SIHTASUTUS Kutsekoda

OCCUPATIONAL QUALIFICATION STANDARD

Chartered Biomedical Engineer, EstQF Level 8

An occupational qualification standard is a document which describes the set of skills, knowledge and attitudes, i.e. competence requirements, needed to successfully accomplish duties. Occupational qualification standards are used for compiling curricula and awarding qualifications.

Occupational title	Level of Estonian Qualifications Framework (EstQF)
Chartered Biomedical Engineer, EstQF Level 8	8

Possible specialisation and titles on occupational certificate	
Specialisation	**Title on occupational qualification certificate**
Jobs related to diagnostic and interventional radiology technology	Expert in Diagnostic and Interventional Radiology Medical Physics, Level 8
Jobs related to nuclear medicine technology	Expert in Nuclear Medical Physics, Level 8
Planning radiotherapy and accompanying procedures	Expert in Radiotherapy Medical Physics, Level 8
Engineering jobs related to medical laboratory devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to medical laboratory devices
Engineering jobs related to anaesthetic and intensive care devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to anaesthetic and intensive care devices
Engineering jobs related to operation devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to operation devices
Engineering jobs related to dentistry devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to dentistry devices
Engineering jobs related to disinfection and sterilisation devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to disinfection and sterilisation devices
Engineering jobs related to dialysis devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to dialysis devices
Engineering jobs related to functional diagnostic devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to functional diagnostic devices
Engineering jobs related to rehabilitation devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to rehabilitation devices
Engineering jobs related to medical exposure devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to medical exposure devices
Engineering jobs related to intracardiac devices	Chartered Biomedical Engineer, EstQF Level 8 Engineering jobs related to intracardiac devices
Jobs related to medical information technology	Chartered Biomedical Engineer, EstQF Level 8 Jobs related to medical information technology

Part A
DESCRIPTION OF WORK

A.1 Description of work
Biomedical engineers work in health institutions, companies manufacturing, installing, maintaining and/or repairing medical devices, universities, test laboratories or other companies. The goal is to support the safe and high-quality functioning of contemporary medicine through engineering, medical physics and medical information technology applications. The activities of Authorised Biomedical Engineering Technologist, Level 8 consist of medical physics, medical information technology or engineering works, incl. tasks related to the functional planning, installation, operation and development of medical devices. The job requires an interdisciplinary, complex and innovative approach both independently and in teams. An authorised biomedical engineering technologist is a senior specialist with comprehensive and broad-ranging knowledge and experience who develops new solutions and methods and independently analyses and synthesises professional ideas. They are willing and able to lead a team or an organisation and cooperate with specialists in related fields. They lead evaluations, audits and examinations as the expert in charge. The European Union guidelines entitled ‘Radiation Protection 174’ (European Guidelines on Medical Physics Expert) form the basis for choosing specialisations and describing the competences of the field of medical physics. When working in health care institutions, the requirements in force in clinical environments must be observed. There is a possibility of contact with poisonous materials, infectious materials or ionising radiation, which requires the use of protective equipment in accordance with the nature of the job.
A.2 Tasks
A.2.1 Operating medical devices and systems A.2.2 Developing medical devices and systems A.2.3 Management
Specialised areas of work
A.2.4 Jobs related to diagnostic and interventional radiology technology A.2.5 Jobs related to nuclear medicine technology A.2.6 Planning radiotherapy and accompanying procedures A.2.7 Engineering jobs related to medical laboratory devices A.2.8 Engineering jobs related to anaesthetic and intensive care devices A.2.9 Engineering jobs related to operation devices A.2.10 Engineering jobs related to dentistry devices A.2.11 Engineering jobs related to disinfection and sterilisation devices A.2.12 Engineering jobs related to dialysis devices A.2.13 Engineering jobs related to functional diagnostic devices A.2.14 Engineering jobs related to rehabilitation devices A.2.15 Engineering jobs related to medical exposure devices A.2.16 Engineering jobs related to intracardiac devices A.2.17 Jobs related to medical information technology
Elective areas of work
A.2.18 Developing medical devices and systems A.2.19 Drawing up medical technology projects for buildings
A.3 Professional preparation
An authorised biomedical engineering technologist has a professional Master's degree and sufficient work experience and has undergone further training.
A.4 Most common occupational titles
Medical engineering technologist, quality engineer, medical physicist, sales engineer, expert in medical physics, etc.
A.5 Regulations governing profession
Possessing the occupational qualification certificate of Biomedical Engineering Technologist, Level 8 is a prerequisite for working in the fields of medical physics (diagnostic radiology, nuclear medicine and radiotherapy).

