

# OCCUPATIONAL QUALIFICATION STANDARD

## Chartered Biomedical Engineer, EstQF Level 8

An occupational standard is a document which describes the set of skills, knowledge and attitudes, i.e. competence requirements, needed to successfully accomplish duties. Occupational 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 relating to diagnostic radiology and nuclear medicine technology	Chartered Biomedical Engineer, EstQF Level 8 Jobs relating to diagnostic radiology and nuclear medicine technology
Planning radiotherapy and accompanying procedures	Chartered Biomedical Engineer, EstQF Level 8 Planning radiotherapy and accompanying procedures

## Part A DESCRIPTION OF WORK

<p><b>A.1 Description of work</b></p> <p>The goal of biomedical engineering technologists is to maintain the medical devices necessary for studying biological systems, diagnostics and treatment and to develop them through engineering and medical physics applications. Action is taken to improve the health and quality of life of people in need.</p> <p>Biomedical engineering technologists are engineering and/or technology specialists or managers with relevant higher education who work in engineering fields associated with medicine and biology: health care institutions and the planning, manufacturing, repair, handling and sales businesses, training institutions, development teams of standards and legislation associated with medical technology, etc.</p> <p>A Chartered Biomedical Engineer, EstQF Level 8 is a senior specialist (expert) with comprehensive knowledge and experience who works independently in situations that are difficult, not clearly defined and call for new strategic approaches in the fields of operating, improving or developing high-tech equipment and/or engineering and technology.</p> <p>The job entails the development of new solutions and methods and the independent analysing and synthesising of ideas relating to the occupation. An Authorised Biomedical Engineering Technologist is responsible for the strategic operations of an organisation. They can lead evaluations, audits and examinations as the expert in charge.</p> <p>The areas of specialisation for authorised biomedical engineering technologists are jobs relating to diagnostic radiology and nuclear medicine technology and planning radiotherapy and accompanying procedures.</p> <p>Related standards: Diploma Biomedical Engineer, EstQF Level 7 Diploma Biomedical Engineer, EstQF Level 7 initial occupational qualification</p>
<p><b>A.2 Tasks</b></p> <p>A.2.1 Operating medical devices and systems. A.2.2 Developing medical devices and systems. A.2.3 Management. A.2.4 Commitment to the occupation. A.2.5 Communication and cooperation.</p>

<b>Specialised areas of work</b>
A.2.6 Jobs relating to diagnostic radiology and nuclear medicine technology. A.2.7 Planning radiotherapy and accompanying procedures.
<b>Elective areas of work</b>
A.2.8 Training activities relating to medical devices and systems. A.2.9 Planning, engineering and optimising medical technology. A.2.10 Developing and producing (manufacturing) medical devices and systems.
<b>A.3 Work environment and specific nature of work</b>
Work is performed both indoors and outdoors. The workload may be distributed unevenly. The work schedule may be flexible. When working in health care institutions, the requirements in force in clinical environments must be observed.
<b>A.4 Tools</b>
A biomedical engineer uses contemporary technical equipment (diagnostic devices and measuring instruments), engineering software and information networks in their work.
<b>A.5 Personal qualities required for work: abilities and characteristics</b>
Traits required in order to be a successful biomedical engineer: logical thinking characteristic of an engineer, visual memory, spatial imagination, ability to concentrate, mathematical capability (understanding quantitative relations), courage to make decisions, punctuality, ethical conduct, accountability and conscientiousness, readiness to communicate and cooperate, adaptability, quality culture and ability to perform under stress.
<b>A.6 Professional preparation</b>
A Chartered Biomedical Engineer has obtained appropriate qualifications from an institute of higher education. They have work experience and have periodically broadened their knowledge. For the prerequisites for applying for the occupational qualification, see "Prerequisites for engineer's occupational qualification" in Annex 2. For the requirements for the continuing education of engineers, see Annex 3 'Accounting of continuing education of engineers'.
<b>A.7 Most common occupational titles</b>
Biomedical engineering technologist, service engineer, quality engineer, medical physicist, etc.
<b>A.8 Regulations governing profession</b>
Possessing the occupational qualification certificate of Chartered Biomedical Engineer, EstQF Level 8 is a prerequisite for working in the fields of diagnostic radiology, nuclear medicine and radiotherapy as a specialist in charge. Basis: Radiation Act, 2013/59/Euratom and 2013/35/EL and associated legislation, Ministry of Social Affairs regulation no. 29 "Radiation safety requirements for executing medicine radiology procedures and the protection of persons undergoing medical exposure" of 15 May 2014.

