

BIOMEDICAL ENGINEERING IN THE CONTEXT OF NEW LEGISLATION IN THE CZECH REPUBLIC

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Abstract: The aim of the paper is to inform about the requirements laid on education in the fields of Biomedical Technology and Biomedical Engineering in the connection with the Law No.96/2004 Coll. on non-medical health service occupations and related regulations. The law and related regulations define completely new position of technical personnel in the health service system. This new legal regulation distinguishes the following categories of technical personnel: another professional, health service specialist with technical competence (biomedical technician, biomedical engineer), and health service professional with specialized competence (clinical technician, clinical engineer). During the preparation of the law, the basic philosophical principle was followed, namely that the qualification of health service professional and specialist will be required for technical professions if the technical professional or specialist comes into contact with a patient or can through his/her activity directly influence patient's health state. The law distinguishes the following types of education: pre-gradual (bachelor, master), accredited qualification course, specialised education and training, and lifelong learning.

Introduction

Biomedical Engineering (BME) represents one of the typical interdisciplinary areas. It is a field with growing interest in education, research and practice as well. It links medicine; electrical engineering, information technology, and mechanical engineering together (just to mention the most important disciplines). During recent years many things have changed and we have acquired new experience in the area of BME. This experience can be divided into several parts: education; students' projects and theses; research; co-operation with universities, research institutes and industrial companies both in the Czech Republic and at the international level. However, these parts are not strictly divided; they interact and influence each other very positively. Other important issues in BME are social and legal aspects of the domain. They must be considered in all above mentioned activities. We will focus in this paper on the legal regulations that

define non-medical health care professions and the procedures that describe the undergraduate and lifelong education, accreditation, and other important aspects of them.

Biomedical Engineering Legislation in the Czech Republic

Since it is assumed that the graduates will find jobs mostly in the health care domain, the education, qualification, accreditation, and occupations are regulated by special legal provisions. During 2004 and 2005 new law and related regulations became effective. The aim of the paper is to inform about the requirements laid on education in the fields of Biomedical Technology and Biomedical Engineering in the connection with the Law No. 96/2004 Coll. on non-medical health service occupations and related regulations. In particular, the following regulations are important:

- No. 394/2004 Coll. - it regulates details about holding the attestation examination, examination for issuing the certificate, final examinations of accredited qualification courses, approbation examinations and examination rules for these examinations;
- No. 470/2004 Coll. – it concerns health capability for performing the occupations of health service professional and another specialist;
- No. 423/2004 Coll. - it defines credit system for issuing certificate to performing health service occupations without expert supervision, further it defines educational activities for that credit points can be awarded and number of credit points;
- No. 424/2004 Coll. - it specifies activities of health service professionals and other employees);
- government decree No. 463/2004 Coll. - it defines fields of specialized education and specification of the expertise of health service professionals;
- government decree No. 39/2005 - it specifies minimum requirements for educational programs leading to qualification to act as health service professional.

The law and related regulations define completely new position of technical personnel in the health service system.

The new position of the technical professionals in the Health Care Service is determined by new legislation in the Czech Republic. The new law No. 96/2004 Coll. on non-medical health service occupations distinguishes the following categories of technical personnel:

- another professional;
- health service professional with technical competence:
 - biomedical technician (B.Sc.);
 - biomedical engineer (Eng., M.Sc.);
- health service specialist with specialised technical competence:
 - clinical technician (B.Sc.);
 - clinical engineer (Eng., M.Sc.).

The qualification of the health service professional and health service specialist is required for technical personnel, where technical professional or technical specialist comes into the contact with a patient or when he/she can through his/her activities directly influence patient's health state.

The Law No. 96/2004 Coll. specifies the following types of educations:

- undergraduate, i.e. bachelor and master study (minimum requirements are given by the official regulations No. 39/2005 Coll.);
- accredited qualification course;
- lifelong education (this education is obligatory for all health service professionals and also for those working in the category another professional in health service).

In this law there are defined following forms of lifelong education:

- specialised education and training for health service professionals (in institutions that have the accreditation from the Ministry of Health Care);
- certified courses (for obtaining the profound knowledge in the concrete field in institutions those that have accreditation from the Ministry of Health Care);
- innovation courses (for obtaining the information about the new knowledge in the branch);
- professionals short-term assignment in the accredited facilities;
- participation in conferences, congresses or symposiums;
- publication, education activity, research activity;
- literature study;
- education in consequential university study programmes.

In each of these forms of lifelong education the participants can obtain the credits. The number of credits that are possible to obtain for the concrete kind of study mentioned above is determined by the official regulation No. 423/2004 Coll.