Basis: Radiation Act, 2013/59/Euratom and 2013/35/EL and associated legislation, Ministry of Social Affairs regulation on medical exposure.

Part B
COMPETENCY REQUIREMENTS

B.1 Structure of occupation
Competences B.2 and B.3.1-B.3.3 must be certified when applying for the qualification of Chartered Biomedical Engineer, EstQF Level 8. In addition, at least one competence from B.3.4-B.3.17 must also be certified. Jobs related to diagnostic and interventional radiology technology – competence B.3.4; Jobs related to nuclear medicine technology – competence B.3.5; Planning radiotherapy and accompanying procedures – competence B.3.6; Engineering jobs related to medical laboratory devices – competence B.3.7; Engineering jobs related to anaesthetic and intensive care devices – competence B.3.8; Engineering jobs related to operation devices – competence B.3.9; Engineering jobs related to dentistry devices – competence B.3.10; Engineering jobs related to disinfection and sterilisation devices – competence B.3.11; Engineering jobs related to dialysis devices – competence B.3.12; Engineering jobs related to functional diagnostic devices – competence B.3.13; Engineering jobs related to rehabilitation devices – competence B.3.14; Engineering jobs related to medical exposure devices – competence B.3.15; Engineering jobs related to intracardiac devices – competence B.3.16; Jobs related to medical information technology – competence B.3.17. Certification of optional competences B.3.18 and B.3.19 is not mandatory.

B.2 General skills of Chartered Biomedical Engineer, EstQF Level 8
1. In their activities, Authorised Biomedical Engineering Technologist, Level 8 relies on knowledge of engineering and medical physics: a) general science (higher mathematics, higher physics, physiology and anatomy); b) engineering (information technology, engineering graphics, electrical engineering, measuring technology and signal- and image-processing); c) concepts of biomedical technology, research methods, possible applications, theoretical trends and topical issues; d) principles of the organisation of medical technology and project management; e) national and international performance, safety and environmental standards required for operation and quality control; f) principles of medical informatics. 2. They participate in team work, share all necessary and useful information with others and work to achieve the best joint result. 3. They create a positive communication environment and act in accordance with best practice in communication. 4. They make use of opportunities for self-improvement and keep informed of developments in professional technology. 5. They use at least Estonian and English at the B2 level (see Annex 1 – Language skills level descriptions). 6. They are guided by the professional ethics and code of conduct of engineers (see Annex 2). 7. They use the sub-skill of digital skills in their job: safety and content creation at the Basic user level and problem-solving, information-processing and communication at the Independent user level (see Annex 3 – Scale of self-assessment in digital competence).

B.3 Competences

MANDATORY COMPETENCES

B.3.1 Operating medical devices and systems	**EstQF Level 8**
Performance indicators:	

1. Follows all implementation and operating procedures of devices and systems both existing and being improved, in line with quality standards. 2. Implements new solutions and procedures using general and specialised expertise in contemporary engineering or medical physics. 3. Trains and supervises users, organises practical training and offers technical support.

B.3.2 Developing medical devices and systems	**EstQF Level 8**
Performance indicators: 1. Organises the development and updating of devices and systems, observing the principles of the quality of healthcare and environmental management. 2. Independently develops and assesses new solutions, technological services and management methods, bearing in mind technological developments. 3. Analyses and synthesises new and difficult ideas related to the occupational qualification.	

B.3.3 Management	**EstQF Level 8**
Performance indicators: 1. Initiates activities, manages their progress and goal-oriented development and makes management decisions. 2. Manages activities: Sets goals, guides and informs, supervises and controls the performance of employees, following the principles of management and organisational behaviour. 3. Develops and finds resources, monitors and analyses processes and organises problem-solving.	