## Part B COMPETENCY REQUIREMENTS

<b>B.1 Structure of occupation</b>
Certifying competences B.2.1-B.2.5 is required for obtaining the qualification of Chartered Biomedical Engineer, EstQF Level 8. Certifying competences B.2.1-B.2.5 and competence B.2.6 is required to certify the occupational qualification of Chartered Biomedical Engineer, EstQF Level 8 specialising in jobs related to diagnostic radiology and nuclear medicine technology. Certifying competences B.2.1-B.2.5 and competence B.2.7 is required to certify the occupational qualification of Chartered Biomedical Engineer, EstQF Level 8 specialising in planning radiotherapy and accompanying procedures. Optional competences B.2.8-B.2.10 are competences expanding the occupational qualification of Chartered Biomedical Engineer, EstQF Level 8 and their certification is voluntary.

## B.2 Competences

### MANDATORY COMPETENCES

<b>B.2.1 Operating medical devices and systems</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>1. Applies engineering and medical physics knowledge and practical skills to the continued operation of existing technology.</li> <li>2. Organises the installation, maintenance, repair and quality assurance of medical devices and systems.</li> <li>3. Trains users of medical devices and systems: organises practical training, offers after-sales support and instructs users.</li> <li>4. Combines general engineering information with knowledge related to specialising in the occupational qualification to optimise technology under development and develop new solutions.</li> <li>5. Devises and plans the use of general and special-purpose application software and apparatus.</li> </ol> <p>Knowledge:</p> <ol style="list-style-type: none"> <li>1) general science (mathematics, physics, physiology and anatomy);</li> <li>2) engineering (information technology, engineering graphics, electrical engineering and measuring technology);</li> <li>3) concepts of biomedical technology, research methods, possible applications, theoretical trends and topical issues;</li> <li>4) principles of the management of medical technology;</li> <li>5) national and international performance, safety and environmental standards required for operation and quality control;</li> <li>6) principles of medical informatics.</li> </ol>	
<b>B.2.2 Developing medical devices and systems</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>1. Works independently in situations that can be difficult, not clearly defined and requiring new strategic approaches: improves existing technologies and develops and evaluates new technologies and systems.</li> <li>2. Independently analyses and synthesises new and difficult ideas relating to the occupational qualification.</li> <li>3. Offers new solutions, technological services and leadership methods.</li> <li>4. Defines, organises and effectively utilises the resources in their field and takes into account quality standards, safety and impact on the environment.</li> </ol> <p>Knowledge:</p> <ol style="list-style-type: none"> <li>1) technical innovations and trends relating to the occupation;</li> <li>2) the feasibility of technological innovations.</li> </ol>	
<b>B.2.3 Management</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>1. Manages teams and coordinates project activities using appropriate management techniques and systems.</li> <li>2. Maintains balance between the project's planned budget and activities.</li> <li>3. Ensures that operations and objectives are in compliance with legislation.</li> <li>4. Gathers ongoing information, analyses results and assesses the novelty, benefits and effectiveness of engineering work related to the occupation.</li> <li>5. Identifies the abilities and development needs of employees and plans their development.</li> <li>6. Plans and manages economic activities in their field.</li> <li>7. Utilises and develops information and communication technology tools and options.</li> </ol> <p>Knowledge:</p> <ol style="list-style-type: none"> <li>1) principles of management and organisational behaviour;</li> <li>2) fundamentals of andragogy and psychology;</li> <li>3) fundamentals of quality and environmental management;</li> <li>4) fundamentals of management in the field of biomedical technology.</li> </ol>	
<b>B.2.4 Commitment to occupation</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>1. Understands the nature of being an engineer and acts in the interests of society, other engineers and the environment.</li> </ol>	

2. Promotes the occupation and protects its interests.
3. Is guided by the engineer's professional ethics and code of conduct (see Annex 4).
4. Is responsible for performance associated with the field in the managed institution.
5. Maintains their qualifications and keeps up to date on technological developments.
6. Plans and implements innovations and supports activities targeted at innovation and creativity.
7. Passes on professional skills and knowledge and coordinates the work of those supervised.
8. Promotes engineering culture and advances the occupational qualification system of engineers, including explaining the opportunities of applying for the occupational qualification.