In this context, it is necessary to stress that in addition to standard accreditation of a study programme or field of undergraduate education performed by the Accreditation Board of the Ministry of Education, Youth and Sports of the Czech Republic, the biomedical study programmes or fields must get the accreditation of the Ministry of Health Care of the Czech Republic in the sense of the law No. 96/2004 Coll. and related regulations. The graduates of these accredited fields get the certificate of qualification to perform health service occupations according to the law No. 96/2004.

The Biomedical Engineer (Biomedical Technician) qualification can be obtained by graduation in the Biomedical Engineering field of study (Biomedical Engineer) or the Biomedical Technology field of study (Biomedical Technician).

The accreditation conditions for the study programme or for the field of study from the Ministry of Health Care are following:

- the structure of the study programme must correspond with the official regulations No. 39/2005 Coll. where the minimum requirements for the contents of bachelor and master study programme are determined;
- the profile of graduates must correspond with the official regulations No. 424/2004 Coll. where permitted activities for technical professionals and technical specialists are determined.

Graduates of another bachelor or master study programme in electrical engineering can obtain the qualification for health service professionals with technical competence if they pass the accredited course in Biomedical Engineering (for Eng.) or Biomedical Technology (for B.Sc.) The accreditation for these courses is delivered by the Ministry of Health Care of the Czech Republic. The conditions for this accreditation are defined in the official regulation No. 424/2004 Coll.

Specialised Education

The specialised technical competence for clinical technicians and clinical engineers can be obtained by passing the specialised education and training finished by official examination. This specialised education and training can be provided only by those institutions that have the accreditation from the Ministry of Health Care. The Clinical Engineering is the specialised education and training for Biomedical Engineers and the Clinical Technology for the Biomedical Technicians.

In the official regulations No. 463/2004 Coll. there are defined the following fields for Clinical Technology education and training:

- signal acquisition and signal processing (Clinical Technicians for signal acquisition and signal processing);
- diagnostic devices (Clinical Technicians for diagnostic devices);
- laboratory devices (Clinical Technicians for laboratory devices);

- therapeutic devices (Clinical Technicians for therapeutic devices);
- diagnostic imaging devices (Clinical Technicians for diagnostic imaging devices);
- perfusiology (Clinical Technicians for perfusiology).

For Clinical Engineering education and training there are defined the same fields. Thus after passing the official examination Biomedical Engineers obtain the official ranking as Clinical Engineers for signal acquisition and signal processing, for diagnostic devices, for laboratory devices, for therapeutic devices, for diagnostic image devices, or for perphusiology.

Biomedical Technicians and Biomedical Engineers can also pass the specialised education in the Health Service Organisation and Control. After the official examination they are ranked as Professionals in Health Service Organisation and Control.

For Health Service professionals (Biomedical Technicians and Biomedical Engineers) and specialists (Clinical Technicians and Clinical Engineers) the Ministry of Health Care issues the official certificate.

Specification of Activities of Biomedical Technicians and Biomedical Engineers

The regulation No. 424/2004 Coll. specifies activities of health service professionals. The biomedical technician can perform activities in the frame of diagnostic and therapeutic care in the field of biomedical technology in cooperation with a biomedical engineer or a physician. The activities are divided into:

- activities performed without specialist supervision and indication;
- activities performed under supervision of a clinical engineer or clinical technician based on indication;
- activities in which he/she participates under direct control of a clinical engineer or clinical technician.

The activities performed without supervision and indication include:

- providing health care in correspondence with legal regulations and standards;
- keeping with hygiene-epidemiological regime according to special legal provisions;
- administration of health care documentation and other documentation according to special legal provisions, work with health information system;
- providing patients with information in correspondence with his/her qualification, and possibly instructions from the doctor;
- participation in practical education at specialized secondary schools, higher specialized schools, and universities performing accredited educational programs leading to health care professional qualification and educational programs of accredited qualification courses;
- participation in preparation of standards.

Health care professionals that need to acquire specialized qualification have to work before under specialized supervision of a health care professional that

has the adequate qualification for work without supervision in the given area.

Specification of the Occupation

Biomedical technician can perform the activities mentioned above. In addition, he/she can work without supervision and indication with medical devices if he/she cannot influence directly the patient health state with his/her activity. These activities include:

- checking and repair of medical devices, administration of their documentation, organization and coordination of technical services connected with operation of medical technology;
- performing technical instruction of professionals in the area of operation of medical devices and labour safety;
- ensuring receiving, control and storing health care means and laundry, manipulation with them, their disinfection and sterilization and their sufficient supplies.

