The Official Gazette A

Ministerial Order on the Bachelor's Degree Programme of Biomedical Laboratory Science

Pursuant to Section 22 of the Act on Academy Profession and Professional Bachelor Programmes, cf. Consolidation Act no. 1147 of 23 October 2014, as amended by Act no. 633 of 12 May 2015, and Section 15 and Section 60 of the Act on Authorisation of Healthcare Professionals and of Professional Healthcare Activity, cf. Consolidation Act no. 877 of 4 August 2011, and after negotiations with the Minister for Health and the Elderly, it is hereby established that:

Part 1

Purpose

1. The purpose of the Bachelor's Degree Programme of Biomedical Laboratory Science is to qualify graduates to independently perform biomedical examinations and analyses, assure their quality, disseminate knowledge of, and interpret, the results, and develop diagnostics in the fields of health technology and laboratory medicine, in monodisciplinary and interprofessional contexts, in both the public and private sectors and with a focus on citizens and patients. The graduate possesses the competencies to participate in research and development work and to participate in theoretical and clinical continuing and further education study programmes.

(2) The graduate possesses the knowledge, skills and competencies specified in Appendix 1.

(3) The programme is based on research and development in the field of biomedical laboratory science, as well as on knowledge of professional practice and the positions for which graduates are qualified.

2. On successful completion of the programme, graduates are entitled to use the title *Professionsbachelor i bioanalytisk diagnostik* in Danish and Bachelor of Biomedical Laboratory Science in English.

(2) The programme's English title is Bachelor's Degree Programme of Biomedical Laboratory Science.

(3) Graduates are authorised pursuant to the Act on Authorisation of Healthcare Professionals and of Professional Healthcare Activity.

Part 2

Duration, structure and organisation

3 The educational institution that provides the study programme is responsible for the Programme of its entirety.

(2) The educational institution works together with the organisation that provides the work placement site (clinical training site) at all levels in order to ensure coordination between the theoretical teaching and the work placement (clinical training). The educational institution is responsible for ensuring that the co-operation is established and maintained. The educational institution and the organisation that provides the work placement site must jointly draw up mutually binding agreements that describe the form of the co-operation. These agreements must be published on the educational institution's website.

(3) The educational institution must approve the work placement site (clinical training site). In managerial terms, an work placement site (clinical training site) constitutes a defined area that is approved by the educational institution, cf. the relevant criteria in the curriculum.

(4) The educational institution holds the work placement site (clinical training site) responsible for ensuring that the work placement (clinical training) is completed as per the guidelines laid down by the educational institution.

(5) It is a condition for approval of the work placement site (clinical training site) that the clinical training is provided by biomedical laboratory scientists with pedagogic qualifications corresponding to 1/6 of a diploma programme.

(6) It is also a condition for approval that the work placement (clinical training) meets the following requirements:

1) The work placement (clinical training) is defined as the part of the study programme during which the student participates in relevant bioanalytical work in an authentic context, and learns to plan, carry out and assess the overall work in the area of bioanalysis.
2) The work placement (clinical training) takes place under supervision in an institution run by either the national government or a regional or local authority, or in a private or another appropriate institution.
3) To a limited extent - as preparation for contact with

patients and citizens, for example - some elements of the work placement (clinical training) may take place in a skills

laboratory or simulation laboratory. However, these must not replace relevant bioanalytical work in an authentic context.

4 The programme is full-time and equivalent to 210 ECTS credits, of which 20 ECTS credits consist of elective elements, 20 ECTS credits consist of interprofessional elements and 20 ECTS credits consist of a bachelor project, of which the work placement (clinical training) accounts for 5 ECTS credits. One student FTE is equivalent to a year of full-time study, and corresponds to 60 ECTS credits.

(2) The study programme is divided into semesters. During each semester, students must achieve 30 ECTS credits. Semesters may be subdivided into modules equivalent to 10 ECTS credits.

5 The study programme consists of theoretical elements equivalent to a total of 135 ECTS credits and work placement (clinical training) equivalent to a total of 75 ECTS credits.

(2) The programme covers the following subject areas:

1) Health science subjects corresponding to 120 ECTS credits.
2) Natural science subjects equivalent to 60 ECTS credits.
3) Humanities subjects equivalent to 10 ECTS credits.
4) Social science subjects equivalent to 20 ECTS credits.

