria of Article 6.

The Medical Director of Health may appoint a special committee to evaluate and comment upon applications for specialist licences.

The Medical Director of Health may elicit opinions from other bodies, as deemed necessary.

SECTION IV

Rights and obligations.

Article 8

Professional standards and responsibility.

A biomedical scientist shall show respect for the patient and perform his/her tasks vigilantly and conscientiously and in accordance with the professional standards required of the profession at any time.

A biomedical scientist must be aware of his/her duties and respect ethical rules of the profession, maintain his/her knowledge and professional skill, and master innovations in his/her field of work.

A biomedical scientist shall be familiar with legislation and regulations applying to healthcare practitioners and healthcare services, and other legislation and government directives, as applicable.

A biomedical scientist is responsible for the research in biological sciences he/she carries out.

A biomedical scientist shall recognise his/her professional limitations, and seek the assistance of another healthcare practitioner as necessary.

Article 9

Duty to inform and keeping of medical records.

The duty of a biomedical scientist to provide information to a patient is subject to the provisions of the Patients' Rights Act, No. 74/1997.

The duty of a biomedical scientist to provide information to the Medical Director of Health, *inter alia* with respect to monitoring and for the purpose of producing health reports, is subject to the provisions of the Medical Director of Health and Public Health Act, No. 41/2007.

A biomedical scientist shall, as appropriate, enter medical records in accordance with the provisions of the Medical Records Act, No. 55/2009, and regulations issued on the basis of the Act.

Article 10

Assistants and trainees.

A biomedical scientist is responsible for assistants and trainees working under his/her management having sufficient competence and knowledge, and receiving the necessary guidance and instructions, to carry out tasks which he/she allots to them.

Article 11

Confidentiality.

A biomedical scientist shall maintain the utmost confidentiality regarding anything of which he/she becomes aware in his/her work about a patient's health, condition, diagnosis, prognosis and treatment, and other personal information. This does not apply where other provisions are made by law, or where reasonable cause exists to breach confidentiality for reasons of urgent necessity.

A biomedical scientist can be released from the obligation of confidentiality by the consent of a patient, or guardian if applicable.

The duty of confidentiality under this Article does not apply to cases in which the biomedical scientist has a duty to report under other legal provisions. In such cases, the duty of the biomedical scientist is to notify the relevant authority.

A biomedical scientist's duty of confidentiality is also subject to the provisions of the Patients' Rights Act, the Medical Records Act and other legislation as applicable.

SECTION V

Various provisions.

Article 12

Further criteria for granting of licences and specialist licences.

An applicant for a licence as a biomedical scientist under Article 2 and a specialist licence in biomedical science under Article 5 who is from a state outside the EEA and Switzerland, with which Iceland has not made an agreement on recognition of professional qualifications and competence, shall submit *inter alia* documentary evidence of nationality, content and duration of education, in addition to an examination certificate, a licence if the profession is an authorised profession in the applicant's state of origin, intended employment in Iceland, and any other documents and certificates deemed by the Medical Director of Health to be necessary for the issue of a licence or specialist licence.

Before an application for a licence or a specialist licence is evaluated, a certified copy of an application for residence and work permits must be submitted, together with a signed contract of employment.

A requirement may be made for knowledge of the Icelandic language and Icelandic healthcare legislation, as well as other legislation and government directives, as deemed necessary in the work of a biomedical scientist, especially with regard to patients' safety and communication with patients.

Should it not have been demonstrated, in the judgement of the Medical Director of Health, that the applicant's qualification fulfils the criteria under the first paragraph of Article 3 or Article 6, account being taken of professional experience, an applicant may be required to submit to a test of competence to demonstrate that he/she possesses the professional knowledge and competence required in a biomedical scientist, or a biomedical scientist holding a specialist licence. An appropriate educational institution shall organise the test for the applicant in consultation with the Medical Director of Health.

Licences and specialist licences are issued when the applicant commences work in Iceland.

Article 13

Fees.

Fees for the issue of a licence or specialist licence are subject to Article 10 of the Treasury Supplementary Revenues Act, No. 88/1991.

Fees for all administration undertaken by the Medical Director of Health with regard to applications for licences and specialist licences, in addition to the fee under the first paragraph, and for tests of professional knowledge and competence, are subject to Regulation on fees for applications for healthcare practitioners' licences and specialist licences, No. 951/2012.

Article 14

General provisions.

The provisions of the Healthcare Practitioners Act, No. 34/2012, the Medical Director of Health and Public Health Act, No. 41/2007, the Medical Records Act, No. 55/2009, the Health Service Act, No. 40/2007, the Patients' Rights Act, No. 74/1997, and other legislation and government directives apply to biomedical scientists as applicable.

Article 15

Entry into force.

This Regulation, issued on the basis of Articles 5, 8, 30 and 31 of the Healthcare Practitioners Act, No. 34/2012, takes effect 1 January 2013. From that time Regulation on medical technicians, No. 186/1976, with subsequent amendments, and Regulation on the granting of specialist licences in biomedical science, No. 323/2007, with subsequent amendments, are abrogated.

Ministry of Welfare, 11 December 2012.

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