COMPETENTCES RELATED TO SPECIALISATION

At least one competence from B.3.4-B.3.17 must also be certified.
Jobs related to diagnostic and interventional radiology technology – competence B.3.4;
Jobs related to nuclear medicine technology – competence B.3.5;
Planning radiotherapy and accompanying procedures – competence B.3.6;
Engineering jobs related to medical laboratory devices – competence B.3.7;
Engineering jobs related to anaesthetic and intensive care devices – competence B.3.8;
Engineering jobs related to operation devices – competence B.3.9;
Engineering jobs related to dentistry devices – competence B.3.10;
Engineering jobs related to disinfection and sterilisation devices – competence B.3.11;
Engineering jobs related to dialysis devices – competence B.3.12;
Engineering jobs related to functional diagnostic devices – competence B.3.13;
Engineering jobs related to rehabilitation devices – competence B.3.14;
Engineering jobs related to medical exposure devices – competence B.3.15;
Engineering jobs related to intracardiac devices – competence B.3.16;
Jobs related to medical information technology – competence B.3.17.

Jobs related to diagnostic and interventional radiology technology	
B.3.4 Jobs related to diagnostic and interventional radiology technology	**EstQF Level 8**
Performance indicators: 1. Organises activities related to diagnostic and interventional radiology technology involving: a) radiation physics and radiation protection applications; b) patient dosimetry; c) the optimisation of medical exposure; d) the application and utilisation of diagnostic reference levels; e) ensuring the quality of medical exposure procedures; f) acquiring and assessing medical exposure devices, protective equipment and measuring instruments; g) preparing the technical specifications of medical exposure devices or structures; h) overseeing installation; i) analysing instances of emergency exposure or unplanned medical exposure; j) training of doctors, nurses, radiology technicians and other employees in radiation protection and the use of devices; k) leading clinical audits.	

2. Organises the development and trialling of methodology for medical exposure device approval and operating tests in compliance with legislation.

Jobs related to nuclear medicine technology	
B.3.5 Jobs related to nuclear medicine technology	**EstQF Level 8**
Performance indicators: 1. Organises activities related to nuclear medicine technology involving: a) radiation physics and radiation protection applications; b) patient dosimetry; c) the optimisation of medical exposure; d) the application and utilisation of diagnostic reference levels; e) ensuring the quality of medical exposure procedures; f) acquiring and assessing medical exposure devices, radiopharmacology devices and measuring instruments; g) preparing the technical specifications of medical exposure devices or structures; h) overseeing installation; i) release and treatment processes of radioactive waste; j) analysing instances of emergency exposure or unplanned medical exposure; k) training of doctors, nurses, radiology technicians and other employees in radiation protection and the use of devices; l) leading clinical audits; 2. Organises the development and trialling of methodology for medical exposure device approval and operating tests in compliance with legislation.	

Planning radiotherapy and accompanying procedures	
B.3.6 Planning radiotherapy and accompanying procedures	**EstQF Level 8**
Performance indicators: 1. Compiles patient radiotherapy plans and makes patient dose measurements and calculations using the results of diagnostic tests; 2. Develops and implements new dosimetry standards and protocols; 3. Compiles treatment guidelines and protocols in cooperation with specialists in other fields; 4. In compliance with legislation, organises activities related to radiotherapy involving: a) radiation physics and radiation protection applications; b) ensuring the quality of medical exposure procedures; c) acquiring and assessing medical exposure devices, protective equipment and measuring instruments; d) preparing the technical specifications of medical exposure devices or structures; e) overseeing installation; f) analysing instances of emergency exposure or unplanned medical exposure; g) trains doctors, nurses, radiology technicians and other employees in radiation protection and the use of devices; h) leading clinical audits; i) the development and trialling of methodology for medical exposure device approval and operating tests in compliance with legislation.	