6 The Programme includes the following compulsory themes during the first two years:

1) Bioanalysis, equivalent to 30 ECTS credits.
2) Quality assurance of bioanalysis, equivalent to 20 ECTS credits.
3) Biomedicine and biomedical laboratory science, equivalent to 30 ECTS credits.
4) Understanding professional practice and identity for biomedical laboratory scientists, equivalent to 20 ECTS credits.
5) Patient-centred health technology and bioanalysis, equivalent to 10 ECTS credits.
6) Innovation, development and research in bioanalysis, equivalent to 10 ECTS credits.

7. Within the framework of this ministerial order, the educational institution lays down more detailed rules in a curriculum for the whole study programme. The curriculum consists of a common part designed to guarantee consistency across educational institutions, and a part specific to the individual institution concerned. The common part is drawn up jointly by the institutions authorised to provide the study programme. The individual institutions authorised to provide the study programme draw up the specific part of the curriculum.

(2) The common part must describe the following:

1) The content of each theme during the first two years, cf. 6.
2) Objectives for learning outcomes after the first two years.
3) The split between theoretical elements and work placement (clinical training), in terms of ECTS credits, during the first two years of the study programme.
4) The ECTS allocation between subject areas, cf. 5 (2), during the first two years of the study programme, including courses equivalent to a minimum of 5 ECTS credits.
5) Exams held during the first two years of the study programme, including which ones are assessed by an external examiner and which ones are clinical and/or theoretical.
6) Requirements for the final bachelor project.
7) Rules on credit.

(3) The part of the curriculum specific to the institution is drawn up in accordance with the rules in the Ministerial Order on Academy Profession Degree Programmes and Professional Bachelor Programmes (the LEP Order). In the specific part, the individual institution describes the compulsory and elective content of the themes during the final 1½ years of the study programme.

Part 3

Examinations, etc.

8 Exams are held at the end of a semester.

(2) In the specific part of the curriculum, the institution describes the objectives for learning outcomes, for which exams are held as per (1).

(3) Attendance during the work placement (clinical training) is mandatory. Attendance is a prerequisite for sitting the exam at the end of the work placement (clinical training).

(4) Otherwise, the rules contained in the Ministerial Order on Tests and Exams in Vocational Higher Education Programmes (the Exam Order) apply.

Part 4

Other regulations

9 Students must complete the programme within six years of commencing their studies. This does not include leave of absence due to childbirth, adoption, long-term illness, national service, UN service, etc. In special circumstances, the institution may extend the programme beyond six years.

10. If any significant changes are made to the curriculum, the relevant authorising bodies must be informed.

(2) Changes may only be made to the common part of the curriculum with the agreement of all of the educational institutions responsible for providing the study programme. Any changes must also be discussed with the educational institution's partners on the study programme.

(3) The rules concerning amendments to curricula contained in the Ministerial Order on Academy Profession Degree Programmes and Professional Bachelor Programmes, as well as in the Act on University Colleges, also apply.

11 The rules concerning professional bachelor study programmes contained in the Ministerial Order on Academy Profession Degree Programmes and Professional Bachelor Programmes, with the exception of the requirements regarding the common part of the curriculum, also apply.

Part 5

Date of commencement, etc.

12. This order enters into force on 1 August 2016.

(2) Ministerial Order no. 652 of 29 June 2009 on the Bachelor's Degree Programme of Biomedical Laboratory Analysis is hereby repealed.

(3) Students who started on the Biomedical Laboratory Analysis study programme before 1 August 2016 may complete the programme

under the ministerial order mentioned in (2) until the summer of 2019, cf., however, (4).

(4) The educational institution may make transitional arrangements so that students who enrolled on the Biomedical Laboratory Science study programme before 1 August 2016 must complete the programme under the rules set out in this ministerial order.

Place

SIGNATORY 1

/Signatory 2

Appendix 1

Objectives for learning outcomes for the Bachelor's Degree Programme of Biomedical Laboratory Science

The objectives for learning outcomes include the knowledge, skills and competencies that a bachelor of biomedical laboratory science must achieve during the programme.