Based on the indication of the physician and in correspondence with diagnosis determined by the physician assuming that he/she can directly influence patient health state by his/her activity, a biomedical technician can work with medical devices under specialized supervision of a clinical engineer or clinical technician with specialized qualification in the area. These activities include:

- calibration of critical blocks of medical devices;
- ensuring technical assistance at electrophysiological examinations, heart impulse therapy and medical imaging examinations;
- modification of diagnostic software for interpretation of electroencephalogram, electrocardiogram and other consultation and knowledge-based diagnostic systems.

Under direct control of a clinical engineer or clinical technician, the biomedical technician participates in:

- selection of medical devices, especially he/she evaluates their properties in relation with provided health care;
- development of concepts of complexes of health care technology;
- operation of medical devices for extracorporeal circulation;
- evaluation and clinical testing of health care devices according to special legal provisions.

Biomedical engineer is a health care professional qualified for health care job without supervision after acquiring technical and specialized competence.

The activities the biomedical engineer can perform are divided into activities he/she performs without indication and activities he/she performs based on indication.

Biomedical engineer can perform the same activities as biomedical technician without supervision and indication (see above). Under specialized supervision of a clinical engineer and without indication of the

physician, he/she works with medical devices in correspondence with diagnosis determined by the physician, if he/she cannot directly influence the patient health state by his/her activity. These activities include:

- ensuring maintenance, technical state, repairs and service of medical devices according special legal provisions;
- organization and coordination of technical services connected with operation of medical devices;
- selection of medical devices with respect to their properties and relation to provided health care;
- calibration of critical blocks of medical devices, modification of basic program setup of these devices according to concrete needs of the workplace or patients;
- performing technical instruction of professionals and in case of need technical supervision in the area of operation of medical devices and labour safety;
- participation in development and construction of medical devices or their complements, possibly he/she can manufacture them;
- participation in clinical evaluation and clinical tests and their statistical evaluation according special legal provisions;
- evaluation of failure cases and undesirable incidents of medical devices, including their keeping on file and documentation according special legal provisions and ensuring their prevention.

Based on indication of the physician and in correspondence with the diagnosis determined by the physician, biomedical engineer works with medical devices under supervision of a clinical engineer with specialized qualification in the field even in cases where he/she can directly influence the patient health state by his/her activity. These activities include:

- operation of medical devices for extracorporeal blood circulation;
- ensuring technical assistance at electrophysiological examinations, heart impulse therapy and medical imaging examinations;
- modification or development of diagnostic software for interpretation of electroencephalogram, electrocardiogram and other consultation and knowledge-based diagnostic systems;
- modification or development of software for health care information systems.

Before the biomedical engineer acquires specialized competence, he/she works in a health care facility under technical supervision of a professional qualified to job without technical supervision, out of which first six months represent work under direct control.

The practice of a profession of biomedical engineer is an activity in the frame of diagnostic and therapeutic care in cooperation with a physician.

It is necessary to stress that for the job of biomedical technician it is supposed that the undergraduate

preparation is such that the technician can perform some activities directly after graduation without supervision. Biomedical engineer profession assumes education significantly more theoretically focused. That means that the biomedical engineer can perform independent activity only after specialized preparation (similar to physicians).

Under profession of another health care professional it is understood performing activities that are directly related to providing health care. The activities that are part of health care can be performed by this professional only under supervision or direct control in the range defined by special legal provisions and as an employee of a health care provider. The technical competence of another health care professional in technical field can be acquired by graduation:

- in accredited master study programme performed at a university in a study programme in electrical engineering area;
- in accredited bachelor study programme performed at a university in a study programme in electrical engineering area;
- at a higher specialized school in a study programme in electrical engineering area;
- at a secondary technical school in a study programme in electrical engineering area.

Another health care professional acquires technical competence for health care job by passing specialized education or accredited qualification course. The activities he/she can be performed are defined in the provision No. 424/2004 Coll.

Specialists with Specialised Competence

The activities of professionals with specialised competence are defined in the regulations No. 424/2004 Coll.

The clinical technician after acquiring specialised competence can perform the activities that are specified for the biomedical technician Further in cooperation with a clinical engineer he/she organises and methodologically controls work of health care and other professionals in the field of his/her specialisation in the process of providing diagnostic and therapeutic care with application of medical devices. He/she can perform following activities without supervision and indication:

- instruction of team members in the area of his/her specialisation;
- evaluation of quality of provided care, i.e. performed activities, environment, and documentation;
- participation in research, especially identification of activities requiring change of procedures, performing research focused on disclosure of causes of insufficiencies in provided care, creation of conditions for application of research results to clinical practice in his/her own institution and in the frame of the field;
- introduction of new methods into everyday practice;

- collaboration on technical aspects in the process of acquisition of clinical information systems;
- participation in development of prevention measures originating from evaluation of cases of medical device failure;
- preparation of standards of specialised procedures in the range of his/her field of activity;
- supervision of specialised education in the area of his/her specialisation.