**Knowledge:**

- 1) institutions and cooperative networks associated with the occupation;
- 2) trends in medicine, industry and the educational system associated with the occupation;
- 3) standards and regulations associated with the occupation.

**B.2.5 Communication and cooperation**

**EstQF Level 8**

**Performance indicators:**

1. Works in an interdisciplinary team and communicates with specialists involved in associated fields.
2. Uses proper spoken and written Estonian in their work and expresses themselves clearly.
3. Uses two foreign languages: English at the B2 level and a second foreign language at the B1 level (see Annex 5).
4. Leads discussions and meetings.
5. Analyses and develops communication skills relating to the job.
6. Compiles technical texts, letters, reports, articles and presentations.
7. Creates a positive communication environment and acts in accordance with best practice in communication.

**Knowledge:**

- 1) principles of communication psychology;
- 2) principles of public speaking;
- 3) presentation techniques.

## COMPETENCES RELATED TO SPECIALISATION

Engineer, EstQF Level 8 specialising in jobs related to diagnostic radiology and nuclear medicine technology. Certifying competences B.2.1-B.2.5 and competence B.2.7 is required to certify the occupational qualification of Chartered Biomedical Engineer, EstQF Level 8 specialising in planning radiotherapy and accompanying procedures.

**Jobs relating to diagnostic radiology and nuclear medicine technology**

**B.2.6 Jobs relating to diagnostic radiology and nuclear medicine technology**

**EstQF Level 8**

**Performance indicators:**

1. Depending on the study or treatment, takes responsibility for dosimetry related to medical exposure, including the physical measurements of the patient dose.
2. Advises on devices used in diagnostic radiology and nuclear medicine, in regard to which:
  - a) takes part in optimising the radiation protection of patients and other individuals subject to medical exposure, including in the application and utilisation of diagnostic reference levels;
  - b) organises and manages regular quality control and participates in quality assurance;
  - c) participates in performing approval tests (acceptance);
  - d) prepares the technical texts of devices and installations;
  - e) oversees installations;
  - f) analyses events accompanied or potentially accompanied by accidental or unintended medical exposure;
  - g) determines the instrumentation for performing radiation protection measurements;
  - h) trains doctors, nurses, radiology technicians and other employees in radiation protection.

**Knowledge:**

- 1) Knowledge listed in the European Commission document Radiation Protection 174, ANNEX 1, tbl 5, 6;
- 2) national legislation on the use of medical exposure;
- 3) quality criteria of devices in the document Radiation Protection 162.

<b>Planning radiotherapy and accompanying procedures</b>	
<b>B.2.7 Planning radiotherapy and accompanying procedures</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>Depending on the study or radiotherapy treatment, takes responsibility for the planning, verifying and dosimetry of the dosage of the medical exposure used.</li> <li>Advises on the devices used in radiotherapy, in regard to which: <ol style="list-style-type: none"> <li>takes part in optimising the radiation protection of patients and other individuals subject to medical exposure;</li> <li>organises and manages regular quality control and participates in quality assurance;</li> <li>participates in performing approval tests (acceptance);</li> <li>introduces medical devices in clinical work (commissioning);</li> <li>prepares the technical texts of devices and installations;</li> <li>oversees installations;</li> <li>analyses events accompanied or potentially accompanied by accidental or unintended medical exposure;</li> <li>determines the instrumentation for performing radiation protection measurements;</li> <li>trains doctors, nurses, radiology technicians and other employees in radiation protection.</li> </ol> </li> </ol> <p>Knowledge:</p> <ol style="list-style-type: none"> <li>Knowledge listed in the European Commission manual Radiation Protection 174, ANNEX 1, tbl 7 about medical physics experts;</li> <li>national legislation on the use of medical exposure;</li> <li>quality criteria of devices in the document Radiation Protection 162.</li> </ol>	

## OPTIONAL COMPETENCES

Optional competences B.2.8-B.2.10 are competences expanding the occupational qualification of Chartered Biomedical Engineer, EstQF Level 8 and their certification is voluntary.