Knowledge

The graduate:

1) is able to understand and reflect on key areas in the health and natural sciences, including bioanalysis, biomedicine and health technology,

2) is able to understand and reflect on the relevance of medical laboratory examinations and analyses in relation to prevention, diagnostics and treatment, as well as how these relate to quality assurance, patient care, safety and finances,

3) is able to understand and reflect on the profession's theories and methods, including relevant research methodologies, theory of science and the importance of these theories for professional practice,

4) possesses knowledge of, and is able to reflect on, the profession's use of information and communication technology, as well as the impact of technology on biomedical laboratory science,

5) possesses knowledge of, and is able to understand and reflect on, the care provided to citizens and patients, and is able to participate in interprofessional and intersectoral collaboration on care packages,

6) possesses knowledge of ethics and is able to reflect on ethical issues related to the profession,

7) possesses knowledge of, and is able to understand, innovation as a method of developing practice,

8) possesses knowledge of, and is able to reflect on the application of, communication theories and methods, and understand the communicative significance in relation to dialogue and forging relationships,

9) possesses knowledge of methods and standards for quality assurance, patient safety and quality enhancement, and is able to reflect on their use,

10) possesses knowledge of, and is able to reflect on, their own practice, as well as their profession's duties and responsibilities, in an organisational, administrative and social perspective and as part of the wider health service,

11) possesses knowledge of the priorities for deploying professional resources under the prevailing framework conditions in the health service,

12) possesses knowledge of, and is able to reflect on, the theory of science, research methods and models for evaluation, quality assurance and quality enhancement, as well as relating this knowledge to research and development work in professional practice.

Skills

The graduate is
able to:

1) use and independently assess medical laboratory examinations and analyses, and justify the solutions chosen in relation to health technology, health pedagogics, diagnostics and treatment, as well as in relation to ethical, working-environment, patient-related and organisational conditions,

2) assess the quality of medical laboratory examinations and analyses, and justify the solutions chosen in relation to health technology, health pedagogics, diagnostics and treatment, as well as in relation to ethical, working-environment, patient-related and organisational conditions,

3) apply and critically assess new evidence-based and experience-based knowledge in relation to professional practice in the relevant research and development fields,

4) justify and disseminate knowledge of the implementation of methods for safeguarding and developing the quality and validity of bioanalytical examinations and analyses, in both monodisciplinary and interdisciplinary contexts,

5) disseminate knowledge of, and communicate professional and practical issues and solutions related to, bioanalysis, using clear terminology, orally and in writing,

6) apply and master professional and situation-based communication, guidance and advice on biomedical laboratory science in citizen and patient care, in professional and interprofessional practice,

7) master interprofessional and intersectoral collaboration in a range of contexts and types of citizen and patient care,

8) use professionally relevant information, communication and health technology that incorporates thinking about the citizen's own resources to the greatest possible extent,

9) use, assess and justify methods and described standards for quality assurance and enhancement,

10) master relevant study and working methods both to search for, assess and interpret empirical evidence, theory and research methods, and to initiate and participate in innovation, development and research work.

Competencies

The graduate is
able to:

1) act professionally and on the basis of sound ethical principles, and assume the responsibilities associated with the profession,

2) independently plan, conduct, develop, assure the quality of and document biomedical laboratory science and treatment, and disseminate knowledge of the implications of these for prevention, diagnostics and treatment,

3) independently identify the prevalence and level of biomarkers in human samples, and assume responsibility for interpreting the results and disseminate knowledge of the implications for prevention, diagnostics and treatment,

4) process complex functional analyses, and assess, interpret and disseminate knowledge of the implications from the perspective of prevention, diagnostics and treatment,

5) independently participate in the development of practice in the health service and the profession, and develop their own practice on the basis of trends in science, technology and society, as well as evidence-based and experience-based knowledge,

6) process and assume responsibility for the development and implementation of new health and information technology solutions based on the perspectives of citizens and patients,

7) process and coordinate complex citizen and patient care packages,

8) assume responsibility, in a manner that demonstrates resourcefulness and independence, for the implementation of new solutions based on the perspectives of citizens and patients,

9) work and independently communicate about biomedical laboratory science with citizens, patients and their relatives and interprofessional partners in a range of contexts,

10) work and independently take part in and coordinate interprofessional and intersectoral collaboration, and, on the basis of a holistic perspective, support citizens and patients as key, active stakeholders in individual care packages,

11) work with, and assume responsibility for, technology, including information and communications technology, relevant to the profession in the relevant context,

12) work with, and assume responsibility for, quality assurance and enhancement,

13) demonstrate personal professional responsibility, and keep up-to-date by identifying and understanding their own learning processes and developmental needs.