Engineering jobs related to medical laboratory devices	
B.3.7 Engineering jobs related to medical laboratory devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to anaesthetic and intensive care devices	
B.3.8 Engineering jobs related to anaesthetic and intensive care devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to operation devices	
B.3.9 Engineering jobs related to operation devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to dentistry devices	
B.3.10 Engineering jobs related to dentistry devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to disinfection and sterilisation devices	
B.3.11 Engineering jobs related to disinfection and sterilisation devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to dialysis devices	
B.3.12 Engineering jobs related to dialysis devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to functional diagnostic devices	
B.3.13 Engineering jobs related to functional diagnostic devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to rehabilitation devices	
B.3.14 Engineering jobs related to rehabilitation devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to medical exposure devices	
B.3.15 Engineering jobs related to medical exposure devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality.	

Engineering jobs related to intracardiac devices	
B.3.16 Engineering jobs related to intracardiac devices	**EstQF Level 8**
Performance indicators: 1. Organises the installation, interconnection and operation of devices as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Analyses the work resources and workloads of existing devices and assesses and recommends new technologies; 3. Organises the necessary infrastructure for installing devices, prepares the technical specifications of devices and installations and supervises the installation of devices; 4. Develops quality requirements and organises for them to be used on a regular basis so as to ensure quality. 5. Consults and advises medical staff during procedures, the installation of a device or follow-up so as to optimise the performance of the device and to obtain the best results from treatment.	

Jobs related to medical information technology	
B.3.17 Jobs related to medical information technology	
Performance indicators: 1. Organises the installation, interconnection and operation of the medical information system as required, incl. maintenance and repairs, and analyses serious incidents involving the devices; 2. Organises the security, availability and integrity of the data in medical information systems in compliance with measures for the protection of personal data;	

3. Organises the operation of the devices used in medical information technology and telemedicine, and in connection with this: a) manages the processes of planning medical information systems and compiles technical specifications; b) carries out checks of compliance with technical requirements; c) implements medical information technology and telemedicine in clinical work; e) supervises systems; g) trains employees on the use of systems.

OPTIONAL COMPETENCES

Certification of optional competences B.3.18 and B.3.19 is not mandatory.

B.3.18 Developing medical devices and systems	**EstQF Level 8**
Performance indicators: 1. Devises, engineers and tests devices or their components; 2. Puts together the technology for manufacturing a device and the product's technical documentation; 3. Organises conformity assessment as required, following the principles of international certification.	
B.3.19 Drawing up medical technology projects for buildings	**EstQF Level 8**
Performance indicators: 1. Provides input for the designers of the special parts of buildings and checks and finalises medicine technology plans and projects for healthcare, educational and scientific institutions; 2. Selects the required normative documents in compliance with legislation; 3. Identifies and assesses risks and risk factors and plans measures to prevent risks.	

Part C
GENERAL INFORMATION AND ANNEXES

C.1 Information concerning compilation and certification of occupational qualification standard and reference to classification of occupations	
1. ID of occupational qualification standard in register of occupational qualifications	24-31012020-02/5k
2. Occupational qualification standard compiled by:	Andres Kaalep, SA Põhja-Eesti Regionaalhaigla Andrus Aavik, SA Tartu Ülikooli Kliinikum Annika Mikola, SA Põhja-Eesti Regionaalhaigla Eduard Gerškevitš, SA Põhja-Eesti Regionaalhaigla Jaanus Lass, AB Medical Group, Eesti Biomeditsiinitehnika ja Meditsiinifüüsika Ühing Joosep Kepler, SA Pärnu Haigla Maie Bachmann, Tallinna Tehnikaülikool Marko Parve, AS Ida-Tallinna Keskhaigla
3. Occupational qualification standard approved by:	Engineering, Manufacturing and Processing
4. No. of decision of Sectoral Council	14
5. Date of decision of Sectoral Council	31.01.2020
6. Occupational qualification standard valid until	05.11.2024
7. Occupational qualification standard version no.	5
8. Reference to International Standard Classification of Occupations (ISCO 08)	2149 Engineering Professionals Not Elsewhere Classified
9. Reference to European Qualifications Framework (EQF)	8
C.2 Occupational title in foreign language	

English:	Chartered Biomedical Engineer, EstQF Level 8
C.3 Annexes	
Lisa 1 Language skills level descriptions	
Lisa 2 Engineer's Professional Ethics and Code Of Conduct	
Lisa 3 Scale of self-assessment in digital competence	