<b>B.2.8 Training activities related to medical devices and systems</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>Assesses and analyses test results and makes generalisations about them.</li> <li>Publishes research results.</li> <li>Takes part in developing curricula and syllabuses.</li> <li>Implements appropriate teaching methods.</li> <li>Develops, organises and carries out further training and courses.</li> <li>Takes part in scientific and development cooperation in Estonia and abroad (between universities, hospitals and other institutions and companies).</li> <li>Popularises the speciality through training (e.g. for students at the undergraduate and secondary school levels).</li> <li>Supervises students.</li> <li>Creates new teaching materials and resources, including e-learning materials.</li> <li>Gives presentations at international science conferences and seminars.</li> </ol> <p>Knowledge:</p> <ol style="list-style-type: none"> <li>thorough expertise in their field;</li> <li>pedagogy and andragogy;</li> <li>scientific methodology;</li> <li>principles of implementing new methods and devices.</li> </ol>	
<b>B.2.9 Planning, engineering and optimising medical technology</b>	<b>EstQF Level 8</b>
<p>Performance indicators:</p> <ol style="list-style-type: none"> <li>Puts together plans and projects for the medical technology of health care, educational and scientific institutions.</li> <li>Selects the required normative documents in compliance with legislation.</li> <li>Identifies and assesses risks and risk factors and plans measures to prevent risks.</li> <li>Puts together, revises and finalises project documentation using adequate software.</li> <li>Assembles the normative documents required for planning.</li> </ol>	

6) Provides input in the planning of buildings and their parts.	
Knowledge: 1) the logic and goal of institutions; 2) the nature of diagnostic, treatment and test procedures and quality criteria; 3) the norms of building and electrical operations; 4) the specific nature of the planned field; 5) engineering software; 6) best practice and methodology in engineering.	
<b>B.2.10 Developing and producing (manufacturing) medical devices and systems</b>	<b>EstQF Level 7</b>
Performance indicators: 1. Devises, engineers, constructs and tests devices or their components. 2. Puts together the technology for manufacturing a device and the product's technical documentation. 3. Arranges for evaluation of conformity and markets the devices.	
Knowledge: 1) principles of certification; 2) legislation associated with the manufacturing of medical devices; 3) product and safety standards.	

## Part C

### GENERAL INFORMATION AND ANNEXES

<b>C.1 Information concerning compilation and certification of occupational qualification standard and reference to classification of occupations</b>	
1. ID of occupational qualification standard in register of occupational qualifications	24-08052019-2.6.2/4k
2. Occupational qualification standard compiled by:	Jaanus Lass, AB Medical Teeninduse OÜ Kalle Kepler, Tartu Ülikool Tairi Täht, Sotsiaalministeerium Ivo Fridolin, Tallinna Tehnikaülikool Andrus Aavik, SA Tartu Ülikooli Kliinikum Kristjan Pilt, Eesti Biomeditsiinitehnika ja Meditsiinifüüsika Ühing
3. Occupational qualification standard approved by:	Engineering, Manufacturing and Processing
4. No. of decision of Sectoral Council	12
5. Date of decision of Sectoral Council	08.05.2019
6. Occupational qualification standard valid until	30.01.2020
7. Occupational qualification standard version no.	4
8. Reference to International Standard Classification of Occupations (ISCO 08)	2111 Physicists and Astronomers
9. Reference to European Qualifications Framework (EQF)	8
<b>C.2 Occupational title in foreign language</b>	
English:	Chartered Biomedical Engineer, EstQF Level 8
Russian:	Уполномоченный инженер по биомедицинской технике
<b>C.3 Annexes</b>	
Lisa 1 <a href="#">Kutsetasemete kirjeldused ja profiilid</a>	
Lisa 2 <a href="#">Insenerikutsete taotlemise eeldused</a>	
Lisa 3 <a href="#">Inseneri täiendusõppe arvestus</a>	

Lisa 4 <a href="#">Engineer's Professional Ethics and Code Of Conduct</a>
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Lisa 5 <a href="#">Language skills level descriptions</a>
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