



VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION **on the education, rights and obligations of biologists** **in healthcare service and criteria for granting of licences,** **No. 1220/2012.**

SECTION I

General provisions.

Article 1

Scope.

This Regulation applies to biologists in healthcare service licensed by the Medical Director of Health under Article 2.

SECTION II

Licences.

Article 2

Professional title.

The right to use the professional title of biologist in healthcare service 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 science from a recognised educational institution at university level with the main emphasis on disciplines within the health sciences, cell and molecular biology, physics and chemistry, biophysics and biochemistry, genetics and biotechnology, microbiology and virology, immunology, transfusion medicine, histology, pathology, epidemiology, statistics and systems biology or other comparable fields, together with one year's clinical training in specialised laboratories of healthcare institutions; or hold a postgraduate qualification in a field 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 biologist in healthcare service who meets the criteria of Directive 2005/36/EC, on the recognition of professional qualifications, with subsequent amendments, is subject to Regulations on recognition of professional qualifications and competence of healthcare practitioners from other EEA states, No. 461/2011.

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.

An applicant for a licence as a biologist in healthcare service under Article 2 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.

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

A requirement may be made for knowledge of the Icelandic language and Icelandic healthcare legislation, and other legislation and government directives, as deemed necessary to the work of a biologist in healthcare service, 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, 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 biologist in healthcare service. An appropriate educational institution shall organise this test in consultation with the Medical Director of Health.

A licence under the third paragraph is issued when the applicant commences work in Iceland.

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 recognised educational institutions at university level with the principal emphasis on disciplines within the 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

Rights and obligations.

Article 5

Professional standards and responsibility.

A biologist in healthcare service 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 biologist in healthcare service 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 biologist in healthcare service shall be familiar with legislation and regulations applying to healthcare practitioners, healthcare service and other legislation and government directives as applicable.

A biologist in healthcare service is responsible as applicable for research/tests in his/her professional field, *inter alia* in diagnosis of disease and processing of data.

A biologist in healthcare service shall recognise his/her professional limitations, and seek assistance from another healthcare practitioner as necessary.

Article 6

Duty to inform and keeping of medical records.

The duty of a biologist in healthcare service to provide information to a patient is subject to the provisions of the Patients' Rights Act, No. 74/1997.

The duty of a biologist in healthcare service 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 biologist in healthcare service 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 7

Assistants and trainees.

A biologist in healthcare service 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 8
Confidentiality.

A biologist in healthcare service 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 biologist in healthcare service 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 biologist in healthcare service has a duty to report under other legal provisions. In such cases, the duty of the biologist in healthcare service is to notify the relevant authority.

The duty of confidentiality of a biologist in healthcare service is also subject to the provisions of the Patients' Rights Act, the Medical Records Act and other legislation as applicable.

SECTION IV
Various provisions.

Article 9
Fees.

Fees for the issue of a 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, 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 10
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 biologists in healthcare service, as applicable.

Article 11
Entry into force.

This Regulation, issued on the basis of Articles 5, 30 and 31 of the Healthcare Practitioners Act, No. 34/2012, takes effect on 1 January 2013. From that time Regulations on the training, rights and obligations of biologists working in specialised laboratories of healthcare facilities, No. 272/1991, with subsequent amendments, is abrogated.

Ministry of Welfare, 11 December 2012.

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*[This translation is published for information only.
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In case of a possible discrepancy, the original Icelandic text applies.]*