In correspondence with the regulations No. 463/2004 Coll. there are distinguished following categories of clinical technicians:

- clinical technician for signal acquisition and signal processing;
- clinical technician for diagnostic devices;
- clinical technician for laboratory devices;
- clinical technician for therapeutic devices;
- clinical technician for diagnostic imaging devices;
- clinical technician for perfusiology.

After acquiring specialised competence, the clinical engineer can perform the activities that are specified for the clinical technician and biomedical engineer without supervision in his/her field of specialisation. In addition, he/she organises, methodologically controls and supervises work of health care and other professionals in the field of his/her specialisation in the process of providing diagnostic and therapeutic care with application of medical devices. Further activities include:

- identification of activities requiring change of procedures, performing research focused on disclosure of causes of insufficiencies in his/her field of specialisation, performing research, development and construction of medical devices or their supplements;
- creation of conditions for application of research results to clinical practice in his/her own institution and in the frame of the field; participation in clinical evaluations and clinical testing according to special legal provisions;
- supervision of specialised education in the area of his/her specialisation;
- preparation of standards of specialised procedures in the range of his/her field of activity.

In correspondence with the regulations No. 463/2004 Coll. there are distinguished following categories of clinical engineers:

- clinical engineer for signal acquisition and signal processing;
- clinical engineer for diagnostic devices;
- clinical engineer for laboratory devices;
- clinical engineer for therapeutic devices;
- clinical engineer for diagnostic imaging devices;
- clinical engineer for perfusiology.

Biomedical technician and biomedical engineer can get also qualification in the specialised education in health care organisation and management. The profession is labelled Specialist in health care organisation and management. After acquiring the

specialised competence, this professional can perform without supervision activities of conceptual character related to health care organisation and management. He/she participates in

- development of goals, strategy and policy of the organisation; control and organisation of the health care institution;
- solving system problems of providing health care, development and realisation of health care policy and succession of health and social care;
- development and application of the concept of the field in practice;
- analysis and interpretation of statistical data concerning providing health care and health state of the population, planning of future needs of health care services;
- introduction of the system of quality assessment and safety of health care and its continuous increase;
- human resources activities and organisation of further education;
- securing satisfying legal provisions and standards concerning the activities of health care providers.

Requirements on Study Programs

The minimum requirements on study programs to acquisition of technical competence for non-physician health care professions (including biomedical technology and biomedical engineering) are defined by legal regulations (decree No. 39/2005). It was prepared by the Ministry of Health Care of the Czech Republic in agreement with the Ministry of Education, Youth and Sports of the Czech Republic. This decree incorporates corresponding regulations of European Community and modifies minimum requirements on study programs to acquisition of technical competence for non-physician health care professions. These minimum requirements are list of theoretical and practical areas necessary for practising regulated profession. It is necessary to stress that the Ministry of Health Care accredits only those study programmes satisfying the requirements. Then the graduates are allowed to certain defined positions in the hospitals and health care institutions. In addition to necessary theoretical and practical technical (engineering) knowledge and skills, the decree specifies which additional knowledge and skills the students have to acquire. They cover topics of:

- ethics of health care;
- administrative activities in health care service, especially in electronic documentation;
- organization and control of health care (including management of medical technology, fundamentals of medical informatics];
- fundamentals of support and protection of public health;
- first aid and ensuring health care in situations of emergency and disaster;

- legal context of providing health care (technical legal provisions and norms relevant to health care, general legal regulations).

Then requirements on medical and technical knowledge are specified in detail for both the bachelor study in biomedical technology and master study in biomedical engineering. In general, the courses can be divided into theoretical courses providing knowledge of medical fundamentals (anatomy, physiology, pathology, pathophysiology), technical area (mathematics, physics, medical devices, signal theory, medical imaging, databases, etc.). Inseparable part of the education is practical training, including practice in health care facilities.

Conclusions

The law No. 96/2004 Coll. and all related legal regulations and provisions have a number of consequences both for undergraduate study and for postgraduate study and lifelong learning. Biomedical technicians and engineers who will be working in the Health Care sector will be involved in a system of education and lifelong learning for acquiring specialised competence that is similar to present system of education and training of medical doctors.

When developing curricula in undergraduate study it is necessary to respect both requirements of the Ministry of Education, Youth and Sports of the Czech Republic and requirements resulting from the law No. 96/2004 Coll. and especially regulations No. 39/2005 Coll. that defines minimum requirements on educational programmes leading to qualification to act as health service professionals. The courses in postgraduate education and lifelong learning are managed by the law No. 96/2004 Coll. And corresponding regulations of the Ministry of Health Care of the Czech Republic.

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